FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 9100 A

Product name: HYCOP

Chemical active substance:

Copper hydroxide, 500 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: May 2019

MS Finalisation date: January 2021, September 2021

Version history

When	What
August 2020	Applicant update
January 2021	Finalisation of the assessment by ZRMS
May 2021	Additional information submitted to zRMS by the applicant
July 2021	Updated RR by the applicant after Commenting period
September 2021	The final version of RR after commenting period.

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

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

9.1 Critical GAP and overall conclusions

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			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	CEU	**Grapevine**	F	Downy mildew *(Plasmopara viticola)*	Foliar Spray	BBCH 15-85	a) 4 b) 4	7-12	a) 2.0 b) 8.0	a) 1.0* b) 4.0*	800-1000	21	* Expressed as Cu							
2	CEU	**Potato**	F	Late blight *(Phytophtora infestans)*	Foliar ~~Spray~~	BBCH 15-85	a) ~~4~~ 3 b) ~~4~~ 3	7-12	a) 2.0-2.4 b) 7.2- 8.0	a) 1.0-1.2* b) 3.6-4.0*	500-1000	14	* Expressed as Cu 3 applications for dose of 2.4 kg/ha, 4 applications for dose of 2.0 kg/ha					An unacceptable risk for NTA at rate 4 x 1kg Cu/ha		
3	CEU	**Solanaceous fruits (Tomato, aubergine)**	F	Late blight *(Phytophtora infestans)*	Foliar Spray	BBCH 15-85	a) 3 b) 3	7-10	a) 1.5-2.4 b) 4.5-7.2	a) 0.75-1.2* b) 2.25-3.6*	500-1000	3	* Expressed as Cu							
4	CEU	**Pome fruit (apple, pear, quince)**	F	Scab (*Venturia spp.*)	Foliar Spray	BBCH 15-85	a) ~~5~~ 3 b) ~~5~~ 3	10-14	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 dose of 2.4 kg/ha, ~~5~~ 3			An unacceptable risk for aquatic organism for early application				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													applications for dose of 1.15 kg/ha			at max. dose 3 x 1.2 kg Cu/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"

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

Remarks table:

(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 (*e.g.* 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 and 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
(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/m³ 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

9.1.1 Overall conclusions

zRMS comments:

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Not agreed or not relevant information is struck through. In blue corrected values or information were added by zRMS, if relevant. After Commenting period the updated information were indicated in yellow.

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)

- Brids

According to screening and tier I assessments for different intended crops uses, TERa and TERlt values are below the Annex VI triggers, indicating that HYCOP 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 hydroxide 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 appli-cations of HYCOP 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 HYCOP presents an unacceptable acute and long-term risk to mammals according to the intended uses. Therefore, an acute and long-term high-er-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 hydroxide presents an unac-ceptable 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 ac-ceptable and, therefore, a WoE is applied. In this context, it can be conclude that the risk is low for mammals exposed to applications of HYCOP 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-$RAC_{sw; ch}$ 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-$RAC_{sw;ch}$ thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of HYCOP with the following risk mitigation measures:

- Grapevine (late): Any no-spray buffer with 90% nozzles reduction OR 5 m 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.
- 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 an unsprayed buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR none unsprayed buffer zone with 90% of nozzles reduction.*

Pome fruit (apple, pear and quince) early application – Spe3: *To protect aquatic organisms respect 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 assessmnt. Further PEC_{sw} calculations should be provided by the applicant to conclude acceptable risk.

ZRMS comments:

The applicant is kindly request for submission of further PECsw calculations based on the lowest RAC of 0.37 µg Cu/L. The risk from the use of Hycop 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 PECsed values to determine protective measures, similar to PECsw value approach. Therefore, the MSs should apply their own mitigation measure at national level.

Overall zRMS's conclusion after Commenting period:

Aquatic organisms

The ratios between predicted environmental concentrations in surface water bodies (PEC_{sw}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended uses in the GAP.
To achieve a concise risk assessment for aquatic dwelling organisms, an ETO-$RAC_{sw;\ ch}$ value of 0.37 µg/L was used as this value was protective of all acute and chronic risks to all relevant aquatic species.
Based on the lowest value **RAC of 0.37 microgram/L for fish** the PEC_{sw}/RAC ratio is below 1, when following risk mitigation measures are applied

- 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine early
- 20 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine late
- 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in potatoes, tomato, aubergine (Solanceous fruit)
- 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate late apples

It should be indicated that no safe risk is identified for apple, pear and quince early application when 50 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels at max. application rate.

The final risk mitigation measures should be decided at MSs level.

Sediment dwelling organism

According to the calculations of PEC/RAC ratio, the risk from the use of active substance for early and late applications in vines, apples and potatoes is not acceptable for sediment dweling organisms considering the active substance-copper. 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 measures at national level.

9.1.2.2 Effects on bees (KCP 10.3.1)

The risk assessment for bees has been done. The Q_{HO} and Q_{HC} values are below 50, indicating a low risk to bees following the application of HYCOP at the proposed label rate.
However, the chronic test for adult bees and larvae should be submitted by the applicant according to REg.284/2009. Based on all available information the following risk mitigation measures to bees should be applied.
SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.
The final risk mitigation measures should be decided at MSs level.

9.1.2.3 Effects on arthropods other than bees (KCP 10.3.2)

No in-field risk assessment is expected after application of Hycop in vines , orchards, potato and fruiting vegetables.
However ,an unacceptable risk in field was conluded for potatoes for max proposed doses 4 x 1000 g Cu/ha.
No ~~in-field and~~ off-field risk to non-target arthropods is expected after the application of ~~SHRIRAM~~ Hycop according to the proposed GAP.

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 HYCOP at the proposed label rate up to 4 kg Cu/ha can be excluded.

9.1.2.5 Effects on soil microbial activity (KCP 10.5)

No risk for soil micro-organisms is expected after the application HYCOP 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 HYCOP 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 HYCOP 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 kg f.p./ha (equivalent to 4 x 1 kg Cu/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 (except soil microorgamisms).
Potato	Potato	Max application rate of 3 x 2.4 kg f.p./ha (equivalent to 3 x 1.2 kg Cu./ha) at BBCH 15-85 Or Max application rate of 4 x 2.0 kg f.p./ha (equivalent to 4 x 1.0 Kg Cu./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**
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 Cu/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 Cu/ha) at BBCH 15-85 Or Max application rate of 5 x 1.15 kg f.p./ha (equivalent to 3 x 575 g Cu/ha) at BBCH 15-85	Birds and mammals, off-field assessment for arthropods other than bees and non-target plants. Highest annual application rate for assessment for soil microorganisms.
All crops	Grapevine Potato Solanaceous fruits (Tomato, aubergine) Pome fruit (apple, pear, quince)	Max application rate (1.2 kg Cu/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 hydroxide. Full details of these studies are provided in the respective EU DAR.

Effects on birds of HYCOP were not evaluated as part of the EU assessment of Copper hydroxide.

However, the provision of further data on the HYCOP 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
Colinus virginianus	Copper hydroxide	Acute	**LD_{50} = 223 mg Cu/kg bw**	EFSA Journal 2018;16(1):5152
Coturnix coturnix japonica	Copper hydroxide	Acute	LD_{50} = 556 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide WP	Acute	LD_{50} = 357 mg Cu/kg bw	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Colinus virginianus	Copper hydroxide	Short-term	NOEL = 123.6 mg Cu/kg bw** NOEC = 883 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Short-term	NOEL = 215.6 mg Cu/kg bw** NOEC = 1053 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide	Short-term	NOEL = 135.2 mg Cu/kg bw** NOEC = 963 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Short-term	NOEL = 190.6mg Cu/kg bw** NOEC = 963 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide	Long-term	**NOEL = 5.05 mg Cu/kg bw*** NOEC = 57.5 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Long-term	NOEL = 42.34 mg Cu/kg bw NOEC = 288 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide	Long-term	NOEL = 25.41 mg Cu/kg bw NOEC = 288 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Long-term	NOEL = 50.3 mg Cu/kg bw NOEC = 288 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Additional higher tier studies (Annex Part A, points 10.1.1.2): 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.
** LD50 was not relevant because of food avoidance
*** LC50 was not relevant because of food avoidance

Species	Substance	Exposure System	Results	Reference
Colinus virginianus	Copper hydroxide	Acute	**LD_{50} = 223 mg Cu/kg bw**	EFSA Journal 2018;16(1):5152
Coturnix coturnix japonica	Copper hydroxide	Acute	LD_{50} = 556 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide WP	Acute	LD_{50} = 357 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper oxychloride	Acute	LD_{50} = 511 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper oxychloride WP	Acute	**LD_{50} = 173 mg Cu/kg bw***	EFSA Journal 2018;16(1):5152
Colinus virginianus	Bordeaux mixture	Acute	LD_{50} > 616 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Bordeaux mixture WP	Acute	LD_{50} > 439.9 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Tribasic copper sulfate	Acute	LD_{50} = 616 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Tribasic copper sulfate SC	Acute	LD_{50} > 72.4 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Coturnix coturnix japonica	Tribasic copper sulfate SC	Acute	LD_{50} = 221 mg Cu/kg bw	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Coturnix coturnix japonica	Copper oxide	Acute	LD_{50} = 1183 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Coturnix coturnix japonica	Copper oxide WG	Acute	LD_{50} = 650 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper oxychloride	Short-term	LC_{50} = 1939 mg Cu/kg bw LD_{50} = 333 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Colinus virginianus	Bordeaux mixture	Short-term	LC_{50} > 1369 mg Cu/kg bw LD_{50} > 334.1 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide	Short-term	NOEL = 123.6 mg Cu/kg bw** NOEC = 883 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Short-term	NOEL = 215.6 mg Cu/kg bw** NOEC = 1053 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide	Short-term	NOEL = 135.2 mg Cu/kg bw** NOEC = 963 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Short-term	NOEL = 190.6mg Cu/kg bw** NOEC = 963 mg Cu/kg feed***	EFSA Journal 2018;16(1):5152
Colinus virginianus	Tribasic copper sulfate	Short-term	NOEL = 89^{b} mg Cu/kg bw/day NOEC = 246^{c} mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Tribasic copper sulfate	Short-term	NOEL = 176.3^{b} mg Cu/kg bw/day NOEC = 530^{c} mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper oxide	Short-term	NOEL = 32^{b} mg Cu/kg bw/day NOEC = 136^{c} mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide	Long-term	**NOEL = 5.05 mg Cu/kg bw*** NOEC = 57.5 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Long-term	NOEL = 42.34 mg Cu/kg bw NOEC = 288 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Colinus virginianus	Copper hydroxide	Long-term	NOEL = 25.41 mg Cu/kg bw NOEC = 288 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Anas platyrhynchos	Copper hydroxide	Long-term	NOEL = 50.3 mg Cu/kg bw NOEC = 288 mg Cu/kg feed	EFSA Journal 2018;16(1):5152
Additional higher tier studies (Annex Part A, points 10.1.1.2): 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.
** LD50 was not relevant because of food avoidance
*** LC50 was not relevant because of food avoidance

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 HYCOP in Grapevine

Intended use		**Grapevine**			
Active substance/product		Copper hydroxide			
Application rate (g/ha)		4 × 1000			
Acute toxicity (mg/kg bw)		223			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard BBCH 10 – 19	Small insectivorous species “Redstart” ground invertebrates without interception 50% ground arthropods 50% foliar arthropods	27.4	1.8	49.32	**4.6**
Vineyard BBCH ≥ 20	Small insectivorous species “Redstart” ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	25.7	1.8	46.26	**4.8**
Vineyard BBCH 10 – 19	Small granivorous bird “Finch” Small seeds 100% weed seeds	14.8	1.8	26.64	**8.4**
Vineyard BBCH 20 – 39	Small granivorous bird “Finch” Small seeds 100% weed seeds	12.4	1.8	22.32	10.0
Vineyard BBCH ≥ 40	Small granivorous bird “Finch” Small seeds 100% weed seeds	7.4	1.8	13.32	16.7
Vineyard BBCH 10 – 19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	14.4	1.8	25.92	**8.6**
Vineyard BBCH 20 – 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	12.0	1.8	21.6	10.3

Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.8	12.96	17.2
Vineyard Ripening	Frugivorous bird "Trush/starling" 100% grapes	28.9	1.8	52.02	**4.3**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**$MAF_m \times$ TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard BBCH 10 – 19	Small insectivorous species "Red-start" ground invertebrates without interception 50% ground arthro-pods 50% foliar arthropods	11.5	2.2 x 0.53	13.41	**0.4**
Vineyard BBCH ≥ 20	Small insectivorous species "Red-start" ground invertebrates with interception 50% ground arthro-pods 50% foliar arthropods	9.9	2.2 x 0.53	11.54	**0.4**
Vineyard BBCH 10 – 19	Small granivorous bird "Finch" Small seeds 100% weed seeds	6.9	2.2 x 0.53	8.05	**0.6**
Vineyard BBCH 20 – 39	Small granivorous bird "Finch" Small seeds 100% weed seeds	5.7	2.2 x 0.53	6.65	**0.8**
Vineyard BBCH ≥ 40	Small granivorous bird "Finch" Small seeds 100% weed seeds	3.4	2.2 x 0.53	3.96	**1.3**
Vineyard BBCH 10 – 19	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.5	2.2 x 0.53	7.58	**0.7**
Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4	2.2 x 0.53	6.30	**0.8**
Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	2.2 x 0.53	3.85	**1.3**
Vineyard Ripening	Frugivorous bird "Trush/starling" 100% grapes	14.4	2.2 x 0.53	16.79	**0.3**

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.

Intended use	**Grapevine**				
Active substance/product	Copper ~~hydroxide~~				
Application rate (g/ha)	4 × 1000				
Acute toxicity (mg/kg bw)	173				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**

Vineyard BBCH 10 – 19	Small insectivorous species “Redstart” ground invertebrates without interception 50% ground arthropods 50% foliar arthropods	27.4	1.8	49.32	**3.5**
Vineyard BBCH ≥ 20	Small insectivorous species “Redstart” ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	25.7	1.8	46.26	**3.7**
Vineyard BBCH 10 – 19	Small granivorous bird “Finch” Small seeds 100% weed seeds	14.8	1.8	26.64	**6.5**
Vineyard BBCH 20 – 39	Small granivorous bird “Finch” Small seeds 100% weed seeds	12.4	1.8	22.32	**7.8**
Vineyard BBCH ≥ 40	Small granivorous bird “Finch” Small seeds 100% weed seeds	7.4	1.8	13.32	13.0
Vineyard BBCH 10 – 19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	14.4	1.8	25.92	**6.7**
Vineyard BBCH 20 – 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	12.0	1.8	21.6	**8.0**
Vineyard BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.8	12.96	13.3
Vineyard Ripening	Frugivorous bird “Trush/starling” 100% grapes	28.9	1.8	52.02	**3.3**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard BBCH 10 – 19	Small insectivorous species “Redstart” ground invertebrates without interception 50% ground arthropods 50% foliar arthropods	11.5	2.2 x 0.53	13.41	**0.4**
Vineyard BBCH ≥ 20	Small insectivorous species “Redstart” ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	9.9	2.2 x 0.53	11.54	**0.4**
Vineyard BBCH 10 – 19	Small granivorous bird “Finch” Small seeds 100% weed seeds	6.9	2.2 x 0.53	8.05	**0.6**
Vineyard BBCH 20 – 39	Small granivorous bird “Finch” Small seeds 100% weed seeds	5.7	2.2 x 0.53	6.65	**0.8**
Vineyard BBCH ≥ 40	Small granivorous bird “Finch” Small seeds 100% weed seeds	3.4	2.2 x 0.53	3.96	**1.3**
Vineyard BBCH 10 – 19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.5	2.2 x 0.53	7.58	**0.7**

Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4	2.2 x 0.53	6.30	**0.8**
Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	2.2 x 0.53	3.85	**1.3**
Vineyard Ripening	Frugivorous bird "Trush/starling" 100% grapes	14.4	2.2 x 0.53	16.79	**0.3**

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

Intended use		Potato use			
Active substance/product		Copper hydroxide			
Application rate (g/ha)		3 × 1200			
Acute toxicity (mg/kg bw)		223			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Potatoes BBCH 10 – 19	Small insectivorous bird "wag-tail" ground invertebrates without interception 50% ground arthro-pods, 50% foliar arthropods	26.8	1.6	51.46	**4.3**
Potatoes BBCH ≥ 20	Small insectivorous bird "wag-tail" ground invertebrates with interception 50% ground arthro-pods, 50% foliar arthropods	25.2	1.6	48.38	**4.6**
Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Combination (invertebrates with-out interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	1.6	46.08	**4.8**
Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates with-out interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.6	13.82	16.1
Reprod. toxicity (mg/kg bw/d)		5.05			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	2.0 x 0.53	14.37	**0.4**
Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	2.0 x 0.53	12.34	**0.4**
Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	2.0 x 0.53	13.86	**0.4**
Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	2.0 x 0.53	4.20	**1.2**

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.

Intended use		**Potato use**			
Active substance/product		Copper ~~hydroxide~~			
Application rate (g/ha)		3 × 1200			
Acute toxicity (mg/kg bw)		173			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	26.8	1.6	51.46	**3.4**
Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	25.2	1.6	48.38	**3.6**
Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	1.6	46.08	**3.8**
Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.6	13.82	12.5
Reprod. toxicity (mg/kg bw/d)		5.05			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	2.0 x 0.53	14.37	**0.4**
Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	2.0 x 0.53	12.34	**0.4**
Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	2.0 x 0.53	13.86	**0.4**
Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	2.0 x 0.53	4.20	**1.2**

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 HYCOP in fruiting vegetables

Intended use		**Solanaceous fruit (tomato and aubergine)**			
Active substance/product		Copper hydroxide			
Application rate (g/ha)		3 x 1200			
Acute toxicity (mg/kg bw)		223			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	26.8	1.6	51.46	**4.3**
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	25.2	1.6	48.38	**4.6**
Fruiting vegetables BBCH 10 – 49	Small granivorous bird "finch" Small seeds 100% weed seeds	24.7	1.6	47.42	**4.7**
Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Small seeds 100% weed seeds	7.4	1.6	14.21	15.7
Fruiting vegetables BBCH 10 – 49	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	1.6	46.08	**4.8**

Fruiting vegetables BBCH ≥ 50	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.6	13.82	16.1
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous bird “Starling” Tomato 100% fruit	49.4	1.6	94.85	**2.4**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Fruiting vegetables BBCH 10 – 19	Small insectivorous bird “wagtail” ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	2.0 x 0.53	14.37	**0.4**
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird “wagtail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	2.0 x 0.53	12.34	**0.4**
Fruiting vegetables BBCH 10 – 49	Small granivorous bird “finch” Small seeds 100% weed seeds	11.4	2.0 x 0.53	14.50	**0.3**
Fruiting vegetables BBCH ≥ 50	Small granivorous bird “finch” Small seeds 100% weed seeds	3.4	2.0 x 0.53	4.32	**1.2**
Fruiting vegetables BBCH 10 – 49	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	2.0 x 0.53	13.86	**0.4**
Fruiting vegetables BBCH ≥ 50	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	2.0 x 0.53	4.20	**1.2**
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous bird “Starling” Tomato 100% fruit	20.7	2.0 x 0.53	26.33	**0.2**

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.

Intended use	**Solanaceous fruit (tomato and aubergine)**				
Active substance/product	Copper ~~hydroxide~~				
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_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**

Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	26.8	1.6	51.46	**3.4**
Fruiting vegetables BBCH $\geq$ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	25.2	1.6	48.38	**3.6**
Fruiting vegetables BBCH 10 – 49	Small granivorous bird "finch" Small seeds 100% weed seeds	24.7	1.6	47.42	**3.6**
Fruiting vegetables BBCH $\geq$ 50	Small granivorous bird "finch" Small seeds 100% weed seeds	7.4	1.6	14.21	12.2
Fruiting vegetables BBCH 10 – 49	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	1.6	46.08	**3.8**
Fruiting vegetables BBCH $\geq$ 50	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.6	13.82	12.6
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous bird "Starling" Tomato 100% fruit	49.4	1.6	94.85	**1.8**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	2.0 x 0.53	14.37	**0.4**
Fruiting vegetables BBCH $\geq$ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	2.0 x 0.53	12.34	**0.4**
Fruiting vegetables BBCH 10 – 49	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	2.0 x 0.53	14.50	**0.3**
Fruiting vegetables BBCH $\geq$ 50	Small granivorous bird "finch" Small seeds 100% weed seeds	3.4	2.0 x 0.53	4.32	**1.2**
Fruiting vegetables BBCH 10 – 49	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	2.0 x 0.53	13.86	**0.4**
Fruiting vegetables BBCH $\geq$ 50	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	2.0 x 0.53	4.20	**1.2**

Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous bird "Starling" Tomato 100% fruit	20.7	2.0 x 0.53	26.33	**0.2**

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 HYCOP in Pome fruits

Intended use	**Pome fruit**				
Active substance/product	Copper hydroxide				
Application rate (g/ha)	3 x 1200				
Acute toxicity (mg/kg bw)	223				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard Crop directed application BBCH 10 – 19	Small granivorous bird "finch" Small seeds 100% seeds	21.9	1.5	39.42	**5.7**
Orchard Crop directed application BBCH 20 – 39	Small granivorous bird "finch" Small seeds 100% seeds	16.4	1.5	29.52	**7.6**
Orchard Crop directed application BBCH ≥ 40	Small granivorous bird "finch" Small seeds 100% seeds	8.2	1.5	14.76	15.1
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	21.0
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	28.2
Orchard Crop directed application BBCH ≥ 40	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	2.2	1.5	3.96	56.3
Orchard Spring Summer,	Small insectivorous bird "tit" Foliar insects 100% foliar insects	46.8	1.5	84.24	**2.6**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Orchard Crop directed application BBCH 10 – 19	Small granivorous bird "finch" Small seeds 100% seeds	10.1	1.8 x 0.53	11.56	**0.4**
Orchard Crop directed application BBCH 20 – 39	Small granivorous bird "finch" Small seeds 100% seeds	7.6	1.8 x 0.53	8.70	**0.6**
Orchard Crop directed application BBCH ≥ 40	Small granivorous bird "finch" Small seeds 100% seeds	3.8	1.8 x 0.53	4.35	**1.2**
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	**2.1**
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	**2.8**
Orchard Crop directed application BBCH ≥ 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	**0.2**

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.

Intended use	**Pome fruit**				
Active substance/product	Copper ~~hydroxide~~				
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_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard Crop directed application BBCH 10 – 19	Small granivorous bird "finch" Small seeds 100% seeds	21.9	1.5	39.42	**4.4**
Orchard Crop directed application BBCH 20 – 39	Small granivorous bird "finch" Small seeds 100% seeds	16.4	1.5	29.52	**5.9**
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	5.9	1.5	10.62	16.3

	dwelling invertebrates				
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 BBCH ≥ 40	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	2.2	1.5	3.96	43.7
Orchard Spring Summer,	Small insectivorous bird "tit" Foliar insects 100% foliar insects	46.8	1.5	84.24	**2.1**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchard Crop directed application BBCH 10 – 19	Small granivorous bird "finch" Small seeds 100% seeds	10.1	1.8 x 0.53	11.56	**0.4**
Orchard Crop directed application BBCH 20 – 39	Small granivorous bird "finch" Small seeds 100% seeds	7.6	1.8 x 0.53	8.70	**0.6**
Orchard Crop directed application BBCH ≥ 40	Small granivorous bird "finch" Small seeds 100% seeds	3.8	1.8 x 0.53	4.35	**1.2**
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	**2.1**
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	**2.8**
Orchard Crop directed application BBCH ≥ 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	**0.2**

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 TERlt values are below the Annex VI triggers, indicating that HYCOP 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_{50} 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)
HYCOP 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)[1], 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 HYCOP in grapevine – refined parameters (*) are further described and justified in the text

Intended use		**Grapevine**					
Active substance/product		Copper hydroxide					
Application rate (g/ha)		4 × 1000					
Acute toxicity (mg/kg bw)		223					
TER criterion		10					
Focal species	**Food category,**	**FIR/bw**	**RUD_{90} ×**	**MAF_{90}***	**PT**	**DDD_{90}**	**TER_a**

[1] 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.

	% in diet		DF* (mg/kg food)			(mg/kg bw/d)	
Black Redstart *(Phoenicurus ochruros)*	50% ground arthropods	0.81[1]	9.7[2] × 0.4[3]	1.0	1.0	1.57	**9.5**
	50% foliar arthropods	0.81[1]	54.1[2] × 1.0	1.0	1.0	21.91	
	whole diet					23.48	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	87.0[2] × 0.4[3]	1.0	1.0	9.74	22.9
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	70.3[2] × 1.0	1.0	1.0	9.14	15.2
	25% weed seeds	0.52[1]	87.0[2] × 0.4[3]	1.0	1.0	4.52	
	50% ground arthopods	0.52[1]	9.7[2] × 0.4[3]	1.0	1.0	1.01	
	whole diet					14.67	
Song Thrush (*Turdus philomelos*)	100% grapes	1.73[1]	16.7 × 1.0	1.0	1.0	28.89	**7.7**
Reprod. toxicity (mg/kg bw/d)	5.05						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Black Redstart *(Phoenicurus ochruros)*	50% ground arthropods	0.81[1]	3.5[2]× 0.4[3]	1.0	1.0	0.57	**0.6**
	50% foliar arthropods	0.81[1]	21.0[2] × 1.0	1.0	1.0	8.51	
	whole diet					9.21	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	40.2[2] × 0.4[3]	1.0	1.0	4.50	**1.1**
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	28.7[2] × 1.0	1.0	1.0	3.73	**0.8**
	25% weed seeds	0.52[1]	40.2[2] × 0.4[3]	1.0	1.0	2.09	
	50% ground arthopods	0.52[1]	3.5[2] × 0.4[3]	1.0	1.0	0.36	
	whole diet					6.19	
Song Thrush (*Turdus philomelos*)	100% grapes	1.73[1]	8.3[2] × 1.0	1.0	1.0	28.89	**0.4**

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.
[1] According to Appendix A of EFSA/2009/1438.
[2] According to table 1 from Appendix F of EFSA/2009/1438.
[3] Deposition factor according to FOCUS groundwater guidance.

Intended use	**Grapevine**						
Active substance/product	Copper ~~hydroxide~~						
Application rate (g/ha)	4000*						
Acute toxicity (mg/kg bw)	173						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD$_{90}$ × DF*** **(mg/kg food)**	**MAF$_{90}$***	**PT**	**DDD$_{90}$** **(mg/kg bw/d)**	**TER$_a$**
Black Redstart *(Phoenicurus ochruros)*	50% ground arthropods	0.81[1]	9.7[2] × 0.4[3]	1.0	1.0	6.29	**1.84**
	50% foliar arthropods	0.81[1]	54.1[2] × 1.0	1.0	1.0	87.64	
	whole diet					93.93	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	87.0[2] × 0.4[3]	1.0	1.0	38.98	**4.44**
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	70.3[2] × 1.0	1.0	1.0	38.98	**2.95**
	25% weed seeds	0.52[1]	87.0[2] × 0.4[3]	1.0	1.0	18.10	
	50% ground arthopods	0.52[1]	9.7[2] × 0.4[3]	1.0	1.0	4.04	
	whole diet					58.7	
Song Thrush (*Turdus philomelos*)	100% grapes	1.73[1]	16.7 × 1.0	1.0	1.0	115.56	**1.50**
Reprod. toxicity (mg/kg bw/d)	5.05						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD$_m$ × DF*** **(mg/kg food)**	**MAF$_m$*× TWA***	**PT**	**DDD$_m$** **(mg/kg bw/d)**	**TER$_{lt}$**
Black Redstart *(Phoenicurus ochruros)*	50% ground arthropods	0.81[1]	3.5[2]× 0.4[3]	1.0	1.0	2.27	**0.14**
	50% foliar arthropods	0.81[1]	21.0[2] × 1.0	1.0	1.0	34.04	
	whole diet					36.31	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	40.2[2] × 0.4[3]	1.0	1.0	18.00	**0.28**
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	28.7[2] × 1.0	1.0	1.0	14.92	**0.20**
	25% weed seeds	0.52[1]	40.2[2] × 0.4[3]	1.0	1.0	8.36	
	50% ground arthopods	0.52[1]	3.5[2] × 0.4[3]	1.0	1.0	1.44	
	whole diet					24.72	
Song Thrush	100% grapes	1.73[1]	8.3[2] × 1.0	1.0	1.0	115.56	**0.04**

(*Turdus philomelos*)							

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.
[1] According to Appendix A of EFSA/2009/1438.
[2] According to table 1 from Appendix F of EFSA/2009/1438.
[3] Deposition factor according to FOCUS groundwater guidance.
* Maximum cumulative annual application rate

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

Intended use	**Potato**						
Active substance/product	Copper hydroxide						
Application rate (g/ha)	3 × 1200						
Acute toxicity (mg/kg bw)	223						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** (mg/kg food)	**MAF_{90}***	**PT**	**DDD_{90}** (mg/kg bw/d)	**TER_a**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.79[1]	9.7[2] × 0.85[3]	1.0	1.0	3.91	**7.5**
	50% foliar arthropods	0.79[1]	54.1[2] × 1.0	1.0	1.0	25.64	
	whole diet					29.55	
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	70.3[2] × 1.0	1.0	1.0	10.97	**8.9**
	25% weed seeds	0.52[1]	87.0[2] × 0.85[3]	1.0	1.0	11.54	
	50% ground arthopods	0.52[1]	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_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.79[1]	3.5[2] × 0.85[3]	1.0	1.0	1.41	**0.4**
	50% foliar arthropods	0.79[1]	21.0[2] × 1.0	1.0	1.0	9.95	
	whole diet					11.36	
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	28.7[2] × 1.0	1.0	1.0	4.48	**0.5**
	25% weed seeds	0.52[1]	40.2[2] × 0.85[3]	1.0	1.0	5.33	
	50% ground arthopods	0.52[1]	3.5[2] × 0.85[3]	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.
[1] According to Appendix A of EFSA/2009/1438.
[2] According to table 1 from Appendix F of EFSA/2009/1438.
[3] Deposition factor according to FOCUS groundwater guidance.

Intended use	**Potato**						
Active substance/product	Copper ~~hydroxide~~						
Application rate (g/ha)	4000*						
Acute toxicity (mg/kg bw)	173						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** **(mg/kg food)**	**MAF_{90}***	**PT**	**DDD_{90}** **(mg/kg bw/d)**	**TER_a**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.79[1]	9.7[2] × 0.85[3]	1.0	1.0	13.03	**1.76**
	50% foliar arthropods	0.79[1]	54.1[2] × 1.0	1.0	1.0	85.48	
	whole diet					98.51	
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	70.3[2] × 1.0	1.0	1.0	36.56	**2.07**
	25% weed seeds	0.52[1]	87.0[2] × 0.85[3]	1.0	1.0	38.45	
	50% ground arthopods	0.52[1]	9.7 × 0.85	1.0	1.0	8.57	
	whole diet					83.58	
Reprod. toxicity (mg/kg bw/d)	5.05						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** **(mg/kg food)**	**MAF_m*× TWA***	**PT**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.79[1]	3.5[2] × 0.85[3]	1.0	1.0	4.70	**0.13**
	50% foliar arthropods	0.79[1]	21.0[2] × 1.0	1.0	1.0	33.18	
	whole diet					37.88	
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	28.7[2] × 1.0	1.0	1.0	14.92	**0.14**
	25% weed seeds	0.52[1]	40.2[2] × 0.85[3]	1.0	1.0	17.77	
	50% ground arthopods	0.52[1]	3.5[2] × 0.85[3]	1.0	1.0	3.09	
	whole diet					35.78	

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.

[1] According to Appendix A of EFSA/2009/1438.
[2] According to table 1 from Appendix F of EFSA/2009/1438.
[3] Deposition factor according to FOCUS groundwater guidance.
* Maximum cumulative annual application rate

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

Intended use	**Solanaceous fruit (tomato and aubergine)**						
Active substance/product	Copper hydroxide						
Application rate (g/ha)	3 x 1200						
Acute toxicity (mg/kg bw)	223						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD$_{90}$ × DF*** (mg/kg food)	**MAF$_{90}$***	**PT**	**DDD$_{90}$** (mg/kg bw/d)	**TER$_a$**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.79[1]	9.7[2] × 0.5[3]	1.0	1.0	2.30	**8.0**
	50% foliar arthropods	0.79[1]	54.1[2] × 1.0	1.0	1.0	25.64	
	whole diet					27.94	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	87.0[2] × 0.5[3]	1.0	1.0	14.62	15.3
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	70.3[2] × 1.0	1.0	1.0	10.97	11.6
	25% weed seeds	0.52[1]	87.0[2] × 0.5[3]	1.0	1.0	6.79	
	50% ground arthopods	0.52[1]	9.7[2] × 0.5[3]	1.0	1.0	1.51	
	whole diet					19.27	
Starling (*Sturnus vulgaris*)	100% tomatoes	1.62[1]	30.6[2]× 1.0	1.0	1.0	59.49	**3.7**
Reprod. toxicity (mg/kg bw/d)	5.05						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD$_m$ × DF*** (mg/kg food)	**MAF$_m$*× TWA***	**PT**	**DDD$_m$** (mg/kg bw/d)	**TER$_{lt}$**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.81[1]	3.5[2]× 0.5[3]	1.0	1.0	0.85	**0.5**
	50% foliar arthropods	0.81[1]	21.0[2] × 1.0	1.0	1.0	10.21	
	whole diet					11.06	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	40.2[2] × 0.5[3]	1.0	1.0	6.75	**0.7**
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	28.7[2] × 1.0	1.0	1.0	4.48	**0.6**

	25% weed seeds	0.52[1]	40.2[2] × 0.5[3]	1.0	1.0	3.14	
	50% ground arthopods	0.52[1]	3.5[2] × 0.5[3]	1.0	1.0	0.55	
	whole diet					8.16	
Starling (*Sturnus vulgaris*)	100% tomatoes	1.62[1]	12.8[2]× 1.0	1.0	1.0	3.60	**0.2**

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.
[1] According to Appendix A of EFSA/2009/1438.
[2] According to table 1 from Appendix F of EFSA/2009/1438.
[3] Deposition factor according to FOCUS groundwater guidance.

Intended use **Active substance/product** **Application rate (g/ha)**	**Solanaceous fruit (tomato and aubergine)** Copper ~~hydroxide~~ 3600*						
Acute toxicity (mg/kg bw) **TER criterion**	173 10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** (mg/kg food)	**MAF_{90}***	**PT**	**DDD_{90}** (mg/kg bw/d)	**TER_a**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.79[1]	9.7[2] × 0.5[3]	1.0	1.0	6.87	**2.06**
	50% foliar arthropods	0.79[1]	54.1[2] × 1.0	1.0	1.0	76.93	
	whole diet					83.80	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	87.0[2] × 0.5[3]	1.0	1.0	43.85	**3.94**
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	70.3[2] × 1.0	1.0	1.0	32.90	2.99
	25% weed seeds	0.52[1]	87.0[2] × 0.5[3]	1.0	1.0	20.36	
	50% ground arthopods	0.52[1]	9.7[2] × 0.5[3]	1.0	1.0	4.54	
	whole diet					57.8	
Starling (*Sturnus vulgaris*)	100% tomatoes	1.62[1]	30.6[2]× 1.0	1.0	1.0	178.46	**0.97**
Reprod. toxicity (mg/kg bw/d) **TER criterion**	5.05 5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Yellow wagtail (*Motacilla flava*)	50% ground arthropods	0.81[1]	3.5[2]× 0.5[3]	1.0	1.0	2.55	**0.15**
	50% foliar arthropods	0.81[1]	21.0[2] × 1.0	1.0	1.0	30.62	

	whole diet					33.17	
Linnet (*Carduelis cannabina*)	100% weed seeds	0.28[1]	40.2[2] × 0.5[3]	1.0	1.0	20.26	**0.25**
Wood Lark (*Lullula arborea*)	25% crop leaves	0.52[1]	28.7[2] × 1.0	1.0	1.0	13.43	**0.21**
	25% weed seeds	0.52[1]	40.2[2] × 0.5[3]	1.0	1.0	9.41	
	50% ground arthopods	0.52[1]	3.5[2] × 0.5[3]	1.0	1.0	1.64	
	whole diet					24.48	
Starling (*Sturnus vulgaris*)	100% tomatoes	1.62[1]	12.8[2]× 1.0	1.0	1.0	74.65	**0.07**

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.
[1] According to Appendix A of EFSA/2009/1438.
[2]According to table 1 from Appendix F of EFSA/2009/1438.
[3]Deposition factor according to FOCUS groundwater guidance.
* Maximum cumulative annual application rate

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

Intended use **Active substance/product** **Application rate (g/ha)**	**Pome fruit** Copper hydroxide 3 x 1200						
Acute toxicity (mg/kg bw) **TER criterion**	223 10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF** (mg/kg food)	**MAF_{90}***	**PT**	**DDD_{90}** (mg/kg bw/d)	**TER_a**
Serin (*Serinus serinus*)	100% weed seeds	0.31[1]	87.0[2] × 0.4[3]	1.0	1.0	12.95	17.2
Bluetit (*Parus caeruleus*)	100% foliar insects	0.86[1]	54.1[2] × 1.0	1.0	1.0	55.83	**4.0**
Reprod. toxicity (mg/kg bw/d) **TER criterion**	5.05 5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Robin (*Erithacus rubecula*)	100% soil dwelling Invertebrates	0.76[1]	3.5[2]× 0.4[3]	1.0	1.0	1.28	**4.0**
Serin (*Serinus serinus*)	100% weed seeds	0.31[1]	40.2[2] × 0.4[3]	1.0	1.0	5.98	**0.8**
Bluetit (*Parus caeruleus*)	100% foliar insects	0.86[1]	21.0[2] × 1.0	1.0	1.0	21.67	**0.2**

Intended use	**Pome fruit**						
Active substance/product	Copper ~~hydroxide~~						
Application rate (g/ha)	3600*						
Acute toxicity (mg/kg bw)	173						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF** (mg/kg food)	**MAF_{90}***	**PT**	**DDD_{90}** (mg/kg bw/d)	**TER_a**
Serin (*Serinus serinus*)	100% weed seeds	0.31[1]	87.0[2] × 0.4[3]	1.0	1.0	38.83	**4.46**
Bluetit (*Parus caeruleus*)	100% foliar insects	0.86[1]	54.1[2] × 1.0	1.0	1.0	167.49	**1.03**
Reprod. toxicity (mg/kg bw/d)	5.05						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Robin (*Erithacus rubecula*)	100% soil dwelling Invertebrates	0.76[1]	3.5[2]× 0.4[3]	1.0	1.0	3.83	**1.32**
Serin (*Serinus serinus*)	100% weed seeds	0.31[1]	40.2[2] × 0.4[3]	1.0	1.0	17.95	**0.28**
Bluetit (*Parus caeruleus*)	100% foliar insects	0.86[1]	21.0[2] × 1.0	1.0	1.0	65.02	**0.08**

* Maximum cumulative annual application rate

After even the refinement, the risk assessment showed that Copper hydroxide 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 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 (Schabacker and Rastall, 2009a; Schabacker and Rastall, 2009b).

