

# DRAFT REGISTRATION REPORT

## **Part B**

### **Section 9**

#### **Ecotoxicology**

Detailed summary of the risk assessment

Product code: SHA 9800 A

Product name: COBRANZA

Chemical active substance:

Copper oxychloride, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

Applicant: Sharda Cropchem España S.L.

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## Version history

When	What
September 2020	Applicant update
October 2020	Finalisation of the evaluation by ZRMS-PL.

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## 9 Ecotoxicology (KCP 10)

### Submission and Evaluation of Copper compounds under Art.33 of 1107/2009

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

EFSA is held to assess plant protection products according to the existing methodology described in a series of guidance documents (GDs). Those have been developed for synthetic, organic molecules, and are in most cases not applicable to minerals and copper. This has led to an EFSA conclusion that indicated a number of critical concerns, or assessments that could not be finalized, which do not reflect any realistic risk, but rather illustrate the inappropriateness of the current GDs for the assessment of copper. This can easily be seen in a number of endpoints that suggest a high risk exists at concentrations below natural background of this essential micronutrient. **This has been recognized by EFSA, the RMS and several MS (see comments from DE and IT in the Peer review Report), and the EU Commission has mandated EFSA with the development with a copper specific guidance (Mandate No. 2019-0036).**

Art.33 submissions and their evaluation by MS are unfortunately due before this GD will be available. The current EFSA conclusion and list of endpoints could at best be considered as a first tier, and applicants as well as MS are required to deviate from the standard procedures described in the GD for the following reasons:

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

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

**Table 9.1-1: Table of critical GAPS**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	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: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. inter- val 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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1	CEU	<b>Grapevine</b>	F	Downy mildew ( <i>Plasmopara viticola</i> )	Foliar Spray	BBCH 15-85	a) 4 b) 4	10-12	a) 2.0 b) 8.0	a) 1.0* b) 4.0*	800-1000	21	* Expressed as Cu							
2	CEU	<b>Potato</b>	F	Late blight ( <i>Phytophthora infestans</i> )	Foliar Spray	BBCH 15-85	a) 4 b) 4	10-12	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 the dose of 2.4 kg/ha, 4 applications for the dose of 2.0 kg/ha							
3	CEU	<b>Solanaceous fruits (Tomato, aubergine)</b>	F	Late blight ( <i>Phytophthora infestans</i> )	Foliar Spray	BBCH 15-85	a) 3 b) 3	10-12	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							
4	CEU	<b>Pome fruit (apple, pear, quince)</b>	F	Scab ( <i>Venturia spp.</i> )	Foliar Spray	BBCH 15-85	a) 5 b) 5	10-12	a) 1.15-2.4 b) 5.75-7.2	a) 0.575-1.2* b) 2.875-3.6*	800-1000	14	* Expressed as Cu 3 applications for the dose of 2.4 kg/ha, 5 applications for the dose of 1.15 kg/ha							

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

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

#### Explanation for column 15 – 21 “Conclusion”

<b>A</b>	Acceptable, Safe use
<b>R</b>	Further refinement and/or risk mitigation measures required
<b>C</b>	To be confirmed by cMS
<b>N</b>	No safe use



<b>Remarks table:</b>	<div> <div> (1) Numeration necessary to allow references  (2) Use official codes/nomenclatures of EU  (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)  (4) 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  (5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named  (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated </div> <div> (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  (8) The maximum number of application possible under practical conditions of use must be provided  (9) Minimum interval (in days) between applications of the same product.  (10) For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products  (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  (12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  (13) PHI - minimum pre-harvest interval  (14) Remarks may include: Extent of use/economic importance/restrictions </div> </div>
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### 9.1.1 Overall conclusions

### 9.1.2 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

- Birds

According to screening and tier I assessments for different intended crops uses, TERa and TERlt values are below the Annex VI triggers, indicating that COBRANZA presents an unacceptable acute and long-term risk to birds according to the intended uses. Therefore, an acute and long-term higher-tier risk assessment was necessary. ~~A refinement based on MAF, TWA and DF was performed. After even the refinement, the risk assessment showed that Copper oxychloride presents an unacceptable acute and long-term risk for some birds in the intended uses. However, confirmatory data has been provided and evaluated at EU level to demonstrate that the risk to birds is acceptable and,~~ Therefore, a WoE is applied. In this context, it can be conclude that the risk is low for birds exposed to applications of COBRANZA at the proposed label rate.

~~Taking into account all the available data and the conclusions were based on a realistic worst case scenario, WoE approach could be used to conclude acceptable risk at dose requested (maximum annual application rate of 4 kg Cu/ha) until the existence of an accepted guidance document.~~

The risk for drinking water exposure is acceptable and the effect of secondary poisoning is not expected.

- Mammals

According to screening and tier I assessments for different intended crops uses, TERa and TERlt values are below the Annex VI triggers, indicating that COBRANZA pre-sents an unacceptable acute and long-term risk to mammals according to the intended uses. There-fore, an acute and long-term higher-tier risk assessment was necessary. ~~A refinement based on MAF, TWA and DF was performed. After even the refinement, the risk assessment showed that Copper oxychloride presents an unacceptable acute and long-term risk for some mammals in the intended uses. However, confirmatory data has been provided and evaluated at EU level to demon-strate that the risk to mammals is acceptable and,~~ Therefore, a WoE is applied. In this context, it can be conclude that the risk is low for mammals exposed to applications of COBRANZA at the proposed label rate.

~~Taking into account all the available data and the conclusions were based on a realistic worst case scenario, WoE approach could be used to conclude acceptable risk at dose requested (maximum annual application rate of 4 kg Cu/ha) until the existence of an accepted guidance document.~~

The risk for drinking water exposure is acceptable and the effect of secondary poisoning is not expected.

#### 9.1.2.1 Effects on aquatic organisms (KCP 10.2)

The ratios between predicted environmental concentrations in surface water bodies ( $PEC_{sw}$ ) and regulatory acceptable concentrations (RAC) for aquatic dwelling organisms are given per intended use for each FOCUS scenario. As discussed above, to achieve a concise risk assessment for aquatic dwelling organisms, an ETO-RAC<sub>sw; ch</sub> value of 4.8 µg/L was used as this value was protective of all acute and chronic risks to all relevant aquatic species.

For all intended uses, following refinement of the risk assessment using the  $PEC_{sw;dissolved}$  was lower than the ETO RAC<sub>sw;ch</sub> thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA with the following risk mitigation measures:

- Grapevine (late): Any no-spray buffer with 50% nozzles reduction OR 10 m no-spray buffer.
- Pome fruits (early): any no-spray buffer zone with 90% nozzles reduction OR 14 m no-spray buffer with 75% nozzles reduction OR 20 m no-spray buffer.
- Pome fruits (late): any no-spray buffer zone with 90% nozzles reduction OR 5 m no-spray buffer with 75% nozzles reduction OR 10 m no-spray buffer with 50% nozzles reduction OR 14 m no-spray buffer.

Therefore, the Applicant concludes an acceptable risk with the following mitigation measures:

**Grapevine (late application)– Spe3:** *To protect aquatic organisms respect an unsprayed buffer zone of 10m to surface water bodies OR none unsprayed buffer zone with 50% of nozzles reduction.*

**Pome fruit (apple, pear and quince) early application – Spe3:** *To protect aquatic organisms respect an unsprayed buffer zone of 20m OR an unsprayed buffer zone of 14m to surface water bodies with 75% of nozzles reduction OR none unsprayed buffer zone with 90% of nozzles reduction.*

**Pome fruit (apple, pear and quince) late application – Spe3:** *To protect aquatic organisms respect an unsprayed buffer zone of 14m to surface water bodies OR an unsprayed buffer zone of 10m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 5m to surface water bodies with 75% of nozzles reduction OR none unsprayed buffer zone with 90% of nozzles reduction.*

The risk assessment for aquatic organism based on risk assessment according to EFSA Conclusion 2018 is not finalised in the current stage of the assessment. Further  $PEC_{sw}$  calculations should be provided by the applicant to conclude acceptable risk according this approach.

#### **9.1.2.2 Effects on bees (KCP 10.3.1)**

The risk assessment for bees has been done. The  $Q_{HC}$  values are below 50, indicating a low risk to bees following the application of COBRANZA at the proposed label rate. However,  $Q_{HO}$  was higher than trigger and risk was detected. After a higher-tier risk assessment based on semi-field study which was conducted with copper oxychloride WP on *Phacelia*, no significant effects were detected at maximum application rate according to GAP.

#### **9.1.2.3 Effects on arthropods other than bees (KCP 10.3.2)**

No in-field and off-field risk to non-target arthropods is expected after the application of COBRANZA according to the proposed GAP.

No in-field risk assessment is expected after application of Cobranza in vines and orchards.

An unacceptable risk in field was concluded for potatoes, for max proposed doses 4 x 1000 g a.s./ha. Acceptable risk could be concluded for 2 x 1000 g a.s./ha.

#### **9.1.2.4 Effects on non-target soil meso- and macrofauna (KCP 10.4)**

The risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) has been done. A risk to earthworms and other non-target soil organisms following the application of COBRANZA at the proposed label rate can be excluded up to 4 kg a.s./ha.

#### **9.1.2.5 Effects on soil microbial activity (KCP 10.5)**

No risk for soil micro-organisms is expected after the application COBRANZA according to the proposed

GAP.

#### 9.1.2.6 Effects on non-target terrestrial plants (KCP 10.6)

The calculated TER values are above the Annex VI trigger of 5 **for seedling emergence and** vegetative vigour when a minimal distance of 3 m is considered for all intended uses ~~except for pome fruits early application.~~

~~Therefore, no potential risk to non-target plants located outside the treated area after application of COBRANZA according to the GAP table is expected when risk mitigation measures are considered:~~

~~**Pome fruits (early application) – Spe3:** To protect non-target plants respect an unsprayed buffer zone of 10m to non-agricultural land OR the use 50% drift reducing nozzles.~~

#### 9.1.2.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

#### 9.1.3 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

**Table 9.1-2: Critical use pattern of COBRANZA grouped according to criterion**

Grouping according to criterion			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
Vineyards	Grapevine	Max application rate of 4 x 2.0 kg f.p./ha (equivalent to 4 x 1.0 kg a.s./ha) at BBCH 15-85	Birds and mammals, off-field assessment for arthropods other than bees and non-target plants. Highest PECsoil for assessment for soil organisms.
Potato	Potato	Max application rate of 3 x 2.4 kg f.p./ha (equivalent to 3 x 1.2 kg a.s./ha) or 4 x 2.0 kg f.p./ha (equivalent to 4 x 1.0 kg a.s./ha) at BBCH 15-85	Birds and mammals, off-field assessment for arthropods other than bees and non-target plants. Max annual application rate for assessment for soil microorganisms.
Fruiting vegetables	Solanaceous fruits (Tomato, aubergine)	Max application rate of 3 x 2.4 kg f.p./ha (equivalent to 3 x 1.2 kg a.s./ha) at BBCH 15-85	Birds and mammals, off-field assessment for arthropods other than bees and non-target plants.
Orchards	Pome fruit (apple, pear, quince)	Max application rate of 3 x 2.4 kg f.p./ha (equivalent to 3 x 1.2 kg a.s./ha) or 5 x 1.15 kg f.p./ha (equivalent to 5 x 0.575 kg a.s./ha) at BBCH 15-85	Birds and mammals, off-field assessment for arthropods other than bees and non-target plants.

Grouping according to criterion			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
All crops	Grapevine Potato Solanaceous fruits (Tomato, aubergine) Pome fruit (apple, pear, quince)	Max application rate (1.2 kg as/ha), same application growth stage (BBCH 15-85)	Highest application rate for assessment for bees.

#### 9.1.4 Consideration of metabolites

Not relevant. There is no relevant metabolite.

### 9.2 Effects on birds (KCP 10.1.1)

#### 9.2.1 Toxicity data

Avian toxicity studies have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR.

Effects on birds of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride.

However, the provision of further data on the COBRANZA is not considered essential, because active substance data on toxicity to birds can be used and additional formulation data are not considered essential.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds**

Species	Substance	Exposure System	Results	Reference
<i>Colinus virginianus</i>	Copper oxychloride	Acute	LD <sub>50</sub> = 511 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
<i>Colinus virginianus</i>	Copper oxychloride WP	Acute	LD <sub>50</sub> = 173 mg Cu/kg bw*	EFSA Journal 2018;16(1):5152
<i>Colinus virginianus</i>	Copper oxychloride	Short-term	LC <sub>50</sub> = 1939 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
<i>Colinus virginianus</i>	Copper hydroxide	Long-term	NOEL = 5.05 mg Cu/kg bw* NOEC = 57.5 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
<b>Additional higher tier studies (Annex Part A, points 10.1.1.2):</b> A literature review provides a weight of evidence approach concluding to acceptable risks to birds for doses of 5 kg Cu/ha/year, for granivorous and insectivorous birds.				EFSA Journal 2018;16(1):5152

\* Data retained by EFSA for the risk assessment.

### 9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

## 9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

### 9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in Grapevine**

Intended use		Grapevine				
Active substance/product		Copper oxychloride				
Application rate (g/ha)		4 × 1000				
Acute toxicity (mg/kg bw)		173				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Vineyard BBCH 10 - 19	Small insectivorous species “Redstart” ground invertebrates without interception 50% ground arthropods 50% foliar arthropods	27.4	1.5	41.10	<b>4.2</b>	
Vineyard BBCH ≥ 20	Small insectivorous species “Redstart” ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	25.7	1.5	38.55	<b>4.5</b>	
Vineyard BBCH 10 - 19	Small granivorous bird “Finch” Small seeds 100% weed seeds	14.8	1.5	22.20	<b>7.8</b>	
Vineyard BBCH 20 - 39	Small granivorous bird “Finch” Small seeds 100% weed seeds	12.4	1.5	18.60	<b>9.3</b>	
Vineyard BBCH ≥ 40	Small granivorous bird “Finch” Small seeds 100% weed seeds	7.4	1.5	11.10	15.6	
Vineyard BBCH 10 - 19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	14.4	1.5	21.60	<b>8.0</b>	
Vineyard BBCH 20 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	12.0	1.5	18.00	<b>9.6</b>	

Vineyard BBCH $\geq$ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.5	10.80	16.0
Vineyard Ripening	Frugivorous bird “Trush/starling” 100% grapes	28.9	1.5	43.35	<b>4.0</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>		5.05			
<b>TER criterion</b>		5			
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>it</sub></b>
Vineyard BBCH 10 - 19	Small insectivorous species “Red-start” ground invertebrates without interception 50% ground arthropods 50% foliar arthropods	11.5	1.9 x 0.53	11.58	<b>0.4</b>
Vineyard BBCH $\geq$ 20	Small insectivorous species “Red-start” ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	9.9	1.9 x 0.53	9.97	<b>0.5</b>
Vineyard BBCH 10 - 19	Small granivorous bird “Finch” Small seeds 100% weed seeds	6.9	1.9 x 0.53	6.95	<b>0.7</b>
Vineyard BBCH 20 - 39	Small granivorous bird “Finch” Small seeds 100% weed seeds	5.7	1.9 x 0.53	5.74	<b>0.9</b>
Vineyard BBCH $\geq$ 40	Small granivorous bird “Finch” Small seeds 100% weed seeds	3.4	1.9 x 0.53	3.42	<b>1.5</b>
Vineyard BBCH 10 - 19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.5	1.9 x 0.53	6.55	<b>0.8</b>
Vineyard BBCH 20 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4	1.9 x 0.53	5.44	<b>0.9</b>
Vineyard BBCH $\geq$ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	1.9 x 0.53	3.32	<b>1.5</b>
Vineyard Ripening	Frugivorous bird “Trush/starling” 100% grapes	14.4	1.9 x 0.53	14.50	<b>0.3</b>

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied

**Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in potato**

<b>Intended use</b>	<b>Potato use</b>  Copper oxychloride  3 × 1200
<b>Active substance/product</b>	
<b>Application rate (g/ha)</b>	

Acute toxicity (mg/kg bw)		173			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Potatoes BBCH 10 - 19	Small insectivorous bird “wag-tail” ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	26.8	1.5	48.24	3.6
Potatoes BBCH ≥ 20	Small insectivorous bird “wag-tail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	25.2	1.5	45.36	3.8
Potatoes BBCH 10 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	1.5	43.20	4.0
Potatoes BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.5	12.96	13.3
Reprod. toxicity (mg/kg bw/d)		5.05			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>
Potatoes BBCH 10 - 19	Small insectivorous bird “wag-tail” ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	1.8 x 0.53	12.94	0.4
Potatoes BBCH ≥ 20	Small insectivorous bird “wag-tail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	1.8 x 0.53	11.10	0.5
Potatoes BBCH 10 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	1.8 x 0.53	12.48	0.4
Potatoes BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	1.8 x 0.53	3.78	1.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied



**Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in fruiting vegetables**

Intended use		Solanaceous fruit (tomato and aubergine)				
Active substance/product		Copper oxychloride				
Application rate (g/ha)		3 x 1200				
Acute toxicity (mg/kg bw)		173				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Fruiting vegetables BBCH 10 - 19	Small insectivorous bird “wag-tail” ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	26.8	1.5	48.24	3.6	
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird “wag-tail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	25.2	1.5	45.36	3.8	
Fruiting vegetables BBCH 10 - 49	Small granivorous bird “finch” Small seeds 100% weed seeds	24.7	1.5	44.46	3.9	
Fruiting vegetables BBCH ≥ 50	Small granivorous bird “finch” Small seeds 100% weed seeds	7.4	1.5	13.32	13.0	
Fruiting vegetables BBCH 10 - 49	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	1.5	43.20	4.0	
Fruiting vegetables BBCH ≥ 50	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.5	12.96	13.3	
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous bird “Starling” Tomato 100% fruit	49.4	1.5	88.92	1.9	
Reprod. toxicity (mg/kg bw/d)		5.05				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Fruiting vegetables BBCH 10 - 19	Small insectivorous bird “wag-tail” ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	1.8 x 0.53	12.94	0.4	
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird “wag-tail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	1.8 x 0.53	11.10	0.5	
Fruiting vegetables BBCH 10 - 49	Small granivorous bird “finch” Small seeds 100% weed seeds	11.4	1.8 x 0.53	13.05	0.4	

Fruiting vegetables BBCH $\geq$ 50	Small granivorous bird “finch” Small seeds 100% weed seeds	3.4	1.8 x 0.53	3.89	<b>1.3</b>
Fruiting vegetables BBCH 10 - 49	Small omnivorous bird “lark” Combination (invertebrates with- out interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	1.8 x 0.53	12.48	<b>0.4</b>
Fruiting vegetables BBCH $\geq$ 50	Small omnivorous bird “lark” Combination (invertebrates with- out interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	1.8 x 0.53	3.78	<b>1.3</b>
Fruiting vegetables Fruit stage BBCH 71- 89	Frugivorous bird “Starling” To- mato 100% fruit	20.7	1.8 x 0.53	23.70	<b>0.2</b>

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied

**Table 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in Pome fruits**

Intended use		Pome fruit				
Active substance/product		Copper oxychloride				
Application rate (g/ha)		3 x 1200				
Acute toxicity (mg/kg bw)		173				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Orchard Crop directed application BBCH 10 - 19	Small granivorous bird "finch" Small seeds 100% seeds	21.9	1.5	39.42	<b>4.4</b>	
Orchard Crop directed application BBCH 20 - 39	Small granivorous bird "finch" Small seeds 100% seeds	16.4	1.5	29.52	<b>5.9</b>	
Orchard Crop directed application BBCH ≥ 40	Small granivorous bird "finch" Small seeds 100% seeds	8.2	1.5	14.76	11.7	
Orchard Crop directed application BBCH 10 - 19	Small insectivorous/worm feeding species “thrush” ground invertebrates with interception 100% soil dwelling invertebrates	5.9	1.5	10.62	16.3	
Orchard Crop directed application BBCH 20 - 39	Small insectivorous/worm feeding species “thrush” ground invertebrates with interception 100% soil dwelling invertebrates	4.4	1.5	7.92	21.8	
Orchard Crop directed application	Small insectivorous/worm feeding species “thrush”	2.2	1.5	3.96	43.7	

BBCH $\geq$ 40	ground invertebrates with interception 100% soil dwelling invertebrates				
Orchard Spring Summer,	Small insectivorous bird "tit" Foliar insects 100% foliar insects	46.8	1.5	84.24	<b>2.1</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>	5.05				
<b>TER criterion</b>	5				
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>It</sub></b>
Orchard Crop directed application BBCH 10 - 19	Small granivorous bird "finch" Small seeds 100% seeds	10.1	1.8 x 0.53	11.56	<b>0.4</b>
Orchard Crop directed application BBCH 20 - 39	Small granivorous bird "finch" Small seeds 100% seeds	7.6	1.8 x 0.53	8.70	<b>0.6</b>
Orchard Crop directed application BBCH $\geq$ 40	Small granivorous bird "finch" Small seeds 100% seeds	3.8	1.8 x 0.53	4.35	<b>1.2</b>
Orchard Crop directed application BBCH 10 - 19	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	2.1	1.8 x 0.53	2.40	<b>2.1</b>
Orchard Crop directed application BBCH 20 - 39	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	1.6	1.8 x 0.53	1.83	<b>2.8</b>
Orchard Crop directed application BBCH $\geq$ 40	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	0.8	1.8 x 0.53	0.92	5.5
Orchard Spring Summer,	Small insectivorous bird "tit" Foliar insects 100% foliar insects	18.2	1.8 x 0.53	20.84	<b>0.2</b>

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

## Conclusion

According to screening and tier I assessments for different intended crops uses, TERa and TERIt values are below the Annex VI triggers, indicating that COBRANZA presents an unacceptable acute and long-term risk to birds according to the intended uses. Therefore, an acute and long-term higher-tier risk assessment is necessary.

### 9.2.2.2 Higher-tier risk assessment

Higher-tier risk assessment is required since the TER values were below the trigger for birds. In order to refine the risk assessment, the following parameters refined below were considered.

#### MAF and TWA

A DT<sub>50</sub> of 10 days for a metal, where degradation does not exist it could be wrong. The Applicant considers that if there are not data to support dissipation for Cu, it seems logic to disregard degradation, therefore, values of MAF and TWA =1 are used in the refinement of risk assessment.

#### Deposition factor (DF)

COBRANZA will be applied directly to crop. Since weed seeds and ground arthropods will be covered by the crop, an interception by the crop has to be taken into account.

For grapevine, BBCH stages 15-85 corresponds with the leaf development, and according to the interception values of FOCUS (2012)<sup>1</sup>, for grapevine at growth stage leaf development, an interception factor of 60% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.4 should be applied.

For potato, BBCH stages 15-85 corresponds with the leaf development, and according to the interception values of FOCUS (2012), for potato at growth stage leaf development, an interception factor of 15% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.85 should be applied.

For solanaceous fruits (tomato and aubergine), BBCH stages 15-85 corresponds with the leaf development, and according to the interception values of FOCUS (2012), for solanaceous fruits (tomato and aubergine) at growth stage leaf development, an interception factor of 50% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.5 should be applied.

For pome fruits, BBCH stages 15-85 corresponds with the flowering, and according to the interception values of FOCUS (2012), for pome fruits at growth stage flowering, an interception factor of 60% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.4 should be applied.

**Table 9.2-6: Higher-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in grapevine – refined parameters (\*) are further described and justified in the text**

<b>Intended use</b>		<b>Grapevine</b>					
<b>Active substance/product</b>		Copper oxychloride					
<b>Application rate (g/ha)</b>		4 × 1000					
<b>Acute toxicity (mg/kg bw)</b>		173					
<b>TER criterion</b>		10					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>90</sub> × DF* (mg/kg food)</b>	<b>MAF<sub>90</sub>*</b>	<b>PT</b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>
Black Redstart ( <i>Phoenicurus ochruros</i> )	50% ground arthropods	0.81 <sup>1</sup>	9.7 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	1.57	<b>7.4</b>
	50% foliar arthropods	0.81 <sup>1</sup>	54.1 <sup>2</sup> × 1.0	1.0	1.0	21.95	

<sup>1</sup> FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

	whole diet					23.52	
Linnet ( <i>Carduelis cannabina</i> )	100% weed seeds	0.28 <sup>1</sup>	$87.0^2 \times 0.4^3$	1.0	1.0	9.74	17.75
Wood Lark ( <i>Lullula arborea</i> )	25% crop leaves	0.52 <sup>1</sup>	$70.3^2 \times 1.0$	1.0	1.0	9.14	11.8
	25% weed seeds	0.52 <sup>1</sup>	$87.0^2 \times 0.4^3$	1.0	1.0	4.52	
	50% ground arthropods	0.52 <sup>1</sup>	$9.7^2 \times 0.4^3$	1.0	1.0	1.01	
	whole diet					14.67	
Song Thrush ( <i>Turdus philomelos</i> )	100% grapes	1.73 <sup>1</sup>	$16.7 \times 1.0$	1.0	1.0	28.89	<b>6.0</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>		5.05					
<b>TER criterion</b>		5					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>m</sub> × DF*</b> (mg/kg food)	<b>MAF<sub>m</sub>* × TWA*</b>	<b>PT</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>lt</sub></b>
Black Redstart ( <i>Phoenicurus ochruros</i> )	50% ground arthropods	0.81 <sup>1</sup>	$3.5^2 \times 0.4^3$	1.0	1.0	0.57	<b>0.6</b>
	50% foliar arthropods	0.81 <sup>1</sup>	$21.0^2 \times 1.0$	1.0	1.0	8.51	
	whole diet					9.21	
Linnet ( <i>Carduelis cannabina</i> )	100% weed seeds	0.28 <sup>1</sup>	$40.2^2 \times 0.4^3$	1.0	1.0	4.50	<b>1.1</b>
Wood Lark ( <i>Lullula arborea</i> )	25% crop leaves	0.52 <sup>1</sup>	$28.7^2 \times 1.0$	1.0	1.0	3.73	<b>0.8</b>
	25% weed seeds	0.52 <sup>1</sup>	$40.2^2 \times 0.4^3$	1.0	1.0	2.09	
	50% ground arthropods	0.52 <sup>1</sup>	$3.5^2 \times 0.4^3$	1.0	1.0	0.36	
	whole diet					6.19	
Song Thrush ( <i>Turdus philomelos</i> )	100% grapes	1.73 <sup>1</sup>	$8.3^2 \times 1.0$	1.0	1.0	28.89	<b>0.4</b>

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> According to Appendix A of EFSA/2009/1438.

<sup>2</sup> According to table 1 from Appendix F of EFSA/2009/1438.

<sup>3</sup> Deposition factor according to FOCUS groundwater guidance.

**Table 9.2-7: Higher-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in potato – refined parameters (\*) are further described and justified in the text**

<b>Intended use</b>	<b>Potato</b>
<b>Active substance/product</b>	Copper oxychloride
<b>Application rate (g/ha)</b>	3 × 1200

Acute toxicity (mg/kg bw)		173					
TER criterion		10					
Focal species	Food category, % in diet	FIR/bw	RUD <sub>90</sub> × DF* (mg/kg food)	MAF <sub>90</sub> *	PT	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Yellow wagtail ( <i>Motacilla flava</i> )	50% ground arthropods	0.79 <sup>1</sup>	9.7 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	3.91	5.9
	50% foliar arthropods	0.79 <sup>1</sup>	54.1 <sup>2</sup> × 1.0	1.0	1.0	25.64	
	whole diet					29.55	
Wood Lark ( <i>Lullula arborea</i> )	25% crop leaves	0.52 <sup>1</sup>	70.3 <sup>2</sup> × 1.0	1.0	1.0	10.97	6.9
	25% weed seeds	0.52 <sup>1</sup>	87.0 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	11.54	
	50% ground arthropods	0.52 <sup>1</sup>	9.7 × 0.85	1.0	1.0	2.57	
	whole diet					25.08	
Reprod. toxicity (mg/kg bw/d)		5.05					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD <sub>m</sub> × DF* (mg/kg food)	MAF <sub>m</sub> * × TWA*	PT	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>
Yellow wagtail ( <i>Motacilla flava</i> )	50% ground arthropods	0.79 <sup>1</sup>	3.5 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	1.41	0.4
	50% foliar arthropods	0.79 <sup>1</sup>	21.0 <sup>2</sup> × 1.0	1.0	1.0	9.95	
	whole diet					11.36	
Wood Lark ( <i>Lullula arborea</i> )	25% crop leaves	0.52 <sup>1</sup>	28.7 <sup>2</sup> × 1.0	1.0	1.0	4.48	0.5
	25% weed seeds	0.52 <sup>1</sup>	40.2 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	5.33	
	50% ground arthropods	0.52 <sup>1</sup>	3.5 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	0.93	
	whole diet					10.74	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> According to Appendix A of EFSA/2009/1438.

<sup>2</sup> According to table 1 from Appendix F of EFSA/2009/1438.

<sup>3</sup> Deposition factor according to FOCUS groundwater guidance.

**Table 9.2-8: Higher-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in solanaceous (tomato and aubergine) – re-fined parameters (\*) are further described and justified in the text**

<b>Intended use</b>	<b>Solanaceous fruit (tomato and aubergine)</b>
<b>Active substance/product</b>	Copper oxychloride
<b>Application rate (g/ha)</b>	3 x 1200

<b>Acute toxicity (mg/kg bw)</b>		173					
<b>TER criterion</b>		10					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>90</sub> × DF* (mg/kg food)</b>	<b>MAF<sub>90</sub>*</b>	<b>PT</b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>
Yellow wagtail ( <i>Motacilla flava</i> )	50% ground arthropods	0.79 <sup>1</sup>	9.7 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	2.30	<b>6.2</b>
	50% foliar arthropods	0.79 <sup>1</sup>	54.1 <sup>2</sup> × 1.0	1.0	1.0	25.64	
	whole diet					27.94	
Linnet ( <i>Carduelis cannabina</i> )	100% weed seeds	0.28 <sup>1</sup>	87.0 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	14.62	11.8
Wood Lark ( <i>Lullula arborea</i> )	25% crop leaves	0.52 <sup>1</sup>	70.3 <sup>2</sup> × 1.0	1.0	1.0	10.97	<b>9.0</b>
	25% weed seeds	0.52 <sup>1</sup>	87.0 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	6.79	
	50% ground arthropods	0.52 <sup>1</sup>	9.7 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	1.51	
	whole diet					19.27	
Starling ( <i>Sturnus vulgaris</i> )	100% tomatoes	1.62 <sup>1</sup>	30.6 <sup>2</sup> × 1.0	1.0	1.0	59.49	<b>2.9</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>		5.05					
<b>TER criterion</b>		5					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>m</sub> × DF* (mg/kg food)</b>	<b>MAF<sub>m</sub>* × TWA*</b>	<b>PT</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>lt</sub></b>
Yellow wagtail ( <i>Motacilla flava</i> )	50% ground arthropods	0.81 <sup>1</sup>	3.5 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	0.85	<b>0.5</b>
	50% foliar arthropods	0.81 <sup>1</sup>	21.0 <sup>2</sup> × 1.0	1.0	1.0	10.21	
	whole diet					11.06	
Linnet ( <i>Carduelis cannabina</i> )	100% weed seeds	0.28 <sup>1</sup>	40.2 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	6.75	<b>0.7</b>
Wood Lark ( <i>Lullula arborea</i> )	25% crop leaves	0.52 <sup>1</sup>	28.7 <sup>2</sup> × 1.0	1.0	1.0	4.48	<b>0.6</b>
	25% weed seeds	0.52 <sup>1</sup>	40.2 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	3.14	
	50% ground arthropods	0.52 <sup>1</sup>	3.5 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	0.55	
	whole diet					8.16	
Starling ( <i>Sturnus vulgaris</i> )	100% tomatoes	1.62 <sup>1</sup>	12.8 <sup>2</sup> × 1.0	1.0	1.0	3.60	<b>0.2</b>

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> According to Appendix A of EFSA/2009/1438.

<sup>2</sup> According to table 1 from Appendix F of EFSA/2009/1438.

<sup>3</sup> Deposition factor according to FOCUS groundwater guidance.

**Table 9.2-9: Higher-tier assessment of the acute and long-term/reproductive risk for birds due to the use of COBRANZA in pome fruits– refined parameters (\*) are further described and justified in the text**

Intended use		Pome fruit						
Active substance/product		Copper oxychloride						
Application rate (g/ha)		3 x 1200						
Acute toxicity (mg/kg bw)		173						
TER criterion		10						
Focal species	Food category, % in diet		FIR/bw	RUD <sub>90</sub> × DF (mg/kg food)	MAF <sub>90</sub> *	PT	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Serin ( <i>Serinus serinus</i> )	100% weed seeds		0.31 <sup>1</sup>	87.0 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	12.95	13.4
Bluetit ( <i>Parus caeruleus</i> )	100% foliar insects		0.86 <sup>1</sup>	54.1 <sup>2</sup> × 1.0	1.0	1.0	55.83	3.1
Reprod. toxicity (mg/kg bw/d)		5.05						
TER criterion		5						
Focal species	Food category, % in diet		FIR/bw	RUD <sub>m</sub> × DF* (mg/kg food)	MAF <sub>m</sub> * × TWA*	PT	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Robin ( <i>Erithacus rubecula</i> )	100% soil dwelling invertebrates		0.76 <sup>1</sup>	3.5 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	1.28	4.0
Serin ( <i>Serinus serinus</i> )	100% weed seeds		0.31 <sup>1</sup>	40.2 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	5.98	0.8
Bluetit ( <i>Parus caeruleus</i> )	100% foliar insects		0.86 <sup>1</sup>	21.0 <sup>2</sup> × 1.0	1.0	1.0	21.67	0.2

After even the refinement, the risk assessment showed that Copper oxychloride presents an unacceptable acute and long-term risk for some birds in the intended uses. However, confirmatory data has been provided and evaluated at EU level to demonstrate that the risk to birds is acceptable and, therefore, a WoE is applied.

#### Weight of evidence

The current EFSA (2009) approach to risk assessment for birds, is not applicable to determine the risks for avian dietary exposure to copper, since it makes no allowance for the mechanisms involved in the regulation of copper – a naturally occurring element and essential micronutrient – in the body, or of the compensatory responses of vertebrates to excess copper intake.

A weight of evidence paper was submitted by the EUCuTF members for the renewal of approval of copper which provided evidence that owing to homeostatic control, **the acute and long-term risks risks to all birds is acceptable**. The RMS/EFSA partially agreed with this and considered that this weight of evidence approach could be used to conclude acceptable acute and long-term risks for granivorous and insectivorous birds for application doses of up to 8 kg Cu/ha as long as the amount applied during the breeding period did not exceed 5 kg/ha (EFSA, 2017).

The method of determining the short-term/acute risks to birds can be regarded as an unrealistic worst case estimation. Even after the application of fungicides, a percentage of feed items will remain uncontaminated and will be available within the field margins (Schabaker & Rastall, 2009a, CA 8.9/01). For those feed items that do contain residues of copper, the level of these residues shows a high level of variability.



It is therefore reasonable to consider that for any individual bird the availability of contaminated and non-contaminated feed items are equally available to them. This is an important factor because there are indications that birds actively avoid contaminated feed items or that they adjust their copper intake through selective feeding (Schabaker & Rastall, 2009a, CA 8.9/01) and the total copper intake is within the range of their natural homeostatic control mechanism. The calculation of TER values also assumes that birds will consume all their daily intake of food within one 'sitting' and within the area of application, i.e. PT = 1, this too is a very conservative assumption.

To provide weight to this premise, there are no descriptions of bird poisoning events that can be clearly traced to copper ingestion noted in the different wildlife monitoring programmes being maintained by various Member States.

The lack of any reports detailing copper-related mortality to bird populations suggests that the treatment of crops with copper poses less acute risks of direct mortality to birds than indicated by the risk assessment according to the EFSA guidance (2009), confirming again that the method in the GD (EFSA 2009) is inadequate for copper.

With regard to the potential long-term risks to birds, again the method of determining these can be regarded as an unrealistic worst case estimation as discussed for the acute/short-term risks. Additional information relating to the long-term risk to birds was presented in the weight of evidence paper submitted by the EUCuTF members for the renewal of approval of copper. This information included recent observations on bird communities in copper-treated orchards and vineyards in southern Europe (Italy, Spain, France) and central Europe (Germany, Poland) which consistently showed no obvious effects on breeding parameters and bird abundance and diversity. In general, the amounts of copper ingested in the diet are almost never harmful to wildlife because they are relatively low and because birds and mammals have the ability to maintain copper homeostasis by a combination of decreased absorption and enhanced excretion when exposed to higher levels.xxxxxx

Field monitoring results indicate that copper uses can result in different copper exposure levels in birds but, as expected from the physiologic background (homeostasis), no evidence was found that in sites where copper is used as a pesticide adverse effects on wildlife occur.

In summary, the presence of species from different dietary guilds and their active and flourishing populations in copper treated habitats (such as for example copper treated orchards and vineyards) indicate that birds as well as mammals with insectivorous as well as frugivorous and omnivorous diets are able to cope with the copper levels they find in their diets. Copper homeostasis based on physiological and behavioural mechanisms will keep internal copper levels below toxic thresholds over extended environmental concentrations.

**After consideration of the above arguments, it is considered that both the short-term and long-term risk to birds (including frugivorous and omnivorous birds) from exposure to copper residues on feed items for application doses of up to 8 kg Cu/ha as long as the amount applied during the breeding period did not exceed 5 kg/ha is acceptable.**

COBRANZA is applied at the maximum dose of 1.2 kg copper oxychloride /ha/application. According to the proposed GAP, the application rate of Copper per season is the following:

- Grapevine use : 4 applications at 1 kg/ha => 4 kg Cu/ha
- Potato use : 3 applications at 1.2 kg/ha or 4 applications at 1.0 kg/ha => 3.6 kg Cu/ha or 4.0 kg Cu/ha
- Solanaceous fruits (Tomato, aubergine) use : 3 applications at 1.2 kg/ha => 3.6 kg Cu/ha
- Pome fruit (apple, pear, quince) use : 3 applications at 1.2 kg/ha or 5 applications at 0.575 kg/ha => 3.6 kg Cu/ha or 2.875 kg Cu/ha

The proposed GAP are in line with the EFSA conclusions (rate lower than 8 kg/ha and lower than 5 Kg/ha during the breeding period). In this context, it can be conclude that the long-term risk is low for birds exposed to applications of COBRANZA.

**ZRMS comments:**

For copper oxychloride endpoints in line with EFSA Journal 2018;16(1):5152 were considered.

The Tier I acute and long-term risk assessment to birds was indicated as high for all the representative uses.

A higher tier risk assessment was performed by the applicant to show an acceptable risk to birds from copper applications, following approach proposed in the Peer Review Expert Meeting 169 (2017). That approach for higher tier agreed in the Peer Review Expert Meeting consider to use  $MAF \times TWA = 1$  for 1 maximum annual application from the GAP, whilst Applicant performed higher tier RA using  $MAF \times TWA = 1$  but still considering number of rates and concentrations as reported in GAP.

The risk assessment shall be conducted using the MAF and  $TWA = 1$  and one maximum cumulative annual application rate.

Further, as risk refinement, position papers were provided where a Weight of evidence (WoE) approach was presented to support a homeostatic mechanism in birds and mammals.

The WoE was discussed at the Pesticides Peer Review Meeting 169; the experts considered the evidence provided as not satisfactory to exclude the acute risk to birds and mammals. Furthermore, the experts concluded that the data from the wildlife reports which were part of the evidence provided along with information of bird population (e.g. abundance and density), may be indicative of the absence of incidents but not sufficient to address the acute risk identified.

The experts concluded that the WoE could be considered acceptable for addressing the long-term risk to birds and mammals for application rate up to 5 kg a.s./ha for granivorous and insectivorous birds; however, further data were considered necessary to draw a conclusion covering all the feeding guild categories, i.e. omnivorous and frugivorous birds and large herbivorous and frugivorous mammals (data gap).

By generating further data, the experts considered it useful to focus on, e.g. further investigation of the avoidance and further data on residue in food items.

Therefore, based on this conclusion further refinement is required at MSs level for omnivorous and frugivorous birds for all proposed uses for copper hydroxide depended on own indicator focal species.

ZRMS-PL is of the same opinion as RMS in RAR revised and, taking into account all the available data and due to the absence of an adapted guide to evaluate elements such as copper and that the conclusions were based on more than a realistic worst case scenario, this WoE approach could be used to conclude acceptable risk at dose requested (maximum annual application rate of 4 kg Cu/ha) until the existence of an accepted guidance document. The final decision should be considered at MSs level.

### 9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

#### Leaf scenario

Since COBRANZA is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

#### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg).

With a  $K_{(d)oc}$  of 19509.9 at pH 4-5 and 33918.3 at pH 5.5-6.5 (geomean values, EFSA Journal 2018;16(1):5152), Copper oxychloride belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the solanaceous fruits use also covers the risk for birds from all other intended uses in grapevines, potatoes and pome fruits (see 9.1-2).

Effective application rate (g/ha)=	2160			
Acute toxicity (mg/kg bw) =	173	quotient	=	12.49
Reprod. toxicity (mg/kg bw/d) =	5.05	quotient	=	427.72

As the ratios do not exceed the value of 3000 for Copper oxychloride, it is not necessary to conduct a drinking water risk assessment for bird.

### 9.2.2.4 Effects of secondary poisoning

A partition coefficient (Log Pow) is not relevant to copper as it is a metal, however, an estimated log  $P_{ow}$  value of 2.78 can be determined by the ratio of the water and n-octanol solubilities (EFSA Journal 2018;16(1):5152). Therefore, it does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required

#### Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

#### Risk assessment for fish-eating birds via secondary poisoning

Not required.

### 9.2.2.5 Biomagnification in terrestrial food chains

A literature review that was submitted for the renewal of approval of copper compounds provided evidence of a lack of bioaccumulation in the food chain (EFSA Journal 2018;16(1):5152).

**ZRMS comments:**

According to EFSA conclusion (EFSA Journal 2018;16(1):5152), a literature review provides evidence of lack of bioaccumulation in aquatic food chain.

### 9.2.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

### 9.2.4 Overall conclusions

According to screening and tier I assessments for different intended crops uses, TERa and TERIt values are below the Annex VI triggers, indicating that COBRANZA presents an unacceptable acute and long-term risk to birds according to the intended uses. ~~Therefore, an acute and long term higher tier risk assessment was necessary. A refinement based on MAF, TWA and DF was performed. After even the refinement, the risk assessment showed that Copper oxychloride presents an unacceptable acute and long-term risk for some birds in the intended uses. However, confirmatory data has been provided and evaluated at EU level to demonstrate that the risk to birds is acceptable and,~~ Therefore, a WoE is applied. In this context, it can be conclude that the risk is low for birds exposed to applications of COBRANZA at the proposed label rate.

The risk for drinking water exposure is acceptable and the effect of secondary poisoning is not expected.

## 9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

### 9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology) of this report.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals**

Species	Substance	Exposure System	Results	Reference
Rat	Tribasic copper sulfate	Oral Acute	LD <sub>50</sub> = 162.6* mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Rat	Copper sulfate	Long-term (90 days)	Males NOEL = 16* mg Cu/kg bw Females NOEL = 17 mg Cu/kg bw	EFSA Journal 2018;16(1):5152

\* Data retained by EFSA for the risk assessment.

### 9.3.1.1 Justification for new endpoints

Not relevant. EU agreed endpoints are used.

### 9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

#### 9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

To achieve a concise risk assessment, the risk envelope approach is applied

**Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in Grapevine**

<b>Intended use</b>		<b>Grapevine</b>				
<b>Active substance/product</b>		Copper oxychloride				
<b>Application rate (g/ha)</b>		4 × 1000				
<b>Acute toxicity (mg/kg bw)</b>		162.6				
<b>TER criterion</b>		10				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>	
Vineyard Application crop directed BBCH 10 - 19	Small herbivorous mammal "vole Grass + cereals 100% grass	81.9	1.5	122.85	<b>1.3</b>	
Vineyard Application crop directed BBCH 20 - 39	Small herbivorous mammal "vole Grass + cereals 100% grass	68.2	1.5	102.30	<b>1.6</b>	
Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.5	61.35	<b>2.7</b>	
Vineyard Application crop directed BBCH 10 - 19	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	10.3	1.5	15.45	10.5	
Vineyard Application crop directed BBCH 20 - 39	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	8.6	1.5	12.90	12.6	

Vineyard Application crop directed BBCH $\geq 40$	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.5	7.80	20.8
Vineyard BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	7.6	1.5	11.40	14.3
Vineyard BBCH $\geq 20$	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4	1.5	8.10	20.1
Vineyard BBCH 10 - 19	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Plant matter	16.3	1.5	24.45	<b>6.7</b>
Vineyard BBCH 20 - 39	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Plant matter	13.6	1.5	20.40	<b>8.0</b>
Vineyard BBCH $\geq 40$	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Plant matter	8.1	1.5	12.15	13.4
<b>Reprod. toxicity (mg/kg bw/d)</b>		16			
<b>TER criterion</b>		5			
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>lt</sub></b>
Vineyard Application crop directed BBCH 10 - 19	Small herbivorous mammal "vole Grass + cereals 100% grass	43.4	1.9 x 0.53	43.70	<b>0.4</b>
Vineyard Application crop directed BBCH 20 - 39	Small herbivorous mammal "vole Grass + cereals 100% grass	36.1	1.9 x 0.53	36.35	<b>0.4</b>
Vineyard Application crop directed BBCH $\geq 40$	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	1.9 x 0.53	21.85	<b>0.7</b>
Vineyard Application crop directed BBCH 10 - 19	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	4.7	1.9 x 0.53	4.73	<b>3.4</b>
Vineyard Application crop directed BBCH 20 - 39	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	1.9 x 0.53	3.93	<b>4.1</b>
Vineyard Application crop directed BBCH $\geq 40$	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1.9 x 0.53	2.32	6.9

Vineyard BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	1.9 x 0.53	4.23	<b>3.8</b>
Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	1.9 x 0.53	1.91	8.4
Vineyard BBCH 10 - 19	Large herbivorous mammal “lag- omorph” Non-grass herbs 100% Plant matter	6.7	1.9 x 0.53	6.75	<b>2.4</b>
Vineyard BBCH 20 - 39	Large herbivorous mammal “lag- omorph” Non-grass herbs 100% Plant matter	5.5	1.9 x 0.53	5.54	<b>2.9</b>
Vineyard BBCH ≥ 40	Large herbivorous mammal “lag- omorph” Non-grass herbs 100% Plant matter	3.3	1.9 x 0.53	3.32	<b>4.8</b>

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied

**Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in potato**

<b>Intended use</b>	Potato				
<b>Active substance/product</b>	Copper oxychloride				
<b>Application rate (g/ha)</b>	3 × 1200				
<b>Acute toxicity (mg/kg bw)</b>	162.6				
<b>TER criterion</b>	10				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>
Potatoes BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	11.40	1.5	13.68	11.9
Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	8.10	1.5	9.72	16.7
Potatoes BBCH 10 - 40	Large herbivorous mammal “lag- omorph” Non-grass herbs 100% Non-grass herbs	52.65	1.5	63.18	<b>2.6</b>
Potatoes BBCH ≥ 40	Large herbivorous mammal “lag- omorph” Non-grass herbs 100% Non-grass herbs	15.75	1.5	18.90	<b>8.6</b>
Potatoes BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	61.35	1.5	73.62	<b>2.2</b>

Potatoes BBCH 10 - 39	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	25.80	1.5	30.96	<b>5.3</b>
Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.80	1.5	9.36	17.4
<b>Reprod. toxicity (mg/kg bw/d)</b>		16			
<b>TER criterion</b>		5			
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>lt</sub></b>
Potatoes BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	1.8 x 0.53	4.81	<b>3.3</b>
Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	1.8 x 0.53	2.18	7.4
Potatoes BBCH 10 - 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	14.3	1.8 x 0.53	16.37	<b>1.0</b>
Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	4.3	1.8 x 0.53	4.92	<b>3.3</b>
Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Grass + cereals 100% grass	21.7	1.8 x 0.53	24.84	<b>0.6</b>
Potatoes BBCH 10 - 39	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1.8 x 0.53	8.93	<b>1.8</b>
Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1.8 x 0.53	2.63	6.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in solanaceous fruits (tomato and aubergine)**

<b>Intended use</b>	Solanaceous fruits (tomato and aubergine)
<b>Active substance/product</b>	Copper oxychloride
<b>Application rate (g/ha)</b>	3 × 1200



<b>Acute toxicity (mg/kg bw)</b>		162.6			
<b>TER criterion</b>		10			
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4	1.5	9.72	16.7
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.5	73.62	<b>2.2</b>
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.5	9.36	17.4
Fruiting vegetables BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	7.6	1.5	13.68	11.9
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	136.4	1.5	245.52	<b>0.7</b>
Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	17.2	1.5	30.96	<b>5.3</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>		16			
<b>TER criterion</b>		5			
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>lt</sub></b>
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	1.8 x 0.53	2.18	7.4
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	1.8 x 0.53	24.84	<b>0.6</b>
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1.8 x 0.53	2.63	6.1
Fruiting vegetables BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	1.8 x 0.53	4.81	<b>3.3</b>
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	72.3	1.8 x 0.53	82.77	<b>0.2</b>

Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1.8 x 0.53	8.93	<b>1.8</b>
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in Pome fruit (apple, pear and quince)**

<b>Intended use</b>	Pome fruit (apple, pear and quince)				
<b>Active substance/product</b>	Copper oxychloride				
<b>Application rate (g/ha)</b>	3 × 1200				
<b>Acute toxicity (mg/kg bw)</b>	162.6				
<b>TER criterion</b>	10				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub> (mg/kg bw/d)</b>	<b>TER<sub>a</sub></b>
<b>Growth stage</b>					
Orchard Application crop directed BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	10.5	1.5	18.90	<b>8.6</b>
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.5	73.62	<b>2.2</b>
Orchard Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.5	9.36	17.4
Orchard Application crop directed BBCH 10-19	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	28.1	1.5	50.58	<b>3.2</b>
Orchard Application crop directed BBCH 10-19	Small herbivorous mammal "vole Grass + cereals 100% grass	109.2	1.5	196.56	<b>0.8</b>
Orchard Application crop directed BBCH 10-19	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	13.8	1.5	24.84	<b>6.5</b>
Orchard Application crop directed BBCH 20-40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	21.1	1.5	37.98	<b>4.3</b>
Orchard Application crop directed BBCH 20-40	Small herbivorous mammal "vole Grass + cereals 100% grass	81.9	1.5	147.42	<b>1.1</b>

Orchard Application crop directed BBCH 20-40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	10.3	1.5	18.54	<b>8.8</b>
Orchard Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse" larger fruits 100% fruit	47.9	1.5	86.22	<b>1.9</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>		16			
<b>TER criterion</b>		5			
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>It</sub></b>
Orchard Application crop directed BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	4.3	1.8 x 0.53	4.92	<b>3.3</b>
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	1.8 x 0.53	24.84	<b>0.6</b>
Orchard Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1.8 x 0.53	2.63	6.1
Orchard Application crop directed BBCH 10-19	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	11.5	1.8 x 0.53	13.17	<b>1.2</b>
Orchard Application crop directed BBCH 10-19	Small herbivorous mammal "vole Grass + cereals 100% grass	57.8	1.8 x 0.53	66.17	<b>0.2</b>
Orchard Application crop directed BBCH 10-19	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	6.2	1.8 x 0.53	7.10	<b>2.3</b>
Orchard Application crop directed BBCH 20-40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	8.6	1.8 x 0.53	9.85	<b>1.6</b>
Orchard Application crop directed BBCH 20-40	Small herbivorous mammal "vole Grass + cereals 100% grass	43.4	1.8 x 0.53	49.68	<b>0.3</b>
Orchard Application crop directed BBCH 20-40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	4.7	1.8 x 0.53	5.38	<b>3.0</b>
Orchard Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse" larger fruits 100% fruit	22.7	1.8 x 0.53	25.99	<b>0.6</b>

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

## Conclusion

According to screening and tier I assessments for different intended crops, TERa and TERlt values are below the Annex VI triggers, indicating that the COBRANZA presents an unacceptable acute and long-term risk to mammals according to the intended uses. Therefore, an acute and long-term higher-tier risk assessment is necessary.

### 9.3.2.2 Higher-tier risk assessment

Higher-tier risk assessment is required since the TER values were below the trigger for mammals. In order to refine the risk assessment, the following parameters refined below were considered.

#### MAF and TWA

A DT<sub>50</sub> of 10 days for a metal, where degradation does not exist it could be wrong. The Applicant considers that if there are not data to support dissipation for Cu, it seems logic to disregard degradation, therefore, values of MAF and TWA =1 are used in the refinement of risk assessment.

#### Deposition factor (DF)

COBRANZA will be applied directly to crop. Since weed seeds and ground arthropods will be covered by the crop, an interception by the crop has to be taken into account.

For grapevine, BBCH stages 15-85 corresponds with the leaf development, and according to the interception values of FOCUS (2012)<sup>2</sup>, for grapevine at growth stage leaf development, an interception factor of 60% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.4 should be applied.

For potato, BBCH stages 15-85 corresponds with the leaf development, and according to the interception values of FOCUS (2012), for potato at growth stage leaf development, an interception factor of 15% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.85 should be applied.

For solanaceous fruits (tomato and aubergine), BBCH stages 15-85 corresponds with the leaf development, and according to the interception values of FOCUS (2012), for solanaceous fruits (tomato and aubergine) at growth stage leaf development, an interception factor of 50% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.5 should be applied.

For pome fruits, BBCH stages 15-85 corresponds with the flowering, and according to the interception values of FOCUS (2012), for pome fruits at growth stage flowering, an interception factor of 60% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.4 should be applied.

**Table 9.3-6: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in grapevine – refined parameters (\*) are further described and justified in the text**

Intended use	Grapevine
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<sup>2</sup> FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

<b>Active substance/product</b>		Copper oxychloride					
<b>Application rate (g/ha)</b>		4 × 1000					
<b>Acute toxicity (mg/kg bw)</b>		162.6					
<b>TER criterion</b>		10					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>90</sub> × DF*</b> (mg/kg food)	<b>MAF<sub>90</sub>*</b>	<b>PT</b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>
Brown Hare ( <i>Lepus europaeus</i> )	100% Plant matter	0.39 <sup>1</sup>	70.3 <sup>2</sup> × 1.0	1.0	1.0	27.42	<b>5.9</b>
Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	102.3 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	54.42	<b>3.0</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>		16					
<b>TER criterion</b>		5					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>m</sub> × DF*</b> (mg/kg food)	<b>MAF<sub>m</sub>* × TWA*</b>	<b>PT</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>lt</sub></b>
Brown Hare ( <i>Lepus europaeus</i> )	100% Plant matter	0.39 <sup>1</sup>	28.7 <sup>2</sup> × 1.0	1.0	1.0	27.42	<b>1.4</b>
Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	54.2 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	28.83	<b>0.6</b>
Wood mouse ( <i>Apodemus sylvaticus</i> )	25% weeds	0.27 <sup>1</sup>	28.7 <sup>2</sup> × 0.4	1.0	1.0	0.77	5.3
	50% weed seeds	0.27 <sup>1</sup>	40.2 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	2.17	
	25% ground arthropods	0.27 <sup>1</sup>	3.5 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	0.09	
	whole diet					3.04	
Common shrew ( <i>Sorex araneus</i> )	100% ground arthropods	0.55 <sup>1</sup>	3.5 <sup>2</sup> × 0.4 <sup>3</sup>	1.0	1.0	0.77	20.8

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> According to Appendix A of EFSA/2009/1438.

<sup>2</sup> According to table 1 from Appendix F of EFSA/2009/1438.

<sup>3</sup> Deposition factor according to FOCUS groundwater guidance.

**Table 9.3-7: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in potato – refined parameters (\*) are further described and justified in the text**

<b>Intended use</b>		<b>Potato</b>					
<b>Active substance/product</b>		Copper oxychloride					
<b>Application rate (g/ha)</b>		3 × 1200					
<b>Acute toxicity (mg/kg bw)</b>		162.6					
<b>TER criterion</b>		10					
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>90</sub> × DF*</b> (mg/kg food)	<b>MAF<sub>90</sub>*</b>	<b>PT</b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>

Rabbit ( <i>Oryctolagus cuniculus</i> )	100% Non-grass herbs	0.50 <sup>1</sup>	70.3 <sup>2</sup> × 1.0	1.0	1.0	42.18	3.9
Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	102.3 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	138.78	1.2
Wood mouse ( <i>Apodemus sylvaticus</i> )	25% weeds	0.27 <sup>1</sup>	70.3 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	4.84	9.3
	50% weed seeds	0.27 <sup>1</sup>	87.0 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	11.98	
	25% ground arthropods	0.27 <sup>1</sup>	9.7 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	0.67	
	whole diet					17.49	
Reprod. toxicity (mg/kg bw/d)		16					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD <sub>m</sub> × DF* (mg/kg food)	MAF <sub>m</sub> * × TWA*	PT	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>
Rabbit ( <i>Oryctolagus cuniculus</i> )	100% Plant matter	0.50 <sup>1</sup>	28.7 <sup>2</sup> × 1.0	1.0	1.0	17.22	0.9
Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	54.2 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	73.53	0.2
Wood mouse ( <i>Apodemus sylvaticus</i> )	25% weeds	0.27 <sup>1</sup>	28.7 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	1.65	2.5
	50% weed seeds	0.27 <sup>1</sup>	40.2 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	4.61	
	25% ground arthropods	0.27 <sup>1</sup>	3.5 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	0.20	
	whole diet					6.46	
Common shrew ( <i>Sorex araneus</i> )	100% ground arthropods	0.55 <sup>1</sup>	3.5 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	1.96	8.1

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> According to Appendix A of EFSA/2009/1438.

<sup>2</sup> According to table 1 from Appendix F of EFSA/2009/1438.

<sup>3</sup> Deposition factor according to FOCUS groundwater guidance.

**Table 9.3-8: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in solanaceous fruit (tomato and aubergine) – refined parameters (\*) are further described and justified in the text**

<b>Intended use</b>	<b>Solanaceous fruit (tomato and aubergine)</b>						
<b>Active substance/product</b>	Copper oxychloride						
<b>Application rate (g/ha)</b>	3 × 1200						
<b>Acute toxicity (mg/kg bw)</b>	162.6						
<b>TER criterion</b>	10						
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>RUD<sub>90</sub> × DF*</b> (mg/kg food)	<b>MAF<sub>90</sub>*</b>	<b>PT</b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>

Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	102.3 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	81.64	<b>2.0</b>
Wood mouse ( <i>Apodemus sylvaticus</i> )	25% weeds	0.27 <sup>1</sup>	70.3 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	2.85	15.8
	50% weed seeds	0.27 <sup>1</sup>	87.0 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	7.05	
	25% ground arthropods	0.27 <sup>1</sup>	9.7 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	0.39	
	whole diet					10.29	
Reprod. toxicity (mg/kg bw/d)		16					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD <sub>m</sub> × DF* (mg/kg food)	MAF <sub>m</sub> * × TWA*	PT	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>
Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	54.2 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	43.25	<b>0.4</b>
Wood mouse ( <i>Apodemus sylvaticus</i> )	25% weeds	0.27 <sup>1</sup>	28.7 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	1.16	<b>3.5</b>
	50% weed seeds	0.27 <sup>1</sup>	40.2 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	3.26	
	25% ground arthropods	0.27 <sup>1</sup>	3.5 <sup>2</sup> × 0.5 <sup>3</sup>	1.0	1.0	0.14	
	whole diet					4.56	
Common shrew ( <i>Sorex araneus</i> )	100% ground arthropods	0.55 <sup>1</sup>	3.5 <sup>2</sup> × 0.85 <sup>3</sup>	1.0	1.0	1.16	13.9

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> According to Appendix A of EFSA/2009/1438.

<sup>2</sup> According to table 1 from Appendix F of EFSA/2009/1438.

<sup>3</sup> Deposition factor according to FOCUS groundwater guidance.

**Table 9.3-9: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of COBRANZA in pome fruits– refined parameters (\*) are further described and justified in the text**

<b>Intended use</b>		<b>Pome fruits</b>					
<b>Active substance/product</b>		Copper oxychloride					
<b>Application rate (g/ha)</b>		3 × 1200					
<b>Acute toxicity (mg/kg bw)</b>		162.6					
<b>TER criterion</b>		10					
Focal species	Food category, % in diet	FIR/bw	$RUD_{90} \times DF^*$ (mg/kg food)	$MAF_{90}^*$	PT	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Rabbit ( <i>Oryctolagus cuniculus</i> )	100% Non-grass herbs	0.50 <sup>1</sup>	$70.3^2 \times 0.4^3$	1.0	1.0	16.87	<b>9.6</b>
Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	$102.3^2 \times 0.4^3$	1.0	1.0	65.31	<b>2.5</b>

Wood mouse ( <i>Apodemus sylvaticus</i> )	25% weeds	0.27 <sup>1</sup>	$70.3^2 \times 0.4^3$	1.0	1.0	2.28	19.8
	50% weed seeds	0.27 <sup>1</sup>	$87.0^2 \times 0.4^3$	1.0	1.0	5.64	
	25% ground arthropods	0.27 <sup>1</sup>	$9.7^2 \times 0.4^3$	1.0	1.0	0.31	
	whole diet					8.23	
Garden dormouse ( <i>Eliomys quercinus</i> )	100% fruit	1.16 <sup>1</sup>	$41.1^2 \times 1.0$	1.0	1.0	57.21	<b>2.8</b>
<b>Reprod. toxicity (mg/kg bw/d)</b>		16					
<b>TER criterion</b>		5					
Focal species	Food category, % in diet	FIR/bw	$RUD_m \times DF^*$ (mg/kg food)	$MAF_m^{**} \times TWA^*$	PT	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>
Rabbit ( <i>Oryctolagus cuniculus</i> )	100% Plant matter	0.50 <sup>1</sup>	$28.7^2 \times 0.4^3$	1.0	1.0	6.89	<b>2.3</b>
Common vole ( <i>Microtus arvalis</i> )	100% grass	1.33 <sup>1</sup>	$54.2^2 \times 0.5^3$	1.0	1.0	34.60	<b>0.5</b>
Wood mouse ( <i>Apodemus sylvaticus</i> )	25% weeds	0.27 <sup>1</sup>	$28.7^2 \times 0.4^3$	1.0	1.0	0.93	<b>4.4</b>
	50% weed seeds	0.27 <sup>1</sup>	$40.2^2 \times 0.4^3$	1.0	1.0	2.60	
	25% ground arthropods	0.27 <sup>1</sup>	$3.5^2 \times 0.4^3$	1.0	1.0	0.11	
	whole diet					3.65	
Garden dormouse ( <i>Eliomys quercinus</i> )	100% fruit	1.16 <sup>1</sup>	$19.5^2 \times 1.0$	1.0	1.0	27.14	<b>0.6</b>

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

<sup>1</sup> According to Appendix A of EFSA/2009/1438.

<sup>2</sup> According to table 1 from Appendix F of EFSA/2009/1438.

<sup>3</sup> Deposition factor according to FOCUS groundwater guidance.

After even the refinement, the risk assessment showed that Copper oxychloride presents an unacceptable acute and long-term risk for some mammals in the intended uses. However, confirmatory data has been provided and evaluated at EU level to demonstrate that the risk to mammals is acceptable and, therefore, a WoE is applied.

#### Weight of evidence

A weight of evidence paper was submitted by the EUCuTF members for the renewal of approval of copper which provided evidence that owing to homeostatic control, the acute and long-term risks to all mammals is acceptable. EFSA disagreed with this and considered that there was still a concern regarding the long-term risk to a single generic focal species, the large herbivorous “lagomorph” (EFSA Journal 2018;16(1):5152).

The agreed long-term endpoint for the mammalian risk assessment is a NOAEL of 16 mg Cu/kg bw/d (EFSA Journal 2018;16(1):5152). Based on this agreed value and a TER trigger value of 5, the lowest Daily Dietary Dose (DDD) that would result in acceptable risks was determined to be 3.2 mg Cu/kg bw/d.



$$DDD = \frac{Toxicity}{TER} = \frac{16}{5} = 3.2$$

Utilizing an ETE approach for a rabbit with a FIR/bw = 0.50 (EFSA, 2009) and assuming a worst case PT of 1, the required concentration of copper in diet that would result in acceptable risks (C) was calculated to be 6.4 mg/kg fresh diet:

$$DDD = ETE = \frac{FIR}{bw} * C * PT$$

$$\text{Therefore } C = \frac{ETE}{FIR/bw} * \frac{1}{PT} = \frac{3.2}{0.50} * \frac{1}{1} = 6.4$$

In a study to assess the effect of dietary copper addition on lipid metabolism in rabbits (Lei, L. *et al.*, 2017) the authors showed that basal control diet containing 8.19 mg Cu/kg had no adverse effect on rabbits over a 30-Day study period, and supplementation of this basal diet with concentrations up to 45 mg Cu/kg had no significant effect on food intake or resulted in any treatment related mortalities. Cooper, G.L., *et al.* (1996) reports a typical copper supplementation of 100 ppm copper in the diet of rabbits held in a commercial fryer ranch and one would assume that for the purposes of breeding, this diet must be suitable. EFSA<sup>3</sup> also documents the Maximum Tolerable Level (MTL) for rabbits to be 500 mg Cu/kg diet based on two studies in which rabbits “received 500 mg Cu/kg diet for up to 32 days without adverse effects on growth performance”.

It should also be noted that copper residues after treatment in grapevine (STMR 0.28 mg/kg), potato (STMR 1.30 mg/kg) and apple (STMR 1.28 mg/kg) are all well below the values fed in these studies (please, refer to dRR B7).

This data indicates that the model for assessing the risks of dietary intake of copper are not appropriate since unacceptable risks are concluded at concentrations that are significantly lower than those that have been assessed in the literature, and at concentrations that are also significantly lower than the EFSA maximum authorised content of copper in rabbit feed.

Therefore, it is considered that the risks to the lagomorph are acceptable and when EFSA publishes its guidance documents on the assessment of risk to mammals from exposure to metals this assessment will be updated.

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<sup>3</sup> EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the revision of the currently authorised maximum copper content in complete feed. EFSA Journal 2016;14(8):4563, 100 pp. doi:10.2903/j.efsa.2016.4563

#### ZRMS comments:

The acute and long-term TER values for copper are below the relevant trigger values at screening step and at Tier 1 for most of the scenarios, according to the use pattern of the product Copper oxyhydroxide 50% (Cobranza).

A higher tier risk assessment was performed by the Applicant to show an acceptable risk to mammals from copper applications, following approach proposed in the Peer Review Expert Meeting 169 (2017). That approach for higher tier agreed in the Peer Review Expert Meeting consider to use  $MAF \times TWA = 1$  for 1 maximum annual application from the GAP, whilst Applicant performed higher tier RA using  $MAF \times TWA = 1$  but still considering number of rates and concentrations as reported in GAP.

Therefore, the risk assessment should be conducted using the MAF and  $TWA = 1$  and one maximum cumulative annual application rate. In ZRMS opinion in light of WoE approach the higher tier calculations are not be considered by ZRMS-PL.

The Applicant submitted a weight of evidence (WoE) approach: according to the information on RAR, EFSA conclusion-2018 and Final Renewal report SANTE/10506/2018.

During the renewal of copper hydroxide the RMS -France concluded the following: “A *weight-of-evidence based approach to refine the mammals risk assessments is submitted. Together with the studies of Schabacker, J. and Rastall, A. 2009 a & b the effects of copper exposure on wild life is studied. The RMS considers that the literature review provided by the notifier (EUCuTF) gives evidence of homeostatic mechanisms for mammals. Theoretical acute and long-term dietary exposure of shrew and vole observed in the papers performed by Hunter et al. (1987a, b; 1989) is much higher than the one calculated for a standard application rate of copper in vineyard and tomato crops. Thus, the acute and the long-term risk to mammals due to copper exposure can be considered acceptable for the small herbivorous mammal “vole” and the small insectivorous mammal “shrew”.*”

Further, according to EFSA Conclusion 2018, literature review provides evidence of homeostatic mechanisms, and allows concluding to acceptable long-term risks based on weight of evidence **except for** large herbivorous

Therefore, based on this conclusion further refinement is required at MSs level for all proposed uses for large herbivorous mammals.

ZRMS-PL is of the same opinion as RMS in RAR revised, and taking into account all the available data and due to the absence of an adapted guide to evaluate elements such as copper and that the conclusions were based on *more than a realistic worst case scenario*, the WoE approach could be used to conclude acceptable risk at the dose rate requested until the existence of an accepted guidance document.

The final decision should be considered at MSs level.

### 9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

#### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg).

With a  $K_{(d)oc}$  of 19509.9 at pH 4-5 and 33918.3 at pH 5.5-6.5 (geomean values, EFSA Journal 2018;16(1):5152), Copper oxychloride belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the grapevine use also covers the risk for mammals from all other intended uses in potatoes, solanaceous fruits and pome fruits (see 9.1-2)

Effective application rate (g/ha) =	2160		
Acute toxicity (mg/kg bw) =	162.6	quotient =	13.28
Reprod. toxicity (mg/kg bw/d) =	16	quotient =	135.00

As the ratios do not exceed the value of 3000 for COBRANZA, it is not necessary to conduct a drinking water risk assessment for mammals.

### 9.3.2.4 Effects of secondary poisoning

A partition coefficient (Log Pow) is not relevant to copper as it is a metal, however, an estimated log  $P_{ow}$  value of 2.78 can be determined by the ratio of the water and n-octanol solubilities (EFSA Journal 2018;16(1):5152). Therefore, it does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

#### Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

### 9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

### 9.3.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

### 9.3.4 Overall conclusions

According to screening and tier I assessments for different intended crops uses, TERa and TERlt values are below the Annex VI triggers, indicating that COBRANZA presents an unacceptable acute and long-term risk to mammals according to the intended uses. Therefore, an acute and long-term higher-tier risk assessment was necessary. A refinement based on MAF, TWA and DF was performed. After even the

~~refinement, the risk assessment showed that Copper oxychloride presents an unacceptable acute and long-term risk for some mammals in the intended uses. However, confirmatory data has been provided and evaluated at EU level to demonstrate that the risk to mammals is acceptable and.~~ Therefore, a WoE is applied. In this context, it can be conclude that the risk is low for mammals exposed to applications of COBRANZA at the proposed label rate.

The risk for drinking water exposure is acceptable and the effect of secondary poisoning is not expected.

## 9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

A literature review that was submitted for the renewal of approval of copper compounds (EFSA Journal 2018;16(1):5152) provided evidence of a range of median lethal or effective concentrations for amphibians from 19.5 to 180 µg Cu/L while the lowest value that caused significant effects to an amphibian (toad) was 4.25 µg/L (measured concentrations) A NOAL value of 283.3 mg/kg soil (mean measured concentrations) was identified. Given the extremely high NOAL value, it is considered that the literature review data provides sufficient evidence of a lack of risk to other terrestrial wildlife (reptiles and amphibians).

## 9.5 Effects on aquatic organisms (KCP 10.2)

### 9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Copper oxychloride**

Species	Substance	Exposure System	Results	Reference
<b>Fish</b>				
<i>O. mykiss</i>	Copper hydroxide WP	96 h, f	Mortality, Total: LC <sub>50</sub> = 0.0165 mg/L <sub>mm</sub> <b>Dissolved: LC<sub>50</sub> = 0.0080 mg/L<sub>mm</sub></b>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper oxychloride	96 h, f	Mortality, Total: LC <sub>50</sub> > 43.8 mg/L <sub>mm</sub> Dissolved: LC <sub>50</sub> > 0.106 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper oxychloride	96 hr, ss	Mortality, Dissolved: EC <sub>50</sub> = 0.047 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper oxychloride WP	96 h, f	Mortality, Total: LC <sub>50</sub> > 0.78 mg/L <sub>mm</sub> Dissolved: LC <sub>50</sub> > 0.0109 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>O. mykiss</i>	Bordeaux mixture	96 hr, ss	Mortality, Total: LC <sub>50</sub> > 21.39 mg/L <sub>mm</sub> Dissolved: LC <sub>50</sub> > 0.125 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Bordeaux mixture	96 hr, ss	Mortality, LC <sub>50</sub> = 0.082 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Bordeaux mixture WP	96 hr, ss	Mortality, LC <sub>50</sub> = 0.052 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Tribasic copper sulfate SC	96 hr, s	Mortality, LC <sub>50</sub> = 13.18 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>C. carpio</i>	Tribasic copper sulfate SC	96 hr, f	Mortality, LC <sub>50</sub> > 19.3 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper oxide	96 h, f	Mortality, Total: LC <sub>50</sub> > 0.207 mg/L <sub>mm</sub> Dissolved: LC <sub>50</sub> = 0.0344 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper oxide WP	96 h, f	Mortality, Total: LC <sub>50</sub> = 0.047 mg/L <sub>mm</sub> Dissolved: LC <sub>50</sub> = 0.0106 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>C. carpio</i>	Copper oxide WG	96 hr, ss	Mortality, LC <sub>50</sub> = 4.37 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper Hydroxide WP (with sediment)	48 h, s	Mortality, Total: LC <sub>50</sub> = 0.54 mg/L <sub>mm</sub> Dissolved: LC <sub>50</sub> = 0.18 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper hydroxide WP	92 d, ELS	Growth: Total: NOEC= 0.0155 mg/L <sub>mm</sub> <b>Dissolved: NOEC = 0.0017 mg/L<sub>mm</sub></b>	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Tribasic copper sulfate SC	21 d, f	Growth: Total: NOEC= 0.97 mg/L <sub>nom</sub>	EFSA Journal 2018;16(1):5152
<i>D. rerio</i> (embryo) <sup>12</sup>	Copper hydroxide	48h, s	Mortality, Total: NOEC ≤ 3.2 mg/L <sub>nom</sub>	EFSA Journal 2018;16(1):5152
<i>D. rerio</i> (embryo) <sup>12</sup>	Copper oxychloride	48h, s	Mortality, Total: NOEC = 18.0 mg/L <sub>nom</sub>	EFSA Journal 2018;16(1):5152
<i>D. rerio</i> (embryo) <sup>12</sup>	Bordeaux mixture	48h, s	Mortality, Total: NOEC = 22.5 mg/L <sub>nom</sub>	EFSA Journal 2018;16(1):5152
<i>D. rerio</i> (embryo) <sup>12</sup>	Tribasic Copper sulphate	48h, s	Mortality, Total: NOEC = 76.8 mg/L <sub>nom</sub>	EFSA Journal 2018;16(1):5152
<i>D. rerio</i> (embryo) <sup>12</sup>	Copper oxide	48h, s	Mortality, Total: NOEC = 1.06 mg/L <sub>nom</sub>	EFSA Journal 2018;16(1):5152
<i>Pimephales promelas</i>	Copper sulfate	270 d, f	Dissolved Cu: NOEC (number of eggs/spawn) = 0.066 mg/L	EFSA Journal 2018;16(1):5152
<i>Perca fluviatilis</i>	Copper sulfate	30 d, f	Mortality: NOEC = 0.188 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Perca fluviatilis</i>	Copper sulfate	18 d, f	Growth rate: NOEC = 0.022 mg/L (total Cu)	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Pimephales notatus</i>	Copper sulfate	60 d, f	Growth rate: NOEC = 0.0441 mg/L (total Cu) Growth rate, mortality: NOEC = 0.0718 mg/L (total Cu) Reproduction: NOEC = 0.0043 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>	Copper chloride	60 d, f	Growth: NOEC = 0.0022 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Salvelinus fontinalis</i>	Copper sulfate	189 and 244 d, f	Growth rate, number of eggs/spawn: 244-d NOEC = 0.0174 mg/L (total Cu) Growth rate, mortality: 189-d NOEC = 0.0095 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Pimephales promelas</i>	Copper sulfate	330 d, f	Growth rate, mortality: NOEC = 0.033 mg/L (total Cu) Reproduction: NOEC = 0.0145 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Pimephales promelas</i>	Copper sulfate	327 d, f	Growth rate, mortality and reproduction: NOEC = 0.0106 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Oncorhynchus kisutch</i>	Cu <sup>2+</sup> (copper salt not reported)	61 d, f	Growth rate: Dissolved Cu : NOEC = 0.021 mg/L Reproduction: Dissolved Cu= 0.018 mg/L	EFSA Journal 2018;16(1):5152
<i>O. mykiss</i>		61 d, f 270 d, f	Growth rate: Dissolved Cu : NOEC = 0.045 mg/L Mortality: Dissolved Cu= 0.024 mg/L	EFSA Journal 2018;16(1):5152
<i>Pimephales promelas</i>	Copper sulfate	7; 97 and 187 d, f	NOEC (growth rate) = 0.0595 mg/L (total Cu) NOEC (eggs/female) = 0.0165 mg/L (total Cu) NOEC (eggs/female) = 0.023 mg/L (total Cu) NOEC (eggs/female) = 0.016 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Ictalurus punctatus</i>	Copper sulfate	60 d, f	NOEC (growth rate, mortality) = 0.013 mg/L (total Cu)	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Salvelinus fontinalis</i>			30-d NOEC (growth rate - soft water) = 0.007 mg/L (total Cu) 30-d NOEC (growth rate, mortality - hard water) = 0.021 mg/L (total Cu) 30-d NOEC (reproduction) = 0.049 mg/L (total Cu) 60-d NOEC (mortality) = 0.013 mg/L (total Cu) 60-d NOEC (reproduction) = 0.007 mg/L (total Cu)	
<i>Pimephales promelas</i>	Copper sulfate	28 d, f	NOEC (mortality) = 0.061 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Neomacheilus barbatulus</i>	Copper sulfate	64 d, f	NOEC (survival) = 0.120 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Pimephales promelas</i>	Copper nitrate	32 d, f	NOEC (mortality, growth) = 0.0048 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Salvenus fontinalis</i>	Copper sulfate	45 d, f	NOEC (mortality, growth) = 0.0114 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Oncorhynchus mykiss</i>		40 d, f	NOEC (mortality, growth) = 0.0129 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Catostomus commersoni</i>		35 d, f	NOEC (mortality, growth) = 0.0349 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Esox lucius</i>		60 d, f	NOEC (mortality, growth) = 0.0223 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
<i>Oncorhynchus mykiss</i>	Copper sulfate	30 d, f	LC <sub>10</sub> (mortality – pH 5.1) = 0.0038 mg/L (dissolved Cu) LC <sub>10</sub> (mortality – pH 6.2) = 0.0047 (dissolved Cu) LC <sub>10</sub> (mortality – pH 7.1) = 0.0039 (dissolved Cu) LC <sub>10</sub> (mortality – pH 7.9) = 0.0076 (dissolved Cu) LC <sub>10</sub> (mortality – pH 8.6) = 0.0161 (dissolved Cu)	EFSA Journal 2018;16(1):5152
<i>Acipenser transmontanus</i>	Copper sulfate	66 d, f	NOEC (mortality) = 0.0059 mg/L (dissolved Cu)	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Acipenser transmontanus</i>	Copper sulfate	14 d; 28 d; 53 d, f	14-d LC <sub>10</sub> (mortality) = 0.00183 mg/L (dissolved Cu) <b>53-d EC<sub>10</sub> (growth) = 0.00112</b> mg/L (dissolved Cu) 28-d LC <sub>10</sub> (mortality) = 0.00372 mg/L (dissolved Cu) 28-d EC <sub>10</sub> (growth) = 0.00196 mg/L (dissolved Cu) 28-d EC <sub>10</sub> (growth) = 0.00203 mg/L (dissolved Cu)	EFSA Journal 2018;16(1):5152
<i>Oncorhynchus mykiss</i>		14 d; 28 d; 53 d, f	21-d LC <sub>10</sub> (mortality) = 0.037 mg/L (dissolved Cu) 52-d LC <sub>10</sub> (mortality) = 0.034 mg/L (dissolved Cu) 21-d EC <sub>10</sub> (biomass) = 0.031 mg/L (dissolved Cu) 28-d LC <sub>10</sub> (mortality) = 0.034 mg/L (dissolved Cu) 28-d EC <sub>10</sub> (growth) = 0.013 mg/L (dissolved Cu) 28-d EC <sub>10</sub> (biomass) =0.025 mg/L (dissolved Cu)	
Aquatic invertebrate				
<i>D. magna</i>	Copper hydroxide	48h, s	Reproduction, Total: EC <sub>50</sub> = 0.038 mg/L <sub>mm</sub> Dissolved: <b>EC<sub>50</sub> = 0.0266 mg/L<sub>mm</sub></b>	EFSA Journal 2018;16(1):5152
<i>D. magna</i>	Copper oxychloride	48h, s	Mortality, Total: EC <sub>50</sub> = 0.29 mg/L <sub>nom</sub> *	EFSA Journal 2018;16(1):5152
<i>D. magna</i>	Bordeaux mixture	48h, s	Mortality, Total: EC <sub>50</sub> = 1.87 mg/L <sub>nom</sub> *	EFSA Journal 2018;16(1):5152
<i>D. magna</i>	Copper oxide	48h, s	Mortality, Total: EC <sub>50</sub> = 0.45 mg/L <sub>nom</sub> *	EFSA Journal 2018;16(1):5152
<i>D. magna</i>	Copper oxychloride	21d, ss	Reproduction, Total: NOEC = 0.0076 mg/L <sub>mm</sub> (geometric mean measured)#	EFSA Journal 2018;16(1):5152
<i>D. magna</i>	Copper oxychloride	21d, ss	Reproduction, Total: NOEC = 0.059 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>D. magna</i>	Tribasic copper sulfate SC	21d, ss	Reproduction, Total: NOEC = 0.057 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
<i>D. magna</i> (21-d studies with sediment)**	Copper hydroxide WP	21d, ss	Mortality, Total: LC <sub>50</sub> = 0.024 mg/L <sub>mm</sub>	EFSA Journal 2018;16(1):5152
			Reproduction, Total: NOEC = 0.0299 mg/L <sub>mm</sub>	
	Copper hydroxide SC	21d, ss	Mortality, Total: LC <sub>50</sub> = 0.0109 mg/L <sub>mm</sub>	
			Reproduction, <b>Total: NOEC = 0.027 mg/L<sub>mm</sub></b>	
	Copper oxychloride WP	21d, ss	Mortality, Total: LC <sub>50</sub> = 0.0298 mg/L <sub>mm</sub>	



Species	Substance	Exposure System	Results	Reference
			Reproduction, Total: NOEC = 0.0461 mg/L <sub>mm</sub>	
	Bordeaux mixture WP	21d, ss	Mortality, Total: LC <sub>50</sub> = 0.0109 mg/L <sub>mm</sub>	
			Reproduction, Total: NOEC = 0.027 mg/L <sub>mm</sub>	
	Tribasic copper sulfate SC	21d, ss	Mortality, Total: LC <sub>50</sub> = 0.0167 mg/L <sub>mm</sub>	
			Reproduction, Total: NOEC = 0.034 mg/L <sub>mm</sub>	
	Copper oxide WP	21d, ss	Mortality, Total: LC <sub>50</sub> = 0.0113 mg/L <sub>mm</sub>	
			Reproduction, Total: NOEC = 0.0122 mg/L <sub>mm</sub>	
Sediment dwelling organisms				
<i>Chironomus riparius</i>	Tribasic copper sulphate *	28d, s spiked sediment	Reproduction, Total: NOEC = 0.50 mg/L <sub>nom</sub>	EFSA Journal 2018;16(1):5152
<i>Chironomus riparius</i>	Copper chloride	28d, s spiked sediment	Survival, NOEC = 64.27 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152
<i>Tubifex tubifex</i>	Copper sulfate	28d, s spiked sediment	Reproduction, NOEC = 152.04 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152
	Copper chloride	28d, ss spiked sediment	Reproduction, growth NOEC = 16.17 mg/kg dry weight normalized to 2.5% OC	
	Copper chloride	28d, s spiked sediment	Reproduction, growth NOEC = 639 mg/kg dry weight normalized to 2.5% OC	
	Copper sulfate	28d, s spiked sediment	Survival, autotomy, reproduction and total growth rate NOEC = 243.97 mg/kg dry weight normalized to 2.5% OC	
<i>Hyalella azteca</i>	Copper chloride	28d, ss spiked sediment	Growth NOEC = 25.70 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152
<i>Lumbriculus variegatus</i>	Copper chloride	28d, ss spiked sediment	Biomass NOEC = 76.82 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152
<i>Gammarus pulex</i>	Copper chloride	28d, ss spiked sediment	Survival NOEC = 27.04 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Hyalella azteca</i>	Copper chloride	28d, ss spiked sediment	Growth NOEC = 50.77 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152
<i>Hexagenia spp.</i>	Copper chloride	28d, ss spiked sediment	Growth NOEC = 116.99 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152
<i>Bellamya aeruginosa</i>	Copper sulfate	28d, ss spiked sediment	Fecundity NOEC = 48.34 mg/kg dry weight normalized to 2.5% OC	EFSA Journal 2018;16(1):5152
<b>Algae</b>				
<i>S. capricornutum</i>	Copper hydroxide WP	72h, s	Biomass: Total $E_bC_{50} = 0.00939 \text{ mg/L}_{nom}$  <b>Growth rate:</b> Total $E_rC_{50} = 0.02229 \text{ mg/L}_{nom}$	EFSA Journal 2018;16(1):5152
<i>S. subspicatus</i>	Copper oxychloride	72h, s	Biomass, Total: $E_bC_{50} = 49.81 \text{ mg/L}_{mm}$ Growth rate, Total: $E_rC_{50} > 165.9 \text{ mg/L}_{mm}$	EFSA Journal 2018;16(1):5152
<i>D. subspicatus</i>	Bordeaux mixture	72h, s	Biomass, Total: $E_bC_{50} = 0.64 \text{ mg/L}_{nom}$  Growth rate, Total: $E_rC_{50} = 11.55 \text{ mg/L}_{nom}$  Biomass, Total: $E_bC_{50} = 0.07 \text{ mg/L}_{nom}$  Growth rate, Total: $E_rC_{50} = 5.54 \text{ mg/L}_{nom}$	EFSA Journal 2018;16(1):5152
<i>P. subcapitata</i>	Copper oxide WP	72h, s	Biomass, Total: $E_bC_{50} = 0.147 \text{ mg/L}_{mm}$  Growth rate, Total: $E_rC_{50} = 0.299 \text{ mg/L}_{mm}$  Biomass, Dissolved: $E_bC_{50} = 0.045 \text{ mg/L}_{mm}$  Growth rate, Dissolved: $E_rC_{50} = 0.133 \text{ mg/L}_{mm}$	EFSA Journal 2018;16(1):5152
<b>Microcosm or mesocosm tests</b>				
Indoor microcosm study	Copper hydroxide WP	6 applications at 10-d interval followed by 250 days of monitoring	Total : NOEC = 0.012 mg/L <sub>nom</sub> <b>Dissolved : 0.0048 mg/L<sub>mm</sub></b> <b>(AF = 2 applied)</b>	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Outdoor mesocosm study including fish	Copper sulfate	18 months, f	Total : NOEC (community) = 5 µg Cu/L Dissolved : NOEC (community) = 4 µg Cu/L	EFSA Journal 2018;16(1):5152
<p><i>Further testing on aquatic organisms</i> Fish, acute, data from 7 fish species available from the literature were used. Therefore, this allows to derived a SSD-HC<sub>5</sub> values of 3.73 µg/L, an AF of 3 is applied. Fish, chronic (based on SSD analysis SSD-HC<sub>5</sub> = 0.00111 mg/L (AF = 4-3) Sediment dwelling organisms (based on toxicity dataset and due considerations of sediment properties) lowest available endpoint = 16.17 mg/kg normalized for 2.5% OC. Considering that data for 5 additionnal species are available (besides the tier 1 <i>Chrinomus riparius</i> and <i>Hyallela Azteca</i> species) an AF = 5 has been set.</p> <p><i>Potential endocrine disrupting properties (Annex Part A, point 8.2.3)</i> No information highlights any ED property of copper.</p>				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations;  
im: based on initial measured concentrations

Note: Data in bold used for the risk assessment.

a (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

# according to the study summary, this study was performed following the guideline OECD 202 and not according to the OECD 211. The full compliance to one of the validity criteria of the OECD 211 could not be confirmed from the information available in the RAR; it is reported that the cumulative number of offspring per female was >40 on day 21, according to the validity criteria the mean number of living offspring produced per parent animal surviving at the end of the test should be > 60. It is noted that in the study summary it is mentioned that this validity criteria cannot be accurately estimated with the test method that was followed.

\* The dilution medium used in this study is the ElenMt M4 medium which contains EDTA. This chelating agent is known to have an outcome on the biological result as it chelates metals such as copper. Therefore, the results from this study should not be used for the purpose of risk assessment.

\*\* Study done in presence of sediment. According to the EFSA aquatic guidance in order to use thi study in the risk assessment a comparison with the predicted exposure scenaris should be performed to demonstrate that the exposure cover the worst case, a full comparison was not done, however, this estudy was not used in the risk assessment.

**Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – COBRANZA**

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	COBRANZA	96 h, s	LC <sub>50</sub> = 49.84 mg f.p./L	KCP 10.2.1-01 xxx
<i>Daphnia magna</i>	COBRANZA	48 h, s	EC <sub>50</sub> = 0.768 mg f.p./L	KCP 10.2.1-02 xxx
<i>Pseudokirchneriella subcapitata</i>	COBRANZA	72 h, s	E <sub>r</sub> C <sub>50</sub> > 100 mg f.p./L E <sub>y</sub> C <sub>50</sub> > 100 mg f.p./L	KCP 10.2.1-03 xxx
<b>Higher-tier studies (micro- or mesocosm studies)</b>				
Not submitted.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

#### 9.5.1.1 Justification for new endpoints

The EU agreed endpoints are uses for the risk assessment, except for formulation, corresponding to data

proper to COBRANZA formulation.

According to R (EU) n° 284/2013: “Possible effects on aquatic species (fish, aquatic invertebrates, algae and in the case of herbicides and plant growth regulators, aquatic macrophytes) shall be investigated except where the possibility that aquatic species will be exposed can be ruled out”. Copper Oxychloride 50% WG is a fungicide therefore the Applicant considers that studies on macrophytes with formulation is not mandatory.

#### 9.5.1.1.1 Use of Biotic Ligand Model

EFSA rejected all novel methods proposed by the notifier for assessing the exposure and risks from the use of copper, stating that the approval review process is not the correct forum for such an assessment. All the details requested regarding the Biotic Ligand Model have been provided and this method has been successfully applied for REACH and BPR dossiers. In addition, further data was provided in two dossier updates in April 2016, where the SSD derivation was explained and a link to the Cu-VRAR (2008) was provided (see <http://echa.europa.eu/nl/copper-voluntary-risk-assessment-reports>) regarding the Biotic Ligand Model; and in July 2017, with a detailed explanation on how the toxicity data was normalised for bioavailability using the Biotic Ligand Model, from which realistic endpoints were derived. The applicant insists that without such normalisation to take into account the bioavailability of copper in different water bodies, the resulting endpoint would be meaningless. Indeed, neglecting the bioavailability could also result in under-protective effect thresholds for highly vulnerable media (with high Cu bioavailability) when the media used for toxicity testing do not adequately cover such scenarios.

Following EFSA comments, a position paper has been developed (xxx) which provides additional detail on the update of bioavailability models for copper and provides realistic endpoints for copper. This position paper is summarized below and based on the conclusions of this position paper, while awaiting the copper GD, the EUCuTF members will continue to use the BLM approach unless different methodology appropriate for data normalisation is provided by MS. Art.33 submissions will provide an update of the BLM and supporting validation data, as well as justifying cross-species extrapolation.

Reference:	CP 10.2/01, Van Sprang, P, 2019
Title:	Response to EFSA comments on the aquatic effects assessment for Cu - extension
Report No.:	Not applicable
Guidelines:	Not applicable
Deviations:	Not applicable
GLP:	No
Published	No
Comment:	-

#### Executive Summary

During the past years, biotic ligand models (BLM) have increasingly been used to account for the influence of water chemistry variables (e.g., pH, water hardness and dissolved organic carbon, DOC) in the evaluation of ecological risks of copper in surface waters. For instance, copper BLMs have been implemented to derive predicted no effect concentrations (PNEC) in the risk assessments performed in the European Union (EU) (ECI 2008). However, recently optimizations of the Cu bioavailability models have been proposed through the use of generalized bioavailability models (gBAMs) (xxx). gBAMs are an alternative to the existing BLMs to predict chronic effect concentrations for copper towards freshwater organisms. The main difference between both models is that in a gBAM the effect of pH on metal toxicity is incorporated as a log-linear relation between pH and free  $\text{Me}^{2+}$  toxicity, while in a traditional BLM the effect of pH is modelled via a linear relation between pH and free  $\text{Me}^{2+}$  toxicity (parametrised via the biotic ligand stability constant; KH-BL). Hence, gBAMs may account for other factors that determine the effect of pH on  $\text{Me}^{2+}$  toxicity besides the competitive effect of  $\text{H}^+$  at the biotic ligand site. At the moment, chronic Cu gBAMs are available for four taxonomic groups: algae (xxx), the crustacean *Daphnia magna* (xxx), fish (xxx) and the higher plant *Lemna minor*.

Currently, the PNEC derivation for Cu includes traditional BLMs, except for algae, for which a gBAM is used. All current bioavailability models are used in combination with WHAM V as speciation pro-gram. However, WHAM V is not always practical in use and is not available online anymore. WHAM VII is the most recent version of the Windermere Humic Aqueous Model and is more user-friendly compared to WHAM V. WHAM VII incorporates the improved Humic-Ion binding model VII (xxx). It was shown that free metal ion activity in natural waters could be calculated rather accurately using WHAM VII (xxx). Hence, WHAM VII can be considered as the most appropriate speciation software to model metal speciation. While the chronic gBAMs for fish (xxx) and *L. minor* were directly developed in combination with WHAM VII, the chronic Cu gBAMs for *D. magna* (xxx) and algae xxx have been originally developed in combination with WHAM xxx recently evaluated the predictive performance of the *D. magna* and algae gBAMs in combination with WHAM VII.

The present report summarizes all available information underlying the update of the Cu bioavailability normalization procedure to the gBAM<sub>WHAMVII</sub>-approach.

Overall, the chronic Cu gBAMs for *D. magna* and algae performed relatively well when the models were calibrated on metal speciation calculated with WHAM VII. A bioavailability model is generally accepted to be sufficiently accurate if the majority of EC<sub>X<sub>Mediss</sub></sub> of an independent dataset is predicted within 2-fold error (xxx; xxx), this was the case for both gBAMs. Additionally, the prediction performance in WHAM VII approached those in the original publications reported for the original gBAMs calibrated with WHAM V (xxx).

The Fish gBAM<sub>WHAMVII</sub> developed by xxx) based on juvenile rainbow trout has also been successfully extrapolated to early life stages of fathead minnow and rainbow trout. The available evidence suggests that at least the pH effect on Cu toxicity of the Fish gBAM<sub>WHAMVII</sub> can be extrapolated to early life stage toxicity data for rainbow trout and fathead minnow. However, because of the limited available bioavailability data for fish it is difficult to evaluate the cross-species and cross-lifestage applicability of the protective effects of other competing ions on early life stage Cu toxicity.

The *L. minor* gBAM<sub>WHAMVII</sub> predicts chronic Cu toxicity to *L. minor* for three endpoints relatively accurately, but a validation with an independent dataset has not yet been performed.

Overall, these combined conclusions indicate that the chronic Cu gBAM<sub>WHAMVII</sub> can be used for predicting chronic Cu toxicity in risk assessment applications, such as deriving site-specific bioavailable PNECs.  
xxx

#### 9.5.1.1.1 Relevance of Standard Assessment Factors for Risk Assessment of Copper

The applicant provided a position paper that thoroughly investigated the relevance of standard assessment factors for risk assessment of the essential element Copper. This position paper has been summarised below (xxx). It was concluded that an assessment factor (AF), which is typically used to compensate for levels of uncertainties, is not justified since most sources of uncertainty (e.g. inter-species variation) are largely covered by the amount of available data on chronic toxicity of Cu to aquatic organisms. Hence, **the use of an assessment factor in this case could lead to wrong decision making process when based on RAC values within background levels of copper.**

<b>Reference:</b>	<b>CP 10.2/02, xxx</b>
<b>Title:</b>	Relevance of Standard Assessment Factors for Risk Assessment of the Essential Element Copper
<b>Report No.:</b>	CuPPP20170705
<b>Guidelines:</b>	Not applicable
<b>Deviations:</b>	Not applicable
<b>GLP:</b>	No
<b>Published</b>	No
<b>Comment:</b>	-

### Executive Summary

Defining regulatory accepted concentrations for copper is a complex process since there are adverse effects from both copper deficiency and copper excess (U shape curve). Moreover, the bioavailability of copper depends on the physicochemical properties of the receiving environment.

For all environmental compartments (water, sediment and soil), reliable chronic toxicity data for Cu overlap with the range in Cu background concentrations in the European environment. Worst-case approaches based on the lowest toxicity thresholds, as typically used in a standard risk assessment framework, without consideration of bioavailability and application of additional assessment factors results in concentrations within the natural background ranges for Cu in European water, sediment and soil. This will lead to over-conservative conclusions and risk identification at natural background concentrations and even may result in maximum thresholds in deficiency conditions in environments with low bioavailability of Cu. When ignoring bioavailability, the selection of a regulatory acceptable concentration strongly depends upon the combinations of sensitive species and sensitive environmental media (water, sediment or soil) that were tested, without considering their relevance for other environments. As such, neglecting bioavailability may also result in under-protective effect thresholds for highly vulnerable media (with high Cu bioavailability) when the media used for toxicity testing do not adequately cover such scenarios.

The application of assessment factors is built in risk characterisation to ensure decision-makers they don't make wrong decisions in case of uncertainty. However, an overestimation of uncertainty in case of data-rich dossiers (like for essential metals as copper) can also lead to making wrong decisions. A sound risk assessment for Cu should therefore consider the uncertainty on the bioavailability of Cu by the use of proper correction and normalization models and worst-case assumptions instead of the application of standard assessment factors that were derived for organic (anthropogenic) chemicals. Because of the data richness of chronic toxicity data for the effect of Cu to aquatic and terrestrial organisms, most sources of uncertainty (e.g. inter-species variation) are also largely covered by the available data. Therefore, the use of a low assessment factor (even 1) for ecological risk assessment of Cu fungicides is justified and will avoid making wrong decisions such as RAC values within background or deficiency ranges for some soils.

#### 9.5.1.1.2 Aquatic dwelling organisms

While awaiting the copper GD, the EUCuTF members will continue to use the SSD and BLM approach and no AF unless different methodology appropriate for data normalisation is provided by MS.

#### Acute and chronic fish endpoints

It is incongruous that the critical aquatic endpoint for fish is less than the 95th percentile concentration of copper in European surface waters. The applicant would like to point out that the RAC derived by EFSA for Plant Protection Products is also much lower than the endpoint derived for REACH and BPR dossier (0.37 µg/L for PPP vs. 7.8 µg/L for REACH/BPD), highlighting large inconsistencies in the methodologies used and leading to unrealistic refined endpoint.

All relevant  $PEC_{sw}$  values were higher than the acute and chronic first-tier  $RAC_{sw}$  values and hence a refined  $HC_{5-50}$  value was calculated from a species sensitivity distribution (SSD) based on reliable quality-screened data found in the open literature regarding chronic toxicity of copper to fish.

These data before being used in the SSD were normalised for bioavailability towards specific European eco-regions using the Chronic Biotic Ligand Model (BLM) and geometric mean values for the most sensitive endpoints have been calculated for 11 different fish species (see document MCA-8, point 8.2.8/02 (xxx)). As discussed above, no assessment factor should be applied and hence the BLM-normalised SSD- $RAC_{sw,ch}$  was determined to be 7.9  $\mu\text{g/L}$ .

Since effects of chronic exposure normally occur at lower concentrations than those of acute exposure,  $RAC_{sw,ch}$  are expected to be lower than and therefore protective for the  $RAC_{sw;ac}$ .

#### Aquatic invertebrate and algae endpoint

All  $PEC_{sw}$  values were higher than the relevant acute and chronic first-tier  $RAC_{sw}$  values for algae and aquatic invertebrates.

In a microcosm study (xxx) (CA 8.2.8/04), an NOEC of 4.8  $\mu\text{g/L}$  (dissolved copper) was determined for the most sensitive species *Chydorus sphaericus*. This study was performed with a mean pH of 9.4; mean DOC of 9.4 mg/L; and a total study duration of 385 days (i.e., the treatment period was 56 days and the post-treatment period (recovery) was 329 days). A very similar microcosm study (mean pH of 9.0; mean DOC of 4.4 mg/L) with a total study duration of 111 days with 2x weekly addition of equilibrated Cu-salt in order to achieve constant copper concentrations was also performed (xxx). Given that DOC, known to mitigate copper toxicity, was much lower in the second study one would expect a lower NOEC in the second study. This was not the case as the NOEC for *Chydorus sphaericus* was found to be much higher, i.e. between 33 and 64  $\mu\text{g/L}$  dissolved Copper. This suggests that the NOEC of 4.8  $\mu\text{g/L}$  found in the initial study was a very conservative endpoint.

Given the exceptionally data richness and the particularity of a homeostatically tight controlled essential element, no further AF should be applied to the endpoint derived from the mesocosm and hence the ETO- $RAC_{sw,ch}$  will be 4.8  $\mu\text{g/L}$ .

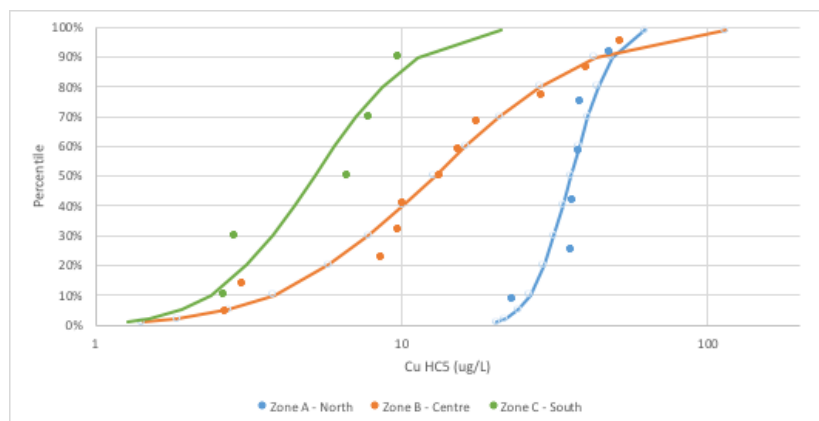
For the acute risks to invertebrates, since effects of chronic exposure normally occur at lower concentrations than those of acute exposure, The  $RAC_{sw,ch}$  is expected to be lower than and therefore protective for the  $RAC_{sw;ac}$ .

#### Overall endpoint

The BLM-normalised SSD- $RAC_{sw,ch}$  value of 7.9  $\mu\text{g/L}$  for fish is significantly higher than the aquatic invertebrate and algae ETO- $RAC_{sw,ch}$  of 4.8  $\mu\text{g/L}$  thereby confirming that fish are not the most sensitive species. **The ETO- $RAC_{sw,ch}$  of 4.8  $\mu\text{g/L}$  is therefore considered by the applicants as sufficiently protective of all aquatic organisms and hence is used as the critical endpoint for the aquatic risk assessment for all aquatic organisms.** Looking on the monitoring data and natural copper contents in surface water, this seems to be a sufficiently conservative value, still significantly lower as those derived under REACH and BPR.

A position paper relating to the use of the updated BLM model (xxx) provided Cu PNEC values for PPP-zones. According to the PPP, a zonal system of authorisation operates in the EU to enable a harmonised and efficient system to operate. The EU is divided into 3 zones; North (Zone A), Central (Zone B) and South (Zone C). Therefore, Cu  $HC_5$  values which are representative for these 3 zones were calculated based on the  $HC_5$  values for the individual countries, i.e. Denmark, Estonia, Latvia, Lithuania, Finland and Sweden for Zone A; Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, The Netherlands, Poland, Slovakia, Slovenia and United Kingdom for Zone B; Spain, France, Greece, Italy and Portugal for Zone C. An overview of the Cu  $HC_5$  cumulative distributions for the different zones, based on the physico-chemical parameters (DOC, pH) from Foregs, is provided in the figure below:

**Figure 9.5-1: Overview of the Cu HC5 cumulative distributions for the different PPP zones**



From Figure 9.5-1 both median (50<sup>th</sup> %) and realistic worst case (10<sup>th</sup> %) HC<sub>5</sub> for Cu could be calculated as shown in Table 9.5-3. Increasing sensitivity towards copper is observed when moving from North to South Europe, with a median HC<sub>5</sub> value of 35.75 µg/L for Zone A (North EU), 12.81 µg/L for Zone B (Central EU) and 5.2 µg/L for Zone C (South EU). As the DOC is the main driver in the mitigation of Cu toxicity, it is no surprise that the highest DOC are noted in North Europe (median DOC of 12.1 mg/L), an intermediate DOC in Central Europe (median DOC of 4.4 mg/L) and a lowest DOC in South Europe (median DOC of 2.9 mg/L).

**Table 9.5-3: Overview of the Cu HC5 values for the different PPP zones**

Percentile	HC <sub>5</sub> – Zone A	HC <sub>5</sub> – Zone B	HC <sub>5</sub> – Zone C
1%	20.44	1.43	1.28
2%	21.82	1.85	1.50
5%	24.07	2.72	1.92
10%	26.27	3.83	2.40
20%	29.20	5.80	3.12
30%	31.51	7.81	3.78
40%	33.63	10.09	4.45
50%	35.75	12.81	5.19
60%	37.99	16.26	6.05
70%	40.55	20.99	7.12
80%	43.76	28.30	8.62
90%	48.64	42.83	11.24
99%	62.52	114.60	21.12

The results of this modelling of copper HC<sub>5</sub> values supports the use of the ETO-RAC<sub>sw;ch</sub> of 4.8 µg/L as being sufficiently protective of all aquatic organisms in the majority of areas where agricultural use of copper occurs, however the MS should pay particular attention to areas where low DOC may occur as this could have a significant effect on the sensitivity of aquatic organisms to dissolved copper.

xxx

A study to model the effects of copper exposure on trout populations was undertaken using experimental data derived from an early-life stage toxicity test with rainbow trout (CA 8.2.2.1/01) to predict effects of trout populations in realistic conditions. The results of this modelling are summarized below:



<b>Reference:</b>	<b>CP 10.2/03, xxx</b>
<b>Title:</b>	Modelling of the Funguran-OH Effects on <i>Onchorhynchus mykiss</i> Populations
<b>Report No.:</b>	Not applicable
<b>Guidelines:</b>	Not applicable
<b>Deviations:</b>	Not applicable
<b>GLP:</b>	No
<b>Published</b>	No
<b>Comment:</b>	-

### Executive Summary

An earlier study on the toxicity of Funguran-OH on early life stage of the rainbow trout was performed by the xxx). Recently, issues have arisen on the applicability of this study under the plant protection products regulation. Arche Consulting was asked to interpret these lab results in a more ecologically realistic context. It is important to understand how the effects of a toxicant on individual-level endpoints (i.e. survival, reproduction) translate to effects on populations. Therefore, in this study the effect of Funguran-OH on the population density of a trout population due to mortality of early life stages was modelled.

To this end, the xxx data was used to parameterize a toxicity model for survival. This model was combined with a population model for trout species and used to predict effects on trout populations in realistic exposure conditions for different application scenarios. A constant exposure to a fixed dissolved copper concentration was used to mimic the conditions of the Fraunhofer test. However, this exposure pattern is not realistic as Funguran-OH is typically applied multiple times per year and will not remain constant in the water. A typical exposure pattern will consist of pulses of copper: peak water concentrations after each application which decrease over time. Therefore, the second scenario “Pulse exposure” includes a worst case realistic use of Funguran-OH with a maximum number of applications during the sensitive life stage possible according to the application guidelines of Funguran-OH.