Field monitoring results indicate that copper uses can result in different copper exposure levels in birds but, as expected from the physiologic background (homoeostasis), 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 deits 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.

HYCOP is applied at the maximum dose of 1.2 kg copper hydroxide/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 => 3.6 kg Cu/ha or 4 applications at 1.0 kg/ha => 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 => 3.6 kg Cu/ha or 5 applications at 1.150 kg/ha => 5.75 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 HYCOP.

ZRMS comments:

For copper hydroxide 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 forall 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 MAFxTWA=1 for 1 maximum annual application from the GAP, whilst Applicant performed higher tier RA using MAFxTWA=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. 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 after commenting period provided required calculations.

Further, as risk refinement, position papers were provided where a Weight of vidence (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 insectivorus 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 cooper 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)

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 HYCOP 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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 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 hydroxide 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 birds from all other intended uses in potatoes, solanaceous fruits and pome fruits (see 9.1-2).

Effective application rate (g/ha) =	2200		
Acute toxicity (mg/kg bw) =	~~223~~173	quotient =	~~9.87~~12.72
Reprod. toxicity (mg/kg bw/d) =	5.05	quotient =	435.64

As the ratios do not exceed the value of 3000 for Copper hydroxide, 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 TERlt values are below the Annex VI triggers, indicating that HYCOP 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 hydroxide 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 HYCOP 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 hydroxide. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of HYCOP were not evaluated as part of the EU assessment of Copper hydroxide. 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_{50} = 162.6 mg Cu/kg bw** to 271*	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 HYCOP in Grapevine

Intended use		**Grapevine**			
Active substance/product		Copper ~~hydroxide~~			
Application rate (g/ha)		4 × 1000			
Acute toxicity (mg/kg bw)		162.6			
TER criterion		10			
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard Application crop directed BBCH 10 – 19	Small herbivorous mammal "vole Grass + cereals 100% grass	81.9	1.8	147.42	**1.1**
Vineyard Application crop directed BBCH 20 – 39	Small herbivorous mammal "vole Grass + cereals 100% grass	68.2	1.8	122.76	**1.3**
Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.8	73.62	**2.2**
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	1.8	18.54	**8.8**
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	1.8	15.48	10.5

Vineyard Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.8	9.36	17.4
Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	7.6	1.8	13.68	11.9
Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	5.4	1.8	9.72	16.7
Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	16.3	1.8	29.34	**5.5**
Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	13.6	1.8	24.48	**6.6**
Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	8.1	1.8	14.58	11.2
Reprod. toxicity (mg/kg bw/d)	16				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard Application crop directed BBCH 10 – 19	Small herbivorous mammal "vole Grass + cereals 100% grass	43.4	2.2 x 0.53	50.60	**0.3**
Vineyard Application crop directed BBCH 20 – 39	Small herbivorous mammal "vole Grass + cereals 100% grass	36.1	2.2 x 0.53	42.09	**0.4**
Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	2.2 x 0.53	25.30	**0.6**
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	2.2 x 0.53	5.48	**2.9**
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	2.2 x 0.53	4.55	**3.5**
Vineyard Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	2.2 x 0.53	2.68	6.0

Vineyard BBCH 10 – 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	2.2 x 0.53	4.90	**3.3**
Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	2.2 x 0.53	2.22	7.2
Vineyard BBCH 10 – 19	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Plant matter	6.7	2.2 x 0.53	7.81	**2.0**
Vineyard BBCH 20 – 39	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Plant matter	5.5	2.2 x 0.53	6.41	**2.5**
Vineyard BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Plant matter	3.3	2.2 x 0.53	3.85	**4.2**

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 HYCOP in potato

Intended use	Potato				
Active substance/product	Copper ~~hydroxide~~				
Application rate (g/ha)	3 × 1200				
Acute toxicity (mg/kg bw)	162.6				
TER criterion	10				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Potatoes BBCH 10 – 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	7.6	1.6	14.59	11.11
Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4	1.6	10.37	15.7
Potatoes BBCH 10 – 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	35.1	1.6	67.39	**2.4**
Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	10.5	1.6	20.16	**8.1**
Potatoes BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.6	78.53	**2.1**

Potatoes BBCH 10 – 39	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	17.2	1.6	33.02	**4.9**
Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.6	9.98	16.3
Reprod. toxicity (mg/kg bw/d)	16				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Potatoes BBCH 10 – 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	2.0 x 0.53	5.34	**3.0**
Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	2.0 x 0.53	2.42	6.6
Potatoes BBCH 10 – 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	14.3	2.0 x 0.53	18.19	**0.9**
Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	4.3	2.0 x 0.53	5.47	**2.9**
Potatoes BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	2.0 x 0.53	27.60	**0.6**
Potatoes BBCH 10 – 39	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	2.0 x 0.53	9.92	**1.6**
Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	2.0 x 0.53	2.93	5.5

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 HYCOP in solanaceous fruits (tomato and aubergine)

Intended use	Solanaceous fruits (tomato and aubergine)
Active substance/product	Copper ~~hydroxide~~
Application rate (g/ha)	3 × 1200
Acute toxicity (mg/kg bw)	162.6

TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4	1.6	10.37	15.7
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.6	78.53	**2.1**
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	5.2	1.6	9.98	16.3
Fruiting vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	7.6	1.6	14.59	11.1
Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole Grass + cereals 100% grass	136.4	1.6	261.89	**0.6**
Fruiting vegetables BBCH 10 – 49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	17.2	1.6	33.02	**4.9**
Reprod. toxicity (mg/kg bw/d)	16				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	2.0 x 0.53	2.42	6.6
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	2.0 x 0.53	27.60	**0.6**
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	2.0 x 0.53	2.93	5.5
Fruiting vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	2.0 x 0.53	5.34	**3.0**
Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole Grass + cereals 100% grass	72.3	2.0 x 0.53	91.97	**0.2**
Fruiting vegetables BBCH 10 – 49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	2.0 x 0.53	9.92	**1.6**

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 HYCOP in Pome fruit (apple, pear and quince)

Intended use	Pome fruit (apple, pear and quince)				
Active substance/product	Copper ~~hydroxide~~				
Application rate (g/ha)	3 × 1200				
Acute toxicity (mg/kg bw)	162.6				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard Application crop directed BBCH ≥ 40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	10.5	1.5	18.90	**8.6**
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	40.9	1.5	73.62	**2.2**
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	**3.2**
Orchard Application crop directed BBCH 10-19	Small herbivorous mammal "vole Grass + cereals 100% grass	109.2	1.5	196.56	**0.8**
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	**6.5**
Orchard Application crop directed BBCH 20-40	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	21.1	1.5	37.98	**4.3**
Orchard Application crop directed BBCH 20-40	Small herbivorous mammal "vole Grass + cereals 100% grass	81.9	1.5	147.42	**1.1**
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	**8.8**

Orchard Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse" larger fruits 100% fruit	47.9	1.5	86.22	**1.9**
Reprod. toxicity (mg/kg bw/d)	16				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
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	**3.3**
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	1.8 x 0.53	24.84	**0.6**
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	**1.2**
Orchard Application crop directed BBCH 10-19	Small herbivorous mammal "vole Grass + cereals 100% grass	57.8	1.8 x 0.53	66.17	**0.2**
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	**2.3**
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	**1.6**
Orchard Application crop directed BBCH 20-40	Small herbivorous mammal "vole Grass + cereals 100% grass	43.4	1.8 x 0.53	49.68	**0.3**
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	**3.0**
Orchard Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse" larger fruits 100% fruit	22.7	1.8 x 0.53	25.99	**0.6**

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 HYCOP 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_{50} 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)
HYCOP 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)[2], 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 HYCOP in grapevine – refined parameters (*) are further described and justified in the text

Intended use	**Grapevine**
Active substance/product	Copper hydroxide
Application rate (g/ha)	4 × 1000
Acute toxicity (mg/kg bw)	162.6

[2] 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.

TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** **(mg/kg food)**	**MAF_{90}***	**PT**	**DDD_{90}** **(mg/kg bw/d)**	**TER_a**
Brown Hare (*Lepus europaeus*)	100% Plant matter	0.39[1]	70.3[2] × 1.0	1.0	1.0	27.42	**5.9**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.4[3]	1.0	1.0	54.42	**3.0**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	70.3[2] × 0.4	1.0	1.0	1.90	23.7
	50% weed seeds	0.27[1]	87.0[2] × 0.4[3]	1.0	1.0	4.70	
	25% ground arthopods	0.27[1]	9.7[2] × 0.4[3]	1.0	1.0	0.26	
	whole diet					6.86	
Reprod. toxicity (mg/kg bw/d)	16						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** **(mg/kg food)**	**MAF_m*× TWA***	**PT**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Brown Hare (*Lepus europaeus*)	100% Plant matter	0.39[1]	28.7[2] × 1.0	1.0	1.0	27.42	**1.4**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.4[3]	1.0	1.0	28.83	**0.6**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.4	1.0	1.0	0.77	5.3
	50% weed seeds	0.27[1]	40.2[2] × 0.4[3]	1.0	1.0	2.17	
	25% ground arthopods	0.27[1]	3.5[2] × 0.4[3]	1.0	1.0	0.09	
	whole diet					3.04	
Common shrew (*Sorex araneus*)	100% ground arthropods	0.55[1]	3.5[2] × 0.4[3]	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.
[1] According to Appendix A of EFSA/2009/1438.
[2] According to table 1 from Appendix F of EFSA/2009/1438.
[3] Deposition factor according to FOCUS groundwater guidance.

Intended use	**Grapevine**						
Active substance/product	Copper ~~hydroxide~~						
Application rate (g/ha)	4000*						
Acute toxicity (mg/kg bw)	162.6						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** **(mg/kg food)**	**MAF_{90}***	**PT**	**DDD_{90}** **(mg/kg bw/d)**	**TER_a**

Brown Hare (*Lepus europaeus*)	100% Plant matter	0.39[1]	70.3[2] × 1.0	1.0	1.0	109.64	**1.48**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.4[3]	1.0	1.0	217.69	**0.75**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	70.3[2] × 0.4	1.0	1.0	7.59	**5.93**
	50% weed seeds	0.27[1]	87.0[2] × 0.4[3]	1.0	1.0	18.79	
	25% ground arthopods	0.27[1]	9.7[2] × 0.4[3]	1.0	1.0	1.05	
	whole diet					27.43	
Reprod. toxicity (mg/kg bw/d)	16						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** **(mg/kg food)**	**MAF_m*× TWA***	**PT**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Brown Hare (*Lepus europaeus*)	100% Plant matter	0.39[1]	28.7[2] × 1.0	1.0	1.0	44.77	**0.36**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.4[3]	1.0	1.0	115.34	**0.14**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.4	1.0	1.0	3.10	**1.32**
	50% weed seeds	0.27[1]	40.2[2] × 0.4[3]	1.0	1.0	8.68	
	25% ground arthopods	0.27[1]	3.5[2] × 0.4[3]	1.0	1.0	0.38	
	whole diet					12.16	
Common shrew (*Sorex araneus*)	100% ground arthropods	0.55[1]	3.5[2] × 0.4[3]	1.0	1.0	3.08	5.19

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.
[1] According to Appendix A of EFSA/2009/1438.
[2]According to table 1 from Appendix F of EFSA/2009/1438.
[3]Deposition factor according to FOCUS groundwater guidance.
* Maximum cumulative annual application rate

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

Intended use	Potato
Active substance/product	Copper hydroxide
Application rate (g/ha)	3 × 1200
Acute toxicity (mg/kg bw)	162.6
TER criterion	10

Focal species	Food category, % in diet	FIR/bw	RUD_{90} × DF* (mg/kg food)	MAF_{90}*	PT	DDD_{90} (mg/kg bw/d)	TER_a
Rabbit (*Oryctolagus cuniculus*)	100% Non-grass herbs	0.50[1]	70.3[2] × 1.0	1.0	1.0	42.18	**3.9**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.85[3]	1.0	1.0	138.78	**1.2**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	70.3[2] × 0.85[3]	1.0	1.0	4.84	**9.3**
	50% weed seeds	0.27[1]	87.0[2] × 0.85[3]	1.0	1.0	11.98	
	25% ground arthopods	0.27[1]	9.7[2] × 0.85[3]	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_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Rabbit (*Oryctolagus cuniculus*)	100% Plant matter	0.50[1]	28.7[2] × 1.0	1.0	1.0	17.22	**0.9**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.85[3]	1.0	1.0	73.53	**0.2**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.85[3]	1.0	1.0	1.65	**2.5**
	50% weed seeds	0.27[1]	40.2[2] × 0.85[3]	1.0	1.0	4.61	
	25% ground arthopods	0.27[1]	3.5[2] × 0.85[3]	1.0	1.0	0.20	
	whole diet					6.46	
Common shrew (*Sorex araneus*)	100% ground arthropods	0.55[1]	3.5[2] × 0.85[3]	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.
[1] According to Appendix A of EFSA/2009/1438.
[2] According to table 1 from Appendix F of EFSA/2009/1438.
[3] Deposition factor according to FOCUS groundwater guidance.

Intended use	**Potato**
Active substance/product	Copper ~~hydroxide~~
Application rate (g/ha)	4000*
Acute toxicity (mg/kg bw)	162.6
TER criterion	10

Focal species	Food category, % in diet	FIR/bw	RUD_{90} × DF* (mg/kg food)	MAF_{90}*	PT	DDD_{90} (mg/kg bw/d)	TER_a
Rabbit (*Oryctolagus cuniculus*)	100% Non-grass herbs	0.50[1]	70.3[2] × 1.0	1.0	1.0	140.6	**1.16**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.85[3]	1.0	1.0	462.60	**0.35**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	70.3[2] × 0.85[3]	1.0	1.0	16.13	**2.79**
	50% weed seeds	0.27[1]	87.0[2] × 0.85[3]	1.0	1.0	39.93	
	25% ground arthopods	0.27[1]	9.7[2] × 0.85[3]	1.0	1.0	2.23	
	whole diet					58.29	
Reprod. toxicity (mg/kg bw/d)	16						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF* (mg/kg food)**	**MAF_m*× TWA***	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Rabbit (*Oryctolagus cuniculus*)	100% Plant matter	0.50[1]	28.7[2] × 1.0	1.0	1.0	57.40	**0.28**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.85[3]	1.0	1.0	245.09	**0.07**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.85[3]	1.0	1.0	6.59	**0.62**
	50% weed seeds	0.27[1]	40.2[2] × 0.85[3]	1.0	1.0	18.45	
	25% ground arthopods	0.27[1]	3.5[2] × 0.85[3]	1.0	1.0	0.80	
	whole diet					25.84	
Common shrew (*Sorex araneus*)	100% ground arthropods	0.55[1]	3.5[2] × 0.85[3]	1.0	1.0	6.55	**2.44**

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.
[1] According to Appendix A of EFSA/2009/1438.
[2]According to table 1 from Appendix F of EFSA/2009/1438.
[3]Deposition factor according to FOCUS groundwater guidance.
* Maximum cumulative annual application rate

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

Intended use	**Solanaceous frui (tomato and aubergine)**
Active substance/product	Copper hydroxide
Application rate (g/ha)	3 × 1200
Acute toxicity (mg/kg bw)	162.6
TER criterion	10

Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** (mg/kg food)	**MAF_{90}***	**PT**	**DDD_{90}** (mg/kg bw/d)	**TER_a**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.5[3]	1.0	1.0	81.64	**2.0**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	70.3[2] × 0.5[3]	1.0	1.0	2.85	15.8
	50% weed seeds	0.27[1]	87.0[2] × 0.5[3]	1.0	1.0	7.05	
	25% ground arthopods	0.27[1]	9.7[2] × 0.5[3]	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_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.5[3]	1.0	1.0	43.25	**0.4**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.5[3]	1.0	1.0	1.16	**3.5**
	50% weed seeds	0.27[1]	40.2[2] × 0.5[3]	1.0	1.0	3.26	
	25% ground arthopods	0.27[1]	3.5[2] × 0.5[3]	1.0	1.0	0.14	
	whole diet					4.56	
Common shrew (*Sorex araneus*)	100% ground arthropods	0.55[1]	3.5[2] × 0.85[3]	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.
[1] According to Appendix A of EFSA/2009/1438.
[2]According to table 1 from Appendix F of EFSA/2009/1438.
[3]Deposition factor according to FOCUS groundwater guidance.

Intended use	**Solanaceous frui (tomato and aubergine)**						
Active substance/product	Copper ~~hydroxide~~						
Application rate (g/ha)	3600*						
Acute toxicity (mg/kg bw)	162.6						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** (mg/kg food)	**MAF_{90}***	**PT**	**DDD_{90}** (mg/kg bw/d)	**TER_a**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.5[3]	1.0	1.0	244.91	**0.66**
Wood mouse (*Apodemus*	25% weeds	0.27[1]	70.3[2] × 0.5[3]	1.0	1.0	8.54	5.27

sylvaticus)	50% weed seeds	0.27[1]	87.0[2] × 0.5[3]	1.0	1.0	21.14	
	25% ground arthopods	0.27[1]	9.7[2] × 0.5[3]	1.0	1.0	1.18	
	whole diet					30.86	
Reprod. toxicity (mg/kg bw/d)	16						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** **(mg/kg food)**	**MAF_m*× TWA***	**PT**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.5[3]	1.0	1.0	129.75	**0.12**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.5[3]	1.0	1.0	3.49	**1.17**
	50% weed seeds	0.27[1]	40.2[2] × 0.5[3]	1.0	1.0	9.77	
	25% ground arthopods	0.27[1]	3.5[2] × 0.5[3]	1.0	1.0	0.43	
	whole diet					13.69	
Common shrew (*Sorex araneus*)	100% ground arthropods	0.55[1]	3.5[2] × 0.85[3]	1.0	1.0	5.89	**2.72**

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.
[1] According to Appendix A of EFSA/2009/1438.
[2]According to table 1 from Appendix F of EFSA/2009/1438.
[3]Deposition factor according to FOCUS groundwater guidance.
* Maximum cumulative annual application rate

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

Intended use	Pome fruits						
Active substance/product	Copper hydroxide						
Application rate (g/ha)	3 × 1200						
Acute toxicity (mg/kg bw)	162.6						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** **(mg/kg food)**	**MAF_{90}***	**PT**	**DDD_{90}** **(mg/kg bw/d)**	**TER_a**
Rabbit (*Oryctolagus cuniculus*)	100% Non-grass herbs	0.50[1]	70.3[2] × 0.4[3]	1.0	1.0	16.87	**9.6**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.4[3]	1.0	1.0	65.31	**2.5**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	70.3[2] × 0.4[3]	1.0	1.0	2.28	19.8
	50% weed seeds	0.27[1]	87.0[2] × 0.4[3]	1.0	1.0	5.64	

	25% ground arthopods	0.27[1]	9.7[2] × 0.4[3]	1.0	1.0	0.31	
	whole diet					8.23	
Garden dormouse (*Eliomys quercinus*)	100% fruit	1.16[1]	41.1[2] × 1.0	1.0	1.0	57.21	**2.8**
Reprod. toxicity (mg/kg bw/d)	16						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** **(mg/kg food)**	**MAF_m*× TWA***	**PT**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Rabbit (*Oryctolagus cuniculus*)	100% Plant matter	0.50[1]	28.7[2] × 0.4[3]	1.0	1.0	6.89	**2.3**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.5[3]	1.0	1.0	34.60	**0.5**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.4[3]	1.0	1.0	0.93	**4.4**
	50% weed seeds	0.27[1]	40.2[2] × 0.4[3]	1.0	1.0	2.60	
	25% ground arthopods	0.27[1]	3.5[2] × 0.4[3]	1.0	1.0	0.11	
	whole diet					3.65	
Garden dormouse (*Eliomys quercinus*)	100% fruit	1.16[1]	19.5[2] × 1.0	1.0	1.0	27.14	**0.6**

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.

[1] According to Appendix A of EFSA/2009/1438.

[2] According to table 1 from Appendix F of EFSA/2009/1438.

[3] Deposition factor according to FOCUS groundwater guidance.

Intended use	**Pome fruits**						
Active substance/product	Copper ~~hydroxide~~						
Application rate (g/ha)	3600*						
Acute toxicity (mg/kg bw)	162.6						
TER criterion	10						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_{90} × DF*** **(mg/kg food)**	**MAF_{90}***	**PT**	**DDD_{90}** **(mg/kg bw/d)**	**TER_a**
Rabbit (*Oryctolagus cuniculus*)	100% Non-grass herbs	0.50[1]	70.3[2] × 0.4[3]	1.0	1.0	50.62	**3.21**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	102.3[2] × 0.4[3]	1.0	1.0	195.92	**0.83**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	70.3[2] × 0.4[3]	1.0	1.0	6.83	**6.59**
	50% weed seeds	0.27[1]	87.0[2] × 0.4[3]	1.0	1.0	16.91	
	25% ground arthopods	0.27[1]	9.7[2] × 0.4[3]	1.0	1.0	0.94	
	whole diet					24.68	

Garden dormouse (*Eliomys quercinus*)	100% fruit	1.16[1]	41.1[2] × 1.0	1.0	1.0	171.63	**0.95**
Reprod. toxicity (mg/kg bw/d)	16						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF*** (mg/kg food)	**MAF_m*× TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Rabbit (*Oryctolagus cuniculus*)	100% Plant matter	0.50[1]	28.7[2] × 0.4[3]	1.0	1.0	20.66	**0.77**
Common vole (*Microtus arvalis*)	100% grass	1.33[1]	54.2[2] × 0.5[3]	1.0	1.0	76.19	**0.21**
Wood mouse (*Apodemus sylvaticus*)	25% weeds	0.27[1]	28.7[2] × 0.4[3]	1.0	1.0	2.79	**1.46**
	50% weed seeds	0.27[1]	40.2[2] × 0.4[3]	1.0	1.0	7.81	
	25% ground arthopods	0.27[1]	3.5[2] × 0.4[3]	1.0	1.0	0.34	
	whole diet					10.94	
Garden dormouse (*Eliomys quercinus*)	100% fruit	1.16[1]	19.5[2] × 1.0	1.0	1.0	81.43	**0.20**

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.

[1] According to Appendix A of EFSA/2009/1438.

[2]According to table 1 from Appendix F of EFSA/2009/1438.

[3]Deposition factor according to FOCUS groundwater guidance.

* Maximum cumulative annual application rate

After even the refinement, the risk assessment showed that Copper hydroxide 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 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:

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

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[3] 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 potato (STMR 1.30 mg/kg) and pepper (STMR 2.59 mg/kg) are all well below the values fed in these studies (please, refer to dRR B7 updated).

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.

ZRMS comments:

Copper hydroxide

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 hydroxide50% (Hycop).

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 MAFxTWA=1 for 1 maximum annual application from the GAP, whilst Applicant performed higher tier RA using MAFxTWA=1 but still considering number of rates and concentrations as reported in GAP.

Therfore, 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 after comenting period for higher tier risk assessment provided required calculations.

Further,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.

[3] 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

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 f**or 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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 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 hydroxide 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) =	2200		
Acute toxicity (mg/kg bw) =	162.6	quotient =	13.53
Reprod. toxicity (mg/kg bw/d) =	16	quotient =	137.50

As the ratios do not exceed the value of 3000 for HYCOP, 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 HYCOP 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 hydroxide 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 HYCOP 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).

zRMS comments:
According to the current state of knowledge, it is not possible to conclude on a lack of risk for amphibians and reptiles as stated by the applicant. Instead it was suggest that Member States should consider how to

deal with a potential risk for terrestrial amphibians and reptiles at national level.

During comenting period it was raised on by coMS-DE that the literature review data provides not sufficient evidence of a lack of risk to other terrestrial wildlife (reptiles and amphibians). It is correct, that there is a big range between the endpoints of the 14 studies of the mentioned literature review. However, the most sensitive endpoints per section are quite low indicating that copper compounds might cause an unacceptable risk to certain specimens and / or developmental stages as the following overview of the most sensitive endpoints per section for amphibians and reptiles is proving:

- Acute: *Duttaphrynus melanostictus,* Copper sulfate 96-h LC50=3 µg Cu/L (measured), Shuhaimi-Othman, M. et al., 2011
- LC50 Larval stages: *Rhinella arenarum,* Copper chloride, Larval stage S 4: 168-h LC50=19.5 µg Cu/L (nom), Aronzon, C.M. et al., 2011
- Chronic: *Bufo arabicus*, Copper sulfate, 20-d NOEC = 4.25 µg Cu/L (measured), Barry, M.J. 2011

Referring to the risk assessment for amphibians and reptiles, there are some recurring issues that we have already raised in the context of other dossier(s), i.e. Further, as pointed out in the latest EFSA Opinion on amphibians and reptiles (EFSA PPR 2018), the risk for amphibians and reptiles cannot adequately be predicted by the assessment of the data obtained with other vertebrates. The acute risk for aquatic stages of amphibians might be estimated on the basis of fish acute data. But, as pointed out by EFSA, the assessment factor to properly address the risk to aquatic stages of amphibians needs to be identified, since it is unclear whether the exposure assessment for other aquatic organisms would also cover the exposure of amphibians in small ponds. Regarding acute and chronic toxicity of pesticides to amphibians and reptiles, the available results from experiments with birds and mammals show no correlation with toxicity endpoints in amphibians and reptiles (Ortiz-Santaliestra et al. 2017*).

The dermal route of exposure is crucial especially for the terrestrial life stages of amphibians (EFSA PPR 2018). However, this exposure route is currently not addressed in the assessment of the risks for birds and mammals. Moreover, the terrestrial life stage phase of Amphibians is not assed based on active substance tests, only the aquatic one; the terrestrial life phase is considered but only once, for a reptile (the Red-Backed Salamanders, *Plethodon cinereus*, Bazar et al. 2008).

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 hydroxide. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of HYCOP were not evaluated as part of the EU assessment of Copper hydroxide.

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 hydroxide

Species	Substance	Exposure System	Results	Reference
Fish				
O. mykiss	Copper hydroxide WP	96 h, f	Mortality, Total: LC_{50} = 0.0165 mg/L $_{mm}$ **Dissolved: LC_{50} = 0.0080 mg/L $_{mm}$**	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
O. mykiss	Copper oxychloride	96 h, f	Mortality, Total: LC_{50} > 43.8 mg/L $_{mm}$ Dissolved: LC_{50} > 0.106 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Copper oxychloride	96 hr, ss	Mortality, Dissolved: EC_{50} = 0.047 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Copper oxychloride WP	96 h, f	Mortality, Total: LC_{50} > 0.78 mg/L $_{mm}$ Dissolved: LC_{50} > 0.0109 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Bordeaux mixture	96 hr, ss	Mortality, Total: LC_{50} > 21.39 mg/L $_{mm}$ Dissolved: LC^{50} > 0.125 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Bordeaux mixture	96 hr, ss	Mortality, LC_{50} = 0.082 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Bordeaux mixture WP	96 hr, ss	Mortality, LC_{50} = 0.052 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Tribasic copper sulfate SC	96 hr, s	Mortality, LC_{50} = 13.18 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
C. carpio	Tribasic copper sulfate SC	96 hr, f	Mortality, LC_{50} > 19.3 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Copper oxide	96 h, f	Mortality, Total: LC_{50} > 0.207 mg/L $_{mm}$ Dissolved: LC_{50} = 0.0344 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Copper oxide WP	96 h, f	Mortality, Total: LC_{50} = 0.047 mg/L $_{mm}$ Dissolved: LC_{50} = 0.0106 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
C. carpio	Copper oxide WG	96 hr, ss	Mortality, LC_{50} = 4.37 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	*Copper Hydroxide WP (with sediment)*	48 h, s	Mortality, Total: LC_{50} = 0.54 mg/L $_{mm}$ Dissolved: LC_{50} = 0.18 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
O. mykiss	Copper hydroxide WP	92 d, ELS	Growth: Total: NOEC= 0.0155 mg/L $_{mm}$ **Dissolved: NOEC = 0.0017 mg/L $_{mm}$**	EFSA Journal 2018;16(1):5152
O. mykiss	Tribasic copper sulfate SC	21 d, f	Growth: Total: NOEC= 0.97 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
D. rerio (embryo)[12]	Copper hydroxide	48h, s	Mortality, Total: NOEC ≤ 3.2 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
D. rerio (embryo)[12]	Copper oxychloride	48h, s	Mortality, Total: NOEC = 18.0 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
D. rerio (embryo)[12]	Bordeaux mixture	48h, s	Mortality, Total: NOEC = 22.5 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
D. rerio (embryo)[12]	Tribasic Copper sulphate	48h, s	Mortality, Total: NOEC = 76.8 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
D. rerio (embryo)[12]	Copper oxide	48h, s	Mortality, Total: NOEC = 1.06 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
Pimephales promelas	Copper sulfate	270 d, f	Dissolved Cu: NOEC (number of eggs/spawn) = 0.066 mg/L	EFSA Journal 2018;16(1):5152
Perca fluviatilis	Copper sulfate	30 d, f	Mortality: NOEC = 0.188 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Perca fluviatilis	Copper sulfate	18 d, f	Growth rate: NOEC = 0.022 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Pimephales notatus	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
O. mykiss	Copper chloride	60 d, f	Growth: NOEC = 0.0022 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Salvelinus fontinalis	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
Pimephales promelas	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
Pimephales promelas	Copper sulfate	327 d, f	Growth rate, mortality and reproduction: NOEC = 0.0106 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Oncorhynchus kisutch	Cu2+ (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
O. mykiss		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
Pimephales promelas	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

Species	Substance	Exposure System	Results	Reference
Ictalurus punctatus	Copper sulfate	60 d, f	NOEC (growth rate, mortality) = 0.013 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Salvelinus fontinalis			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)	
Pimephales promelas	Copper sulfate	28 d, f	NOEC (mortality) = 0.061 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Neomacheilus barbatulus	Copper sulfate	64 d, f	NOEC (survival) = 0.120 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Pimephales promelas	Copper nitrate	32 d, f	NOEC (mortality, growth) = 0.0048 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Salvenus fontinalis	Copper sulfate	45 d, f	NOEC (mortality, growth) = 0.0114 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Oncorhynchus mykiss		40 d, f	NOEC (mortality, growth) = 0.0129 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Catostomus commersoni		35 d, f	NOEC (mortality, growth) = 0.0349 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Esox lucius		60 d, f	NOEC (mortality, growth) = 0.0223 mg/L (total Cu)	EFSA Journal 2018;16(1):5152
Oncorhynchus mykiss	Copper sulfate	30 d, f	LC_{10} (mortality – pH 5.1) = 0.0038 mg/L (dissolved Cu) LC_{10} (mortality – pH 6.2) = 0.0047 (dissolved Cu) LC_{10} (mortality – pH 7.1) = 0.0039 (dissolved Cu) LC_{10} (mortality – pH 7.9) =0.0076 (dissolved Cu) LC_{10} (mortality – pH 8.6) = 0.0161 (dissolved Cu)	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Acipenser transmontanus	Copper sulfate	66 d, f	NOEC (mortality) = 0.0059 mg/L (dissolved Cu)	EFSA Journal 2018;16(1):5152
Acipenser transmontanus	Copper sulfate	14 d; 28 d; 53 d, f	14-d LC_{10} (mortality) = 0.00183 mg/L (dissolved Cu) **53-d EC_{10} (growth) = 0.00112** mg/L (dissolved Cu) 28-d LC10 (mortality) = 0.00372 mg/L (dissolved Cu) 28-d EC_{10} (growth) = 0.00196 mg/L (dissolved Cu) 28-d EC_{10} (growth) = 0.00203 mg/L (dissolved Cu)	EFSA Journal 2018;16(1):5152
Oncorhynchus mykiss		14 d; 28 d; 53 d, f	21-d LC_{10} (mortality) = 0.037 mg/L (dissolved Cu) 52-d LC_{10} (mortality) = 0.034 mg/L (dissolved Cu) 21-d EC_{10} (biomass) = 0.031 mg/L (dissolved Cu) 28-d LC10 (mortality) = 0.034 mg/L (dissolved Cu) 28-d EC_{10} (growth) = 0.013 mg/L (dissolved Cu) 28-d EC_{10} (biomass) =0.025 mg/L (dissolved Cu)	
Aquatic invertebrate				
D. magna	Copper hydroxide	48h, s	Reproduction, Total: EC_{50} = 0.038 mg/L $_{mm}$ Dissolved: **EC_{50} = 0.0266 mg/L $_{mm}$**	EFSA Journal 2018;16(1):5152
D. magna	Copper oxychloride	48h, s	Mortality, Total: EC_{50} = 0.29 mg/L $_{nom}$*	EFSA Journal 2018;16(1):5152
D. magna	Bordeaux mixture	48h, s	Mortality, Total: EC_{50} = 1.87 mg/L $_{nom}$*	EFSA Journal 2018;16(1):5152
D. magna	Copper oxide	48h, s	Mortality, Total: EC_{50} = 0.45 mg/L $_{nom}$*	EFSA Journal 2018;16(1):5152
D. magna	Copper oxychloride	21d, ss	Reproduction, Total: NOEC = 0.0076 mg/L $_{mm}$ (geometric mean measured)#	EFSA Journal 2018;16(1):5152
D. magna	Copper oxychloride	21d, ss	Reproduction, Total: NOEC = 0.059 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
D. magna	Tribasic copper sulfate SC *	21d, ss	Reproduction, Total: NOEC = 0.057 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
D. magna (21-d studies with sediment)**	Copper hydroxide WP	21d, ss	Mortality, Total: LC_{50} = 0.024 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
			Reproduction, Total: NOEC = 0.0299 mg/L $_{mm}$	
	Copper hydroxide SC	21d, ss	Mortality, Total: LC_{50} = 0.0109 mg/L $_{mm}$	

Species	Substance	Exposure System	Results	Reference
			Reproduction, **Total: NOEC = 0.027 mg/L $_{mm}$**	
	Copper oxychloride WP	21d, ss	Mortality, Total: LC_{50} = 0.0298 mg/L $_{mm}$	
			Reproduction, Total: NOEC = 0.0461 mg/L $_{mm}$	
	Bordeaux mixture WP	21d, ss	Mortality, Total: LC_{50} = 0.0109 mg/L $_{mm}$	
			Reproduction, Total: NOEC = 0.027 mg/L $_{mm}$	
	Tribasic copper sulfate SC	21d, ss	Mortality, Total: LC_{50} = 0.0167 mg/L $_{mm}$	
			Reproduction, Total: NOEC = 0.034 mg/L $_{mm}$	
	Copper oxide WP	21d, ss	Mortality, Total: LC_{50} = 0.0113 mg/L $_{mm}$	
			Reproduction, Total: NOEC = 0.0122 mg/L $_{mm}$	
Sediment dwelling organisms				
Chironomus riparius	Tribasic copper sulphate	28d, s spiked sediment	Reproduction, Total: NOEC = 0.50 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
Chironomus riparius	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
Tubifex tubifex	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	
Hyalella azteca	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
Lumbriculus variegatus	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

Species	Substance	Exposure System	Results	Reference
Gammarus pulex	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
Hyalella azteca	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
Hexagenia spp.	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
Bellamya aeruginosa	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
Algae				
S. capricornutum	Copper hydroxide WP	72h, s	Biomass: Total E_bC_{50} = 0.00939 mg/L $_{nom}$ **Growth rate:** **Total E_rC_{50} = 0.02229** mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
S. subspicatus	Copper oxychloride	72h, s	Biomass, Total: E_bC_{50} = 49.81 mg/L $_{mm}$ Growth rate, Total: ErC_{50} > 165.9 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
D. subspicatus	Bordeaux mixture	72h, s	Biomass, Total: E_bC_{50} = 0.64 mg/L $_{nom}$ Growth rate, Total: ErC_{50} = 11.55 mg/L $_{nom}$ Biomass, Total: E_bC_{50} = 0.07 mg/L $_{nom}$ Growth rate, Total: ErC_{50} = 5.54 mg/L $_{nom}$	EFSA Journal 2018;16(1):5152
P. subcapitata	Copper oxide WP	72h, s	Biomass, Total: E_bC_{50} = 0.147 mg/L $_{mm}$ Growth rate, Total: ErC_{50} = 0.299 mg/L $_{mm}$ Biomass, Dissolved: E_bC_{50} = 0.045 mg/L $_{mm}$ Growth rate, Dissolved: ErC_{50} = 0.133 mg/L $_{mm}$	EFSA Journal 2018;16(1):5152
Microcosm or mesocosm tests				

Species	Substance	Exposure System	Results	Reference
Indoor microcosm study	Copper hydroxide WP	6 applications at 10-d interval followed by 250 days of monitoring	Total : NOEC = 0.012 mg/L $_{nom}$ **Dissolved : 0.0048 mg/L$_{mmb}$** **(AF = 2 applied)**	EFSA Journal 2018;16(1):5152
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
Further testing on aquatic organisms Fish, acute, data from 7 fish species available from the literature were used. Therefore, this allows to derived a SSD-HC_5 values of 3.73 µg/L, an AF of 3 is applied. Fish, chronic (based on SSD analysis SSD-HC_5 = 0.00111 mg/L (AF = 43) 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 *Chrinomus riparius* and *Hyallela Azteca* species) an AF = 5 has been set.				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) No information highlights any ED property of copper.				