In a population context, effects of Funguran-OH were observed at higher concentrations compared to the toxicity test ( $EC_{10} = 1.7 \mu\text{g Cu/L}$  and  $EC_{50} = 4.4 \mu\text{g Cu/L}$ ): the  $EC_{10}$  for population density ( $3.3 \mu\text{g Cu/L}$ ) was a factor two higher for the continuous exposure scenario and a factor 3 higher for the pulse exposure scenario ( $4.5 \mu\text{g/L}$ ). Although roughly the same for the continuous exposure scenario, the  $EC_{50}$  value for the pulse exposure scenario ( $25.4 \mu\text{g/L}$ ) was a factor 5 higher compared to the toxicity experiment.

Janssen, S.D. et al., 2019

The  $EC_{10}$  of  $4.5 \mu\text{g/L}$  from the pulse exposure scenario further supports the use of the  $ETO-RAC_{sw;ch}$  of  $4.8 \mu\text{g/L}$  as being sufficiently protective of all aquatic organisms

#### 9.5.1.1.4 Sediment dwellers

It is incongruous that the critical endpoint for sediment dwellers of  $3.23 \text{ mg/kg}$  is significantly less than the average natural concentration of copper in European sediments ( $17 \text{ mg/kg}$ ). The applicants would like to point out that the RAC derived by EFSA for Plant Protection Products is also much lower than the endpoint derived for REACH and BPR dossier, highlighting large inconsistencies in the methodologies used and leading to unrealistic refined endpoint ( $3.23 \text{ mg/kg}$  for PPP versus  $87 \text{ mg/kg}$  for REACH/BPR). The applicant insists that neglecting the bioavailability also leads to meaningless endpoints.

The EUCuTF has submitted an position paper on a revised PNEC sediment for copper for sediment effects which is summarised below (Vangheluwe, 2019). While awaiting the copper GD, the EUCuTF members will continue to use the bioavailability approach (e.g. AVS) and no AF unless different methodology appropriate for data normalisation is provided by MS. Art.43 submissions will provide an update of the approach already used in the EU dossier, but **accept the normalization should be done to sediments containing 2.5% organic carbon, which will lower the RAC to  $40.4 \text{ mg/kg dry wt}$ .**

<b>Reference:</b>	<b>CP 10.2/04, xxx</b>
<b>Title:</b>	Revised PNEC sediment copper for the sediment effects assessment for Cu : extending the database with additional species
<b>Report No.:</b>	Not applicable
<b>Guidelines:</b>	Not applicable
<b>Deviations:</b>	Not applicable
<b>GLP:</b>	No
<b>Published</b>	No
<b>Comment:</b>	-

### Executive Summary

Currently, a quality-screened database on the toxicity of Cu towards freshwater sediment-dwelling organisms representing a variety of feeding strategies and taxonomic groups has been compiled (xxx) combining the data from the VRAR (2008) and the results from newly retrieved literature (search 2007-2015). The following species are covered in the database: amphipods (*Hyalella azteca*, *Gammarus pulex*), mayfly (*Hexagenia sp*), oligochaetes (*Tubifex tubifex*, *Lumbriculus variegatus*), Gastropod (*Bellamya aeruginosa*) and the midge (*Chironomus riparius*). The chronic toxicity tests covered different endpoints such as abundance, survival, growth/biomass, reproduction and fecundity. Geometric mean values for the most sensitive endpoints were calculated for 7 different sediment species (representing 65 NOEC values) and were used to populate a species sensitivity distribution curve (SSD) and to derive a realistic worst-case Predicted No Effect Concentration (RWC-PNEC) for copper. In order to capture the variability introduced by the presence of toxicity values generated at different organic carbon concentrations each NOEC value was normalised for organic carbon. The safe threshold for freshwater sediment organisms towards Cu was then calculated from the 5<sup>th</sup> percentile (HC5) of the SSD based on chronic toxicity and yielded a value of 1,360 µg Cu/gOC. This can be translated to a HC5 value of 68 mg/kg dry weight (for sediments with 5 % O.C.) or a HC5 value of 34 mg/kg dry weight (for sediments with 2.5 % O.C.) as suggested by the EFSA guidance.

Recently, this database and approach to derive the HC5 value was discussed at EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, France, and co-rapporteur Member State, Germany, for the pesticide active substance copper compounds (EFSA Journal 2018;16(1):5152). The endpoints to be used in the risk assessment for aquatic organisms (including sediment dwellers) were further discussed at the Pesticide Peer Review meeting 133-169. It was concluded that

- 1) the data set as such is based on different ecologically relevant chronic endpoints for risk assessment purposes (NOEC) derived for observations made for reproduction, survival, growth, emergence, fecundity and biomass. However, it was pointed out that these endpoints should not be used altogether to derive a HC<sub>5</sub>. HC<sub>5</sub> calculated for survival, reproduction, biomass, etc. independently, shall be calculated if enough data are available". Concerning the dataset in the present study, enough data are available for chronic endpoints based on survival and growth to derive a SSD and calculate a HC5 (according to EFSA 6 data are available in both cases). The endpoint growth is the most conservative for all tested species.
- 2) according to EFSA aquatic guidance toxicity data for at least eight different benthic species should be used as a required minimum to derive a SSD.
- 3) use of geomean with chronic data is not recommended by the opinion of EFSA regarding sediment organisms (2015, EFSA Journal 13(7): 4176).

The present study aimed to re-evaluate and extend the current database in order to set a safe threshold of copper for the freshwater compartment taking into account the recently made comments of EFSA. Different scenarios were presented including the use of the geomean and the use of the lowest NOECs.

The copper database has been extended with two additional species (the macrophyte *V. spiralis* and the gastropod *P. antipodarum*) resulting in a database with 9 species and 5 taxonomic groups representing different feeding strategies and living habits. If the geometric mean is used **a HC5 of 40.4 mg/kg dry wt for a sediment containing 2.5% OC is obtained**. The use of a geometric mean for the chronic sediment data as has been proposed here by the EUCuTF in the copper case is deemed to be justified since all sediment test concentrations have been normalized for the organic carbon content allowing to compare the different tests at similar test conditions.

Vangheluwe, M, 2019.

**ZRMS comments:**

**Point: 9.5.1.1.2**

In response to decision from EFSA conclusion 2018 the applicant has submitted some summaries of new reports intending to justify the new endpoints used in this risk assessment in the current RAR. However, it should be noted, that the studies in which the new documents are based on, were included in the update of the RAR and were considered in the EFSA's Peer Review and, at zonal level, the endpoints would not be refined with documentation previously submitted in the renewal of approval of the active substance.

The short summary of these reports are summarised below.

**1. xxx Response to EFSA comments on the aquatic effects assessment for Cu – extension.**

According to the this report, the applicant indicates the results from Biotic Ligan Models (BLM) may be more realistic and could be useful for refining.

This model used by the applicant for the refinement of the endpoints was not admitted by the experts: the peer review did not consider acceptable the use of the BLM as proposed parameters were not duly validated.

The RMS indicated that new tools such as model and therefore the BLM should be validated and discussed at the European level first before being used in monographs in order to refine and predict toxicity values for various aquatic taxa across Europe (Copper\_RAR\_11\_Volume\_3CA\_B-9\_2018-05).

In the current report by Van Sprang-2019, different models are summarized to predict the bioavailability of copper to adjust its toxicity in different organisms.

On one hand the increased use of the traditional Biotic Ligand Models (BLM) approach is exposed (it has been observed that the bioavailability of metals has a strong influence by the chemistry factors such as pH, water hardness and dissolved organic carbon (DOC)). This models have also been optimized with the new generalized bioavailability models (gBAMs) as an alternative to predict chronic effects concentrations for copper, incorporating a log-linear relation between pH and free metal ion toxicity (instead of using a stability constant as a biotic ligand).

On the other hand, the models have also been used together with the speciation programs WHAM V and WHAM VII (Windermere Humic Aqueous Model) which aims to predict the competitive reactions of the metal with natural organic matter.

The report offers a study of the development and validation of these models, comparing observed dissolved Cu toxicity to the predicted dissolved Cu toxicity obtained in the models, using the dataset on which the model is developed in one way and using an independent dataset in other way (preferably toxicity data in natural waters).

The next groups of aquatic organism data were considered: *Daphnia magna* chronic toxicity, algae chronic toxicity (*Pseudokirchneriella subcapitata*, *Chlorella vulgaris*), *Lemna minor* chronic toxicity and fish chronic (*Pimephales promelas*, *Oncorhynchus mykiss*; early life and juvenile stages).

The report summarizes the current available models to account for the bioavailability of metals in the aquatic environment. This compilation of the methods (development and validation) is described in

order to show that this bioavailability should be considered when evaluating the risk of copper compounds, and that nowadays they are the only way to estimate possible PNECs of bioavailability for chronic copper toxicity.

The modeling indicated has enough data for *Daphnia* and algae species.

Nevertheless, due to the limited available chronic bioavailability data for fish it was considered difficult to evaluate the protective effects of other ions on early life stage copper toxicity (at least, the pH effect on copper predicted toxicity can be extrapolated to early life stage toxicity data for the two species).

However it should be noted that the dissolved organic carbon is an important factor in this model, but the extrapolation to region with lower concentration of dissolved organic carbon can be difficult.

The extrapolation of this model to the different agro-environmental characteristic in Europe should be ensured.

## 2. xxx

Relevance of Standard Assessment Factors for Risk Assessment of the Essential Element Copper.

The applicant is in the opinion that assessment factors should not be applied to endpoints for chronic toxicity of copper to aquatic organisms, as the bioavailability of copper has not been considered and standard factors would not be applied to counteract uncertainty in organic compounds.

It is exposed that for elements such as Cu, a particularized and standardized correction would be necessary instead of the application of standardized AF for organic compounds.

The text in Executive Summarize and Conclusion is exactly the same as the previous 2017 document included in the Revised RAR (Copper\_RAR\_11\_Volume\_3CA\_B-9\_2017-09).

In this report, an uncertainty assessment has been added to the original document (point 4), which refers to the Guidance on Uncertainty Analysis in Scientific Assessments-2018 (EFSA Journal 2018; 16 (1): 5123).

An uncertainty analysis is carried out in which it is considered that the use of AF can be too conservative and that it is possible to take uncertainty into account through other approaches, distinguishing between quantifiable and non-quantifiable uncertainty, considering that the latter can only be described qualitatively.

It is proposed to cover uncertainties, that are normally covered with the AF, with other types of factors such as: assumption of worst case, inter-species variability reduced by sufficient number of tests available (to SSD - HC<sub>5</sub>), the use of high quality data on SSD, the normalization of data for SSD for a worse case of bioavailability, taking into account bioavailability model, (facing laboratory-to-field uncertainty), the historical burden of expression of the RAC as total Cu.

In opinion of the applicant a more coherent approach would be guaranteed with the allocation of AF, distinguishing between those cases in which the availability of data is greater and those in which the number of data is less.

It is indicated that in those cases where it is not possible to express the effects in quantitative terms (which is recommended by the EFSA 2018 guide), it would be necessary to carry out a qualitative analysis. This occurs in elements such as Cu, in which a high AF has been derived considering a very worse case.

It was concluded that if the effects of bioavailability are considered, which is in turn strongly depends on the physical-chemical properties of the environment, the AF should be reduced.

## 3. xxx , Modelling of the Funguran-OH Effects on *Onchorhynchus mykiss* Populations.

In this report it is indicated that the effects can be extrapolated/calculated to population based on a new modelling, with original data from a study in the year 2000th with Funguran-OH ( xxx ), in which the exposure (only for *Onchorhynchus mykiss* populations) is assumed to occur in more realistic conditions.

Specifically, it is a matter of measuring the effects of the product on the density of trout population considering mortality in the early stages of life, establishing a toxicity model for survival.

The reference data was taken from the Schäfers study, and those data for dissolved copper concentration were used and only related to larval survival in yolk-sac stage, since only significant effects were found in that stage. It should be indicated that not enough information was available on the water chemistry to perform a bioavailability correction and for this reason the dissolved copper concentrations were used for the toxicity model

The model used was the General Unified Threshold for Survival (GUTS) in its “reduced” form (combining the toxicokinetic model with the damage model: the external concentration is directly translated to the damage level) and using the mean concentration of Cu dissolved in the yolk-sac stage as input of the toxicide.

The worst case resulting from the possible death mechanisms of the model (stochastic, individual limit or both combined) is chosen and implemented in the population model InSTREAM-Gen (Ayllón et al. 2016): individual model for trout in stream environments, in which the entire life cycle is modeled following daily routine. Adaptations were made for rainbow trout and a mortality function for copper toxicity was added. The model was implemented by adding two redd variables, the level of damage and limit levels of the eggs/larvae in the redd.

To consider the exposure, several scenarios were simulated and only two of them have been included in the report: one for continuous exposure of the toxicide (it has to be noted that a NOEC of 2 µg dissolved Cu/L was observed on the population) and another one for exposure by pulses (worst realistic case in which 1.2 kg Funguran-OH/ha was applied, which would be a PECini of 4.8 microg Cu dissolved/L, was applied 5 times with an interval of 7 days, DT<sub>50</sub> Funguran-OH = 1 day).

In the continuous exposure scenario, clear effects would be found on the mean population density at 4 µg/L (EC<sub>10</sub> = 3.51; EC<sub>50</sub> = 3.97).

On the other hand, in the pulse exposure scenario, no effects on population density were predicted at the concentration of 4.8 µg/L. The mean values of the effects obtained per year were EC<sub>10</sub> = 7.99 µg/L and EC<sub>50</sub> = 9.57 µg/L.

#### 4. xxx, Revised PNEC sediment copper for the sediment effects assessment for Cu: extending the database with additional species.

In this report, the new calculations of endpoint for sediment dwelling organism were provide as an extension to the study CA 8.2.5.4/01 “Environmental hazard assessment of copper: sediment-dwelling organisms” ( xxx ).

This calculation by xxx -2015 was not accepted at the expert meeting of October 2017, due to not following the aquatic guidance document indications, which establishes a minimum of 8 species to do the SSD approach and since the use of the geometric mean is not recommended for chronic values. The selected endpoints were based on different types of chronic endpoints, with which the RMS did not agree.

The RMS proposed in the RAR Revised 2017 to obtain an HC<sub>5</sub> through a selection of endpoints of the same type (*growth*) but for only the original 6 different organisms, considering a geometric mean from the most conservative chronic values.

In Vangheluwe-2019, two new species-endpoints are assumed to be provided. However, it has to be noted that the study with *V. spiralis* was not used in RAR as results were reported for macrophytes only, and the study with *P. antipodarum* was not considered reliable as there was “a potential bias through copper exposure via the overlying water”.

The geometric mean NOEC and the worst case NOEC obtained from these studies have been incorporated to the data base by Vangheluwe-2019, to reach 9 intended species data points and new HC<sub>5</sub> have been recalculated (featuring a total of 9 species of 5 different taxonomic groups).

In this report several SSD-HC<sub>5</sub> calculations have been proposed: SSD based on calculations with 6 species (the original ones of the calculation specified in the RAR) or 9 species (the original ones plus *L. Variegatus*, plus the two species mentioned above; the studies for these species were included in the RAR but were not taken into account). The endpoints have been selected only for "growth" and both the average and lowest values have been considered.

- Using 9 species (all available data according to the applicant), geometric mean NOEC and

normalizing to 2.5% OC, the HC<sub>5</sub> would be **40.4 mg Cu/kg dw- preferred Applicant's proposal**

- Using the lowest NOEC value per available species data according to the applicant, and normalizing to 2.5% CO content, the HC<sub>5</sub> would be 19.4 mg Cu/kg dw.
- Using the lowest NOEC value per available species data and normalizing to 2.5% CO content, the HC<sub>5</sub> for the 6 original species would be 13.4 mg Cu / kg dw.

The applicant emphasized that it is incongruous that the critical endpoint according to the EFSA conclusion for sediment dwellers was significantly less than the average natural concentration of copper in European sediments.

However, the experts of EFSA as the RMS concluded that “from the results of the updated literature data on the levels of copper in sediments of water bodies in winegrowing areas, the exposure and the risk in these sites could be higher than the assessment done during the European peer review of the renewal dossier for copper compounds” (EFSA Supporting publication 2018:EN-1486, Outcome of the consultation, August 2018, No. 4(14), page 14), and “no further information was provided in order to investigate if natural background levels of copper increased and consequently to assess the relevance of the median concentrations of copper in European stream sediment”.

No further information has been provided in order to assess this formulated product either.

In the overall position for the evaluation of the copper effects in aquatic organisms, it is indicated that the applicant will continue to use the bioavailability approach and will not apply any AF: for sediment dwellers the standardisation of the endpoint to an organic content of 2.5% has been applied, which makes it a proposal of RAC seddwellers of 40.4 mg/kg (including the concerning species added to the SSD data, and taking into account the use of a geometric mean for the chronic data -not recommended- and for the rest of aquatic organisms an ETO-RAC of 4.8 µg/L has been considered by the applicant as protective value of all acute and chronic risk.

### **Overall conclusion**

It has to be noted that there is no specific guide to evaluate metal compounds and that the methodology according to EFSA conclusion is based on a conservative worst case and in which it has not been established to take into account the bioavailability of copper, both from the concentration predicted as a result of the current application of the product, and from the accumulated concentration over the years, although it must be said that many of the available data on chronic toxicity to aquatic organisms were obtained under laboratory conditions, where the accumulated copper does not influence the results of the studies.

EFSA experts in their 2018 conclusion accepted a PEC<sub>sw</sub> calculation methodology with which the ZRMS agrees. However, it should be taken into account that it is based on a worse conservative case since: a conversion factor of 1 in the affectation of total Cu to dissolved Cu has been considered, crop interception has not been taken into account due to the non-degradable characteristics of the substance and it has been calculated with the current model for degradable substances and which is not adapted to metal elements.

The zonal-RMS-PL is in agreement with the calculated maximum mitigations that could be allowed according to the EFSA conclusion. However, when estimating the risk, it is considered that it should be taken into account that there is currently no model / guide adapted to metals such as copper and therefore, the considerations of the current guide for aquatic organisms assessments would be used with caution and taking into account all available information on Cu. Thus, the use of the necessary AF proposed according to the current guideline is presumed to be very conservative.

Taking into account the available information, accepting the way in which the calculations of expected concentrations are carried out, it could be proposed to consider a maximum concentration the limit of 4.8 µg Cu/L for aquatic organisms (concerning the water medium) based on available data and models developed for the decision for each of MSs level.

For Poland the risk assessment based on EFSA Conclusion 2018 for aquatic organism is considered.

With regard to sediment dwellers organisms (concerning the solid medium), it is important to take into

account the effect of the accumulation over time of the metal in the sediment medium. The average amount according to the latest monitored studies for conservative calculation is 17 mg/kg. But it would be necessary to follow a more zonally specific monitoring and also consider the non-total mobilisation of copper and therefore the relative availability of it by aquatic organisms.

**Therefore, further consideration of the risk assessment for sediment dwelling organism should be decided at MSs level.**

### **9.5.2 Risk assessment**

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance

with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

During the review of the renewal of approval of copper the EUCuTF made the claim that the standard models used to predict the PEC of copper in surface water are not relevant to metals such as copper. The Commission has agreed with this premise and in their Renewal Report (SANTE/10506/2018) called for more relevant models to be developed.

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1 and 2  $PEC_{sw}$  for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below. The applicant would like to reiterate that FOCUS modelling is not designed or validated to predict the behaviour of metals in the environment, and thus is not suitable for copper predictions and was only carried out for completeness. The applicant would like to request that more suitable assessment protocols are used for minerals such as copper.

As discussed above, to achieve a concise risk assessment for aquatic dwelling organisms, an ETO- $RAC_{sw; ch}$  value of 4.8  $\mu g/L$  was used as this value was protective of all acute and chronic risks to all relevant aquatic species.

#### 9.5.2.1 Risk Assessment for Aquatic Dwelling Organisms

In the following tables, the ratios between predicted environmental concentrations in surface water bodies ( $PEC_{sw}$ ) and regulatory acceptable concentrations (RAC) for aquatic dwelling organisms are given per intended use for each FOCUS scenario. As discussed above, to achieve a concise risk assessment for aquatic dwelling organisms, an ETO- $RAC_{sw; ch}$  value of 4.8  $\mu g/L$  was used as this value was protective of all acute and chronic risks to all relevant aquatic species.

Predicted concentrations in surface water have been calculated for copper as follows:-

The applicants would like to point out that on page 15 of the EFSA conclusion that they are pleased to see that EFSA recognises that due to the very rapid dissipation of copper ( $Cu^{2+}$  ions) from surface waters to sediment, **it was considered that the single application scenario represents the worst-case for the exposure assessment**. As a result of this statement the notifier would like the PEC surface water modelling results for multiple applications from Appendix A (LoEP) to be considered as irrelevant, as they ignore any dissipation from the water phase.

##### Grapevine (early application)

Standard FOCUS Step 1 and 2  $PEC_{sw}$  values as described below were calculated for vine early:

$PEC_{sw}$  without spray drift mitigation:

FOCUS Step 1 and 2  $PEC_{sw}$  values (FOCUS Steps 1 and 2, version 3.2) were calculated considering all entry routes to water bodies with an interception of 0% (no cover crop) selected as a worst-case scenario.



<b>Group</b>	Aquatic dwelling organisms						
<b>Endpoint (NOEC, µg/L)</b>	4.8						
<b>AF</b>	1						
<b>ETO RAC<sub>sw</sub> (µg/L)</b>	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	N and S	16.21	<b>3.38</b>	9.00	<b>1.88</b>

All PEC<sub>sw</sub> values are higher than the ETO RAC<sub>sw;ch</sub> value for aquatic organisms thus indicating a concern regarding the acute and chronic risk to aquatic organisms from the proposed use of COBRANZA in vines at the proposed application rates. It is therefore considered that a refined acute risk assessment for aquatic organisms exposed to copper from the proposed uses of COBRANZA is required.

Step 1 and 2 PEC<sub>sw</sub> values with mitigation were calculated as described below:

- 1) Focus Step 1 and 2 values were firstly calculated with the no spray drift option to derive the PEC from runoff and drainage only. Mitigation measures for 10m of vegetative buffer strip (60% of reduction) were used.
- 2) Focus Step 1 and 2 values were then calculated using the no drainage and runoff option with spray drift values for a single application. These values were then factored down based on different spray drift mitigation values taken for different distances from the FOCUS spray drift calculator (version 1.1) in the SWASH shell, not going beyond 95% mitigation. Also 50, 75 and 90% of nozzles were applied. These values were then added to the values estimated from the runoff and drainage calculation. These results were based on the highest acceptable mitigation for all entry routes to water bodies (95% limit on spray drift mitigation). These values were then added to the values estimated from the runoff and drainage calculation in step 1 above.

**Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines early application (only entry routes by Run-off/Drainage to water bodies considered)**

<b>Group</b>	Aquatic dwelling organisms
<b>Endpoint (NOEC, µg/L)</b>	4.8
<b>AF</b>	1

<b>ETO RAC<sub>sw</sub> (µg/L)</b>	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S	7.21	1.50	2.88	0.60
			N			1.44	0.30

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-6:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines early application (only entry routes by spray drift to water bodies considered)

<b>Group</b>	Aquatic dwelling organisms						
<b>Endpoint (NOEC, µg/L)</b>	4.8						
<b>AF</b>	1						
<b>ETO RAC<sub>sw</sub> (µg/L)</b>	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S and N	16.21	<b>3.38</b>	9.00	<b>1.88</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold



**Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines early application (drift mitigation considered)**

<b>Group</b>	Aquatic dwelling organisms										
<b>Endpoint (NOEC, µg/L)</b>	4.8										
<b>AF</b>	1										
<b>ETO RAC<sub>sw</sub> (µg/L)</b>	4.8										
Uses	Application pattern	Season of application	Region	Step 2							
				Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S and N	3	None	7.12	<b>1.48</b>	5	None	3.41	0.71
					50%	3.56	0.74				

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines early application (runoff/drainage plus spray drift with mitigation) - TOTAL copper**

<b>Group</b>	Aquatic dwelling organisms
<b>Endpoint (NOEC, µg/L)</b>	4.8
<b>AF</b>	1

<b>ETO RAC<sub>sw</sub> (µg/L)</b>	4.8																		
Uses	Ap- pli- cation pat- tern	Season of appli- cation	Re- gion	PEC <sub>sw</sub> (µg/L) (consid- ering Run- off/drainag e only)	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./h a	March- May	S and N	2.88*	3	None	7.12	4.66	0.97	5	None	3.41	4.59	0.96	10	None	1.20	4.08	0.85
						75%	1.78				50%	1.71							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*Worst case from Southern calculations

Under the spray drift scenario the particulate, barely water soluble copper compound that hits the surface water will start dissolving while complexation to DOC and sedimentation remove copper from the dissolved fraction. The results from the Blust and Joosen 2016 study (CP9.2.3/01) have demonstrated that in a realistic water/sediment scenario the total copper declines very rapidly in the water phase while dissolved copper was at least a factor of 10 lower. This study describes best the speciation and kinetic behaviour of copper in an aquatic environment following a spray drift event. Despite, the EUCuTF has proposed a more conservative total/dissolved value of 3 for use in the risk assessment, based on the measurements in the mesocosm study.

The EFSA evaluation used a total/dissolved ratio of 1, which suggests that all copper is dissolved. This is against all observations in the monitoring studies and studies from the dossier cited above. The Art.33 evaluation should apply a total to dissolved copper ratio of at least 3.

The following table summarises the risk assessment for aquatic dwelling organisms based on the FOCUS Step 2 maximum  $PEC_{sw}$  values following a single application to vines early. These  $PEC_{sw}$  values are without mitigation measures considering all entry routes and are converted to dissolved copper concentration using a total to dissolved copper ratio of 3.

**Table 9.5-9: Aquatic organisms: acceptability of risk ( $PEC/RAC < 1$ ) based on FOCUS Step 2 maximum  $PEC_{sw}$  values for the use of COBRANZA following a single application to vines early application (without mitigation measures considering all entry routes) - DISSOLVED copper**

Group	Aquatic dwelling organisms				
Endpoint (NOEC, $\mu g/L$ )	4.8				
AF	1				
ETO $RAC_{sw}$ ( $\mu g/L$ )	4.8				
Uses	Application pattern	Season of application	Region	Step 2	
				Max dissolved $PEC_{sw}$ (considering all entry routes) ( $\mu g/L$ )	PEC/RAC
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S and N	3.00	0.63

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Following refinement of the risk assessment using the  $PEC_{sw;dissolved}$  was lower than the  $ETO RAC_{sw;ch}$  thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA in vines early.

### **Grapevine (late application)**

Standard FOCUS Step 1 and 2 PEC<sub>sw</sub> values as described below were calculated for vine late as it is representative of the risk envelope for copper:

PEC<sub>sw</sub> without spray drift mitigation:

FOCUS Step 1 and 2 PEC<sub>sw</sub> values (FOCUS Steps 1 and 2, version 3.2) were calculated considering all entry routes to water bodies with an interception of 0% (no cover crop) selected as a worst-case scenario.

**Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on standard FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines late application (all entry routes to water bodies considered)**

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	S and N	33.97	<b>7.08</b>	26.76	<b>5.58</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

All PEC<sub>sw</sub> values are higher than the ETO RAC<sub>sw;ch</sub> value for aquatic organisms thus indicating a concern regarding the acute and chronic risk to aquatic organisms from the proposed use of COBRANZA in vines at the proposed application rates. It is therefore considered that a refined acute risk assessment for aquatic organisms exposed to copper from the proposed uses of COBRANZA is required.

PEC<sub>sw</sub> with spray drift mitigation:

Step 1 and 2 PEC<sub>sw</sub> values with mitigation were calculated as described below:

- 1) Focus Step 1 and 2 values were firstly calculated with the no spray drift option to derive the PEC from runoff and drainage only. Mitigation measures for 10m of vegetative buffer strip (60% of reduction) were used.
- 2) Focus Step 1 and 2 values were then calculated using the no drainage and runoff option with spray drift values for a single application. These values were then factored down based on different spray drift mitigation values taken for different distances from the FOCUS spray drift calculator (version 1.1) in the SWASH shell, not going beyond 95% mitigation. Also 50, 75 and 90% of nozzles were applied. These values were then added to the values estimated from the runoff and drainage calculation. These results were based on the highest acceptable mitigation for all entry routes to water bodies (95% limit on spray drift mitigation). These values were then added to the values estimated from the runoff and drainage calculation in step 1 above.

The results of the PEC<sub>sw</sub> modelling with spray drift mitigation according to the above scheme, along with relevant PEC/RAC ratios are summarised in the following tables:

**Table 9.5-11:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines late application (only entry routes by Runoff/Drainage to water bodies considered)

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	S	7.21	1.50	2.88	0.60
			N			3.57	0.74

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-12:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines late application (only entry routes by spray drift to water bodies considered)

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	S and N	33.97	<b>7.08</b>	26.76	<b>5.58</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold



**Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines late application (drift mitigation considered)**

Group	Aquatic dwelling organisms															
End-point (NOEC, µg/L)	4.8															
AF	1															
ETO RAC <sub>sw</sub> (µg/L)	4.8															
Uses	Applica- tion pat- tern	Season of applica- tion	Re- gion	Step 2												
				Buff- er (m)	Nozzles reduc- tion (%)	PECs w (µg/L)	PEC/RA C	Buff- er (m)	Nozzles reduc- tion (%)	PECs w (µg/L)	PEC/RA C	Buff- er (m)	Nozzles reduc- tion (%)	PECs w (µg/L)	PEC/RA C	
Vines BBCH 85 Late drift rates – BBCH 85 on- wards	4 x 1000 g a.s./ha	March- May	S and N	3	None	21.32	4.44	5	None	10.43	2.17	10	None	3.78	0.79	
					50%	10.66	2.22		50%	5.22	1.09					
					75%	5.33	1.11		75%	2.61	0.54					
					90%	2.13	0.44									

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-14:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines late application (runoff/drainage plus spray drift with mitigation) - TOTAL copper

Group	Aquatic dwelling organisms																							
Endpoint (NOEC, µg/L)	4.8																							
AF	1																							
ETO RAC <sub>sw</sub> (µg/L)	4.8																							
Uses	Ap- pli- cati- on pat- tern	Sea- son of ap- pli- cati- on	Re- gio- n	PEC <sub>sw</sub> (µg/L) (con- sider- ing Run- off/dra- inage only)	Bu- ffe- r (m)	Noz- zles re- duc- tion (%)	PEC <sub>s</sub> w (µg/L) (con- sideri- ng drift only)	PEC sw (µg/ L) (To- tal)	PEC/ RAC	Bu- ffer (m)	Noz- zles re- duc- tion (%)	PEC <sub>s</sub> w (µg/L) (con- sideri- ng drift only)	PE Cs w (µg/ L) (Tota- l)	PEC /RAC	Bu- ffe- r (m)	Noz- zles re- duc- tion (%)	PEC <sub>s</sub> w (µg/L) (con- sideri- ng drift only)	PE Cs w (µg/ L) (Tota- l)	PEC /RAC	Bu- ffe- r (m)	Noz- zles re- duc- tion (%)	PEC <sub>s</sub> w (µg/L) (con- sideri- ng drift only)	PE Cs w (µg/ L) (Tota- l)	PEC /RAC
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March- May	Sand N	3.60*	3	None	21.32	5.73	1.19	5	None	10.43	4.64	0.97	10	None	3.78	4.55	0.95	20	None	1.32	4.26	0.89
						90%	2.13				90%	1.04				75%	0.95				50%	0.66		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*Worst case from Northern calculations

**Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines late application (runoff/drainage with 60% of reduction (10m of vegetative strip buffer) plus spray drift with mitigation measures)**

Group	Aquatic dwelling organisms														
Endpoint (NOEC, µg/L)	4.8														
AF	1														
ETO RAC <sub>sw</sub> (µg/L)	4.8														
Uses	Application pattern	Season of application	Region	PEC <sub>sw</sub> (µg/L) (considering Run-off/drainage only)	PEC <sub>sw</sub> (µg/L) (considering 10m of vfs)	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L) (considering drift only)	PEC <sub>sw</sub> (µg/L) (Total)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L) (considering drift only)	PEC <sub>sw</sub> (µg/L) (Total)	PEC/RAC
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March- May	S and N	3.60*	1.44	10	None	3.78	3.33	0.69	14	None	2.28	3.72	0.78
							50%	1.89							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

\*Worst case from Northern calculations



Under the spray drift scenario the particulate, barely water soluble copper compound that hits the surface water will start dissolving while complexation to DOC and sedimentation remove copper from the dissolved fraction. The results from the Blust and Joosen 2016 study (CP9.2.3/01) have demonstrated that in a realistic water/sediment scenario the total copper declines very rapidly in the water phase while dissolved copper was at least a factor of 10 lower. This study describes best the speciation and kinetic behaviour of copper in an aquatic environment following a spray drift event. Despite, the EUCuTF has proposed a more conservative total/dissolved value of 3 for use in the risk assessment, based on the measurements in the mesocosm study.

The EFSA evaluation used a total/dissolved ratio of 1, which suggests that all copper is dissolved. This is against all observations in the monitoring studies and studies from the dossier cited above. The Art.33 evaluation should apply a total to dissolved copper ratio of at least 3.

The following table summarises the risk assessment for aquatic dwelling organisms based on the FOCUS Step 2 maximum PEC<sub>sw</sub> values following a single application to vines late. These PEC<sub>sw</sub> values are without mitigation measures considering all entry routes and are converted to dissolved copper concentration using a total to dissolved copper ratio of 3.

**Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to vines late application (without mitigation measures considering all entry routes) - DISSOLVED copper**

Group	Aquatic dwelling organisms												
End-point (NOEC, µg/L)	4.8												
AF	1												
ETO RAC <sub>sw</sub> (µg/L)	4.8												
Uses	Application pattern	Season of application	Region	PEC <sub>sw</sub> (µg/L) (considering Run-off/drainage only)	Max dissolved PEC <sub>sw</sub> (considering all entry routes) (µg/L)	Buffer (m)	Nozzles reduction (%)	Max dissolved PEC <sub>sw</sub> (considering only drift) (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	Max dissolved PEC <sub>sw</sub> (considering only drift) (µg/L)	PEC/RAC

Vines BBCH 85 Late drift rates – BBCH 85 on- wards	4 x 1000 g a.s./ha	March- May	S and N	1.20*	8.92	3	50%	3.55	0.74	10	None	1.26	0.26
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AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*Worst case from Northern calculations

Following refinement of the risk assessment using the  $PEC_{sw;dissolved}$  was lower than the ETO  $RAC_{sw;ch}$  thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA in vines late application with the following risk mitigation measures:

- Any no-spray buffer with 50% nozzles reduction OR 10 m no-spray buffer.



### Potatoes and solanaceous

Standard FOCUS Step 1 and 2 PEC<sub>sw</sub> values as described below were calculated for potatoes and solanaceous as it is representative of the risk envelope for copper:

#### PEC<sub>sw</sub> without spray drift mitigation:

FOCUS Step 1 and 2 PEC<sub>sw</sub> values (FOCUS Steps 1 and 2, version 3.2) were calculated considering all entry routes to water bodies with an interception of 0% (no cover crop) selected as a worst-case scenario.

**Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on standard FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to potatoes and solanaceous (fruiting vegetables) (all entry routes to water bodies considered)**

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	S and N	19.69	<b>4.10</b>	11.04	<b>2.30</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

All PEC<sub>sw</sub> values are higher than the ETO RAC<sub>sw;ch</sub> value for aquatic organisms thus indicating a concern regarding the acute and chronic risk to aquatic organisms from the proposed use of COBRANZA in vines at the proposed application rates. It is therefore considered that a refined acute risk assessment for aquatic organisms exposed to copper from the proposed uses of COBRANZA is required.

#### PEC<sub>sw</sub> with spray drift mitigation:

Step 1 and 2 PEC<sub>sw</sub> values with mitigation were calculated as described below:

- 1) Focus Step 1 and 2 values were firstly calculated with the no spray drift option to derive the PEC from runoff and drainage only. Mitigation measures for 10m of vegetative buffer strip (60% of reduction) were used.
- 2) Focus Step 1 and 2 values were then calculated using the no drainage and runoff option with spray drift values for a single application. These values were then factored down based on different spray drift mitigation values taken for different distances from the FOCUS spray drift calculator (version 1.1) in the SWASH shell, not going beyond 95% mitigation. Also 50, 75 and 90% of nozzles were applied. These values were then added to the values estimated from the runoff and drainage calculation. These results were based on the highest acceptable mitigation for all entry routes to water bodies (95% limit on spray drift mitigation). These values were then added to the values estimated from the runoff and drainage calculation in step 1 above.

The results of the PEC<sub>sw</sub> modelling with spray drift mitigation according to the above scheme, along with relevant PEC/RAC ratios are summarised in the following tables:



**Table 9.5-18:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to potatoes and solanaceous (fruiting vegetables) (only entry routes by Runoff/Drainage to water bodies considered)

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	S	8.65	1.80	3.45	0.72
			N			1.73	0.36

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-19:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to potatoes and solanaceous (fruiting vegetables) (only entry routes by spray drift to water bodies considered)

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	S and N	19.69	<b>4.10</b>	11.04	<b>2.30</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to potatoes and solanaceous (fruiting vegetables) (drift mitigation considered)**

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 2			
				Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	N and S	3	None	3.264	0.68

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to potatoes and solanaceous (fruiting vegetables) (runoff/drainage plus spray drift with mitigation) - TOTAL copper**

Group	Aquatic dwelling organisms																		
Endpoint (NOEC, µg/L)	4.8																		
AF	1																		
ETO RAC <sub>sw</sub> (µg/L)	4.8																		
Uses	Ap- pli- cation pat- tern	Season of appli- cation	Re- gion	PEC <sub>sw</sub> (µg/L) (consid- ering Run- off/drainag e only)	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC
Potatoes BBCH 15-85	3 x 1200 g a.s./h a	March- May	S and N	3.45*	3	None	3.264	4.27	0.89	5	None	2.090	4.50	0.94	10	None	1.108	4.56	0.95
						75%	0.816				50%	1.045							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*Worst case from Southern calculations

Under the spray drift scenario the particulate, barely water soluble copper compound that hits the surface water will start dissolving while complexation to DOC and sedimentation remove copper from the dissolved fraction. The results from the Blust and Joosen 2016 study (CP9.2.3/01) have demonstrated that in a realistic water/sediment scenario the total copper declines very rapidly in the water phase while dissolved copper was at least a factor of 10 lower. This study describes best the speciation and kinetic behaviour of copper in an aquatic environment following a spray drift event. Despite, the EUCuTF has proposed a more conservative total/dissolved value of 3 for use in the risk assessment, based on the measurements in the mesocosm study.

The EFSA evaluation used a total/dissolved ratio of 1, which suggests that all copper is dissolved. This is against all observations in the monitoring studies and studies from the dossier cited above. The Art.33 evaluation should apply a total to dissolved copper ratio of at least 3.

The following table summarises the risk assessment for aquatic dwelling organisms based on the FOCUS Step 2 maximum  $PEC_{sw}$  values following a single application to potatoes and solanaceous (fruiting vegetables). These  $PEC_{sw}$  values are without mitigation measures considering all entry routes and are converted to dissolved copper concentration using a total to dissolved copper ratio of 3.

**Table 9.5-22: Aquatic organisms: acceptability of risk ( $PEC/RAC < 1$ ) based on FOCUS Step 2 maximum  $PEC_{sw}$  values for the use of COBRANZA following a single application to potatoes and solanaceous (fruiting vegetables) (without mitigation measures considering all entry routes) - DISSOLVED copper**

Group	Aquatic dwelling organisms				
Endpoint (NOEC, $\mu\text{g/L}$ )	4.8				
AF	1				
ETO $RAC_{sw}$ ( $\mu\text{g/L}$ )	4.8				
Uses	Application pattern	Season of application	Region	Step 2	
				Max dissolved $PEC_{sw}$ (considering all entry routes) ( $\mu\text{g/L}$ )	PEC/RAC
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	N and S	3.68	0.77

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold



Following refinement of the risk assessment using the  $PEC_{sw;dissolved}$  was lower than the  $ETO RAC_{sw;ch}$  thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA in potatoes and solanaceous.

### **Apple (early application)**

Standard FOCUS Step 1 and 2  $PEC_{sw}$  values as described below were calculated for apple early as it is representative of the risk envelope for copper:

#### **$PEC_{sw}$ without spray drift mitigation:**

FOCUS Step 1 and 2  $PEC_{sw}$  values (FOCUS Steps 1 and 2, version 3.2) were calculated considering all entry routes to water bodies with an interception of 0% (no cover crop) selected as a worst-case scenario.

**Table 9.5-23: Aquatic organisms: acceptability of risk ( $PEC/RAC < 1$ ) based on standard FOCUS Step 1, 2 maximum  $PEC_{sw}$  values for the use of COBRANZA following a single application to apple early application (all entry routes to water bodies considered)**

Group	Aquatic dwelling organisms						
Endpoint (NOEC, $\mu\text{g/L}$ )	4.8						
AF	1						
ETO $RAC_{sw}$ ( $\mu\text{g/L}$ )	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				$PEC_{sw}$ ( $\mu\text{g/L}$ )	$PEC/RAC$	$PEC_{sw}$ ( $\mu\text{g/L}$ )	$PEC/RAC$
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S and N	125.44	<b>26.13</b>	116.79	<b>24.33</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;  $PEC/RAC$  ratios above the relevant trigger of 1 are shown in bold

All  $PEC_{sw}$  values are higher than the  $ETO RAC_{sw;ch}$  value for aquatic organisms thus indicating a concern regarding the acute and chronic risk to aquatic organisms from the proposed use of COBRANZA in apple at the proposed application rates. It is therefore considered that a refined acute risk assessment for aquatic organisms exposed to copper from the proposed uses of COBRANZA is required.

#### **$PEC_{sw}$ with spray drift mitigation:**

Step 1 and 2  $PEC_{sw}$  values with mitigation were calculated as described below:

- 1) Focus Step 1 and 2 values were firstly calculated with the no spray drift option to derive the PEC from runoff and drainage only. Mitigation measures for 10m of vegetative buffer strip (60% of reduction) were used.
- 2) Focus Step 1 and 2 values were then calculated using the no drainage and runoff option with spray drift values for a single application. These values were then factored down based on different spray drift mitigation values taken for different distances from the FOCUS spray drift calculator (version 1.1) in the SWASH shell, not going beyond 95% mitigation. Also 50, 75 and 90% of nozzles were applied. These values were then added to the values estimated from the runoff and drainage calculation. These results were based on the highest acceptable mitigation for all entry routes to water bodies (95% limit on spray drift mitigation). These values were then added to the values estimated from the runoff and drainage calculation in step 1 above.

The results of the PEC<sub>sw</sub> modelling with spray drift mitigation according to the above scheme, along with relevant PEC/RAC ratios are summarised in the following tables:

**Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple early application (only entry routes by Run-off/Drainage to water bodies considered)**

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S	8.65	<b>1.80</b>	3.45	0.72
			N			1.73	0.36

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple early application (only entry routes by spray drift to water bodies considered)**

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S and N	125.44	<b>26.13</b>	116.79	<b>24.33</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold





**Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple early application (drift mitigation considered)**

Group	Aquatic dwelling organisms																		
End-point (NOEC, µg/L)	4.8																		
AF	1																		
ETO RAC <sub>sw</sub> (µg/L)	4.8																		
Uses	Application pattern	Season of application	Region	Step 2															
				Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S	3	None	104.48	<b>21.77</b>	10	None	45.55	<b>9.49</b>	20	None	10.42	<b>2.17</b>	25	None	6.14	<b>1.28</b>
					50%	52.24	<b>10.88</b>		50%	22.78	<b>4.75</b>		50%	5.21	<b>1.09</b>				
					75%	26.12	<b>5.44</b>		75%	11.39	<b>2.37</b>		75%	2.61	0.54		50%	3.07	0.64
					90%	10.45	<b>2.18</b>		90%	4.56	0.95								

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple early application (runoff/drainage plus spray drift with mitigation) - TOTAL copper**

Group														
Aquatic dwelling organisms														
End-point (NOEC, µg/L)														
4.8														
AF														
1														
ETO RAC <sub>sw</sub> (µg/L)														
4.8														
Uses	Ap- pli- cati- on pat- tern	Season of appli- cation	Re- gion	PEC <sub>sw</sub> (µg/L) (consider- ing Run- off/draina- ge only)	Buf- fer (m)	Noz- zles re- duc- tion (%)	PEC <sub>sw</sub> (µg/L) (con- sidering drift only)	PEC sw (µg/ L) (To- tal)	PEC/ RAC	Buf- fer (m)	Noz- zles re- duc- tion (%)	PEC <sub>sw</sub> (µg/L) (con- sidering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ ha	March- May	S and N	3.45*	20	None	10.42	4.49	0.94	25	None	6.14	4.06	0.85
						90%	1.04				90%	0.61		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

**Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple early application (runoff/drainage with 60% of reduction (10m of vegetative strip buffer) plus spray drift with mitigation measures)**

\*Worst case from Southern calculations

Group	Aquatic dwelling organisms														
Endpoint (NOEC, µg/L)	4.8														
AF	1														
ETO RAC <sub>sw</sub> (µg/L)	4.8														
Uses	Application pattern	Season of application	Region	PEC <sub>sw</sub> (µg/L) (considering Run-off/drainage only)	PEC <sub>sw</sub> (µg/L) (considering 10m of vfs)	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC <sub>sw</sub> (µg/L) (Total)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC <sub>sw</sub> (µg/L) (Total)	PEC/RAC
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S and N	3.45*	1.38	20	None	10.42	3.99	0.83	25	None	6.14	4.45	0.93
							75%	2.61				50%	3.07		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

\*Worst case from Southern calculations

Under the spray drift scenario the particulate, barely water soluble copper compound that hits the surface water will start dissolving while complexation to DOC and sedimentation remove copper from the dissolved fraction. The results from the Blust and Joosen 2016 study (CP9.2.3/01) have demonstrated that in a realistic water/sediment scenario the total copper declines very rapidly in the water phase while dissolved copper was at least a factor of 10 lower. This study describes best the speciation and kinetic behaviour of copper in an aquatic environment following a spray drift event. Despite, the EUCuTF has proposed a more conservative total/dissolved value of 3 for use in the risk assessment, based on the measurements in the mesocosm study.

The EFSA evaluation used a total/dissolved ratio of 1, which suggests that all copper is dissolved. This is against all observations in the monitoring studies and studies from the dossier cited above. The Art.33 evaluation should apply a total to dissolved copper ratio of at least 3.

The following table summarises the risk assessment for aquatic dwelling organisms based on the FOCUS Step 2 maximum PEC<sub>sw</sub> values following a single application to apple early. These PEC<sub>sw</sub> values are without mitigation measures considering all entry routes and are converted to dissolved copper concentration using a total to dissolved copper ratio of 3.

**Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple early application (without mitigation measures considering all entry routes) - DISSOLVED copper**

Group	Aquatic dwelling organisms																
End-point (NOEC, µg/L)	4.8																
AF	1																
ETO RAC <sub>sw</sub> (µg/L)	4.8																
Uses	Application pattern	Season of application	Region	Step 2													
				Max dissolved PEC <sub>sw</sub> (considering all entry routes)	Max dissolved PEC <sub>sw</sub> (considering only run off/drainage)	Buffer (m)	Nozzles reduction (%)	Max dissolved PEC <sub>sw</sub> (considering only drift)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC

				(µg/L)	(µg/L)			(µg/L)									
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March- May	S and N	38.93	1.15*	3	90%	3.48	0.73	14	75%	2.01	0.42	20	None	3.47	0.72

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*Worst case from Southern calculations

Following refinement of the risk assessment using the  $PEC_{sw;dissolved}$  was lower than the ETO  $RAC_{sw;ch}$  thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA in apple early with the following risk mitigation measures:

- any no-spray buffer zone with 90% nozzles reduction OR 14 m no-spray buffer with 75% nozzles reduction OR 20 m no-spray buffer.

### Apple (late application)

Standard FOCUS Step 1 and 2 PEC<sub>sw</sub> values as described below were calculated for apple late as it is representative of the risk envelope for copper:

PEC<sub>sw</sub> without spray drift mitigation:

FOCUS Step 1 and 2 PEC<sub>sw</sub> values (FOCUS Steps 1 and 2, version 3.2) were calculated considering all entry routes to water bodies with an interception of 0% (no cover crop) selected as a worst-case scenario.

**Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on standard FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple late application (all entry routes to water bodies considered)**

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	S and N	71.55	<b>14.91</b>	62.90	<b>13.10</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

All PEC<sub>sw</sub> values are higher than the ETO RAC<sub>sw;ch</sub> value for aquatic organisms thus indicating a concern regarding the acute and chronic risk to aquatic organisms from the proposed use of COBRANZA in apple at the proposed application rates. It is therefore considered that a refined acute risk assessment for aquatic organisms exposed to copper from the proposed uses of COBRANZA is required.

PEC<sub>sw</sub> with spray drift mitigation:

Step 1 and 2 PEC<sub>sw</sub> values with mitigation were calculated as described below:

- 1) Focus Step 1 and 2 values were firstly calculated with the no spray drift option to derive the PEC from runoff and drainage only. Mitigation measures for 10m of vegetative buffer strip (60% of reduction) were used.
- 2) Focus Step 1 and 2 values were then calculated using the no drainage and runoff option with spray drift values for a single application. These values were then factored down based on different spray drift mitigation values taken for different distances from the FOCUS spray drift calculator (version 1.1) in the SWASH shell, not going beyond 95% mitigation. Also 50, 75 and 90% of nozzles were applied. These values were then added to the values estimated from the runoff and drainage calculation. These results were based on the highest acceptable mitigation for all entry routes to water bodies (95% limit on spray drift mitigation). These values were then added to the values estimated from the runoff and drainage calculation in step 1 above.

The results of the PEC<sub>sw</sub> modelling with spray drift mitigation according to the above scheme, along with relevant PEC/RAC ratios are summarised in the following tables:

**Table 9.5-31:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple late application (only entry routes by Runoff/Drainage to water bodies considered)

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	S	8.65	<b>1.80</b>	2.59	0.54
			N			1.73	0.36

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-32:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple late application (only entry routes by spray drift to water bodies considered)

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC <sub>sw</sub> (µg/L)	4.8						
Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC/RAC	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	S and N	71.55	<b>14.91</b>	62.90	<b>13.10</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-33: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple late application (drift mitigation considered)**

Group	Aquatic dwelling organisms																						
End point (NOEC, µg/L)	4.8																						
AF	1																						
ETORA C <sub>sw</sub> (µg/L)	4.8																						
Uses	Application pattern	Season of application	Region	Step 2																			
				Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PEC <sub>sw</sub> (µg/L)	PEC/RAC
Apple BBC H 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	S and N	3	None	52.57	<b>10.95</b>	5	None	30.05	<b>6.26</b>	10	None	13.43	<b>2.80</b>	14	None	7.63	<b>1.59</b>	20	None	4.14	0.86
					50%	26.29	<b>5.48</b>		50%	15.03	<b>3.13</b>		50%	6.72	<b>1.40</b>		50%	3.82	0.80				
					75%	13.14	<b>2.74</b>		75%	7.51	<b>1.56</b>		75%	3.36	0.70		50%	3.82	0.80				
					90%	5.26	1.10		90%	3.01	0.63		75%	3.36	0.70		50%	3.82	0.80				

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold



**Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple late application (runoff/drainage plus spray drift with mitigation) - TOTAL copper**

Group																			
Aquatic dwelling organisms																			
End-point (NOEC, µg/L)																			
AF																			
ETO RAC <sub>sw</sub> (µg/L)																			
4.8																			
1																			
Uses	Ap- pli- cati- on pat- tern	Season of ap- plica- tion	Re- gion	PEC <sub>sw</sub> (µg/L) (consid- ing Run- off/drainag e only)	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC	Buff er (m)	Noz- zles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (consid- ering drift only)	PEC sw (µg/ L) (To- tal)	PEC/R AC	Buffer (m)	Nozzles reduc- tion (%)	PEC <sub>sw</sub> (µg/L) (con- sider- ing drift only)	PEC <sub>sw</sub> (µg/L) (Total)	PEC/R AC
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./h a	March- May	S and N	2.59*	10	None	13.43	3.93	0.82	14	None	7.63	4.50	0.94	20	None	4.14	4.66	0.97
						90%	1.34				75%	1.91				50%	2.07		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*Worst case from Southern calculations

Under the spray drift scenario the particulate, barely water soluble copper compound that hits the surface water will start dissolving while complexation to DOC and sedimentation remove copper from the dissolved fraction. The results from the Blust and Joosen 2016 study (CP9.2.3/01) have demonstrated that in a realistic water/sediment scenario the total copper declines very rapidly in the water phase while dissolved copper was at least a factor of 10 lower. This study describes best the speciation and kinetic behaviour of copper in an aquatic environment following a spray drift event. Despite, the EUCuTF has proposed a more conservative total/dissolved value of 3 for use in the risk assessment, based on the measurements in the mesocosm study.

The EFSA evaluation used a total/dissolved ratio of 1, which suggests that all copper is dissolved. This is against all observations in the monitoring studies and studies from the dossier cited above. The Art.33 evaluation should apply a total to dissolved copper ratio of at least 3.

The following table summarises the risk assessment for aquatic dwelling organisms based on the FOCUS Step 2 maximum PEC<sub>sw</sub> values following a single application to apple late. These PEC<sub>sw</sub> values are without mitigation measures considering all entry routes and are converted to dissolved copper concentration using a total to dissolved copper ratio of 3.

**Table 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sw</sub> values for the use of COBRANZA following a single application to apple late application (without mitigation measures considering all entry routes) - DISSOLVED copper**

<b>Group</b>	Aquatic dwelling organisms																					
<b>End-point (NOEC, µg/L)</b>	4.8																					
<b>AF</b>	1																					
<b>ETO RAC<sub>s</sub> w (µg/L)</b>	4.8																					
<b>Uses</b>	<b>Application pattern</b>	<b>Season of application</b>	<b>Region</b>	<b>Step 2</b>																		
				<b>Max dissolved PEC<sub>sw</sub> (considering all entry routes) (µg/L)</b>	<b>Buffer (m)</b>	<b>Nozzles reduction (%)</b>	<b>Max dissolved PEC<sub>sw</sub> (considering only drift) (µg/L)</b>	<b>PEC/RAC</b>	<b>Buffer (m)</b>	<b>Nozzles reduction (%)</b>	<b>PEC<sub>sw</sub> (µg/L)</b>	<b>PEC/RAC</b>	<b>Buffer (m)</b>	<b>Nozzles reduction (%)</b>	<b>PEC<sub>sw</sub> (µg/L)</b>	<b>PEC/RAC</b>	<b>Buffer (m)</b>	<b>Nozzles reduction (%)</b>	<b>PEC<sub>sw</sub> (µg/L)</b>	<b>PEC/RAC</b>	<b>Max dissolved PEC<sub>sw</sub> (considering only run off/drainage) (µg/L)</b>	<b>PEC/RAC</b>

Apple BBC H 15 Late drift rates	3 x 1200 g a.s./ha	March- May	S and N	20.97	3	90%	1.75	0.36	5	75%	2.50	0.52	10	50%	2.24	0.47	14	None	2.54	0.53	0.86*	0.18
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AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*From Southern calculations (worst case)

Following refinement of the risk assessment using the  $PEC_{sw;dissolved}$  was lower than the  $ETO RAC_{sw;ch}$  thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA in apple late with the following risk mitigation measures:

- any no-spray buffer zone with 90% nozzles reduction OR 5 m no-spray buffer with 75% nozzles reduction OR 10 m no-spray buffer with 50% nozzles reduction OR 14 m no-spray buffer.

**ZRMS comments to aquatic risk assessment:** ZRMS-PL used EU agreed endpoints according to the EFSA Journal 2018;16(1):5152 as was agreed at the Pesticides Peer Review Meeting 169.

The risk assessment provided by ZRMS according EFSA endpoint is presented in the Tables below ( in blue):

**Table 9.5.2-1 Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Cobranza in vines (early application ).**

Group			Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sediment dwelling		Sediment dwelling
Test species			<i>Oncorhynchus mykiss</i>	<i>Acipenser transmontanus</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Selenasrtum capricornutum</i>	<i>Chironomus ripatius</i>		<i>Tubifex tubifex</i>
Endpoint (µg/L)			LC <sub>50</sub> 207	NOEC 1.12	EC <sub>50</sub> 26.6	NOEC 7.6	E <sub>r</sub> C <sub>50</sub> 22.29	NOEC 500		NOEC 16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	Season of application	PEC sw-max (µg/L)	PEC/RAC ratios						PEC sed <sub>max</sub> (mg/kg)	PEC/RAC ratios
Step 1		16.21	7.83	135.08	60.94	21.33	7.27	0.32	2510	756.02
Step 2										
N-Europe	March-May	9.00	4.35	75.00	33.83	11.84	4.04	0.18	553.28	166.65
S-Europe	March-May								1040	313.25

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

\*according to the EFSA Journal 2018;16(1):5152

**Table 9.5.2-2 Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Cobranza in vines ( late application).**

Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sediment dwelling		Sediment dwelling
Test species			<i>Oncorhynchus mykiss</i>	<i>Acipenser transmontanus</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Selenasrtum capricornutum</i>	<i>Chironomus riparius</i>		<i>Tubifex tubifex</i>
Endpoint (µg/L)			LC <sub>50</sub> 207	NOEC 1.12	EC <sub>50</sub> 26.6	NOEC 7.6	ErC <sub>50</sub> 22.29	NOEC 500		NOEC 16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	Season of application	PEC <sub>SW-max</sub> (µg/L)	PEC/RAC ratios						PEC <sub>sed max</sub> (mg/k)	PEC/RAC ratios
Step 1		33.97	<b>16.41</b>	<b>283.08</b>	<b>127.71</b>	<b>44.70</b>	<b>15.24</b>	0.68	2640	<b>313.25</b>
	Step 2									
N-Europe	March-May	26.76	<b>12.93</b>	<b>223.00</b>	<b>100.60</b>	<b>35.21</b>	<b>12.01</b>		683.17	<b>795.18</b>
S-Europe	March-May							0.54	1170	<b>205.77</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

\*according to the EFSA Journal 2018;16(1):5152

**Table 9.5.2-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Cobranza in potatoes and fruiting vegetables.**

Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sediment dwelling		Sediment dwelling
Test species			<i>Oncorhynchus mykiss</i>	<i>Acipenser transmontanus</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Selenastrum capricornutum</i>	<i>Chironomus riparius</i>		<i>Tubifex tubifex</i>
Endpoint (µg/L)			LC <sub>50</sub> 207	NOEC 1.12	EC <sub>50</sub> 26.6	NOEC 7.6	E <sub>r</sub> C <sub>50</sub> 22.29	NOEC 500		NOEC 16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	Season of application	PEC <sub>sw-max</sub> (µg/L)	PEC/RAC ratios						PEC <sub>sed max</sub> (mg/kg)	PEC/RAC ratios
Step 1		<b>19.69</b>	<b>9.51</b>	<b>164.08</b>	<b>74.02</b>	<b>25.91</b>	<b>8.83</b>	0.39	3010	<b>931.89</b>
Step 2										
N-Europe	March-May	<b>11.04</b>	<b>5.33</b>	<b>92.00</b>	<b>41.50</b>	<b>14.53</b>	<b>4.95</b>	0.22	665.69	<b>206.10</b>
S-Europe	March-May								1250	<b>387.00</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;

PEC/RAC ratios above the relevant trigger of 1 are shown in bold

\*according to the EFSA Journal 2018;16(1):5152

**Table 9.5.2-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Cobranza in early application to apple.**

Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sediment dwelling		Sediment dwelling
Test species			<i>Oncorhynchus mykiss</i>	<i>Acipenser transmontanus</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Selenasrtum capricornutum</i>	<i>Chironomus riparius</i>		<i>Tubifex tubifex</i>
Endpoint (µg/L)			LC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	E <sub>r</sub> C <sub>50</sub>	NOEC		NOEC
AF			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
RAC (µg/L)			100	10	100	10	10	10		5*
			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	Season of application	PEC sw-max (µg/L)	PEC/RAC ratios						PEC sed max (mg/kg)	PEC/RAC ratios
Step 1		125.44	60.60	<b>1045.33</b>	<b>471.58</b>	<b>165.05</b>	<b>56.28</b>	<b>2.51</b>	<b>3790</b>	<b>1173.37</b>
Step 2										
N-Europe	March-May	116.79	56.42	<b>973.25</b>	<b>439.06</b>	<b>153.67</b>	<b>52.40</b>	<b>2.34</b>	<b>843.36</b>	<b>261.10</b>
S-Europe										

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

\*according to the EFSA Journal 2018;16(1):5152

**Table 9.5.2-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Cobranza in late application to apple.**

Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sediment dwelling		Sediment dwelling
Test species			<i>Oncorhynchus mykiss</i>	<i>Acipenser transmontanus</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Selenasrtum capricornutum</i>	<i>Chironomus riparius</i>		<i>Tubifex tubifex</i>



Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sediment dwelling		Sediment dwelling
Endpoint (µg/L)			LC <sub>50</sub> 207	NOEC 1.12	EC <sub>50</sub> 26.6	NOEC 7.6	E <sub>r</sub> C <sub>50</sub> 22.29	NOEC 500		NOEC 16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	Season of application	PEC sw-max (µg/L)	PEC/RAC ratios						PEC sed <sub>max</sub> (mg/kg)	PEC/RAC ratios
Step 1		71.55	<b>34.57</b>	<b>596.25</b>	<b>268.98</b>	<b>94.14</b>	<b>32.10</b>	<b>1.43</b>	<b>3390</b>	<b>1049.54</b>
Step 2										
N-Europe	March-May	62.9	<b>30.39</b>	<b>524.17</b>	<b>236.47</b>	<b>82.76</b>	<b>28.22</b>	<b>1.26</b>	<b>1040</b>	<b>321.98</b>
S-Europe									<b>1340</b>	<b>414.86</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

\*according to the EFSA Journal 2018;16(1):5152

Based on the results performed in the Tables above, the PEC/RAC ratio is above trigger of 1 for fish, aquatic invertebrates and algae. In case of sediment dwelling organism for species *Chironmus riparius* (spiked in water) the an unacceptable risk is identified for early and late applications in apples.

In addition, the risk for sediment dwelling organism (spiked in sediment) needs further consideration.

Refined endpoints based on species sensitivity distribution (SSD) were available for both the acute and chronic risk assessment for fish and were discussed and agreed on in the Pesticide Peer Review meeting. The respective endpoints are reported in the EFSA conclusion (EFSA Journal 2018;16(1):5152) and considered for the higher tier risk assessment below. It was agreed that total or dissolved copper might be considered as equivalent; and that the SSD could be built using data expressed both as total and dissolved copper, depending on how the studies had been designed and reported.

With respect to algae and aquatic invertebrates, a microcosm study was available. The experts at the Pesticide Peer Review meeting agreed to use the end point derived from this study (ETO-RAC) together with an assessment factor of 2.

**Table 9.5.2-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC<sub>sw</sub> of total copper (PEC<sub>sw</sub>) or based on maximum PEC<sub>sw</sub> of dissolved copper (PEC<sub>sw</sub>) considering different mitigation options for the use of Cobranza in vines, early application.**

Group		Fish acute (higher tier)	Fish pro- longed (high- er tier)	Inverteb. Acute (high- er tier)	Inverteb. prolonged (higher tier)	Algae (higher tier)
Test species		7 fish species		Indoor microcosm study		
Endpoint (µg/L)		SSD-HC <sub>5</sub> 3.73	SSD-HC <sub>5</sub> 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
Total copper	Max. PEC <sub>sw</sub> (µg/L)					
STEP 2 (all entry routes)	9.0	7.26	24.32	3.75		
STEP 2 (runoff/drainge)	2.88	2.32 SE	7.78	1.20		
	1.44	1.16 N	3.89	0.60		
STEP 2 (only drift)	9.0	7.26	24.32	3.75		
STEP 2 (drift mitigation considered)						
3 m unsprayed buffer zone +50% DRT	3.56	2.87	9.62	1.48		
3 m unsprayed buffer zone + 75% DRT	1.78	1.44	4.81	0.74		
5 m unsprayed buffer zone+50% DRT	1.71	1.38	4.62	0.71		
10 m unsprayed buffer zone	1.20	0.97	3.24	0.50		
STEP 2 (runoff/drainge+spraydrift with mitigation measures)						
3 m unsprayed zone +75% DRT	4.66	3.76	12.59	1.94		
5 m unsprayed zone +50% DRT	4.59	3.70	12.41	1.91		
10 m unsprayed buffer zone	4.08	3.29	11.03	1.70		
	Max. PEC <sub>sw</sub> (µg/L)					
STEP 2 ( dissolved copper)						
	3	2.42	8.11	1.25		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip; DRT = drift reducing technology; SE = South Europe, N-North Europe

**Table 9.5.2-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC<sub>sw</sub> of total copper (tier 1a PEC<sub>sw</sub>) or based on maximum PEC<sub>sw</sub> of dissolved copper (tier 1b PEC<sub>sw</sub>) considering different mitigation options for the use of Cobranza in vines, late application**

Group		Fish acute (higher tier)	Fish pro-longed (higher tier)	Inverteb. Acute (higher tier)	Inverteb. prolonged (higher tier)	Algae (higher tier)
Test species		7 fish species		Indoor microcosm study		
Endpoint (µg/L)		SSD-HC <sub>5</sub> 3.73	SSD-HC <sub>5</sub> 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
Total copper	Max. PEC <sub>sw</sub> (µg/L)					
STEP 2 (all entry routes)	26.76	21.58	72.32	11.15		
STEP 2 (runoff/drainge)	2.88 SE	2.32	7.78	1.20		
	3.30 N	2.66	8.92	1.38		
STEP 2 (only drift)	26.76	21.58	72.32	11.15		
STEP 2 (drift mitigation considered)						
3 m unsprayed buffer zone+50% DRT	10.66	8.60	28.81	4.44		
3 m unsprayed buffer zone + 75% DRT	5.33	4.30	14.41	2.22		
3 m unsprayed buffer zone+90% DRT	2.13	1.72	5.76	0.89		
5 m unsprayed buffer zone +50% DRT	5.22	4.21	14.11	2.18		
5 m unsprayed buffer zone+ 75% DRT	2.61	2.10	7.05	1.09		
5 m unsprayed buffer zone+90% DRT	1.04	0.84	2.81	0.43		
10 m unsprayed buffer zone+50% DRT	1.89	1.52	5.11	0.79		

10 m unsprayed buffer zone+75% DRT	0.95	0.77	<b>2.57</b>	0.40
14 m unsprayed buffer zone+50% DRT	1.14	0.92	<b>3.08</b>	0.48
20 m unsprayed bufferzone +50% DRT	0.66	0.53	<b>1.78</b>	0.28
STEP 2 (runoff/drainge+spraydrift with mitigation measures)				
3 m unsprayed buffer zone+90% DRT	5.73	<b>4.62</b>	<b>15.49</b>	<b>2.39</b>
5 m unsprayed buffer zone+90% DRT	4.64	<b>3.74</b>	<b>12.54</b>	<b>1.93</b>
10 m unsprayed bufferzone +75% DRT	4.55	<b>3.67</b>	<b>12.30</b>	<b>1.90</b>
14 m unsprayed buffer zone+50% DRT	4.74	<b>3.82</b>	<b>12.81</b>	<b>1.98</b>
20 m unsprayed buffer zone+50% DRT	4.26	<b>3.44</b>	<b>11.51</b>	<b>1.78</b>
STEP 2 (runoff /drainge with 60 % of reduction ( 10 meter VFS) + spraydrift with mitigation measures)				
10 m unsprayed buffer zone +50% DRT	3.33	<b>2.69</b>	<b>9.00</b>	<b>1.39</b>
14m unsprayed buffer zone	3.72	<b>3.00</b>	<b>10.05</b>	<b>1.55</b>
20 m unsprayed buffer zone	2.76	<b>2.23</b>	<b>7.46</b>	<b>1.15</b>
	Max. PEC <sub>sw</sub> (µg/L)			
STEP 2 (dissolved cooper)				
3 m unsprayed buffer zone +75% DRT	2.67	<b>2.15</b>	<b>7.22</b>	<b>1.11</b>
5 m unsprayed buffer zone + 50 % DRT	1.74	<b>1.40</b>	<b>4.70</b>	0.73
10 m unsprayed buffer zone	1.26	<b>1.02</b>	<b>3.41</b>	0.53

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip;; DRT = drift reducing technology; SE = South Europe N=North Europe

**Table 9.5.2-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC<sub>sw</sub> of total copper (PEC<sub>sw</sub>) or based on maximum PEC<sub>sw</sub> of dissolved copper (PEC<sub>sw</sub>) considering different mitigation options for the use of Cobranza in to potatoes and solanaceous (fruiting vegetables)**

Group		Fish acute (higher tier)	Fish pro- longed (high- er tier)	Inverteb. Acute (high- er tier)	Inverteb. prolonged (higher tier)	Algae (higher tier)
Test species		7 fish species		Indoor microcosm study		
Endpoint (µg/L)		SSD-HC <sub>5</sub> 3.73	SSD-HC <sub>5</sub> 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
Total copper	Max. PEC <sub>sw</sub> (µg/L)					
STEP 2 (all entry routes)	11.04	8.90	29.84	4.60		
STEP 2 (runoff/drainge)	3.45SE	2.78	9.32	1.44		
	1.73 N	1.40	4.68	0.72		
STEP 2 (only drift)	11.04	8.90	29.84	4.60		
STEP 2 (drift mitigation considered)						
3 m unsprayed buffer zone+50% DRT	1.632	1.32	4.41	0.68		
3 m unsprayed buffer zone+ 75% DRT	0.816	0.66	2.21	0.34		
5 m unsprayed buffer zone+50% DRT	1.045	0.84	2.82	0.44		
10 m unsprayed buffer zone	1.108	0.89	2.99	0.46		
STEP 2 (runoff/drainge+spraydrift with mitigation measures)						
3 m unsprayed buffer zone+ 75% DRT	4.27	3.44	11.54	1.78		
5 m unsprayed buffer zone+50% DRT	4.50	3.63	12.16	1.88		
10 m unsprayed buffer zone	4.56	3.68	12.32	1.90		
	Max. PEC <sub>sw</sub> (µg/L)					
STEP 2 ( dissolved cooper)						
	3.68	2.97	9.95	1.53		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip;; DRT = drift reducing technology; SE = South Europe, N-North Europe

**Table 9.5.2-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC<sub>sw</sub> of total copper (PEC<sub>sw</sub>) or based on maximum PEC<sub>sw</sub> of dissolved copper (PEC<sub>sw</sub>) considering different mitigation options for the use of Cobranza in apples, early application**

Group		Fish acute (higher tier)	Fish pro-longed (higher tier)	Inver-teb. Acute (higher tier)	Inverteb. pro-longed (higher tier)	Algae (higher tier)
Test species		7 fish species		Indoor microcosm study		
Endpoint (µg/L)		SSD-HC <sub>5</sub> 3.73	SSD-HC <sub>5</sub> 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
STEP 2 Total copper	Max. PEC <sub>sw</sub> (µg/L)					
STEP 2 (all entry routes)	116.79	94.19	315.65	48.66		
STEP 2 (runoff/drainge)	3.45SE	2.78	9.32	1.44		
	1.73N	1.40	4.68	0.72		
STEP 2 (only drift)	116.79	94.19	315.65	48.66		
STEP 2 (drift mitigation considered)						
3 m unsprayed buffer zone+ 50% DRT	52.24	42.13	141.19	21.77		
3 m unsprayed buffer zone + 75% DRT	26.12	21.06	70.59	10.88		
3 m unsprayed buffer zone+90% DRT	10.45	8.43	28.24	4.35		
5 m unsprayed buffer zone+50% DRT	37.09	29.91	100.24	15.45		
5 m unsprayed buffer zone+75% DRT	18.54	14.95	50.11	7.73		
5 m unsprayed buffer zone+ 90% DRT	7.42	5.98	20.05	3.09		

10 m unsprayed buffer zone +50% DRT	22.78	18.37	61.57	9.49
10 m b unsprayed buffer zone+75% DRT	11.39	9.19	30.78	4.75
10 m unsprayed buffer zone + 90% DRT	4.56	3.68	12.32	1.90
14 m unsprayed buffer zone +50% DRT	12.04	9.71	32.54	5.02
14 m unsprayed buffer zone +75% DRT	6.02	4.85	16.27	2.51
14 m unsprayed buffer zone+ 90% DRT	2.41	1.94	6.51	1.00
20 m b unsprayed buffer zone+50% DRT	5.21	4.20	14.08	2.17
20 m unsprayed buffer zone +75% DRT	2.61	2.10	7.05	1.09
20 m unsprayed buffer zone+ 90% DRT	1.04	0.84	2.81	0.43
25 m unsprayed buffer zone+50% DRT	3.07	2.48	8.30	1.28
25m unsprayed buffer zone+75% DRT	1.54	1.24	4.16	0.64
25 m unsprayed buffer zone+ 90% DRT	0.61	0.49	1.65	0.25
STEP 2 (runoff/drainge+spray drift with mitigation measures)				
20 m unsprayed buffer zone + 90% DRT	4.49	3.62	12.14	1.87
25 m unsprayed buffer zone +90% DRT	4.06	3.27	10.97	1.69
STEP 2 (runoff /drainge with 60 % of reduction ( 10 meter VFS) + spraydrift with mitigation measures	Max. PEC <sub>sw</sub> (µg/L)			
25 m unsprayed buffer zone +75% DRT	3.99	3.22	10.78	1.66
20 meter unsprayed buffer zone +50% DRT	4.45	3.59	12.03	1.85
	Max. PEC <sub>sw</sub> (µg/L)			
STEP 2 ( dissolved copper)				
3 m unsprayed buffer zone + 90% DRT	3.48	2.81	9.41	1.45
5 m unsprayed buffer zone + 90% DRT	2.47	1.99	6.68	1.03
10 m unsprayed buffer zone + 90% DRT	1.52	1.23	4.11	0.63
14 m unsprayed buffer zone + 75% DRT	2.01	1.62	5.43	0.84
20 m unsprayed buffer zone	3.47	2.80	9.38	1.45

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip;; DRT = drift reducing technology; SE = South Europe, N-North Europe

**Table 9.5.2-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC<sub>sw</sub> of total copper (tier 1a PEC<sub>sw</sub>) or based on maximum PEC<sub>sw</sub> of dissolved copper (tier 1b PEC<sub>sw</sub>) considering different mitigation options for the use of Cobranza in apples, late application.**

Group		Fish acute (higher tier)	Fish pro- longed (high- er tier)	Inverteb. Acute (high- er tier)	Inverteb. prolonged (higher tier)	Algae (higher tier)
Test species		7 fish species		Indoor microcosm study		
Endpoint (µg/L)		SSD-HC <sub>5</sub> 3.73	SSD-HC <sub>5</sub> 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
TIER-total copper	Max. PEC <sub>sw</sub> (µg/L)					
STEP 2 (all entry routes)	62.9	50.73	170.00	26.21		
STEP 2 (runoff/drainge)	2.59 SE	2.09	7.00	1.08		
	1.73N	1.40	4.68	0.72		
STEP 2 (only drift)	62.9	50.73	170.00	26.21		
STEP 2 (drift mitigation considered)						
3 m unsprayed buffer zone +50% DRT	26.29	21.20	71.05	10.95		
3 m unsprayed buffer zone + 75% DRT	13.14	10.60	35.51	5.48		
3 m unsprayed buffer zone +90% DRT	5.26	4.24	14.22	2.19		
5 m unsprayed buffer zone +50% DRT	15.03	12.12	40.62	6.26		
5 m unsprayed buffer zone + 75% DRT	7.51	6.06	20.30	3.13		
5 m unsprayed buffer zone +90% DRT	3.01	2.43	8.14	1.25		
10 m unsprayed buffer zone +50% DRT	6.72	5.42	18.16	2.80		
10 m unsprayed buffer zone +75% DRT	3.36	2.71	9.08	1.40		
10 m unsprayed buffer zone +90% DRT	1.34	1.08	3.62	0.56		
14 m unsprayed buffer zone +50% DRT	3.82	3.08	10.32	1.59		



14 m unsprayed buffer zone + 75% DRT	1.91	<b>1.54</b>	<b>5.16</b>	0.80
20 m unsprayed buffer zone +50% DRT	2.07	<b>1.67</b>	<b>5.59</b>	0.86
STEP 2 (runoff/drainge+spraydrift with mitigation measures)				
10 m unsprayed buffer zone + 90% DRT	3.93	<b>3.17</b>	<b>10.62</b>	<b>1.64</b>
14 m unsprayed buffer zone +75% DRT	4.50	<b>3.63</b>	<b>12.16</b>	<b>1.88</b>
20 m unsprayed buffer zone + 50% DRT	4.60	<b>3.71</b>	<b>12.43</b>	<b>1.92</b>
	<b>Max. PEC<sub>sw</sub></b> <b>(µg/L)</b>			
<b>STEP 2 (dissolved copper)</b>				
3 m unsprayed buffer zone + 90% DRT	1.75	1.41	<b>4.73</b>	0.73
5 m unsprayed buffer zone + 75 % DRT	2.50	<b>2.02</b>	<b>6.76</b>	<b>1.04</b>
10 m unsprayed buffer zone +50% DRT	2.24	<b>1.81</b>	<b>6.05</b>	0.93
14 meter unsprayed buffer zone	2.54	<b>2.05</b>	<b>6.86</b>	<b>1.06</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip; ; DRT = drift reducing technology; SE = South Europe, N=North Europe

For the risk assessment with very conservative exposure approach proposed by EFSA, it can be concluded that even with mitigation measures a high risk could be identified for fish and aquatic invertebrates for all proposed uses, and for algae in some uses.

If a more realistic exposure regime is used, were a factor is introduced that relates the simulated total copper PEC<sub>sw</sub> value to dissolved copper, PEC<sub>sw</sub> values are divided by three, and lead to lower PEC/RAC ratios. However, also here further refinements are deemed necessary for the above mentioned organism groups.

Further calculations of PEC<sub>sw</sub> should be provided by the applicant to conclude acceptable risk assessment to aquatic organism according to Tables above.

We would like to emphasize clearly that if the other MSs are different opinion referred to the risk assessment proposed by the ZRMS they are considered it further at National level with consideration all data presented in this dossier.

#### 9.5.2.2 Risk Assessment for Sediment Dwelling Organisms

In the following tables, the ratios between predicted environmental concentrations in sediment ( $PEC_{sed}$ ) and the regulatory acceptable concentration (RAC) for sediment dwelling organisms are given per intended use for each FOCUS scenario.

To calculate the PEC sediment accumulation over seven years, the FOCUS Step 1 sediment via spray drift and run-off /drainage with a  $K_{doc}$  worst case default value of 10,000 mL/g values are added to a median **background level of copper in European sediments of 17 mg/kg**.

As the aquatic dwelling organism risk assessment indicated that mitigation measures were required for each FOCUS scenario, these measures were also included in the assessment of risk to sediment dwelling organisms.

**Table 9.5-36: Sediment dwelling organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1 maximum PEC<sub>sed</sub> accumulation values for the use of COBRANZA following seven years application to vines early application (all entry routes without mitigation measures)**

Group	Sediment dwelling organisms						
Endpoint (HC <sub>5</sub> , mg/kg)	40.4						
AF	1						
ETO RAC <sub>sed</sub> (mg/kg)	40.4						
Uses	Application pattern	Season of application	Region	PEC <sub>sed</sub> (mg/kg)		PEC <sub>sed</sub> , accumulation Total copper (7 years accumulation) + background (mg/kg)	
				Step 1		Mitigation	PEC/RAC
				1 year	7 years	None	
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S and N	2.39	16.73	33.73	0.83
Vines BBCH 85 Late drift rates – BBCH 85 onwards				2.51	17.57	34.57	0.86

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC values for sediment dwelling organisms were all lower than 1 thus indicating no concerns regarding the acute or chronic risks to sediment dwelling organisms from the proposed uses of COBRANZA in vines early and late applications.

**Table 9.5-37: Sediment dwelling organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1 maximum PEC<sub>sed</sub> accumulation values for the use of COBRANZA following seven years application to potatoes and solanaceous (fruiting vegetables) (all entry routes without mitigation measures)**

Group	Sediment dwelling organisms						
Endpoint (HC <sub>5</sub> , mg/kg)	40.4						
AF	1						
ETO RAC <sub>sed</sub> (mg/kg)	40.4						
Uses	Application pattern	Season of application	Region	PEC <sub>sed</sub> (mg/kg)		PEC <sub>sed</sub> , accumulation Total copper (7 years accumulation) + background (mg/kg)	
				Step 1		Mitigation	PEC/RAC
					1 year	7 years	

Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	S and N	2.87	20.09	37.09	0.92
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AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC values for sediment dwelling organisms were all lower than 1 thus indicating no concerns regarding the acute or chronic risks to sediment dwelling organisms from the proposed uses of COBRANZA in potatoes and solanaceous (fruiting vegetables).

**Table 9.5-38: Sediment dwelling organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sed</sub> accumulation values for the use of COBRANZA following seven years application to pome fruits (all entry routes without mitigation measures)**

Group		Sediment dwelling organisms					
Endpoint (HC <sub>5</sub> , mg/kg)		40.4					
AF		1					
ETO RAC <sub>sed</sub> (mg/kg)		40.4					
Uses	Application pattern	Season of application	Region	PEC <sub>sed</sub> (mg/kg)		PEC <sub>sed, accumulation</sub> Total copper (7 years accumulation) + background (mg/kg)	
				Step 1		Mitigation	PEC/RAC
				1 year	7 years	None	
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S and N	1.92*	13.44	30.44	0.75
Apple BBCH 60 onwards Late drift rates				1.65	25.20	28.55	0.71

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*From Southern calculations (worst case)

For all intended uses, following refinement of the risk assessment using the  $PEC_{sw;dissolved}$  was lower than the  $ETO RAC_{sw;ch}$  thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA with the following risk mitigation measures:

- Grapevine (late): Any no-spray buffer with 50% nozzles reduction OR 10 m no-spray buffer.
- Pome fruits (early): any no-spray buffer zone with 90% nozzles reduction OR 14 m no-spray buffer with 75% nozzles reduction OR 20 m no-spray buffer.
- Pome fruits (late): any no-spray buffer zone with 90% nozzles reduction OR 5 m no-spray buffer with 75% nozzles reduction OR 10 m no-spray buffer with 50% nozzles reduction OR 14 m no-spray buffer.

#### ZRMS comments:

The risk assessment for sediment dwelling organism with consideration the endpoint proposed by the applicant HC5= 40.4 mg a.s./kg is not considered in the risk assessment ( please see : commenting box under Point: 9.5.1.1.2).

The risk assessment for sediment dwellers was based on HC5 of 16.7 mg/kg, in line with EFSA PPR Panel (2015) with AF of 5 giving RAC =3.23 mg a.s./kg sediment.

**Table 9.5-39-1:Sediment dwelling organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1 maximum PEC<sub>sed</sub> accumulation values for the use of Cobranza following seven years application to vines early application (all entry routes without mitigation measures).**

Use of "Castranza" following seven years application to vines early application (in early routes without mitigation measures).

Group	Sediment dwelling organisms								
Endpoint (HC <sub>5</sub> , mg/kg)	16.7								
AF	5								
ETO RAC <sub>sed</sub> (mg/kg)	3.23								
Uses	Application pattern	Season of appli- cation	Region	PEC <sub>sed</sub> (mg/kg)		PEC <sub>sed</sub> /RAC (mg/kg)		PEC <sub>sed</sub> , accumulation Total copper (7 years accumula- tion) + background (mg/kg)	
				Step 1		Step 1		Mitigation	PEC/RAC
				1 year	7 years	1 year	7 years	None	
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S and N	2.39	16.73	0.73	5.17	33.73	10.44
Vines BBCH 85 Late drift rates – BBCH 85 on- wards				2.51	17.57	0.77	5.41	34.57	10.77

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-40-1: Sediment dwelling organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1 maximum PEC<sub>sed</sub> accumulation values for the use of Cobranza following seven years application to potatoes and solanaceous (fruiting vegetables) (all entry routes without mitigation measures)**

Group	Sediment dwelling organisms
Endpoint ( mg/kg)	16.7
AF	5

ETO RAC <sub>sed</sub> (mg/kg)		3.23							
Uses	Application pattern	Season of application	Region	PEC <sub>sed</sub> (mg/kg)		PEC/RAC	PEC/RAC	PEC <sub>sed, accumulation</sub> Total copper (7 years accumulation) + background (mg/kg)	
				Step 1		Step 1		Mitigation	PEC/RAC
				1 year	7 years	1 year	7 years	None	
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	S and N	2.87	20.09	0.88	<b>6.21</b>	37.09	<b>11.48</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-41-1: Sediment dwelling organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PEC<sub>sed</sub> accumulation values for the use of Cobranza following seven years application to pome fruits (all entry routes without mitigation measures)**

Group	Sediment dwelling organisms								
Endpoint (mg/kg)	16.7								
AF	5								
ETO RAC <sub>sed</sub> (mg/kg)	3.23								
Uses	Application pattern	Season of application	Region	PEC <sub>sed</sub> (mg/kg)		PEC/RAC	PEC/RAC	PEC <sub>sed, accumulation</sub> Total copper (7 years accumulation) + background (mg/kg)	
				Step 1		Step 1		Mitigation	PEC/RAC
				1 year	7 years	1 year	7 years	None	
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S and N	1.92*	13.44	0.59	<b>4.16</b>	30.44	<b>9.42</b>
Apple BBCH 60 onwards Late drift rates				1.65	25.20	0.51	<b>7.80</b>	28.55	<b>8.83</b>

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

\*From Southern calculations (worst case)

According to the calculations performed in tables above , the risk from the use of active substance for early and late applications in vines, apples and potatoes is not acceptable for sediment dwelling organisms considering the active substance. Further refinement is required.

However, there is no approved guideline for calculating PECsed values to determine protective measures, similar to PECsw value approach. Therefore, a high risk to sediment dwellers (exposure via sediment) was still concluded for proposed use according to EFSA 2018 endpoint.

**The MSs should apply their own mitigation measure at national level.**





### 9.5.3 Overall conclusions

The ratios between predicted environmental concentrations in surface water bodies ( $PEC_{sw}$ ) and regulatory acceptable concentrations (RAC) for aquatic dwelling organisms are given per intended use for each FOCUS scenario. As discussed above, to achieve a concise risk assessment for aquatic dwelling organisms, an ETO- $RAC_{sw; ch}$  value of 4.8  $\mu\text{g/L}$  was used as this value was protective of all acute and chronic risks to all relevant aquatic species.

For all intended uses, following refinement of the risk assessment using the  $PEC_{sw; dissolved}$  was lower than the ETO  $RAC_{sw; ch}$  thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of COBRANZA with the following risk mitigation measures:

- Grapevine (late): Any no-spray buffer with 50% nozzles reduction OR 10 m no-spray buffer.
- Pome fruits (early): any no-spray buffer zone with 90% nozzles reduction OR 14 m no-spray buffer with 75% nozzles reduction OR 20 m no-spray buffer.
- Pome fruits (late): any no-spray buffer zone with 90% nozzles reduction OR 5 m no-spray buffer with 75% nozzles reduction OR 10 m no-spray buffer with 50% nozzles reduction OR 14 m no-spray buffer.

Therefore, the Applicant concludes an acceptable risk with the following mitigation measures:

**Grapevine (late application)– Spe3:** To protect aquatic organisms respect an unsprayed buffer zone of 10m to surface water bodies OR none unsprayed buffer zone with 50% of nozzles reduction.

**Pome fruit (apple, pear and quince) early application – Spe3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m OR an unsprayed buffer zone of 14m to surface water bodies with 75% of nozzles reduction OR none unsprayed buffer zone with 90% of nozzles reduction.

**Pome fruit (apple, pear and quince) late application – Spe3:** To protect aquatic organisms respect an unsprayed buffer zone of 14m to surface water bodies OR an unsprayed buffer zone of 10m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 5m to surface water bodies with 75% of nozzles reduction OR none unsprayed buffer zone with 90% of nozzles reduction.

#### ZRMS comments:

The applicant is kindly request for submission of further  $PEC_{sw}$  calculations based on the lowest RAC of 0.37  $\mu\text{g Cu/L}$  ( total and dissolved copper). The risk from the use of Cobranza for early and late applications in vines, apples and potatoes, tomatoes and is not acceptable for sediment dweling organisms. Further refinement is required.

However, there is no approved guideline for calculating  $PEC_{sed}$  values to determine protective measures, similar to  $PEC_{sw}$  value approach. Therefore, the MSs should apply their own mitigation measure at national level.

## 9.6 Effects on bees (KCP 10.3.1)

### 9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

**Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees**

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Copper hydroxide technical	Contact	LD <sub>50</sub> = 44.46 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Copper hydroxide 50% WP	Oral	LD <sub>50</sub> = 49.0 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Copper hydroxide 50% WP	Contact	LD <sub>50</sub> > 57.0 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Copper oxychloride	Oral	<b>LD<sub>50</sub> = 12.1 µg/bee*</b>	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Copper oxychloride	Contact	<b>LD<sub>50</sub> = 44.3 µg/bee*</b>	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Bordeaux mixture WP	Oral	LD <sub>50</sub> = 23.3 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Bordeaux mixture WP	Contact	LD <sub>50</sub> > 25.2 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Tribasic copper sulphate SC	Oral	LD <sub>50</sub> = 40.0 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Tribasic copper sulphate SC	Contact	LD <sub>50</sub> > 23.5 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Copper oxide technical	Contact	LD <sub>50</sub> > 22.0 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Copper oxide WG	Oral	LD <sub>50</sub> > 116.0 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	Copper oxide WP	Contact	LD <sub>50</sub> > 82.5 µg/bee	EFSA Journal 2018;16(1):5152
<i>Apis mellifera</i>	<b>COBRANZA</b>	<b>Oral</b>	<b>LD<sub>50</sub> = 50.68 µg f.p./bee (equivalent to 25.39 a.s./bee)</b>	<b>KCP 10.3.1.1.1</b> xxx
<i>Apis mellifera</i>	COBRANZA	Contact	LD <sub>50</sub> > 200.00 µg f.p./bee (equivalent to >100.2 a.s./bee)	KCP 10.3.1.1.2 xxx
<b>Higher-tier studies (tunnel test, field studies)</b>				

Species	Substance	Exposure System	Results	Reference
Two outdoor cages were performed with Copper Oxychloride WP and Bordeaux mixture WP. No significant effects at rates up to 1.25 kg a.s/ha Tunnel test performed with Copper Oxychloride WP on phacelia– single application of 2.5 kg a.s./ha. a Statistically significant reduction is observed on flight intensity at t rate of 2.5 kg a.s/ha.				

\* Data retained by EFSA for the risk assessment.

### 9.6.1.1 Justification for new endpoints

The EU agreed endpoints are used for the risk assessment. Studies were conducted with COBRANZA and were also considered for the risk assessment.

### 9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group all crops also covers the risk for bees from all other intended uses (see 9.1.2).

#### 9.6.2.1 Hazard quotients for bees

**Table 9.6-2: First-tier assessment of the risk for bees due to the use of COBRANZA in All crops**

Intended use	All crops		
Active substance	Copper oxychloride		
Application rate (g a.s./ha)	1200		
Test design	LD <sub>50</sub> (lab.) (µg a.s./bee)	Single application rate (g a.s./ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	12.1	1200	99.17
Contact toxicity	44.3		27.09
Product	COBRANZA		
Application rate (g f.p./ha)	2400		
Test design	LD <sub>50</sub> (lab.) (µg f.p./bee)	Single application rate (g f.p./ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	50.68	2400	47.36
Contact toxicity	>200		<12.00

Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in bold breach the relevant trigger.

According to results above, no unacceptable risk on honeybees is obtained for formulated COBRANZA. However, according to data from Monograph, Q<sub>HO</sub> above the trigger of 50 was obtained after acute oral risk assessment, therefore, a higher-tier risk assessment will be needed.

#### 9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

A semi-field study was conducted with copper oxychloride WP on *Phacalia* with a single application at 2.5 kg a.s/ha (above the maximum application rate of 1.2 kg a.s./ha according to proposed GAP). Statistically significant reduction (30%) is observed on flight intensity at a rate of 2.5 kg a.s/ha and only on the day of application, total recovery was noted from Day 2, suggesting a transient effect. (France, 2017). In addition, literature data was submitted for the renewal of approval of copper compounds which provided evidence that chronic exposure of copper via feeding of copper solutions as an anti-varroa treatment in hives did not show adverse effects on bees at doses of 1-2 g copper/L. The RMS (France, 2018) concluded that “...the articles submitted by the applicant show that chronic exposure of bees to copper does not induce adverse effects at individual colony level. Therefore, this literature review and the tunnel tests submitted in the frame of the re-approval of copper bring evidence that no chronic adverse effects are expected for bees and colonies when exposed to copper following the application of copper-based formulations”.

##### ZRMS comments:

The risk assessment for acute oral and contact exposure for bees has been accepted by ZRMS-PL.

Applicant provided formulation toxicity data from a chronic laboratory feeding study for adult honey bees and a honey bee larvae study, according to requirements set out in Reg. EU 284/2013.

Formulation used to perform such chronic studies is Copper oxychloride 50% WP, instead a Copper Oxychloride WG, as COBRANZA.

The applicant provided a statement indicated the formulated Copper oxychloride WP and Copper oxychloride WG are ecotoxicologically similar.

During the renewal of the active substance two studies were performed, a semi-field study and a cage test. The results indicated that no significant effects on the numbers of dead bees or on their behavior or brood development up to concentrations of 1.25 kg Cu/ha. The risk is considered to be acceptable with a restriction up to 1.25 kg Cu/ha. The maximum single application rate is 1.2 kg Cu/ha, therefore the risk is acceptable for the requested GAP.

#### 9.6.3 Effects on bumble bees

Not relevant.

#### 9.6.4 Effects on solitary bees

Not relevant.

#### 9.6.5 Overall conclusions

The risk assessment for bees has been done. The  $Q_{HC}$  values are below 50, indicating a low risk to bees following the application of COBRANZA at the proposed label rate. However,  $Q_{HO}$  was higher than trigger and risk was detected. After a higher-tier risk assessment based on semi-field study which was con-

ducted with copper oxychloride WP on *Phacalia*, no significant effects were detected at maximum application rate according to GAP.

## 9.7 Effects on arthropods other than bees (KCP 10.3.2)

### 9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods**

Species	Substance	Exposure System	Results	Reference
<i>A. rhopalosiphi</i> (adults)	Copper hydroxide 50 % WP	Laboratory test glass plates (2D)	Mortality : <b>LR<sub>50</sub> = 0.05 kg/ha</b>	EFSA Journal 2018;16(1):5152
<i>A. rhopalosiphi</i> (adults)	Bordeaux Mixture	Laboratory test glass plates (2D)	Mortality : LR <sub>50</sub> > 14.7 kg/ha	EFSA Journal 2018;16(1):5152
<i>A. rhopalosiphi</i> (adults)	Tribasic copper sulphate 190 g/L SC	Laboratory test glass plates (2D)	Mortality : LR <sub>50</sub> > 0.1344 kg/ha	EFSA Journal 2018;16(1):5152
<i>A. rhopalosiphi</i> (adults)	Copper oxide 75% WP	Laboratory test glass plates (2D)	Mortality : LR <sub>50</sub> = 39.2 kg/ha	EFSA Journal 2018;16(1):5152
<i>T. pyri</i> (protonymphs)	Copper hydroxide 50 % WP	Laboratory test glass plates (2D)	Mortality : <b>LR<sub>50</sub> &gt; 14.88 kg/ha</b>	EFSA Journal 2018;16(1):5152
<i>T. pyri</i> (protonymphs)	Copper oxychloride 50% WP	Laboratory test glass plates (2D)	Mortality : LR <sub>50</sub> > 14.89 kg/ha	EFSA Journal 2018;16(1):5152
<i>T. pyri</i> (protonymphs)	Bordeaux Mixture	Laboratory test glass plates (2D)	Mortality : LR <sub>50</sub> > 13.2 kg/ha	EFSA Journal 2018;16(1):5152
<i>T. pyri</i> (protonymphs)	Tribasic copper sulphate 190 g/L SC	Laboratory test glass plates (2D)	Mortality : LR <sub>50</sub> > 0.08 kg/ha	EFSA Journal 2018;16(1):5152
<i>T. pyri</i> (protonymphs)	Copper oxide 75% WP	Laboratory test glass plates (2D)	Mortality : LR <sub>50</sub> > 26.1 kg/ha	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>T. cacoeciae</i>	Copper hydroxide 50 % WP	Extended laboratory test Glass plates (2D)	Parasitisation: 6.4 % at 590 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>T. cacoeciae</i>	Copper oxychloride 50% WP	Extended laboratory test Glass plates (2D)	Parasitisation: -42.9 % at 2020 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>D. rapae</i>	Copper hydroxide 50 % WP	Extended laboratory test Glass plates (2D)	Mortality: 14.8 % at 590 g Cu /ha Parasitisation: 52.5 % at 590 g/ Cu ha	EFSA Journal 2018;16(1):5152
<i>P. cupreus</i>	Copper hydroxide WP	Laboratory test Quartz sand (2D)	Mortality: 0 % at 590 g Cu /ha Predation: 8% at 590 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>P. amentata</i>	Tribasic copper sulphate 190 g/L SC	Laboratory test Quartz sand (2D)	Mortality: 2.9% at 20.2 g Cu /ha Predation: 4.39% at 268.8 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>C. carnea</i> (larvae)	Copper hydroxide 50 % WP	Laboratory test Glass plates (2D)	Mortality: 55.6 % at 560 g Cu /ha Fecundity: 71.1 % at 560 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>C. 7-punctata</i>	Copper oxychloride 50% WP	Laboratory test Glass plates (2D)	Mortality: 17.5% at 580 g Cu /ha Fecundity: - 149% at 580 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>C. 7-punctata</i>	Tribasic copper sulphate 190 g/L SC	Laboratory test Glass plates (2D)	Mortality: 20.88% at 6.7g Cu /ha Fecundity: 43.8% at 134.4g Cu /ha	EFSA Journal 2018;16(1):5152
<i>A. rhopalosiphi</i> (adults)	Copper hydroxide 35.6 % WP	Extended laboratory test Barley seed (3D)	Mortality: <b>10 % at 3213 g Cu /ha</b> Fecundity: -7.4% at 3213 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>A. rhopalosiphi</i> (adults)	Copper oxychloride 50% WP	Extended laboratory test Barley seedlings (3D)	Mortality: 0 % at 1000 g Cu /ha 0 % at 3970 g Cu/ha Parasitisation: -22.38 % at 1000 g Cu /ha 10.89 % at 3970 g Cu /ha	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>A. rhopalosiphi</i> (adults)	Tribasic copper sulphate 190 g/L SC	Extended laboratory test Barley seedlings (3D)	Mortality: 0.0 % at 1.54 g Cu /ha 2.5 % at 7.68 g Cu/ha 2.5 % at 38.4 g Cu/ha 5.0 % al 192 g Cu/ha 2.5 % at 960 g Cu/ha  Paratisation: -29.8 % at 1.54 g Cu /ha -72.6 % at 7.68 g Cu/ha -40.4 % at 38.4 g Cu/ha -13.8 % al 192 g Cu/ha 30.5 % at 960 g Cu/ha	EFSA Journal 2018;16(1):5152
<i>T. pyri</i> (protonymphs)	Copper hydroxide 35.6 % WP	Extended laboratory test Bean leaves (2D)	Mortality: -7.4 % at 3213 g Cu /ha  Fecundity: 16.9 % at 3213 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>T. pyri</i> (protonymphs)	Tribasic copper sulphate 190 g/L SC	Extended laboratory test Vine leaves (2D)	Mortality: 1.8 % at 15 g Cu /ha 3.5 % at 60 g Cu/ha 13.9% at 250 g Cu/ha 3.5 % al 1010 g Cu/ha 0.0% at 4032 g Cu/ha  Fecundity: -7.3% at 15 g Cu /ha -17.1% at 60 g Cu/ha -11.0% at 250 g Cu/ha 12.2% al 1010 g Cu/ha 31.7% at 4032 g Cu/ha	EFSA Journal 2018;16(1):5152
<i>C. carnea</i> (larvae)	Copper hydroxide 35.6 % WP	Extended laboratory test Bean leaves (2D)	Mortality: 12.5 % at 1922 g Cu /ha  Fecundity: 0 % at 1922 g Cu /ha	EFSA Journal 2018;16(1):5152
<i>C. carnea</i> (larvae)	Copper oxychloride 50% WP	Extended laboratory test Apple leaves (2D)	Mortality: 4.8 % at 500 g Cu /ha 21.4 % at 1000 g Cu/ha 11.9 % at 2000 g Cu/ha 23.8 % al 4000 g Cu/ha 40.5 % at 8000 g Cu/ha  Fecundity: 1.7 % at 500 g Cu /ha 16.7 % at 1000 g Cu/ha 7.9 % at 2000 g Cu/ha 15.3 % al 4000 g Cu/ha 6.7 % at 8000 g Cu/ha	EFSA Journal 2018;16(1):5152



Species	Substance	Exposure System	Results	Reference
<i>T. pyri</i> (protonymphs)	COBRANZA	Extended laboratory test Bean leaves (2D)	LR <sub>50</sub> > 30.0 kg f.p./ha (equivalent to >15.0 kg a.s./ha)  <b>ER<sub>50</sub> &gt; 30.0 kg f.p./ha (equivalent to &gt;15.0 kg a.s./ha)</b>	KCP 10.3.2.2-01 Parma, P. 2019 B/34/17
<i>A. rhopalosiphi</i> (adults)	Copper hydroxide 50% WP	Extended laboratory test Barley seedlings (3D)	LR <sub>50</sub> > 16 kg f.p./ha (equivalent to >8.0 kg a.s./ha)  <b>ER<sub>50</sub> = 7.9 kg f.p./ha (equivalent to 4.0 kg a.s./ha)</b>	KCP 10.3.2.2-02 Parma, P. 2019 B/37/17
<b><i>C. carnea</i> (larvae)</b>	<b>COBRANZA</b>	<b>Extended study on bean leaves (2D)</b>	<b>LR<sub>50</sub> &gt; 13.50 kg f.p./ha (equivalent to &gt;6.76 kg a.s./ha)</b>  <b>ER<sub>50</sub> = 10.58 kg f.p./ha (equivalent to 5.30 kg a.s./ha)</b>	<b>KCP 10.3.2.2-03 xxx 7547/2020</b>
<b><i>C. 7-punctata</i></b>	<b>COBRANZA</b>	<b>Extended study on bean leaves (2D)</b>	<b>LR<sub>50</sub> = 7.61 kg f.p./ha (equivalent to 3812.61 g a.s./ha)</b>  <b>ER<sub>50</sub> = 7.26 kg f.p./ha (equivalent to 3637.26 g a.s./ha)</b>	<b>KCP 10.3.2.2-04 xxx 7548/2020</b>
<b>Field or semi-field tests</b>				
None				

#### 9.7.1.1 Justification for new endpoints

Extended study on *T.Pyri* was conducted with COBRANZA and on *Aphidius* with Copper hydroxide 50% WP. Endpoints expressed in terms of g a.s./ha were considered for the risk assessment. The Applicant wishes to indicate that both formulations present a similar composition. Moreover, the endpoints of the studies performed on non-target arthropods are also expressed in terms of g a.s./ha, which means that only the toxicity of the a.s is considered. Therefore, the Applicant assumes that reference to the extended study on *Aphidius* of Copper hydroxide 50% WP in the risk assessment is fully justified.

#### 9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

### 9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of COBRANZA in grapevine**

Intended use	Grapevine		
Active substance/product	Copper oxychloride / COBRANZA		
Application rate (g/ha)	4 x 1000 g a.s./ha		
MAF	2.7 (foliar)		
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER <sub>in-field</sub> (g/ha)	PER <sub>in-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	2700 g a.s./ha	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		Yes
<i>C. carnea</i>	>5300 g a.s./ha		Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		Yes
Intended use	Grapevine		
Active substance/product	Copper oxychloride / COBRANZA		
Application rate (g/ha)	4 x 800** g a.s./ha 4 x 1000 g a.s./ha		
MAF	3.4 (soil)-1		
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER <sub>in-field</sub> (g/ha)	PER <sub>in-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	1360 g a.s./ha 4000 g a.s./ha 2000 g a.s./ha <sup>1</sup>	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		Yes
<i>C. carnea</i>	>5300 g a.s./ha		Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		No Yes <sup>1</sup>

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

\*\*rate with a 60% of interception at BBCH from 15-85. According to the interception values of FOCUS (2012)<sup>4</sup>.

<sup>1</sup> 0.5 according to ESCORT 2

Here, the assessment for the potato use also covers the in-field risk for non-target arthropods from all other intended uses in group solanaceous fruits (tomato and aubergine) (see 9.1-2).

**Table 9.7-3: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of COBRANZA in potato**

<b>Intended use</b>	Potato and Solanaceous fruits (tomato and aubergine) <sup>a</sup>
<b>Active substance/product</b>	Copper oxychloride / COBRANZA
<b>Application rate (g/ha)<sup>1</sup></b>	3 x 1200* g a.s./ha or 4 x 1000** g a.s./ha
<b>MAF</b>	2.3 (foliar), 2.7 ( foliar)

<sup>4</sup> FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER <sub>in-field</sub> (g/ha)	PER <sub>in-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	2760* g a.s./ha	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha	2700** g a.s./ha	Yes
<i>C. carnea</i>	>5300 g a.s./ha		Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		Yes
<b>Intended use</b> <b>Active substance/product</b> <b>Application rate (g/ha)<sup>1</sup></b> <b>MAF</b>		Potato Copper oxychloride / COBRANZA <del>4 x 1000 g a.s./ha / 4 x 850** g a.s./ha</del> <b>3 x 1200* g a.s./ha or 4 x 1000** g a.s./ha</b> <del>3.4 (soil) 1</del>	
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER <sub>in-field</sub> (g/ha)	PER <sub>in-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	<del>2890 g a.s./ha</del>	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha	3600*	Yes
<i>C. carnea</i>	>5300 g a.s./ha	4000**	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		Yes * No **

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.  
Criteria values shown in bold breach the relevant trigger.

<sup>1</sup>Worst case of application rate.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

~~\*\*rate with a 15% of interception at BBCH from 15-85. According to the interception values of FOCUS (2012)<sup>5</sup>.~~

<sup>a</sup> the max application rate for for Solanaceous fruits (tomato and aubergine) - 3 x 1200 g a.s./ha, the max application rate for potato is 4 x 1000 g a.s. or 3 x 1200 g a.s./ha

**Table 9.7-4: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of COBRANZA in pome fruits**

<b>Intended use</b> <b>Active substance/product</b> <b>Application rate (g/ha)</b> <b>MAF</b>		Pome fruits Copper oxychloride / COBRANZA 3 x 1200 g a.s./ha 2.3 (foliar)	
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER <sub>in-field</sub> (g/ha)	PER <sub>in-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	2760 g a.s./ha	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		Yes
<i>C. carnea</i>	>5300 g a.s./ha		Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		Yes
<b>Intended use</b> <b>Active substance/product</b> <b>Application rate (g/ha)<sup>1</sup></b>		Pome fruits Copper oxychloride / COBRANZA <del>3 x 480** a.s./ha</del> <b>3 x 1200 g a.s./ha</b>	

<sup>5</sup> FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

MAF		2.7 (soil) <b>1</b>	
Test species Higher-tier	Rate with ≤ 50 % effect*	PER <sub>in-field</sub> (g/ha)	PER <sub>in-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	<del>1296 g a.s./ha</del>	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha	<b>3600 g a.s./ha</b>	Yes
<b>C. carnea</b>	<b>&gt;5300 g a.s./ha</b>		<b>Yes</b>
<b>C. 7-punctata</b>	<b>3637.26 g a.s./ha</b>		<b>Yes</b>

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.  
Criteria values shown in bold breach the relevant trigger.