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 Elendt M4 medium which contains EDTA. This chelating agent is known to have an outcome on the biological resulst 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 – HYCOP

Species	Substance	Exposure System	Results	Reference
O. mykiss	HYCOP	96 h, s	LC_{50} = 0.0594 mg f.p./L $_{nom}$ (equivalent to 0.0298 mg Cu/L)^{nom}	KCP 10.2.1-01 XXX, M. 2020 5695/2019
Daphnia magna	HYCOP	48 h, s	EC_{50} = 0.109 mg f.p./L $_{nom}$ (equivalent to 0.055 mg Cu/L)^{nom}	KCP 10.2.1-02 XXX, K. 2019 5697/2019

Species	Substance	Exposure System	Results	Reference
Pseudokirchneriella subcapitata	HYCOP	72 h	E_rC_{50} = 0.0465 mg f.p./L $_{nom}$ (equivalent to 0.0233 mg Cu/L)^{nom} E_yC_{50} = 0.0096 mg f.p./L $_{nom}$ (equivalent to 0.0048 mg Cu/L)^{nom}	KCP 10.2.1-03 XXX, D. 2019 5696/2019

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

9.5.1.1 Justification for new endpoints

The EU agreed endpoints are uses for the risk assessment.

According to R (EU) nº 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*". HYCOP 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 XXX, 2019) 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, XXX XXX, 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 per-formed 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 Regenmortel et al. 2015, De Schamphelaere 2018). 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 Me^{2+} toxicity, while in a traditional BLM the effect of pH is modelled via a linear relation between pH and free 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 Me^{2+} toxicity besides the competitive effect of H^{+} at the biotic ligand site. At the moment, chronic Cu gBAMs are available for four taxonomic groups: algae (De Schamphelaere & XXX 2006), the crus-tacean *Daphnia magna* (XXX Regenmortel et al. 2015), fish (De Schamphelaere 2018) 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 (Tipping et al. 2011). It was shown that free metal ion activity in natural waters could be calculated rather accurately using WHAM VII (Lofts & Tipping 2011). Hence, WHAM VII can be considered as the most appropriate speciation software to model metal speciation. While the chronic gBAMs for fish (De Schamphelaere 2018) and *L. minor* were directly developed in combination with WHAM VII, the chronic Cu gBAMs for D. magna (XXX Regenmortel et al. 2015) and algae (De Schamphelaere & XXX 2006) have been originally developed in combination with WHAM V. However, XXX Regenmortel (2017) 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 $gBAM_{WHAMVII}$-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 ECx_{Mediss} of an independent dataset is predicted within 2-fold error (Di Toro et al. 2001; De Schamphelaere & XXX 2006; XXX Regenmortel et al. 2015), 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 (De Schamphelaere & XXX 2006; XXX Regenmortel et al. 2015).

The Fish $gBAM_{WHAMVII}$ developed by De Schamphelaere (2018) 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 $gBAM_{WHAMVII}$ 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* $gBAM_{WHAMVII}$ 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 $gBAM_{WHAMVII}$ can be used for predicting chronic Cu toxicity in risk assessment applications, such as deriving site-specific bioavailable PNECs. *XXX XXX, P, 2019*

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 and XXX, 2019). 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**.

Reference:	**CP 10.2/02, XXX, K and XXX, F, 2019**
Title:	Relevance of Standard Assessment Factors for Risk Assessment of the Essential Element Copper
Report No.:	CuPPP20170705
Guidelines:	Not applicable
Deviations:	Not applicable
GLP:	No
Published	No
Comment:	-

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.

Comments to the study after commenting period:

The cMS DE pointed out to that a similar approach presented by XXX (2015) was discussed in most recent Renewal on Copper (rev. rev. RAR, Vol. 3, CA, B9, Nov. 2017; listed under: CA 8.4.1/01. XXX, K. 2015c, study report: CuPPP20150701)) where the RMS (DE) concluded, "that many uncertainties remained considering the derivation of a reliable RAC for earthworms". Several aspects and drawbacks raised in the evaluation of the study of XXX (2015) are also valid for XXX and Peeters (2019). In addition, this approach has not followed the 'Scientific Opinion on good modelling practice' according to EFSA (2014).

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 XXX, 2015)). As discussed above, no assessment factor should be applied and hence the BLM-normalised SSD-$RAC_{sw,ch}$ was determined to be 7.9 µg/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 (Schäfers, 2000) (CA 8.2.8/04), an NOEC of 4.8 µg/L (dissolved copper) was determined for the most sensitive species *Chydorus sphaericus*. This study was performed with a mean pH of 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 (Schäfers, 2001), 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 µg/L dissolved Copper. This suggests that the NOEC of 4.8 µg/L found in the initial study was a very conservative endpoint.

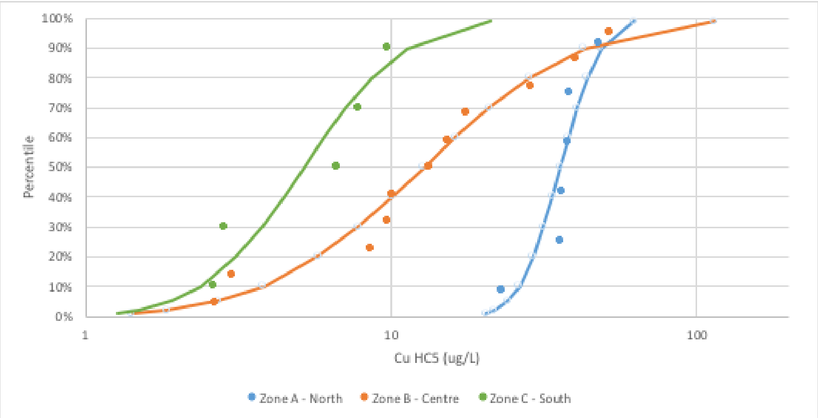
Given the exceptionally data richness and the particularity of a homeostatically tight controlled essential element, no further AF should be applied to the endpoint derived from the mesocosm and hence the ETO-$RAC_{sw;ch}$ will be 4.8 µg/L.

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 µg/L for fish is significantly higher than the aquatic invertebrate and algae ETO-$RAC_{sw;ch}$ of 4.8 µg/L thereby confirming that fish are not the most sensitive species. **The ETO-$RAC_{sw;ch}$ of 4.8 µg/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 XXX, 2019) 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 HC5 values which are representative for these 3 zones were calculated based on the HC5 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 HC5 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 (50th %) and realistic worst case (10th %) HC5 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 HC5 value of 35.75 µg/L for Zone A (North EU), 12.81µg/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	HC5 – Zone A	HC5 – Zone B	HC5 – 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 HC5 values supports the use of the ETO-$RAC_{sw;ch}$ 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, K and XXX, F, 2019

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:

Reference:	**CP 10.2/03, XXX, S.D., XXX, K., XXX XXX, P., XXX, K., 2019**
Title:	Modelling of the Funguran-OH Effects on *Onchorhynchus mykiss* Populations
Report No.:	Not applicable
Guidelines:	Not applicable
Deviations:	Not applicable
GLP:	No
Published	No
Comment:	-

Executive Summary
An earlier study on the toxicity of Funguran-OH on early life stage of the rainbow trout was performed by the Fraunhofer Institute in 2000 (URA-001/4-18). 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 Fraunhofer Institute 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 µg Cu/L and EC_{50} = 4.4 µg Cu/L): the EC_{10} for population density (3.3 µg Cu/L) was a factor two higher for the continuous exposure scenario and a factor 3 higher for the pulse exposure scenario (4.5 µg/L). Although roughly the same for the continuous exposure scenario, the EC_{50} value for the pulse exposure scenario (25.4 µg/L) was a factor 5 higher compared to the toxicity experiment.
XXX, S.D. et al., 2019

The EC_{10} of 4.5 µg/L from the pulse exposure scenario further supports the use of the ETO-$RAC_{sw;ch}$ of 4.8 µg/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 mg/kg is significantly less than the average natural concentration of copper in European sediments (17 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 mg/kg for PPP versus 87 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 (XXX, 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 mg/kg dry wt.**

Reference:	**CP 10.2/04, XXX, M, 2019**
Title:	Revised PNEC sediment copper for the sediment effects assessment for Cu : extending the database with additional species
Report No.:	Not applicable
Guidelines:	Not applicable
Deviations:	Not applicable
GLP:	No
Published	No
Comment:	-

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 et al, 2016) 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 (*Chironumus 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^{th} 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 comp.ounds (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 HC5. HC5 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.
XXX, M, 2019.

ZRMS comments:
Point: 9.5.1.1.1 and 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 summerised below.

1.XXX XXX, P, 2019, 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 XXX XXX-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*), *Lemma 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, Kand XXX, F, 2019:
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_5), 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 applicat 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, S.D., XXX, K., XXX XXX, P., XXX, K., 2019, 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 (Shäfers, Fraunhofer Institute), 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 Shäfers 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_{50} Funguran-OH = 1 day).
In the continuous exposure scenario, clear effects would be found on the mean population density at 4 µg/L (EC_{10} = 3.51; EC_{50} = 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_{10} = 7.99 µg/L and EC_{50} = 9.57 µg/L.

4. XXX, M, 2019, 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" (Vangheluve, M., 2015, in RAR Revised 2017).

This calculation by Vangheluve-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_5 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 Vangheluve-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 Vangheluve-2019, to reach 9 intended species data points and new HC_5 have been recalculated (featuring a total of 9 species of 5 different taxonomic groups).
In this report several SSD-HC_5 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_5 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_5 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_5 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 PECsw 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 avalible data and models developed for the decision for each of MSs level.~~
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 µg/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 µg/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 late as it is representative of the risk envelope for copper:

PEC_{sw} without spray drift mitigation:

FOCUS Step 1 and 2 PECsw 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 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on standard FOCUS Step 1, 2 maximum PECsw values for the use of HYCOP following a single application to vines early application (all entry routes to water bodies considered)

Group	Aquatic dwelling organisms						
Endpoint (NOEC, µg/L)	4.8						
AF	1						
ETO RAC_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**

Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S	16.21	**3.38**	9.00	**1.88**
			N				

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 HYCOP 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 HYCOP is required.

PECsw with spray drift mitigation:

Step 1 and 2 PECsw 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_{sw} modelling with spray drift mitigation according to the above scheme, along with relevant PEC/RAC ratios are summarised in the following tables:

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PECsw values for the use of HYCOP following a single application to vines early 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (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 PECsw values for the use of HYCOP following a single application to vines 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	S	16.21	**3.38**	9.00	**1.88**
			N				

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 PECsw values for the use of HYCOP following a single application to vines early application (drift mitigation considered)

Group	Aquatic dwelling organisms										
Endpoint (NOEC, µg/L)	4.8										
AF	1										
ETO RAC_{sw} (µg/L)	4.8										
Uses	**Application pattern**	**Season of application**	**Region**	**Step 2**							
				Buffer (m)	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	N and S	3	None	7.12	**1.48**	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 PECsw values for the use of HYCOP following a single application to vines early application (runoff/drainage plus spray drift with mitigation) - TOTAL copper

Group	Aquatic dwelling organisms																		
Endpoint (NOEC, µg/L)	4.8																		
AF	1																		
ETO RAC_{sw} (µg/L)	4.8																		
Uses	**Application pattern**	**Season of application**	**Region**	**PECsw (µg/L) (considering Run-off/drainage only)**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**
Vines BBCH 15 Early drift rates	4 x 1000 g a.s./ha	March-May	N and S	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 PECsw values for the use of HYCOP following a single application to vines early application (without mitigation measures considering all entry routes) - DISSOLVED copper

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

Grapevine (late application)

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

PEC_{sw} without spray drift mitigation:

FOCUS Step 1 and 2 PECsw 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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	S	33.97	**7.08**	26.76	**5.58**
			N				

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 HYCOP 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 HYCOP is required.

PECsw with spray drift mitigation:

Step 1 and 2 PECsw 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_{sw} 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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (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			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 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	S	33.97	**7.08**	26.76	**5.58**
			N				

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 PECsw values for the use of HYCOP following a single application to vines late application (drift mitigation considered)

Group	Aquatic dwelling organisms														
Endpoint (NOEC, µg/L)	4.8														
AF	1														
ETO RAC$_{sw}$ (µg/L)	4.8														
Uses	**Application pattern**	**Season of application**	**Region**	**Step 2**											
				Buffer (m)	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	N and S	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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8

Uses	Application pattern	Season of application	Region	PECsw (µg/L) (considering Runoff/drainage only)	Buffer (m)	Nozzles reduction (%)	PECsw (µg/L) (considering drift only)	PECsw (µg/L) (Total)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PECsw (µg/L) (considering drift only)	PECsw (µg/L) (Total)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PECsw (µg/L) (considering drift only)	PECsw (µg/L) (Total)	PEC/RAC	Buffer (m)	Nozzles reduction (%)	PECsw (µg/L) (considering drift only)	PECsw (µg/L) (Total)	PEC/RAC
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	N and S	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	14	None	2.28	4.74	0.99
						90%	2.13				90%	1.04				75%	0.95				50%	1.14		

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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8								
Uses	**Application pattern**	**Season of application**	**Region**	**PECsw (µg/L) (considering Runoff/drainage only)**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering 10m of vfs)**	**PECsw (µg/L) (Total)**	**PEC/RAC**
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	N and S	3.60*	3	None	1.44	3.33	0.69
						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_{sw} values following a single application to vines late. 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 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PECsw values for the use of HYCOP following a single application to vines late application (without mitigation measures considering all entry routes) - DISSOLVED copper

Group	Aquatic dwelling organisms																
Endpoint (NOEC, µg/L)	4.8																
AF	1																
ETO RAC_{sw} (µg/L)	4.8																
Uses	**Application pattern**	**Season of application**	**Region**	**PECsw (µg/L) (considering Run-off/drainage only)**	**Max dissolved PECsw (considering all entry routes) (µg/L)**	**Buffer (m)**	**Nozzles reduction (%)**	**Max dissolved PECsw (considering only drift) (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**Max dissolved PECsw (considering only drift) (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**Max dissolved PECsw (considering only drift) (µg/L)**	**PEC/RAC**
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	N and S	1.20*	8.92	3	75%	2.67	0.56	5	50%	2.67 1.74	0.56 0.36	10	None	1.26	0.26

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 HYCOP in vines late application with the following risk mitigation measures:

- Any no-spray buffer with 90% nozzles reduction OR 5 m no-spray buffer with 50% nozzles reduction OR 10 m no-spray buffer.

Potatoes and solanaceous

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

PEC_{sw} without spray drift mitigation:

FOCUS Step 1 and 2 PECsw 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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	S	19.69	**4.10**	11.04	**2.30**
			N				

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 HYCOP 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 HYCOP is required.

PECsw with spray drift mitigation:

Step 1 and 2 PECsw 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_{sw} 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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	S	19.69	**4.10**	11.04	**2.30**
			N				

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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 2**			
				Buffer (m)	**Nozzles reduction (%)**	**PECsw (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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8

Uses	**Application pattern**	**Season of application**	**Region**	**PECsw (µg/L) (considering Run-off/drainage only)**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	N and S	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 PECsw values for the use of HYCOP 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, µg/L)	4.8				
AF	1				
ETO RAC_{sw} (µg/L)	4.8				
Uses	**Application pattern**	**Season of application**	**Region**	**Step 2**	
				Max dissolved PECsw (considering all entry routes) (µg/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 HYCOP 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 PECsw 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 PECsw values for the use of HYCOP following a single application to apple early application (all entry routes to water bodies considered)

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

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 HYCOP 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 HYCOP is required.

PECsw with spray drift mitigation:

Step 1 and 2 PECsw 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_{sw} 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 PECsw values for the use of HYCOP following a single application to apple early 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Apple BBCH 15 Early drift rates	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 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 1, 2 maximum PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	S	125.44	**26.13**	116.79	**24.33**
			N				

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 PECsw values for the use of HYCOP 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 RACsw (µg/L)	4.8

Uses	**Application pattern**	**Season of application**	**Region**	**Step 2**															
				Buffer (m)	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	N and S	3	None	104.48	**21.77**	10	None	45.55	**9.49**	20	None	10.42	**2.17**	25	None	6.14	**1.28**
					50%	52.24	**10.88**		50%	22.78	**4.75**		50%	5.21	**1.09**				
					75%	26.12	**5.44**		75%	11.39	**2.37**		75%	2.61	0.54		50%	3.07	0.64
					90%	10.45	**2.18**		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 PECsw values for the use of HYCOP following a single application to apple early application (runoff/drainage plus spray drift with mitigation) - TOTAL copper

Group	Aquatic dwelling organisms													
Endpoint (NOEC, µg/L)	4.8													
AF	1													
ETO RAC_{sw} (µg/L)	4.8													
Uses	**Application pattern**	**Season of application**	**Region**	**PECsw (µg/L) (considering Run-off/drainage only)**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PEC sw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PEC sw (µg/L) (Total)**	**PEC/RAC**
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	N and S	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.
*Worst case from Southern calculations

Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PECsw values for the use of HYCOP 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)

Group	Aquatic dwelling organisms														
Endpoint (NOEC, µg/L)	4.8														
AF	1														
ETO RAC_{sw} (µg/L)	4.8														
Uses	**Application pattern**	**Season of application**	**Region**	**PECsw (µg/L) (considering Run-off/drainage only)**	**PECsw (µg/L) (considering 10m of vfs)**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC sw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PEC sw (µg/L)**	**PEC sw (µg/L) (Total)**	**PEC/RAC**
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	N and S	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_{sw} values following a single application to apple 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 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8													
				Step 2										
Uses	**Application pattern**	**Season of application**	**Region**	**Max dissolved PECsw (considering all entry routes) (µg/L)**	**Buffer (m)**	**Nozzles reduction (%)**	**Max dissolved PECsw (considering only drift) (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Max dissolved PECsw (considering only run off/drainage) (µg/L)**	**PEC/RAC**
Apple BBCH 15 Early drift rates	3 x 1200 g a.s./ha	March-May	N and S	38.93	3	90%	3.48	**0.73**	14	75%	2.01	0.42	1.15*	0.24

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 HYCOP 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.

Apple (late application)

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

PEC_{sw} without spray drift mitigation:

FOCUS Step 1 and 2 PECsw 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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	S	71.55	**14.91**	62.90	**13.10**
			N				

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 HYCOP 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 HYCOP is required.

PECsw with spray drift mitigation:

Step 1 and 2 PECsw 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_{sw} 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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	S	8.65	**1.80**	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 PECsw values for the use of HYCOP 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_{sw} (µg/L)	4.8						
Uses	**Application pattern**	**Season of application**	**Region**	**Step 1**		**Step 2**	
				PECsw (µg/L)	**PEC/RAC**	**PECsw (µg/L)**	**PEC/RAC**
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	S	71.55	**14.91**	62.90	**13.10**
			N				

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 PECsw values for the use of HYCOP following a single application to apple late application (drift mitigation considered)

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

Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PECsw values for the use of HYCOP following a single application to apple 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_{sw} (µg/L)	4.8																		
Uses	**Application pattern**	**Season of application**	**Region**	**PECsw (µg/L) (considering Run-off/drainage only)**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L) (considering drift only)**	**PECsw (µg/L) (Total)**	**PEC/RAC**
Apple BBCH 60 onwards Late drift rates	3 x 1200 g a.s./ha	March-May	N and S	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_{sw} values following a single application to apple late. 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 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) based on FOCUS Step 2 maximum PECsw values for the use of HYCOP following a single application to apple late application (without mitigation measures considering all entry routes) - DISSOLVED copper

Group	Aquatic dwelling organisms																					
Endpoint (NOEC, µg/L)	4.8																					
AF	1																					
ETO RAC$_{sw}$ (µg/L)	4.8																					
				Step 2																		
Uses	**Application pattern**	**Season of application**	**Region**	**Max dissolved PECsw (considering all entry routes) (µg/L)**	**Buffer (m)**	**Nozzles reduction (%)**	**Max dissolved PECsw (considering only drift) (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Buffer (m)**	**Nozzles reduction (%)**	**PECsw (µg/L)**	**PEC/RAC**	**Max dissolved PECsw (considering only run off/drainage) (µg/L)**	**PEC/RAC**
Apple BBCH 15 Late drift rates	3 x 1200 g a.s./ha	March-May	N and S	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

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 HYCOP 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 asessment: 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 Hycop in vines (early application).

Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sediment dwelling		Sediment dwelling
Test species			*Oncorhynchus mykiss*	*Acipenser transmontanus*	*Daphnia magna*	*Daphnia magna*	*Selenasrtum capricornutum*	*Chironomus ripatius*		*Tubifex tubifex*
Endpoint (µg/L)			LC_{50} 207	NOEC 1.12	EC_{50} 26.6	NOEC 7.6	E_rC_{50} 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 $_{max}$ (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 Hycop in vines (late application).

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sediment dwelling**		**Sediment dwell-ing**
Test species			*Oncorhynchus mykiss*	*Acipenser transmontanus*	*Daphnia magna*	*Daphnia magna*	*Selenasrtum capricornutum*	*Chironomus ripatius*		*Tubifex tubifex*
Endpoint (µg/L)			LC_{50} 207	NOEC 1.12	EC_{50} 26.6	NOEC 7.6	E_rC_{50} 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 $_{max}$ (mg/k)**	**PEC/RAC ratios**
Step 1		33.97	**16.41**	**283.08**	**127.71**	**44.70**	**15.24**	0.68	2640	**313.25**
	Step 2									
N-Europe	March-May	26.76	**12.93**	**223.00**	**100.60**	**35.21**	**12.01**	0.54	683.17	**795.18**
S-Europe	March-May								1170	**205.77**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*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 Hycopin potatoes and solanaceous (fruiting vegetables).

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sediment dwell-ing**		**Sediment dwell-ing**
Test species			*Oncorhynchus mykiss*	*Acipenser transmonta-nus*	*Daphnia magna*	*Daphnia magna*	*Selenasrtum capricornutum*	*Chironomus ripatius*		*Tubifex tubifex*
Endpoint **(µg/L)**			LC_{50} 207	NOEC 1.12	EC_{50} 26.6	NOEC 7.6	E_rC_{50} 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 $_{max}$ (mg/kg)**	**PEC/RAC ratios**
Step 1		**19.69**	**9.51**	**164.08**	**74.02**	**25.91**	**8.83**	0.39	3010	**931.89**
Step 2										
N-Europe	March-May	**11.04**	**5.33**	**92.00**	**41.50**	**14.53**	**4.95**	0.22	665.69	**206.10**
S-Europe	March-May								1250	**387.00**

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 Hycop in early application to apple.**~~

~~**Group**~~			~~**Fish acute**~~	~~**Fish pro-longed**~~	~~**Inverteb. acute**~~	~~**Inverteb. pro-longed**~~	~~**Algae**~~	~~**Sediment dwell-ing**~~		~~**Sediment dwell-ing**~~
~~**Test species**~~			~~***Oncorhynchus mykiss***~~	~~***Acipenser transmontanus***~~	~~***Daphnia magna***~~	~~***Daphnia magna***~~	~~***Selenasrtum capricornutum***~~	~~***Chironomus ripatius***~~		~~***Tubifex tubifex***~~
~~**Endpoint**~~ ~~**(µg/L)**~~			~~LC_{50}~~ ~~207~~	~~NOEC~~ ~~1.12~~	~~EC_{50}~~ ~~26.6~~	~~NOEC~~ ~~7.6~~	~~E_rC_{50}~~ ~~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 $_{max}$ (mg/kg)**~~	~~**PEC/ RAC ratios**~~
~~Step 1~~		~~125.44~~	~~60.60~~	~~**1045.33**~~	~~**471.58**~~	~~**165.05**~~	~~**56.28**~~	~~**2.51**~~	~~**3790**~~	~~**1173.37**~~
~~Step 2~~										
~~N-Europe~~ ~~S-Europe~~	~~March-May~~	~~116.79~~	~~56.42~~	~~**973.25**~~	~~**439.06**~~	~~**153.67**~~	~~**52.40**~~	~~**2.34**~~	~~**843.36**~~	~~**261.10**~~

~~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 Hycop in late application to apple.

Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sediment dwelling		Sediment dwelling
Test species			*Oncorhynchus mykiss*	*Acipenser transmontanus*	*Daphnia magna*	*Daphnia magna*	*Selenasrtum capricornutum*	*Chironomus ripatius*		*Tubifex tubifex*
Endpoint (µg/L)			LC_{50} 207	NOEC 1.12	EC_{50} 26.6	NOEC 7.6	E_rC_{50} 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 $_{max}$ (mg/kg)**	**PEC/ RAC ratios**
Step 1		71.55	**34.57**	**596.25**	**268.98**	**94.14**	**32.10**	**1.43**	**3390**	**1049.54**
Step 2										
N-Europe	March-May	62.9	**30.39**	**524.17**	**236.47**	**82.76**	**28.22**	**1.26**	**1040**	**321.98**
S-Europe									**1340**	**414.86**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*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 organim (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_{sw} of total copper (PECsw) or based on maximum PECsw of dissolved copper (PECsw) considering different mitigation options for the use of Hycop 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_5 3.73~~	~~SSD-HC_5 1.11~~	~~ETO-RAC = 4.8~~		
~~AF~~	-	~~3~~	~~3~~	~~2~~		
~~RAC (µg/L)~~	-	~~1.24~~	~~0.37~~	~~2.4~~		
~~Total copper~~	~~Max. PEC_{sw} (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 buffer 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$_{sw}$ (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$_{sw}$ of total copper (tier 1a PECsw) or based on maximum PECsw of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Hycop 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$_5$ 3.73	SSD-HC$_5$ 1.11	ETO-RAC = 4.8		
AF	-	3	3	2		
RAC (µg/L)	-	1.24	0.37	2.4		
Total copper	**Max. PEC$_{sw}$ (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~~	~~**2.57**~~	~~0.40~~
~~14 m unsprayed buffer zone+50% DRT~~	~~1.14~~	~~0.92~~	~~**3.08**~~	~~0.48~~
~~20 m unsprayed bufferzone +50% DRT~~	~~0.66~~	~~0.53~~	~~**1.78**~~	~~0.28~~
~~STEP 2 (runoff/drainge+spraydrift with mitigation measures)~~				
~~3 m unsprayed buffer zone+90% DRT~~	~~5.73~~	~~**4.62**~~	~~**15.49**~~	~~**2.39**~~
~~5 m unsprayed buffer zone+90% DRT~~	~~4.64~~	~~**3.74**~~	~~**12.54**~~	~~**1.93**~~
~~10 m unsprayed bufferzone +75% DRT~~	~~4.55~~	~~**3.67**~~	~~**12.30**~~	~~**1.90**~~
~~14 m unsprayed buffer zone+50% DRT~~	~~4.74~~	~~**3.82**~~	~~**12.81**~~	~~**1.98**~~
~~20 m unsprayed buffer zone+50% DRT~~	~~4.26~~	~~**3.44**~~	~~**11.51**~~	~~**1.78**~~
~~STEP 2 (runoff /drainge with 60 % of reduction (10 meter VFS) + spraydrift with mitigation measures~~				
~~10 m unsprayed buffer zone +50% DRT~~	~~3.33~~	~~**2.69**~~	~~**9.00**~~	~~**1.39**~~
~~14m unsprayed buffer zone~~	~~3.72~~	~~**3.00**~~	~~**10.05**~~	~~**1.55**~~
~~20 m unsprayed buffer zone~~	~~2.76~~	~~**2.23**~~	~~**7.46**~~	~~**1.15**~~
	~~**Max. PEC$_{sw}$ (µg/L)**~~			
~~**STEP 2** (dissolved cooper)~~				
~~3 m unsprayed buffer zone +75% DRT~~	~~2.67~~	~~**2.15**~~	~~**7.22**~~	~~**1.11**~~
~~5 m unsprayed buffer zone + 50 % DRT~~	~~1.74~~	~~**1.40**~~	~~**4.70**~~	~~0.73~~
~~10 m unsprayed buffer zone~~	~~1.26~~	~~**1.02**~~	~~**3.41**~~	~~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_{sw} of total copper (PECsw) or based on maximum PECsw of dissolved copper (PECsw) considering different mitigation options for the use of Hycopin to potatoes and solanaceous (fruiting vegetables)

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_5 3.73**	**SSD-HC_5 1.11**	**ETO-RAC = 4.8**		
AF	-	3	3	2		
RAC (µg/L)	-	1.24	0.37	2.4		
Total copper	**Max. PEC_{sw} (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_{sw}					

	(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_{sw} of total copper (PECsw) or based on maximum PECsw of dissolved copper (PECsw) considering different mitigation options for the use of Hycop in apples, early aplication

Group	-	**Fish acute (higher tier)**	**Fish prolonged (higher tier)**	**Invertеb. Acute (higher tier)**	**Inverteb. prolonged (higher tier)**	**Algae (higher tier)**
Test species	-	**7 fish species**		**Indoor microcosm study**		
Endpoint (µg/L)	-	SSD-HC_5 3.73	SSD-HC_5 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_{sw} (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$_{sw}$ (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$_{sw}$ (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-NorthEurope

Table 9.5.2-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC_{sw} of total copper (tier 1a PECsw) or based on maximum PECsw of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Hycop in apples, 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_5 3.73	SSD-HC_5 1.11	ETO-RAC = 4.8		
AF	-	3	3	2		
RAC (µg/L)	-	1.24	0.37	2.4		
TIER-total copper	Max. PEC_{sw} (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	**1.54**	**5.16**	0.80
20 m unsprayed buffer zone +50% DRT	2.07	**1.67**	**5.59**	0.86
STEP 2 (runoff/drainge+spraydrift with mitigation measures)				
10 m unsprayed buffer zone + 90% DRT	3.93	**3.17**	**10.62**	**1.64**
14 m unsprayed buffer zone +75% DRT	4.50	**3.63**	**12.16**	**1.88**
20 m unsprayed buffer zone + 50% DRT	4.60	**3.71**	**12.43**	**1.92**
	Max. PEC_{sw} (µg/L)			
STEP 2 (dissolved copper)				
3 m unsprayed buffer zone + 90% DRT	1.75	1.41	**4.73**	0.73
5 m unsprayed buffer zone + 75 % DRT	2.50	**2.02**	**6.76**	**1.04**
10 m unsprayed buffer zone +50% DRT	2.24	**1.81**	**6.05**	0.93
14 meter unsprayed buffer zone	2.54	**2.05**	**6.86**	**1.06**

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_{sw} value to dissolved copper, PEC_{sw} 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_{sw} 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 diffrent opinion refered to the risk assessment proposed by the ZRMS they are considered it further at National level with consideration all data presented in this dossier.

zRMS comments:

After commenting period the new calculations of PECsw were provided in Section 8 and the aquatic risk assessment was updated by zRMS-PL.
The updated aguatic risk assessment was presented for aquatic organism and for sediment dwelling organism separetly according to recommendation given in AGD EFSA, 2013

Aquatic organism

The PECsw have been calculated by zRMS in Section 8 taking into account the protection zones (WBZ and NSZ) and use of appropriate anti-drift techniques.
For the entry via drift into water bodies, e -fate expert in Section 8 is of the opinion that according to the EFSA Journal (2018), the single application scenario represents the worst-case for the exposure assessment due to the very rapid dissipation of copper from surface waters. Single application scenario considered as a realistic worst-case for the calculatiosn of PEC_{sw} values.
Predicted environmental concentrations in surface water bodies (PECsw and PECsed) were calculated to simulate applications of copper to vines, potatoes, fruiting vegetables and orchards for exposure via spray drift. The PEC_{sw} and PEC_{sed} concentrations of copper were determined using the following assumptions:

PECsw and PECsed values for active substance copper following a single application to all proposed crop in GAP.

Crop	Calculations with drift and run off mitigation and 90% mitigation nozzle reduction							
	Exposure by runoff and drainage		Exposure by drift					
	PECsw (runoff and drainage) STEP2 unmitigated µg/L)	PECsw with 90% reduction runoff (20 m VBZ) µg/L)	PECsw (drift) STEP2 unmitigated µg/L)	PECsw (90% reduction drift) µg/L)	10m NSZ (µg/L)	20m NSZ (µg/L)	30m NSZ (µg/L)	50m NSZ (µg/L)
Vine early 1x 1000g Cu /ha	0.842	0.084	9.00	0.90	0.12	0.04	-	-
Vine late 1x 1000g Cu/ha	0.84	0.084	26.76	2.68	0.38	0.13	0.07	0.032
Potatoes 1x1200g Cu/ha	1.0.1	0.101	11.04	1.04	0.11	0.058	0.039	0.029

Tomato, aubergine (Solanaceous fruit) 1x 1200g Cu/ha	1.01	0.101	11.04	1.10	0.11	0.058	0.039	0.029
Apple, pear, quince early 1x1200g Cu/ha	5.8	0.58	116.79	11.17	4.55	1.62	0.39	0.11
Apple, pear, quince Late 1x1200g Cu/ha	1.26	0.12	62.90	6.29	1.p4	0.41	0.21	0.08

Sum PECsw (drift and runoff) values for active substance copper following a single application to all proposed crop in GAP after risk mitigation measure

Crop	Sum of concentrations µg/L of copper and 90% mitigation nozzle reduction			
	20 m VBZ 10 m NSZ	20 m VBZ 20 m NSZ	20 m VBZ 30 m NSZ	20 m VBZ 50 m NSZ
Vine early 1x 1000g Cu /ha	**0.204**	-	-	-
Vine late 1x 1000g Cu/ha	0.47	**0.124**	-	-
Potatoes 1x1200g Cu/ha	**0.254**	-	-	-
Tomato, aubergine (Solanaceous fruit) 1x 1200g Cu/ha	**0.211**	-	-	-
Apple, pear, quince early 1x1200g Cu/ha	1.46	2.20	0.97	**0.69**
Apple, pear, quince Late 1x1200g Cu/ha	1.440	0.53	**0.33**	-

VBZ vegetative buffer zone

NSZ-no spray zone

Table 9.5.2-1$_{corr.}$ 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 Hycop in vines (early application).

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint (µg/L)			LC_{50} 8	NOEC 1.12	EC_{50} 26.6	NOEC 7.6	E_rC_{50} 22.29	NOEC 500		NOEC 16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			0.08	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		16.21	**202.625**	**135.08**	**60.94**	**21.33**	**7.27**	0.32	**2510**	**756.02**
Step 2										
N-Europe	March-May	9.00	**112.5**	**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$_{corr}$. 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 Hycop in vines (late application).

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species		***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricor-nutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC

(µg/L)				1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			0.08	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/k)**	**PEC/RAC ratios**
Step 1		33.97		**283.08**	**127.71**	**44.70**	**15.24**	0.68	2640	**313.25**
	Step 2									
N-Europe	March-May	26.76	**424.62**	**223.00**	**100.60**	**35.21**	**12.01**	0.54	683.17	**795.18**
S-Europe	March-May								1170	**205.77**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Table 9.5.2-3$_{corr}$: 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 Hycop in potatoes and fruiting vegetables.

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			8	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			0.008	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		**19.69**	**246.12**	**164.08**	**74.02**	**25.91**	**8.83**	0.39	3010	**931.89**
Step 2										
N-Europe	March-May	**11.04**	**138**	**92.00**	**41.50**	**14.53**	**4.95**		665.69	**206.10**

S-Europe	March-May							0.22	1250	**387.00**

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$_{corr}$: 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 Hycop in early application to apple.

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. Acute**	**Inverteb. pro-longed**	**Algae**	**Sediment dwell-ing**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			8	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			0.08	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	1568	**1045.33**	**471.58**	**165.05**	**56.28**	**2.51**	**3790**	**1173.37**
Step 2										
N-Europe	March-May	116.79	**1459.9**	**973.25**	**439.06**	**153.67**	**52.40**	**2.34**	**843.36**	**261.10**
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$_{corr}$: 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 Hycop in late application to apple.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwell-ing**		**Sediment dwelling**
Test species		***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***

Endpoint			LC$_{50}$	NOEC	EC$_{50}$	NOEC	E$_r$C$_{50}$	NOEC		NOEC
(µg/L)			8	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			0.08	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		71.55	**14.31**	**596.25**	**268.98**	**94.14**	**32.10**	**<u>1.43</u>**	**3390**	**1049.54**
Step 2										
N-Europe	March-May	62.9	**786.25**	**524.17**	**236.47**	**82.76**	**28.22**	**<u>1.26</u>**	**1040**	**321.98**
S-Europe									**1340**	**414.86**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*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 organim (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$_{corr}$: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC$_{sw}$ of total copper (PECsw) or based on maximum PECsw of dissolved copper (PECsw) considering different mitigation options for the use of Hycop in vines, early application.

Group		Fish acute (higher tier)	Fish prolonged (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_5 3.73	SSD-HC_5 1.11	ETO-RAC = 4.8
AF		3	3	2
RAC (µg/L)		1.24	0.37	2.4
Total copper	**Max. PEC_{sw} (µg/L)**			
STEP 2 (all entry routes)	9.0	**7.26**	**24.32**	**3.75**
20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine early	0.204	0.16	0.55	0.08

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 9.5.2-7$_{corr}$: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC_{sw} of total copper (PECsw) or based on maximum PECsw considering different mitigation options for the use of Hycop in vines, late application.

Group		**Fish acute (higher tier)**	**Fish prolonged (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_5 3.73	SSD-HC_5 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
Total copper	**Max. PEC_{sw} (µg/L)**					
STEP 2 (all entry routes)	26.76	**21.58**	**72.32**	**11.15**		
20 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine late	0.124	0.1	0.33	0.051		

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 9.5.2-8$_{corr}$: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC$_{sw}$ of total copper (PECsw) considering different mitigation options for the use of Hycop in to potato.