<sup>1</sup>Worst case of application rate.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

~~\*\*rate with a 60% of interception at BBCH from 15-85. According to the interception values of FOCUS (2012)<sup>6</sup>.~~

## Conclusion

It can therefore be concluded that the in-field risk to non-target arthropods is low for all the representative uses.

### 9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of COBRANZA in grapevine**

Intended use		Grapevine			
Active substance/product		Copper oxychloride / COBRANZA			
Application rate (g/ha)		4 x 1000 g a.s./ha			
MAF		2.7 (foliar)			
vdf		10 (2D studies) / 1 (3D studies)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER <sub>off-field</sub> (g/ha)	CF	corr. PER <sub>off-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	0.0671	18.12 g a.s./ha	5	yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		181.17 g a.s./ha	5	yes
<i>C. carnea</i>	>5300 g a.s./ha		18.12 g a.s./ha	5	yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		18.12 g a.s./ha	5	yes
MAF =1 soil					
<i>T. pyri</i>	>15000 g a.s./ha	0.0671	26.84	5	yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		268.4	5	yes
<i>C. carnea</i>	>5300 g a.s./ha		26.84	5	yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		26.84	5	yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with

<sup>6</sup> FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

≤ 50 % effect.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.7-6: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of COBRANZA in potato**

Intended use		Potato			
Active substance/product		Copper oxychloride / COBRANZA			
Application rate (g/ha)		3 x 1200 g a.s./ha			
MAF		2.3 (foliar)			
vdf		10 (2D studies) / 1 (3D studies)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER <sub>off-field</sub> (g/ha)	CF	corr. PER <sub>off-field</sub> below rate with ≤ 50 % effect?
<i>T. pyri</i>	>15000 g a.s./ha	0.0201	5.55 g a.s./ha	5	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		55.48 g a.s./ha	5	Yes
<i>C. carnea</i>	>5300 g a.s./ha		5.55 g a.s./ha	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		5.55 g a.s./ha	5	Yes
MAF soil =1					
<i>T. pyri</i>	>15000 g a.s./ha	0.0201	7.23	5	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		72.3	5	Yes
<i>C. carnea</i>	>5300 g a.s./ha		7.23	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		7.23	5	Yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.7-7: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of COBRANZA in solanaceous fruits (tomato and aubergine) (late as worst case)**

<b>Intended use</b>		Solanaceous fruits (tomato and aubergine)			
<b>Active substance/product</b>		Copper oxychloride / COBRANZA			
<b>Application rate (g/ha)</b>		3 x 1200 g a.s./ha			
<b>MAF</b>		2.3 (foliar)			
<b>vdf</b>		10 (2D studies) / 1 (3D studies)			
<b>Test species Higher-tier</b>	<b>Rate with ≤ 50 % effect* (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>CF</b>	<b>corr. PER<sub>off-field</sub> below rate with ≤ 50 % effect?</b>
<i>T. pyri</i>	>15000 g a.s./ha	0.069	19.04 g a.s./ha	5	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		190.44 g a.s./ha	5	Yes
<i>C. carnea</i>	>5300 g a.s./ha		19.04 g a.s./ha	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		19.04 g a.s./ha	5	Yes
MAF soil =1					

<i>T. pyri</i>	>15000 g a.s./ha	0.069	24.8	5	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		248.4	5	Yes
<i>C. carnea</i>	>5300 g a.s./ha		24.8	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		24.8	5	Yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.7-8: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of COBRANZA in pome fruits (apple, pear and quince) (early application)**

<b>Intended use</b>		Pome fruits (apple, pear and quince) – early application			
<b>Active substance/product</b>		Copper oxychloride / COBRANZA			
<b>Application rate (g/ha)<sup>1</sup></b>		3 x 1200 g a.s./ha			
<b>MAF</b>		2.3 (foliar)			
<b>vdf</b>		10 (2D studies) / 1 (3D studies)			
<b>Test species Higher-tier</b>	<b>Rate with ≤ 50 % effect* (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>CF</b>	<b>corr. PER<sub>off-field</sub> below rate with ≤ 50 % effect?</b>
<i>T. pyri</i>	>15000 g a.s./ha	0.2396	66.13 g a.s./ha	5	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		661.30 g a.s./ha	5	No
<i>C. carnea</i>	>5300 g a.s./ha		66.13 g a.s./ha	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		66.13 g a.s./ha	5	Yes
<b>MAF=1 soil</b>					
<i>T. pyri</i>	>15000 g a.s./ha	0.2396	86.26	5	Yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		862.6	5	No
<i>C. carnea</i>	>5300 g a.s./ha		86.26	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		86.26	5	Yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

<sup>1</sup>Worst case of application rate.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

**Table 9.7-9: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of COBRANZA in pome fruits (apple, pear and quince) (late application)**

<b>Intended use</b>		Pome fruits (apple, pear and quince) – late application			
<b>Active substance/product</b>		Copper oxychloride / COBRANZA			
<b>Application rate (g/ha)</b>		3 x 2400 g f.p./ha ( 3 x 1200 g a.s./ha)			
<b>MAF</b>		2.3 (foliar)			
<b>vdf</b>		10 (2D studies) / 1 (3D studies)			
<b>Test species Higher-tier</b>	<b>Rate with ≤ 50 % effect* (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>CF</b>	<b>corr. PER<sub>off-field</sub> below rate with ≤ 50 % effect?</b>
<i>T. pyri</i>	>15000 g a.s./ha	0.1101	30.39 g a.s./ha	5	yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		303.88 g a.s./ha	5	yes
<i>C. carnea</i>	>5300 g a.s./ha		66.13 g a.s./ha	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		66.13 g a.s./ha	5	Yes
<b>MAF=1 soil</b>					
<i>T. pyri</i>	>15000 g a.s./ha	0.1101	39.63	5	yes
<i>A. rhopalosiphi</i>	4000 g a.s./ha		396.3	5	yes
<i>C. carnea</i>	>5300 g a.s./ha		39.63	5	Yes
<i>C. 7-punctata</i>	3637.26 g a.s./ha		396.3	5	Yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

## Conclusion

It can therefore be concluded that the off-field risk to non-target arthropods is low for all the representative uses.

## ZRMS comments:

The in-field risk to non-target arthropods is considered as low for all the representative uses when foliar MAF was considered.

However, during the Ecotox Expert Meeting 169 it was suggested that for soil the total amount applied in the season should be used since it cannot be ensured that dissipation occur between applications.

The experts agreed to use the total amount applied in the year in the risk assessment for soil NTA for application < 20 BBCH.

Based on calculated PER<sub>soil</sub> in-field an unacceptable risk was indicated for all proposed uses for max doses applied.

A reducing in the application dose in orchards and grapes by a factor of 0.5 was performed by ZRMS as recommended in the guidance document ESCORT 2 and then, acceptable risk is concluded for grapevines and apples.

Unacceptable risk in-field is observed in for the maximum annual dose intended 4 x 1000 g a.s./ha for potato.

For potato the acceptable the risk could be achieved for application dose of 2 x 1 kg a.s./ha.

Further consideration of the risk refinement for potato should be decided at MSs level.



### 9.7.2.3 Additional higher-tier risk assessment

Not relevant.

### 9.7.2.4 Risk mitigation measures

Not relevant.

### 9.7.3 Overall conclusions

No in-field and off-field risk to non-target arthropods is expected after the application of COBRANZA according to the proposed GAP.

## 9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

### 9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)**

Species	Substance	Exposure System	Results	Reference
<b>Earthworms</b>				
<i>Eisenia fetida</i>	Copper oxychloride	Chronic, 56 d OECD soil	NOEC <sub>r(cp)</sub> < 40.5 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia andrei</i>	Copper chloride	Chronic, 28 d LUFA: 3.9% OECD: 10%	NOEC <sub>r(cp)</sub> = 8.4 mg Cu/kg soil (LUFA 2.2 soil) NOEC <sub>r(cp)</sub> = 103.2 mg Cu/kg soil (OECD soil) NOEC <sub>r(jp)</sub> = 103.2 mg Cu/kg soil (OECD soil)	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Copper chloride	Chronic, 28 d OM: 10%	NOEC <sub>r(cp)</sub> = 13.2 mg Cu/kg soil (OECD soil) NOEC <sub>r(jp)</sub> = 35.2 mg Cu/kg soil (OECD soil) and 37.2 mg Cu/kg soil (LUF 2.2 soil)	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	Copper chloride	Chronic, 21 d OM: 4.7%	NOEC <sub>g</sub> = 715 mg Cu/kg soil NOEC <sub>r</sub> = 115 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	Cu oxychloride	Chronic, 28 d OM: 10%	NOEC <sub>r(cp)</sub> = 83.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	Cu(NO <sub>3</sub> ) <sub>2</sub> ·3H <sub>2</sub> O	Chronic, 28 d OM: 10%	NOEC <sub>r(cp)</sub> = 28.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	Copper nitrate	Chronic, 56 d OM: 10%	LC <sub>50</sub> = 555 mg Cu/kg soil NOEC <sub>m</sub> = 202.4 mg Cu/kg soil EC <sub>50</sub> (cocoons) = 53.3 mg Cu/kg soil NOEC <sub>r(cp)</sub> = 12.4 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	Copper nitrate	Chronic, 21 d OM: 10%	NOEC <sub>r(cp)</sub> = 32.3 mg Cu/kg soil NOEC <sub>g</sub> = 728.2 mg Cu/kg soil NOEC <sub>m</sub> = 296.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	Cu acetate	Chronic, 28 d	LC <sub>50</sub> = 82.8 – 3717 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	CuCl <sub>2</sub>	Chronic, 21 d	NOEC=300 mg Cu/kg soil (mortality and growth)	EFSA Journal 2018;16(1):5152
<i>Eisenia fetida</i>	Copper chloride	Chronic, 28 d	EC <sub>10,r</sub> = 54 – 324 mg Cu/kg soil (17 values for different soil types)	EFSA Journal 2018;16(1):5152
<i>Eisenia andrei</i>	Unknown	Chronic, 28 d OM: 3.7%	EC <sub>10,r</sub> = 159 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia andrei</i>	Copper chloride	Chronic, 28 d OM: 0.5%	NOEC <sub>m</sub> = 192 mg Cu/kg soil NOEC <sub>r</sub> = 192 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia andrei</i>	Copper salt	Chronic, 84 d OM: 10%	NOEC <sub>g</sub> = 59.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Eisenia andrei</i>	Copper chloride	Chronic, 28 d OM: 10%	NOEC <sub>r(cp)</sub> = 123.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Eisenia andrei</i>	Copper chloride	Chronic, 84 d OM: 10%	EC50 > 100 mg Cu/kg soil NOEC <sub>g</sub> = 62 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Lumbricus rubellus</i>	Copper chloride	Chronic, 84 d	NOEC <sub>m</sub> = 162 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Lumbricus rubellus</i>	Copper chloride	Chronic, 42 d OM: 3.4-5.7%	NOEC <sub>r</sub> = 54 mg Cu/kg soil NOEC <sub>lb</sub> = 54 mg Cu/kg soil NOEC <sub>g</sub> = 131 mg Cu/kg soil NOEC <sub>m</sub> = 131 mg Cu/kg soil NOEC <sub>lb</sub> = 63 mg Cu/kg soil NOEC <sub>m</sub> = 136 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Lumbricus rubellus</i>	Copper chloride	Chronic, 294 d OM: 9.8%	NOEC <sub>g</sub> = 154 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Lumbricus rubellus</i>	Copper chloride	Chronic, 110 d OM: 0.5%	NOEC <sub>g</sub> = 76 mg Cu/kg soil NOEC <sub>m</sub> = 153 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Allobophora caliginosa</i> (= <i>Aporrectodea caliginosa</i> )	Copper sulfate	Chronic, 14 d	NOEC <sub>m</sub> = 511 mg Cu/kg soil NOEC <sub>r(cp)</sub> = 60.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Aporrectodea caliginosa</i>	Copper sulfate	Chronic, 42 d and 56 d OM: 21.6%	NOEC <sub>g</sub> = 35.7 mg Cu/kg soil NOEC <sub>r(cp)</sub> = 80.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Dendrobaena rubida</i>	Copper nitrate	Chronic, 90 d OM: 7.7-11.7%	NOEC <sub>r(cp)</sub> = 100 (pH 5.5) and 101.3 mg Cu/kg soil (pH 6.5)	EFSA Journal 2018;16(1):5152
<i>Dendrobaena rubida</i>	Copper nitrate	Chronic, 120 d OM: 7.7-11.7%	4 month-NOEC (cocoon reduction) = 100 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Octolasion cyaneum</i>	Copper sulfate	Chronic, 14 d and 30 d OM: 5.4-72%	30 d – NOEC <sub>m</sub> = 153 mg Cu/kg soil 14 d – NOEC <sub>m</sub> = 1214 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Eisenia andrei</i>	COBRANZA	Chronic, 56d	EC <sub>10</sub> >1000 mg f.p./kg dw soil  NOEC ≥ 1000 mg f.p./kg dw soil  NOEC <sub>corr</sub> *≥ 500 mg f.p./kg dw soil	KCP 10.4.1.1 xxx G/45/18
<b>Other soil macroorganisms</b>				
<i>Enchytraeidae (Oligochaeta, Annelida)</i>				
<i>Cognettia sphagnetorum</i>	Copper chloride	Chronic, 70 d OM: 66%	35-day EC <sub>10, g</sub> = 73.7 mg Cu/kg soil 63-day EC <sub>10, g</sub> = 451.7 mg Cu/kg soil 42-day EC <sub>10, g</sub> = 322.7 mg Cu/kg soil 70-day EC <sub>10, f</sub> = 465.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>E. albidus</i>	Copper chloride	Chronic, 42 d OM: 5.5%	EC <sub>10, m</sub> = 347 mg Cu/kg soil EC <sub>10, r</sub> = 71 mg Cu/kg soil EC <sub>10, a</sub> = 362 mg Cu/kg soil NOEC <sub>m</sub> = 430 mg Cu/kg soil NOEC <sub>r</sub> = 230 mg Cu/kg soil NOEC <sub>a</sub> = 230 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>E. albidus</i>	Copper chloride	Chronic, 42 d OM: 3.6%	EC <sub>10, r</sub> (soil 1) = 355 mg Cu/kg soil EC <sub>10, r</sub> (soil 2) = 107 mg Cu/kg soil EC <sub>10, r</sub> (soil 3) = 72 mg Cu/kg soil EC <sub>10, r</sub> (soil 4) = 119 mg Cu/kg soil EC <sub>10, r</sub> (soil 5) = 399 mg Cu/kg soil EC <sub>10, r</sub> (soil 6) = 241 mg Cu/kg soil NOEC in field transects: 418 to ≥ 689 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>E. crypticus</i>	Copper chloride	Chronic, 56 d OM: 3.9%	EC <sub>50</sub> (reprod., 11°C) ≈ 70 mg Cu/kg soil EC <sub>50</sub> (reprod., 18°C) ≈ 160 mg Cu/kg soil EC <sub>50</sub> (reprod., 25°C) ≈ 180 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>E. crypticus</i>	Copper chloride	Chronic, 21 d OM: 4.6%	EC <sub>10, r</sub> = 126.5 mg Cu/kg soil NOEC <sub>r</sub> = 135 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>E. crypticus</i>	Copper chloride	Chronic, 63 d OM: 3.9%	21-day EC <sub>10, r</sub> = 180.2 mg Cu/kg soil 63-day EC <sub>10, r</sub> = 90.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>E. crypticus</i>	Copper chloride	OM: 3.9%	EC <sub>10, r</sub> = 55 mg Cu/kg soil EC <sub>10, m</sub> = 62 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Collembola (Hexapoda, Arthropoda)</i>				
<i>Folsomia candida</i>	Copper chloride	Chronic, 28 d OM: 1.4-37%	EC <sub>10, r</sub> = 31 – 1460 mg Cu/kg soil (21 values for different soil types)	EFSA Journal 2018;16(1):5152
<i>Folsomia candida</i>	Copper nitrate	Chronic, 28 d	EC <sub>50, r</sub> (pH 6.0) = 703.2 mg Cu/kg soil NOEC <sub>r</sub> (pH 6.0) = 203.2 mg Cu/kg soil NOEC <sub>m</sub> (pH 6.0) = ≥3003.2 mg Cu/kg soil EC <sub>50, r</sub> (pH 5.0) = 713.2 mg Cu/kg soil NOEC <sub>r</sub> (pH 5.0) = 203.2 mg Cu/kg soil NOEC <sub>m</sub> (pH 5.0) = 43.2 mg Cu/kg soil EC <sub>50, r</sub> (pH 4.5) = 1483.2 mg Cu/kg soil NOEC <sub>r</sub> (pH 4.5) = 1003.2 mg Cu/kg soil NOEC <sub>m</sub> (pH 4.5) = ≥3003.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Folsomia candida</i>	Copper chloride	Chronic, 42 d OM: 10%	NOEC <sub>r</sub> = 203.2 mg Cu/kg soil NOEC <sub>m</sub> = 1003.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Folsomia candida</i>	Copper chloride	Chronic, 28 d OM: 10%	NOEC <sub>ri</sub> = 803.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Folsomia candida</i>	Copper chloride	Chronic, 21 or 56 d	21-day NOEC <sub>g</sub> (LUFA 2.2) = 205.2 mg Cu/kg soil 21-day NOEC <sub>r</sub> (LUFA 2.2) = 405.2 mg Cu/kg soil 56-day NOEC <sub>g</sub> (OECD) = 803.2 mg Cu/kg soil 56-day NOEC <sub>r</sub> (OECD) = 403.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Folsomia candida</i>	Copper chloride	OM: 3%	EC <sub>10, r</sub> = 212 mg Cu/kg soil NOEC = 320 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Folsomia candida</i>	COBRANZA	Chronic, 28d Mixed into soil 5% peat	EC <sub>10</sub> = 116.902 mg f.p./kg dw soil  <b>EC<sub>10 corr</sub> = 58.451 mg f.p./kg dw soil</b>  NOEC= 320 mg f.p./kg dw soil	KCP 10.4.2.1-01 xxx G/46/18
<i>Folsomia fimetaria</i>	Copper chloride	Chronic, 21 d OM: 3.9%	14-day EC <sub>10, r</sub> = 43* mg Cu/kg soil 21-day EC <sub>10, r</sub> = 61* mg Cu/kg soil 21-day EC <sub>10, g</sub> (male) = 850 mg Cu/kg soil 21-day EC <sub>10, g</sub> (female) = 547 mg Cu/kg soil 21-day EC <sub>10, g</sub> (juvenile) = 532 mg Cu/kg soil 21-day NOEC <sub>m</sub> (male and female) ≥ 1005 mg Cu/kg soil 21-day EC <sub>10, m</sub> (juvenile) = 883 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Folsomia fimetaria</i>	Copper chloride	Chronic, 21 d OM: 4.7%	EC <sub>10, m</sub> (overall) = 828 mg Cu/kg soil EC <sub>10, m</sub> (female) = 519 mg Cu/kg soil EC <sub>10, m</sub> (male) = 771 mg Cu/kg soil EC <sub>10, g</sub> (overall) = 1090 mg Cu/kg soil EC <sub>10, g</sub> (overall) = 997 mg Cu/kg soil EC <sub>10, g</sub> (overall) = 1242 mg Cu/kg soil EC <sub>10, r</sub> = 352 mg Cu/kg soil EC <sub>10</sub> > 2911 mg Cu/kg soil (high background - historical Cu contaminated site)	EFSA Journal 2018;16(1):5152
<i>Folsomia fimetaria</i>	Copper sulfate	Chronic, 21 d OM: 4.5%	EC <sub>10, r</sub> = 141 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Folsomia fimetaria</i>	Copper sulfate	Chronic, 21 d OM: 4.5%	EC <sub>10, r</sub> = 667 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<i>Isotoma viridis</i>	Copper chloride	Chronic, 56 d OM: 3.9%	NOEC <sub>g</sub> (LUFA 2.2) = 55.2 mg Cu/kg soil NOEC <sub>g</sub> (OECD) = 403 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Isopoda (Crustacea, Arthropoda)</i>				
<i>Porcellio scaber</i>	Copper chloride	Chronic, 4 and 8 weeks	8-week LC <sub>50</sub> = 2880 mg Cu/kg soil 4-week EC <sub>10, g</sub> (body mass gain) = 349 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Acari (Arachnida, Arthropoda)</i>				
<i>Platynothrus peltifer</i>	Copper nitrate	Chronic, 90 d OM: 3.9%	NOEC <sub>m</sub> ≥ 1498 mg Cu/kg soil NOEC <sub>g</sub> = 598 mg Cu/kg soil NOEC <sub>r</sub> = 168 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Platynothrus peltifer</i>	Copper chloride	Chronic, 70 d OM: 3.9%	NOEC <sub>r</sub> = 68.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Hypoaspis aculeifer</i>	Copper chloride	Chronic, 21 d OM: 3.9%	<b>EC10 = 179</b> mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Hypoaspis aculeifer</i>	Copper chloride	OM: 3.0%	EC <sub>10, r</sub> = 2* mg Cu/kg soil NOEC <sub>r</sub> = 320 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<i>Hypoaspis aculeifer</i>	<b>COBRANZA</b>	Chronic, 14d OM: 5%	EC <sub>10</sub> > 1000 mg f.p./kg dw soil  NOEC = 555.56 mg f.p./kg dw soil  NOEC <sub>corr</sub> * = 277.78 mg f.p./kg dw soil	<b>KCP 10.4.2.1-02 xxx 6728/2019</b>
<i>Nematoda (Nematoda)</i>				
<i>Plectus acuminatus</i>	Copper chloride	Chronic, 21 d	EC <sub>50, r(jp)</sub> = 165.2 mg Cu/kg soil NOEC <sub>r(jp)</sub> = 35.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
<b>Higher tier testing (e.g. modelling or field studies)</b>				
<b>Earthworms</b> Field study - A field study on earthworm populations has been conducted over 10 years on grassland, with copper applications every year. After 10 years of treatment with copper the NOAEC of the study is the dose rate 4 kg copper/ha/year.				

\* EC<sub>10</sub> below lowest dose tested and therefore not considered reliable (OECD, 2006<sub>13</sub>)

\*\* Data in bold retained by EFSA and used for the risk assessment.

1 NOEC<sub>r(cp)</sub>=NOEC reproduction based on cocoons production; NOEC<sub>r(jp)</sub>= NOEC reproduction based on juveniles production; NOEC<sub>g</sub>= NOEC based on growth; NOEC<sub>m</sub>= NOEC based on mortality; NOEC<sub>lb</sub>= NOEC based on litter breakdown; EC<sub>10, f</sub>= EC10 based on fragmentation; EC<sub>10, a</sub>= EC10 based on avoidance

### 9.8.1.1 Justification for new endpoints

The EU agreed endpoints are used for the risk assessment. Studies were conducted with COBRANZA and were also considered for the risk assessment.

### 9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

#### 9.8.2.1 First-tier risk assessment

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Copper oxychloride.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group grapevine also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses on potatoes, solanaceous fruits (tomato, aubergine) and pome fruits (apple, pear and quince).

A need to include natural background levels of copper originating from geogenic copper and previous anthropogenic copper inputs from a variety of sources in the soil exposure assessment was identified (EFSA, 2013). This requirement to include sources other than the regulated use is exceptional, possibly uniquely required for copper, so a standard soil exposure assessment is not possible.

European monitoring programs provided a comprehensive overview of copper levels in agricultural soils. Concentrations suitable for use in soil exposure assessments, including sources other than the regulated use, were identified. Accumulated  $PEC_{soil}$  values were calculated for repeated annual applications. More details on the predicted environmental concentrations (standard field calculations) in soil ( $PEC_{soil}$ ) for copper in soil are presented in Part B.8 point KCP 9.1.3.

The  $PEC_{soil}$  accumulated values identified for use in risk assessments are 165.33 mg total Cu/kg (based on background level, 90th centile) and 66.8 mg total Cu/kg (based on background level, 10th centile) in vineyards.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of COBRANZA in grapevine (worst case)**

Intended use	Grapevine		
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Copper oxychloride	8.4	165.33 <sup>1</sup>	0.05
Copper oxychloride	8.4	66.8 <sup>2</sup>	0.13
COBRANZA	≥500 <sup>3</sup>	10.67	≥46.86



<b>Chronic effects on other soil macro- and mesofauna – <i>Folsomia candida</i></b>			
<b>Product/active substance</b>	<b>EC<sub>10</sub> (mg/kg dw)</b>	<b>PEC<sub>soil</sub> (mg/kg dw)</b>	<b>TER<sub>It</sub> (criterion TER ≥ 5)</b>
Copper oxychloride	31	165.33 <sup>1</sup>	<b>0.19</b>
Copper oxychloride	31	66.8 <sup>2</sup>	<b>0.46</b>
COBRANZA	58.451 <sup>3</sup>	10.67	5.48
<b>Chronic effects on other soil macro- and mesofauna – <i>Hypoaspis aculeifer</i></b>			
<b>Product/active substance</b>	<b>EC<sub>10</sub> (mg/kg dw)</b>	<b>PEC<sub>soil</sub> (mg/kg dw)</b>	<b>TER<sub>It</sub> (criterion TER ≥ 5)</b>
Copper oxychloride	179	165.33 <sup>1</sup>	<b>1.08</b>
Copper oxychloride	179	66.8 <sup>2</sup>	<b>2.68</b>
<b>COBRANZA</b>	<b>277.78<sup>3</sup></b>	<b>10.67</b>	<b>26.03</b>

TER values shown in bold fall below the relevant trigger.

<sup>1</sup> Overall PEC<sub>soil</sub>, accumulation at 90<sup>th</sup> percentile.

<sup>2</sup> Overall PEC<sub>soil</sub>, accumulation at 10<sup>th</sup> percentile.

<sup>3</sup>The endpoint was divided by 2 since log Kow>2.

The long-term TER values for Copper are below the trigger value of 5, indicating a risk to earthworms and other non-target soil organisms (meso- and macrofauna). A higher-tier risk assessment is needed. However, no risk is obtained for **earthworms and** *Folsomia candida* for formulated COBRANZA.

## 9.8.2.2 Higher-tier risk assessment

So far, the following soil invertebrate species have been tested in the laboratory: most often the lumbricid species *E. fetida* and *E. andrei* but also several species belonging to the invertebrate mesofauna: the springtail *Folsomia candida*, the predatory mite *Hypoaspis aculeifer* (see Table 9.8-2), and the enchytraeid *Enchytraeus crypticus* (see e.g. App. 2 KCP 10.4.1.2-03 xxx <sup>7</sup>). Referring to the information presented above it seems that earthworms are the most sensitive species among those tested so far. However, in higher-tier tests only earthworms and, partly, enchytraeids have been studied (see CA 8.4.2.1/07 xxx <sup>8</sup>). In terms of sensitivity all data gained so far indicate that earthworms react most sensitively to the exposure to copper, meaning that they are the main invertebrate group to be considered in risk assessment.

However, there are more good reasons to focus higher-tier, in particular, field studies on the effects of copper in the soil compartment on earthworms: in temperate regions they are in many, especially agricultural (crop sites, grasslands) soils the dominant soil invertebrate group in terms of their ecological functions. In comparison to most other soil organisms lumbricid earthworms are relatively large and provide in many soils the highest biomass. Ecologically, they are divided in three ecological groups (xxx <sup>9</sup>): litter dwellers (epigeics) (1) live at or close to the soil surface in the organic matter such as leaf litter. Actually, the well-known test species *Eisenia fetida* and *E. andrei* belong to this group. Mineral dwellers such as the (“endogeics”) (2) live in horizontal burrows in the mineral soil. The globally widely distributed species *Aporrectodea caliginosa* belongs to this group. Vertical burrowers (anecics) (3) live in deep vertical burrows. Best example for this group is *Lumbricus terrestris* which act as “ecosystem engineers”, i.e. organisms which “directly or indirectly modulate the availability of resources to other species, by causing physical state changes in biotic or abiotic materials. In so doing they modify, maintain and create habi-

<sup>7</sup> xxx Copper toxicity in a natural reference soil: ecotoxicological data for the derivation of preliminary soil screening values. Ecotoxicology 25, 163–177.

<sup>8</sup> xxx Effects of temperature and copper pollution on soil community—extreme temperature events can lead to community extinction. Environmental Toxicology and Chemistry 32, 2678–2685.

<sup>9</sup> xxx Soil Organisms as Components of Ecosystems, pp. 122–132.

tats” (xxx<sup>10</sup>). Earthworms provide an impressive list of ecological services, especially at agricultural sites, where at least several species provide several ecosystem services, such as nutrient cycling, drainage, and regulating greenhouse gas emissions. Probably from a human point of view their ability to stimulate crop growth is their the most important contribution (e.g. xxx<sup>11</sup>), but their positive influence on other services such as water drainage, soil aggregate stability, distribution of microbial populations or being a relevant food source for many predators should also not be forgotten.

The field study (CA 8.4.1/02. xxx) was performed to evaluate the effects of copper on the earthworm fauna in Central Europe. Copper oxychloride was applied over a period of 10 years on two investigation sites with three different doses (T1: 4 kg/ha/year; T2: 8 kg/ha/year; T3: 40 kg/ha/year). The collected data on earthworm abundance, biomass, and earthworm species were evaluated using different statistical methods.

In an addendum to the final report of the field study, the applied statistical methods are described and discussed in detail (xxx. Addendum 1 to final report). A summary of the basics is given below:

- Analysis of variance (ANOVA) and Analysis of covariance (ANCOVA):
  - analysis calculated and each treatment compared to the control using a two-sided Dunnett’s t-test at the 5% significance level
  - robust and sensitive way to analyse for potential significant treatment effects
  - procedure recommended by ISO (ISO 11268-3, ISO 2014) and by xxx al. (2006)<sup>12</sup>
- Principal response curve (PRC):
  - a common multivariate analysis, a special type of redundancy analysis (time as covariate, interaction between time and treatment as environmental factor to show differences from the control), evaluation of extent and course of development of the earthworm abundance compared to the control taking into account the time factor and random changes
  - univariate analysis of the PRC scores of the first axis to identify differences between individual sampling points
  - time as a covariate, aims to translate the responses from a large number of taxa into a smaller number of components that can be interpreted as representing the response of the whole community
  - method to be used to refine the interpretation of effects on the population level
  - procedure listed as viable method in ISO 11268-3 (ISO 2014) and recommend by xxx al. (2010)<sup>13</sup> for the analysis of non-target arthropod field studies
- Linear mixed models (LMM):
  - also includes time to the interpretation of results
  - its ability to detect significant treatment effects is limited due to the restriction of normal distributed data
  - Tukey test (results comparable to ANOVA/ANCOVA)
  - LSD test: over-conservative due to expected and observed alpha inflation increasing the overall chance of a type I error to theoretically 14% instead of 5%. According to Environment Canada (2005)<sup>14</sup>, the LSD test should only be used for a small pre-selected selection of all possible comparisons to avoid this inflation of false positives (type I error).

Significant effects on earthworms were observed in the highest treatment only (40 kg/ha/year), while the two lower treatments showed only individual and isolated differences compared to the water-control

<sup>10</sup> xxx (1997): Positive and negative effects of organisms as physical ecosystem engineers. *Ecology* 78:1946-1957.

<sup>11</sup> xxx): Earthworms increase plant production: a meta-analysis. – *Scientific Reports* 4: 6365; DOI: 10.1038/srep06365.

<sup>12</sup> xxx) Guidance for summarising earthworm field studies – A guidance document of the Dutch platform for the assessment of higher tier studies. RIVM, The Netherlands, 47 pp. xxx. 2002-2008 (2008) SAS® Proprietary Software 9.2; Cary, NC, USA.

<sup>13</sup> xxx (2010) Guidance for summarizing and evaluating field studies with nontarget arthropods, xxx The Netherlands.

<sup>14</sup> ENVIRONMENT CANADA (2005) Guidance Document on Statistical Methods. EPS, I/RM/46. Ottawa, ON, Canada.

treatment. These isolated cases (for some species or groupings) were e.g. significant reductions in abundance and biomass in the two lower treatments (T1: 4 kg Cu/ha/year; T2: 8 kg Cu/ha/year) which were detected at different sampling dates but which were not observed on consecutive sampling dates. It seemed that these significant reductions appeared sporadically but disappeared again in later samplings. Similar observations are considered in long-term studies as normal sporadic changes in earthworm species abundance and has been confirmed by the PRC analysis at community level (and the linear mixed model). Due to the erratic nature of significances observed in T1 and T2, those effects were not considered caused by the treatment with copper. As agreed by the expert panel, these effects are not significant at the community level (see EU Dossier Vol. 3, B.9 (AS), p. 454-455).

The results of the study after 8 years of application were reviewed by an independent expert panel (xxx). **All three experts supported a NOEC of 8 kg/ha/year.**

According to the RMS, additional statistical analysis using the LMM provided in the study report (CA 8.4.1/02. xxx) show that specific effects were observed during 2011 and 2013 also in the two lower treatments (T1 and T2). The LMM was performed using two methods: 1) Tukey and 2) LSD. The LMM was applied to investigate effects abundances and biomass at the samplings for individual species, ecotypes and other groupings. The Tukey test only identified significant effects for the highest treatment (40 kg/ha/year), while the LSD method detected several significant effects in the T1 as well as the T2 treatment. For both methods the significance level was set at  $\alpha = 5\%$ . With regard to the results of the LMM statistical evaluation, the RMS proposes a no observed adverse effect concentration (NOAEC) of 4 kg/ha/year.

As described above, the LSD test is over-conservative as it is prone to alpha-inflation, which results in false positives seeing significant effects where in reality no effects are. In case of this field study, the theoretical chance of a type I error increases from the selected 5% to 14.3% when performing all possible pairwise comparisons for a given taxon on the data set (26 sampling occasions, 26 comparisons). As described above, Environment Canada restricts the use of the LSD test procedure.

In conclusion, the results of the statistical evaluation with the LMM and the LSD test should not be considered for the derivation of the NOE(A)C of this earthworm field study. As only individual, isolated significant effects were observed at the T1 and the T2 treatment levels based on the other reliable and recommended statistical methods, **a NOEC of 8 kg Cu/ha/year is plausible.**

In addition to the field study (CA 8.4.1/02. xxx), a long-term laboratory study with earthworms and soil from the investigated sites of the field study was performed (Klein, 2019; see Appendix 2: KCP 10.4.1.2-01). This study was designed to determine the effects of Cu-level and soil properties in different Cu-loaded soils originating from two field sites on adult mortality, body weight change and on reproduction of field-collected adult *Aporrectodea caliginosa* SAVIGNY (Annelida, Lumbricidae), an earthworm species which is known to be sensitive to high soil Cu concentrations. The test organisms originated from the same field sites as the soils and a crossover design was used: earthworms from both field sites were exposed to soils of both field sites. According to the study director, this was the first attempt to study chronic effects in *A. caliginosa*. Therefore, no guidance and experience were available.

The findings observed during the course of the study have been found related to missing guidance on how to conduct such a study and maintain *A. caliginosa* for an extended period in the laboratory environment. No adverse effects could be derived from the presence of copper in the field sampled soils.

The following observations were made during the study:

- The Cu concentration in the sampled top soils (0-5 cm) were at a similar level (control soils: Niefern: 26.5 mg/kg soil dw; Heiligenzimmern: 25.9 mg/kg soil dw; treated soils: Niefern: 135.2 mg/kg soil dw; Heiligenzimmern: 142.2 mg/kg soil dw). In the treated plots, Cu had been applied three times per year at a nominal rate of 8 kg Cu/ha/year for the past 14 years. However, the soil samples differed in ecologically relevant physicochemical parameters

- (WHC<sub>max</sub>, soil texture (% sand, silt and clay), content of organic matter).
- Adult mortality was not affected by the Cu-treated soils compared to the control soils after 112 days. Mortality in the treated soils was lower than in the control soils where a maximum mortality of 20% was reached after 112 days.
  - During the exposure phase an increasing number of the adult worms were observed to have entered a stage of quiescence. After 112 days of exposure to the test soils, almost half of the worms had entered the quiescent stage. The presence of copper did not have an effect on the appearance of quiescence. A continuous loss of biomass was also observed during the 112 days of exposure in each of the treatment groups. Loss of biomass and the increasing number of worms entering a stage of quiescence indicated adverse changes in the test soil environment. The test conditions were most likely mainly influenced by the fluctuation and the decrease of the moisture content of the test soils.
  - The adult biomass change was influenced by the following factors: origin of worms, treatment of soil. A third factor, the origin of the soil, did not solely affect the earthworm biomass. Earthworms originating from Niefern had a higher initial biomass than Heiligenzimmern worms and showed a higher biomass loss. In the Cu-treated soils a higher biomass loss was observed than in the control soils.
  - The number of juveniles was affected by the following factors: origin of soil (higher reproductive output in Heiligenzimmern soils) and treatment of soil (higher reproductive output in Cu-treated soils), but not solely affected by the factor origin of worms. There was a significant two-factor interaction between treatment of soil and origin of soil (difference in juvenile numbers between Cu and control treatment more pronounced in the Heiligenzimmern soil) and between treatment of soil and origin of worms (difference in juvenile numbers between Cu and control treatment more pronounced in the Heiligenzimmern worms) as well as an interaction between all three factors. Higher reproductive output in Cu-treated soils compared to control soils can most probably not be attributed to the presence of higher Cu concentrations in the treated soils but rather to differences among physicochemical soil parameters between Cu-treated and control soils (e.g. water availability, water potential).

It can be concluded that the field-aged copper concentrations of 135 and 142 mg/kg soil dw, which resulted from an application of 8 kg Cu/ha/year for the past 14 years (3 times/year), did not cause any adverse effects on *A. caliginosa*.

**This lab study supports the derivation of the NOEC of 8 kg Cu/ha/year based on the long-term field study.**

Short-term effects of Cu fungicide (Cu oxychloride) on enchytraeid and earthworm communities were investigated under field conditions (Amossé et al., 2018; see Appendix 2: KCP 10.4.1.2-02). The Cu fungicide was applied at two doses (0.75 and 7.5 kg Cu/ha). At both concentrations no effect was observed on the earthworm population. With regard to the EFSA opinion (EFSA PPR Panel 2017), this corresponds to negligible effects (i.e., reduction up to 10%). Thus, **this study also supports the NOEC of 8 kg Cu/ha/year** derived from the long-term field study (CA 8.4.1/02. xxx).

In addition to the above derived NOEC of 8 kg Cu/ha/year, regulatory acceptable concentrations (RAC) for copper exposure to earthworms have been derived for the major regulatory zones of Europe and three types of land coverage by Oorts & Peeters (2019<sup>15</sup>).

These RACs are based on an evaluation of a quality-screened database on chronic toxicity of Cu to earthworms (CA 8.4.1/01. xxx). 62 reliable EC<sub>10</sub>/NOEC values for long-term effects on earthworms (*Eisenia andrei*, *Eisenia fetida*, *Lumbricus rubellus*, *Aporrectodea caliginosa*, *Dendrobaena rubida*, *Octolasion cyaneum*) were selected. Some of the data had to be corrected for the type of Cu application (freshly spiked soils vs. aged Cu contamination) using a lab-to-field factor of 4. Geometric mean normalized

<sup>15</sup> xxx (2019 - DRAFT). Distribution of RAC values for effect of Cu to soil invertebrates in Europe. ARCHE Consulting, Belgium. Research report submitted to the European Copper Task Force. 19 pp.

NOEC/EC<sub>10</sub> values for the most sensitive endpoint could be calculated only for 3 different earthworm species (*Eisenia andrei*, *Eisenia fetida* and *Lumbricus rubellus*). The lowest geometric mean normalized NOEC/EC<sub>10</sub> value from each of three species was selected as the regulatory acceptable concentration (RAC) for effects of Cu on earthworms. Without information on soil properties of a site of interest, the lowest species mean value for a reasonable worst-case soil with eCEC of 8 cmolc/kg, i.e. 159 mg Cu/kg, is selected as an appropriate regulatory acceptable concentration (RAC) value for risk assessment.

As the bioavailability of copper is influenced by the soil properties, European data for soil properties from the Land Use and Cover Area frame Statistical survey (LUCAS) database were extracted to calculate adapted RACs (Europe: 21980 data points). Four typical soil properties (pH, organic carbon content, clay content, CEC) were considered as they are strongly variable among soils across Europe.

Distributions of RAC values for the EU and the regulatory zones (North, Centre and South) were calculated non-parametrically because of the high amount of data points available and the 10th, 50th (median) and 90th percentiles, together with minimum and maximum values, of the copper RAC data are reported (Tables 3 and 4 below). In addition, the distribution of RAC values for specific land cover types (fruit trees, vineyards and olive groves) was also calculated. The 10<sup>th</sup> percentile (P10) should be selected as a conservative value to protect most terrestrial scenarios.

With regard to the three major zones of Europe, the RACs increase from north to south at the P10 and median level. The P10 RAC for Europe was calculated to be 111 mg/kg soil dw. The RAC for the northern zone is slightly lower with 94 mg Cu/kg soil dw. The highest RAC was calculated for the southern zone (132 mg Cu/kg soil dw). The RACs (P10) for the three relevant types of land coverage are higher than the regionally adapted RACs ranging between 143 and 165 mg Cu/kg soil dw. The RACs for vineyards and olive groves are almost identical (164 and 165 mg Cu/kg soil dw).

In the long-term field study (CA 8.4.1/02. xxx 2015) the NOEC was determined to be 8 kg Cu/ha/year. Soil samples from the upper soil layer (0–5 cm) contained approximately 130 mg Cu/kg soil dw at both study sites, which is in good agreement with the RACs for the three major regulatory zones (94–132 mg Cu/kg soil dw) as well as with the three types of land coverage (143–165 mg Cu/kg soil dw).

**Table 3: Distributions of regulatory acceptable concentrations (RAC) for Cu in soil (mg Cu/kg soil dw) in the whole of Europe and major regulatory zones.**

Zone	# of data points	Min	P10	Median	P90	Max
EU	21980	46	<b>111</b>	215	374	1158
North	5129	46	<b>94</b>	175	367	1158
Centre	8133	46	<b>107</b>	219	383	1034
South	8609	46	<b>132</b>	230	369	753

**Table 4: Distributions of regulatory acceptable concentrations (RAC) for Cu in soil for the land coverages under scrutiny.**

Land cover	# of data points	Min	P10	Median	P90	Max
Vineyards	326	46	<b>164</b>	239	345	468
Olive groves	409	46	<b>165</b>	252	345	528
Fruit trees	279	46	<b>143</b>	227	369	523

Given that laboratory derived toxicity data for earthworms and other non-target soil macro-organisms showed that earthworms were more sensitive to copper than the other tested macro-organisms, it is considered that the NOEC of 8 kg Cu/ha/year determined from the long-term field study performed on earthworms is protective of other non-target soil macro-organisms.

COBRANZA is applied at the maximum dose of 1.2 kg Copper oxychloride/ha/application. According to the proposed GAP, the application rate of Copper per season is the following:

- Grapevine use : 4 applications at 1 kg/ha => 4 kg Cu/ha
- Potato use : 3 applications at 1.2 kg/ha or 4 applications at 1.0 kg/ha => 3.6 kg Cu/ha or 4.0 kg Cu/ha
- Solanaceous fruits (Tomato, aubergine) use : 3 applications at 1.2 kg/ha => 3.6 kg Cu/ha
- Pome fruit (apple, pear, quince) use : 3 applications at 1.2 kg/ha or 5 applications at 0.575 kg/ha => 3.6 kg Cu/ha or 2.875 kg Cu/ha

The proposed GAP are in line with the EFSA conclusions (rate lower than 8 kg/ha per year). In this context, it can be conclude that the long-term risk is low for earthworms exposed to applications COBRANZA.

Therefore, according to the higher-tier risk assessment presented above, the available bibliographic data indicate that soil macro-organisms are relatively more tolerant to copper than earthworms. Therefore, based on the confirmatory data a RAC of 8 kg Cu/ha per year which was determined addressing the risk to earthworms and whereas the proposed GAP does not exceed the RAC value, the risk to soil macro-organisms is considered to be acceptable.

**ZRMS comments:**

Several studies were assessed during the RAR, it was concluded an acceptable risk to earthworms at the maximum dose rate of 4 kg Cu /ha per year.

During expert meeting (Report from Pesticides Peer Review Meeting 169, 09-10 October 2017, Copper compounds) it was concluded that earthworms seem to be the most sensitive group.

In the same time the risk for soil – macroorganism was not able to be ruled out ( TER<sub>it</sub> below 5)

Considering all the available information, ZRMS-PL is of the same opinion as RMS in RAR, and considers that the long-term risk of copper compounds would be acceptable for an annual dose rate not higher than 4 kg Cu/ha per year for all soil macroorganism.

***Spe 1: To protect soil organisms do not apply this or any other product containing copper for an annual dose rate higher than 4 kg Cu/ha per year.***

### 9.8.3 Overall conclusions

The risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) has been done. A risk to earthworms and other non-target soil organisms following the application of COBRANZA at the proposed label rate can be excluded.

**ZRMS comments:**

Considering all the available information, ZRMS-PL that the long-term risk of copper compounds would be acceptable for an annual dose rate not higher than 4 kg Cu/ha per year.

**Spe 1: To protect soil organisms do not apply this or any other product containing copper for an annual dose rate higher than 4 kg Cu/ha per year.**

## 9.9 Effects on soil microbial activity (KCP 10.5)

### 9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms**

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Copper hydroxide WP	62d	<b>No effect at day 62 at 12.5kg Cu/ ha</b>	EFSA Journal 2018;16(1):5152
N-mineralisation	Copper oxychloride WP	28d	no effect at day 28 at 12.4 kg Cu/ha	EFSA Journal 2018;16(1):5152
N-mineralisation	Copper oxychloride WP	28d	no effect at day 28 at 18.1 kg Cu/ha	EFSA Journal 2018;16(1):5152
N-mineralisation	Bordeaux mixture WP	28d	no effect at day 28 at 20.0 kg Cu/ha	EFSA Journal 2018;16(1):5152
N-mineralisation	Tribasic copper sulphate SC	28d	no effect at day 28 at 11.6 kg Cu/ha	EFSA Journal 2018;16(1):5152
N-mineralisation	Copper oxide WP	28d	no effect at day 28 at 15.0 kg Cu/ha	EFSA Journal 2018;16(1):5152
<b>N-mineralisation</b>	<b>COBRANZA</b>	<b>28d</b>	<b>no effect at day 28 at 133.30 mg f.p./kg dw soil</b>	<b>KCP 10.5-01 xxx. 2020 G/44/18</b>
<b>C-mineralisation</b>	<b>COBRANZA</b>	<b>28d</b>	<b>no effect at day 28 at 133.30 mg f.p./kg dw soil</b>	<b>KCP 10.5-02 xxx. 2020 G/43/18</b>
<b>Field studies</b>				
A multi-field site study was carried out in three sites in France. Up to four months after treatment with Copper Hydroxide WP (8 x 2 kg Cu/ha and 48 kg Cu/ha) there were no effects on the CO <sub>2</sub> evolution and nitrogen mineralization. There was no either evidence of significant effects on evolved CO <sub>2</sub> and nitrogen nitrification after a 28-day incubation in the presence of ground vine leaves, based on soils contaminated with Copper Hydroxide WP at 16 kg and 48 kg Cu/ha.				

\* Data in bold used for the risk assessment.

### 9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. Studies were conducted with COBRANZA and were also considered for the risk assessment.

### 9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant  $PEC_{soil}$  for risk assessment covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group potatoes also covers the risk for the soil microorganisms from all other intended uses (see 9.1-2).

**Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of COBRANZA in potatoes**

Intended use	Pome fruits		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (kg a.s./ha)	Maximum annual appli- cation (kg a.s./ha)	Risk acceptable?
Copper oxychloride	12.5 (at 62 d)	4.0	Yes
Product	Max. conc. with effects ≤ 25 % (mg f.p./kg dw soil)	Maximum annual appli- cation (mg f.p./kg dw soil)	Risk acceptable?
COBRANZA	133.30	10.67	Yes
C-mineralisation			
Product	Max. conc. with effects ≤ 25 % (mg f.p./kg dw soil)	Maximum annual appli- cation (mg f.p./kg dw soil)	Risk acceptable?
COBRANZA	133.30	10.67	Yes

#### ZRMS comments:

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant  $PEC_{soil}$  for risk assessment covering the proposed use pattern are taken from Section 8 (Environmental Fate).

To achieve a concise risk assessment, the risk envelope approach is applied. The assessment for the use



group potatoes also covers the risk for the soil microorganisms from all other intended uses .  
No risk for soil micro-organisms is expected after the application COBRANZA according to the proposed GAP as the <25% effects were observed for 133.30 mg product/kg dws.

### 9.9.3 Overall conclusions

No risk for soil micro-organisms is expected after the application COBRANZA according to the proposed GAP.

## 9.10 Effects on non-target terrestrial plants (KCP 10.6)

### 9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Copper oxychloride. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of COBRANZA were not evaluated as part of the EU assessment of Copper oxychloride. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants**

Species	Substance	Exposure System	Results	Reference
6 species	5 different copper-based test item	21 d Vegetative vigour	ER <sub>50</sub> > 2000 g Cu/ha	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
<sup>1)</sup> Glycine max <sup>d</sup> , <sup>2)</sup> Zea mays <sup>m</sup> , <sup>3)</sup> Pisum sativum <sup>d</sup> , <sup>4)</sup> Sinapsis alba <sup>d</sup> , <sup>5)</sup> Raphanus sativus <sup>d</sup> and <sup>6)</sup> Solanum lycopersicon <sup>d</sup>	COBRANZA	14 d Seedling emergence	<sup>1)</sup> ER <sub>50</sub> = 13.88 Kg f.p./ha (equivalent to 6953.9 g a.s./ha) <sup>2)</sup> ER <sub>50</sub> = 13.88 Kg f.p./ha (equivalent to 6953.9 g a.s./ha) <sup>3)</sup> ER <sub>50</sub> = 13.38 Kg f.p./ha (equivalent to 6703.4 g a.s./ha) <sup>4)</sup> ER <sub>50</sub> = <b>12.94 Kg f.p./ha (equivalent to 6482.9 g a.s./ha)</b> <sup>5)</sup> ER <sub>50</sub> = 13.24 Kg f.p./ha (equivalent to 6633.2 g a.s./ha) <sup>6)</sup> ER <sub>50</sub> = 13.27 Kg f.p./ha (equivalent to 6648.3 g a.s./ha)	KCP 10.6.2-01 xxx 2020 7545/2020
<sup>1)</sup> Glycine max <sup>d</sup> , <sup>2)</sup> Zea mays <sup>m</sup> , <sup>3)</sup> Pisum sativum <sup>d</sup> , <sup>4)</sup> Sinapsis alba <sup>d</sup> , <sup>5)</sup> Raphanus sativus <sup>d</sup> and <sup>6)</sup> Solanum lycopersicon <sup>d</sup>	COBRANZA	21 d Vegetative vigour	<sup>1)</sup> ER <sub>50</sub> = 13.19 Kg f.p./ha (equivalent to 6608.2 g a.s./ha) <sup>2)</sup> ER <sub>50</sub> = 13.19 Kg f.p./ha (equivalent to 6608.2 g a.s./ha) <sup>3)</sup> ER <sub>50</sub> = 13.50 Kg f.p./ha (equivalent to 6763.5 g a.s./ha) <sup>4)</sup> ER <sub>50</sub> = 13.95 Kg f.p./ha (equivalent to 6989 g a.s./ha) <sup>5)</sup> ER <sub>50</sub> = <b>13.03 Kg f.p./ha (equivalent to 6528 g a.s./ha)</b> <sup>6)</sup> ER <sub>50</sub> = 13.19 Kg f.p./ha (equivalent to 6608.2 g a.s./ha)	KCP 10.6.2-02 xxx. 2020 7546/2020

m: monocotyledonous; d: dicotyledonous

### 9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. According to R (EU) n° 284/2013: “Studies of effects on non-target plants shall be required for herbicide and plant growth regulator plant protection products and for other plant protection products, where risk cannot be predicted from screening data (see point 10.6.1) or when the risk cannot be reliably predicted on the basis of the active substance data generated..”. COBRANZA is a fungicide therefore the Applicant considers that studies on non-target plants with formulation is not mandatory. Nevertheless, new studies on non-target plants were conducted with COBRANZA and were also considered for the risk assessment.

## 9.10.2 Risk assessment

### 9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

### 9.10.2.2 Tier-2 risk assessment (based on dose-response data)

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.10-2: Assessment of the risk for non-target plants due to the use of COBRANZA in grapevine**

<b>Intended use</b>		Grapevine		
<b>Active substance/product</b>		Copper oxychloride / COBRANZA		
<b>Application rate (g a.s./ha)</b>		4 × 1000		
<b>MAF</b>		2.7		
<b>Test species</b>	<b>ER<sub>50</sub> (g a.s./ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g a.s./ha)</b>	<b>TER criterion: TER ≥ 5</b>
6 species <i>Sinapsis alba</i> (seedling emergence)	≥2000 6482.9	0.0671	181.17	≥11.04 35.78
<i>Raphanus sativus</i> (vegetative vigour)	6528			36.03

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.10-3: Assessment of the risk for non-target plants due to the use of COBRANZA in potato**

<b>Intended use</b>		Potato		
<b>Active substance/product</b>		Copper oxychloride / COBRANZA		
<b>Application rate (g a.s./ha)</b>		3 × 1200		
<b>MAF</b>		2.3		
<b>Test species</b>	<b>ER<sub>50</sub> (g a.s./ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g a.s./ha)</b>	<b>TER criterion: TER ≥ 5</b>
6 species <i>Sinapsis alba</i> (seedling emergence)	≥2000 6482.9	0.0201	55.48	≥36.05 116.86
<i>Raphanus sativus</i> (vegetative vigour)	6528			117.67

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.10-4: Assessment of the risk for non-target plants due to the use of COBRANZA in solanaceous fruits (tomato and aubergine)**

<b>Intended use</b>		Solanaceous fruits (tomato and aubergine)		
<b>Active substance/product</b>		Copper oxychloride / COBRANZA		
<b>Application rate (g a.s./ha)</b>		3 × 1200		
<b>MAF</b>		2.3		
<b>Test species</b>	<b>ER<sub>50</sub> (g a.s./ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g a.s./ha)</b>	<b>TER criterion: TER ≥ 5</b>
6 species <i>Sinapsis alba</i> (seedling emergence)	≥2000 6482.9	0.0690	190.44	≥10.50 34.04
<i>Raphanus sativus</i> (vegetative vigour)	6528			34.28

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.10-5: Assessment of the risk for non-target plants due to the use of COBRANZA in pome fruits (apple, pear and quince) – early application**

<b>Intended use</b>		Pome fruits (apple, pear and quince) – early application		
<b>Active substance/product</b>		Copper oxychloride / COBRANZA		
<b>Application rate (g a.s./ha)</b>		3 × 1200		
<b>MAF</b>		2.3		
<b>Test species</b>	<b>ER<sub>50</sub> (g a.s./ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g a.s./ha)</b>	<b>TER criterion: TER ≥ 5</b>
6 species <i>Sinapsis alba</i> (seedling emergence)	≥2000 6482.9	0.2396	661.30	≥3.02 9.80
<i>Raphanus sativus</i> (vegetative vigour)	6528			9.87

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied.

**Table 9.10-6: Assessment of the risk for non-target plants due to the use of COBRANZA in pome fruits (apple, pear and quince) – late application**

<b>Intended use</b>		Pome fruits (apple, pear and quince) – late application		
<b>Active substance/product</b>		Copper oxychloride / COBRANZA		
<b>Application rate (g a.s./ha)</b>		3 × 1200		
<b>MAF</b>		2.3		
<b>Test species</b>	<b>ER<sub>50</sub> (g a.s./ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g a.s./ha)</b>	<b>TER criterion: TER ≥ 5</b>
6 species <i>Sinapsis alba</i> (seedling emergence)	≥2000 6482.9	0.2396 0.1101	303.88	≥6.58 21.33

<b>Raphanus sativus</b> (vegetative vigour)	<b>6528</b>			<b>21.48</b>
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MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

~~A risk in the Tier 2 risk assessment was obtained for pome fruits (early application), therefore, risk mitigation measures will be needed.~~

Whilst the Tier-2 risk assessment showed acceptable risk for all crops ~~except to pome fruits early application where mitigation measures will be needed~~, due to the special nature of copper and it's potential to accumulate in soils, a higher tier risk assessment based on a literature review was also undertaken.

#### **ZRMS comments:**

The calculated TER values are above the Annex VI trigger of 5 based on ER<sub>50</sub> values from seedling emergence and vegetative vigour and PER<sub>off</sub> field, indicating acceptable risk to non-target plants.

### **9.10.2.3 Higher-tier risk assessment**

In a literature review (Hoare, 2015) a worst-case approach of exposure to copper was made on the assumption that copper would be applied to a vineyard for 100 years at a rate of six applications per year at 1.0 kg Cu/ha. Referencing the drift values according to Ganzelmeier *et al*, the predicted total added copper to the soil in the off-crop areas 3 m outside of the vineyard under this scenario was calculated to be approximately 52 mg/kg above the background level.

In order to calculate the total added copper in the off crop area several assumptions have been made.

- An annual field application rate of 6×1.0 kg Cu/ha.
- The basic drift value (after Ganzelmeier) will be used for six applications (70<sup>th</sup> percentile) at 1m distance for field crops (1.64%) and at 3m distance for vines, late application (6.41%).
- All loadings are cumulative, i.e. copper will accumulate in the soil with no dissipation between successive applications via run-off, vertical movement or by plant uptake.
- Soil depth and density will be 5 cm and 1500 kg/m<sup>3</sup> respectively.

The total added copper was calculated for 10, 25, 50 and 100 years of successive applications of copper, see the table below.

**Table 9.10-7: Theoretical increase in off-field soil-copper concentration after 10, 25, 50 and 100 years of successive applications of copper at a rate of 6 kg/ha/yr**

Number of years of successive application	Total added copper (mg/kg)	
	Field crops	Vineyards
10	1.312	5.128
25	3.280	12.82
50	6.560	25.64
100	13.12	51.28

The worst case increase in total off-field soil-copper concentration was determined to be approximately 52 mg/kg after 100 years of successive applications to vines.

As a conservative estimate, the soil-copper concentration of historically untreated areas is 32 mg/kg. After 100 years of continued application on vineyards at a rate of 6 kg/ha/yr the soil-copper concentration in these areas has been estimated to increase to approximately 84 mg/kg.

This level is below the suggested threshold limit of 100 mg/kg.

It must be remembered that this is a worst-case prediction. No account has been taken of the potential removal of the added copper via leaching, run-off or plant uptake, and crucially, no account has been made for the aging process which reduces the bio-availability of copper.

Overall it is concluded that even after 100 years of continued application, the application of copper based fungicides at rates of up to 6 kg/ha/yr poses acceptable risks to non-target plants growing in off-crop areas.

The literature review (Hoare, 2015) therefore brings evidence that for applications up to 6 kg Cu/ha/y the risk to non-target plants is acceptable, even after accumulation of copper in soil.

#### 9.10.2.4 Risk mitigation measures

In order to reduce the off field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no spray buffer zones of 5 or 10 m; drift reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

**Table 9.10-8: Risk assessment for non-target terrestrial plants due to the use of COBRANZA in pome fruits (early application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**

<b>Intended use</b>		Pome fruits (apple, pear and quince) — early application			
<b>Active substance/product</b>		Copper oxychloride / COBRANZA			
<b>Application rate (g/ha)</b>		3 × 1200			
<b>MAF</b>		2.3			
<b>Buffer strip (m)</b>	<b>Drift rate (%)</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>PER<sub>off-field</sub> 50 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 75 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 90 % drift red. (g/ha)</b>
3	23.96	661.30	330.65	-	-
5	15.79	435.80	217.90	-	-
10	8.96	247.30	-	-	-
<b>Toxicity value</b>		<b>TER</b>			
<b>ER<sub>50</sub> &gt; 2000 g/ha</b>		<b>criterion: TER ≥ 5</b>			
3		≥ <b>3.02</b>	≥6.05	-	-
5		≥ <b>4.59</b>	≥9.18	-	-
10		≥ <b>8.09</b>	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

Not relevant.

### 9.10.3 Overall conclusions

The calculated TER values are above the Annex VI trigger of 5 for seedling emergence and vegetative vigour when a minimal distance of 3 m is considered for all intended uses except for pome fruits early application.

Therefore, no potential risk to non-target plants located outside the treated area after application of COBRANZA according to the GAP table is expected when risk mitigation measures are considered:

~~*Pome fruits (early application) — Spe3: To protect non-target plants respect an unsprayed buffer zone of 10m to non-agricultural land OR the use 50% drift reducing nozzles.*~~

### 9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

### 9.12 Monitoring data (KCP 10.8)

Not relevant.

### 9.13 Classification and Labelling

	COBRANZA
Common Name	Copper oxychloride 50% WG
<b>Classification and proposed labelling</b>	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Aquatic Acute Category 1 Aquatic Chronic Category 1 Code(s) for hazard pictogram(s): GHS 09 Signal word: Warning Hazard statement(s): H410 Very toxic to aquatic life with long lasting effects Precautionary statement: P273, P391, P501

## 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 10.2.1-01		2020	Rainbow trout ( <i>Oncorhynchus mykiss</i> ), acute toxicity test with Copper oxychloride 50% WG Report No 6732/2019 XXXX GLP Unpublished	Y	Sharda Cropchem Ltd.
KCP 10.2.1-02	xxx	2020	Study of <i>Daphnia magna</i> acute immobilization with Copper oxychloride 50% WG Report No 6729/2019 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.2.1-03	xxx	2020	Study of algal growth inhibition with Copper oxychloride 50% WG Report No 6731/2019 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.1.1.1	xxx	2020	Acute oral toxicity of Copper 50% (as Oxychloride) WG on honey bee Report No 7620/2020 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.1.1.2	xxx	2018	Copper 50% (as Oxychloride) WG Honeybees ( <i>Apis mellifera</i> L.), Acute Contact Toxicity Test Report No B/32/17 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-01	xxx	2019	An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Report No B/34/17 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-02	xxx	2019	An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (De Stefani - Perez) Report No B/37/17 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.



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 10.3.2.2-03	Xxxx	2020	An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on larvae of the green lacewing <i>Chrysoperla carnea</i> (L.) (Neuroptera: Chrysopidae) Report No 7547/2020 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-04	Xxxx	2020	An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on the seven spotted lady bird beetle, <i>Coccinella septempunctata</i> (L.) Report No 7548/2020 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.4.1.1	xxx	2020	Cooper 50% (as Oxychloride) WG Earthworm Reproduction Test ( <i>Eisenia andrei</i> ) Report No G/46/18 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.4.2.1-01	xxx	2019	Copper 50% (as Oxychloride) WG Collembolan ( <i>Folsomia candida</i> ) Reproduction Test Report No G/46/18 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.4.2.1-02	xxx	2019	Effect of Copper oxychloride 50% WG on the reproductive output of the predatory soil mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil Report No 6728/2019 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.5-01	xxxx	2020	Copper 50% (as Oxychloride) WG Soil Microorganisms: Nitrogen Transformation Test Report No G/44/18 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.5-02	xxxx	2020	Copper 50% (as Oxychloride) WG Soil Microorganisms: Carbon Transformation Test Report No G/43/18 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.6.2-01	xxxx.	2020	Effect of Copper 50% (as Oxychloride) WG on seedling emergence and seedling growth of terrestrial plants Report No 7545/2020 XXXX Unpublished	N	Sharda Cropchem Ltd.
KCP 10.6.2-02	xxxx	2020	Effect of Copper 50% (as Oxychloride) WG on vegetative vigour of terrestrial plants Report No 7546/2020 XXXX GLP Unpublished	N	Sharda Cropchem Ltd.

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

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

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

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

**Additional documents provided by the Applicant.**

KCP 10.2/01	XXXX	2019	RESPONSE TO EFSA COMMENTS ON THE AQUATIC EFFECTS ASSESSMENT FOR CU - EXTENSION EU Copper Task Force, not available not available GLP/GEP: no Published: no	N	EUCuTF
KCP 10.2/02	XXXX	2019	RELEVANCE OF STANDARD ASSESSMENT FACTORS FOR RISK ASSESSMENT OF THE ESSENTIAL ELEMENT COPPER EU Copper Task Force, CuPPP20170705 not available GLP/GEP: no Published: no	N	EUCuTF
KCP 10.2/03	XXXX	2019	MODELLING OF THE FUNGURAN-OH EFFECTS ON <i>ONCHORHYNCHUS MYKISS</i> POPULATIONS EU Copper Task Force, not available not available GLP/GEP: no Published: no	N	EUCuTF
KCP 10.2/04	XXXX	2019	REVISED PNEC SEDIMENT COPPER FOR THE SEDIMENT EFFECTS ASSESSMENT FOR CU : EXTENDING THE DATABASE WITH ADDITIONAL SPECIES EU Copper Task Force, not available not available GLP/GEP: no Published: no	N	EUCuTF

**List of data relied on 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
KCP 10.4.1.2-01	XXXX O.	2019	Addendum to Final Report: A Field Study to Evaluate the Effects of Copper on the Earthworm Fauna in Central Europe: Statistical Analysis of a long term earthworm field study Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany Addendum 1 to Final Report 20031343/G1-NFEw Non GLP	N	European Union Copper Task Force

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Unpublished		
KCP 10.4.1.2-02	XXXX	2018	Short-term effects of two fungicides on enchytraeid and earthworm communities under field conditions. Ecotoxicology. Paper: April 2018, Volume 27, Issue 3, pp 300–312 GLP Published	N	European Union Copper Task Force
KCP 10.4.1.2-03	XXXX	2015	Copper toxicity in a natural reference soil: ecotoxicological data for the derivation of preliminary soil screening values Ecotoxicology. Paper: January 2016, Volume 25, Issue 1, pp 163–177   Cite as GLP Published	N	European Union Copper Task Force

## **Appendix 2 Detailed evaluation of the new studies**

### **A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates**

#### **A 2.1.1 KCP 10.1.1 Effects on birds**

##### **A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity**

##### **A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds**

#### **A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds**

##### **A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals**

##### **A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals**

#### **A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)**

### **Formulatin WG and WP**

The Applicant wishes to indicate that the formulation Copper oxychloride 50% WP presents a similar ecotoxicological behaviour than COBRANZA (please, refer to the table below).

Chemical Name	CAS-No. / EC No. Registration number	Concentration in Copper oxychloride 50% WP	Concentration in COBRANZA
Copper oxychloride	1332-65-6 or 1332-40-7	50 % w/w	50 % w/w
Type of formulation	-	Wettable powder	Water dispersible granules

In addition, the Applicant wishes to consider the toxicological comparison on aquatic invertebrates, bees and non-target arthropods between both formulations:

Organisms	Toxicological endpoint	
	Copper oxychloride 50% WP	COBRANZA
<i>Daphnia magna</i>	EC <sub>50</sub> (48h) = 0.0298 mg a.s./L	EC <sub>50</sub> (48h) = 0.384 mg a.s./L
<i>Apis mellifera</i>	LD <sub>50</sub> (72h)-Oral > <b>12.1 µ a.s./bee</b> LD <sub>50</sub> (48h)-Contact > <b>44.3 µ a.s./bee</b>	LD <sub>50</sub> (48h)-Oral = 50.68 µ f.p./bee ( <b>equivalent to 25.39 µ a.s./bee</b> ) LD <sub>50</sub> (48h)-Contact > 200 µ f.p./bee ( <b>equivalent to &gt; 100.2 µ a.s./bee</b> )
<i>A. rhopalosiphi</i> (adults)	Mortality: 0 % at 1000 g Cu /ha <b>0 % at 3970 g Cu/ha</b>	Mortality: <b>0 % at 3800 g Cu /ha</b> 3.3 % at 7500 g Cu/ha 16.7% at 15000 g Cu/ha

According to the comparison above, the Applicant considers that both formulations present a similar toxicity on bees, even, Copper oxychloride 50% WP is slightly more toxic than COBRANZA according to data from table above.

In addition, the toxicity on aquatic invertebrates for Copper oxychloride 50% WP is higher than the toxicity for COBRANZA in more than one order of magnitude. Moreover, a similar mortality is obtained for both formulations in the most sensitive non-target arthropod *Aphidius*. Therefore, a similar behaviour of the toxicity on bees between both formulations is expected.

Moreover, the endpoints of the chronic studies performed on bees in Monograph are expressed in terms of a.s./bee, which means that only the toxicity of the a.s is considered.

Therefore, the Applicant assumes that reference to these studies of Copper oxychloride 50% WP is fully justified.

## A 2.2 KCP 10.2 Effects on aquatic organisms

### A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

<b>Comments of zRMS:</b>	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> <li>No mortality and signs of toxicity were detected in the control group throughout the experimental period.</li> <li>The active ingredient concentration analysis in all test concentrations showed that the percent agreement with claimed concentration was in the range of 98.3 to 101.7% at the start of the test and 99.3 to 101.7% at the end(96 hour) indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of <math>\leq 20\%</math>).</li> </ul> <p><b>Agreed endpoints:</b></p> <p>The 96 h NOEC of Copper oxychloride 50% WG = 6.2625 mg/L</p> <p>The 96 h LOEC of Copper oxychloride 50% WG = 12.5250 mg/L</p>
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<b>Reference:</b>	KCP 10.2.1 - 01
<b>Report</b>	“Rainbow trout ( <i>Oncorhynchus mykiss</i> ), acute toxicity test with Copper oxychloride 50% WG”. M. Xxxx (2020). Study No. 6732/2019. XXXX
<b>Guideline(s):</b>	Yes, OECD Guideline No. 203 (2019)
<b>Deviations:</b>	No
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	Not relevant

### Materials and methods

Test item:	<p>Description: Copper oxychloride 50% WG</p> <p>Production batch: SCL - 160002</p> <p>A.i. content: copper 50.1% (w/w)</p>
Test system:	<p>Species: Rainbow trout (<i>Oncorhynchus mykiss</i>)</p> <p>Strain: -</p> <p>Age: Approximately 2 months</p> <p>Average weight: 0.6645 - 0.7842 g</p> <p>Average length: 3.8 – 4.7 cm</p> <p>Source: XXXX</p> <p>Acclimation period: 9 days</p> <p>Diet: standard granulated fish food in the amount of 2% of their average body weight per day (standard dry food, TayoAini fish feed)</p>

**Experimental conditions:**

Temperature:	11.6 – 12.1°C
Dissolved O <sub>2</sub> :	69 – 70%
Hardness:	-
pH:	6.8 – 7.0
Light and photoperiod:	16h light and 8h dark (850-1000 lux)
Loading:	-
Test procedure:	Static
Experimental period:	96h

**Test design and treatment:**

Static design for 96 hours, one replicate of seven fish for each test item concentration and the control.

According to a range finding test, the following nominal test item concentrations were used: 1.5625, 3.125, 6.25, 12.5, 25, 50 and 100 mg/L plus a negative control. The fish were observed for toxic signs and mortality after 2, 5, 24, 30, 48, 54, 72, 78 and 96 h.

The concentrations of the active substances were chemically determined using a validated atomic absorption spectrometry (ASS) method. The stability test results concluded that the test item was stable during 96h under test conditions. The active ingredient concentration analysis in all test concentrations showed that the percent agreement with claimed concentration was in the range of 98.3 to 101.7% at the start of the test and 99.3 to 101.7% at the end(96 hour) indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of  $\leq 20\%$ ).

The endpoint values were determined after 96h of the exposure period by using a Probit analysis in the NCSS (Number Cruncher Statistical System)

Results of the determination of copper oxychloride in the test samples.



Hour	Sample/test item concentration (mg/L)		Nominal concentration* (mg/L)	Mean determined concentration (mg/L)	SD	Recovery (%)
0	Control	0.0	0.00000	ND	0	-
	T1	1.5625	0.78281	0.78047	0.00000	99.7
	T2	3.125	1.56563	1.57298	0.00341	100.5
	T3	6.25	3.13125	3.14496	0.00000	100.4
	T4	12.5	6.26250	6.25869	0.01383	99.9
	T5	25	12.52500	12.4332	0.02206	99.3
	T6	50	25.05000	24.84521	0.03706	99.2
	T7	100	50.10000	50.03747	0.06347	99.9
96	Control	0.0	0.00000	ND	0	-
	T1	1.5625	0.78281	0.78177	0.01591	99.9
	T2	3.125	1.56563	1.55669	0.00365	99.4
	T3	6.25	3.13125	3.15298	0.02344	100.7
	T4	12.5	6.26250	6.27978	0.06853	100.3
	T5	25	12.52500	12.43343	0.00000	99.3
	T6	50	25.05000	24.99528	0.00000	99.8
	T7	100	50.10000	49.87585	0.36610	99.6

\*Based on the content of active substance in the test item determined at Bioscience Research Foundation at the level of 50.23% (w/w).  
SD: standard deviation;  
ND: not determined

#### Biological results:

On the definitive test, the percent mortalities up to 96 h post treatment were 0, 0, 0, 0, 20, 40 and 90% at the tested concentrations of 1.5625, 3.125, 6.25, 12.5, 25, 50 and 100 mg/L, respectively. No signs of toxicity were detected in the control group and in the test item concentration of 1.5625, 3.125, 6.25 and 12.5 mg/L throughout the experimental period. In turn, loss of equilibrium, abnormal swimming behaviour and abnormal ventilatory function were recorded in the test item concentrations of 25-100 mg/L during the exposure period.

- The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:  
The LC<sub>50</sub>/96 h value is equal to 49.84 (46.96 – 52.71) mg/L  
The NOEC/96 h value is equal to 12.5 mg/L  
The LOEC/96 h value is equal to 25 mg/L
- The endpoint values determined on the basis of nominal concentrations of Copper oxychloride 50% WG:  
The LC<sub>50</sub>/96 h value is equal to 24.97 (23.53 – 26.41) mg/L  
The NOEC/96 h value is equal to 6.2625 mg/L  
The LOEC/96 h value is equal to 12.5250 mg/L

#### Conclusion

The 96 h NOEC of Copper oxychloride 50% WG is 6.2625 mg/L.  
The 96 h LOEC of Copper oxychloride 50% WG is 12.5250 mg/L.  
The LC<sub>50</sub> value of Copper oxychloride 50% WG at 96 h was 24.97 mg/L with fiducial limits of 23.53 to 26.41 mg/L.

<b>Comments of zRMS:</b>	The study is considered valid. All validity criteria were met.
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	<ul style="list-style-type: none"> <li>There was no immobilization of daphnia in the negative control during the test period, which is within the allowed 10 percent immobilization of daphnids.</li> <li>The dissolved oxygen concentration at the end of the test was 3.9 – 4.2 mg/L in test vessels.</li> </ul> <p><b>The agreed endpoints:</b></p> <p>The EC<sub>50</sub> = 0.768 mg test item/L or 0.384 mg copper/L</p> <p>The EC<sub>20</sub> = 0.389 mg test item/L or 0.195 mg copper/L</p> <p>The EC<sub>10</sub> = 0.273 mg test item/L or 0.137 mg copper/L</p> <p>NOEC (No Observed Effect Concentration) = 0.156 mg test item/L or 0.0783 mg copper/L.</p>
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**Reference:** KCP 10.2.1-02

**Report** “Study of *Daphnia magna* acute immobilization with Copper oxychloride 50% WG”, XXXX), Study No. 6729/2019. XXXX

**Guideline(s):** OECD Guideline No. 202 (2004)

**Deviations:** No

**GLP:** Yes

**Acceptability:** Yes

**Duplication (if vertebrate study)** Not relevant

## Materials and methods

Immobilization of young *Daphnia magna* (< 24 hours old) exposed to Copper oxychloride 50% WG (batch No. SCL – 160002) was investigated during a 48-hour test in static design. Seven test item concentrations: 0.156, 0.313, 0.625, 1.25, 2.5, 5 and 10 mg/L plus the control were used according to a range finding test. Four replicates of each test item concentration and the control with five *Daphnia magna* per replicate were used. The *Daphnia magna* were observed for immobilization after 24 and 48 hours of exposure.

All the test concentrations along with the negative control were analysed for the test item concentration at the beginning and end of test. For analysis, single composite sample was drawn from prepared test concentrations. Analysis was conducted using a validated method of atomic absorption spectrometry (ASS). The criteria for acceptance of analysis results of test concentration were 80 to 120 % of claimed concentration with ≤ 20% RSD of analysed concentration.

The active ingredient concentration analysis in all test concentrations showed that the percent agreement with claimed concentration was 99.4 to 101.1 % at the start of test and 100.0 to 100.7 % at the end of the test (48 hour), indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of ≤ 20%).

The endpoint values were determined based on nominal concentrations.

## Results

Results of the determination of copper oxychloride in the test samples

Hour	Sample/test item concentration (mg/L)		Nominal concentration* (mg/L)	Mean determined concentration (mg/L)	SD*	Recovery (%)
0 (fresh)	Control	0.0	0	ND	-	-
	T1	0.156	0.07816	0.07765	0.00230	99.4
	T2	0.313	0.15681	0.15706	0.00138	100.2
	T3	0.625	0.31313	0.31292	0.00260	99.9
	T4	1.25	0.62625	0.63313	0.00788	101.1
	T5	2.5	1.25250	1.25214	0.01191	100
	T6	5	2.50500	2.51368	0.01009	100.3
	T7	10	5.01000	4.98954	0.04013	99.6
48 (spent)	Control	0.0	0	ND	-	-
	T1	0.156	0.07816	0.07818	0.00353	100.0
	T2	0.313	0.15681	0.15681	0.00191	100.0
	T3	0.625	0.31313	0.3138	0.00088	100.2
	T4	1.25	0.62625	0.63039	0.00394	100.7
	T5	2.5	1.25250	1.25213	0.00812	100.0
	T6	5	2.50500	2.51433	0.00685	100.4
	T7	10	5.01000	5.02627	0.00588	100.3

\*Based on the content of active substance in the test item determined at Bioscience Research Foundation at the level of 50.10% (w/w)

SD: standard deviation

ND: not determined

### Definitive test

In the definitive test *Daphnia magna* was exposed to the test item concentrations 0.156, 0.313, 0.625, 1.25, 2.5, 5 and 10 mg/L of Copper oxychloride 50% WG plus the control for 48 hours in a static system. The results are summarized in the table below.

**Table 10.2.1-02-01 Immobilization of *Daphnia magna*, definitive test**

Nominal test item concentration [mg/L]	Number of <i>Daphnia magna</i>	Number of immobilized <i>Daphnia magna</i>								Total of immobilized <i>Daphnia magna</i> [%]	
		24 h				48 h				24 h	48 h
		Replicates									
		R1	R2	R3	R4	R1	R2	R3	R4		
Control	20	0	0	0	0	0	0	0	0	0	0
0.156	20	0	0	0	0	0	0	0	0	0	0
0.313	20	0	1	1	0	1	1	1	1	10	20
0.625	20	1	1	0	1	2	2	1	2	15	35
1.25	20	2	2	2	2	4	4	3	3	40	70
2.5	20	3	3	2	3	5	4	5	5	55	95
5	20	5	4	4	5	5	5	5	5	90	100
10	20	5	5	5	5	5	5	5	5	100	100

### Validity criteria

In the definitive test the validity criteria were met according to OECD Guideline No. 202 (2004):

- There was no immobilization of daphnia in the negative control during the test period, which is within the allowed 10 percent immobilization of daphnids.

- The dissolved oxygen concentration at the end of the test was 3.9 – 4.2 mg/L in test vessels.

## Conclusion

The EC50 value for Copper oxychloride 50% WG at 48 hours was 0.768 mg test item/L or 0.384 mg copper/L with fiducial limits being 0.725 to 0.811 mg/L.

The EC20 value for Copper oxychloride 50% WG at 48 hours was 0.389 mg test item/L or 0.195 mg copper/L with fiducial limits being 0.361 to 0.418 mg/L.

The EC10 value for Copper oxychloride 50% WG at 48 hours was 0.273 mg test item/L or 0.137 mg copper/L with fiducial limits being 0.249 to 0.297 mg/L.

On the basis of the observations made during this test, the NOEC (No Observed Effect Concentration) was 0.156 mg test item/L or 0.0783 mg copper/L.

On the basis of the observations made during this test, the LOEC (Lowest Observed Effect Concentration) was 0.313 mg test item/L or 0.1566 mg copper/L.

<b>Comments of zRMS:</b>	<p>The study is considered valid . All validity criteria were met.</p> <ul style="list-style-type: none"> <li>• There was an increase in cell concentration of the negative control culture by a factor of 117 which is more than the required factor limit of at least 16 at the end of the test.</li> <li>• The mean coefficient of variation for section by section specific growth rates in the negative control cultures during the course of the test was 13 % which is within the required limit of 35%.</li> <li>• The coefficient of variation of average growth rate between replicate cultures of negative control was 2.19% which is within the required limit of 7 %.</li> </ul> <p><b>Agreed endpoints:</b></p> <p>The endpoint values determined on the basis of the nominal test item concentrations:</p> <p>The concentration causing a 50% inhibition of the growth rate of <i>Pseudokirchneriella subcapitata</i>, i.e. the ErC<sub>50</sub>/72 h value is &gt;100 mg/L.                      The ErC<sub>20</sub>/72 h value is &gt;100 mg/L.                      The ErC<sub>10</sub>/72 h value is &gt;100 mg/L.                      The concentration causing a 50% inhibition of yield of <i>Pseudokirchneriella subcapitata</i>, i.e. the EyC<sub>50</sub>/72 h value is &gt;100 mg/L.                      The EyC<sub>20</sub>/72 h value is &gt;100 mg/L.                      The EyC<sub>10</sub>/72 h value is &gt;100 mg/L.</p> <p>The endpoint values determined on the basis of the active substance concentrations:</p> <ul style="list-style-type: none"> <li>• <b>Cooper oxychloride:</b>                          The ErC<sub>50</sub>/72 h value is &gt;50.1000 mg/L                          The ErC<sub>20</sub>/72 h value is &gt;50.1000 mg/L                          The ErC<sub>10</sub>/72 h value is &gt;50.1000 mg/L                          The EyC<sub>50</sub>/72 h value is &gt;50.1000 mg/L                          The EyC<sub>20</sub>/72 h value is &gt;50.1000 mg/L                          The EyC<sub>10</sub>/72 h value is &gt;50.1000 mg/L</li> </ul>
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<b>Reference:</b>	KCP 10.2.1-03
<b>Report</b>	Study of algal growth inhibition with Copper oxychloride 50% WG. xxxx S. (2020) Study No. 6731/2019. XXXX
<b>Guideline(s):</b>	OECD Guideline No. 201 (2006)
<b>Deviations:</b>	No
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	Not relevant

## Materials and methods

The growth of the green algae *Pseudokirchneriella subcapitata* exposed to the test item Copper oxychloride 50% WG (batch No. SCL – 160002) was investigated during a 72-hour test. The test was performed in conical flasks of 250 mL capacity covered with cotton plugs. Each of them contained 100 mL of a given test item concentration and the control. The initial density of the algae was  $0.9 \times 10^4$  cells/mL. The following test item concentrations were used on the definitive test: 1.5625, 3.125, 6.25, 12.5, 25.0, 50 and 100 mg/L plus the control. Three replicates were used for each test item concentration, whereas six replicates were used for control.

The concentrations of the test item were chemically determined and the active ingredient concentration analysis in all test concentrations showed that the percent agreement with the nominal concentration was 99.2 to 100.5 % at the start of the test and 99.3 to 100.7 % at the end of the test (72 hour), within the acceptable limit (80 to 120 % of the claimed concentration with an RSD  $\leq$  20%)

The endpoint values were determined on the basis of the nominal test item concentrations.

## Results

### Algal growth rate and yield based on cell density.

Group/ Concentration of the test item (mg/L)	Algal cell density at the beginning of the experiment ( $\times 10^6$ cells/mL)	Replicate/ Mean/SD	Algal cell density during the experiment ( $\times 10^6$ cells/mL)			Growth rate ( $\times 10^6$ cells/mL)				Yield ( $\times 10^6$ cells/mL)
						Section-by-section growth rate			Growth rate	
			24 h	48 h	72 h	0 – 24 h	24 – 48 h	48 – 72 h	0 – 72 h	
Control (0.0)	0.009	1	0.031	0.700	0.997	1.237	3.117	0.354	1.569	0.988
		2	0.032	0.680	0.960	1.269	3.056	0.345	1.557	0.951
		3	0.028	0.768	1.100	1.135	3.312	0.359	1.602	1.091
		4	0.030	0.708	1.218	1.204	3.161	0.543	1.636	1.209
		5	0.036	0.670	1.244	1.386	2.924	0.619	1.643	1.235
		6	0.027	0.693	1.059	1.099	3.245	0.424	1.589	1.05
		Mean	0.031	0.703	1.096	1.222	3.136	0.413	1.599	1.087
		SD	0.003	0.035	0.115	0.102	0.138	0.115	0.035	0.115
T1 (1.5625)	0.009	1	0.027	0.697	0.997	1.099	3.251	0.358	1.569	0.988
		2	0.033	0.689	1.059	1.299	3.039	0.430	1.589	1.05
		3	0.031	0.701	1.100	1.237	3.119	0.451	1.602	1.091
		Mean	0.030	0.696	1.052	1.212	3.122	0.413	1.587	1.043
		SD	0.003	0.006	0.052	0.103	0.107	0.049	0.017	0.052
T2 (3.125)	0.009	1	0.027	0.697	0.997	1.099	3.251	0.358	1.569	0.988
		2	0.031	0.689	1.059	1.237	3.101	0.430	1.589	1.05
		3	0.032	0.701	1.100	1.269	3.087	0.451	1.602	1.091
		Mean	0.030	0.696	1.052	1.201	3.146	0.413	1.587	1.043
		SD	0.003	0.006	0.052	0.090	0.091	0.049	0.017	0.052

Group/ Concentration of the test item (mg/L)	Algal cell density at the beginning of the experiment ( $\times 10^6$ cells/mL)	Replicate/ Mean/SD	Algal cell density during the experiment ( $\times 10^6$ cells/mL)			Growth rate ( $\times 10^6$ cells/mL)				Yield ( $\times 10^6$ cells/mL)
						Section-by-section growth rate			Growth rate	
			24 h	48 h	72 h	0 – 24 h	24 – 48 h	48 – 72 h	0 – 72 h	72 h
<b>T3 (6.25)</b>	0.009	1	0.026	0.697	0.997	1.061	3.289	0.358	1.569	0.988
		2	0.032	0.689	1.059	1.269	3.070	0.430	1.589	1.05
		3	0.034	0.701	1.100	1.329	3.026	0.451	1.602	1.091
		<b>Mean</b>	<b>0.031</b>	<b>0.696</b>	<b>1.052</b>	<b>1.220</b>	<b>3.128</b>	<b>0.413</b>	<b>1.587</b>	<b>1.043</b>
		<b>SD</b>	<b>0.004</b>	<b>0.006</b>	<b>0.052</b>	<b>0.141</b>	<b>0.141</b>	<b>0.049</b>	<b>0.017</b>	<b>0.052</b>
<b>T4 (12.5)</b>	0.009	1	0.026	0.697	0.997	1.061	3.289	0.358	1.569	0.988
		2	0.030	0.689	1.059	1.204	3.134	0.430	1.589	1.05
		3	0.033	0.701	1.100	1.299	3.056	0.451	1.602	1.091
		<b>Mean</b>	<b>0.030</b>	<b>0.696</b>	<b>1.052</b>	<b>1.188</b>	<b>3.160</b>	<b>0.413</b>	<b>1.587</b>	<b>1.043</b>
		<b>SD</b>	<b>0.003</b>	<b>0.006</b>	<b>0.052</b>	<b>0.120</b>	<b>0.118</b>	<b>0.049</b>	<b>0.017</b>	<b>0.052</b>
<b>T5 (25)</b>	0.009	1	0.026	0.697	0.997	1.061	3.289	0.358	1.569	0.988
		2	0.031	0.689	1.059	1.237	3.101	0.430	1.589	1.05
		3	0.032	0.701	1.100	1.269	3.087	0.451	1.602	1.091
		<b>Mean</b>	<b>0.030</b>	<b>0.696</b>	<b>1.052</b>	<b>1.189</b>	<b>3.159</b>	<b>0.413</b>	<b>1.587</b>	<b>1.043</b>
		<b>SD</b>	<b>0.003</b>	<b>0.006</b>	<b>0.052</b>	<b>0.112</b>	<b>0.113</b>	<b>0.049</b>	<b>0.017</b>	<b>0.052</b>
<b>T6 (50)</b>	0.009	1	0.026	0.697	0.997	1.061	3.289	0.358	1.569	0.988
		2	0.030	0.689	1.056	1.204	3.134	0.427	1.588	1.047
		3	0.032	0.700	1.100	1.269	3.085	0.452	1.602	1.091
		<b>Mean</b>	<b>0.029</b>	<b>0.695</b>	<b>1.051</b>	<b>1.178</b>	<b>3.169</b>	<b>0.412</b>	<b>1.586</b>	<b>1.042</b>
		<b>SD</b>	<b>0.003</b>	<b>0.006</b>	<b>0.052</b>	<b>0.106</b>	<b>0.106</b>	<b>0.049</b>	<b>0.016</b>	<b>0.052</b>

Group/ Concentration of the test item (mg/L)	Algal cell density at the beginning of the experiment ( $\times 10^6$ cells/mL)	Replicate/ Mean/SD	Algal cell density during the experiment ( $\times 10^6$ cells/mL)			Growth rate ( $\times 10^6$ cells/mL)				Yield ( $\times 10^6$ cells/mL)
						Section-by-section growth rate			Growth rate	
			24 h	48 h	72 h	0 – 24 h	24 – 48 h	48 – 72 h	0 – 72 h	72 h
<b>T7 (100)</b>	0.009	1	0.026	0.697	0.997	1.061	3.289	0.358	1.569	0.988
		2	0.030	0.688	1.059	1.204	3.133	0.431	1.589	1.05
		3	0.031	0.701	1.095	1.237	3.119	0.446	1.600	1.086
		<b>Mean</b>	<b>0.029</b>	<b>0.695</b>	<b>1.050</b>	<b>1.167</b>	<b>3.180</b>	<b>0.412</b>	<b>1.586</b>	<b>1.041</b>
		<b>SD</b>	<b>0.003</b>	<b>0.007</b>	<b>0.049</b>	<b>0.094</b>	<b>0.094</b>	<b>0.047</b>	<b>0.016</b>	<b>0.050</b>

## Results of the determination of copper oxychloride in the test samples

Sample/test item concentration (mg/L)		Control	T1	T2	T3	T4	T5	T6	T7
<b>0.0</b>		<b>0.0</b>	<b>1.5625</b>	<b>3.125</b>	<b>6.25</b>	<b>12.5</b>	<b>25</b>	<b>50</b>	<b>100</b>
<b>Nominal concentration* (mg/L)</b>		<b>0.0</b>	<b>0.78281</b>	<b>1.56563</b>	<b>3.13125</b>	<b>6.26250</b>	<b>12.52500</b>	<b>25.05000</b>	<b>50.10000</b>
<b>0 h</b>	<b>Mean determined concentration (mg/L)</b>	ND	0.78047	1.57298	3.14496	6.25869	12.43320	24.84521	50.03747
	<b>SD</b>	0	0.00000	0.00341	0.00000	0.01383	0.02206	0.03706	0.06347
	<b>Recovery (%)</b>	-	99.7	100.5	100.4	99.9	99.3	99.2	99.9
<b>72 h</b>	<b>Mean determined concentration (mg/L)</b>	ND	0.78177	1.55669	3.15298	6.27978	12.43343	24.99528	49.87585
	<b>SD</b>	0	0.01591	0.00365	0.02344	0.06853	0.00000	0.00000	0.3661
	<b>Recovery (%)</b>	-	99.9	99.4	100.7	100.3	99.3	99.8	99.6

\*Based on the content of active substance in the test item determined at Bioscience Research Foundation at the level of 50.10% (w/w)  
SD: standard deviation; ND: not determined



### Definitive test

In the definitive test, the algae, *Pseudokirchneriella subcapitata*, with an initial cell density of  $0.9 \times 10^4$  cells/mL were exposed to the test item concentrations: 1.5625, 3.125, 6.25, 12.5, 25.0, 50 and 100 mg/L plus the control. The results are summarized in the table below.

**Table X.2 Growth rate and yield inhibition, definitive test**

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	-	-
1.5625	0.8	4.08
3.125	0.8	4.08
6.25	0.8	4.08
12.5	0.8	4.08
25.0	0.8	4.08
50	0.8	4.17
100	0.8	4.23

### Validity criteria

In the definitive test, the following validity criteria specified in OECD Guideline No. 201 (2006) were met:

- There was an increase in cell concentration of the negative control culture by a factor of 117 which is more than the required factor limit of at least 16 at the end of the test.
- The mean coefficient of variation for section by section specific growth rates in the negative control cultures during the course of the test was 13 % which is within the required limit of 35%.
- The coefficient of variation of average growth rate between replicate cultures of negative control was 2.19% which is within the required limit of 7 %.

### Conclusion

The endpoint values determined on the basis of the nominal test item concentrations:

The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata*, i.e. the  $ErC_{50/72\text{ h}}$  value is >100 mg/L.

The  $ErC_{20/72\text{ h}}$  value is >100 mg/L.

The  $ErC_{10/72\text{ h}}$  value is >100 mg/L.

The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the  $EyC_{50/72\text{ h}}$  value is >100 mg/L.

The  $EyC_{20/72\text{ h}}$  value is >100 mg/L.

The  $EyC_{10/72\text{ h}}$  value is >100 mg/L.

The endpoint values determined on the basis of the active substance concentrations:

- Cooper oxychloride:

The  $ErC_{50/72\text{ h}}$  value is >50.1000 mg/L

The  $ErC_{20/72\text{ h}}$  value is >50.1000 mg/L

The  $ErC_{10/72\text{ h}}$  value is >50.1000 mg/L

The  $EyC_{50/72\text{ h}}$  value is >50.1000 mg/L

The  $EyC_{20/72\text{ h}}$  value is >50.1000 mg/L

The  $EyC_{10/72\text{ h}}$  value is >50.1000 mg/L

**A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms**

**A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms**

**A 2.3 KCP 10.3 Effects on arthropods**

**A 2.3.1 KCP 10.3.1 Effects on bees**

**A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees**

**A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees**

<b>Comments of zRMS:</b>	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> <li>The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%).</li> <li>The 24-hour LD<sub>50</sub> of the reference item (dimethoate) was 0.1236 µg/bee (criterion: 0.11 - 0.32 µg a.i./bee)</li> </ul> <p><b>Agreed endpoints:</b></p> <p>LD<sub>50</sub> /48 h 50.68 (46.01-55.34) µg test item/bee, respectively or 25.39 (23.05-27.73) µg ai/bee</p> <p>At 48h following exposure normal, lethargy, spam and mortality was observed in bees exposed to all item treatments.</p>
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**Reference:** KCP 10.3.1.1.1

**Report** "Acute Oral Toxicity of Copper 50% (as Oxychloride) WG on Honey bee".  
XXXX Study code 7620/2020

**Guideline(s):** OECD Guideline for the Testing of Chemicals No. 213 (1998)

**Deviations:** No

**GLP:** Yes

**Acceptability:** Yes

## Materials and methods

The acute oral toxicity study of Copper 50% (as Oxychloride) WG (batch number: SCL-160002) was conducted to determine the LD<sub>50</sub> values for honeybees. Five doses of the test item were used. These included: 12.21, 19.53, 31.25, 50 and 80 µg/honeybee (i.e. 0.05, 0.1, 0.15, 0.2 and 0.3 µg a.i./bee) and a control (0.0 µg/bee). The range of doses was selected on the basis of the preliminary test results. Each group of 10 bees (3 replicates containing 10 bees each) was fed with 200 µL of a 50% sucrose solution, containing the test item at the doses enumerated above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.



The general condition of the test honeybees and the reliability of the test conducted on them were controlled using the recommended reference item - dimethoate.

After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

## Results

**Table 10.3.1.1.1-01: Acute oral toxicity on honeybees (*Apis mellifera* L.)**

Dose		N° of tested bees	Mortality after 48 h		LD <sub>50</sub>	
			Total			
			[no.]	[%]		
[µg /bee] <sup>a</sup>	[µg a.i./bee] <sup>b</sup>					
0.0 (Control)		30	0	0.0	50.68 (46.01-55.34)	25.39 (27.73-23.05)
12.21	6.12	30	0	0.0		
19.53	9.78	30	2	6.67		
31.25	15.66	30	8	26.67		
50	25.05	30	15	50		
80	40.08	30	22	73.33		

a: µg test item/ bee

b: µg active ingredient /bee

## Findings

- The mortality in the test item treatments at 12.21, 19.53 and 31.25 µg /bee after 48 hours was lower than 50% when compared to the control.
- The median lethal doses of Cooper 50% (as oxymethionide) WG (LD<sub>50</sub>) after 24 and 48 hours of the exposure are 76.85 (65.10-88.60) and 50.68 (46.01-55.34) µg test item/bee, respectively.
- At 48h following exposure normal, lethargy, spam and mortality was observed in bees exposed to all item treatments.

## Validity criteria

The following validity criteria were met during the test:

- The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%).
- The 24-hour LD<sub>50</sub> of the reference item (dimethoate) was 0.1236 µg/bee (criterion: 0.11 - 0.32 µg a.i./bee)

## Conclusion

The median lethal doses (LD<sub>50</sub>/24 h and LD<sub>50</sub>/48 h contact) are 76.85 (65.10-88.60) and 50.68 (46.01-55.34) µg test item/bee, respectively or 38.50 (32.62-44.39 µg ai/bee, 25.39 (23.05-27.73) µg ai/bee, respectively.

With respect to the test results, it can be concluded that the test item, Cooper 50% (as oxymethionide) WG had adverse effect on mortality of honeybees (*Apis mellifera* L.).

At 48h following exposure normal, lethargy, spam and mortality was observed in bees exposed to all item treatments.

#### A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

<b>Comments of zRMS:</b>	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> <li>The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%),</li> <li>The LD<sub>50</sub>/24 h of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).</li> </ul> <p><b>Agreed endpoints:</b></p> <p>LD<sub>50</sub>/48 h<sub>contact</sub> &gt; 200.0 µg/honeybee (100.2 µg a.i./honeybee).</p>
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<b>Reference:</b>	KCP 10.3.1.1.2
<b>Report</b>	“Copper 50% (as Oxychloride) WG: Honeybees ( <i>Apis mellifera</i> L.), Acute Contact Toxicity Test”. Paweł Parma,, 2018, B/32/17. XXXX
<b>Guideline(s):</b>	Yes, OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)
<b>Deviations:</b>	Yes. According to the Study Plan the study should be completed in November 2018, while it ended in December 2018. Above deviation did not have any influence on the final results of the study.
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	No

#### Materials and methods

Test item:	<p>Description: Copper 50% (as Oxychloride) WG</p> <p>Production batch: SCL - 43298</p> <p>A.i. content: 50.1% [w/w]</p>
Test system:	<p>Species: <i>Apis mellifera</i></p> <p>Strain: carnica</p> <p>Age: approximately 3 weeks</p> <p>Average weight: -</p> <p>Average length: -</p> <p>Source: An apiary at XXXX</p> <p>Acclimation period: 20 hours</p> <p>Diet: 50% (v/v) sucrose solution</p>
Experimental conditions:	<p>Temperature: 25 – 26°C</p> <p>Humidity: 61 – 67%</p> <p>Hardness: -</p> <p>pH: -</p> <p>Light and photoperiod: 24h darkness (except during observations).</p> <p>Loading: 3 replicates per dose, 10 bees per replicate</p> <p>Test procedure: The honeybees were anaesthetized with carbon dioxide, transferred to plastic trays and dosed on the dorsal</p>

side of the thorax with 1 µl of test solution containing the test substance or reference substance.

Experimental period: 48h

### Test design and treatment

Plastic cages with an opening on each side to allow the feeding with syringes.

A preliminary test was done at the dose of 8.0, 40.0 and 200.0 µg test item/bee. According to the results, the following nominal test item concentrations were used: 12.5, 25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee). The honeybees were observed for mortality and behavioural abnormalities after 4, 24 and 48 h of exposure.

### Results

On the preliminary test, mortality of the control group after 48 hours of exposure was 10.0%. The percentages of mortality of the bees treated with the test item at the doses of 8.0, 40.0 and 200.0 µg/honeybee were 10.0, 10.0 and 0.0%, respectively. No abnormal behavioural effects were observed during the test.

On the definitive test, mortality of the control group and the treated groups 12.5, 25.0, 50.0 and 100.0 µg/honeybee after 48 hours of exposure were 0.0%. Mortality in the dose of 200.0 µg/honeybee after 48 hours of exposure was 3.3%, respectively. No abnormal behavioural effects were observed during the test. The median lethal doses (LD<sub>50</sub>/24 h and LD<sub>50</sub>/48 h contact) are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee (100.2 µg a.i./honeybee).

The median lethal dose of dimethoate (LD<sub>50</sub>/24 h) determined with the log-probit method is 0.26 µg/bee (95% confidence limits: 0.23 - 0.30 µg a.i./bee).

### Contact toxicity test results

Dosage		Number of tested bees [no.]	Mortality after 48 h			LD <sub>50</sub> /48 h	
µg/bee	µg a.i./bee		Total		Corrected	µg/bee	µg a.i./bee
			[no.]	[%]			
0.0 (Control)		30	0	0.0	-	above 200.0	above 100.2
12.5	6.3	30	0	0.0	-		
25.0	12.5	30	0	0.0	-		
50.0	25.1	30	0	0.0	-		
100.0	50.1	30	0	0.0	-		
200.0	100.2	30	1	3.3	-		

The following validity criteria were met during the test:

- the average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%),
- the LD<sub>50</sub>/24 h of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

### Conclusion

The median lethal doses (LD<sub>50</sub>/24 h and LD<sub>50</sub>/48 h contact) are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee (100.2 µg a.i./honeybee).

<b>A 2.3.1.3</b>	<b>KCP 10.3.1.3</b>	<b>Effects on honey bee development and other honey bee life stages</b>
<b>A 2.3.1.4</b>	<b>KCP 10.3.1.4</b>	<b>Sub-lethal effects</b>
<b>A 2.3.1.5</b>	<b>KCP 10.3.1.5</b>	<b>Cage and tunnel tests</b>
<b>A 2.3.1.6</b>	<b>KCP 10.3.1.6</b>	<b>Field tests with honeybees</b>
<b>A 2.3.2</b>	<b>KCP 10.3.2</b>	<b>Effects on non-target arthropods other than bees</b>
<b>A 2.3.2.1</b>	<b>KCP 10.3.2.1</b>	<b>Standard laboratory testing for non-target arthropods</b>
<b>A 2.3.2.2</b>	<b>KCP 10.3.2.2</b>	<b>Extended laboratory testing, aged residue with non-target arthropods</b>

Comments of zRMS:	The study is considered vali. All validity criteria were met.									
	– mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),									
	– mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 81.7% on day 7 of exposure (criterion: a minimum of 50%),									
	– the mean number of eggs per female in the control group was 4.1 (required: ≥ 4 eggs per female).									
	Agreed endpoints:									
	Study group [application rate]		Parameter (endpoints)							
			Mortality after 7 days of the exposure		Reproduction					
	Test item		To- tal [%]	LR <sub>50</sub>		Mean number of eggs/ fe- male (Rr) [no.]	Reproduc- tion reduc- tion Pr [%]	ER <sub>50</sub>		
	[kg /ha]	[kg a.i./ha]		[kg /ha]	[kg a.i./ha]			[kg /ha]	[kg a.i./ha]	
	Control (0.0)		0.0	-		4.1	-	-		
	3.75	1.9	3.3	> 30.0	> 15.0	4.3	-4.3*	> 30.0	> 15.0	
	7.5	3.8	18.3 +			5.3	-27.5*			
	15.0	7.5	21.7 +			5.0	-21.1*			
	30.0	15.0	26.7 +			5.1	-22.2*			
	NOER <sub>mortality</sub>			3.75	1.9	NOER <sub>reproduction</sub>		≥ 30.0	≥ 15.0	
	Reference item		Bi 58 Top 400 EC							
	[mL /ha]	[g a.i./ha]								
	9.0	3.6	81.7	-						
+: statistically significant differences										
*: the negative value indicate that number of eggs per female in the treated group is higher than in the control										

**Reference:** KCP 10.3.2..2-01

<b>Report</b>	“An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on the predatory mite, <i>Typhlodromus pyri</i> (Sch.)”. XXXX
<b>Guideline(s):</b>	ESCORT 1 (XXXX) and the ESCORT 2 (XXXX., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (XXXX et al., 2000)
<b>Deviations:</b>	Yes. Short term deviation in humidity in definitive test occurred. According to the Study Plan the study should be completed in November 2018, while it ended in January 2019. Above deviations did not have any influence on the final results of the study.
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	Not relevant

## Materials and methods

The aim of the extended laboratory test was to evaluate the effects of the test item, Copper 50% (as Oxychloride) WG on mortality and reproduction of the predatory mite, *T. pyri* (Sch.).

On the basis of the preliminary test results it was decided to use four rates of the test item in the definitive test. These were: 3.75, 7.5, 15.0 and 30.0 kg/ha. The mites, *T. pyri* at the protonymphal stage (24 hours old) were exposed to the test item applied to been leaf discs. The mites were fed with pine pollen (*Pinus* sp.). Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and groups treated with the test item at the rates of 3.75, 7.5, 15.0 and 30.0 kg/ha were made after 8, 11, and 14 days of the treatment.

Mortality of *T.pyri* after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.

To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, Bi 58 Top 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 9.0 mL/ha (3.6 g a.i./ha). The control group was treated with distilled water.

## Results

The effects of Copper 50% (as Oxychloride) WG on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized below.