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$_5$ 3.73**	**SSD-HC$_5$ 1.11**	**ETO-RAC = 4.8**		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
Total copper	**Max. PEC$_{sw}$ (µg/L)**					
STEP 2 (all entry routes)	11.04	**8.90**	**29.84**	**4.60**		
20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Potato	0.254	0.20	0.69	0.1		

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 9.5.2-9$_{corr}$:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC$_{sw}$ of total copper (PECsw) considering different mitigation options for the use of Hycop in to fruiting vegetables.

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$_5$ 3.73**	**SSD-HC$_5$ 1.11**	**ETO-RAC = 4.8**		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		

Total copper	**Max. PEC_{sw} (µg/L)**			
STEP 2 (all entry routes)	11.04	**8.90**	**29.84**	**4.60**
20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Fruiting vegetables	0.211	0.17	0.57	0.08

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 9.5.2-10 $_{corr}$:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC_{sw} of total copper (PECsw) considering different mitigation options for the use of Hycop in apples, early 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_5 3.73	SSD-HC_5 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_{sw} (µg/L)**					
STEP 2 (all entry routes)	116.79	**94.19**	**315.65**	**48.66**		
50 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in apples early	0.69	0.55	**1.86**	0.29		

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 9.5.2-11$_{corr}$:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PEC_{sw} of total copper or based on maximum PECsw considering different mitigation options for the use of Hycop in apples, 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$_5$ 3.73	SSD-HC$_5$ 1.11	ETO-RAC = 4.8
AF		3	3	2
RAC (µg/L)		1.24	0.37	2.4
TIER-total copper	**Max. PEC$_{sw}$ (µg/L)**			
STEP 2 (all entry routes)	62.9	**50.73**	**170.00**	**26.21**
30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in apples late	0.33	0.27	0.90	0.13

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

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 and for algae for all proposed uses,.

Further calculations of PEC$_{sw}$ /RAC ratio was provided by the zRMS with PECsw valuse ageed be e-fate experts in updated Section 8, Final RR, 2021 to conclude acceptable risk assessment to aquatic organism.

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

Based on the lowest value **RAC of 0.37 microgram/L for fish** the PEC$_{sw}$/RAC ratio is below 1, when following risk mitigation measures are applied:

- 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine early
- 20 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine late
- 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in potatoes, tomato, aubergine (Solanceous fruit)
- 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate late apples

It should be indicated that no safe risk is identified for apple, pear and quince early application when 50 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels is applied.

The final risk mitigation measures should be decided at MSs level.

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 PECsed accumulation values for the use of HYCOP following seven years application to vines early application (all entry routes without mitigation measures)

Group	Sediment dwelling organisms						
Endpoint (HC_5, mg/kg)	40.4						
AF	1						
ETO RAC_{sed} (mg/kg)	40.4						
Uses	**Application pattern**	**Season of application**	**Region**	**PEC_{sed} (mg/kg)**		**$PEC_{sed, accumulation}$ 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	N and S	2.39	16.73	33.73	0.83
Vines BBCH 85 Late drift rates – BBCH 85 onwards	4 x 1000 g a.s./ha	March-May	N and S	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 HYCOP 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 PECsed accumulation values for the use of HYCOP following seven years application to potatoes and solanaceous (fruiting vegetables) (all entry routes without mitigation measures)

Group	Sediment dwelling organisms						
Endpoint (HC_5, mg/kg)	40.4						
AF	1						
ETO RAC_{sed} (mg/kg)	40.4						
Uses	**Application pattern**	**Season of application**	**Region**	**PEC_{sed} (mg/kg)**		**$PEC_{sed, accumulation}$ Total copper (7 years accumulation) + background (mg/kg)**	
				Step 1		**Mitigation**	**PEC/RAC**
				1 year	**7 years**	**None**	
Potatoes BBCH 15-85	3 x 1200 g a.s./ha	March-May	N and S	2.87	20.09	37.09	0.92

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 HYCOP in potatoes and solanaceous (fruiting vegetables).

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

Group	Sediment dwelling organisms						
Endpoint (HC_5, mg/kg)	40.4						
AF	1						
ETO RAC_{sed} (mg/kg)	40.4						
Uses	**Application pattern**	**Season of application**	**Region**	**PEC_{sed} (mg/kg)**		**$PEC_{sed, accumulation}$ 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	N and S	1.92*	13.44	30.44	0.75
Apple BBCH 60 onwards				1.65*	25.20	28.55	0.71

Late drift rates							

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)

ZRMS comments:

The risk assessment for sediment dwelling organism with consideration the endpint proposed by the applicant HC5= 40.4 mg a.s./kg is not considered in the risk assessment (please see at 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 PECsed accumulation values for the use of HYCOP following seven years application to vines early application (all entry routes without mitigation measures).**~~

~~Group~~	~~Sediment dwelling organisms~~								
~~Endpoint (HC_5, mg/kg)~~	~~16.7~~								
~~AF~~	~~5~~								
~~ETO RAC_{sed} (mg/kg)~~	~~3.23~~								
~~Uses~~	~~Application pattern~~	~~Season of application~~	~~Region~~	~~PEC_{sed} (mg/kg)~~		~~PECsed/RAC (mg/kg)~~		~~$PEC_{sed, accumulation}$ Total copper (7 years accumulation) + 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 onwards~~				~~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 PECsed accumulation values for the use of HYCOP 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$_{sed}$ (mg/kg)	3.23								
Uses	Application pattern	Season of application	Region	PEC$_{sed}$ (mg/kg)		PEC/RAC	PEC/RAC	PEC$_{sed, accumulation}$ 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	**6.21**	37.09	**11.48**

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 PECsed accumulation values for the use of HYCOP 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$_{sed}$ (mg/kg)	3.23								
Uses	Application pattern	Season of application	Region	PEC$_{sed}$ (mg/kg)		PEC/RAC	PEC/RAC	PEC$_{sed, accumulation}$ 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	**4.16**	30.44	**9.42**
Apple BBCH 60 onwards Late drift rates				1.65	25.20	0.51	**7.80**	28.55	**8.83**

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 dweling 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.

After Commenting period the new caculations of PEC_{sed} agreed by e-fate expert in updated Section 8 were considered in the udated risk assessment provided

Table 9.5-42-1$_{updated}$: Sediment dwelling organisms: acceptability of risk (PEC/RAC < 1) based on sum PECsed (drift and runoff) and $PECsed_{acc}$ values for active substance copper for all proposed crops in GAP after risk mitigation measures.

Group	**Sediment dwelling organism**										
Endpoint (HC_5, mg/kg)	**16.7**										
AF	**5**										
ETO RAC_{sed} (mg/kg)	**3.23**										
Uses	**Application pattern**	**PECsed (mg /kg)**				**$PEC_{sed, accumulation}$ Total copper + background (17 mg/kg)**	**PECsed/RAC (mg/kg)**	**$PECsed_{acc}$/RAC (mg/kg)**	**$PECsed_{acc}$/RAC (mg/kg)**	**$PEC_{sedacc,/RAC}$ (mg/kg)**	**PECsedacc/RAC (mg/kg) Total copper + background (17 mg/kg)**
		1 year	**7 years acc.**	**10 years acc.**	**20 years acc.**	**7 years**	**1 year**	**7 years**	**10 years**	**20 years**	**7 years**
Vine early	4000 g Cu /ha	4.84	33.88	48.4	96.8	50.88	**1.50**	**10.49**	**14.98**	**29.97**	**15.75**
Vine early 90% runoff reduction 20m	4000 g Cu /ha	0.48	3.36	4.8	9.6	26.6	0.15	**1.04**	**1.49**	**2.97**	**8.24**
Vine late	4000 g Cu/ha	4.84	33.88	48.4	96.8	50.88	**1.50**	**10.49**	**14.98**	**29.97**	**15.75**
Vine late 90% runoff reduction 20m	4000 g Cu/ha	0.48	3.36	4.8	9.6	26.6	0.15	**1.04**	**1.49**	**2.97**	**8.24**

Potatoes	3600 g Cu/ha	1.44	10.08	14.4	28.8	27.08	0.45	**3.12**	**4.46**	**8.92**	**8.38**
Potatoes 90% runoff reduction 20m	3600 g Cu/ha	0.14	1.08	1.77	2.88	18.08	0.04	0.33	0.55	0.89	**5.60**
Tomato. aubergine (Solanaceous fruit)	3600 g Cu/ha	4.04	28.28	40.4	80.8	45.28	**1.25**	**8.76**	**12.51**	25.02	**14.02**
Tomato. aubergine (Solanaceous fruit) 90% runoff reduction 20m	3600 g Cu/ha	0.40	2.83	4.04	8.08	19.83	0.12	0.88	**1.25**	**2.50**	**6.14**
Apple. pear. quince Early	3600 g Cu/ha	5.8	40.6	58.00	116	57.6	**1.80**	**12.57**	**17.96**	**35.91**	**17.83**
Apple. pear. quince early 90% runoff reduction 20m	3600 g Cu/ha	0.58	4.06	5.80	11.6	28.6	0.18	**1.26**	**1.80**	**3.59**	**8.85**
Apple. pear. quince Late	3600 g Cu/ha	1.2	8.4	12.00	24.00	25.4	0.37	**2.60**	**3.72**	**7.43**	**7.86**
Apple. pear. quince Late 90% runoff reduction 20m	3600 g Cu/ha	0.12	0.84	1.20	2.4	17.84	0.04	**0.26**	**0.37**	**0.74**	**5.52**

According to the calculations of PEC/RAC ratio performed in table above , the risk from the use of active substance for early and late applications in vines, apples and potatoes and vines is not acceptable for sediment dweling organisms considering the active substance-copper. Further refinement is required.

However, there is no approved guideline for calculating $PECsed_{acc}$ values to determine protective measures, similar to PEC_{sw} 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 measures at national level.

~~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 HYCOP with the following risk mitigation measures:~~

- ~~Grapevine (late): Any no-spray buffer with 90% nozzles reduction OR 5 m 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.~~
- ~~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.~~

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 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 $RAC_{sw;ch}$ thus indicating no concerns regarding the acute or chronic risks to aquatic organisms from the proposed uses of HYCOP with the following risk mitigation measures:~~

- ~~Grapevine (late): Any no-spray buffer with 90% nozzles reduction OR 5 m 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.~~
- ~~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 an unsprayed buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR none unsprayed buffer zone with 90% of nozzles reduction.*~~

~~***Pome fruit (apple, pear and quince) early application – Spe3:*** *To protect aquatic organisms respect 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 PECsw calculations based on the lowest RAC of 0.37 µg Cu/L. The risk from the use of Hycop 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 PECsed values to determine protective measures, similar to PECsw value approach. Therefore, the MSs should apply their own mitigation measure at national level.~~

Overall zRMS's conclusion of the risk assessment for aquatic and sediment dwelling organism after Commenting period:

Aquatic organisms

The ratios between predicted environmental concentrations in surface water bodies (PEC_{sw}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended uses in the GAP.

To achieve a concise risk assessment for aquatic dwelling organisms, an ETO-$RAC_{sw;\ ch}$ value of 0.37 µg/L was used as this value was protective of all acute and chronic risks to all relevant aquatic species.

Based on the lowest value **RAC of 0.37 microgram/L for fish** the PEC_{sw}/RAC ratio is below 1, when following risk mitigation measures are applied

The final risk mitigation measures should be decided at MSs level.

- 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine early
- 20 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in Vine late
- 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in potatoes, tomato, aubergine (Solanceous fruit)
- 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate late apples

It should be indicated that no safe risk is identified for apple, pear and quince early application when 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels is applied to surface water bodies.

The final risk mitigation measures should be decided at MSs level.

Sediment dwelling organism

According to the calculations of PEC/RAC ratio , the risk from the use of active substance for early and late applications in vines, apples and potatoes is not acceptable for sediment dweling organisms considering the active substance-copper. 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 measures 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 hydroxide. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of HYCOP were not evaluated as part of the EU assessment of Copper hydroxide. 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
Apis mellifera	Copper hydroxide technical	Contact	**LD_{50} = 44.46 µg/bee**	EFSA Journal 2018;16(1):5152
Apis mellifera	Copper hydroxide 50% WP	Oral	**LD_{50} = 49.0 µg/bee**	EFSA Journal 2018;16(1):5152
Apis mellifera	Copper hydroxide 50% WP	Contact	LD_{50} > 57.0 µg/bee	EFSA Journal 2018;16(1):5152
Apis mellifera	Copper oxychloride	Oral	LD_{50} = 12.1 µg/bee*	EFSA Journal 2018;16(1):5152
Apis mellifera	Copper oxychloride	Contact	LD_{50} = 44.3 µg/bee*	EFSA Journal 2018;16(1):5152
Apis mellifera	Bordeaux mixture WP	Oral	LD_{50} = 23.3 µg/bee	EFSA Journal 2018;16(1):5152
Apis mellifera	Bordeaux mixture WP	Contact	LD_{50} > 25.2 µg/bee	EFSA Journal 2018;16(1):5152
Apis mellifera	Tribasic copper sulphate SC	Oral	LD_{50} = 40.0 µg/bee	EFSA Journal 2018;16(1):5152
Apis mellifera	Tribasic copper sulphate SC	Contact	LD_{50} > 23.5 µg/bee	EFSA Journal 2018;16(1):5152
Apis mellifera	Copper oxide technical	Contact	LD_{50} > 22.0 µg/bee	EFSA Journal 2018;16(1):5152
Apis mellifera	Copper oxide WG	Oral	LD_{50} > 116.0 µg/bee	EFSA Journal 2018;16(1):5152
Apis mellifera	Copper oxide WP	Contact	LD_{50} > 82.5 µg/bee	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Apis mellifera	HYCOP	Oral	LD_{50} = 49.61 µg f.p./bee (equivalent to 24.91 Cu/bee)	KCP 10.3.1.1.1 XXX, G. 2020 7621/2020
Apis mellifera	HYCOP	Contact	LD_{50} = 198.2 µg f.p./bee (equivalent to 99.5 Cu./bee)	KCP 10.3.1.1.2 XXX, P. 2018 B/36/17
Higher-tier studies (tunnel test, field studies)				
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 HYCOP 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 (SANCO/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 HYCOP in All crops

Intended use	All crops		
Active substance	Copper ~~hydroxide~~		
Application rate (g a.s./ha)	1200		
Test design	**LD_{50} (lab.) (µg a.s./bee)**	**Single application rate (g a.s./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	49	1200	24.49
Contact toxicity	44.46		26.99
Product	HYCOP		
Application rate (g f.p./ha)	2400		
Test design	**LD_{50} (lab.) (µg f.p./bee)**	**Single application rate (g f.p./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	49.61	2400	48.38
Contact toxicity	198.2		12.11

Product	HYCOP		
Application rate (g Cu/ha)	1200		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g Cu/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	24.91	1200	48.17
Contact toxicity	99.5		12.06

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

ZRMS comments:

The risk assessment for acute oral and contact for a.s. and the product exposure for bees has been accepted by ZRMS-PL. The chronic tests for bees were not submitted by the applicant.

According to Reg 284/2009 the chronic tests for adult bees and larvae should be provided by the applicant.

It should be noted that 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.

However, no chronic studies to Hycop are provided by the applicant.

Therefore, to protect bees the following restriction are proposed by zRMS:

SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.

The final risk mitigation measures should be decided at MSs level.

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

Not relevant.

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_{HO} and Q_{HC} values are below 50, indicating a low risk to bees following the application of HYCOP at the proposed label rate.

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 hydroxide. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of HYCOP were not evaluated as part of the EU assessment of Copper hydroxide. 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
A. rhopalosiphi (adults)	Copper hydroxide 50 % WP	Laboratory test glass plates (2D)	Mortality : **LR_{50} = 50g/ha**	EFSA Journal 2018;16(1):5152
A. rhopalosiphi (adults)	Bordeaux Mixture	Laboratory test glass plates (2D)	Mortality : LR_{50} > 14700 g/ha	EFSA Journal 2018;16(1):5152
A. rhopalosiphi (adults)	Tribasic copper sulphate 190 g/L SC	Laboratory test glass plates (2D)	Mortality : LR_{50} > 134.4 g/ha	EFSA Journal 2018;16(1):5152
A. rhopalosiphi (adults)	Copper oxide 75%WP	Laboratory test glass plates (2D)	Mortality : LR_{50} = 39200 g/ha	EFSA Journal 2018;16(1):5152
T. pyri (protonymphs)	Copper hydroxide 50 % WP	Laboratory test glass plates (2D)	Mortality : **LR_{50} > 14880 g/ha**	EFSA Journal 2018;16(1):5152
T. pyri (protonymphs)	Copper oxychloride 50% WP	Laboratory test glass plates (2D)	Mortality : LR_{50} > 14890 kg/ha	EFSA Journal 2018;16(1):5152
T. pyri (protonymphs)	Bordeaux Mixture	Laboratory test glass plates (2D)	Mortality : LR_{50} > 13200 g/ha	EFSA Journal 2018;16(1):5152
T. pyri (protonymphs)	Tribasic copper sulphate 190 g/L SC	Laboratory test glass plates (2D)	Mortality : LR_{50} > 80 g/ha	EFSA Journal 2018;16(1):5152
T. pyri (protonymphs)	Copper oxide 75%WP	Laboratory test glass plates (2D)	Mortality : LR_{50} > 26 100 g/ha	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
T. cacoeciae	Copper hydroxide 50 % WP	Extended laboratory test Glass plates (2D)	Parasitisation: 6.4 % at 590 g Cu /ha	EFSA Journal 2018;16(1):5152
T. cacoeciae	Copper oxychloride 50% WP	Extended laboratory test Glass plates (2D)	Parasitisation: -42.9 % at 2020 g Cu /ha	EFSA Journal 2018;16(1):5152
D. rapae	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
P. cupreus	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
P. amentata	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
C. carnea (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
C. 7-punctata	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
C. 7-punctata	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
A. rhopalosiphi (adults)	Copper hydroxide 35.6 % WP	Extended laboratory test Barley seed (3D)	Mortality: **10 % at 3213 g Cu /ha** Fecundity: -7.4% at 3213 g Cu /ha	EFSA Journal 2018;16(1):5152
A. rhopalosiphi (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
A. rhopalosiphi (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 Paratisitation: -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
T. pyri (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
T. pyri (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
C. carnea (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
C. carnea (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
T. pyri (protonymphs)	HYCOP	Extended laboratory test Apple leaves (2D)	LR_{50} > 16 kg f.p./ha (equivalent to >8.0 kg Cu/ha) **ER_{50} = 9.8 kg f.p./ha (equivalent to 4.9 kg Cu/ha correspond to 4900 gCu/ha))**	KCP 10.3.2.2-01 XXX, P. 2019 B/38/17
A. rhopalosiphi (adults)	HYCOP	Extended laboratory test Barley seedlings (3D)	LR_{50} > 16 kg f.p./ha (equivalent to >8.0 kg Cu/ha) **ER_{50} = 7.9 kg f.p./ha (equivalent to 4.0 kg Cu/ha correspond to 4000 g Cu/ha)**	KCP 10.3.2.2-02 XXX, P. 2019 B/37/17
C. carnea (larvae)	HYCOP	Extended laboratory test on bean leaves (2D)	LR_{50} >2761 g Cu/ha **ER_{50} >2761 g Cu/ha**	KCP 10.3.2.2-03 XXX, P. 2020 7543/2020
Coccinella sep-tempunctata (larvae)	HYCOP	Extended laboratory test on bean leaves (2D)	LR_{50} >2761 g Cu/ha **ER_{50} >2761 g Cu/ha**	KCP 10.3.2.2-04 XXX, S. 2020 7544/2020
C. carnea (larvae)	Copper oxychloride 50% WG	Extended laboratory test on bean leaves (2D)	LR_{50} > 13.50 kg f.p./ha (equivalent to >6.76 kg Cu/ha) **ER_{50} = 10.58 kg f.p./ha (equivalent to 5.30 kg Cu/ha correspond to 5300 g Cu/ha)**	KCP 10.3.2.2-05 XXX, M., 2020 7547/2020
Coccinella sep-tempunctata (larvae)	Copper oxychloride 50% WG	Extended study on bean leaves (2D)	LR_{50} = 7.61 kg f.p./ha (equivalent to 3812.61 g Cu/ha) **ER_{50} = 7.26 kg f.p./ha (equivalent to 3637.26 g Cu/ha)**	KCP 10.3.2.2-06 XXX, G., M., 2020 7548/2020
Field or semi-field tests				
None				

* Data in bold used for the risk assessment.

9.7.1.1 Justification for new endpoints

Studies were conducted with HYCOP and were also considered for the risk assessment. New studies on additional species *C. carnea* and *C. septempunctata*. These species are non-target foliar-dwelling arthropods, therefore, $PER_{in\text{-}field}$ foliar is performed in the risk assessment.
The endpoints of both studies with HYCOP on C. carnea and C. septempunctata showed that LR50 and ER50 endpoints were higher than the higher tested dose (> 2761 g Cu/ha) and that at such dose, the effects on mortality and reproduction on both species were clearly below the trigger value of 50%. Therefore, it is clear that the LR_{50} and ER_{50} endpoints would be higher for both species.

Applicant conducted extended studies on Chrysoperla carnea and Coccinella septempunctata with the formulation Copper oxychloride 50% WG and the endpoints of both studies expressed in terms of g Cu/ha were considered for the risk assessment. Applicant wishes to indicate that both formulations, Copper oxychloride 50% WG and HYCOP present a similar composition. Moreover, the endpoints of the studies performed on non-target arthropods are also expressed in terms of g Cu/ha, which means that only the toxicity of the Cu is considered. Therefore, applicant considers that reference to the extended studies on C. carnea and C. septempunctata with Copper oxychloride 50% WG in the risk assessment is fully justified to demonstrate a safe use.

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

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

Intended use	Grapevine		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)	4 x 2000 g f.p./ha (equivalent to 4 x 1000 g Cu/ha)		
MAF	2.7 (foliar)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**PER$_{in-field}$ (g/ha)**	**PER$_{in-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	5400 g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		Yes
C. carnea	> 2761 g Cu/ha	2700 g Cu/ha	Yes
C. septempunctata	> 2761 g Cu/ha		Yes
Intended use	Grapevine		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)	4 x 2000 g f.p./ha / ~~4 x 800** g f.p./ha~~ (4 x 1000 g Cu/ha)		
MAF	~~3.4~~ (soil) 1		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**PER$_{in-field}$ (g/ha)**	**PER$_{in-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	~~2720 g f.p./ha~~ 8000 g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		~~Yes~~ **No**
C. carnea	> 2761 g Cu/ha	4000 g Cu/ha	**No**
C. septempunctata	> 2761 g Cu/ha		**No**
C. carnea	> 2761 g Cu/ha	2000 [1] g Cu/ha	**Yes**
C. septempunctata	> 2761 g Cu/ha		**Yes**

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_{50} or ER_{50} 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)[4].~~

*** During the ecotox expert meeting 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

[1] 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) for application of 3 x 1200 g Cu/ha (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 HYCOP in potato

Intended use	Potato, tomato and aubergine		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)[1]	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)		
MAF	2.3 (foliar)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in-field}$ (g/ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	5520 g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		Yes
C. carnea	> 2761 g Cu/ha	2760 g Cu/ha	Yes
C. septempunctata	> 2761 g Cu/ha		Yes
C. carnea	5300 g Cu/ha	2760 g Cu/ha	Yes
C. septempunctata	3637.26 g Cu/ha		Yes
Intended use	Potato		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)[1]	3 x 2400 g f.p./ha ~~/ 4 x 1700** g f.p./ha~~ (equivalent to 3 x 1200 g Cu/ha)		
MAF	1 ~~3.4~~ (soil)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in-field}$ (g/ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	~~5780~~ g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha	7200 g f.p./ha	Yes
C. carnea	> 2761 g Cu/ha	3600 g Cu/ha	**No**
C. septempunctata	> 2761 g Cu/ha		**No**
C. carnea	5300 g Cu/ha	3600 g Cu/ha	Yes
C. septempunctata	3637.26 g Cu/ha		Yes
Intended use	Potato		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)[1]	4 x 2000 g f.p./ha (equivalent to 4 x 1000 g Cu/ha)		
MAF	2.7 (foliar)		

[4] 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)	$PER_{in-field}$ (g/ha)	$PER_{in-field}$ below rate with ≤ 50 % effect?
T. pyri	9800 g f.p./ha	5400g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		Yes
C. carnea	> 2761 g Cu/ha	2700 g Cu/ha	Yes
C. septempunctata	> 2761 g Cu/ha		Yes
C. carnea	5300 g Cu/ha	2700 g Cu/ha	Yes
C. septempunctata	3637.26 g Cu/ha		Yes

Intended use	Potato
Active substance/product	Copper hydroxide / HYCOP
Application rate (g/ha)[1]	4 x 2000 g f.p./ha (equivalent to 4 x 1000 g Cu/ha)
MAF	1 (soil)

Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	$PER_{in-field}$ (g/ha)	$PER_{in-field}$ below rate with ≤ 50 % effect?
T. pyri	9800 g f.p./ha	8000 g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		Yes
C. carnea	> 2761 g Cu/ha	4000 g Cu/ha	**No**
C. septempunctata	> 2761 g Cu/ha		**No**
C. carnea	5300 g Cu/ha	4000 g Cu/ha	Yes
C. septempunctata	3637.26 g Cu/ha		**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.
[1]Worst case of application rate.
* If an LR_{50} or ER_{50} 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)[5].
*** During the ecotox expert meeting 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.
[1] 0.5 according to ESCORT 2

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

Intended use	Pome fruits
Active substance/product	Copper hydroxide / HYCOP
Application rate (g/ha)	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)
MAF	2.3 (foliar)

Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	$PER_{in-field}$ (g/ha)	$PER_{in-field}$ below rate with ≤ 50 % effect?
T. pyri	9800 g f.p./ha	5520 g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		Yes
C. carnea	> 2761 g Cu/ha	2760 g Cu/ha	Yes

[5] 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.

C. septempunctata	> 2761 g Cu/ha		Yes
Intended use	Pome fruits		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)[1]	3 x 2400 g f.p./ha / ~~5 x 960** g f.p./ha~~		
MAF	~~2.7~~ 1 (soil)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**PER$_{in-field}$ (g/ha)/(g.Cu/ha)**	**PER$_{in-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	~~2592 g f.p./ha~~ 7200 g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		Yes
C. carnea	> 2761 g Cu/ha	3600 g Cu/ha	**No**
C. septempunctata	> 2761 g Cu/ha	3600 g Cu/ha	**No**
C. carnea	> 2761 g Cu/ha	1800 [1] g Cu/ha	Yes
C. septempunctata	> 2761 g Cu/ha	1800 [1] g Cu/ha	Yes

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.
[1]Worst case of application rate.
* If an LR_{50} or ER_{50} 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)[6].~~
[1]0.5 according to ESCORT 2

Conclusion

It can therefore be concluded that the in-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 PERsoil $_{in-field}$ an unaccepatable risk was indicatedfor all proposed uses for max doses applied.

Deposition factor proposed by the Applicant could be not considered in case of foliar arthropods.

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, acceptale risk is concluded for grape and apples.

[6] 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.

Unaceptable risk in-field is observed in other crops beside orchards and vines for the maximum annual dose intended (**potato, tomato and aubergine).**

The applicant updated the risk assessment after commentinfg period for potato, tomato and aubergine with the endpoints of the extended studies on C. carnea and C. septempunctata with the formulation Copper Oxycloride 50% WG. From the updated in-field applicant's risk assessment, there is no risk for potato, tomato and aubergine when considering applications of 3 x 2.4 kg fp/ha (3 x 1200 g Cu/ha).

Therefore, for fruiting vegetables - tomato and aubergine the min. proposed dose according to the GAP is 3 x 0.75 kg Cu/ha.

The ZRMS provided the risk at the proposed min. dose in the Table below.

The in-field risk for non-target arthropods due to the use of HYCOP in fruiting vegetables at rate 3 x 1500 g product/ha.

Intended use	Fructing vegetables		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)[1]	3 x 1500 g f.p/ha(egivalent to 3 x 750 g Cu/ha)		
MAF	2.3 (foliar)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in-field}$ (g/ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	3450 g f.p./ha	Yes
A. rhopalosiphi	7900 g f.p./ha		Yes
C. carnea	> 2761 g Cu/ha	1725 g Cu/ha	Yes
C. septempunctata	> 2761 g Cu/ha		Yes
Intended use	Potato		
Active substance/product	Copper hydroxide / HYCOP		
Application rate (g/ha)[1]	3 x 1500 g f.p/ha(egivalent to 3 x 750 g Cu/ha)		
MAF	1 (soil)		
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in-field}$ (g/ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	4500 g f.p./ha	**Yes**
A. rhopalosiphi	7900 g f.p./ha		**Yes**
C. carnea	> 2761 g Cu/ha	2250 g Cu/ha	**Yes**
C. septempunctata	> 2761 g Cu/ha		**Yes**

The an acceptable risk is considered at a proposed dose of 0.75 kg Cu/ha in fruiting vegetables.

Based on the results an acceptable risk for NTA arthropods is concluded except intended use for potatao for max. rate of 1 x4000 g Cu/ha.

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 HYCOP in grapevine

Intended use	Grapevine				
Active substance/product	Copper hydroxide / HYCOP				
Application rate (g/ha)	4 x 2000 g f.p./ha (equivalent to 4 x 1000 g Cu/ha)				
MAF	2.7 (foliar)				
vdf	10 (2D studies) / 1 (3D studies)				
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	0.0671	36.23 g f.p./ha	5	yes
A. rhopalosiphi	7900 g f.p./ha		362.34 g f.p./ha	5	yes
C. carnea	> 2761 g Cu/ha		18.12 g Cu/ha	5	yes
C. septempunctata	> 2761 g Cu/ha			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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Table 9.7-6-1: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in grapevine

Intended use	Grapevine				
Active substance/product	Copper hydroxide / HYCOP				
Application rate (g/ha)	4 x 2000 g f.p./ha (equivalent to 4 x 1000 g Cu/ha)				
MAF	1 (soil)				
vdf	10 (2D studies) / 1 (3D studies)				
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}fieldcorr}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
Using MAF soil =1					
T. pyri	9800 g f.p./ha	0.0671 late	268.4 g f.p./ha	5	Yes
A. rhopalosiphi	7900 g f.p./ha		2684 g f.p./ha	5	Yes
C. carnea	> 2761 g Cu/ha		134.2 g Cu/ha	5	Yes
C. septempunctata	> 2761 g Cu/ha			5	Yes
T. pyri	9800 g f.p./ha	0.0244 early	97.6 g f.p./ha	5	Yes
A. rhopalosiphi	7900 g f.p./ha			5	Yes
C. carnea	> 2761 g Cu/ha		4.88 g Cu/ha	5	Yes
C. septempunctata	> 2761 g Cu/ha			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_{50} or ER_{50} 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)[7].

*** During the ecotox expert meeting 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.

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 HYCOP in potato

Intended use	Potato				
Active substance/product	Copper hydroxide / HYCOP				
Application rate (g/ha)	3 x 2400 g f.p./ha, 4 x 2000 g .f.p/ha (equivalent to 3 x 1200 g Cu/ha) or 4 x 1000 g Cu/ha or 4 x 1000 g Cu/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$_{off-field}$ (g/ha)**	**CF**	**corr. PER$_{off-field}$ below rate with ≤ 50 % effect?**
3 x 1200 g a.s./ha					
T. pyri	9800 g f.p./ha	0.0201	11.10 g f.p./ha	5	Yes
A. rhopalosiphi	7900 g f.p./ha		110.95 g f.p./ha	5	Yes
C. carnea	> 2761 g Cu/ha		5.55 g Cu/ha	5	Yes
C. septempunctata	> 2761 g Cu/ha			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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Table 9.7-8-1: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in potato

Intended use	Potato				
Active substance/product	Copper hydroxide / HYCOP				
Application rate (g/ha)	3 x 2400 g f.p./ha or 4 x 2000 g f.p/ha (equivalent to 3 x 1200 g Cu/ha or 4 x 1000 g Cu/ha)				
MAF	1 (soil)				
vdf	10 (2D studies) / 1 (3D studies)				
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**PER$_{off-fieldcorr}$ (g/ha)/g Cu/ha**	**CF**	**corr. PER$_{off-field}$ below rate with ≤ 50 % effect?**
Using MAF soil =1, 3 x 1200 g a.s./ha					
T. pyri	9800 g f.p./ha	0.0201	82.8 g f.p./ha	5	yes
A. rhopalosiphi	7900 g f.p./ha		828 g f.p./ha	5	yes
C. carnea	> 2761 g Cu/ha		36.18 g Cu/ha	5	yes
C. septempunctata	> 2761 g Cu/ha			5	yes

[7] 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.

Using MAF soil =1, 4 x 1000 g a.s./ha					
T. pyri	9800 g f.p./ha	0.0201	80.4 g f.p./ha	5	yes
A. rhopalosiphi	7900 g f.p./ha		804 g f.p./ha	5	yes
C. carnea	> 2761 g Cu/ha		40.2 g Cu/ha	5	yes
C. septempunctata	> 2761 g Cu/ha			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_{50} or ER_{50} 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)[8].~~
*** During the ecotox expert meeting 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

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

Table 9.7-9: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in solanaceous fruits (tomato and aubergine) (late as worst case)

Intended use	Solanaceous fruits (tomato and aubergine)				
Active substance/product	Copper hydroxide / HYCOP				
Application rate (g/ha)	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)				
MAF	2.3 (foliar)				
vdf	10 (2D studies) / 1 (3D studies)				
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off-field}$ (g/ha)**	**CF**	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	0.069	38.09 g f.p./ha	5	Yes
A. rhopalosiphi	7900 g f.p./ha		380.88 g f.p./ha	5	Yes
C. carnea	> 2761 g Cu/ha		19.04 g Cu/ha	5	Yes
C. septempunctata	> 2761 g Cu/ha		19.04 g Cu/ha	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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Table 9.7-1-1: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in potato

Intended use	Solanaceous fruits (tomato and aubergine)				
Active substance/product	Copper hydroxide / HYCOP				
Application rate (g/ha)	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)				
MAF	1 (soil)				
vdf	10 (2D studies) / 1 (3D studies)				
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off-fieldcorr}$ (g/ha)/ g Cu/ha**	**CF**	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect?**

[8] 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.

Using MAF soil =1					
T. pyri	9800 g f.p./ha		248.4 g f.p./ha	5	yes
A. rhopalosiphi	7900 g f.p./ha		2484 g f.p./ha	5	yes
C. carnea	> 2761 g Cu/ha		124.2 g Cu/ha	5	yes
C. septempunctata	> 2761 g Cu/ha			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_{50} or ER_{50} 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)[9].~~

*** During the ecotox expert meeting 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

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

Table 9.7-10: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in pome fruits (apple, pear and quince) (early application)

Intended use	Pome fruits (apple, pear and quince) – early application				
Active substance/product	Copper hydroxide / HYCOP				
Application rate (g/ha)[1]	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)				
MAF	2.3 (foliar)				
vdf	10 (2D studies) / 1 (3D studies)				
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
T. pyri	9800 g f.p./ha	0.2396	132.26 g f.p./ha	5	Yes
A. rhopalosiphi	7900 g f.p./ha		1322.59 g f.p./ha	5	Yes
C. carnea	> 2761 g Cu/ha		66.13 g Cu/ha	5	Yes
C. septempunctata	> 2761 g Cu/ha			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.

[1]Worst case of application rate.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Table 9.7-8-1: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in pome fruits (apple, pear and quince) (early application)

Intended use	Pome fruits (apple, pear and quince) – early application
Active substance/product	Copper hydroxide / HYCOP
Application rate (g/ha)	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)
MAF	1 (soil)
vdf	10 (2D studies) / 1 (3D studies)

[9] 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)	Drift rate	$PER_{off-fieldcorr}$ (g/ha)	CF	corr. $PER_{off-field}$ below rate with ≤ 50 % effect?
Using MAF soil =1					
T. pyri	9800 g f.p./ha	0.2396	287.52 g f.p./ha	5	Yes
A. rhopalosiphi	7900 g f.p./ha		2875.2 g f.p./ha	5	Yes
C. carnea	> 2761 g Cu/ha		431.28 g Cu/ha	5	Yes
C. septempunctata	> 2761 g Cu/ha			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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

*** During the ecotox expert meeting 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

Table 9.7-11: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in pome fruits (apple, pear and quince) (late application)

Intended use	Pome fruits (apple, pear and quince) – late application
Active substance/product	Copper hydroxide / HYCOP
Application rate (g/ha)	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)
MAF	2.3 (foliar)
vdf	10 (2D studies) / 1 (3D studies)

Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	$PER_{off-field}$ (g/ha)	CF	corr. $PER_{off-field}$ below rate with ≤ 50 % effect?
T. pyri	9800 g f.p./ha	0.1101	60.78 g f.p./ha	5	yes
A. rhopalosiphi	7900 g f.p./ha		607.75 g f.p./ha	5	yes
C. carnea	> 2761 g Cu/ha		30.39 g Cu/ha	5	yes
C. septempunctata	> 2761 g Cu/ha		30.39 g Cu/ha	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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Table 9.7-9-1: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of HYCOP in pome fruits (apple, pear and quince) (late application)

Intended use	Pome fruits (apple, pear and quince) – late application
Active substance/product	Copper hydroxide / HYCOP
Application rate (g/ha)	3 x 2400 g f.p./ha (equivalent to 3 x 1200 g Cu/ha)
MAF	1 soil
vdf	10 (2D studies) / 1 (3D studies)

Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	$PER_{off-field}$ (g/ha)	CF	corr. $PER_{off-field}$ below rate with ≤ 50 % effect?

Using MAF soil =1					
T. pyri	9800 g f.p./ha	0.1101	132.12 g f.p./ha	5	Yes
A. rhopalosiphi	7900 g f.p./ha		1321.2 g f.p./ha	5	Yes
C. carnea	> 2761 g Cu/ha		198.18 g Cu/ha	5	Yes
C. septempunctata	> 2761 g Cu/ha			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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

*** During the ecotox expert meeting 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

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 calculations of the risk assessment off-field for Hycop for two indicator species and two additional species C.carnea and C. septempunctata were accepted by ZRMS-PL.

zRMS recalculated acceptability according to approach agreed on Expert Meeting (169).

Therefore, MAF soil of 1 was used in the risk assessment.

Based on the results provided in the Tables above according to ZRMS's assessment, Hycop poses an acceptable risk for off-field to non-target arthropods according to the proposed use patterns.

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 ~~SHRIRAM~~ HYCOP 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 hydroxide. 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 HYCOP were not evaluated as part of the EU assessment of Copper hydroxide. 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
Earthworms				
Eisenia fetida	Copper oxychloride	Chronic, 56 d OECD soil	$NOEC_{r(cp)}$ <40.5 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 28 d LUFA: 3.9% OECD: 10%	**$NOEC_{r(cp)}$ = 8.4 mg Cu/kg soil (LUFA 2.2 soil)** $NOEC_{r(cp)}$ = 103.2 mg Cu/kg soil (OECD soil) $NOEC_{r(jp)}$ = 103.2 mg Cu/kg soil (OECD soil)	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper chloride	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 13.2 mg Cu/kg soil (OECD soil) $NOEC_{r(jp)}$ = 35.2 mg Cu/kg soil (OECD soil) and 37.2 mg Cu/kg soil (LUFA 2.2 soil)	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper chloride	Chronic, 21 d OM: 4.7%	$NOEC_g$ = 715 mg Cu/kg soil $NOEC_r$ = 115 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	Cu oxychloride	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 83.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	$Cu(NO_3)_2.3H_2O$	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 28.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper nitrate	Chronic, 56 d OM: 10%	LC_{50} = 555 mg Cu/kg soil $NOEC_m$ = 202.4 mg Cu/kg soil EC_{50} (cocoons) = 53.3 mg Cu/kg soil $NOEC_{r(cp)}$ = 12.4 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper nitrate	Chronic, 21 d OM: 10%	$NOEC_{r(cp)}$ = 32.3 mg Cu/kg soil $NOEC_g$ = 728.2 mg Cu/kg soil $NOEC_m$ = 296.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Cu acetate	Chronic, 28 d	LC_{50} = 82.8 – 3717 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	$CuCl_2$	Chronic, 21 d	NOEC=300 mg Cu/kg soil (mortality and growth)	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper chloride	Chronic, 28 d	$EC_{10,r}$ = 54 – 324 mg Cu/kg soil (17 values for different soil types)	EFSA Journal 2018;16(1):5152
Eisenia andrei	Unknown	Chronic, 28 d OM: 3.7%	$EC_{10,r}$ = 159 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 28 d OM: 0.5%	$NOEC_m$ = 192 mg Cu/kg soil $NOEC_r$ = 192 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper salt	Chronic, 84 d OM: 10%	$NOEC_g$ = 59.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 123.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 84 d OM: 10%	EC50 > 100 mg Cu/kg soil $NOEC_g$ = 62 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 84 d	$NOEC_m$ = 162 mg Cu/kg soi	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 42 d OM: 3.4-5.7%	$NOEC_r$ = 54 mg Cu/kg soil $NOEC_{lb}$ = 54 mg Cu/kg soil $NOEC_g$ = 131 mg Cu/kg soil $NOEC_m$ = 131 mg Cu/kg soil $NOEC_{lb}$ = 63 mg Cu/kg soil $NOEC_m$ = 136 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 294 d OM: 9.8%	$NOEC_g$ = 154 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 110 d OM: 0.5%	$NOEC_g$ = 76 mg Cu/kg soil $NOEC_m$ = 153 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Allobophora calliginosa (=*Aporrectodea caliginosa*)	Copper sulfate	Chronic, 14 d	$NOEC_m$ = 511 mg Cu/kg soil $NOEC_{r(cp)}$ = 60.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Aporrectodea caliginosa	Copper sulfate	Chronic, 42 d and 56 d OM: 21.6%	$NOEC_g$ = 35.7 mg Cu/kg soil $NOEC_{r(cp)}$ = 80.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Dendrobaena rubida	Copper nitrate	Chronic, 90 d OM: 7.7-11.7%	$NOEC_{r(cp)}$ = 100 (pH 5.5) and 101.3 mg Cu/kg soil (pH 6.5)	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Dendrobaena rubida	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
Octalasium cyaneum	Copper sulfate	Chronic, 14 d and 30 d OM: 5.4-72%	30 d – $NOEC_m$ =153 mg Cu/kg soil 14 d – $NOEC_m$ =1214 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	HYCOP	Chronic, 54 d peat: 10%	EC_{10} = 100.9 mg f.p./kg dw soil (50.7 mg Cu/kg dw soil) NOEC= 100 mg f.p./kg dw soil (50.2 mg Cu/kg dw soil) **$NOEC_{corr}$ = 50 mg f.p./kg dw soil** (25.1 mg Cu/kg dw soil)	KCP 10.4.1.1 XXX, P. 2019 G/91/18
Other soil macroorganisms				
Enchytraeidae (Oligochaeta, Annelida)				
Cognettia sphagnetorum	Copper chloride	Chronic, 70 d OM: 66%	35-day $EC_{10,\,g}$ = 73.7 mg Cu/kg soil 63-day $EC_{10,\,g}$ = 451.7 mg Cu/kg soil 42-day $EC_{10,\,g}$ = 322.7 mg Cu/kg soil 70-day $EC_{10,\,f}$ = 465.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. albidus	Copper chloride	Chronic, 42 d OM: 5.5%	$EC_{10,\,m}$ = 347 mg Cu/kg soil $EC_{10,\,r}$ = 71 mg Cu/kg soil $EC_{10,\,a}$ = 362 mg Cu/kg soil $NOEC_m$ = 430 mg Cu/kg soil $NOEC_r$ = 230 mg Cu/kg soil $NOEC_a$ = 230 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. albidus	Copper chloride	Chronic, 42 d OM: 3.6%	$EC_{10,\,r}$ (soil 1) = 355 mg Cu/kg soil $EC_{10,\,r}$ (soil 2) = 107 mg Cu/kg soil $EC_{10,\,r}$ (soil 3) = 72 mg Cu/kg soil $EC_{10,\,r}$ (soil 4) = 119 mg Cu/kg soil $EC_{10,\,r}$ (soil 5) = 399 mg Cu/kg soil $EC_{10,\,r}$ (soil 6) = 241 mg Cu/kg soil NOEC in field transects: 418 to ≥ 689 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
E. crypticus	Copper chloride	Chronic, 56 d OM: 3.9%	EC_{50} (reprod., 11°C) ≈ 70 mg Cu/kg soil EC_{50} (reprod., 18°C) ≈ 160 mg Cu/kg soil EC_{50} (reprod., 25°C) ≈ 180 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. crypticus	Copper chloride	Chronic, 21 d OM: 4.6%	$EC_{10, r}$ = 126.5 mg Cu/kg soil $NOEC_r$ = 135 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. crypticus	Copper chloride	Chronic, 63 d OM: 3.9%	21-day $EC_{10, r}$ = 180.2 mg Cu/kg soil 63-day $EC_{10, r}$ = 90.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. crypticus	Copper chloride	OM: 3.9%	$EC_{10, r}$ = 55 mg Cu/kg soil $EC_{10, m}$ = 62 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Collembola (Hexapoda, Arthropoda)				
Folsomia candida	Copper chloride	Chronic, 28 d OM: 1.4-37%	**$EC_{10, r}$ = 31** – 1460 mg Cu/kg soil (21 values for different soil types)	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper nitrate	Chronic, 28 d	$EC_{50, r}$ (pH 6.0)= 703.2 mg Cu/kg soil $NOEC_r$ (pH 6.0)= 203.2 mg Cu/kg soil $NOEC_m$ (pH 6.0)= ≥3003.2 mg Cu/kg soil $EC_{50, r}$ (pH 5.0) = 713.2 mg Cu/kg soil $NOEC_r$ (pH 5.0) = 203.2 mg Cu/kg soil $NOEC_m$ (pH 5.0) = 43.2 mg Cu/kg soil $EC_{50, r}$ (pH 4.5) = 1483.2 mg Cu/kg soil $NOEC_r$ (pH 4.5) = 1003.2 mg Cu/kg soil $NOEC_m$ (pH 4.5) = ≥3003.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper chloride	Chronic, 42 d OM: 10%	$NOEC_r$ = 203.2 mg Cu/kg soil $NOEC_m$ = 1003.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper chloride	Chronic, 28 d OM: 10%	$NOEC_{ri}$ = 803.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper chloride	Chronic, 21 or 56 d	21-day $NOEC_g$ (LUFA 2.2) = 205.2 mg Cu/kg soil 21-day $NOEC_r$ (LUFA 2.2) = 405.2 mg Cu/kg soil 56-day $NOEC_g$ (OECD) = 803.2 mg Cu/kg soil 56-day $NOEC_r$ (OECD) = 403.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Folsomia candida	Copper chloride	OM: 3%	$EC_{10, r}$ = 212 mg Cu/kg soil NOEC = 320 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia candida	HYCOP	Chronic, 28d Mixed into soil 5% peat	EC_{10} = 225.8 mg f.p./kg dw soil (113.4 mg Cu/kg dw soil) **$EC_{10\ corr}$ = 112.90 mg f.p./kg dw soil** (56.7 mg Cu/kg dw soil) NOEC= 320 mg f.p./kg dw soil (160.6 mg Cu/kg dw soil)	KCP 10.4.2-01 XXX, P. 2019 G/89/18
Folsomia fimetaria	Copper chloride	Chronic, 21 d OM: 3.9%	14-day $EC_{10, r}$ = 43* mg Cu/kg soil 21-day $EC_{10, r}$ = 61* mg Cu/kg soil 21-day $EC_{10, g}$ (male) = 850 mg Cu/kg soil 21-day $EC_{10, g}$ (female) = 547 mg Cu/kg soil 21-day $EC_{10, g}$ (juvenile) = 532 mg Cu/kg soil 21-day $NOEC_m$ (male and female) ≥ 1005 mg Cu/kg soil 21-day $EC_{10, m}$ (juvenile) = 883 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia fimetaria	Copper chloride	Chronic, 21 d OM: 4.7%	$EC_{10, m}$ (overall) = 828 mg Cu/kg soil $EC_{10, m}$ (female) = 519 mg Cu/kg soil $EC_{10, m}$ (male) = 771 mg Cu/kg soil $EC_{10, g}$ (overall) = 1090 mg Cu/kg soil $EC_{10, g}$ (overall) = 997 mg Cu/kg soil $EC_{10, g}$ (overall) = 1242 mg Cu/kg soil $EC_{10, r}$ = 352 mg Cu/kg soil EC_{10} > 2911 mg Cu/kg soil (high background - historical Cu contaminated site)	EFSA Journal 2018;16(1):5152
Folsomia fimetaria	Copper sulfate	Chronic, 21 d OM: 4.5%	$EC_{10, r}$ = 141 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia fimetaria	Copper sulfate	Chronic, 21 d OM: 4.5%	$EC_{10, r}$ = 667 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Isotoma viridis	Copper chloride	Chronic, 56 d OM: 3.9%	$NOEC_g$ (LUFA 2.2) = 55.2 mg Cu/kg soil $NOEC_g$ (OECD) = 403 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Isopoda (Crustacea, Arthropoda)				
Porcellio scaber	Copper chloride	Chronic, 4 and 8 weeks	8-week LC_{50} = 2880 mg Cu/kg soil 4-week $EC_{10, g}$ (body mass gain) = 349 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Acari (Arachnica, Arthropoda)				
Platynothrus peltifer	Copper nitrate	Chronic, 90 d OM: 3.9%	$NOEC_m \geq$ 1498 mg Cu/kg soil $NOEC_g$ = 598 mg Cu/kg soil $NOEC_r$ = 168 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Platynothrus peltifer	Copper chloride	Chronic, 70 d OM: 3.9%	$NOEC_r$ = 68.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Hypoaspis aculeifer	Copper chloride	Chronic, 21 d OM: 3.9%	**EC10 = 179** mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Hypoaspis aculeifer	Copper chloride	OM: 3.0%	$EC_{10, r}$ = 2* mg Cu/kg soil $NOEC_r$ = 320 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Hypoaspis aculeifer	HYCOP	Chronic, 14 d Peat: 5%	EC_{10} > 1000 mg f.p./kg dw soil (>502 mg Cu/kg dw soil) NOEC ≥ 1000 mg f.p./kg dw soil (≥ 502 mg Cu/kg dw soil) **NOEC/EC10corr ≥ 500 mg f.p./kg dw soil** (251 mg Cu/kg dw soil)	KCP 10.4.2.1-02 XXX, V. 2019 5699/2019
Nematoda (Nematoda)				
Plectus acuminatus	Copper chloride	Chronic, 21 d	$EC_{50, r(jp)}$ = 165.2 mg Cu/kg soil $NOEC_{r(jp)}$ = 35.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Higher tier testing (e.g. modelling or field studies)				
Earthworms 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_{10} below lowest dose tested and therefore not considered reliable (OECD, 2006[13])
** Data in bold retained by EFSA and used for the risk assessment.
1 $NOEC_{r(cp)}$=NOEC reproduction based on cocoons production; $NOEC_{r(jp)}$= NOEC reproduction based on juveniles production; $NOEC_g$= NOEC based on growth; $NOEC_m$= NOEC based on mortality; $NOEC_{lb}$= NOEC based on litter breakdown; $EC_{10, f}$= EC10 based on fragmentation; $EC_{10, a}$= 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 HYCOP 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 Eco-toxicology", 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 hydroxide.

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 PECsoil values were calculated for repeated annual applications. More details on the predicted environmental concentrations (standard field calculations) in soil (PECsoil) for copper in soil are presented in Part B.8 point KCP 9.1.3.

The PECsoil 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 HYCOP in grapevine (worst case)

Intended use	Grapevine		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper hydroxide	8.4	165.33[1]	**0.05**
Copper hydroxide	8.4	66.8[2]	**0.13**
HYCOP	50[3]	10.67	**4.69**

HYCOP	50	9.070 [4]	5.51
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper hydroxide	31	165.33[1]	**0.19**
Copper hydroxide	31	66.8[2]	**0.46**
HYCOP	112.90[3]	10.67	10.58
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper hydroxide	179	165.33[1]	**1.08**
Copper hydroxide	179	66.8[2]	**2.68**
HYCOP	≥ 500[3]	10.67	≥ 46.86

TER values shown in bold fall below the relevant trigger.
[1] Overall $PEC_{soil,\ accumulation}$ at 90[th] percentile.
[2] Overall $PEC_{soil,\ accumulation}$ at 10[th] percentile.
[3]The endpoint was divided by 2 since log Kow>2.
[4]PECsoil considering an interception factor of 15% at BBCH 15-85 according to FOCUS (2012)[10]

zRMS comment:

The risk assessment provided by the applicant was corrected by zRMS.
The PEC soil calculations for copper evaluated by e-fate experts in Section 8 was taken into account.The Cu added to soil as plant protection product only.
The predicted environmental concentrations are estimated to be higher, if background values of copper in soil will be added. The 7 years' and 10 and 20 years 's period was considered and additionally, the natural copper background was taken into consideration.
The national background values which cover environmental and land use conditions in the member states should be used for decision-making in terms of authorisations on national level and that outcomes of national risk assessments, if are available.

Table 9.8-3corr: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) for copper in grapevine as worst case.

Intended use	Grapevine (worst case scenario for copper)		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper hydroxide (as a copper)	8.4	197.1 [1] 213 [2] 266 [3]	**0.042** **0.04** **0.031**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**

[10] 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.

Copper hydroxide (as a copper)	31	197.1 [1] 213 [2] 266 [3]	**0.16** **0.14** **0.12**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper hydroxide	179	197.1 [1] 213 [2] 266 [3]	**0.91** **0.84** **0.67**

TER values shown in bold fall below the relevant trigger.

[1] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 7 years

[2] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 10 years

[3] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 20 years

Table 9.8-4corr: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) for Hycop (expressed as a copper) for proposed GAP.

Intended use	**Grape**						
Chronic effects on earthworms							
Product/active substance	**$NOEC_{corr}$ (mgCu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PEC_{soil} (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	25.1	109.1	125	178	**0.23**	**0.20**	**0.14**
		197.1	213	266	**0.13**	**0.11**	**0.094**
		104.1	120	173	**0.24**	**0.21**	**0.14**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*							
Product/active substance	**EC_{10} (mg Cu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PEC_{soil} (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	56.7	109.1	125	178	**0.52**	**0.45**	**0.31**
		197.1	213	266	**0.29**	**0.23**	**0.21**
		104.1	120	173	**0.54**	**0.48**	**0.32**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*							
Product/active substance	**EC_{10} (mgCu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PEC_{soil} (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	251	109.1	125	178	**2.3**	**2.00**	**1.41**
		197.1	213	266	**1.23**	**1.18**	**0.94**
		104.1	120	173	**2.41**	**1.10**	**1.45**

TER values shown in bold fall below the relevant trigger.

[1] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 7 years

[2] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean

value) + Clow + PECsoil, initial over 10 years)
[3] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 20 years)

Table continued.

Intended use	Potato						
Chronic effects on earthworms							
Product/active substance	**$NOEC_{corr}$ (mg Cu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PEC_{soil} (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	25.1	46.6	61	109	**0.53**	**0.41**	**0.23**
		59.6	74	122	**0.42**	**0.34**	**0.20**
		48.6	63	78	**0.51**	**0.40**	**0.32**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*							
Product/active substance	**$EC_{10\ corr}$ (mgCu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PEC_{soil} (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	56.7	46.6	61	109	**1.21**	**0.92**	**0.52**
		59.6	74	122	**0.95**	**0.76**	**0.46**
		48.6	63	78	**1.16**	**0.9**	**0.73**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*							
Product/active substance	**$EC_{10\ corr}$ (mg Cu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PEC_{soil} (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	251	46.6	61	109	5.38	**4.11**	**2.30**
		59.6	74	122	**4.21**	**3.4**	**4.211**
		48.6	63	78	5.16	**4.0**	**3.21**

TER values shown in bold fall below the relevant trigger.
[1] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 7 years
[2] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value + Clow + PECsoil, initial over 10 years
[3] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 20 years)

Table continued.

Intended use	Fruting vegetables						
Chronic effects on earthworms							
Product/active substance	**$NOEC_{corr}$ (mgCu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PECsoil (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	25.1	46.6	61	109	**0.53**	**0.411**	**0.23**
		59.6	74	122	**0.42**	**0.34**	**0.20**
		48.6	63	78	**0.52**	**0.40**	**0.32**

Chronic effects on other soil macro- and mesofauna – *Folsomia candida*							
Product/active substance	**$EC_{10\ corr}$ (mg Cu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PECsoil (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	56.7	46.6	61	109	**1.21**	**0.92**	**0.52**
		59.6	74	122	**0.95**	**0.76**	**0.46**
		48.6	63	78	**1.16**	**0.9**	**0.73**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*							
Product/active substance	**$EC_{10\ corr}$ (mgCu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PECsoil (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	251	46.6	61	109	5.38	**4.11**	**2.3**
		59.6	74	122	**4.21**	**3.4**	**2.06**
		48.6	63	78	5.16	**3.98**	**3.21**

TER values shown in bold fall below the relevant trigger.

[1] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 7 years)

[2] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 10 years)

[3] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 20 years)

Table continued

Intended use	Orchards						
Chronic effects on earthworms							
Product/active substance	**$NOEC_{corr}$ (mg Cu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PECsoil (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	25.1	81.6	96	144	**0.31**	**0.26**	**0.30**
		91.6	106	154	**0.27**	**0.24**	**0.27**
		55.6	70	118	**0.45**	**0.36**	**69.72**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*							
Product/active substance	**$EC_{10\ corr}$ (mg Cu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PECsoil (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**
Hycop	56.7	81.6	96	144	**0.70**	**0.6**	**0.4**
		91.6	106	154	**0.61**	**0.53**	**0.37**
		55.6	70	118	**1.02**	**0.81**	**0.48**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*							
Product/active substance	**$EC_{10\ corr}$ (mg Cu/kg dw)**	**PEC_{soil} (mg/kg dw) 7 years [1]**	**PEC_{soil} (mg/kg dw) 10 years [2]**	**PECsoil (mg/kg dw) 20 years [3]**	**TER_{LT} 7 years**	**TER_{LT} 10 years**	**TER_{LT} 20 years**

Hycop	251	81.6	96	144	**3.07**	**2.61**	**1.74**
		91.6	106	154	**2.74**	**2.36**	**1.63**
		55.6	70	118	**4.51**	**3.59**	**4.51**

TER values shown in bold fall below the relevant trigger.

[1] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 7 years)

[2] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 10 years)

[3] Overall PECsoil, accumulation = Background monitoring value (overall median value, 90th percentile value and overall mean value) + Clow + PECsoil, initial over 20 years)

The TER_{LT} values are below trigger value of 5 , indicating further refinment for earthworms and soil macroorganism for all proposed uses of Hycop.

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 et al. 2015[11]). 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 Menezes-Oliveira et al. 2011[12], 2013[13]). 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 (Bouché 1977[14]): 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 habitats" (Jones et al., 1997[15]). Earthworms provide an impressive list of ecological services, espe-

[11] Caetano, A. Luísa; Marques, C. Ribeiro; Gonçalves, F., da Silva, E. Ferreira, and Pereira, R. (2015): Copper toxicity in a natural reference soil: ecotoxicological data for the derivation of preliminary soil screening values. Ecotoxicology 25, 163–177.

[12] Menezes-Oliveira, V. B., Scott-Fordsmand, J. J., Rocco, A., Soares, A., and Amorim, M. J.B. (2011) Interaction between density and Cu toxicity for *Enchytraeus crypticus* and *Eisenia fetida* reflecting field scenarios. Science of the Total Environment 409, 3370–3374.

[13] Menezes-Oliveira, V. B., Scott-Fordsmand, J. J., Soares, A. MVM, and Amorim, M. J. B. (2013): Effects of temperature and copper pollution on soil community—extreme temperature events can lead to community extinction. Environmental Toxicology and Chemistry 32, 2678–2685.

[14] Bouché, M.B. (1977): Strategies lombriciennes. In: Lohm, U., Persson, T. (Eds.), Soil Organisms as Components of Ecosystems, pp. 122–132.

[15] Jones, C. G., J. H. Lawton, and M. Shachak (1997): Positive and negative effects of organisms as physical ecosystem engineers. Ecology 78:1946-1957.

cially 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 Groenigen et al. 2014[16]), 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, O. 2015) was performed to evaluate the effects of copper on the earthworm fauna in Central Europe. Copper hydroxide 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, O., 2019. Addendum 1 to final report, KCP 10.4.1.2-01). 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 De Jong et al. (2006)[17]
- 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 De Jong et al. (2010)[18] 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)[19], 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).

[16] Van Groenigen, J. W., I. M. Lubbers, H. M. J. Vos, G. G. Brown, G. B. De Deyn and K. J. van Groenigen (2014): Earthworms increase plant production: a meta-analysis. – Scientific Reports 4: 6365; DOI: 10.1038/srep06365.
[17] De Jong, F.M.W., Van Beelen, P., Smit, C.E. & Montforts, M.H.M.M. (2006) 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. SAS INSTITUTE INC. 2002-2008 (2008) SAS® Proprietary Software 9.2; Cary, NC, USA.
[18] De Jong, F.M.W, Bakker, F.M, Brown, K, Jilesen, C.J.T.J, Posthuma-Dodeman, C.J.A.M., Smit, C.E., Van der Steen, J.J.M. & Van Eekelen, G.M.A. (2010) Guidance for summarizing and evaluating field studies with nontarget arthropods, National Institute for Public Health and the Environment, The Netherlands.
[19] ENVIRONMENT CANADA (2005) Guidance Document on Statistical Methods. EPS, l/RM/46. Ottawa, ON, Canada.

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 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 (Dr. K.C. Brown, Prof. Dr. P. XXX den Brink; Dr. C.A.M.XXX Gestel). **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, O. 2015) 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, O. 2015), a long-term laboratory study with earthworms and soil from the investigated sites of the field study was performed (XXX (2019)~~XXX, 2019;~~ see Appendix 2: KCP 10.4.1.1/03). 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_{max}, 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, O. 2015).

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 XXX & Peeters (2019[20]).

These RACs are based on an evaluation of a quality-screened database on chronic toxicity of Cu to

[20] Oorts K. and Peeters B. (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.

earthworms (CA 8.4.1/01. XXX, K. 2015c). 62 reliable EC_{10}/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 NOEC/EC_{10} 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_{10} 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^{th} 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, O. 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 5: 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	**111**	215	374	1158
North	5129	46	**94**	175	367	1158
Centre	8133	46	**107**	219	383	1034
South	8609	46	**132**	230	369	753

Table 6: 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	**164**	239	345	468
Olive groves	409	46	**165**	252	345	528
Fruit trees	279	46	**143**	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.

HYCOP is applied at the maximum dose of 1.2 kg copper hydroxide/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 => 3.6 kg Cu/ha or 4 applications at 1.0 kg/ha => 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 => 3.6 kg Cu/ha or 5 applications at 1.150 kg/ha => 5.75 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 of HYCOP.

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_{lt} 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 HYCOP at the proposed label rate can be excluded.

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 hydroxide. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of HYCOP were not evaluated as part of the EU assessment of Copper hydroxide. 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	**No effect at day 62 at 12.5kg Cu/ ha**	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
N-mineralisation	HYCOP	98d	-18.1% of deviation from the control based on nitrate formation rate at 99.9 mg f.p./kg dw soil (50.1 mg Cu/kg dw soil)	KCP 10.5.1 XXX, P. 2019 G/90/18
C- mineralisation	HYCOP	28d	-2.5% of deviation from the control based on Oxygen (O_2) consumption at 333 mg f.p./kg dw soil (167.2 mg Cu/kg dw soil)	KCP 10.5.2 XXX, P. 2019 G/93/18
Field studies				
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_2 evolution and nitrogen mineralization. There was no either evidence of significant effects on evolved CO_2 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 HYCOP 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 ~~pome fruits~~ vineyard also covers the risk for the soil microorganisms from all other intended uses. The overall PECsoil, accumulation = Background monitoring value (+ Clow + PECsoil, initial over 7 years) was considered in the risk assessment.

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of HYCOP ~~in pome fruits~~ in vineyard s the worst case scenario.

Intended use	Pome fruits		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % ~~(kg a.s./ha)~~**	**Maximum annual application (kg a.s./ha)**	**Risk acceptable?**
Copper hydroxide	12.5 (at 62 d)	5.75	Yes
Product/active substance	**Max. conc. with effects ≤ 25 % mg f.p./kg dw soil/ or mg Cu/kg dws**	**Maximum annual application mg f.p./kg dw soil/ or mg Cukg dws**	**Risk acceptable?**
HYCOP	99.9 (at 98d) 50.1 mg Cu/kg dw soil)	10.67 197.1	Yes No
~~C-mineralisation~~			
~~Product/active substance~~	~~Max. conc. with effects ≤ 25 % (kg a.s./ha) mg f.p./kg dw soil~~	~~Maximum annual application (kg a.s./ha) mg f.p./kg dw soil~~	~~Risk acceptable?~~
~~HYCOP~~	~~333 (at 28d)~~	~~10.67~~	~~Yes~~ ~~No~~

9.9.3 Overall conclusions

No risk for soil micro-organisms is expected after the application HYCOP according to the proposed GAP.

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),

No risk for soil micro-organisms is expected after the application HYCOP according to the proposed GAP as the <25% effects were observed for 99.9 mg product/kg dws.

It should be noted that the TER value for copper not achived the acceptable risk for N-mineralisation when $PECs_{acc}$ was used. However, 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 CO2 evolution and nitrogen mineralization.

There was no either evidence of significant effects on 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.

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 hydroxide. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of HYCOP were not evaluated as part of the EU assessment of Copper hydroxide. 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_{50} > 2000 g Cu/ha	EFSA Journal 2018;16(1):5152
Glycine max[d], *Zea mays*[m], *Pisum sativum*[d], *Sinapsis alba*[d], *Raphanus sativus*[d] and *Solanum lycopersicon*[d]	HYCOP	14 d Seedling emergence	ER_{50} > 16.00 Kg f.p./ha (> 8032 g Cu/ha)	KCP 10.6.2-01 XXX, S. 2020 5700/2019

Species	Substance	Exposure System	Results	Reference
Glycine max[d], *Zea mays*[m], *Pisum sativum*[d], *Sinapsis alba*[d], *Raphanus sativus*[d] and *Solanum lycopersicon*[d]	HYCOP	21 d Vegetative vigour	ER_{50} > 16.00 Kg f.p./ha (> 8032 g Cu/ha)	KCP 10.6.2-02 XXX, S. 2020 5701/2019

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. Studies were conducted with HYCOP 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 HYCOP in grapevine

Intended use	Grapevine			
~~Active substance~~/product	~~Copper hydroxide /~~ HYCOP			
Application rate (g/ha)	~~4 × 1000~~ 4 × 2000 g f.p./ha or 4 x 1000 g Cu/ha			
MAF	2.7			
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off-field}$ (g/ha)**	**TER criterion: TER ≥ 5**
~~6 species~~ *Glycine max*[d], *Zea mays*[m], *Pisum sativum*[d], *Sinapsis alba*[d], *Raphanus sativus*[d] and *Solanum lycopersicon*[d]	~~>2000~~ >16000 g f.p./ha 8032 g Cu/ha	0.0671	~~181.17~~ 362.34 g f.p./ha 181.17 Cu/ha	~~>11.04~~ >44.16 >44.3

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 HYCOP in potato

Intended use	Potato			
~~Active substance~~/product	~~Copper hydroxide /~~ HYCOP			
Application rate (g/ha)	~~3 × 1200~~ 3 × 2400 g f.p./ha or 3 x1200 g Cu/ha			
MAF	2.3			
Test species	**ER$_{50}$ (g/ha)**	**Drift rate**	**PER$_{off-field}$ (g/ha)**	**TER criterion: TER ≥ 5**
~~6 species~~ *Glycine max*[d], *Zea mays*[m], *Pisum sativum*[d], *Sinapsis alba*[d], *Raphanus sativus*[d] and *Solanum lycopersicon*[d]	~~>2000~~ >16000 g f.p./ha 8032 g Cu/ha	0.0201	~~55.48~~ 110.95 g f.p./ha 72.40	~~>36.05~~ >144.21 >110.94

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 HYCOP in solanaceous fruits (tomato and aubergine)

Intended use	Solanaceous fruits (tomato and aubergine)			
~~Active substance~~/product	~~Copper hydroxide /~~ HYCOP			
Application rate (g/ha)	~~3 × 1200~~ 3 × 2400 g f.p./ha or 3x 1200 g Cu/ha			
MAF	2.3			
Test species	**ER$_{50}$ (g/ha)**	**Drift rate**	**PER$_{off-field}$ (g/ha)**	**TER criterion: TER ≥ 5**
~~6 species~~ *Glycine max*[d], *Zea mays*[m], *Pisum sativum*[d], *Sinapsis alba*[d], *Raphanus sativus*[d] and *Solanum lycopersicon*[d]	~~>2000~~ >16000 g f.p./ha >8032 g Cu/ha)	0.0690	~~190.44~~ 380.88 g f.p./ha 190.44	~~>10.50~~ >42.01 >42.17

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 HYCOP in pome fruits (apple, pear and quince) – early application

Intended use	Pome fruits (apple, pear and quince) – early application
~~Active substance~~/product	~~Copper hydroxide /~~ HYCOP
Application rate (g/ha)	~~3 × 1200~~ 3 × 2400 g f.p./ha or 3x 1200 g Cu/ha
MAF	2.3

Test species	ER_{50} (g/ha)	Drift rate	$PER_{off-field}$ (g/ha)	TER criterion: TER ≥ 5
6 species *Glycine max*[d], *Zea mays*[m], *Pisum sativum*[d], *Sinapsis alba*[d], *Raphanus sativus*[d] and *Solanum lycopersicon*[d]	>2000 >16000 g f.p./ha 8032 g Cu/ha	0.2396	661.30 1322.59 g f.p./ha 661.3	**>3.02** >12.10 >12.14

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 HYCOP in pome fruits (apple, pear and quince) – late application

Intended use	Pome fruits (apple, pear and quince) – late application			
Active substance/product	Copper hydroxide / HYCOP			
Application rate (g/ha)	3 × 1200 3 × 2400 g f.p./ha or 3x1200 g Cu/ha			
MAF	2.3			
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off-field}$ (g/ha)**	**TER criterion: TER ≥ 5**
6 species *Glycine max*[d], *Zea mays*[m], *Pisum sativum*[d], *Sinapsis alba*[d], *Raphanus sativus*[d] and *Solanum lycopersicon*[d]	>2000 >16000 g f.p./ha 8032 g Cu/ha	0.2396 0.1101	303.88 607.75 g f.p./ha 303.876	>6.58 >26.33 >26.43

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 value is above the Annex VI trigger of 5 for seedling emergence and vegetative vigour tests indicated acceptable risk for 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 (70th 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/m³ 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 HYCOP in pome fruits (early application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**~~

Intended use		Pome fruits (apple, pear and quince) – early application			
Active substance/product		Copper hydroxide / HYCOP			
Application rate (g/ha)		3 × 1200			
MAF		2.3			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
3	23.96	661.30	330.65	-	-
5	15.79	435.80	217.90	-	-
10	8.96	247.30	-	-	-
Toxicity value ER_{50} > 2000 g/ha		**TER** **criterion: TER ≥ 5**			
3		**>3.02**	>6.05	-	-
5		**>4.59**	>9.18	-	-
10		>8.09	-	-	-

~~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 HY-COP 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

	HYCOP
Common Name	Copper hydroxide 50% WP
Classification and proposed labelling	
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): GHS09 Signal word: Danger Hazard statement(s): H400, H410 Precautionary statement: P391, P501

Copper hydroxide is classified as Aquatic Acute Category 1 (M = 10) and Aquatic Chronic Category 1 (M = 1). HYCOP contains 82.58% of copper hydroxide technical. Then 10 × 82.58 > 25% [M × Acute 1 ≥ 25%] and 1 × 82.58 > 25% [M × Chronic 1 ≥ 25%], therefore hazard statement H400 and H410 with pictogram GHS09 and signal word “Warning” is proposed.

Other co-formulants do not trigger further classification statements.
(please refer to part C).

ZRMS comments:

ZRMS agrees with the Classification and Labelling for aquatic organism:

<u>Hazard classes (s), categories:</u>

Aquatic Acute Category 1

Aquatic Chronic Category 1

<u>Hazard statement(s):</u>

H400, H410

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	XXX, M.	2020	Rainbow trout (*Oncorhynchus mykiss*), acute toxicity test with Copper hydroxide 50% WP Report No 5695/2019 Bioscience Research Foundation GLP Unpublished	Y	Sharda Cropchem Ltd.
KCP 10.2.1-02	XXX, K.	2019	Study of *Daphnia magna*, acute immobilization with Copper hydroxide 50% WP Report No 5697/2019 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.2.1-03	XXX, D.	2019	Study of algal growth inhibition with Copper hydroxide 50% WP Report No 5696/2019 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.1.1.1	XXX, G.	2020	Acute oral toxicity of Copper hydroxide 50% WP on honey bee Report No 7621/2020 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.1.1.2	XXX, P.	2018	Copper hydroxide 50% WP Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Report No B/36/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-01	XXX, P.	2019	An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on the predatory mite, *Typhlodromus pyri* (Sch.) Report No B/38/17 Institute of Industrial Organic Chemistry Branch Pszczyna 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 10.3.2.2-02	XXX, P.	2019	An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) Report No B/37/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-03	XXX, M.	2020	An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on larvae of the green Lacewing *Chrysoperla carnea* L. (Neuroptera: Chrysopidae) Report No 7543/2020 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-04	XXX, S.	2020	Anextended laboratory test for evaluating the effects of Copper hydroxide 50% WP on the seven spotted ladybird beetle, *Coccinella septempunctata* (L.) Report No 7544/2020 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-05	XXX, M.	2020	An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on larvae of the green lacewig *Chrysoperla carnea* (L.) (Neuroptera: Chrysopidae) Report No 7547/2020 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-06	XXX, M.	2020	An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on the seven spotted lady bird beetle, *Coccinella septempunctata* (L.) Report No 7548/2020 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.4.1.1	XXX, P.	2019	Copper hydroxide 50% WP Earthworm Reproduction Test (*Eisenia andrei*) Report No G/91/18 Institute of Industrial Organic Chemistry Branch Pszczyna 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 10.4.2.1-01	XXX, P.	2019	Copper hydroxide 50% WP Collembolan (Folsomia candida) Reproduction Test Report No G/89/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.4.2.1-02	XXX, V.	2019	Effect of Copper hydroxide 50% WP of the reproductive output of the predatory soil mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in artificial soil Report No 5699/2019 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.5.1	XXX, P.	2019	Copper hydroxide 50% WP: Soil microorganisms: Nitrogen Transforamtion Test Report No G/90/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.5.2	XXX, P.	2019	Copper hydroxide 50% WP: Soil Microorganisms: Carbon Transformation Test Report No G/93/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.6.2-01	XXX, S.	2020	Effect of Copper hydroxide 50% WP on seedling emergence and seedling growth of terrestrial plants Report No 5700/2019 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.6.2-02	XXX, S.	2020	Effect of Copper hydroxide 50% WP on vegetative vigour of terrestrial plants Report No 5701/2019 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.