Study group [application rate]		Parameter (endpoints)						
		Mortality after 7 days of the exposure			Reproduction			
Test item		Total [%]	LR <sub>50</sub>		Mean number of eggs/ female (Rr) [no.]	Reproduction reduction Pr [%]	ER <sub>50</sub>	
[kg /ha]	[kg a.i./ha]		[kg /ha]	[kg a.i./ha]			[kg /ha]	[kg a.i./ha]
Control (0.0)		0.0	-		4.1	-	-	
3.75	1.9	3.3	> 30.0	> 15.0	4.3	-4.3*	> 30.0	> 15.0
7.5	3.8	18.3 <sup>+</sup>			5.3	-27.5*		
15.0	7.5	21.7 <sup>+</sup>			5.0	-21.1*		
30.0	15.0	26.7 <sup>+</sup>			5.1	-22.2*		
NOER <sub>mortality</sub>			3.75	1.9	NOER <sub>reproduction</sub>		≥ 30.0	≥ 15.0
Reference item		Bi 58 Top 400 EC						
[mL /ha]	[g a.i./ha]							
9.0	3.6	81.7	-					

+: statistically significant differences

\*: the negative value indicate that number of eggs per female in the treated group is higher than in the control

## Findings

- In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to Copper 50% (as Oxychloride) WG at the rates of 3.75, 7.5, 15.0 and 30.0 kg/ha the percentages of mortality of *T. pyri*, were 3.3, 18.3, 21.7 and 26.7%, respectively.
- On the basis of the obtained mortality results, the LR50 value could not be determined. It can only be concluded that the LR50 is higher than the maximum rate used in the experiment, i.e. > 30.0 kg/ha (> 15.0 kg a.i./ha). The NOER<sub>mortality</sub> value is equal to 3.75 kg/ha (1.9 kg a.i./ha).
- At the significance level of 0.1, there were no statistically significant differences in mortality between the group treated with the test item at the rate of 3.75 and the control group. However, there were statistically significant differences in mortality between the group treated with the test item at the rates of 7.5, 15.0 and 30.0 kg/ha and the control group (Step-down Cochran-Armitage Test Procedure,  $p(\text{trend}) > 0.1$ ).
- After 7 days of exposure to Bi 58 Top 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha), mortality of the mites, was 81.7%. Therefore, the validity criterion specified in the Method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.
- The mean reproduction rate (Rr) in the control group was 4.1 eggs/female. The mean reproduction rates after 14 days of exposure to Copper 50% (as Oxychloride) WG at the rates of 3.75, 7.5, 15.0 and 30.0 kg/ha were 4.3, 5.3, 5.0 and 5.1 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by Copper 50% (as Oxychloride) WG at the rates of 3.75, 7.5, 15.0 and 30.0 kg/ha were (-4.3), (-27.5), (-21.1), and (-22.2)% respectively. The negative value indicate that number of eggs per female in the treated group is higher than in the control.
- At the significance level of  $\alpha \leq 0.1$ , there were no statistically significant differences in reproduction between the group treated with the test item at the rates of 3.75, 7.5, 15.0 and 30.0 kg/ha and the control group (Dunnett's Multiple t-test Procedure,  $|t| > |t^*|$ ).
- On the basis of the obtained reproduction results, the ER50 and NOER<sub>reproduction</sub> values could not be determined. It can only be concluded that the ER50 is higher than the maximum rate used in the experiment, i.e. > 30.0 kg/ha (> 15.0 kg a.i./ha) and NOER<sub>reproduction</sub> value is higher or equal to 30.0 kg/ha ( $\geq 15.0$  kg a.i./ha).

<b>Comments of zRMS:</b>	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> <li>• The following validity criteria were met during the study:</li> <li>• after 48 hours mortality of the control group 0.0% (criterion: a maximum of 10.0%),</li> <li>• after 48 hours mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 76.7% (criterion: a minimum of 50%),</li> <li>• all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),</li> <li>• the mean number of mummies per female in the control group was 22.7 (criterion: a minimum of 5.0 mummies/female),</li> <li>• all wasps in the control group gave offspring (criterion: a maximum of 2</li> </ul>
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females giving no offspring)								
Agreed endpoints:								
Mortality and fecundity of <i>Aphidius rhopalosiphi</i> in the laboratory test.								
Study group [application rate]		Parameter (endpoint)						
		Mortality			Reproduction			
Test item		To- tal [% ]	LR <sub>50</sub>		Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER <sub>50</sub>	
[kg/h a]	[kg a.i./ha]		[kg/h a]	[kg a.i./ha]			[kg/ha ]	[kg a.i./ha]
Control (0.0)		0.0	-		22.2	-	-	
2.0	1.0	3.3	> 16.0	> 8.0	22.2	2.1	7.9  (3.3 - 40.6)*	4.0  (1.7 - 20.3)*
4.0	2.0	3.3			16.5	27.1		
8.0	4.0	0.0			10.9 <sup>+</sup>	51.8		
16.0	8.0	3.3			8.3 <sup>+</sup>	63.5		
NOER <sub>mortality</sub>			≥ 16.0	≥ 8.0	NOER <sub>fecundity</sub>		4.0	2.0
Reference item		Mortality after 48 h						
[mL/ ha]	[g a.i./ha]							
5.0	2.0	76.7						
+ : statistically significant difference								
* : 95% confidence limits								

**Reference:** KCP 10.3.2.2-02

**Report** “An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on the parasitic wasp, *Aphidius rhopalosiphi* (XXXX)”. Paweł Parma, 2019, B/37/17. XXXX

**Guideline(s):** ESCORT 1 (XXXX. et al., 1994) and the ESCORT 2 (XXXX. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (XXXX. et al., 2000; XXXX 2010)

**Deviations:** According to the Study Plan the study should be completed in November 2018, while it ended in March 2019, which had no impact on the results.

**GLP:** Yes

**Acceptability:** Yes

**Duplication  
(if vertebrate study)** Not relevant

## Materials and methods

The extended laboratory test involved the evaluation of the effects of the test item, Copper hydroxide 50% WP on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*.

Four application rates of the test item and a control were used. The rates were 2.0, 4.0, 8.0 and 16.0 kg/ha. The range of rates was selected on the basis of the non-GLP preliminary test results and consultation with the Sponsor.

Adult female wasps were exposed to the test item applied to barley plants. Observations of settling behaviour were made during initial 3 hours of exposure. The aims were to determine repellent effects of Copper

hydroxide 50% WP and to check if the test insects had contact with barley plants sprayed with the test item. Settling behaviour of the wasps from each replicate was observed five times. Mortality assessments were made 2, 24 and 48 hours after the introduction of the wasps to the test arenas.

Then, females which survived 48-hour exposure to Copper hydroxide 50% WP and the ones from the control group were assessed for fecundity. To allow the oviposition, fifteen female wasps from the groups treated with Copper hydroxide 50% WP at the rates were 2.0, 4.0, 8.0 and 16.0 kg/ha and the control group were individually introduced into fecundity units containing barley plants infested with the aphid, *Rhopalosiphum padi*. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which wasps' pupae were developing) was recorded.

Mortality of the wasps after 48 hours of exposure and the percentage of fecundity reduction (Pr) after 12 days after the oviposition were the endpoints.

To verify the sensitivity of the test system and the precision of the test procedure, an insecticide, i.e. Bi 58 Top 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 5.0 mL/ha (2.0 g dimethoate/ha). The control group was treated with distilled water.

## Results

### Mortality and fecundity of *Aphidius rhopalosiphi* in the laboratory test

Study group [application rate]		Parameter (endpoint)						
		Mortality		Reproduction				
Test item		Total [%]	LR <sub>50</sub>		Mean no. of mummies/ female	Fecundity re- duction Pr [%]	ER <sub>50</sub>	
[kg/ha]	[kg a.i./ha]		[kg/ha]	[kg a.i./ha]			[kg/ha]	[kg a.i./ha]
Control (0.0)		0.0	-		22.2	-	-	
2.0	1.0	3.3	> 16.0	> 8.0	22.2	2.1	7.9 (3.3 - 40.6)*	4.0 (1.7 - 20.3)*
4.0	2.0	3.3			16.5	27.1		
8.0	4.0	0.0			10.9 <sup>+</sup>	51.8		
16.0	8.0	3.3			8.3 <sup>+</sup>	63.5		
NOER <sub>mortality</sub>			≥ 16.0	≥ 8.0	NOER <sub>recundity</sub>		4.0	2.0
Reference item		Mortality after 48 h						
[mL/ha]	[g a.i./ha]							
5.0	2.0	76.7						

+: statistically significant difference

\*: 95% confidence limits

## Findings

In the definitive test, mortality of the control group after 48 hours of the exposure was 0.0%. After 48 hours of the exposure to Copper hydroxide 50% WP at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha, the percentages of mortality of *A. rhopalosiphi*, were 3.3, 3.3, 0.0 and 3.3% respectively.

At the significance level of 0.05, there were no statistically significant difference in mortality between the wasps exposed to the test item at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha and the control group (Chi<sup>2</sup> 2x2 Table Test with Bonferroni Correction, p(z) > alpha\*).

On the basis of the obtained mortality results, the LR<sub>50</sub> and NOER<sub>mortality</sub> values could not be determined. It can only be concluded that the LR<sub>50</sub> and the NOER<sub>mortality</sub> values are higher than or equal to the maximum rate used in the experiment, i.e. ≥ 16.0 kg/ha.

Mortality of the wasps exposed to Bi 58 Top 400 EC at the rate of 5.0 mL/ha was 76.7% after 48 hours. Therefore, the validity criterion specified in the Method description was met. The results showed that the test organisms were sensitive to dimethoate.



The fecundity assessment showed that the mean number of mummies per female in the control group was 22.7. As for the wasps treated with Copper hydroxide 50% WP at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha, the numbers of mummies/female were 22.2, 16.5, 10.9 and 8.3, respectively.

Fecundity reduction (Pr) in the group treated with Copper hydroxide 50% WP at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha were 2.1, 27.1, 51.8 and 63.5%, respectively.

At the significance level  $\alpha$  of 0.05, there were no statistically significant difference in fecundity between the wasps exposed to the test item at the rates of 2.0 and 4.0 kg/ha and the control group. However there were statistically significant difference in fecundity between the wasps exposed to the test item at the rates of 8.0 and 16.0 kg/ha and the control group (Multiple Sequentially-rejective Median (2x2-Table) Test after Bonferroni-Holm,  $p > \alpha^*$  ).

On the basis of the obtained fecundity results, the  $ER_{50}$  value is equal to 7.9 kg/ha and  $NOER_{\text{fecundity}}$  value is equal to 4.0 kg/ha.

- The following validity criteria were met during the study:
- after 48 hours mortality of the control group 0.0% (criterion: a maximum of 10.0%),
- after 48 hours mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 76.7% (criterion: a minimum of 50%),
- all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
- the mean number of mummies per female in the control group was 22.7 (criterion: a minimum of 5.0 mummies/female),
- all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

On the basis of the obtained results it can be concluded that Copper hydroxide 50% WP at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha has no adverse effect on wasps mortality. However, the test item has adverse effect on fecundity of the wasps at the rates of 8.0 and 16.0 kg/ha.

<b>Comments of zRMS:</b>	The study is considered valid. All validity criteria were met.				
	<ul style="list-style-type: none"> <li>Maximum acceptable cumulative mortality (dead larvae and pupae, adults dying during emergence or not successfully moulted): ≤ 20 % (10.00 %).</li> <li>Fecundity (mean number of eggs per female and day): ≥ 15 (38.4).</li> <li>Fertility (mean hatching rate): ≥ 70 % (98.81 %).</li> <li>Mortality in the reference product treatment was higher than 50 % (100 %, corrected to control).</li> </ul>				
	<b><u>Agreed endpoints:</u></b>				
Application rate		Parameter (endpoints)			
Test item		Total % Pre-adult mortality	% Corrected Mortality	Fecundity (Mean eggs/female/day)	Fertility (Mean % eggs viability)
kg FP/ha	kg a.s./ha	(28 d)	(28 d)	(24 h)	(24 h)
Control (0.0)		10.00	-	38.4	98.81
1	0.501	13.33	3.70	33.7	98.35
2	1.002	16.67	7.41	28	97.33
4	2.004	26.67	18.52	24.5	95.91
8	4.008	46.67	40.74	20.6	94.84
16	8.016	56.67	51.85	17.6	92.92
Reference item					
L FP/ha	g a.s./ha				
0.65	195	100.00	100.00	-	-
<b>Endpoints</b>		<b>LR<sub>50</sub>mortality</b>	13.50 Kg f.p./ha (6.76	<b>ER<sub>50</sub>fecundity</b>	10.58 Kg f.p./ha (5.30 Kg a.s./ha)

			Kg a.s./ha)		
		<b>NOER<sub>mortality</sub></b>	4 Kg f.p./ha (2.004 Kg a.s/ha)	<b>NOER<sub>fecundity</sub></b>	>1 Kg f.p./ha (>0.501 Kg a.s./ha)

**Report:** KCP 10.3.2.2-03

**Title:** An extended laboratory test for evaluating the effects of Copper 50% (as Ox-  
ychloride) WG on larvae of the green lacewing *Chrysoperla carnea* (L.)  
(Neuroptera: Chrysopidae). Xxxx, M., 2020. XXXX  
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**Document No:** 7547/2020

**Guidelines:** ESCORT 1 (XXXX) and the ESCORT 2 (XXXX) guidance documents and the  
guidelines developed by the IOBC/WPRS (XXXX 2001)

**GLP** Yes

### Summary

The aim of the study was to determine under extended laboratory conditions the effects of fresh residues of the formulation Copper 50% (as Oxychloride) WG on the green lacewing *Chrysoperla carnea* Steph. (Neuroptera: Chrysopidae). A range of five rates of the test product (1, 2, 4, 8 and 16 kg/ha of formulated product) were sprayed per treatment.

Application was performed on bean leaves with a laboratory track sprayer. First instar larvae of *Chrysoperla carnea* (2-3 days old) were isolated and exposed to the test item on the leaves. The larvae were continuously exposed to the residue until pupation. Thirty larvae per treatment were individually confined within test units.

Viable adults from each treatment (control and test product) were used to study fecundity and fertility. Adults emerging within a discrete time period were housed in one box per treatment group in the same environmental controlled room. Fecundity assessments began seven days after eggs were first observed in the control treatment.

Mortality of the larvae exposed to the residues up to the completion of adult emergence was evaluated. The sub-lethal effects on the reproductive performance (fecundity and fertility) were also evaluated in treatments of the test product with a corrected mortality compared to the control less than 50 % (all tested rates of the test product: of 1, 2, 4, 8 and 16 kg/ha).

To control the sensitivity of the biological test system and the relative susceptibility of the test method, ROGOHIT (30% dimethoate, w/w) was used as a reference item. The reference item was applied at a rate of 0.65 L /ha. A water control was also tested.

### Material and methods

**Test item:** Copper 50% (as Oxychloride) WG: content: 50.1% ; Batch No.: SCL-160002;  
manufacturing date: September 15<sup>th</sup>, 2019; expiry date: September 14<sup>th</sup>, 2021

**Biological test system:** green lacewing (*Chrysoperla carnea*)

- age: Instar larvae, 2-3 days old
- source: BRF Insectary

Experimental design: 7 test groups:

- Control (0 kg product/ha)
  - Copper 50% (as Oxychloride) WG at a rate of 1 kg product/ha
  - Copper 50% (as Oxychloride) WG at a rate of 2 kg product/ha
  - Copper 50% (as Oxychloride) WG at a rate of 4 kg product/ha
  - Copper 50% (as Oxychloride) WG at a rate of 8 kg product/ha
  - Copper 50% (as Oxychloride) WG at a rate of 16 kg product/ha
  - ROGOHIT at a rate of 0.65 L product/ha
- 30 larvae/group; Viable adults from each treatment were used to study fecundity and fertility.

Test conditions - mortality:

- temperature: 24.0 – 27.0 °C
- relative air humidity: 63.0 – 80.0 %
- photoperiod: 16 hours light : 8 hours dark; 1100-1800 lux.

Test conditions - fecundity and fertility:

- temperature: 24.0 – 27.0 °C
- relative air humidity: 63.0 – 80.0 %
- photoperiod: 16 hours light : 8 hours dark; 1100-1800 lux.

**Statistics:** The endpoint values were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.

**Endpoints:**

- Total juvenile mortality (larvae, pupae and pre-adult phase)
- Reproductive performance in terms of number of eggs produced per female (fecundity) and the percentage hatching rate (fertility)

## Results

Total juvenile mortality (larvae and pupae) in the control treatment was less than 20 % (10.00 %). Mortality in the reference product treatment was 100 %. Mortality (pre-adult phase) was less than 50 % in the assayed rates, up to 8.0 kg FP/ha (51.85 % corrected mortality as maximum observed mortality at the rate of 16 kg FP/ha). Therefore, the LR<sub>50</sub> for the test product Copper 50% (as Oxychloride) WG on *Chrysoperla carnea* was estimated to be 13.50 kg/ha of formulated product (equivalent to 6.76 kg a.s./ha)

There were significant differences compared to control on juvenile mortality with the tested rates 8 and 16 kg/ha (one-way ANOVA,  $p < 0.05$ ). Therefore, the NOER of the test product Copper 50% (as Oxychloride) WG on *Chrysoperla carnea* (no observed-lethal effect rate) was determined to be 4 kg/ha (equivalent to 2.004 kg a.i./ha).

Fecundity in the group treated with Copper 50% (as Oxychloride) WG at rates of 1,2, 4, 8 and 16 kg/ha was 33.7, 28, 24.5, 20.6 and 17.6, respectively. Fecundity reduction in the group treated with Copper 50% (as Oxychloride) WG at rates of 1,2, 4, 8 and 16 kg/ha was 12.24, 27.08, 36.20, 46.35 and 54.17, respectively in comparison with the control group.

There were significant difference in fecundity reduction between group treated with the test item at the rate of all doses and the control group (one-way ANOVA,  $p < 0.05$ ). Therefore, the NOER of the test product Copper 50% (as Oxychloride) WG on *Chrysoperla carnea* (no observed-lethal effect rate) was determined to be greater than 1 kg/ha (equivalent to  $>0.501$  kg a.i./ha)

Fertility in the group treated with Copper 50% (as Oxychloride) WG at rates of 1,2, 4, 8 and 16 kg/ha was 98.35, 97.33, 95.91, 94.84 and 92.92%, respectively. Fertility reduction in the group treated with Copper 50% (as Oxychloride) WG at rates of 1,2, 4, 8 and 16 kg/ha was 0.47, 1.50, 2.93, 4.02 and 5.96%, respectively in comparison with the control group.

There were no significant difference in fertility between group treated with the test item at the rate of 4, 8 and 16 kg/ha and the control group (one-way ANOVA,  $p < 0.05$ )

Application rate		Parameter (endpoints)			
Test item		Total % Pre-adult mortality	% Corrected Mortality	Fecundity (Mean eggs/female/day)	Fertility (Mean % eggs viability)
kg FP/ha	kg a.s./ha	(28 d)	(28 d)	(24 h)	(24 h)
Control (0.0)		10.00	-	38.4	98.81
1	0.501	13.33	3.70	33.7	98.35
2	1.002	16.67	7.41	28	97.33
4	2.004	26.67	18.52	24.5	95.91
8	4.008	46.67	40.74	20.6	94.84
16	8.016	56.67	51.85	17.6	92.92
Reference item					
L FP/ha	g a.s./ha				
0.65	195	100.00	100.00	-	-
Endpoints		LR <sub>50</sub> mortality	13.50 Kg f.p./ha (6.76 Kg a.s./ha)	ER <sub>50</sub> fecundity	10.58 Kg f.p./ha (5.30 Kg a.s./ha)
		NOER <sub>mortality</sub>	4 Kg f.p./ha (2.004 Kg a.s./ha)	NOER <sub>fecundity</sub>	>1 Kg f.p./ha (>0.501 Kg a.s./ha)

#### Test validity criteria

The following validity criteria were met in the control during the study:

- Maximum acceptable cumulative mortality (dead larvae and pupae, adults dying during emergence or not successfully moulted):  $\leq 20$  % (10.00 %).
- Fecundity (mean number of eggs per female and day):  $\geq 15$  (38.4).
- Fertility (mean hatching rate):  $\geq 70$  % (98.81 %).
- Mortality in the reference product treatment was higher than 50 % (100 %, corrected to control).

Comments of zRMS:

The study is considered valid. All validity criteria were met.

- There was no mortality of the larvae in the control group (criterion: less than 20%).
- The average mortality of the larvae in the reference group was 90.00% (criterion: 50-100%).
- The average number of viable eggs laid by the adult control ladybirds per day was 3.3 (criterion: ≥2 fertile eggs per viable female per day).

**Agreed endpoints:**

Study group (application rate) (kg/ha)	Mortality		Reproduction					
	Total (%)	Corrected* (%)	Mean number of eggs laid/day	Eggs hatched/day		Mean number of eggs laid/viable female/day	Mean number of viable eggs laid/viable female/day	Fecundity reduction* [%]
				Mean [No]	Mean [%]			
Control	0	-	108.8	105.0	96.6	3.4	3.3	-
Copper 50% (as Oxychloride) WG								
1.87	5	-	106.07	100.86	95.1	3.2	3.1	6.06
3.75	12.5	-	87.36	69.71	79.7	2.9	2.3	30.30
7.5	55	-	35.93	25.57	71.0	2.4	1.7	48.48
15	75	-	-	-	-	-	-	-
30	100	-	-	-	-	-	-	-
LR <sub>50</sub> mortality	7.61 kg/ha (3812.61 g a.i./ha)		ER <sub>50</sub> fecundity		7.26 kg/ha (3637.26 g a.i./ha)			
NOER mortality	3.75 kg/ha (1879 g a.i./ha)		NOER fecundity		1.87 kg/ha (937g a.i./ha)			
Reference item - TAFGOR (Dimethoate 30% EC)								
0.65 L/ha	90	-	-					

\*: Mortality corrected according to Abbott's formula:  
Corrected mortality [%] = ((Mt - Mc) + (100 - MC)) x 100; Mt = Mortality treated, Mc = Mortality control  
\*\* : based on the mean number of eggs laid/viable female/day obtained for treatments in relation to the control group  
#: reproduction phase was not performed due to mortality higher than 50% in comparison with the control group  
+: statistically significant differences at  $p < 0.05$

**Reference:** KCP 10.3.2.2-04

**Report** “An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on the seven spotted lady bird beetle, *Coccinella septempunctata* (L.)”. XXXX

**Guideline(s):** ESCORT 1 (XXXX, el al. 1994) and ESCORT 2 (XXXX., 2001) IOBC, BART, and EPPO Joint Initiative (XXXX)

**Deviations:** No

**GLP:** Yes

**Acceptability:** Yes

**Duplication (if vertebrate study)** No

## Summary

The aim of the extended laboratory test was to assess the impact of Copper 50% (as Oxychloride) WG on mortality and fecundity of the seven-spotted lady bird, *Coccinella septempunctata* L. (Coleoptera: Coccinellidae). The study was carried out based on Sponsor recommended rates for the test item as the definitive test, i.e. 1.87, 3.75, 7.5, 15 and 30 kg/ha. Four days old larvae were exposed to the test item applied to bean leaf disc as substrate. The duration of the study was 49 days. The total pre-imaginal mor-

tality of *C. septempunctata* during the 21 -day exposure phase was assessed three times per week and larval mortality, pupation as well as adult hatching were recorded. Any behavioural abnormalities of the larvae and abnormal appearance of the larvae, pupae or adults were also noted. The assessment of the reproductive performance started one week after the control beetles started lay eggs. Over a period of two weeks, all eggs laid were collected daily (except on weekends) and checked for fertility (larvae hatch). Pre-imaginal mortality after 21 days of exposure and fecundity of females over a period of two weeks were the endpoints.

## Materials and methods

Test item:	Name: Copper 50% (as Oxychloride) WG Batch number: SCL-160002 Manufacturing date: 15 <sup>th</sup> September, 2019 Expiry date: 14 <sup>th</sup> September, 2021
Reference item:	Name: TAFGOR contains 30% of dimethoate EC Manufacturing date: 22 <sup>th</sup> May, 2020 Expiry date: November 19 <sup>th</sup> November, 2021
Test organism:	Species: the seven-spotted lady bird, <i>Coccinella septempunctata</i> (L.) Coleoptera: Coccinellida Life stage: Four days old of <i>C. septempunctata</i> larvae hatched from the egg clutches were collected on the day before testing from the breeding containers and maintained solitarily overnight with food until larvae were transferred on to dried glass plates. Source: BRF Insectary
Application rates:	control, 1.87, 3.75, 7.5, 15, 30 kg test item/ha
Test design:	Number of treatments: 7 (1-control, 5 treatments and 1- reference item) Number of replications: 4 Number of larvae per treatment/replicate: 40/10
Plant material:	Bean leaf
Experimental conditions:	Temperature: 20.5 - 21.9 °C (exposure phase) 20.7 - 21.8 °C (reproduction phase) Relative humidity: 65 - 78% (exposure phase) 69 - 80% (reproduction phase) Photoperiod: 16 h light: 8 h dark Light intensity: 940 - 1115 lux
Test duration:	49 days: exposure phase - 21 days, pre-reproduction phase - 14 days and reproduction phase - 14 days,
Statistical analysis:	LR <sub>50</sub> and NOER for mortality and the ER <sub>50</sub> and NOER for fecundity were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0.
Validity criteria:	- there was no mortality of the larvae in the control group (criterion: less than 20%). - the average mortality of the larvae in the reference group was 90.00% (criterion: 50-100%). - the average number of viable eggs laid by the adult control ladybirds per day was 3.3 (criterion: $\geq 2$ fertile eggs per viable female per day).

## Findings:

Study group (application)	Mortality		Reproduction				
	Total	Corrected*	Mean	Eggs	Mean	Mean	Fecundity

rate) (kg/ha)	(%)	(%)	number of eggs laid/day	hatched/day		number of eggs laid/viable female/day	number of viable eggs laid/viable female/day	reduction* [%]
				Mean [No]	Mean [%]			
Control	0	-	108.8	105.0	96.6	3.4	3.3	-
Copper 50% (as Oxychloride) WG								
1.87	5	-	106.07	100.86	95.1	3.2	3.1	6.06
3.75	12.5	-	87.36	69.71	79.7	2.9	2.3	30.30
7.5	55	-	35.93	25.57	71.0	2.4	1.7	48.48
15	75	-	-	-	-	-	-	-
30	100	-	-	-	-	-	-	-
LR <sub>50</sub> mortality	7.61 kg/ha (3812.61 g a.i./ha)		ER <sub>50</sub> fecundity		7.26 kg/ha (3637.26 g a.i./ha)			
NOER mortality	3.75 kg/ha (1879 g a.i./ha)		NOER fecundity		1.87 kg/ha (937g a.i./ha)			
Reference item - TAFGOR (Dimethoate 30% EC)								
0.65 L/ha	90	-	-					

\*: Mortality corrected according to Abbott's formula:

Corrected mortality [%] = ((Mt - Mc) + (100 - MC)) x 100; Mt = Mortality treated, Mc = Mortality control

\*\* : based on the mean number of eggs laid/viable female/day obtained for treatments in relation to the control group

#: reproduction phase was not performed due to mortality higher than 50% in comparison with the control group

+: statistically significant differences at  $p < 0.05$

### Conclusions:

On the basis of the obtained results, it can be concluded that Copper 50% (as Oxychloride) WG had no adverse effects on mortality of *Coccinella septempunctata* at rates of 1.87 and 3.75 kg/ha and fecundity at rates on 1.87 kg/ha, respectively.

### A 2.3.2.3 KCP 10.3.2.3 Semi-field studies with non-target arthropod

Not required.

### A 2.3.2.4 KCP 10.3.2.4 Field studies with non-target arthropods

Not required.

### A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

#### A 2.4.1 KCP 10.4.1 Earthworms

##### A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects



<b>Comments of zRMS:</b>	The study is considered valid. All validity criteria were met.		
	<ul style="list-style-type: none"> <li>each replicate produced 66 juveniles (mean) at the end of the experiment - (criterion: <math>\geq 30</math> juveniles by the end of the experiment),</li> <li>the coefficient of variation of reproduction was 21.4% (criterion: <math>\leq 30\%</math>),</li> <li>adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion: <math>\leq 10\%</math>).</li> </ul>		
	<b>Agreed endpoints:</b>		
	<b>Parameter</b>	<b>Value [mg test item/kg dry weight of artificial soil]</b>	<b>Value [mg of copper oxychloride/kg dry weight of artificial soil]</b>
	EC <sub>10</sub>	>1000	>501
	EC <sub>20</sub>	>1000	>501
	EC <sub>50</sub>	>1000	>501
	NOEC (reproduction)	$\geq 1000$	$\geq 501$
	LOEC (reproduction)	>1000	>501
	LC <sub>50</sub>	>1000	>501
	NOEC (survival)	$\geq 1000$	$\geq 501$
	LOEC (survival)	>1000	>501

**Reference  
Report**

KCP 10.4.1.1  
“Copper 50% (as Oxychloride) WG. Earthworm Reproduction Test (*Eisenia andrei*)” XXXX Study code: G/45/18. XXXX

**Guideline(s)  
Deviations**

OECD Guideline No. 222 (2016)  
Yes; Contrary to what had been planned, the study finished in February 2020, and not in November 2019.  
This deviation did not affect the study results.

**GLP  
Acceptability  
Duplication  
(if vertebrate study)**

Yes  
Yes  
No

**Materials and methods**

Test item	Copper 50% (as Oxychloride) WG. SCL – 43298, active substance: copper 50.1% w/w
Artificial soil	10% sphagnum peat, 20% kaolin clay, 70% air-dried quartz sand
Test organism	Earthworm, <i>Eisenia andrei</i> obtained from a standard laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Soil Toxicology
Test design	Test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicates
Concentration of the test item	Definitive test: A control; 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000 mg of the test item/kg of dry weight of the artificial soil.
Test conditions	temperature: 19.8 – 21.9°C; pH at the beginning of the experiment: 5.62 – 5.66; pH at the end of the experiment: 5.50 – 5.55; soil moisture content at the beginning of the experiment: 21.3 – 24.8% (46.8 – 54.5% of the maximum water holding capacity); soil moisture content at the end of the experiment: 21.0 – 22.8% (46.2 – 50.1% of the maximum water holding capacity);

#### Statistical analysis

light-dark cycle: 16h : 8h;  
light intensity at the beginning of the experiment: 708 – 773 lux  
light intensity at the end of the experiment: 728 – 783 lux  
The EC<sub>10</sub>, EC<sub>20</sub>, EC<sub>50</sub>, LC<sub>50</sub> values were determined using probit analysis using linear max. likelihood regression  
The NOEC was calculated using the following tests:  
NOEC (number of juveniles):  
- Shapiro-Wilk's Test on Normal Distribution,  
- Bartlett's Test Procedure on Variance Homogeneity  
- Williams Multiple Sequential t-test Procedure,  
NOEC (survival):  
- Fisher's Exact Binomial Test with Bonferroni Correction.

#### Endpoints

EC<sub>10</sub>, EC<sub>20</sub>, EC<sub>50</sub>, NOEC, LOEC  
LC<sub>50</sub>, NOEC, LOEC

### Results and discussions

After 4 weeks of the experiment, earthworms mortality was observed at the concentration 560 mg/kg dry artificial soil. It was equal to 2.5%. No mortality of earthworms at the concentrations 5.6, 10, 18, 32, 56, 100, 180, 320 and 1000 mg/kg dry artificial soil was observed. Mortality in the control group was not observed. It was equal to 0.0%.

The concentration of the test item causing 50% mortality of the adult earthworms (LC<sub>50</sub>) is above 1000 mg/kg dry weight of artificial soil (501 mg of copper oxychloride/kg dry weight of artificial soil).

After 4 weeks of the experiment, the treated living earthworms did not exhibit any changes in appearance and behaviour.

After the application of the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of artificial soil, the body weight increase was between 1.0 to 11.5%. As for the control group, the body weight increase was equal to 1.1%.

After the application of the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 59 and 90 per replicate. The mean number of juveniles in the control group was equal to 66 per replicate.

After 8 weeks of the experiment, it was concluded that Copper 50% (as Oxychloride) WG had no statistically significant impact on reproduction of the earthworms at concentrations between 5.6 and 1000 mg/kg dry weight of artificial soil.

The concentration of the test item causing a 10% reduction in the number of juveniles produced within the exposure period (EC<sub>10</sub>) is above 1000 mg/kg dry weight of artificial soil (501 mg of copper oxychloride/kg dry weight of artificial soil).

The concentration of the test item causing a 20% reduction in the number of juveniles produced within the exposure period (EC<sub>20</sub>) is above 1000 mg/kg dry weight of artificial soil (501 mg of copper oxychloride/kg dry weight of artificial soil).

The concentration of the test item causing a 50% reduction in the number of juveniles produced within the exposure period (EC<sub>50</sub>) is above 1000 mg/kg dry weight of artificial soil (501 mg of copper oxychloride/kg dry weight of artificial soil).

The highest concentration at which the test item is observed to have no statistically significant effects on reproduction (NOEC) is higher than or equal to 1000 mg/kg dry weight of artificial soil (501 mg of copper oxychloride/kg dry weight of artificial soil).

The lowest concentration at which the test item is observed to have a statistically significant effect on reproduction (LOEC) is higher than 1000 mg/kg dry weight of artificial soil (501 mg of copper oxychloride/kg dry weight of artificial soil).

After 8 weeks of the experiment, the juveniles of earthworms did not exhibit any changes in appearance and behaviour.

### Validity criteria

The results are considered valid because the following criteria were satisfied in the controls:

- each replicate produced 66 juveniles (mean) at the end of the experiment - (criterion:  $\geq 30$  juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 21.4% (criterion:  $\leq 30\%$ ),
- adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion:  $\leq 10\%$ ).

### Conclusion

The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below.

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of copper oxychloride/kg dry weight of artificial soil]
EC <sub>10</sub>	>1000	>501
EC <sub>20</sub>	>1000	>501
EC <sub>50</sub>	>1000	>501
NOEC (reproduction)	$\geq 1000$	$\geq 501$
LOEC (reproduction)	>1000	>501
LC <sub>50</sub>	>1000	>501
NOEC (survival)	$\geq 1000$	$\geq 501$
LOEC (survival)	>1000	>501

#### A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Comments of zRMS:	Accepted as additional information. Please be aware that any supporting literature should be attached also to submission fully as original publication.
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**Reference:** KCP 10.4.1.2-01

**Report** XXXX Addendum to Final Report: A Field Study to Evaluate the Effects of Copper on the Earthworm Fauna in Central Europe: Statistical Analysis of a long term earthworm field study. Testing facility: XXXX. Addendum 1 to Final Report 20031343/G1-NFEw. Date: XX-XX-2019. 23 pp.

**Guideline(s):** Not applicable – Expert opinion on statistical evaluation

**Deviations:** No (not applicable)

**GLP:** Not applicable – Expert opinion on statistical evaluation

**Acceptability:** Yes

**Duplication (if vertebrate study)** Not applicable.

### Executive summary

The assessment of the earthworm population in the long-term earthworm field study 20031343/G1-NFEw was evaluated with different statistical methods, including ANOVA/ANCOVA, pairwise comparisons, principal response curve analysis (PRC), and linear mixed model analysis (LMM).

An analysis of variance (ANOVA, SAS) and an analysis of covariance (ANCOVA, SAS) was calculated and each treatment was compared to the control using a two-sided Dunnett's t-test at the 5% significance level.

Additionally, a common multivariate analysis was run (principal response curve (PRC), CANOCO). The results show the extent and course of development of the earthworm abundance compared to the control taking into account the time factor and random changes. PRCs are a special type of redundancy analysis, which use the time as covariate and the interaction between time and treatment as environmental factor to show differences from the control.

Furthermore, the analysis with a linear mixed model system (LMM, SAS) was performed.

Statistical analysis using a classical approach with ANOVA / ANCOVA test procedures followed by Dunnett's significance tests for the copper treatment data applied in different rates is a robust and sensitive way to analyse for potential significant treatment effects. This procedure is also recommended in the ISO guideline (ISO 11268-3, ISO 2014) and by De Jong et al. (2006) for the statistical evaluation of earthworm field studies.

The PRC analysis involves time in the analysis as a covariate and aims to translate the responses from a large number of taxa into a smaller number of components that can then be interpreted as representing the response of the whole community. Due to the large set of data and the time effect, it makes sense to use this approach to refine the interpretation of effects on the population level. This method has also the advantage of considering information from all species (even low-frequency taxa) found at the field site in the statistical evaluation, in contrast to the other statistical methods that can only be used to analyse taxa with a certain minimum abundance and that are thus typically limited to the analysis of the 2 or 3 dominant species. The PRC analysis is also mentioned as a viable method for statistical analysis in the ISO-11268-3 guideline (ISO 2014). It is also recommended for the analysis of non-target arthropod field studies (De Jong et al. 2010).

The analysis using Linear Mixed Models aims also to include the time factor to the interpretation of the results but its ability to detect significant treatment effects is limited due to the restriction of normal distributed data. Using the Tukey test procedure it produces results comparable to the ANOVA / ANCOVA approach. The use of the LSD test procedure is over conservative due to the expected and observed alpha inflation increasing the overall chance of a Type I error (of falsely claiming an effect, when there is in fact none) to theoretically 14 % instead of 5%. According to Environment Canada (2005), the LSD test should only be used for a small pre-selected selection of all possible comparisons to avoid this inflation of false positives (type I errors).

## A. STUDY DESIGN AND METHODS

Information on the study design and methods is given in the summary of the final study report in the Draft Renewal Assessment Report "Copper Compounds – Volume 3 – B.9 (AS)" (version: May 2018) in chapter B.9.4.1.2.

The statistical methods which were applied for the evaluation of the study are summarized in the table below.

TABLE 9: Statistical test approaches and their significance tests

Test	Significance tests
ANOVA / ANCOVA (copper	Dunnett's t-test ( $\alpha = 0.05$ , two sided), irrespective of outcome of pre-tests on normality and homogeneity of variance

treatment)	
Pairwise comparison (toxic reference)	a) Student t-test ( $\alpha = 0.05$ , two sided). d) Satterthwaite t-test ( $\alpha = 0.05$ , two sided). b) pair-wise U-Test (Wilcoxon) with Exact-Statement ( $\alpha = 0.05$ , two-sided).
Linear mixed model	Tukey Test: advantage is that the test is more robust and that the risk of type 1 errors is low (stays at $\alpha = 5\%$ ). Least Significance Difference Test (LSD Test): advantage to be very sensitive, but the risk of type 1 errors is high (in this test design, $\alpha$ reached $14\%$ ).
CANOCO PRC analysis (copper treatments and toxic reference)	Copper treatment: Permutation test for test item treatments a) Dunnett Test ( $\alpha = 0.05$ ) of PRC scores c) Jonckheere-Terpstra Test ( $\alpha = 0.05$ , two sided) of PRC scores. Toxic reference item: Permutation test for reference treatment a) pooled t-Test. b) pair-wise Mann-Whitney-U Test ( $\alpha = 0.05$ , exact) c) Satterthwaite t-test ( $\alpha = 0.05$ ).

- a) data normally distributed with variance homogeneity  
b) data without normality  
c) data without normality or without variance homogeneity  
d) data normally distributed without variance homogeneity

## B. Explanation of the applied statistical methods

### B.1 ANOVA/ANCOVA

The statistical evaluation using ANOVA and ANCOVA procedures can be seen as the classical approach. This method is recommended in the ISO guideline ISO 11268-3 (ISO, 2014) and by De Jong et al. (2006) for the evaluation of earthworm field studies.

The ANOVA was applied on the pre-treatment counts and weights. The pooled estimate of residual error variance obtained was used to compare each treatment to the control using a two-sided Dunnett's t-test at 5% significance level.

As the test organism is naturally distributed over the field site and that the distribution of earthworms depends amongst others on site-inherent factors (e.g. soil conditions, soil moisture regime, soil compaction etc.) an ANCOVA was selected. These site-inherent factors do not change in this spatial scale at the field site in a short time. Therefore, the spatial distribution of earthworms at trial start had to be considered in order to eliminate these influences. Otherwise, these influences could interfere with possible effects of the test item. The covariance analysis should correct the comparison of the investigated criterion in a way that important influencing variables which do not have any relation to the treatment effect are eliminated. Thus, an ANCOVA could work out more decisively a possible treatment effect.

An analysis of covariance (ANCOVA) was performed on the post-treatment numbers, using the pre-treatment numbers (data before any treatment from the first pre-treatment sampling) as covariate, and on the post-treatment weights, using the pre-treatment weights (data before any treatment from the first pre-treatment sampling) as covariate. Additionally, an analysis of covariance was performed using the replicate dependent numbers and weights as covariates. These analyses were followed by an F-test for significance at the 5 % level to elucidate two questions: first, if the pre-treatment numbers/weights influence the post-treatment number/weights, and second, if the replicates influence the numbers/weights. If the covariate was found to be significant, an analysis of covariance was selected, whereas if the covariate was found to be non-significant an analysis of variance was selected. For both, counts and weights, the pooled estimate of residual error variance obtained from the selected form of analysis (ANOVA or ANCOVA) was used to compare each treatment to the control using a two-sided Dunnett's t-test at the 5% significance level (XXXX).

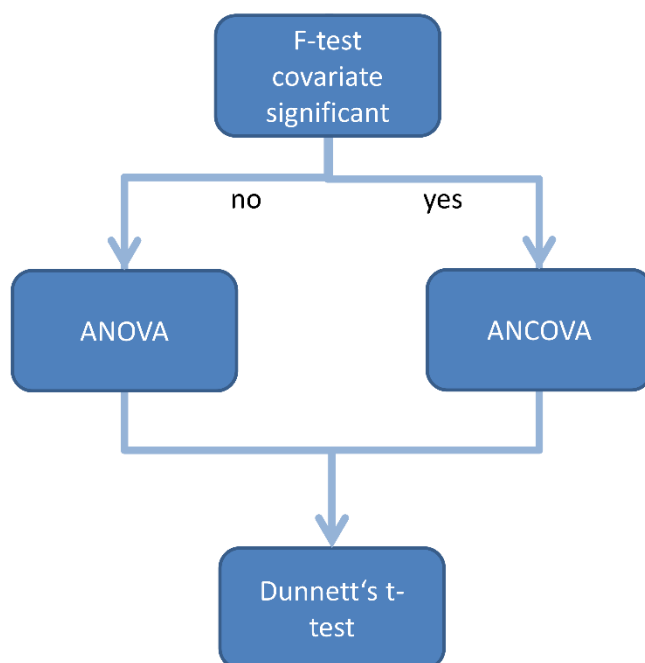


Figure 1: Decision tree for ANOVA/ANCOVA test procedure.

<b>Comments of zRMS:</b>	Accepted as additional information. Please be aware that any supporting literature should be attached also to submission fully as original publication.
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**Reference:** KCP 10.4.1.2-02

**Report** Short-term effects of two fungicides on enchytraeid and earthworm communities under field conditions. Ecotoxicology, XXXX et al., 2018, <https://doi.org/10.1007/s10646-018-1895-7>

Title, author(s), year, report No, document No, Authority registration No

**Guideline(s):** ISO 11268-3, 2014a

**Deviations:** No (not applicable)

**GLP:** Yes (certified laboratory).

**Acceptability:** Yes

**Duplication (if vertebrate study)** Not applicable.

### Executive summary

The purpose of this study was to investigate the patterns of diversity and community structure of earthworms and enchytraeids in response to pesticide exposure (i.e., two commercial formulations) under field conditions. During the procedure the effects of different concentrations of two fungicide formulations, i.e., Cuprafor Micro (composed of 500 g kg<sup>-1</sup> copper oxychloride) and Swing Gold (composed of 50 g l<sup>-1</sup> epoxiconazole and 133 g l<sup>-1</sup> dimoxystrobin) were tested on two families of terrestrial oligochaetes (*Lumbricidae* and *Enchytraeidae*) after 1 month of exposure. The experimental trial consisted of four replicates of 6 treatments (including the control) randomly located. The exposure period was 1 month.

The following endpoints were assessed: density, diversity indices and some ecological and functional traits (i.e., ecological categories for earthworms, proportion of r-strategists for enchytraeids) of each family. They were determined at the end of the test procedure (1 month).

Along with the feeding activity, the enchytraeid density, diversity and communities were not different in the control and the contaminated plots. The copper fungicide (at 0.75 and 7.5 kg Cu ha<sup>-1</sup>) and the treatment with the pesticide mixture (Cuprafor Micro at 0.75 kg Cu ha<sup>-1</sup> and Swing Gold at the recommended dose) did not affect *Oligochaeta* communities compared with the control, except the Shannon index for earthworms in the mixture of both fungicides. Responses of the two annelid families to the tested pesticides were different with higher effects observed on the diversity and the community structure of earthworms compared with enchytraeids. This study allowed detecting early changes on oligochaete populations after pesticide application.

## A. MATERIALS

### 1 Test materials:

**Test item:** Cuprafor Micro  
**Source:** Industrias Químicas del Valles  
**Purity:** 500 g/kg copper oxychloride, Cu<sub>2</sub>Cl(OH)<sub>3</sub>  
**Date of expiry:**

### 2 Test concentrations:

**Test item:** Luvisol, Versailles, France  
**Treatment groups:** Control (T), Cuprafor Micro at 0.75 kg Cu/ha (C1) —equal to one of the three to four copper applications per year in an agronomical context and 7.5 kg Cu/ha (C10).

### 3 Test organisms:

**Species:** *Lumbricidae* and *Enchytraeidae*  
**Source:** Not applicable  
**Age:** Not applicable  
**Feeding:**

### 4 Environmental conditions:

**Air temperature:** mean air temperature of 11.1 °C.  
**Soil temperature:** 15.9 °C in average of all plots  
**Relative humidity:** the cumulated rainfall during the procedure was 54 mm  
**Photoperiod:** Field study  
**Soil:** Luvisol (loam texture (USDA), OM content 11%, pH<sub>H2O</sub> 7.5 and Cutot 25.2 mg kg<sup>-1</sup>)

## B. STUDY DESIGN AND METHODS

### 1. In-life phase: April – May 2016

### 2. Test organism assignment and treatment

This is a field study. The field plots were treated in April 2016 using a manual sprayer (capacity of twenty liters). Before pesticide application, the vegetation was cut as short as possible and the residues were removed with a lawn mower.

### 3. Dose preparation

The pesticides were diluted within eight litres of water and applied homogeneously on each plot. A volume of eight litres of water was also spiked in the control plots.

### 4. Measurements and observations

The climate was oceanic and the temperate and rainfall data were recorded daily at the weather station at 500 m from the study site, La lanterne, Versailles. Soil temperature and moisture were checked at the experimental site to ensure earthworm sampling conditions.

Soil temperature was measured in the field with an electronic digital thermometer at 10 cm of soil depth. For soil moisture, soil cores were sampled with a metal cylinder (5 cm internal diameter) at two soil depths i.e., 10 cm for enchytraeids (i.e., 25.7% in average of all plots) and 20 cm (i.e., 22.6%) for earthworms. Soil moisture was then measured in the laboratory after drying soil samples for 72 h at 105 °C.

One month after pesticide application (i.e., in May 2016), earthworms were extracted by using an expellant solution of allyl isothiocyanate diluted with isopropanol (propan-2-ol) and water to obtain a 0.1 g l<sup>-1</sup> solution. In each of the 24 plots, four sampling points were done. For each sampling point, twice 3.2 L of the expellant solution were poured in a metal frame of 0.16 m<sup>2</sup> surface (0.4 × 0.4 m). After 20 min during which emerging earthworms were retrieved, a block of soil (i.e., 40 × 40 × 20 cm) was excavated in the same squares and the last earthworms were extracted manually.

Earthworms were stored in a 4% formaldehyde solution. Adult, sub-adult individuals and juveniles were identified at the species level. In cases where species-level identification was impossible (e.g., no discrimination characters between juveniles of *Aporrectodea longa* and *Aporrectodea giardi*), juvenile individuals were allocated to species proportionally to the number of adults and sub-adults. All individuals were counted, weighted, and classified according to three ecological categories defined by Bouché (1977), i.e., epigeic, endogeic and anecic.

Enchytraeids were sampled in each plot using a split soil corer (diameter of 5 cm) at 10 cm depth. Each sample was transferred separately into a plastic bag and stored at 4 °C. Enchytraeids were extracted using wet funnel extractors under a light from incandescent light bulbs (40 W). Soil samples were heated up from 17 to 43 °C on their upper surface for 3 h. All individuals were kept in Petri dishes with tap water and counted. Adult and sub-adult individuals were identified at the species level under a light microscope. Not Identified (NI) enchytraeids (e.g., dead specimens) were also counted. The total enchytraeid density, the density of each species and the proportion of r-strategist species were determined.

The global rate and the vertical distribution of the feeding activity were measured and calculated using the bait lamina method (ISO 18311, 2014b).

## 5. Statistics

For each plot, measurement endpoints for the group of annelids (i.e., total density, species density, epigeic, anecic and endogeic density, proportion of r-strategist enchytraeids) were calculated from the sum of the four samples and expressed as density (ind m<sup>-2</sup>). Mean values of each variable were then averaged on the four replicates of each treatment. The differences in diversity indices, i.e., species richness, Shannon and Pielou's evenness, and feeding activity between all treatments were assessed on log transformed data (log(x + 1)) using parametric tests (one way ANOVA followed by a multiple comparison Dunnett test, Hothorn et al. 2017 (multcomp.glt)) if the homogeneity of variance (XXXX 1989) and the normality of residuals (Shapiro test) were respected. Non-parametric tests (Kruskal–Wallis test followed by a multiple comparison *kruskalmc* test, Giraudoux 2017 (*pgirmess.kruskalmc*)) were used if these conditions were not respected. At each multiple post-hoc test, adjusted p-values based on Bonferroni's corrections were applied (XXXX). All statistical analyses were done with n = 4. The level of significance was fixed at p < 0.05. Minimum Detectable Differences (MDDs) were calculated for key species and ecological groups of earthworms according to Brock et al. (2015). They were expressed as percentage (% MDD, 4 replicates) of the control after backtransformation of the data.

The correlations between enchytraeid and earthworm variables, and between annelid variables and feeding activity were tested using Pearson or Kendall coefficient of correlation (for normal and non-normal distribution of the data, respectively). Given the high number of tests, Bonferroni's corrections to p-values were also applied. Relationships between earthworm and enchytraeid communities were assessed in the different treatments using Mantel tests (XXXX) using *vegan* (XXXX) on Bray–Curtis dissimilarity transformation matrices (p < 0.05, 23 permutations).

All analyses were carried out with R statistical software (XXXX).



## II. RESULTS AND DISCUSSION

### A. Enchytraeids

A total of 5637 enchytraeids were collected from all plots. The mean density of total enchytraeids varied from 24,574 (in C10) to 36,733 ind m<sup>-2</sup> (in M) without any significant difference between treatments (Fig. 2). Similarly, no difference was observed for the diversity metrics (i.e., species richness, Shannon index, proportion of r-strategists, and evenness) between plots treated with or without pesticides. Species richness was positively correlated ( $r = 0.348$ ,  $p$ -value = 0.025) with the enchytraeid density (Supplementary table 1). A total of 21 enchytraeid species were identified in the six treatments. The most abundant species was the r-strategist *Enchytraeus buchholzi*, followed by *Fridericia galba* and then *Fridericia is-seli*. The density of each species was not significantly different between treatments (Table 1).

Table 1 Enchytraeid and earthworm densities, diversity metrics and community composition (n = 4,  $\pm$ standard deviation) in the six treatments

Soil faunal group	Variable	T	C1	C10	D1	D10	M
Enchytraeids	Density (ind m <sup>-2</sup> )	29667 $\pm$ 11519	27948 $\pm$ 10458	24574 $\pm$ 5430	29857 $\pm$ 13684	30653 $\pm$ 8163	36733 $\pm$ 14726
	Species richness	9.8 $\pm$ 1	10 $\pm$ 2.5	9.8 $\pm$ 1.7	10.5 $\pm$ 1	9.8 $\pm$ 1.5	10 $\pm$ 2.9
	Shannon index	6.61 $\pm$ 0.75	6.92 $\pm$ 1.38	6.32 $\pm$ 1.07	5.61 $\pm$ 1.21	6.06 $\pm$ 1.26	6.12 $\pm$ 1.91
	Evenness	0.83 $\pm$ 0.06	0.84 $\pm$ 0.03	0.81 $\pm$ 0.01	0.73 $\pm$ 0.07	0.79 $\pm$ 0.09	0.61 $\pm$ 0.11
	r-strategists (%)	25.8 $\pm$ 9.5	26.1 $\pm$ 5.3	33.5 $\pm$ 14.8	33.7 $\pm$ 22.1	32 $\pm$ 8.5	33.7 $\pm$ 20.1
Earthworms	Density (ind m <sup>-2</sup> )	231 $\pm$ 147	211 $\pm$ 84	264 $\pm$ 131	214 $\pm$ 109	127 $\pm$ 46	231 $\pm$ 126
	Biomass (ind m <sup>-2</sup> )	86.8 $\pm$ 32.4	79.5 $\pm$ 28.4	93.6 $\pm$ 34.7	78.9 $\pm$ 27.1	48.3 $\pm$ 14	83.1 $\pm$ 33.9
	Species richness	7 $\pm$ 1.4	5.8 $\pm$ 1	6.3 $\pm$ 1.7	7.8 $\pm$ 1	2.8 $\pm$ 0.5	5.5 $\pm$ 1
	Shannon index	3.07 $\pm$ 0.74	2.45 $\pm$ 0.28	2.48 $\pm$ 0.51	3.11 $\pm$ 0.61	1.17 $\pm$ 0.08	2.13 $\pm$ 0.28
	Evenness	0.52 $\pm$ 0.09	0.51 $\pm$ 0.14	0.55 $\pm$ 0.09	0.57 $\pm$ 0.09	0.16 $\pm$ 0.05	0.44 $\pm$ 0.04
	Epigeic (ind m <sup>-2</sup> )	12.9 $\pm$ 13	10.2 $\pm$ 4.5	7.4 $\pm$ 3.9	8.2 $\pm$ 4.1	0 $\pm$ 0	3.1 $\pm$ 2.9
	Endogeic (ind m <sup>-2</sup> )	184 $\pm$ 124	168 $\pm$ 70	211 $\pm$ 121	178 $\pm$ 94	124 $\pm$ 45	198 $\pm$ 107
	Anecic (ind m <sup>-2</sup> )	34 $\pm$ 13	34 $\pm$ 18	47 $\pm$ 18	28 $\pm$ 17	3 $\pm$ 1	31 $\pm$ 17

Treatments are: control (T), Cuprafor Micro at 0.75 kg Cu ha<sup>-1</sup> (C1) and 7.5 kg Cu ha<sup>-1</sup> (C10), Swing Gold at the (D1) and at ten (D10) times the recommended dose, and a mixture of Cuprafor Micro 0.75 kg Cu ha<sup>-1</sup> and Swing Gold at the recommended dose (M)

### B. Oligochaeta

A total of 3274 earthworms were collected from all plots. The mean density of total earthworms ranged from 127 (in D10) to 264 ind m<sup>-2</sup> (in C10) (Fig. 2) and the mean biomass ranged from 48.3 (in D10) to 93.6 g m<sup>-2</sup> (in C10). Density and biomass of earthworms were highly correlated ( $r = 0.941$ ,  $p < 0.001$ ). No significant difference was observed between treatments (Table 1).