Additional documents provided by the Applicant-LoA

KCP 10.2/01	XXX XXX, P.	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	XXX, K and XXX, F	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	XXX, S.D., XXX, K., XXX XXX, P., XXX, K.	2019	MODELLING OF THE FUNGURAN-OH EFFECTS ON *ONCHORHYNCHUS MYKISS* POPULATIONS EU Copper Task Force, not available not available GLP/GEP: no Published: no	N	EUCuTF
KCP 10.2/04	XXX, M.	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
KCP 10.4.1.1/03	XXX, E., 2019		LABORATORY STUDY ON THE SENSITIVITY OF FIELD-CAUGHT EARTHWORMS APORRECTODEA CALIGINOSA (ANNELIDA, LUMBRICIDAE) TO COPPER IN GRASSLAND SOILS COLLECTED AT TWO FIELD SITES IN SOUTHWESTERN GERMANY: A CROSSOVER EXPERIMENT, , REPORT NO. S18-00119	N	EUCuTF

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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	XXX, 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 Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.2-02	XXX, J.	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	Sharda Cropchem Limited
KCP 10.4.1.2-03	XXX et al.,	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	Sharda Cropchem Limited

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)

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

Comments of zRMS:	The study is considered valid. All validity criteria were met. • The mortality of fish in the control was 0% after 96 h (criterion: < 10%), • The dissolved oxygen concentrations were within the range of 69–70% of air saturation value (criterion: > 60% of air saturation). **Agreed endpoints**: **LC_{50}=0.0594 mg product/L correspond to LC_{50}= 0.0298 mg Cu/L**

Reference: KCP 10.2.1-01

Report: "Rainbow trout (*Oncorhynchus mykiss*), acute toxicity test with Copper hydroxide 50% WP". XXX M., 5695/2019, 2020. Bioscience Research Foundation

Guideline(s): OECD No. 203 (2019)

Deviations: Yes
The study finished in January 2020, not in December 2019 as it had been planned.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Summary

The acute toxicity of the test item Copper hydroxide 50% WP on fish (*Oncorhynchus mykiss*) was determined in a 96-hour static test. The fish were exposed to aqueous test media containing test item at seven different nominal concentrations: 0.0156, 0.0313, 0.0625, 0.125, 0.25, 0.5 and 1 mg/L plus control. The fish were observed for mortality and intoxication symptoms after 2, 5, 24, 30, 48, 54, 72, 78 and 96 h of exposure. Each group had 10 fish. The endpoint values were determined based on the nominal test item concentrations and nominal concentrations of copper hydroxide in the test item.

Material and methods

Test item:	Name: Copper hydroxide 50% WP Batch number: SCL-98802 Production date: 4th April, 2018 Expiry date: 3rd April, 2020
Test organism:	Rainbow trout (*Oncorhynchus mykiss*) purchased from a Tharun aqua fish farm, Padappai-601301, Tamil Nadu, India. Age: approximately 2 months
Weight / Length of fish prior to the experiment :	0.5902– 0.7842 g / 3.4– 4.7 cm (Table 1)
Weight / Length of fish after the experiment :	0.5940 – 0.7901 g/ 3.6 – 4.7cm (Table 1)
Test duration:	96 hours
Test water:	ground water - Hardness as CaCO: 84 mg /L - Chemical oxygen demand: 3.92 mg/L - Nitrate content (NO3):1.0015 mg/L
Test conditions:	Temperature: Control: 11.8–12.1ºC / Treatments: 11.8–12.1ºC pH of test medium: Control: 6.8–7.0 / Treatments: 6.8–7.0 Photoperiod: 16h light, 8h dark Light intensity: 850 – 1000 Lux Oxygen concentration: Control: 69–70% / Treatments: 69–70%
Test concentrations:	control, 0.0156, 0.0313, 0.0625, 0.125, 0.25, 0.5 and 1 mg/L
Statistical analysis:	Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0.
Validity criteria:	- the mortality of fish in the control was 0% after 96 h (criterion: < 10%),

- the dissolved oxygen concentrations were within the range of 69–70% of air saturation value (criterion: > 60% of air saturation).

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11.3 Results of chemical determinations

In fresh samples of the test item concentrations, the determined concentrations of **Copper hydroxide 50% WP** were between 98.2and 101.7% of the nominal concentrations (Table 8). The results confirm that the test item concentrations were prepared correctly.

In samples of the test item concentrations collected after 96 h, the determined concentrations of **Copper hydroxide 50% WP** were between 99.2and 101.4% of the nominal concentrations (Table 8). Therefore, the concentrations of copper hydroxide were stable during 96 h under test conditions.

Since the concentrations of copper hydroxide was within the range of 80–120% of the nominal concentration, it can be concluded that the concentrations of analyzed substance were stable under test conditions. If the concentrations of the detected substance is in the range of 80–120% of the nominal concentration, the effect concentrations is determined on the basic of the nominal concentrations of substance.

Table 8. Results of the determination of copper hydroxide 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	0.0156	0.00784	0.00785	0.00014	100.1
	T2	0.0313	0.01572	0.01575	0.00003	100.2
	T3	0.0625	0.03139	0.03142	0.00034	100.1
	T4	0.125	0.06279	0.06169	0.00188	98.2
	T5	0.25	0.12558	0.12775	0.00163	101.7
	T6	0.5	0.25115	0.25508	0.00074	101.6
	T7	1	0.50230	0.49357	0.00312	98.3
96	Control	0.0	0.00000	ND	0	-
	T1	0.0156	0.00784	0.00778	0.00150	99.2
	T2	0.0313	0.01572	0.01568	0.00025	99.7
	T3	0.0625	0.03139	0.03152	0.00008	100.4
	T4	0.125	0.06279	0.06369	0.00007	101.4
	T5	0.25	0.12558	0.12542	0.00010	99.9
	T6	0.5	0.25115	0.25116	0.00071	100.0
	T7	1	0.50230	0.50702	0.00253	100.9

*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

No symptoms of intoxication were observed in the control group and in the test item concentration of 0.0156 mg/L throughout the experimental period. In turn, loss of equilibrium, abnoraml swimming behaviour and abnoraml ventilatory function were recorded in the test

Cumulative mortality at the end of 96-hour experimental period was 0, 20, 60,80, 100, 100 and 100% in the test item concentrations of 0.0156, 0.0313, 0.0625, 0.125, 0.25, 0.5 and 1 mg/L, respectively. No mortality was observed in the control group throughout the experimental period.The highest concentration (1 mg/L) caused 100% mortality of fish, whereas the lowest

concentration (0.0156 mg/L) caused 0.0% mortality at the end of the observation period

Findings

Endpoints	Test item [mg/L]	Active substance [mg Cu/ L]
LC_{50}	**0.0594** (0.0562 – 0.0626)	**0.0298** (0.0282 – 0.0314)
NOEC	**0.0156**	**0.0078**
LOEC	**0.0313**	**0.0157**

Comments of zRMS:	The study is considered valid. All validity criteria were met. • The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%) • The dissolved oxygen concentrations in the test vessels were within the range of 3.6 - 3.9 mg/L (criterion: not less than 3 mg/L). **Agreed endpoints**:

Endpoint	Value [mg test item/L]	Active substance [mg Cu/L]
EC_{50}	**0.109** (0.103 - 0.1 14)	**0.055** (0.052 0.057)

Reference: KCP 10.2.1-02

Report: "Study of *Daphnia magna* acute immobilization with Copper hydroxide 50% WP". XXX K. Study code: 5697/2019, 2019. Bioscience Research Foundation

Guideline(s): OECD Guideline No. 202 (2004)

Deviations: Yes
The study finished in November 2019, not in September 2019 as it had been planned.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Summary

The aim of the study was to assess the impact of Copper hydroxide 50% WP on *Daphnia magna* to determine the concentration of the test item causing 50% immobilization of *Daphnia magna* as well as the

NOEC and LOEC values. The test was conducted in a static design with seven concentrations of the test item plus the control. The control and each concentration was divided into four replicates with five daphnids each. The study groups were as follows:

Groups	**Concentration of the test item (mg/L)**	**Concentration of active substances* (mg/L)**
Control	0.0	0.0
T1	0.0156	0.0078
T2	0.0313	0.0157
T3	0.0625	0.0314
T4	0.125	0.0628
T5	0.25	0.1255
T6	0.5	0.2510
T7	1	0.5020

*based on the content of Copper ~~hydroxide~~ in the test item, i.e. 50.2% (w/w) provided by the Sponsor

The daphnids were observed for immobilization after 24 and 48 h of exposure. The daphnids were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel.
The endpoint values were determined based on the nominal test item concentrations and nominal concentrations of copper hydroxide in the test item.

Material and methods

Test item:	Name: Copper hydroxide 50% WP Batch No. SCL-98802 Production date: 4th April, 2018 Expiry date: 3rd April, 2020
Reference item	Name: Potassium dichromate AR-500GM Batch No. J071B18 Expiry date: January, 2023
Test organisms:	*Daphnia magna* Source: Culture maintained at BRF, India. Age: less than 24 h old
Test design:	Seven concentrations of the test item were used in the experiment.. The concentrations were arranged in a geometric series with a separation factor of 2. There were 4 replicates of each test concentration. There was also a concurrent control group, also divided into four replicates. Five daphnids were introduced into each replicate. The daphnids were exposed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control. The beakers were covered with transparent lids in order to minimize evaporation and to prevent accidental contamination. During exposure, the daphnids were not fed. An artificial fluorescent light source was used.
Test medium:	The reconstituted water recommended by the OECD Guideline No. 202 (2004)
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC.
Test concentration:	control, 0.0156, 0.0313, 0.0625, 0.125, 0.25, 0.5 and 1 mg/L
Test conditions:	Temperature: Control: 20.3 - 20.4°C / Treatments: 20.3 - 20.6°C Oxygen: Control: 3.8 — 3.9 mg/L / Treatments: 3.6 — mg/L pH: Control: 7.7 - 7.8 / Treatments: 7.5 - 7.7

	Lighting: 16 - hour light and 8 - hour dark regime, 1284 - 1296 lux
Statistical analysis:	Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0.
Validity criteria:	The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%)
	The dissolved oxygen concentrations in the test vessels were within the range of 3.6 - 3.9 mg/L (criterion: not less than 3 mg/L).

Results:

Table 6. Results of the determination of Copper hydroxide 50% WP – stability test.

Active substance	Hour	Sample (mg/L)	Nominal concentration* (mg/L)	Mean determined concentration (mg/L)	SD*	Recovery (%)
Copper hydroxide	0	Control	0.00000	ND	0	-
		10	5.02300	5.00693	0.02941	99.7
	24	Control	0.00000	ND	0	-
		10	5.02300	5.04587	0.06718	100.5
	48	Control	0.00000	ND	0	-
		10	5.02300	4.93036	0.03057	98.2

*Based on the content of active substance in the test item determined at Bioscience Research Foundation at level of 50.23% (w/w)
SD: standard deviation
ND: not determined

Table 7. Results of the determination of Copper hydroxide 50% WP in the test samples – main test.

Hour	Sample/test item concentration (mg/L)		Nominal concentration* (mg/L)	Mean determined concentration (mg/L)	SD*	Recovery (%)
0 (fresh)	Control	0.0	0.00000	ND	0	-
	T1	0.0156	0.00784	0.00785	0.00005	100.1
	T2	0.0313	0.01572	0.01577	0.00000	100.3
	T3	0.0625	0.03139	0.03124	0.00033	99.5
	T4	0.125	0.06279	0.06239	0.00020	99.4
	T5	0.25	0.12558	0.12469	0.00176	99.3
	T6	0.5	0.25115	0.24924	0.00240	99.2
	T7	1	0.50230	0.50544	0.00141	100.6
48 (spent)	Control	0.0	0.00000	ND	0	-
	T1	0.0156	0.00784	0.00782	0.00005	99.7
	T2	0.0313	0.01572	0.01576	0.00020	100.3
	T3	0.0625	0.03139	0.03130	0.00054	99.7
	T4	0.125	0.06279	0.06353	0.00030	101.2
	T5	0.25	0.12558	0.12534	0.00049	99.8
	T6	0.5	0.25115	0.24799	0.00000	98.7
	T7	1	0.50230	0.50549	0.00141	100.6

*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

Findings

Immobilization of *Daphnia magna* – main test

Sample/test item concentration (mg/L)		Number of daph-nids	Number of immobilized daphnids after 24h				%	Number of immobilized daphnids after 48h				%
			R1	R2	R3	R4		R1	R2	R3	R4	
Control	0.0	20	0	0	0	0	0	0	0	0	0	0
T1	0.0156	20	0	0	0	0	0	0	0	0	0	0
T2	0.0313	20	0	0	0	0	0	0	0	0	1	5
T3	0.0625	20	0	0	1	1	10	1	0	1	1	15
T4	0.125	20	2	1	2	2	35	3	2	3	4	60
T5	0.25	20	4	3	3	4	70	5	4	4	5	90
T6	0.5	20	5	4	4	5	90	5	5	5	5	100
T7	1	20	5	5	5	4	95	5	5	5	5	100

Endpoints

Endpoint	Value [mg test item/L]	Active substance [mg Cu/L]
EC_{10}	**0.046** (0.042 - 0.050)	**0.023** (0.021 - 0.025)
EC_{20}	**0.062** (0.058 - 0.066)	**0.031** (0.029 - 0.033)
EC_{50}	**0.109** (0.103 - 0.1 14)	**0.055** (0.052 0.057)
NOEC	**0.0625**	**0.0314**
LOEC	**0.125**	**0.0628**

<table>
<tr><td>Comments of zRMS:</td><td>The study is considered valid. All validity criteria were met.

The biomass in the control increased by a factor of 33.0 within the 72-hour test period (criterion: at least a 16-fold growth),
The coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation exposure termination) in the control culture was 1.2 (criterion: it must not exceed 7%),
the mean coefficient of variation for the section-by-section growth rate in the control culture was 4.1% (criterion: it must not exceed 35%).

Agreed endpoints:
<table>
<tr><th>Endpoint</th><th>Test item mg/L
(based on nominal concentrations)</th><th>Active substance mg Cu/L
(based on nominal concentrations*)</th></tr>
<tr><td colspan="3">Growth rate</td></tr>
<tr><td>ErC₅₀</td><td>0.0465
(0.0413 - 0.0517)</td><td>0.0233
(0.0207 - 0.0259)</td></tr>
<tr><td colspan="3">Yield</td></tr>
<tr><td>EyC₅₀</td><td>0.0096
(0.0076 - 0.01 16)</td><td>0.0048
(0.0038 - 0.0058)</td></tr>
</table>
* Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis</td></tr>
</table>

Reference:	KCP 10.2.1-03
Report:	"Study of algal growth inhibition with Copper hydroxide 50% WP". XXX D., Study code: 5696/2019, 2019. Bioscience Research Foundation
Guideline(s):	OECD No. 201 (2006)
Deviations:	Yes The study finished in November 2019, not in September 2019 as it had been planned.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The influence of the test item Copper hydroxide 50% WP on the growth of the green algal species *Raphidocelis subcapitata (FORMERLY Pseudokirchneriella subcapitata)* was investigated in a 72-hour test. The algae were exposed to an aqueous test medium containing the test item at the nominal concentrations of 0.0156, 0.0313, 0.0625, 0.125, 0.25, 0.5 and 1 mg/L, along with a negative control. Six replicates were maintained for the negative control and three replicates for each test concentrations. The initial cell density of algal cells at the start of exposure was 0.8 x 10^4 cells/mL. The number of algal cells was determined with direct method, which involves counting the number of algal cells in Bürker chamber in each replicate after 24, 48 and 72 h of exposure.

Material and methods

Test item: Name: Copper hydroxide 50% WP

	Batch number: SCL-98802 Manufacturing date: 4th April, 2018 Expiry date: 3rd April, 2020
Test organism:	Species: *Raphidocelis subcapitata (formerly Pseudokirchneriella subcapitata*) Source: BRF test facility Age: 3 days old
Test duration:	72 hours
Test water:	OECD medium prepared according to OECD Guideline 201
Test conditions:	Temperature: 21.2 – 22.9°C pH: Control: 7.9 - 8.1 / Treatments: 7.5 - 8.1 Lighting: continuous illumination Light intensity: 5650 - 5810 lux
Test concentrations:	control, 0.0156, 0.0313, 0.0625, 0.125, 0.25, 0.5 and 1 mg/L
Statistical analysis:	Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0..
Validity criteria:	- the biomass in the control increased by a factor of 33.0 within the 72-hour test period (criterion: at least a 16-fold growth), - the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation exposure termination) in the control culture was 1.2 (criterion: it must not exceed 7%), - the mean coefficient of variation for the section-by-section growth rate in the control culture was 4.1% (criterion: it must not exceed 35%).

Results:

Table 10. Results of the determination of Copper hydroxide – stability test

Active substance	Hour	Sample (mg/L)	Nominal concentration* (mg/L)	Mean determined concentration (mg/L)	SD	Recovery (%)
Copper hydroxide	0	Control	0.000	ND	0	-
		10	5.02300	5.02705	0.02491	100.1
	24	Control	0.000	ND	0	-
		10	5.02300	4.95676	0.06122	98.7
	48	Control	0.000	ND	0	-
		10	5.02300	5.01182	0.06687	99.8
	72	Control	0.000	ND	0	-
		10	5.02300	4.97037	0.10862	99.0

*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

Table 11. Results of the determination of Copper hydroxide in the test samples

Sample/test item concentration (mg/L)		Control	T1	T2	T3	T4	T5	T6	T7
		0.0	0.0156	0.0313	0.0625	0.125	0.25	0.5	1
Nominal concentration* (mg/L)		0.0	0.00784	0.01572	0.03139	0.06279	0.12558	0.25115	0.50230
0 h	Mean determined concentration (mg/L)	ND	0.00762	0.01521	0.03045	0.06104	0.12340	0.24207	0.48562
	SD	0	0.00000	0.00021	0.00023	0.00009	0.00106	0.00101	0.00133
	Recovery (%)	-	97.2	96.8	97.0	97.2	98.3	96.4	96.7
72 h	Mean determined concentration (mg/L)	ND	0.00771	0.01572	0.03146	0.06305	0.12302	0.24901	0.50127
	SD	0	0.00018	0.00010	0.00007	0.00042	0.00034	0.00119	0.00249
	Recovery (%)	-	98.3	100.0	100.2	100.4	98.0	99.1	99.8

*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

Table 7. Algal growth rate and yield based on the cell density – main test

Group/ Concentration of the test item (mg/L)	Algal cell density at the beginning of the experiment ($\times10^6$ cells/mL)	Replicate/ Mean/SD	Algal cell density during the experiment ($\times10^6$ cells/mL)			Growth rate ($\times10^6$ cells/mL)				Yield ($\times10^6$ 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
Control (0.0)	0.008	1	0.028	0.072	0.251	1.253	0.944	1.249	1.149	0.243
		2	0.034	0.089	0.270	1.447	0.962	1.110	1.173	0.262
		3	0.034	0.077	0.250	1.447	0.817	1.178	1.147	0.242
		4	0.028	0.071	0.269	1.253	0.930	1.332	1.172	0.261
		5	0.035	0.081	0.273	1.476	0.839	1.215	1.177	0.265
		6	0.032	0.078	0.271	1.386	0.891	1.245	1.174	0.263
		Mean	**0.032**	**0.078**	**0.264**	**1.377**	**0.897**	**1.221**	**1.165**	**0.256**
		SD	**0.003**	**0.007**	**0.011**	**0.101**	**0.059**	**0.075**	**0.013**	**0.011**
T1 (0.0156)	0.008	1	0.031	0.054	0.128	1.355	0.555	0.863	0.924	0.120
		2	0.029	0.052	0.121	1.288	0.584	0.845	0.905	0.113
		3	0.028	0.064	0.129	1.253	0.827	0.701	0.927	0.121
		Mean	**0.029**	**0.057**	**0.126**	**1.298**	**0.655**	**0.803**	**0.919**	**0.118**
		SD	**0.002**	**0.006**	**0.004**	**0.052**	**0.149**	**0.089**	**0.012**	**0.004**
T2 (0.0313)	0.008	1	0.028	0.041	0.042	1.253	0.381	0.024	0.553	0.034
		2	0.029	0.032	0.038	1.288	0.098	0.172	0.519	0.030
		3	0.028	0.061	0.064	1.253	0.779	0.048	0.693	0.056
		Mean	**0.028**	**0.045**	**0.048**	**1.264**	**0.419**	**0.081**	**0.588**	**0.040**
		SD	**0.001**	**0.015**	**0.014**	**0.020**	**0.342**	**0.079**	**0.092**	**0.014**

Table 7 (continued). Algal growth rate and yield based on the cell density – main test

Group/ Concentration of the test item (mg/L)	Algal cell density at the beginning of the experiment (×10^6 cells/mL)	Replicate/ Mean/SD	Algal cell density during the experiment (×10^6 cells/mL)			Growth rate (×10^6 cells/mL) Section-by-section growth rate			Growth rate	Yield (×10^6 cells/mL)
			24 h	48 h	72 h	0 – 24 h	24 – 48 h	48 – 72 h	0 – 72 h	72 h
T3 (0.0625)	0.008	1	0.025	0.031	0.033	1.139	0.215	0.063	0.472	0.025
		2	0.027	0.039	0.046	1.216	0.368	0.165	0.583	0.038
		3	0.029	0.049	0.050	1.288	0.525	0.020	0.611	0.042
		Mean	**0.027**	**0.040**	**0.043**	**1.215**	**0.369**	**0.083**	**0.555**	**0.035**
		SD	**0.002**	**0.009**	**0.009**	**0.074**	**0.155**	**0.074**	**0.073**	**0.009**
T4 (0.125)	0.008	1	0.013	0.014	0.015	0.486	0.074	0.069	0.210	0.007
		2	0.019	0.020	0.022	0.865	0.051	0.095	0.337	0.014
		3	0.010	0.022	0.023	0.223	0.788	0.044	0.352	0.015
		Mean	**0.014**	**0.019**	**0.020**	**0.525**	**0.305**	**0.070**	**0.300**	**0.012**
		SD	**0.005**	**0.004**	**0.004**	**0.323**	**0.419**	**0.025**	**0.078**	**0.004**
T5 (0.25)	0.008	1	0.013	0.009	0.011	0.486	-0.368	0.201	0.106	0.003
		2	0.019	0.009	0.009	0.865	-0.747	0.000	0.039	0.001
		3	0.010	0.025	0.025	0.223	0.916	0.000	0.380	0.017
		Mean	**0.014**	**0.014**	**0.015**	**0.525**	**-0.066**	**0.067**	**0.175**	**0.007**
		SD	**0.004**	**0.009**	**0.009**	**0.323**	**0.872**	**0.116**	**0.180**	**0.009**
T6 (0.5)	0.008	1	0.010	0.011	0.012	0.223	0.095	0.087	0.135	0.004
		2	0.009	0.010	0.010	0.118	0.105	0.000	0.074	0.002
		3	0.011	0.013	0.014	0.318	0.167	0.074	0.187	0.006
		Mean	**0.010**	**0.011**	**0.012**	**0.220**	**0.123**	**0.054**	**0.132**	**0.004**
		SD	**0.001**	**0.002**	**0.002**	**0.100**	**0.039**	**0.047**	**0.056**	**0.002**

Table 7 (continued). Algal growth rate and yield based on the cell density – main test

Group/ Concentration of the test item (mg/L)	Algal cell density at the beginning of the experiment (×10^6 cells/mL)	Replicate/ Mean/SD	Algal cell density during the experiment (×10^6 cells/mL)			Growth rate (×10^6 cells/mL) Section-by-section growth rate			Growth rate	Yield (×10^6 cells/mL)
			24 h	48 h	72 h	0 – 24 h	24 – 48 h	48 – 72 h	0 – 72 h	72 h
T7 (1)	0.008	1	0.006	0.008	0.009	-0.288	0.288	0.118	0.039	0.001
		2	0.017	0.012	0.011	0.754	-0.348	-0.087	0.106	0.003
		3	0.008	0.009	0.010	0.000	0.118	0.105	0.074	0.002
		Mean	**0.010**	**0.010**	**0.010**	**0.155**	**0.019**	**0.045**	**0.073**	**0.002**
		SD	**0.006**	**0.002**	**0.001**	**0.538**	**0.329**	**0.115**	**0.033**	**0.001**

The EC_{50} value for growth rate and yield on the basis of the nominal concentration of the test item are presented below:

Endpoint	**Test item mg/L** (based on nominal concentrations)	**Active substance mg Cu/L** (based on nominal concentrations*)
Growth rate		
ErC_{10}	**0.0045** (0.0034 - 0.0056)	**0.0023** (0.0017 - 0.0028
ErC_{20}	**0.0100** (0.0080 0.0120)	**0.0050** (0.0040 - 0.0060)
ErC_{50}	**0.0465** (0.0413 - 0.0517)	**0.0233** (0.0207 - 0.0259)
NOEC	**<0.0156**	**<0.0078**
LOEC	**0.0156**	**0.0078**
Yield		
EyC_{10}	**0.0011** (0.0006 0.0016)	**0.0006** (0.0003 - 0.0008)
EyC_{20}	**0.0024** (0.0015 - 0.0033)	**0.0012** (0.0008 - 0.0017)
EyC_{50}	**0.0096** (0.0076 - 0.01 16)	**0.0048** (0.0038 - 0.0058)

NOEC	**<0.0156**	**<0.0078**
LOEC	**0.0156**	**0.0078**

* Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis

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

Comments of zRMS:

The study is considered valid. All validity criteria were met.

However, it should be noted that the formulation used is WP instead of WG.

- 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_{50} of the reference item (dimethoate) was 0.12 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee)

Agreed endpoints:

The 48 h LD_{50} of Copper hydroxide 50% WP =49.61 µg/bee (lower limit 45.29-upper limit 53.94 µg/bee).

Based on the content of Copper 50% (~~as oxychloride~~) WP was determined as 24.91 µg Cu/bee (lower limit 22.73-upper limit 27.08 µg/bee)

Reference:	KCP 10.3.1.1.1
Report	"Acute Oral Toxicity of Copper hydroxide 50% WP on Honey bee". G. XXX, 2020, Study code 7621/2020
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 hydroxide 50% WP (batch number: SCL-993056) was conducted to determine the LD_{50} values for honeybees. Five doses of the test item were used. These included: 14.52, 21.78, 32.67, 49 and 73.5 µg/honeybee 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		Nº of tested bees	Mortality after 48 h Total		LD_{50}	
[µg /bee]	[µg a.i./bee]		[no.]	[%]	[µg /bee]	[µg Cu/bee]
0.0 (Control)		30	0	0.0	49.61 (45.29-53.94)	24.91 (22.73-27.08)
14.52	7.29	30	0	0.0		
21.78	10.93	30	3	10		
32.67	16.40	30	10	33.33		
49	24.60	30	13	43.33		
73.5	36.90	30	22	73.33		

Findings

- The mortality the test item treatment of 73.5 µg/bee after 48 hours was higher than 50% when compared to the control.
- The LD50 of Copper hydroxide 50% WP was determined as 49.61 µg/bee (lower limit 45.29-upper limit 53.94 µg/bee) concentrations for 48 h
- At the 48h observation the bees exposed to 14.52 µg/bee concentration was found to be normal whereas normal and lethargy was observed in bees exposed to 21.78 µg/bee concentration. Normal, spam, lethargy and mortality were observed in bees exposed to 32.67, 49 and 73.5 µg/bee concentration, respectively.

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_{50} of the reference item (dimethoate) was 0.12 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee)

Conclusion

The LD_{50} of Copper hydroxide 50% WP was determined as 49.61 µg/bee (lower limit 45.29-upper limit 53.94 µg/bee) concentrations for 48 h. Based on the content of Copper 50% (~~as oxychloride~~) WP was determined as 24.91 µg Cu./bee (lower limit 22.73-upper limit 27.08 µg Cu/bee) concentrations for 48h. The LD_{50} value of Dimethoate was found to be 0.12 µg/bee s (lower limit 0.11-upper limit 0.13 µg/bee) concentration for 24 h period.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study is considered valid. All validity criteria were met. However, it should be noted that the formulation used is WP instead of WG. • The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%), • The LD_{50}/24 h of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee). **Agreed endpoints:** 48 h LD_{50}= 198.2 µg product/bee correspond to LD_{50} = 99.50 µg/bee

Reference: KCP 10.3.1.1.2

Report "Copper hydroxide 50% WP: Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test". Paweł XXX, 2018, B/36/17. Institute of Industrial Organic Chemistry Branch Pszczyna

Guideline(s): Yes, OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:

Description: Copper hydroxide 50% WP
Production batch: SCL - 97561
A.i. content: 50.2% Copper hydroxide [w/w]

Test system:

Species: *Apis mellifera*
Strain: carnica
Age: approximately 3 weeks
Average weight: -
Average length: -
Source: An apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna
Acclimation period: 20 hours

Diet: 50% (v/v) sucrose solution

Experimental conditions:

Temperature: 25 – 26°C
Humidity: 61 – 68%
Hardness: -
pH: -
Light and photoperiod: 24h darkness (except during observations).
Loading: 3 replicates per dose, 10 bees per replicate
Test procedure: The honeybees were anaesthetized with carbon dioxide, transferred to plastic trays and dosed on the dorsal 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 a.i./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 a.i./bee. The honeybees were observed for mortality and behavioural abnormalities after 4, 24 and 48 h of exposure.
The mortality data was analysed with regression analysis using the log-probit method. The endpoints were the honeybee mortality after 48 hours of the exposure, the contact LD_{50} of the test item after 24 and 48 hours of the exposure and the contact LD_{50}/24 h of the reference item (dimethoate).

Results

The acute contact toxicity study of the test item, Copper hydroxide 50% WP on honeybees (Apis mellifera L.) in the laboratory test are summarized below.

Contact toxicity test results

Dosage		Number of tested bees	Mortality after 48 h after the beginning of the treatment		LD_{50}	
			Total			
µg/bee	µg a.i./bee	[no.]	[no.]	[%]	µg/bee	µg a.i./bee
0.0 (Control)		30	0	0.0	198.2 (148.1 – 337.9)*	99.5 (74.3 – 169.3)*
12.5	6.3	30	0	0.0		
25.0	12.6	30	1	3.3		
50.0	25.1	30	1	3.3		
100.0	50.2	30	6	20.0		
200.0	100.4	30	18	53.3		

*: the LD_{50} (with 95% confidence limits) was calculated with the log-probit method (ToxRat Proffesional 3.2.1 computer [SOP/B/67]).

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_{50}/24 h of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

Conclusion

Mortality of the control group and the treated group 12.5 µg/honeybee after 48 hours of exposure were 0.0%. Mortality in the doses of 25.0, 50.0, 100.0 and 200.0 µg/honeybee after 48 hours of exposure was 3.3, 3.3, 20.0 and 53.3%, respectively.
No abnormal behavioural effects were observed during the test .

The median lethal doses LD_{50}/24 h and LD_{50}/48 h are equal to 198.2 µg t.i./honeybee.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

Comments of zRMS:

The study is considered valid. 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 71.7% 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:

Mortality and reproduction of *T. pyri* in the laboratory test

Study group [application rate]		Parameter (endpoint)						
		Mortality			Reproduction			
Test item		Total	LR_{50}		Mean number of eggs/ female (Rr) [no.]	Reproduc-tion reduc-tion Pr [%]	ER_{50}	
[kg/ha]	[kg a.i./ha]	[%]	[kg/ha]	[kg Cu/ha]			[kg/ha]	[kg Cu/ha]
Control (0.0)		0.0	-		4.1	-	-	
2.0	1.0	1.7	> 16.0	> 8.0	3.1	24.2	9.8	4.9
4.0	2.0	8.6*			2.0*	51.1		
8.0	4.0	10.0*			2.1*	48.3		

	16.0	8.0	13.3*			2.0	50.6		
	NOER$_{mortality}$			2.0	1.0	**NOER$_{reproduction}$**		2.0	1.0
	Reference item		**Bi 58 Top 400 EC**						
	[mL/ha]	**[g a.i./ha]**							
	9.0	3.6	71.7	-					
	*: statistically significant differences								

Reference: KCP 10.3.2.2-01

Report “An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on the predatory mite, *Typhlodromus pyri* (Sch.)”. Paweł XXX, 2019, B/38/17. Institute of Industrial Organic Chemistry Branch Pszczyna

Guideline(s): ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The aim of the study was to determine the impact of Copper hydroxide 50% WP on mortality and reproduction of the predatory mite, *Typhlodromus pyri*. The endpoints of this test were mortality of the mites after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment.

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: 2.0, 4.0, 8.0 and 16.0 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 2.0, 4.0, 8.0 and 16.0 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.

Each treatment group included 3 replicates containing 20 impartially selected protonymphs.

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

Mortality and reproduction of *T. pyri* in the laboratory test

Study group [application rate]		Parameter (endpoint)						
		Mortality			Reproduction			
Test item		Total	LR_{50}		Mean number of eggs/ female (Rr) [no.]	Reproduction reduction Pr [%]	ER_{50}	
[kg/ha]	[kg Cu./ha]	[%]	[kg/ha]	[kg Cu/ha]			[kg/ha]	[kg Cu/ha]
Control (0.0)		0.0	-		4.1	-	-	
2.0	1.0	1.7	> 16.0	> 8.0	3.1	24.2	9.8	4.9
4.0	2.0	8.6*			2.0*	51.1		
8.0	4.0	10.0*			2.1*	48.3		
16.0	8.0	13.3*			2.0	50.6		
$NOER_{mortality}$			2.0	1.0	$NOER_{reproduction}$		2.0	1.0
Reference item		Bi 58 Top 400 EC						
[mL/ha]	[g a.i./ha]							
9.0	3.6	71.7	-					

*: statistically significant differences

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 hydroxide 50% WP at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha the percentages of mortality of *T. pyri*, were 1.7, 8.3, 10.0 and 13.3%, 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. > 16.0 kg/ha (> 8.0 kg Cu./ha). The $NOER_{mortality}$ value is equal to 2.0 kg/ha (1.0 kg Cu/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 2.0 and the control group. However, there were statistically significant differences in mortality between the group treated with the test item at the rates of 4.0, 8.0 and 16.0 kg/ha and the control group (Step-down Cochran-Armitage Test Procedure, p(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 71.7%. 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 hydroxide 50% WP at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha were 3.1, 2.0, 2.1 and 2.0 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by Copper hydroxide 50% WP at the rates of 2.0, 4.0, 8.0 and 16.0 kg/ha were 24.2, 51.1, 48.3 and 50.6% respectively.
- On the basis of the obtained reproduction results, the ER50 value is equal to 9.8 kg/ha (4.9 kg Cu/ha) and $NOER_{reproduction}$ value is equal to 2.0 kg/ha (1.0 kg Cu./ha).
- At the significance level of $\alpha \leq 0.1$, there were no statistically significant differences in mortality between the group treated with the test item at the rate of 2.0 and the control group. However, there were statistically significant differences in mortality between the group treated with the test item at the rates of 4.0, 8.0 and 16.0 kg/ha and the control group (Williams Multiple Sequential t-test Procedure, |t|>|t*|).

Validity criteria

The following validity criteria were met during the study:

- 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 71.7% 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).

Conclusion

On the basis of the obtained results it can be concluded that Copper hydroxide 50% WP at the rates of 4.0, 8.0 and 16.0 kg/ha has adverse effect on mortality of the mites.

The test item at the rates of 4.0, 8.0 and 16.0 kg/ha has also adverse effect on reproduction of the mites.

Comments of zRMS:

The study is considered valid. All validity criteria were met.

- 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).

Agreed endpoints:

Mortality and fecundity of *Aphidius rhopalosiphi* in the laboratory test

Study group [application rate]		Parameter (endpoint)						
		Mortality			Reproduction			
Test item		Total [%]	LR_{50}		Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER_{50}	
[kg/ha]	[kg Cu/ha]		[kg/ha]	[kg Cu/ha]			[kg/ha]	[kg Cu/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+	51.8		
16.0	8.0	3.3			8.3+	63.5		
$NOER_{mortality}$			≥ 16.0	≥ 8.0	**$NOER_{fecundity}$**		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* (De Stefani - Perez)". Paweł XXX, 2019, B/37/17. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 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_{50}	Mean no. of	Fecundity re-	ER_{50}

[kg/ha]	[kg a.i./ha]	[%]	[kg/ha]	[kg Cu/ha]	mummies/ female	duction Pr [%]	[kg/ha]	[kg Cu/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^{+}	51.8		
16.0	8.0	3.3			8.3^{+}	63.5		
NOER$_{mortality}$			≥ 16.0	≥ 8.0	**NOER$_{fecundity}$**		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 (Chi2 2x2 Table Test with Bonferroni Correction, p(z) > alpha*).
- On the basis of the obtained mortality results, the LR_{50} and $NOER_{mortality}$ values could not be determined. It can only be concluded that the LR_{50} and the $NOER_{mortality}$ 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 α 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 > α*).
- On the basis of the obtained fecundity results, the ER_{50} value is equal to 7.9 kg/ha and $NOER_{fecundity}$ value is equal to 4.0 kg/ha.
- **Validity criteria**

- 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).

Conclusion

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.

ZRMS comments:

The study is considered valid. All validity criteria were met.

- Mortality (dead larvae and pupae and adults dying during emergence or not successfully moulted) in the control: 6.67% (a criterion: ≤20 %)
- Fecundity (mean number of eggs per female per day) in the control 38 (criterion: ≥15)
- Fertility (mean hatching rate) in the control: 98.59% (criterion: ≥70%)
- Mortality in the reference item treatment was 100% (criterion: >50%)

Agreed endpoints:

Study group (application rate) (g/ha)	Mortality		Reproduction			
	Total (%)	Corrected# (%)	Fecundity (No)	Fecundity reduction (%)	Fertility (%)	Fertility reduction (%)
Control						
0.0	6.67	-	38	-	98.59	-
Copper hydroxide 50% WP						
343.75	10.00	3.57	33.7	11.32	97.62	0.98
687.50	13.33	7.14	30.5	19.74	96.38	2.24
1375.00	16.67	10.71	26.8	29.47	94.20	4.45
2750.00	16.67	10.71	22.9	39.74	93.10	5.57
5500.00	26.67	21.43	21	44.74	89.61	9.11
Endpoints	$LR50_{mortality}$		>5500 g/ha (>2761 a.i g/ha)	$ER50_{fecundity}$	>5500 g/ha (>2761 a.i g/ha)	
	$NOER_{mortality}$		1375 g/ha (690.25 a.i g/ha)	$NOER_{fecundity}$	≤ 343.75 g/ha (≤172.56 a.i g/ha)	
Reference item - ROGOHIT (DIMETHOATE 30% EC)						
0.65	100	100	-			

#: Mortality corrected according to Abbott's formula:
Corrected mortality [%] = ((Mt - Mc) ÷ (100 - Mc)) × 100; Mt = Mortality treated, Mc = Mortality control

Reference:	KCP 10.3.2.2 - 03
Report	"An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on larvae of the green Lacewing *Chrysoperla carnea* L. (Neuroptera: Chrysopidae)". XXX, M. 2020, Study Code 7543/2020, BIOSCIENCE RESEARCH FOUNDATION
Guideline(s):	According to the ESCORT 1 (Barrett K. L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and the guidelines developed by the IOBC/ WPRS(Candolfi M. P. et al.,2001)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Summary

The aim of the study was to determine under extended laboratory conditions the effects of fresh residues of the formulation Copper hydroxide 50% WP applied to maize leaves, on the green lacewing *Chrysoperla carnea* Steph. (Neuroptera: Chrysopidae). A range of five rates of the test product (343.75, 687.50, 1375, 2750 and 5500 g/ha of formulated product) were sprayed per treatment.

Application was performed on maize leaves with a laboratory track sprayer. First instar larvae of Chrysoperla carnea (2-3 days old) were isolated and exposed to the fresh and dry residues on maize 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 343.75, 687.50, 1375, 2750 and 5500 g/ha).

To verify the sensitivity of the biological test system and the precision of the test procedure, the insecticide, TAFGOR (30% dimethoate, w/w) was used as a reference item. The rate of the reference item was 0.65 L/ha. The control group was treated with distilled water.

Material and methods

Test item:	Copper hydroxide 50% WP: content: 50.2% w/w.; Batch No.: SCL-993056; manufacturing date: December 9th, 2019; expiry date: December 8th, 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 L product/ha)
– Copper hydroxide 50% WP at a rate of 343.75 g product/ha
– Copper hydroxide 50% WP at a rate of 687.50 g product/ha
– Copper hydroxide 50% WP at a rate of 1375.0 g product/ha
– Copper hydroxide 50% WP at a rate of 2750.0 g product/ha
– Copper hydroxide 50% WP at a rate of 5500.0 g product/ha
– TAFGOR 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
– temperature: 24.0 – 27.0 ºC
– relative air humidity: 62.0 – 80.0 %
– photoperiod: 16 hours light : 8 hours dark; 1100-1800 lux.

Statistics: Based upon the results, the LR50 and NOER for mortality and the ER50 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. 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 % (6.67 %). Mortality in the reference product treatment was 100 %. Mortality (pre-adult phase) was less than 50 % in the assayed rates, 21.43 % corrected mortality as maximum observed mortality at the rate of 5500 g FP/ha. Therefore, the LR_{50} for the test product Copper hydroxide 50% WP on *Chrysoperla carnea* was estimated to be greater than the maximum rate tested of 5500 g /ha of formulated product (equivalent to >2761 g Cu/ha)

There were statistically significant differences in mortality between group treated with the test item at the rates of 343.8, 687.5 and 1375 L/ha and the control group. The $NOER_{mortality}$ value is 1375 L Copper hydroxide 50% WP/ha, i.e., 690.25 g Cu/ha.

In the group treated with Copper hydroxide 50% WP at rates of 343.75, 687.50, 1375, 2750 and 5500 g/ha was 33.7, 30.5, 26.8, 22.9 and 21 respectively. Fecundity reduction in the group treated with Copper hydroxide 50% WP at rates of 343.75, 687.50, 1375, 2750 and 5500 g/ha was 11.32, 19.74, 29.47, 39.74 and 44.74, respectively in comparison with the control group.
There were no statistically significant difference in fecundity between group treated with the test item at the rate of all doses and the control group.

The validity criterion for fertility was met, because the mean hatching rate in the control group was 98.59% (criterion: ≥70%), whereas in the group treated with Copper hydroxide 50% WP at rates of 343.75, 687.50, 1375, 2750 and 5500L/ha was 96.41, 93.88, 90.59, 88.55 and 78.21%, respectively. Fertility reduction in the group treated with Copper hydroxide 50% WP at rates of 343.75, 687.50, 1375, 2750 and 5500L /ha was 2.21, 4.78, 8.11, 10.18 and 20.67%, respectively in comparison with the control group.

There were statistically significant differences in fertility between group treated with the test item at rates of 343.75 L/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)**
g/ha	g Cu/ha	(28 d)	(28 d)	(24 h)	(24 h)
Control (0.0)		6.67	-	38	98.59
343.75	172.56	10.00	3.57	33.7	97.62
687.50	345.13	13.33	7.14	30.5	96.38
1375.0	690.25	16.67	10.71	26.8	94.20
2750.0	1380.50	16.67	10.71	22.9	93.10
5500.0	2761.00	26.67	21.43	21	89.61
Reference item					
L /ha	g a.s./ha				
0.65	195	100	100	-	-

Test validity criteria

The following validity criteria were met during the study:

- mortality (dead larvae and pupae and adults dying during emergence or not successfully moulted) in the control: 6.67% (a criterion: ≤20 %)
- fecundity (mean number of eggs per female per day) in the control 38 (criterion: ≥15),
- fertility (mean hatching rate) in the control: 98.59% (criterion: ≥70%).
- mortality in the reference item treatment was 100% (criterion: >50%).

Comments of zRMS:

The study is considered valid. All validity criteria were met.

- The 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 3.46 (criterion: ≥2 fertile eggs per viable female per day).

Agreed endpoints:

Study group (application rate) (g/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	-	119.93	114.14	95.18	3.63	3.46	-
Copper hydroxide 50% WP								
343.75	0	-	118.79	111.29	93.68	3.60	3.37	2.60
687.50	5	-	113.50	102.50	90.37	3.55	3.20	7.51[+]
1375.00	10	-	106.57	88.43	83.11	3.44	2.85	17.63[+]
2750.00	15	-	89.00	73.21	82.29	2.87	2.36	31.79[+]
5500.00	40[+]	-	58.21	44.93	77.55	2.77	2.14	38.15[+]
$LR50_{mortality}$	**>5500.00 g/ha** >(2761.00 g a.i./ha)		**$ER50_{fecundity}$**		**>5500.00 g/ha** >(2761.00 g a.i./ha)			
$NOER_{mortality}$	**2750.00 g/ha** (1380.50 g a.i./ha)		**$NOER_{fecundity}$**		**343.75 g/ha** (172.56 g a.i. /ha)			
Reference item - TAFGOR (DIMETHOATE 30% EC)								
0.65 L/ha	90	90.0	-					

*: Mortality corrected according to Abbott's formula:
Corrected mortality [%] = ((Mt - Mc) ÷ (100 - Mc)) × 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 hydroxide 50% WP on the seven spotted ladybird beetle, Coccinella septempunctata (L.)". S. XXX, 2020, Study Code 7544/2020, BIOSCIENCE RESEARCH FOUNDATION

Guideline(s): According to the ESCORT 1 (Barrett K.L. et al., 1994)
and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents
and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item: Copper hydroxide 50% WP; Batch Number SCL-993056; active substance: 50.2% w/w

Test species:	Ladybird beetle *(Coccinella septempunctata),* Coleoptera field collected, 4 days old larvae. Four days old of C. Septempunctata 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.
Plant material:	The test substance was thoroughly diluted in deionised water and sprayed onto a clean glass plate (size 40x18x0.6 cm).
Study design:	The total pre-imaginal mortality 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). The mean number of eggs laid per female per day was determined by dividing the total number of eggs laid within each treatment group by the mean number of viable females in that treatment group. In addition, the percentage of fertile eggs was assessed from the larval hatch.
Application rate:	Nominally 200 L/ha
Test conditions:	Temperature: 20.5 – 21.9 (exposure phase) and 20.1-21.8ºC (reproduction phase) °C; humidity: 65% - 76% (exposure phase) and 65%-78% (reproduction phase); lighting: 16 h light : 8 h dark; light intensity: 949 – 1130 Lux
Statistical analysis:	Based upon the results, the LR_{50} and NOER for mortality and the ER_{50} 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. The means and standard deviations were calculated using validated Excel sheets
Endpoints:	- values for LR_{10}, LR_{50} - values for NOER and LOER - mean female fecundity (defined as number of laid eggs per female per day) - mean fertility (defined as % of fertile eggs)

Results and Conclusions

Pre-imaginal mortality:

There was no mortality was observed in the control group, whereas mean mortality % of larvae after exposure to Copper hydroxide 50% WP at rates of 343.75, 687.50,1375.00, 2750.00 and 5500.00 g/ha was 0, 5, 10, 15 and 40 % respectively.

There were no statistically significant differences in mortality between group treated with the test item at rates of 343.75, 687.50, 1375.00 and 2750.00g/ha and the control group (one-way ANOVA, $p< 0.05$)

Toxic metric:	**LR_{50}**	**NOER**
Value [g a.i./ha]	2761.00	1380.50

Reproductive performance:

The mean number of eggs laid per viable female per day in the control group was 3.30, whereas in the group treated with Copper hydroxide at rates of 343.75, 687.5, 1375.00 , 2750.00 and 5500.00g/ha was 3.60, 3.55, 3.44, 2.87 and 2.77 respectively. Fecundity reduction in the group treated with Copper hydroxide at rates of 343.75, 687.5, 1375.0, 2750.00 and 5500.00 g/ha was 2.50, 7.39, 17.53, 31.15 and 38.15%, respectively in comparison with the control group.

There were statistically significant differences in fecundity between group treated with the test item at the all the test rate except 343.75 g/ha and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained fecundity results, the ER_{50} value is >5500.00 g Copper hydroxide 50% WP /ha, i.e., >(2761.00g Cu/ha). The $NOER_{fecundity}$ value is 343.75g Cu/ha, i.e., 172 /ha

Copper hydroxide 50% WP is summarized in the table below:

Table 10.3.2.2-03.1. Mortality and reproductive performance of *C. septempunctata* in individual treatments. Treatments with significantly higher mortality than in the untreated control (UC) are marked with asterisks

Treatment details				**Larval mortality**		**Reproductive performance**	
Treatment	Test substance	Application rate (g test item/ha)	Application rate (g Cu/ha)	Mean mortality (%)	Mean mortality correction (%)	Female fecundity: Mean number of eggs per female per day	% fecundity reduction
UC	water only	n/a	n/a	0	-	3.63	-
T1	Copper hydroxide 50% WP	343.75	172.56	0	-	3.60	2.50
T2		687.50	345.13	5	-	3.55	7.39*
T3		1375.00	690.25	10	-	3.44	17.53*
T4		2750.00	1380.50	15	-	2.87	31.72*
T5		5500.00	2761.00	40*	-	2.77	38.15*
REF	TAFGOR (DIMETHOATE 30% EC)	0.65 L/ha	195	90	90	-	-

Conclusions:
On the basis of the obtained results, it can be concluded that Copper hydroxide 50% WP had no adverse effects on mortality of *Coccinella septempunctata* at rates of 343.75, 687.50, 1375.00 and 2750.00 g/ha and fecundity at rates on 343.75 g/ha, respectively.

Comments of zRMS:

The study is considered valid. All validity criteria were met.

- Maximum acceptable cumulative mortality (dead larvae and pupae, adults dying during emergence or not successfully moulted): ≤ 20 % (10.00 %).
- Fecundity (mean number of eggs per female and day): ≥ 15 (38.4).
- Fertility (mean hatching rate): ≥ 70 % (98.81 %).
- Mortality in the reference product treatment was higher than 50 % (100 %, corrected to control).

<u>Agreed endpoints:</u>

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 Cu/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$_{50mortality}$**	13.50 Kg f.p./ha (6.76 Kg Cu./ha)	**ER$_{50fecundity}$**	10.58 Kg f.p./ha (5.30 Kg Cu./ha)
		NOER$_{mortality}$	4 Kg f.p./ha (2.004 Kg Cu/ha)	**NOER$_{fecundity}$**	>1 Kg f.p./ha (>0.501 Kg Cu/ha)

Report:	KCP 10.3.2.2-05
Title:	An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on larvae of the green lacewing *Chrysoperla carnea (L.)* (Neuroptera: Chrysopidae). XXX, M,. 2020. Bioscience Research Foundation.
Document No:	7547/2020
Guidelines:	ESCORT 1 (Barrett et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC/WPRS (Candolfi M.P. et al., 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 15th, 2019; expiry date: September 14th, 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 ºC
– 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 ºC
– 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_{50} 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 Cu/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 Cu/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 Cu/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 Cu/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		**$LR_{50mortality}$**	13.50 Kg	**$ER_{50fecundity}$**	10.58 Kg f.p./ha

		f.p./ha (6.76 Kg Cu/ha)		(5.30 Kg Cu/ha)
	NOERmortality	4 Kg f.p./ha (2.004 Kg Cu/ha)	**NOER**fecundity	>1 Kg f.p./ha (>0.501 Kg Cu/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): ≤ 20 % (10.00 %).
- Fecundity (mean number of eggs per female and day): ≥ 15 (38.4).
- Fertility (mean hatching rate): ≥ 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 [No]	Eggs hatched/day Mean [%]	Mean number of eggs laid/viable female/day	Mean number of viable eggs laid/viablc female/day	Fecundity reduction* [%]
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$_{50}$ mortality	**7.61 kg/ha** (3812.61 g Cu/ha)		**ER$_{50}$ fecundity**	**7.26 kg/ha** (3637.26 g Cu/ha)				
NOER mortality	**3.75 kg/ha** (1879 g Cu/ha)		**NOER fecundity**	**1.87 kg/ha** (937g Cu/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 10.3.2.2-06
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.)". XXX G., 7548/2020, 2020. BIOSCIENCE RESEARCH FOUNDATION
Guideline(s):	ESCORT 1 (Barrett K.L. el al. 1994) and ESCORT 2 (Candolfi M P. et al., 2001) IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)
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 mortality 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: 15th September, 2019 Expiry date: 14th September, 2021
Reference item:	Name: TAFGOR contains 30% of dimethoate EC Manufacturing date: 22th May, 2020 Expiry date: November 19th November, 2021
Test organism:	Species: the seven-spotted lady bird, *Coccinella septempunctata* (L.) Coleoptera: Coccinellida Life stage: Four days old of *C. septempunctata* 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_{50} and NOER for mortality and the ER_{50} 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: ≥2 fertile eggs per viable female per day).

Findings:

Study group (application rate) (kg/ha)	Mortality		Reproduction					
	Total (%)	Corrected* (%)	Mean number of eggs laid/day	Eggs hatched/day Mean [No]	Eggs hatched/day Mean [%]	Mean number of eggs laid/viable female/day	Mean number of viable eggs laid/viable female/day	Fecundity reduction* [%]
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_{50} mortality	**7.61 kg/ha** (3812.61 g Cu/ha)		**ER_{50} fecundity**		**7.26 kg/ha** (3637.26 g Cu/ha)			
NOER mortality	**3.75 kg/ha** (1879 g Cu/ha)		**NOER fecundity**		**1.87 kg/ha** (937g Cu/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

Comments of zRMS:

The study is considered valid. All validity criteria were met.

- Each replicate produced 107.3 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- The coefficient of variation of reproduction was 19.5% (criterion: ≤ 30%),
- Adult mortality over the initial 4 weeks of the experiment was 0 % (criterion: ≤ 10%).

Agreed endpoints

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of Cu./kg dry soil]
LC50	>1000	>502
NOEC (survival)	≥1000	≥502
LOEC (survival)	>1000	>502

Impact of the Copper hydroxide 50% WP on reproduction of *Eisenia fetida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of Cu./kg dry soil]
EC_{10}	100.9 (36.6 – 363.5)	50.7 (18.4 – 182.5)
EC_{20}	158.3 (62.2 – 799.4)	79.5 (31.2 – 401.3)
EC50	375.2 (139.3 - >1000*)	188.4 (69.9 - >502*)

	NOEC (reproduction)	**100**	**50.2**
	LOEC (reproduction)	**180**	**90.4**
	* value obtained above the tested concentrations range		

Reference:	KCP 10.4.1.1
Report:	"Copper hydroxide 50% WP Earthworm Reproduction Test (*Eisenia andrei*)". XXX P. Study code: G/91/18, 2019. Institute of Industrial Organic Chemistry, Branch Pszczyna
Guideline(s):	OECD No. 222 (2016)
Deviations:	Yes The study was finished in June 2019 and not in November 2018 as it had been planned before.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The aims of the study were to assess the impact of Copper hydroxide 50% WP on reproduction of the earthworm, *Eisenia andrei*. The test item in the form of an aqueous suspension was mixed with a suitable amount of the artificial soil. The concentrations of the test item were 5.6, 10, 18, 32, 56, 100, 180, 320, 560 and 1000 mg/kg dry soil. There were also untreated control. Each of concentrations were divided into four replicates, control was divided into eight replicates. There were also untreated control. The experiment lasted 8 weeks. After 4 weeks, all adult earthworms were removed from the test containers and observed. The number of earthworms and their body weights were also determined. The impact of the test item on reproduction was evaluated after an additional 4-week period on the basis of the number of juveniles hatched from cocoons during the experiment.

Material and methods

Test item:	Name: Copper hydroxide 50% WP Batch number: SCL-97561 Manufacturing date: 4th April, 2018 Expiry date: 3rd April, 2020
Test organism:	The earthworm *Eisenia fetida* 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 mites: 10 earthworms/replicate
Artificial soil:	10% sphagnum peat, 20% kaolin clay, and 70% air-dried quartz sand
Endpoints:	EC_{10}, EC_{20}, EC_{50}, and NOEC.

Test conditions:	Temperature: 18.5 - 21.0°C pH at the beginning of the test: 6.18 – 6.39 pH at the end of the test: 6.24– 6.73 Soil moisture content at the beginning of the test: 24.9 – 27.3 % Soil moisture content at the end of the test: 24.5 – 28.4 % Lighting: 16 h light and 8 h dark Light intensity at the beginning of the test 643 - 671 lux Light intensity at the end of the test: 655 to 681 lux
Concentrations of the test item:	control, 5.6, 10, 18, 32, 56, 100, 180, 320, 560 and 1000 mg/kg dry weight of artificial soil
Statistical analysis:	EC10, EC20, EC50 – the probit method NOEC (reproduction) – Shapiro-Wilk's Test on Normal Distribution, Barlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure NOEC (survival) – Fisher's Exact Binomial Test with Bonferroni Correction
Validity criteria:	- each replicate produced 107.3 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment), - the coefficient of variation of reproduction was 19.5% (criterion: ≤ 30%), - adult mortality over the initial 4 weeks of the experiment was 0 % (criterion: ≤ 10%).

Findings

Impact of Copper hydroxide 50% WP on survival of *Eisenia fetida*.

Endpoint	**Value [mg of test item/kg dry soil]**	**Value [mg of Cu/kg dry soil]**
LC50	**>1000**	**>502**
NOEC (survival)	**≥1000**	**≥502**
LOEC (survival)	**>1000**	**>502**

Impact of the Copper hydroxide 50% WP on reproduction of *Eisenia fetida*.

Endpoint	**Value [mg of test item/kg dry soil]**	**Value [mg of Cu/kg dry soil]**
EC_{10}	**100.9** (36.6 – 363.5)	**50.7** (18.4 – 182.5)
EC_{20}	**158.3** (62.2 – 799.4)	**79.5** (31.2 – 401.3)
EC50	**375.2** (139.3 - >1000*)	**188.4** (69.9 - >502*)
NOEC (reproduction)	**100**	**50.2**
LOEC (reproduction)	**180**	**90.4**

* value obtained above the tested concentrations range

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Comments of zRMS:	Accepted as additional information. **Comment from coMS-DE during commenting period** Due to the high relevance of the original study XXX, 2015, to demonstrate a safe use in the risk assessment of non-target soil meso- and macrofauna, the statistical re-analysis of the XXX (2015) data by XXX (2019) is evaluated and discussed at the EU level before being used in zonal or national application processes like it was done in the past with XXX, 2015.

Reference:	KCP 10.4.1.2-01
Report	XXX 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. Testing facility: Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany. 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 treatment)	Dunnett’s t-test (α = 0.05, two sided), irrespective of outcome of pre-tests on normality and homogeneity of variance
Pairwise comparison (toxic reference)	[a] Student t-test (α = 0.05, two sided). [d] Satterthwaite t-test (α = 0.05, two sided). [b] pair-wise U-Test (Wilcoxon) with Exact-Statement (α = 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 (α = 0.05) of PRC scores [c] Jonckheere-Terpstra Test (α = 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 (α = 0.05, exact) [c] Satterthwaite t-test (α = 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 (Dunnett, 1955).

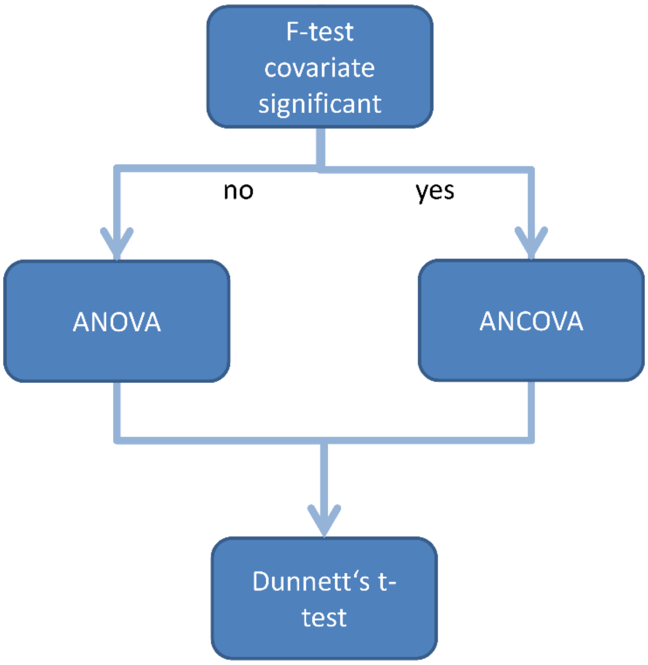

Figure 1: Decision tree for ANOVA/ANCOVA test procedure.

Comments of zRMS:	Accepted as additional information. **Comment from coMS-DE during commenting period:** There are some information necessary for transparency and reproducibility missing related to the test item (batch number, purity, content a.i., expiration data) and the test organisms *F. candida* (number of specimens or soil added per test vessel,

	number of replicates). However, as the reproduction tests on *E. andrei*, *E. crypticus* and *F. candida* after all were performed according to ISO 11268-2(2012), ISO 16387 (2004) and ISO 11267 (1999) (with some adjustments). Co-MS (DE) comments to Reference KCP 10.4.1.2-02, page 211 (Amossé et al., 2018): • The study authors stated that the results are in contrast to other studies, mainly explainable by the mode of contamination, the number of tested contaminants, test design, i.e. controlled laboratory versus different field conditions. • Further, the results based on a short-term, one-month study with a one-time application. This is in contrast to the present product application (accord. to GAP multiple uses, several times per season) and to other long-term field studies like XXX (2015) highlighting that effects on Oligochaeta might appear after several years of copper-fungicide application and thus copper accumulating in soil by time. Besides, that copper effects on Oligochaeta might appear after several year of application, in a long-time perspective, is one reason why the continuation of the XXX (2015) field study by the EUCuTF is so valuable to understand which effects might occur or vanish by time, although still such short-term and intermediate field- and lab. Study can increase the understanding of copper (compounds) effecting Oligochaeta, e.g. in short-term or mechanistic understanding.

Reference: KCP 10.4.1.2-02

Report Short-term effects of two fungicides on enchytraeid and earthworm communities under field conditions. Ecotoxicology, J. Amossé 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−1 copper oxychloride) and Swing Gold (composed of 50 g l−1 epoxiconazole and 133 g l−1 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−1) and the treatment with the pesticide mixture (Cuprafor Micro at 0.75 kg Cu ha−1 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 Quimicas del Valles
Purity:	500 g/kg copper oxychloride, Cu2Cl(OH)3
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%, pHH2O 7.5 and Cutot 25.2 mg kg−1)

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^{-1} 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^2 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^{-2}). 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.glht)) if the homogeneity of variance (Bartlett-test, Snedecor and Cochran 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 (Bland and Altman 1995). 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 (Mantel 1967) using vegan (Oksanen et al. 2015) on Bray–Curtis dissimilarity transformation matrices ($p < 0.05$, 23 permutations).

All analyses were carried out with R statistical software (R Development Core Team 2016).

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^{-2} (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 isseli*. 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, ±standard deviation) in the six treatments

Soil faunal group	Variable	T	C1	C10	D1	D10	M
Enchytraeids	Density (ind m^{-2})	**29667 ± 11519**	**27948 ± 10458**	**24574 ± 5430**	29857 ± 13684	30653 ± 8163	**36733 ± 14726**
	Species richness	**9.8 ± 1**	**10 ± 2.5**	**9.8 ± 1.7**	10.5 ± 1	9.8 ± 1.5	**10 ± 2.9**
	Shannon index	**6.61 ± 0.75**	**6.92 ± 1.38**	**6.32 ± 1.07**	5.61 ± 1.21	6.06 ± 1.26	**6.12 ± 1.91**
	Evenness	**0.83 ± 0.06**	**0.84 ± 0.03**	**0.81 ± 0.01**	0.73 ± 0.07	0.79 ± 0.09	**0.61 ± 0.11**
	r-strategists (%)	**25.8 ± 9.5**	**26.1 ± 5.3**	**33.5 ± 14.8**	33.7 ± 22.1	32 ± 8.5	**33.7 ± 20.1**
Earthworms	Density (ind m^{-2})	**231 ± 147**	**211 ± 84**	**264 ± 131**	214 ± 109	127 ± 46	**231 ± 126**
	Biomass (ind m^{-2})	**86.8 ± 32.4**	**79.5 ± 28.4**	**93.6 ± 34.7**	78.9 ± 27.1	48.3 ± 14	**83.1 ± 33.9**
	Species richness	**7 ± 1.4**	**5.8 ± 1**	**6.3 ± 1.7**	7.8 ± 1	2.8 ± 0.5	**5.5 ± 1**
	Shannon index	**3.07 ± 0.74**	**2.45 ± 0.28**	**2.48 ± 0.51**	3.11 ± 0.61	1.17 ± 0.08	**2.13 ± 0.28**
	Evenness	**0.52 ± 0.09**	**0.51 ± 0.14**	**0.55 ± 0.09**	0.57 ± 0.09	0.16 ± 0.05	**0.44 ± 0.04**
	Epigeic (ind m^{-2})	**12.9 ± 13**	**10.2 ± 4.5**	**7.4 ± 3.9**	8.2 ± 4.1	0 ± 0	**3.1 ± 2.9**
	Endogeic (ind m^{-2})	**184 ± 124**	**168 ± 70**	**211 ± 121**	178 ± 94	124 ± 45	**198 ± 107**
	Anecic (ind m^{-2})	**34 ± 13**	**34 ± 18**	**47 ± 18**	28 ± 17	3 ± 1	**31 ± 17**

Treatments are: control (T), Cuprafor Micro at 0.75 kg Cu ha−1 (C1) and 7.5 kg Cu ha−1 (C10), Swing Gold at tne (D1) and at ten (D10) times the recommended dose, and a mixture of Cuprafor Micro 0.75 kg Cu ha−1 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^{-2} (in C10) (Fig. 2) and the mean biomass ranged from 48.3 (in D10) to 93.6 g m^{-2} (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.

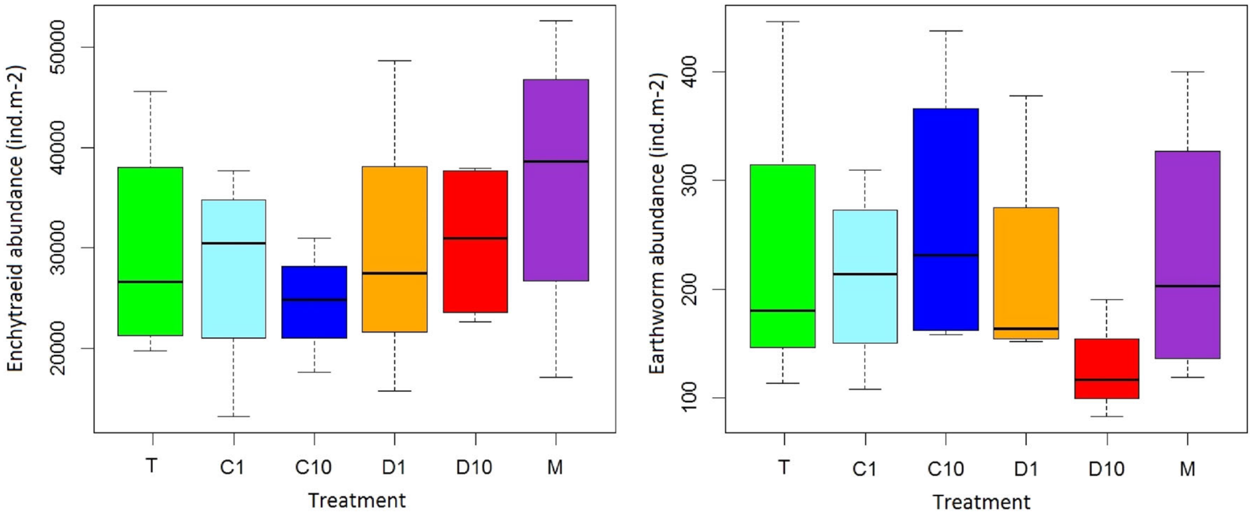

Figure 2. Total densities of enchytraeids (on the left) and earthworms (on the right) per treatment. Treatments are: control (T), Cuprafor Micro at 0.75 kg Cu ha−1 (C1) and 7.5 kg Cu ha−1 (C10), Swing Gold® at one (D1) and at ten (D10) times the recommended dose, and a mixture of Cuprafor Micro 0.75 kg Cu ha^{-1} 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-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-value = 0.551 for enchytraeids; r = −0.227, p-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%).

Comments of zRMS:	Accepted as additional information. **Comment from coMS-DE during commenting period**: There are some information necessary for transparency and reproducibility missing related to the test item (batch number, purity, content a.i., expiration data) and the test organisms *F. candida* (number of specimens or soil added per test vessel, number of replicates). However, as the reproduction tests on *E. andrei, E. crypticus* and *F. candida* after all were performed according to ISO 11268-2(2012), ISO 16387 (2004) and ISO 11267 (1999) (with some adjustments).

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, XXX et al., 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 ($CuSO_4*5H_2O$)

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 ± 0.02 mS/cm
	Organic matter	6.5 ± 0.004%
	Water Holding Capacity (WHC)	23.9 ± 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-1 soildw 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 (WHCmax) 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 ($CaSO_4$*$2H_2O$) were additionally performed at 2303.2, 366.3 mg of $CaSO_4$*$2H_2O$K/g soildw for *Eisenia andrei* and *Enchytraeus crypticus,* respectively.

Table 1. Copper concentrations used in the ecotoxicological assessment (mg Cu/Kg soil dw)

Biochemical parameters	***E. Andrei***	***E. crypticus***
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 soildw).

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 soildw, respectively, and no juveniles were produced by potworms above 681.1 mgKg-1 soil dw (Fig. 2; Table 2).

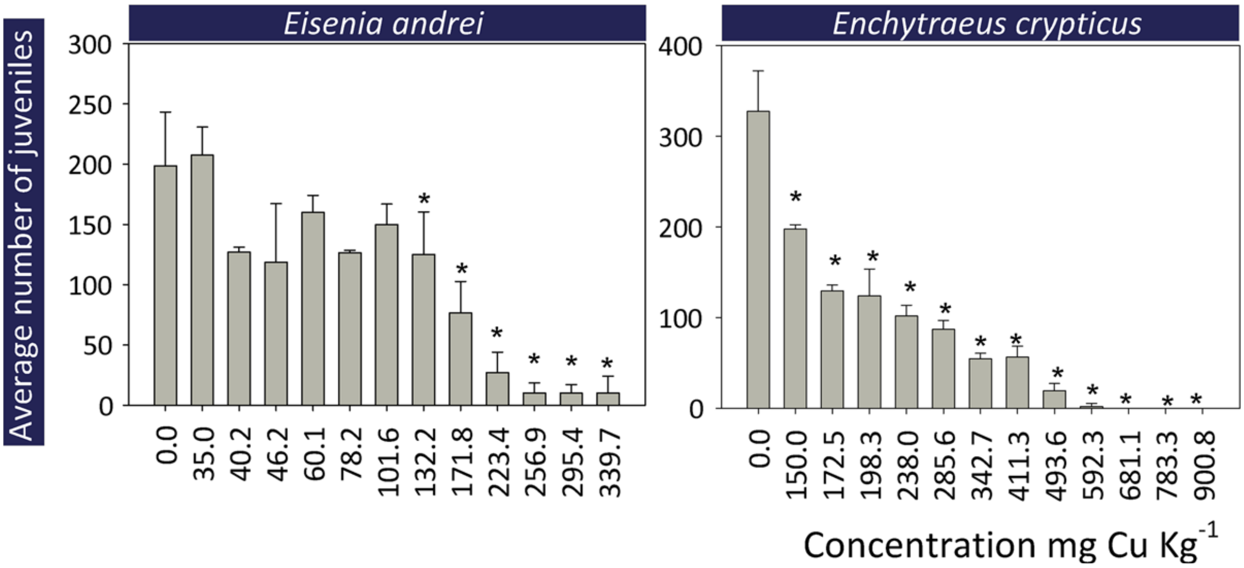

Fig. 1 Reproductive output of *Eisenia andrei*, *Enchytraeus crypticus* exposed to the natural soil PTRS1 spiked with increasing copper concentrations. Error bars indicate the standard error and asterisks sign out significant differences between the treatment and the control (0.0 mg Cu Kg/dw) (p\0.05)

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-1 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
Eisenia andrei	56 days	101.6	132.2	73 (34.94 – 111.14)	130.9 (91.69 – 170.14)
Enchytraeus crypticus	28 days	<150	150	150	165.1 (146.84 – 183.27)

Comments to the study during commenting period:

According to the study authors, no significant effects on adult mortality, body weight change or reproductive output that could be attributed to copper at an application rate of 8 kg Cu/ha/year were observed after 112 days under laboratory conditions. However, the study has several weaknesses which can be summarized into two major topics:
Differences in soil characteristics of the eight treatment groups (control soils drier and more drying than

copper-treated soils; control and copper-treated soil of one test site cannot regarded as identic soils considering their characteristic's)
There are two indications to a severe adverse change in environmental conditions: high ratio (48%) of earthworms in the quiescence stage at day 112 (the day the statistical analysed data based upon) and continuous loss of adult biomass till day 112.
It cannot be excluded that these test deficiencies might have interfered with the study outcome and the applicant finding ("study supports the derivation of the NOEC of 8 kg Cu/ha/year"). **Against this background, zRMS and other c_MS-DE with the applicant's derivation of a NOEC of 8 kg Cu/ha/year since we consider that these outcomes are not acceptable.**

Reference:	KCP 10.4.1.1/03
Report	Laboratory study on the sensitivity of field-caught earthworms *Aporrectodea caliginosa* (Annelida, Lumbricidae) to Copper in grassland soils collected at two field sites in south-western Germany: a crossover experiment, **XXX, E., 2019, Report no. S18-00119**
Guideline(s):	No specific guideline available
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes (certified laboratory)
Acceptability:	Yes
Duplication (if vertebrate study)	Not applicable

Executive Summary

The purpose of this study was to determine the effects of Copper-level and soil properties in different Copper-loaded soils originating from two field sites on adult mortality, body weight change and on reproduction of field-collected adult *Aporrectodea caliginosa* SAVIGNY.

The study was conducted using a full 2 × 2 × 2-factorial design with the following three factors, each one with two levels:

- factor 1: treatment of soil (Copper-treated vs. control),
- factor 2: origin of soil (Niefern vs. Heiligenzimmern),
- factor 3: origin of earthworms (Niefern vs. Heiligenzimmern),

resulting in 8 treatment groups. Each treatment group consisted of four replicates and 20 adult earthworms (i.e. five animals per single replicate). Since the adult worms continuously lost biomass and a high proportion entered a quiescence stage after 112 days, the exposure phase was terminated, i.e. the last biological assessment was performed at day 112.

The following endpoints were assessed: Mortality, biomass, and the percentage of animals in a quiescence stage (identified by the formation of an estivation chamber in which the inactive worm perseveres in a coiled position). They were determined every 28 days until day 112; reproductive output (i.e. number of cocoons and juveniles produced) was determined after 112 days.

Generally, mortality of the introduced adult worms in the different treatment groups, including the Copper-treated test soils, remained on a low level throughout the whole exposure phase with a maximum of 20% mortality after 112 days. During progression of the exposure phase, especially from day 56 onwards, an increasing number of the adult worms entered the stage of quiescence in each of the treatment groups. During the course of exposure to the test soils, there was a continuous loss of mean biomass in each of the treatment groups until day 112; the main drop of biomass was observed at the day 84 and day 112 assessment. Only after 28 days an increase of biomass was observed in six of the treatment groups, mainly in the Copper-treated soils. After 112 days of exposure to the test soils, mean loss of biomass in each treatment group ranged between 20.7% and 44.8%. The initial difference in individual worm biomass from the two different field sites (i.e. Niefern worms with a higher mass of 85.0 mg compared to Heiligenzimmern worms) decreased during the exposure phase in the laboratory; after 112 days of exposure to the different test soils the mean worm weights from both field sites were nearly the same (i.e. Niefern worms with a

higher mass of 2.1 mg only compared to Heiligenzimmern worms). As parameter of reproduction the number of juveniles was evaluated statistically only.