The most abundant species was the endogeic *Aporrectodea icterica* followed by *Lumbricus terrestris* and then *Aporrectodea caliginosa*. The density of endogeic earthworms was not significantly different between treatments. Epigeic, earthworms were found in all treatments with copper. The anecic density was significantly lower in the D10 treatment compared with the control.

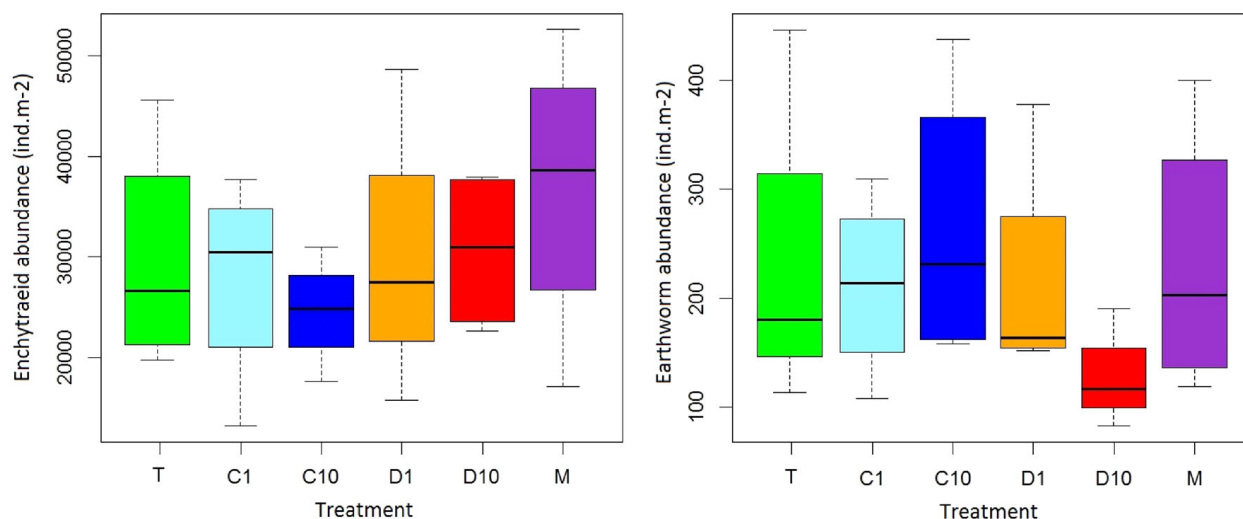


Figure 2. Total densities of enchytraeids (on the left) and earthworms (on the right) per treatment. Treatments are: control (T), Cuprafor Micro at 0.75 kg Cu ha<sup>-1</sup> (C1) and 7.5 kg Cu ha<sup>-1</sup> (C10), Swing Gold® at one (D1) and at ten (D10) times the recommended dose, and a mixture of Cuprafor Micro 0.75 kg Cu ha<sup>-1</sup> and Swing Gold at the recommended dose (M)

### C. Annelid community patterns

No significant correlation was observed between earthworms and enchytraeid species richness, functional groups (ecological categories for earthworms and percentage of r-strategists for enchytraeids). Moreover, mantel tests did not reveal any significant relationship between enchytraeid and earthworm communities in treated and non-treated soils, except a positive relationship between enchytraeid and earthworm communities in C10 ( $r = 0.743$ ,  $p\text{-value} = 0.042$ ). Earthworm and enchytraeid communities were not different in the control (T) and the other treatments.

### D. Feeding activity

The feeding rate varied from 16.7% (in C10) to 24.1% (in C1), but no significant difference was observed between treatments. In the first three centimeters of soil, the feeding rate was higher in C1 compared with the other treatments. No relationship was found between the density of each annelid families and the feeding activity ( $r = 0.088$ ,  $p\text{-value} = 0.551$  for enchytraeids;  $r = -0.227$ ,  $p\text{-value} = 0.123$  for earthworms).

## III. CONCLUSION

### A. Enchytraeids

It was found in the study that enchytraeids were not affected by a pesticide formulation with copper (Cuprafor Micro) whatever the fungicide concentrations.

### B. Earthworms.

Concerning the copper fungicide, no effect was observed on earthworm populations. Based on the results, it can be concluded that copper at the tested concentrations had no short-term impact on Oligochaeta populations.

### C. Feeding activity

In the study, enchytraeid density, diversity and community structure did not change after copper pesticide application. This suggested that no habitat competition occurred between earthworms and enchytraeids.

This study revealed contrasting patterns among annelid groups (i.e., earthworms and enchytraeids) in response to pesticide exposure.

#### D. Overall conclusion

Based on the EFSA's opinion (EFSA PPR Panel 2017), it was considered that effects of tested pesticides on enchytraeids are negligible (i.e., reduction up to 10%) to small (i.e., reduction above 10% and below 35% four weeks after pesticide application) compared with the control. The magnitude of effects is considered to allow for internal recovery of enchytraeids populations and would have no consequences on the provision of ecosystem services (EFSA PPR Panel 2017).

No effects of the copper fungicide were observed concerning earthworm populations at concentrations of 0.75 kg Cu/ha and 7.5 kg Cu/ha. With regard to the EFSA opinion (EFSA PPR Panel 2017), this corresponds to negligible effects (i.e., reduction up to 10%).

<b>Comments of zRMS:</b>	Accepted as additional information. Please be aware that any supporting literature should be attached also to submission fully as original publication.
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**Reference:** KCP 10.4.1.2-03

**Report** Copper toxicity in a natural reference soil: ecotoxicological data for the derivation of preliminary soil screening values. Ecotoxicology, xxxx 2015, DOI 10.1007/s10646-015-1577-7

**Guideline(s):** ISO 11268-2 (2012, *E. andrei*); ISO 16387 (2004, *E. crypticus*)

**Deviations:** No (not applicable)

**GLP:**

**Acceptability:** Yes

**Duplication  
(if vertebrate study)** Not applicable.

#### Executive summary

The main objective of the present work is to generate ecotoxicological data for Cu in different terrestrial species (microorganisms, invertebrates and plants), endpoints and functions, using a Portuguese natural soil (PTRS1). The obtained dataset will be used to derive a SSV range for Cu based on the Assessment Factor approach. Furthermore, metal bioavailability will be taken into consideration in these estimations, by integrating a lab/field factor (formerly named as leaching/aging factor) to the toxicity values achieved in soil-spiking experiments, hence harmonizing with toxic effects in field.

Two replicates per concentration were prepared in the reproduction tests with *E. andrei*, and three in the potworm assay. All the controls were run with five replicates. The exposure period was 1 month.

The following endpoints were assessed: reproduction. They were determined at the end of the test procedure (1 month).

#### A. MATERIALS

##### 1 Test materials:

**Test item:** Copper (II) sulfate pentahydrate ( $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ )  
**Source:** Merck Ensure  
**Purity:**  
**Date of expiry:**

##### 2 Test concentrations:

**Test item:** PTRS1 Soil, non-impacted, non-industrial  
**Source:** Ervas Tenras (Pinhel, Guard, center of Portugal)  
**Conductivity**  $4.8 \pm 0.02 \text{ mS/cm}$

- Organic matter**  $6.5 \pm 0.004\%$   
**Water Holding Capacity (WHC)**  $23.9 \pm 1.84\%$   
**Treatment groups**
- 3 Test organisms:**
- Species** The earthworm *E. andrei* (*Oligochaeta: Lumbricidae*), the potworm *E. crypticus* (*Oligochaeta: Enchytraeidae*)
- Source** From a culture kept in the laboratory, under environmental conditions
- Age** Age-synchronized
- Feeding** The earthworms were fed every 2 weeks with oatmeal previously hydrated with deionized water and cooked for 5 min. The potworms were fed twice a week with a small amount of grounded oat.
- 4 Environmental conditions:**
- Air temperature**
- Soil temperature**
- Relative humidity**
- Photoperiod**
- Soil**

## B. STUDY DESIGN AND METHODS

### 1. In-life phase:

### 2. Test organism assignment and treatment

For the tests with invertebrates, the soil was air-dried and then sieved through a 4 mm sieve, and the 4 mm fraction was defaunated through two freeze–thawing cycles (48 h at -20 °C followed by 48 h at 25 °C), before the beginning of the assays.

The earthworms selected for the test presented a developed clitellum and were pre-weighed to an individual fresh weight between 250 and 600 mg. The organisms were acclimatized in PTRS1 soil for 24 h and then introduced into each test container with 500 g of dry soil, hence totaling ten individual replicates. During the test, the worms were weekly fed with 5 g of defaunated horse manure (see previous subsection) per box.

Ten potworms with 12–14 mm size were introduced in each test vessel containing 20 g of dry soil. The adults were exposed during 28 days. Rolled oats were placed on the soil surface weekly to feed them.

### 3. Dose preparation

The stock solution was prepared with Milli-Q water (hereinafter referred as deionized water), in order to obtain the different ranges of concentrations to be tested (0 mg Cu Kg<sup>-1</sup> soil dw corresponded no the negative controls; Table 1). These concentrations were defined based on the results of range finding tests performed with the test organisms, besides taking into consideration the recommendations set in the OECD (2008) guideline. The amount of deionized water required to adjust soil water content to 45 % of its maximum water holding capacity (WHC<sub>max</sub>) was used to dilute the stock solution for the tests with invertebrates. Prior to the test start, the spiked soil was allowed to equilibrate for 48 h.

In order to discard the potential effect of sulfate on the highest concentrations of copper sulfate, controls with calcium sulfate (CaSO<sub>4</sub>\*2H<sub>2</sub>O) were additionally performed at 2303.2, 366.3 mg of CaSO<sub>4</sub>\*2H<sub>2</sub>O/g soil dw for *Eisenia andrei* and *Enchytraeus crypticus*, respectively.

Table 1. Copper concentrations used in the ecotoxicological assessment (mg Cu/Kg soil dw)

Biochemical parameters	<i>E. andrei</i>	<i>E. crypticus</i>
0.0	0.0	0.0

80.7	35.0	150.0
96.9	40.2	172.5
116.2	46.2	198.3
139.5	60.1	238.0
167.4	78.2	285.6
200.9	101.6	342.7
241.1	132.2	411.3
289.3	171.8	493.6
347.2	223.4	592.3
416.6	256.9	681.1
500.0	295.4	783.3
600.0	339.7	900.8

#### 4. Measurements and observations

Adult earthworms were removed from the test containers after 28 days of exposure. No mortality of adult organisms was recorded during this period. The produced cocoons were left in the soil until 56 days of experiment. At the end of this period, the juveniles from each test container were counted after making them float in a water bath at 50–60 °C. At the end of the test, the potworms were killed with alcohol, colored with Bengal red and counted according to the Ludox Flotation Method.

#### 5. Statistics

The number of juveniles produced by earthworms and potworms were compared to the respective controls by a one-way ANOVA (SigmaPlot 11.0 for Windows). The Kolmogorov–Smirnov test was applied to check data normality, whereas homoscedasticity of variances was checked by the Levene’s test. Whenever the ANOVA assumptions were not met, a Kruskal–Wallis analysis was performed (SigmaPlot 11.0 for Windows). If statistically significant differences were determined, the post hoc Dunnett’s (for parametric one-way ANOVA) or the Dunn’s test (for non-parametric ANOVA) were carried out to perceive which concentrations were significantly different from the respective control. The noobserved-effect-concentration (NOEC) and low-observedeffect-concentration (LOEC) values were determined based on the outcomes of the post hoc tests. The metal concentration producing a 20 % (EC20) and a 50 % (EC50) reduction in the tested endpoints was calculated after fitting the data to a logistic model for the reproduction of invertebrates, using the STATISTICA software version 7.0.

## II. RESULTS AND DISCUSSION

A 100 % survival was recorded for *E. andrei* adults in all treatments. No mortality was observed for *E. crypticus* adults in the control. However, an average of 16 % mortality was obtained in the lowest tested concentration, while it was between 70 and 100 % in higher Cu concentrations (411.3–900.8 mg Cu/Kg soil dw).

A significant impairment on the reproduction of all invertebrates was recorded under Cu exposure ( $F = 11.3$ , d.f. = 16,12,  $p < 0.05$  for *E. andrei*;  $F = 15.9$ , d.f. = 22,12,  $p < 0.05$  for *E. crypticus*). The LOEC for *E. andrei* and *E. crypticus* was 132.2 and 150.0 mg Cu/Kg soil dw, respectively, and no juveniles were produced by potworms above 681.1 mg/Kg-1 soil dw (Fig. 2; Table 2).

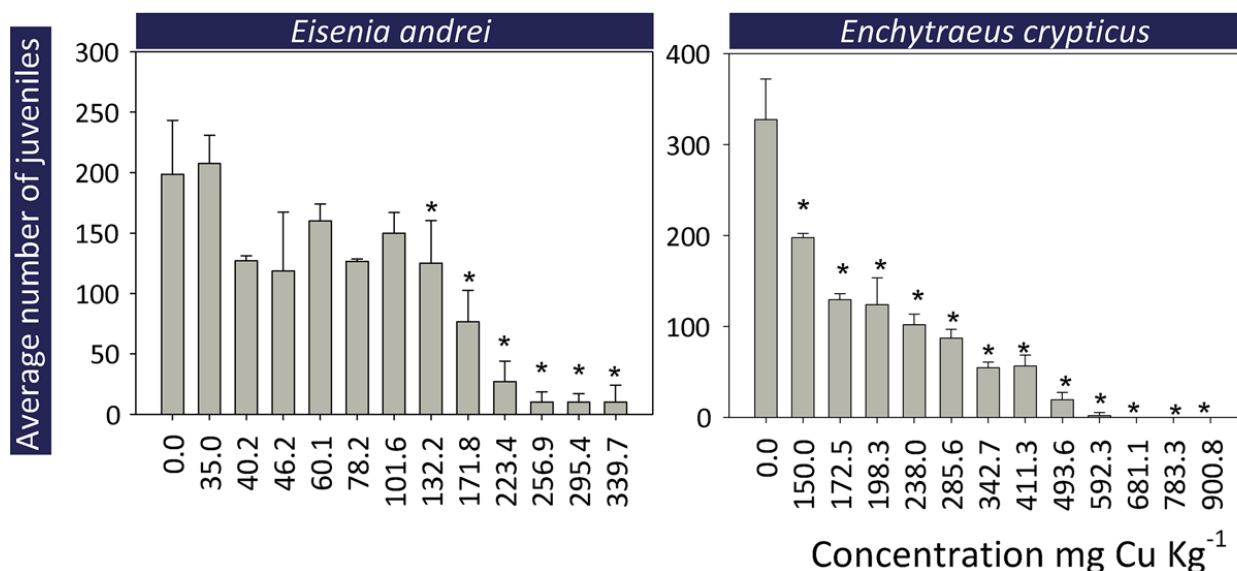


Fig. 1 Reproductive output of *Eisenia andrei*, *Enchytraeus crypticus* exposed to the natural soil PTRS1 spiked with increasing copper concentrations. Error bars indicate the standard error and asterisks sign out significant differences between the treatment and the control (0.0 mg Cu Kg/dw) (p<0.05)

### III. CONCLUSION

The results accomplished in this study strengthened the toxicity of Cu reported in the literature for different soil organisms and endpoints. The estimated EC20 (65.8 to 150.0 mg Kg<sup>-1</sup> soil dw) and EC50 (130.9–191.6 mg/Kg soil dw) values were similar for both invertebrates (Table 2). But based on the latter point estimate, the species can be ranked along a decreasing sensitivity order: *E. andrei*, *E. albidus*. This ranking is in agreement with previous studies, pointing out the influence of different exposure routes on metal uptake by soil invertebrates. In this context, soft-body invertebrates are normally exposed to metals through pore-water and dietary intake. Consequently, Cu toxicity to soft-body invertebrates tends to be more pronounced.

Table 2. Toxicity data obtained for copper (mg Cu/ Kg soil dw) in PTRS1 soil on invertebrates.

Test organism	Test duration	NOEC	LOEC	EC20	EC50
<i>Eisenia andrei</i>	56 days	101.6	132.2	73 (34.94 – 111.14)	130.9 (91.69 – 170.14)
<i>Enchytraeus crypticus</i>	28 days	<150	150	150	165.1 (146.84 – 183.27)

than earthworms)

#### A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:

The study is considered valid. All validity criteria were met.

- mean adult mortality: 1.3% (criterion:  $\leq 20\%$ ),
- the mean number of juveniles per vessel at the end of the test: 549.3 (criterion:  $\geq 100$  juveniles at the end of the test),
- the coefficient of variation calculated for the number of juveniles: 17.4 (criterion:  $\leq 30\%$ ).

Agreed endpoints:

LC<sub>10</sub>, LC<sub>20</sub>, LC<sub>50</sub> and NOEC values

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of pyrimethanil /kg dry weight of the artificial soil]
LC <sub>10</sub>	>1000	>501
LC <sub>20</sub>	>1000	>501
LC <sub>50</sub>	>1000	>501
NOEC	$\geq 1000$	$\geq 501$

EC<sub>10</sub>, EC<sub>20</sub>, EC<sub>50</sub> and NOEC values

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of pyrimethanil /kg dry weight of the artificial soil]
EC <sub>10</sub>	116.902	58.567
EC <sub>20</sub>	>1000	>502.0
EC <sub>50</sub>	>1000	>502.0
NOEC	320	160.32

<b>Reference:</b>	KCP 10.4.2.1 - 01
<b>Report</b>	“Copper 50% (as Oxychloride) WG: Collembolan ( <i>Folsomia candida</i> ) reproduction test”. XXXX
<b>Guideline(s):</b>	OECD Guideline No. 232 (2016)
<b>Deviations:</b>	Yes. At the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016). Physiological or pathological symptoms or distinct changes in behavior were not described. The study finished on March 2019, not on December 2018, as it was planned. These deviations did not affect the study results.
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	No

#### Materials and methods

Test item:	Copper 50% (as Oxychloride) WG; Batch Number SCL- 43298; active substance: Copper oxychloride – 50.1% w/w
Test species:	<i>Folsomia candida</i> obtained from a standard laboratory culture at the Institute of

	XXXX. The collembolans used in the study were 9 – 12 days old.
Soil:	5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of collembolans: 10 / replicate Test duration: 28 days
Application rates:	Control, 5.6; 10.0; 18.0, 32.0; 56.0; 100.0; 180.0; 320.0; 560.0; and 1000.0 mg of the test item/kg of dry weight of the artificial soil
Test conditions:	Temperature: 19.0 – 22.0 °C; humidity: 12.2 – 14.2% (41.11 – 47.84% of the maximum water holding capacity); lighting: 16 h light : 8 h dark; light intensity: 550 – 650 lux; pH: 5.53 – 6.05
Statistical analysis:	EC <sub>10</sub> , EC <sub>20</sub> , EC <sub>50</sub> , LC <sub>10</sub> , LC <sub>20</sub> , and LC <sub>50</sub> - a probit analysis NOEC (number of juveniles): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - Williams Multiple Sequential t-test Procedure NOEC (survival) – Fisher's Exact Binomial Test with Bonferroni Correction
Endpoints:	EC <sub>10</sub> , EC <sub>20</sub> , EC <sub>50</sub> , NOEC, LOEC LC <sub>10</sub> , LC <sub>20</sub> , LC <sub>50</sub> , NOEC, LOEC

## Results and Conclusions

Mortality at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil ranged from 0 to 10%. As for the control group, it was equal to 1.3%.

The concentration of the test item causing a 50% mortality of adults within the exposure period (LC<sub>50</sub>) is above 1000 mg/kg dry weight of the artificial soil (501 mg of copper oxychloride/kg dry weight of the artificial soil).

The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

### LC<sub>10</sub>, LC<sub>20</sub>, LC<sub>50</sub> and NOEC values

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of pyrimethanil /kg dry weight of the artificial soil]
LC <sub>10</sub>	>1000	>501
LC <sub>20</sub>	>1000	>501
LC <sub>50</sub>	>1000	>501
NOEC	≥1000	≥501

After the exposure of collembolans to the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 403.3 – 705.0 per replicate. As for the control group, the number of juveniles was equal to 549.3 per replicate.

The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

### EC<sub>10</sub>, EC<sub>20</sub>, EC<sub>50</sub> and NOEC values

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of pyrimethanil /kg dry weight of the artificial soil]
EC <sub>10</sub>	116.902	58.567
EC <sub>20</sub>	>1000	>502.0
EC <sub>50</sub>	>1000	>502.0
NOEC	320	160.32

<b>Comments of zRMS:</b>	The study is considered valid. All validity criteria were met.
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	<ul style="list-style-type: none"> <li>mean adult mortality; 2.5% (criterion: <math>\leq 20\%</math>),</li> <li>the mean number of juveniles per replicate at the end of the test: 129.63 (criterion: <math>\geq 50</math> juveniles at the end of the test),</li> <li>the coefficient of variation for the number of juveniles: 2.86 (criterion: <math>\leq 30\%</math>).</li> </ul>	
	<b>Agreed endpoints:</b>	
	<b>Survival of the adult females (<i>Hypoaspis aculeifer</i>).</b>	
	<b>Parameter</b>	<b>Value</b>
		<b>[mg test item/kg dry soil] [mg of the active substance/kg dry soil]</b>
	LC <sub>10</sub>	> 1000.0 (n.d.) > 501 (n.d.)
	LC <sub>20</sub>	> 1000.0 (n.d.) > 501 (n.d.)
	LC <sub>50</sub>	> 1000.0 (n.d.) > 501 (n.d.)
	NOEC	$\geq 1000.0$ $\geq 501$
	LOEC	> 1000.0 > 501
	n.d – not determined	
	<b>Reproduction of the predatory mites (<i>Hypoaspis aculeifer</i>)</b>	
	<b>Parameter</b>	<b>Value</b>
		<b>[mg test item/kg dry soil] [mg of the active substance/kg dry soil]</b>
	EC <sub>10</sub>	> 1000.0 (n.d.) > 501 (n.d.)
	EC <sub>20</sub>	> 1000.0 (n.d.) > 501 (n.d.)
	EC <sub>50</sub>	> 1000.0 (n.d.) > 501 (n.d.)
	NOEC	555.56 278.33
	LOEC	> 1000.0 > 501
	n.d – not determined	

**Reference:** KCP 10.4.2.1 - 02

**Report** “Effect of Copper oxychloride 50% WG on the reproductive output of the predatory soil mite *Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae)* in artificial soil”. XXXX

**Guideline(s):** OECD Guideline No. 226 (2016)

**Deviations:** No

**GLP:** Yes

**Acceptability:** Yes

**Duplication (if vertebrate study)** No

## Materials and methods

**Test item:** Copper oxychloride 50% WG; Batch code: SCL-160002; a.i.: copper 50.1% w/w

**Test species:** *Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae)* (adult female mites) obtained from synchronized cohort. Mites were introduced 33 days after the start of the egg-laying period for synchronisation. The organisms were obtained from BRF Insectary.

**Soil:** 5 % peat, 20% kaolin clay and 75% air-dried industrial sand

**Study design:** Adult females were exposed to the test item in artificial soil. After 14 days, the surviving individuals were extracted from the test units. The number of adult mites and juveniles were determined separately.  
4 replicates/concentration + 10 mites/replicate.

	Test duration: 14 days + 48 hours (extraction)
Application rates:	a control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg test item/kg soil dry weight.
Test conditions:	soil pH 5.98 to 6.31 at test initiation and pH 6.09 to 6.40 at test termination; soil moisture content at test initiation 20.71% to 21.30% (51.87 – 52.52% of the WHCmax), 19.65 – 20.75% (49.69 – 51.92% of the WHCmax) at test termination; temperature during exposure: 21.2 °C to 21.9 °C; 16:8 light:dark cycles (long day conditions), and light intensity 455 lux to 520 lux.
Statistical analysis:	The endpoints values for mortality and reproduction were determined by using a Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviation were calculated using validated Excel sheets.
Endpoints:	EC <sub>10</sub> , EC <sub>20</sub> , EC <sub>50</sub> , LOEC and NOEC LC <sub>10</sub> , LC <sub>20</sub> , LC <sub>50</sub> , LOEC and NOEC

## Results and Conclusions

After the application of the test item at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of soil, survival of the predatory mites was between 100.0% and 92.5%. Survival of the control group was 97.5 %.

Summary of the results are presented in Tables below.

### Summary of the results – number of adult mites and juveniles.

Concentration [mg/kg dry weight of soil]	Adult mites		Number of juveniles (mean)
	Number of tested mites	Number of living mites after 14 days	
Control	80	78	129.63
5.04	40	40	129.00
9.07	40	40	128.25
16.33	40	39	127.75
29.40	40	40	127.25
52.92	40	39	126.75
95.26	40	38	126.25
171.47	40	38	125.50
308.64	40	36	124.50
555.56	40	38	122.50
1000.00	40	36	118.50

### Summary of the results – endpoint values for the impact of the test item on survival of the adult females (*Hypoaspis aculeifer*).

Parameter	Value	
	[mg test item/kg dry soil]	[mg of the active substance/kg dry soil]
LC <sub>10</sub>	> 1000.0 (n.d.)	> 501 (n.d.)
LC <sub>20</sub>	> 1000.0 (n.d.)	> 501 (n.d.)
LC <sub>50</sub>	> 1000.0 (n.d.)	> 501 (n.d.)
NOEC	≥ 1000.0	≥ 501
LOEC	> 1000.0	> 501

n.d – not determined

### Summary of the results – endpoint values for the impact of the test item on reproduction of the predatory mites (*Hypoaspis aculeifer*).

Parameter	Value	
	[mg test item/kg dry soil]	[mg of the active substance/kg dry soil]
EC <sub>10</sub>	> 1000.0 (n.d.)	> 501 (n.d.)
EC <sub>20</sub>	> 1000.0 (n.d.)	> 501 (n.d.)
EC <sub>50</sub>	> 1000.0 (n.d.)	> 501 (n.d.)
NOEC	555.56	278.33
LOEC	> 1000.0	> 501

n.d – not determined

#### A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

#### A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	<p>The study is considered valid. All validity criteria were met.</p> <p><b>Agreed endpoints:</b></p> <p>On the basis of the results, it was concluded that Copper 50% (as Oxychloride) WG at the concentration corresponding to the PEC: 53.32 mg of test item/kg of dry weight soil (i.e. 26.71 mg of copper oxychloride/kg of dry weight soil) and upper PEC: 133.30 mg of test item/kg of dry weight soil (i.e. 66.78 mg of copper oxychloride/kg of dry weight soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.</p>
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Reference:	KCP 10.5-01
Report	“Copper 50% (as Oxychloride) WG. Soil Microorganisms: Nitrogen Transformation Test”. XXXX January, 2020, G/44/18
Guideline(s):	OECD Guideline No. 216 (2000) / EU Method C.21.
Deviations:	Yes. The study finished in January 2020, not in November 2019, as it was planned. The deviations did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

#### Materials and methods

Test item:	
Description:	Copper 50% (as Oxychloride) WG
Production batch:	SCL- 43298
Active ingredients content:	copper oxychloride – 50.1% w/w
Vehicle and control:	Distilled water
Test system:	
Species:	Microorganisms
Source:	Agricultural soil collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.

#### Experimental conditions:

Temperature: 20.9 – 22.0°C  
Humidity: 46.2% – 52.1% MWHC incubation in darkness.

#### Study design and methods

##### Test design and treatment:

Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days.

##### Concentrations of the test item:

control, PEC: 53.32 mg of test item/kg of dry weight soil (i.e. 26.71 mg of copper oxychloride/kg of dry weight soil), upper PEC: 133.30 mg of test item/kg of dry weight soil (i.e. 66.78 mg of copper oxychloride/kg of dry weight soil).

#### Results

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC and upper PEC did not exceed 25% on 28 day of analysis.

#### Deviations from the control based on nitrates formation rate for selected time interval [%]:

Time interval [d]	PEC	5 x PEC
0 - 7	16.5	5.9
0 - 14	19.2	-2.6
0 - 28	-0.9	-14.5

#### Validity

The coefficients of variation (CV) in the control group were 2.66, 9.12, 7.38 and 6.82%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than  $\pm 15\%$ .

#### Conclusion

On the basis of the results, it was concluded that Copper 50% (as Oxychloride) WG at the concentration corresponding to the PEC: 53.32 mg of test item/kg of dry weight soil (i.e. 26.71 mg of copper oxychloride/kg of dry weight soil) and upper PEC: 133.30 mg of test item/kg of dry weight soil (i.e. 66.78 mg of copper oxychloride/kg of dry weight soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

<b>Comments of zRMS:</b>	<p>The study is considered valid. All validity criteria were met.</p> <p><b>Agreed endpoints:</b></p> <p>On the basis of the results, it was concluded that Copper 50% (as Oxychloride) WG at the concentrations corresponding to PEC: 53.32 mg of test item/kg of dry weight soil (i.e. 26.71 mg of copper oxychloride/kg of dry weight soil) and upper PEC: 133.30 mg of test item/kg of dry weight soil (i.e. 66.78 mg of copper oxychloride/kg of dry weight soil) did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.</p>
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<b>Reference:</b>	KCP 10.5-02
<b>Report</b>	“Copper 50% (as Oxychloride) WG. Soil Microorganisms: Carbon Transformation Test. XXXX, January, 2020, G/43/18.
<b>Guideline(s):</b>	OECD Guideline No. 217 (2000) / EU Method C.22
<b>Deviations:</b>	<p>Deviations from OECD Guideline No. 217 (2000), EU Method C.22: The predicted environmental concentration (PEC) was calculated assuming 1 cm of the soil depth according to the German conditions for the active substances with the mobility in soil K<sub>Foc</sub> &gt; 500 mL/g. Thus, the applied soil depth is a deviation from OECD Guideline No. 217 (2000), the EU Method C.22 where the PEC is calculated by using 5 cm of the soil depth (chapter 3.3.).</p> <p>Deviations from the Study Plan:</p> <p>The study finished in January 2020, not in November 2019, as it was planned. These deviations did not affect the results of the study.</p>
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	-

## Materials and methods

### Materials

<b>Test item:</b>	
Description:	Copper 50% (as Oxychloride) WG
Production batch:	SCL- 43298
Active ingredients content:	copper oxychloride – 50.1% w/w

**Test system:**

**Species:**

**Source:**

**Microorganisms**

Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.

**Experimental conditions:**

**Temperature:**

20.9 – 22.0°C

**Humidity:**

48.1 – 54.5% of MWHC

**Air changes:**

-

**Light and photoperiod:**

Dark (24/24h)

**Study design and methods**

**Test design and treatment:**

3 portions of soil: one control group and two groups containing the test item weighing 1500 g each. Every portion was divided into three replicates weighing 500 g each. Test duration: 28 days.

**Concentrations of the test material:**

control, PEC: 53.32 mg of test item/kg of dry weight soil (i.e. 26.71 mg of copper oxychloride/kg of dry weight soil), upper PEC: 133.30 mg of test item/kg of dry weight soil (i.e. 66.78 mg of copper oxychloride/kg of dry weight soil).

**Statistics:**

In order to determine significance in the soil respiration rate of differences between the control and the treated groups, Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity and Williams Multiple Sequential t-test Procedure were used.

**Results**

The difference in the soil respiration rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC soil and upper PEC did not exceed 25% on 28 day of analysis.

Oxygen (O<sub>2</sub>) consumption - deviations from the control [%]:

Day	PEC	5 x PEC
0	-11.1	-2.0
7	5.5	7.8
14	3.5	-0.2
28	4.8	5.1

“-“ the value of the oxygen consumption higher than the one obtained for the control group

**Conclusion**

On the basis of the results, it was concluded that Copper 50% (as Oxychloride) WG at the concentrations corresponding to PEC: 53.32 mg of test item/kg of dry weight soil (i.e. 26.71 mg of copper oxychloride/kg of dry weight soil) did not exceed 25% on 28 day of analysis.

Comments of zRMS:	The study is considered valid. All validity criteria were met.						
	- The seedling emergence in the control (validity criterion: at least 70%) was as follows: 100.0% – soybean, 95.2% – corn, 100.0% – pea, 100.0% – white mustard, 100% – radish, 95.2% – tomato,, - the mean survival of the emerged control seedlings was 100% for sun-flower, pea, cabbage, onion and oats (validity criterion: at least 90%); - the control seedlings did not exhibit any visible phytotoxic symptoms - environmental conditions for all plants belonging to the same species were identical.						
	According to the OECD 227, “one to two corn, soybean, tomato, cucumber, or sugar beet plants per 15 cm container; three rape or pea plants per 15 cm container; and 5 to 10 onion, wheat, or other small seeds per 15 cm container are recommended.”						
	In the study for each treatment, 7 replicates, with 3 seeds each, were prepared Pots with a diameter of 16 cm were used for the study. In ZRMS opinion the shape of the used pots resulting in a sufficient volume to accommodate seedling growth for the duration of the test.						
	Agreed endpoints:						
Copper Oxychloride 50% WGS: ER <sub>50</sub> , and NOER values.							
Endpoint value	Soybean <i>Glycine max</i>	Corn <i>Zea mays</i>	Pea <i>Pisum sativum</i>	White mustard <i>Sinapis alba</i>	Radish <i>Raphanus sativus</i>	Tomato <i>Solanum, lycopersicon</i>	
Plant number at the end of the experiment							

ER <sub>50</sub>	Kg/h a	13.88	14.56	14.11	13.57	14.11	13.27
	g/ha	6953.9	7294.6	7069.1	6798.6	7069.1	6648.3
NOER	Kg/h a	4	4	4	4	4	4
	g/ha	2004	2004	2004	2004	2004	2004
<b>Shoot length (plants without roots)</b>							
ER <sub>50</sub>	Kg/h a	14.47	13.88	13.38	13.73	13.62	14.74
	g/ha	7249.5	6953.9	6703.4	6878.7	6823.6	7384.7
NOER	Kg/h a	4	4	4	4	4	4
	g/ha	2004	2004	2004	2004	2004	2004
<b>Plant dry weight (plants without roots)</b>							
ER <sub>50</sub>	Kg/h a	15.05	14.18	13.52	12.94	13.24	13.92
	g/ha	7540.1	7104.2	6773.5	6482.9	6633.2	6973.9
NOER	Kg/h a	4	4	4	4	4	4
	g/ha	2004	2004	2004	2004	2004	2004

### Phytotoxicity effects:

#### Soybean

Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
2	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
4	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
8	R1	0	2.86	N, C	0	7.86	N, C, Ld
	R2	5			10		
	R3	0			0		
	R4	5			20		
	R5	0			0		
	R6	10			20		
	R7	0			5		
16	R1	10	7.14	N,C,Ld	20	13.57	N, C, Ld, SD, W
	R2	0			0		
	R3	15			25		
	R4	0			0		
	R5	5			15		
	R6	10			20		
	R7	10			15		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W: Wilting  
\*: lack of plants

#### Corn:



Application rateKg/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms		
0	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
1	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
2	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
4	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
8	R1	10	N,C	15	7.14	N,C,Ld	
	R2	0		0			
	R3	0		0			
	R4	5		10			
	R5	0		0			
	R6	5		10			
	R7	10		15			
16	R1	0	N,C, Ld, Sd	0	10.71	N,C, Ld, Sd, W	
	R2	10		20			
	R3	0		0			
	R4	15		25			
	R5	10		15			
	R6	0		5			
	R7	5		10			

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne:Necrosis, W-Wilting  
\*: lack of plants

#### Pea:

Application rateKg/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms		
0	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
1	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
2	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
4	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
8	R1	0	N, C	10	7.86	N, C, Ld	
	R2	5		0			
	R3	0		0			
	R4	10		20			
	R5	0		0			
	R6	5		10			
	R7	10		15			
16	R1	0	N, C, Ld, Sd	0	10	N, C, Ld, Sd, Ne	
	R2	10		20			
	R3	0		0			
	R4	20		25			
	R5	0		5			
	R6	15		20			
	R7	0		0			

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne:Necrosis, W-Wilting  
\*: lack of plants

#### White mustard:

Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms		
0	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
1	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
2	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
4	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
8	R1	5	N, C	10	8.57	N, C, Ld	
	R2	0		0			
	R3	10		20			
	R4	0		0			
	R5	0		10			
	R6	10		20			
	R7	0		0			
16	R1	5	N, C, Ld	10	11.43	N, C, Ld, Sd, W	
	R2	10		20			
	R3	10		15			
	R4	0		0			
	R5	15		25			
	R6	0		0			
	R7	0		10			

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne:Necrosis, W-Wilting  
\*: lack of plants

## Radish:

Application rateKg/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms		
0	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
1	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
2	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
4	R1	0	N	0	0.00	N	
	R2	0		0			
	R3	0		0			
	R4	0		0			
	R5	0		0			
	R6	0		0			
	R7	0		0			
8	R1	10	N,C	15	7.14	N,C,Ld	
	R2	0		0			
	R3	0		0			
	R4	5		10			
	R5	0		0			
	R6	5		10			
	R7	10		15			
16	R1	0	N,C, Ld, Sd	0	11.43	N,C, Ld, Sd, W	
	R2	10		25			
	R3	0		0			
	R4	15		25			
	R5	10		15			
	R6	0		5			
	R7	5		10			

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne:Necrosis, W-Wilting  
\*: lack of plants

**Tomato:**

Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]	Symptoms		Mean effect [%]	Symptoms	
0	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
1	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
2	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
4	R1	0	0.00	N	0	0.00	N
	R2	0			0		
	R3	0			0		
	R4	0			0		
	R5	0			0		
	R6	0			0		
	R7	0			0		
8	R1	0	4.29	N, C	0	7.86	N, C, Ld
	R2	5			10		
	R3	0			0		
	R4	10			20		
	R5	0			0		
	R6	5			10		
	R7	10			15		
16	R1	0	6.43	N, C, Ld, Sd	0	10	N, C, Ld, Sd, Ne
	R2	10			20		
	R3	0			0		
	R4	20			25		
	R5	0			5		
	R6	15			20		
	R7	0			0		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation, Ne: Necrosis, W-Wilting  
\*: lack of plants

**Reference:**

KCP 10.6.2-01

**Report:**

“Effect of Copper 50% (as Oxychloride) WG on Seedling Emergence and Seedling Growth of terrestrial plants”.  
xxxx, 7545/2020  
XXXX

**Guideline(s):**

OECD No. 208 (2006)

**Deviations:**

Deviation from the Study Plan:  
The study finished in August 2020, not in July 2020, as it had been planned.  
This deviation did not affect the study results.

**GLP:**

Yes

**Acceptability:**

Yes

**Duplication  
(if vertebrate study):**

No

**Summary**

The study, aimed at evaluating the effect of Copper 50% (as Oxychloride) WG on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 5 dicotyledonous and 1 monocotyledonous species. The test item was sprayed onto the soil surface. For each species, five application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots 3 seeds/pot, i.e. 21 seeds/application rate (7 pots/application rate). The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence every day and visual phytotoxicity (after 7 and 14 days). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60°C, and weighed.

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER<sub>10</sub>, ER<sub>25</sub>, ER<sub>50</sub>, and NOER.

### Material and methods

Test item:	Copper 50% (as Oxychloride) WG Batch number: SCL-160002 Production date: September 15, 2019 Expiry date: September 14, 2021
Test species::	soybean ( <i>Glycine max</i> ) pea ( <i>Pisum sativum</i> ), tomato ( <i>Solanum Lycopersicon</i> ), radish ( <i>Raphanus sativus</i> ), white mustard ( <i>Sinapis alba</i> ), corn ( <i>Zea mays</i> ).
Test design:	Number of rates: 5 application rates + control Number of replicates: 7 Number of seeds: 21 The total number of plants per application rate: 21 Test termination: 14 days after the emergence of 50% of the control seedlings
Test duration:	14 days after 50 % emergence of the control seedlings.
Application rates:	control, 1, 2, 4, 8 and 16 Kg/ha (i.e. 501, 1002, 2004, 4008 and 8016 g of copper oxychloride/ha)
Soil:	sandy loam
Endpoints:	ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> , NOER
Test conditions:	Temperature: 21.7 – 22.8°C Humidity: 58.2 – 69.4% Photoperiod – 16h day:8h night Light intensity: 343 – 400 µE/m <sup>2</sup> /s Carbon dioxide concentration: 346– 365 ppm
Statistical analysis:	ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> and NOER values were determined by using a probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0, respectively.
Validity criteria:	- the seedling emergence in the control (validity criterion: at least 70%) was as follows: 100.0% – soybean, 95.2% – corn, 100.0% – pea, 100.0% – white mustard, 100% – radish,

95.2% – tomato,,

- the mean survival of the emerged control seedlings was 100% for sunflower, pea, cabbage, onion and oats (validity criterion: at least 90%);

- the control seedlings did not exhibit any visible phytotoxic symptoms

- environmental conditions for all plants belonging to the same species were identical.

The number of seeds per pot and the total number of seeds per application rate were as follows:

- Soybean - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Corn - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Radish - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Pea - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- White mustard - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Tomato- 3 seeds/pot – 21 seeds/application rate (7 pots/application rate).

## Findings

### Copper Oxchloride 50% WGSL: ER<sub>50</sub> and NOER values.

Endpoint value		Soybean <i>Glycine max</i>	Corn <i>Zea mays</i>	Pea <i>Pisum sativum</i>	White mustard <i>Sinapis alba</i>	Radish <i>Raphanus sativus</i>	Tomato <i>Solanum, lycopersicon</i>
<b>Plant number at the end of the experiment</b>							
ER <sub>50</sub>	Kg/ha	13.88	14.56	14.11	13.57	14.11	13.27
	g/ha	6953.9	7294.6	7069.1	6798.6	7069.1	6648.3
NOER	Kg/ha	4	4	4	4	4	4
	g/ha	2004	2004	2004	2004	2004	2004
<b>Shoot length (plants without roots)</b>							
ER <sub>50</sub>	Kg/ha	14.47	13.88	13.38	13.73	13.62	14.74
	g/ha	7249.5	6953.9	6703.4	6878.7	6823.6	7384.7
NOER	Kg/ha	4	4	4	4	4	4
	g/ha	2004	2004	2004	2004	2004	2004
<b>Plant dry weight (plants without roots)</b>							
ER <sub>50</sub>	Kg/ha	15.05	14.18	13.52	12.94	13.24	13.92
	g/ha	7540.1	7104.2	6773.5	6482.9	6633.2	6973.9
NOER	Kg/ha	4	4	4	4	4	4
	g/ha	2004	2004	2004	2004	2004	2004

**Comments of zRMS:** The study is considered valid. All validity criteria were met.

The following validity criteria were met:

- the seedling emergence (validity criterion: at least 70%) was as follows:
  - 100% – soybean,
  - 100% – corn,
  - 100% – pea,
  - 100%– radish,
  - 100%– white mustard,
  - 100%– tomato,
- the mean survival of the emerged control seedlings was 100% in case of all experimental species (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

According to the OECD 227, “one to two corn, soybean, tomato, cucumber, or sugar beet plants per 15 cm container; three rape or pea plants per 15 cm container; and 5 to 10 onion, wheat, or other small seeds per 15 cm container are recommended.”

In the study for each treatment, 7 replicates, with 3 seeds each, were prepared Pots with a diameter of 16 cm were used for the study. In ZRMS opinion the shape of the used pots resulting in a sufficient volume to accommodate seedling growth for the duration of the test.

#### Agreed endpoints:

Endpoint value		Soybean ( <i>Glycine max</i> )	Corn ( <i>Zea mays</i> )	Pea ( <i>Pisum sativum</i> )	White mustard ( <i>Sinapis alba</i> )	Radish ( <i>Raphanus sativus</i> )
Plant number						
ER <sub>50</sub>	Kg/ha <sup>a</sup>	14.08	13.19	14.08	14.11	13.03
	g/ha <sup>b</sup>	7054.1	6608.2	7054.1	7069.1	6528
NOE R	Kg/ha <sup>a</sup>	4	4	4	4	4
	g/ha <sup>b</sup>	2004	2004	2004	2004	2004
Shoot length (plants without roots)						
ER <sub>50</sub>	Kg/ha <sup>a</sup>	13.19	14.44	13.65	13.95	14.24
	g/ha <sup>b</sup>	6608.2	7234.4	6838.7	6989	7134.2
NOE R	Kg/ha <sup>a</sup>	4	4	4	4	4
	g/ha <sup>b</sup>	2004	2004	2004	2004	2004
Plant dry weight (plants without roots)						
ER <sub>50</sub>	Kg/ha <sup>a</sup>	13.81	14.32	13.50	14.82	14.56
	g/ha <sup>b</sup>	6918.8	7174.3	6763.5	7424.8	7294
NOE R	Kg/ha <sup>a</sup>	4	4	4	4	4
	g/ha <sup>b</sup>	2004	2004	2004	2004	2004

a: value for the test item,  
b: value for the active substance

#### Phytotoxicity effects:

## Soybean

Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms
0.0	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
1	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
2	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
4	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
8	R1	0	N,C	0	N,C, Ld	0	N,C,Ld, Sd
	R2	0		0		10	
	R3	0		0		20	
	R4	5		10		20	
	R5	0		0		25	
	R6	10		20		25	
	R7	0		0		0	
16	R1	0	N,C	0	N,C, Ld,Sd	0	N,C, Ld,Sd,W
	R2	0		0		10	
	R3	0		0		20	
	R4	0		0		25	
	R5	10		15		20	
	R6	0		0		0	
	R7	5		10		15	

N: normal, C: chlorosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

## Corn:

Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms
0.0	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
1	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
2	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
4	R1	0	N	0	N	0	N
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
8	R1	5	N,C	0	N,C,Ld	15	N,C,Ld,Sd
	R2	0		0		0	
	R3	0		0		25	
	R4	10		20		10	
	R5	0		5		10	
	R6	0		0		15	
	R7	5		10		15	
16	R1	0	N,C	0	N,C,Ld	0	N,C,Ld,SD, Ne
	R2	10		0		25	
	R3	0		0		0	
	R4	0		0		10	
	R5	10		15		20	
	R6	0		0		0	
	R7	5		10		20	

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

## Pea:

Application rate Kg/ha	Replicate	Phytotoxic effects							
		Day 7		Day 14		Day 21		Symptoms	Symptoms
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms		
0.0	R1	0	0.00	N	0.00	N	0.0	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
1	R1	0	0.0	N	0.0	N	0.0	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
2	R1	0	0.0	N	0.0	N	0.0	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
4	R1	0	0.0	N	0.0	N	0.0	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
8	R1	5	1.43	N,C	3.57	N,C, Ld	7.14	N,C,Ld, Sd	
	R2	0							
	R3	0							
	R4	5							
	R5	0							
	R6	0							
	R7	0							
16	R1	0	3.57	N,C	7.14	N,C, Ld,Sd	10.71	N,C, Ld,Sd,W	
	R2	10							
	R3	0							
	R4	0							
	R5	10							
	R6	0							
	R7	5							

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

### White mustard:

Application rate Kg/ha	Replicate	Phytotoxic effects							
		Day 7		Day 14		Day 21		Symptoms	Symptoms
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms		
0.0	R1	0	0.00	N	0.00	N	0.00	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
1	R1	0	0.0	N	0.0	N	0.0	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
2	R1	0	0.0	N	0.0	N	0.0	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
4	R1	0	0.0	N	0.0	N	0.0	N	
	R2	0							
	R3	0							
	R4	0							
	R5	0							
	R6	0							
	R7	0							
8	R1	0	1.43	N,C	3.57	N,C,Ld	6.43	N,C,Ld	
	R2	5							
	R3	0							
	R4	0							
	R5	5							
	R6	0							
	R7	0							
16	R1	0	3.57	N,C	6.43	N,C,Ld,Sd	10	N,C,Ld,Sd,W	
	R2	10							
	R3	0							
	R4	0							
	R5	0							
	R6	5							
	R7	10							

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

### Radish:



Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms
0.0	R1	0	0.00	0	0.00	0	0.00
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
1	R1	0	0.0	0	0.0	0	0.0
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
2	R1	0	0.0	0	0.0	0	0.0
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
4	R1	0	0.0	0	0.0	0	0.0
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
8	R1	5	2.86	10	6.43	15	10
	R2	0		0		0	
	R3	0		0		5	
	R4	10		20		25	
	R5	0		5		10	
	R6	0		0		0	
	R7	5		10		15	
16	R1	0	3.57	0	7.14	0	10.71
	R2	10		20		25	
	R3	0		0		0	
	R4	0		5		10	
	R5	10		15		20	
	R6	0		0		0	
	R7	5		10		20	

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

### Tomato:

Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effect [%]	Symptoms	Mean effect [%]	Symptoms	Mean effect [%]	Symptoms
0.0	R1	0	0.00	0	0.00	0	0.00
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
1	R1	0	0.0	0	0.0	0	0.0
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
2	R1	0	0.0	0	0.0	0	0.0
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
4	R1	0	0.0	0	0.0	0	0.0
	R2	0		0		0	
	R3	0		0		0	
	R4	0		0		0	
	R5	0		0		0	
	R6	0		0		0	
	R7	0		0		0	
8	R1	5	1.43	10	3.57	15	7.14
	R2	0		0		0	
	R3	0		0		0	
	R4	5		10		20	
	R5	0		0		0	
	R6	0		5		15	
	R7	0		0		0	
16	R1	0	3.57	0	7.14	0	10.71
	R2	10		20		25	
	R3	0		0		0	
	R4	0		5		10	
	R5	10		15		20	
	R6	0		0		5	
	R7	5		10		15	

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead  
\*: all plants dead

<b>Reference:</b>	KCP 10.6.2-02
<b>Report</b>	“Effect of Copper 50% (as oxychloride) WG on vegetative vigour of terrestrial plants”. xxxx 2020, Report number 7546/2019. XXXX
<b>Guideline(s):</b>	OECD Guideline No. 227 (2006)
<b>Deviations:</b>	No
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	No

### Materials and methods

Test item:	Copper 50% (as oxychloride) WG; Batch Number SCL-160002; active substance: copper oxychloride 50.1% (w/w)
Test species:	Soybean ( <i>Glycine max</i> ), Corn ( <i>Zea mays</i> ), radish ( <i>Raphanus sativus</i> ), pea ( <i>Pisum sativum</i> ), tomato ( <i>Solanum lycopersicon</i> ) and white mustard ( <i>Sinapsis alba</i> )
Soil:	Sandy loam soil containing 1.2% organic carbon
Study design:	number of rates: 5 application rates + control; number of replicates: 7 pots/application rate and 3 seeds/plot. test termination: 21 days after the spraying.
Application rates:	Water control, 1, 2, 4, 8 and 16 kg test item/ha Volume of deionised water used to prepare the highest rate: 300 L water/ha
Test conditions:	temperature: 21.7 – 22.8°C, humidity: 58.2 – 69.4%, light – dark cycles (16h:8h), light intensity: 343 – 400 $\mu\text{E}/\text{m}^2/\text{s}$ , carbon dioxide concentration: 346 – 365 ppm.
Statistical analysis:	The ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> and NOEC values were determined by using a Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0.
Endpoints:	ER <sub>10</sub> , ER <sub>25</sub> , ER <sub>50</sub> and NOEC

The number of seeds per pot and the total number of seeds per application rate were as follows:

- Soybean - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Corn - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Radish - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Pea - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- White mustard - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Tomato - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate).

### Results and Conclusions

The test item, i.e. Copper 50% (as oxychloride) WG applied at rates ranging from 1 to 16 kg test item/ha had a varied impact on vegetative vigour of all the plant species tested. The impact depended on the rate of the test item and species used.

There was mortality observed for all the plant species tested at rates ranging from 8 to 16 kg test item/ha. The phytotoxic symptoms for all plant species tested were observed at rates of 8 to 16 kg/ha the test item used. The following phytotoxic symptoms were observed on 21 days after the test item application: chlorosis, necrosis, wilting, leaf deformation, stem deformation or death.

The endpoint values showing the impact of the test item on vegetative vigour of the plant species tested are presented in table given below:

Endpoint value		Soybean ( <i>Glycine max</i> )	Corn ( <i>Zea mays</i> )	Pea ( <i>Pisum sativum</i> )	White mustard ( <i>Sinapis alba</i> )	Radish ( <i>Raphanus sativus</i> )	Tomato ( <i>Solanum lycopersicon</i> )
Plant number							
ER <sub>50</sub>	Kg/ha <sup>a</sup>	14.08	13.19	14.08	14.11	13.03	13.19
	g/ha <sup>b</sup>	7054.1	6608.2	7054.1	7069.1	6528	6608.2
NOER	Kg/ha <sup>a</sup>	4	4	4	4	4	4
	g/ha <sup>b</sup>	2004	2004	2004	2004	2004	2004
Shoot length (plants without roots)							
ER <sub>50</sub>	Kg/ha <sup>a</sup>	13.19	14.44	13.65	13.95	14.24	14.43
	g/ha <sup>b</sup>	6608.2	7234.4	6838.7	6989	7134.2	7229.4
NOER	Kg/ha <sup>a</sup>	4	4	4	4	4	4
	g/ha <sup>b</sup>	2004	2004	2004	2004	2004	2004
Plant dry weight (plants without roots)							
ER <sub>50</sub>	Kg/ha <sup>a</sup>	13.81	14.32	13.50	14.82	14.56	14.21
	g/ha <sup>b</sup>	6918.8	7174.3	6763.5	7424.8	7294	7119.2
NOER	Kg/ha <sup>a</sup>	4	4	4	4	4	4
	g/ha <sup>b</sup>	2004	2004	2004	2004	2004	2004

a: value for the test item,

b: value for the active substance

**A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants**

**A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)**

**A 2.8 KCP 10.8 Monitoring data**