MATERIALS AND METHODS

Test Item	
Designation	Copper
Lot / Batch no.	Not stated
Purity	Not stated
Stability (expiry date)	Not stated
Test System	
Species	*Aporrectodea caliginosa*
Source	Copper-untreated plots of the two different field sites of a long-term field study (S13-02262) in South-Western Germany (Niefern and Heiligenzimmern)
Age	Adult earthworms
Feeding	At the start of exposure, the test soils contained plant material originating from the vegetation (organic matter content ranged between 5.10 and 7.24% of dry mass) and therefore no additional food was provided within the first 28 days. From day 28 onwards, however, the worms were additionally fed with finely ground air-dried cow manure. Every 28 days, per replicate an amount of 3–5 g air-dried cow manure was mixed into the test soil (day 28: 3.0 g, day 56: 3.0 g, day 84: 5.0 g; total amount: 11.0 g).
Test Conditions	
Temperature	17.4 – 19.6ºC
Photoperiod	Start: 46.1 – 60.4%, End: 38 – 53.6%
Light intensity	16 hours light / 8 hours dark
Study Design and Methods	
In-life dates	08.11.2017 - 23.03.2018
Test facility	Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany
Test concentrations	Niefern: (control) 26.5 and 135.2 mg/kg soil dw); Heiligenzimmern: (control) 25.9 and 142.2 mg/kg soil dw
Test organism assignment and treatment	The test organisms were sorted by hand from Copper-untreated plots of the same two different field sites (Niefern and Heiligenzimmern) of the long-term field study (S13-02262), where also the test soils from the control had been collected. Collection of the worms was conducted on 15 November 2017. Until the start of the exposure, the worms were maintained in the test facility in untreated soil from the field site where they originated. On the day of the start of the exposure phase, the worms were washed, rinsed and blotted dry, and they were weighed individually (the initial weight of each worm was recorded). The weight range of the worms was between 392 and 701 mg (mean ± SD: 549 ± 76 mg) for Niefern and between 304 and 656 mg (mean ± SD: 464 ± 81 mg) for Heiligenzimmern, respectively. Groups of five test organisms were distributed randomly throughout all treatment groups. All organisms used for the test were healthy and showed the presence of a clitellum. After placement of the worms onto the surface of the test soils, the test units were closed with the lids allowing ventilation and then incubated under the specified test condition.

Dose preparation	Copper had been applied three times per year at a nominal rate of 8 kg Cu/ha/year in the past 14 years. The soils from both field sites and treatments (Niefern/control, Niefern/Copper-treated, Heiligenzimmern/control, and Heiligenzimmern/Copper-treated) were frozen, dried, homogenized and used as test soils during the exposure phase.
Measurements and observations	The temperature in the climate chamber was recorded continuously with appropriate, calibrated equipment. The climatic chamber was ventilated during the study. The illumination was measured once during light hours to be between 550 and 800 lux (target: 400 to 800 lux). At the start of the exposure phase and after 121 days, soil samples from each treatment group were taken and the pH was measured using a calibrated electrode (in 0.01 M $CaCl_2$ solution). The water content of the test soils was determined at the start of the exposure phase and after 112 days. Soil samples from each treatment group were taken and weighed before and after drying overnight at 105°C. Every 28 days, the test units were emptied on a metallic tray and the adult earthworms were sorted from the soil while their reaction to a gentle mechanical stimulus at the anterior end was tested. At the beginning of the exposure phase, the earthworms were weighed individually. Every 28 days, the total weight of all surviving earthworms per replicate was determined. Prior to weighing, the worms were washed, rinsed and blotted dry. After 112 days of exposure, the juvenile earthworms and the cocoons were sorted from the soil by hand and the total number of juveniles and cocoons per replicate was recorded.
Statistics	Statistics was performed for the day 112-assessment only. The level of significance was set to $\alpha = 0.05$ for each of the tests. Prior to hypothesis testing, data were analysed for normality and variance homogeneity. Normality was checked using Shapiro-Wilk test or Kolmogorov-Smirnov test and by visual inspection of the respective histogram of residuals. Homogeneity of variances was checked using Brown-Forsythe test. Mean biomass of the worms from both field sites at test start were analysed for a difference using Student's t-test (two-sided). Mortality data and the frequency of adult worms in quiescence (expressed as % of surviving worms) for each treatment group were analysed for significant differences for all meaningful pair-wise comparisons (i.e. comparisons between two treatment groups which differed within the two levels of one factor only) using multiple Fisher's exact test with Bonferroni-Holm adjustment (two-sided). A three-way ANOVA was used to analyse the data of juvenile production and biomass change after 112 days of exposure (in order to fulfil the criteria of normality and variance homogeneity percent-ages of body weight change were arcsine-square root transformed beforehand) on the explanatory value of the simple three main factors [1] origin of soil, [2] treatment of soil, and [3] origin of worms and for their different interactions. In case that one factor significantly explained part of the variance on $\alpha = 0.05$-level, the post-hoc Holm-Sidak test was used to detect differences between the two levels of that factor. For data evaluation the statistical programme SIGMAPLOT 13 (© 2014) was used. Bonferroni-Holm adjustment (adult mortality and occurrence of diapausing worms) was performed with a self-programmed MS-Excel-file.

RESULTS AND DISCUSSION

Characteristics of the test soils

The two test soils originating from the same field site (control vs. Copper-treated) both for Niefern and Heiligenzimmern differed in terms of WHC_{max}, soil texture (% sand, silt and clay) and content of organic matter. This means that the two soils from each of the same field site cannot be regarded as identical soils which differ in the concentration of Copper only (**Table A 2.4.1.1.1.2-1**).

Table A 2.4.1.1.2-1 Characteristics of the test soils

Test soil	WHC $_{max}$ [%]	pH ($CaCl_2$)	pH (H_2O)	Sand [%][1)]	Silt [%][1)]	Clay [%][1)]	Classification[1)]	TOC (% C)	OM [%]	CEC [mmol/ 100 g]	CEC [meq/ 100 g]
Niefern/ control	79.8	5.3	6.1	24.2	72.7	3.1	Silt loam	3.2	5.4	16.1	4.0
Niefern/ Copper	89.0	5.3	5.9	12.9	79.4	7.8	Silt loam	3.0	5.2	16.4	3.9
Heiligen-zimmern/ control	77.0	6.8	7.2	17.8	52.1	30.1	Silty clay loam	4.3	7.5	15.4	15.5
Heiligen-zimmern/ Copper	80.5	6.6	7.2	14.2	47.1	38.8	Silty clay loam	4.0	6.98	14.0	15.5

WHC_{max}: maximum water-holding capacity; TOC: total organic carbon; OM: organic matter; CEC: cation exchange capacity; OM: organic matter
[1)] according to USDA

Copper Residues in the Test Soils

Total concentrations of Copper in the test soils of both field sites were almost equivalent both for the control soils (background concentrations) and for the Copper-treated soils (**Table A 2.4.1.1.2-2**).

Table A 2.4.1.1.2-2 Copper residues in the test soils (given as mean of the analytical and retain sample)

Test soil	Concentration of total Copper [mg/kg soil dry weight]
Niefern/control	26.5
Niefern/Copper	135.2
Heiligenzimmern/control	25.9
Heiligenzimmern/Copper	142.2

Adult Mortality

Generally, mortality of the introduced adult worms in the different treatment groups, including the Copper-treated test soils, remained on a low level throughout the whole exposure phase with a maximum of 20% mortality after 112 days.

Table A 2.4.1.1.2-3 Cumulated mortality of adult Aporrectodea caliginosa after 28, 56, 84 and 112 days of exposure to the test soils

Origin of soil	Treatment of soil	Origin of worms	Cumulated mortality [%]			
			Day 28	Day 56	Day 84	Day 112
Niefern	Control	Niefern	5.0	10.0	10.0	20.0
Niefern	Control	Heiligenzimmern	0.0	0.0	0.0	10.0
Niefern	Copper	Niefern	0.0	5.0	5.0	5.0
Niefern	Copper	Heiligenzimmern	0.0	0.0	0.0	0.0
Heiligenzimmern	Control	Heiligenzimmern	0.0	0.0	0.0	0.0
Heiligenzimmern	Control	Niefern	0.0	0.0	0.0	0.0

Heiligenzimmern	Copper	Heiligenzimmern	0.0	0.0	0.0	0.0
Heiligenzimmern	Copper	Niefern	0.0	5.0	10.0	15.0

All pairwise comparisons (i.e. comparisons between two treatment groups which differed within the two levels of one factor only) did not show statistically significant differences even before Bonferroni-Holm adjustment was applied to keep the global α = 0.05-level (multiple Fisher's exact tests: two-sided, all p > 0.05). This means that neither the exposure to Copper nor to the soil of the field site from which the worms originated have had a negative effect on adult survival after 112 days.

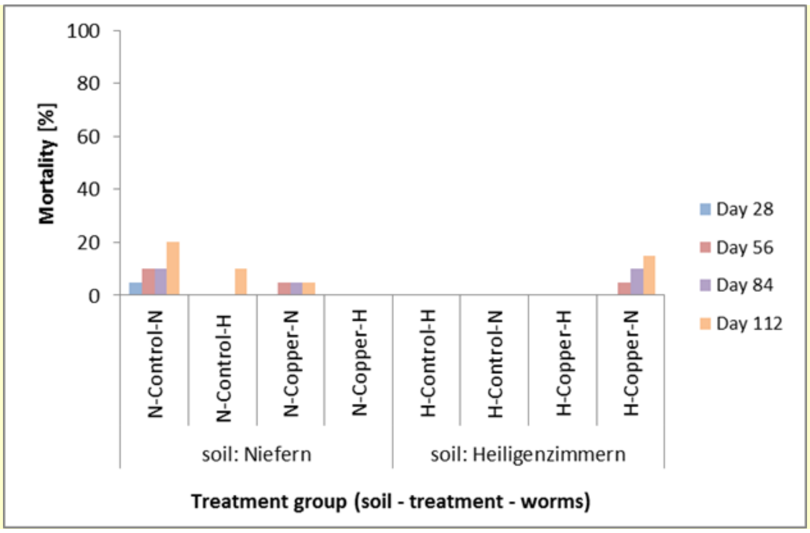

Figure A 2.4.1.1.2-1 Mortality of adult *Aporrectodea caliginosa* for each of the eight treatment groups after 28, 56, 84 and 112 days of exposure to the test soils (naming of treatment groups: N-Control-N: Niefern soil, control treatment, Niefern worms, etc.)

Entering into quiescence stage

During progression of the exposure phase, especially from day 56 onwards, an increasing number of the surviving adult worms entered a stage of quiescence in each of the treatment groups (see **Table A 2.4.1.1.2-4**). After 112 days of exposure to the test soils, almost half of the worms had entered the quiescent stage. Twenty-seven out of 72 surviving worms (37.5%) with origin Niefern entered quiescence compared to 45 individuals out of 78 surviving worms (57.7%) with origin Heiligenzimmern.

Table A 2.4.1.1.2-4 Appearance of quiescence in adult Aporrectodea caliginosa after 28, 56, 84 and 112 days of exposure to the test soils, given as absolute number of worms in quiescence and as % of surviving worms (the two treatment groups highlighted in bold differed significantly in the proportion of diapausing adult worms on global α = 0.05-level after Bonferroni-Holm correction)

Origin of soil	Treatment of soil	Origin of worms	Number of adult worms in quiescence (absolute number of worms and % of surviving worms in brackets)			
			Day 28	Day 56	Day 84	Day 112
Niefern	Control	Niefern	0 (0%)	0 (0%)	5 (28%)	6 (38%)
Niefern	Control	Heiligenzimmern	0 (0%)	0 (0%)	3 (15%)	8 (44%)
Niefern	Copper	Niefern	0 (0%)	1 (5%)	2 (11%)	9 (47%)
Niefern	**Copper**	**Heiligenzimmern**	0 (0%)	0 (0%)	3 (15%)	**7 (35%)**
Heiligenzimmern	Control	Heiligenzimmern	0 (0%)	0 (0%)	0 (0%)	13 (65%)
Heiligenzimmern	Control	Niefern	0 (0%)	0 (0%)	5 (25%)	4 (20%)

Heiligenzimmern	**Copper**	**Heiligenzimmern**	0 (0%)	1 (5%)	1 (5%)	**17 (85%)**
Heiligenzimmern	Copper	Niefern	0 (0%)	1 (5%)	6 (33%)	8 (47%)
all soils combined			0 (0%)	3 (2%)	25 (16%)	72 (48%)

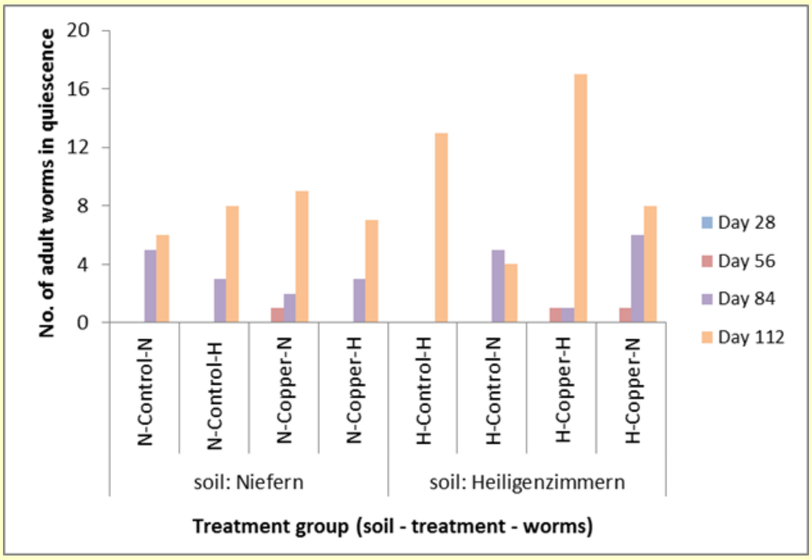

Figure A 2.4.1.1.2-2 Appearance of the quiescence stage in adult *Aporrectodea caliginosa* after 28, 56, 84 and 112 days of exposure to the test soils (naming of treatment groups: N-Control-N: Niefern soil, control treatment, Niefern worms, etc.)

Adult Biomass

At test start, biomass of the worms originating from Niefern was significantly higher compared to the worms originating from Heiligenzimmern (Student's t-test: two-sided, $\alpha = 0.05$).

During the course of exposure to the test soils, there was a continuous loss of mean biomass in each of the treatment groups until day 112; the main drop of biomass was observed at the day 84 and day 112 assessment (see **Figure A 2.4.1.1.2-3** below). Only after 28 days an increase of biomass was observed in six of the treatment groups, mainly in the Copper-treated soils. After 112 days of exposure to the test soils, mean loss of biomass in each treatment group ranged between 20.7% and 44.8%. The initial difference in individual worm biomass from the two different field sites (i.e. Niefern worms with a higher mass of 85.0 mg compared to Heiligenzimmern worms) decreased during the exposure phase in the laboratory; after 112 days of exposure to the different test soils the mean worm weights from both field sites were nearly the same (i.e. Niefern worms with a higher mass of 2.1 mg only compared to Heiligenzimmern worms).

Three-way ANOVA (normality and variance homogeneity had been confirmed beforehand: Kolmogorov-Smirnov test: $p = 0.303$, Brown-Forsythe test: $p = 0.248$) revealed a significant simple main effect for the factors origin of worms ($F = 16.421$, $df = 1$, $p < 0.001$) and treatment of soil ($F = 8.698$, $df = 1$, $p = 0.007$) on % biomass change (arcsine-square root transformed) of the adult worms between day 0 and day 112. Irrespective of the factors origin of soil and treatment of soil, biomass loss was higher in the worms from Niefern as in the worms from Heiligenzimmern (Holm-Sidak test: $p < 0.001$). Irrespective of the factors origin of soil and origin of worms, biomass loss was higher in the control soil as in the Copper-treated soil (Holm-Sidak test: $p = 0.007$). There was no significant simple main effect of the factor origin of soil on % biomass change of the adult worms between day 0 and day 112 ($F = 1.135$, $df = 1$, $p = 0.297$). Moreover, there was no significant interaction for each combination of two factors and for the combination of all three factors (all combinations: $p > 0.05$).

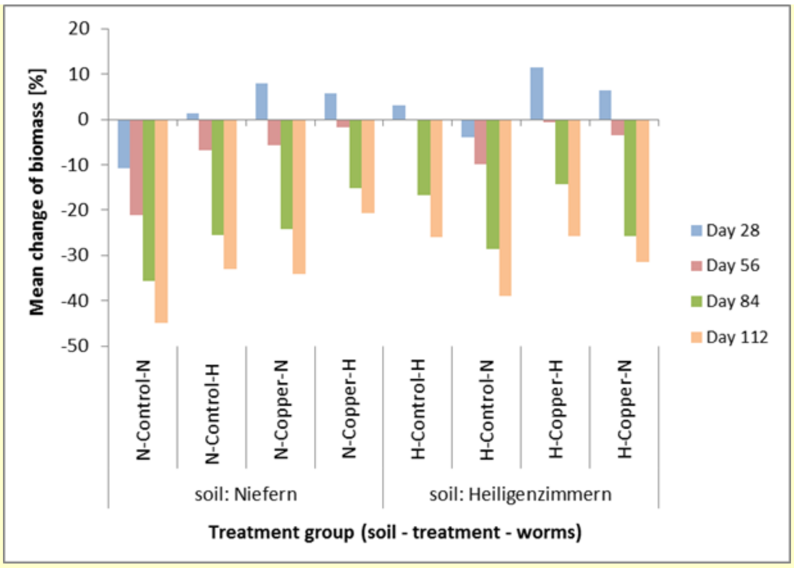

Figure A 2.4.1.1.2-3 Biomass development (mean % change per treatment group) of adult *Aporrectodea caliginosa* after 28, 56, 84 and 112 days of exposure to the test soils (naming of treatment groups: N-Control-N: Niefern soil, control treatment, Niefern worms, etc.)

Reproduction

Variance homogeneity was confirmed by Brown-Forsythe test (p = 0.06). The test on normality, however, failed (Kolmogorov-Smirnov test: p < 0.05) but nevertheless a parametric test was used. The results on juvenile production for each treatment group are shown in the **Figure A 2.4.1.1.2-4** below:

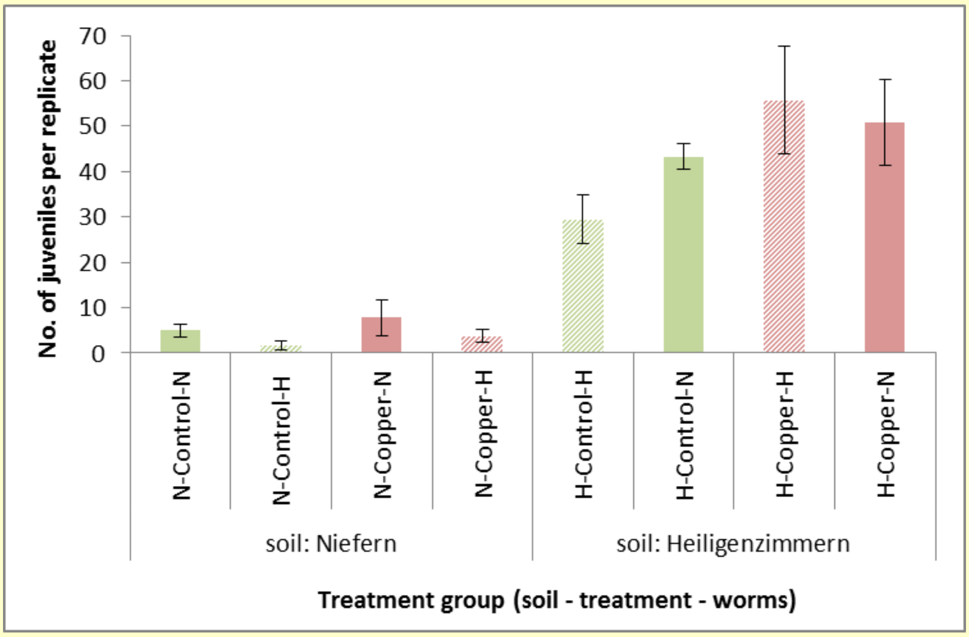

Figure A 2.4.1.1.2-4 Number of juveniles per replicate (mean ± sd) of *Aporrectodea caliginosa* after 112 days of exposure to the test soils (green columns: control soils, red columns: Copper-treated soils; filled columns: Niefern worms, dashed columns: Heiligenzimmern worms; naming of treatment groups: N-Control-N = Niefern soil / control treatment / Niefern worms, etc.)

Three-way ANOVA revealed a significant simple main effect for the factors *origin of soil* (F = 361.899, df = 1, p < 0.001) and *treatment of soil* (F = 20.695, df = 1, p < 0.001) on juvenile production after day 112. Irrespective of the factors *treatment of soil* and *origin of worms*, reproductive output was higher in the soil from Heiligenzimmern as in the soil from Niefern (Holm-Sidak test: $p < 0.001$). Irrespective of the factors *origin of soil* and *origin of worms*, reproductive output was higher in the Copper-treated soil as in the control soil (Holm-Sidak test: $p < 0.001$). There was no significant simple main effect of the factor *origin of worms* on reproductive output after 112 days ($F = 3.574$, df = 1, $p = 0.071$).

There was no significant two-way interaction between the factors *origin of soil* and *origin of worms* (*soil x worms*: $F = 0.031$, df = 1, $p = 0.861$).

However, there was a significant two-way interaction between the factors *origin of soil* and *treatment of soil* (*soil x treatment*: $F = 11.742$, df = 1, $p = 0.002$); irrespective of the *origin of worms*, the mean number of juveniles of the worms in the control soil and Copper-treated soil from Niefern was quite similar (difference between means: 2.4) whereas in the Heiligenzimmern soils the mean number of juveniles was markedly higher in the Copper-treated soil as in the control soil (difference between means: 16.9).

There was another significant two-way interaction between the factors *treatment of soil* and *origin of worms* (*worm x treatment*: $F = 4.524$, df = 1, $p = 0.044$): irrespective of the *origin of soil*, reproductive output in the Copper-treated soils was similar for worms from Niefern and from Heiligenzimmern (Holm-Sidak test: $p > 0.05$) whereas in the control soils reproductive output of the worms from Niefern was significantly higher than that of the worms from Heiligenzimmern (Holm-Sidak test: $p = 0.009$).

Finally, there was a significant three-way interaction between the tested factors (*soil x treatment x worms*: $F = 5.309$, df = 1, $p = 0.030$).

CONCLUSIONS

Concentrations of Copper.

The test item concentration in the test soils of both field sites were almost equivalent both for the control soils (background concentrations) and for the Copper-treated soils, indicating similar conditions among the two soil origins with regard to Copper concentrations.

Soil parameters.

The two test soils of the same field site (control vs. Copper-treated) both for Niefern and Heiligenzimmer differed in ecologically relevant physiochemical soil parameters, mainly in terms of WHC_{max}, soil texture (% sand, silt and clay) and content of organic matter. This in turn means that possible differences in earthworms' performance and response to the Copper-treated and control soil of the same field site could not be ascribed to the presence of higher or lower Copper concentrations solely but might also be influenced or mimicked by differences in physiochemical soil parameters (WHC_{max}, water potential, texture, organic matter, etc.). There was a decline of the water content in all test soils between day 0 and day 112, which was most probably caused by evaporation during day 98 and day 112 and by the addition of dry cow manure as food for the worms.

Adult mortality

No difference was detected between the treatment groups. That is, adult survival was not negatively affected by the presence of increased Copper concentrations, equivalent to 8 kg Cu/ha/year (i.e. 135.2 and 142.2 mg Cu/kg soil dry weight), in the test soils even after 112 days of exposure. Moreover, adult mortality in this test was on a rather low level (< 20%) in all treatment groups (including Copper-treated soils) even after 112 days; after 56 days, adult mortality was within the accepted range (≤ 10%) for the control group within a study using *E. fetida* in artificial soil to be valid (OECD 222, 2016).

Entering into quiescence stage

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 and therefore the last biological assessment was performed at day 112. The presence of Copper at 8 kg/ha/year in the test soils did not have an effect on the appearance of quiescence in the test organisms in the laboratory.

Adult biomass

During the course of the study a continuous loss of earthworm biomass of *A. caliginosa* was observed in each of the treatment groups accompanied by an increasing number of worms entering a stage of quiescence, indicating adverse changes in the test soil environment. One reason for this to happen could have been the fluctuation and finally the decrease of the moisture content of the test soils. Adult biomass change was affected by the factors origin of worms (higher biomass loss in Niefern worms, which had higher biomass at test start than Heiligenzimmern worms) and treatment of soil (higher biomass loss in control soils), but not solely affected by the factor origin of soil. There was no interaction between any combinations of the three factors.

Reproduction

The number of juveniles was affected by the factors origin of soil (higher reproductive output in Heiligenzimmern soils) and treatment of soil (higher reproductive output in Copper-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 Copper and control treatment more pronounced in the Heiligenzimmern soil) and between treatment of soil and origin of worms (difference in juvenile numbers between Copper and control treatment more pronounced in the Heiligenzimmern worms) as well as an interaction between all three factors. Higher reproductive output in Copper-treated soils compared to control soils can most probably not be attributed to the presence of higher Copper concentrations in the treated soils but rather to differences among physiochemical soil parameters between Copper-treated and control soils (e.g. water availability, water potential).

This study was conducted with field sampled soils and earthworm and to our knowledge is one of the first attempts to test chronic effects on *A. caliginosa* in the lab. Any 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.

However, it can be concluded, that no adverse effects could be derived from the presence of Copper in the field sampled soils and therefore it can be concluded that the field aged Copper concentrations of 135 and 142 mg/kg did not cause any adverse effects on *A. caliginosa.*

9.5.1.1.3 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. Art.43 submissions will provide an update of the approach already used in the EU dossier.

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 (XXX XXX, 2015). As discussed above, no assessment factor should be applied and hence the BLM-normalised SSD-$RAC_{SW,ch}$ was determined to be 7.9 µg/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 (Schäfers, 2000), a NOEC of 4.8 µg/L (dissolved Copper) was determined for the most sensitive species *Chydorus sphaericus*. This study was performed with a mean pH of 9.4; mean dissolved organic Copper (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 2 × weekly addition of equilibrated Cu-salt in order to achieve constant Copper concentrations was also performed (Schäfers, 2001). 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 µg/L dissolved Copper. This suggests that the NOEC of 4.8 µg/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 µg/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 mg/L for fish is significantly higher than the aquatic invertebrate and algae ETO- $RAC_{SW,ch}$ of 4.8 µg/L thereby confirming that fish are not the most sensitive species. **The ETO-$RAC_{SW,ch}$ of 4.8 µg/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 XXX, 2019) 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 HC5 values which are representative for these 3 zones were calculated based on the HC5 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 HC5 cumulative distributions for the different zones, based on the physico-chemical parameters (DOC, pH) from Foregs, is provided in the **Figure 9.5.1.1.3-1** below:

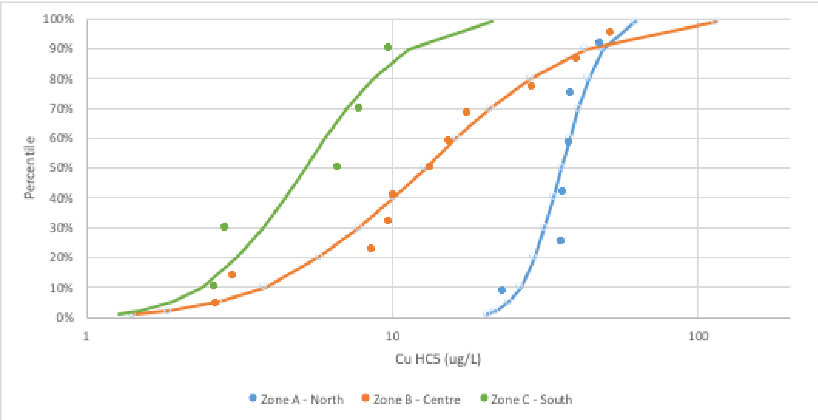

Figure 9.5.1.1.3-1 Overview of the Cu HC5 cumulative distributions for the different PPP zones

From **Figure 9.5.1.1.3-1** both median (50th%) and realistic worst case (10th%) HC5 for Cu could be calculated as shown in **Table 9.5.1.1.3-1.** Increasing sensitivity towards Copper is observed when moving from North to South Europe, with a median HC5 value of 35.75 µg/L for Zone A (North EU), 12.81µg/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 9.5.1.1.3-1 Overview of the Cu HC5 values for the different PPP zones

Percentile	**HC5 – Zone A**	**HC5 – Zone B**	**HC5 – 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

Percentile	HC5 – Zone A	HC5 – Zone B	HC5 – Zone C
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 HC5 values supports the use of the ETO-$RAC_{SW;ch}$ of 4.8 mg/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.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other 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: 6.3% (criterion: ≤ 20%),
- the mean number of juveniles per vessel at the end of the test: 970.3 (criterion: ≥ 100 juveniles at the end of the test),
- the coefficient of variation calculated for the number of juveniles: 12.2 (criterion: ≤ 30%).

Agreed endpoints:

LC_{10}, LC_{20}, LC_{50}, NOEC and LOEC

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of Cu /kg dry weight of the artificial soil]
LC_{10}	299.2 (81.3 - >1000*)	150.2 (40.8 - >502*)
LC_{20}	>1000	>502.0
LC_{50}	>1000	>502.0
NOEC	≥1000	≥502.0
LOEC	>1000	>502.0

* value obtained above the tested concentrations range

EC_{10}, EC_{20}, EC_{50}, NOEC and LOEC

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of Cu/kg dry weight of the artificial soil]
EC_{10}	225.8 (19.1 - >1000*)	113.4 (9.6 - >502*)
EC_{20}	>1000	>502.0
EC_{50}	>1000	>502.0
NOEC	320	160.1
LOEC	560	281.1

* value obtained above the tested concentrations range

Reference: KCP 10.4.2.1 – 01

Report “Copper hydroxide 50% WP: Collembolan (*Folsomia candida*) reproduction

	test". Paweł XXX, 2019, G/89/18. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline No. 232 (2016)
Deviations:	Yes. The temperature in the test room was between 17.0 – 21.0°C. According to OECD Guideline No. 232 (2016) SOP/G/87 and the Study Plan, it should be from 18 to 22°C. 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 was finished in May 2019 and not in October 2018 as it had been planned. These deviations did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Copper hydroxide 50% WP; Batch Number SCL- 97561; active substance: 50.2% w/v
Test species:	*Folsomia candida* obtained from a standard laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology. 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: 17.0 – 22.0℃; humidity: 12.6 – 14.4% (44.0 – 50.1% of the maximum water holding capacity); lighting: 16 h light : 8 h dark; light intensity: 581 – 603 lux; pH: 6.14 – 6.34
Statistical analysis:	EC_{10}, EC_{20}, EC_{50}, LC_{10}, LC_{20}, and LC_{50} - a probit analysis NOEC: - 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 LOEC – a value suggested by the program
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC LC_{10}, LC_{20}, LC_{50}, NOEC, LOEC

Results and Conclusions

Mortality at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil ranged from 2.5 to 22.5%. As for the control group, it was equal to 6.3%.
The concentration of the test item causing a 50% mortality of adults within the exposure period (LC_{50}) is above 1000 mg/kg dry weight of the artificial soil (502 mg of Cu/dry weight of the artificial soil).
The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the table given below.

LC_{10}, LC_{20}, LC_{50}, NOEC and LOEC values

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of Cu/kg dry weight of the artificial soil]
LC_{10}	299.2 (81.3 - >1000*)	150.2 (40.8 - >502*)
LC_{20}	>1000	>502.0
LC_{50}	>1000	>502.0
NOEC	≥1000	≥502.0
LOEC	>1000	>502.0

* value obtained above the tested concentrations range

After the exposure of collembolans to 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 813.3 – 1133.5 per replicate. As for the control group, the number of juveniles was equal to 970.3 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_{10}, EC_{20}, EC_{50}, NOEC and LOEC values

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of Cu/kg dry weight of the artificial soil]
EC_{10}	225.8 (19.1 - >1000*)	113.4 (9.6 - >502*)
EC_{20}	>1000	>502.0
EC_{50}	>1000	>502.0
NOEC	320	160.1
LOEC	560	281.1

* value obtained above the tested concentrations range

Comments of zRMS:

The study is considered valid. All validity criteria were met

- Mean adult mortality was 2.5% (criterion: ≤ 20%);
- The mean number of juveniles per vessel was 124.25 at the end of the test (criterion: ≥ 50 juveniles at the end of the test);
- The coefficient of variation for the number of juveniles was 2.68 (criterion: ≤ 30%).

Agreed endpoints:

Survial of *Hypoaspis aculetfer*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of Cu/kg dry soil]
LC_{10}	> 1000 (n.d.)	> 502 (n.d.)
LC_{20}	> 1000 (n.d.)	> 502 (n.d.)
LC_{50}	> 1000 (n.d.)	> 502 (n.d.)
NOEC	1000	502
LOEC	> 1000	> 502

n.d. - not determined

Reproduction of *Hypoaspis aculetfer*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of Cu/kg dry soil]
EC_{10}	> 1000 (n.d.)	> 502 (n.d.)
EC_{20}	> 1000	> 502

	(n.d.)	(n.d.)
EC_{50}	> 1000 (n.d.)	> 502 (n.d.)
NOEC	1000	502
LOEC	> 1000 (n.d.)	> 502 (n.d.)

n.d. - not determined

Reference: KCP 10.4.2.1-02

Report: "Effect of Copper hydroxide 50% WP on the reproductive output of the predatory soil mite *Hypoaspis* (*Geolaelaps*) *aculeifer* Canestrini (Acari: Laelapidae) in artificial soil". XXX V., Study code: 5699/2019, 2019. Bioscience Research Foundation

Guideline(s): OECD No. 226 (2016)

Deviations: Yes
The study finished in October 2019, not in September 2019 as it had been planned.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Summary

The aim of the study was to assess the impact of Copper hydroxide 50% WP on mortality and reproductive output of the predatory soil mite, *Hypoaspis aculetfer*. Ten concentrations of the test item were used. These were 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of water emulsion was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The experiment lasted 14 days. After that, the mites were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

Material and methods

Test item:	Name: Copper hydroxide 50% WP Batch number: SCL-98802 Manufacturing date: 4th April, 2018 Expiry date: 3rd April, 2020
Test organism:	The predatory mites, *Hypoaspis (Geolaelaps) aculeifer* (adult female) obtained from BRF Insectary.
Test design:	Test duration: 14 days Number of replicates: 4 replicates/concentration + 8 replicates/control Number of mites: 10 mites/replicate
Artificial soil:	5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand

Test conditions:	Temperature: 21.0 – 22.2°C pH at the beginning of the test: 5.98 – 6.31 pH at the end of the test: 6.09 – 6.40 Soil moisture content at the beginning of the test: 20.71 – 21.30% Soil moisture content at the end of the test: 19.65 – 20.75% Lighting: 16 h light and 8 h dark Light intensity: 480 – 550 lux
Concentrations of the test item:	control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000mg/kg dry weight of soil
Statistical analysis:	The endpoint values for mortality and reproduction were determined by using a Probit analysis in the NCSS and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.
Validity criteria:	- mean adult mortality was 2.5% (criterion: ≤ 20%); - the mean number of juveniles per vessel was 124.25 at the end of the test (criterion: ≥ 50 juveniles at the end of the test); - the coefficient of variation for the number of juveniles was 2.68 (criterion: ≤ 30%).

Findings

Impact of the Copper hydroxide 50% WP on survival of *Hypoaspis aculetfer*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of Cu/kg dry soil]
LC_{10}	> 1000 (n.d.)	> 502 (n.d.)
LC_{20}	> 1000 (n.d.)	> 502 (n.d.)
LC_{50}	> 1000 (n.d.)	> 502 (n.d.)
NOEC	1000	502
LOEC	> 1000	> 502

n.d. - not determined

Impact of the Copper hydroxide 50% WP on reproduction of *Hypoaspis aculetfer*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of Cu/kg dry soil]
EC_{10}	> 1000 (n.d.)	> 502 (n.d.)
EC_{20}	> 1000 (n.d.)	> 502 (n.d.)
EC_{50}	> 1000 (n.d.)	> 502 (n.d.)
NOEC	1000	502
LOEC	> 1000 (n.d.)	> 502 (n.d.)

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:	The study is considered valid. All validity criteria were met. • The coefficients of variation (CV) in the control group were 3.6, 14.2, 1.6, 3.8, 4.2, 1.6, 4.4, 2.2 and 3.2%, after 0, 7, 14, 28, 42, 56, 70, 84 and 98 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%. **Agreed endpoints:** It was concluded that Copper hydroxide 50% WP at the concentration 99.9 mg of test item/kg of dry weight soil (i.e. 50.1 mg of the Cu/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Reference: KCP 10.5.1

Report: "Copper hydroxide 50% WP Soil microorganisms: Nitrogen Transformation test".
XXX P., Study code: G/90/18, 2019. Institute of Industrial Organic Chemistry, Branch Pszczyna

Guideline(s): OECD Guideline No. 216 (2000)
EU Method C.21.
Standard Operating Procedure SOP/G/32:

Deviations: Yes
The experiment could be finished on day 84 of the analysis, upon the Sponsor's request, the experiment was continued until the difference in the nitrate formation rate between the control and the both concentrations was lower or equal to 25% or for a maximum 100 days.
The extraction was performed at 90 rpm for 24 hours not at 150 rpm for 60 min.
PEC was calculated assuming 1 cm of soil depth, unlike OECD Guideline 216 (2000) and EU method C.21, where PEC is calculated using 5 cm of soil depth.
The substrate should have a favourable carbon to nitrogen ratio (usually between 12/1 and 16/1). In this study a C/N ratio is lower than in the used guidelines.
The study was finished in September 2019 and not in August 2019, as it had been planned.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Summary
The aim of the study was to assess the impact of Copper hydroxide 50% WP on the processes of nitrogen transformation in aerobic surface soils. The effect of the test item was investigated in a agricultural soil.

The test was carried out for 98 days. The concentrations of the test item were: low concentration level of 99.9 mg test item/kg dry weight of soil and high concentration level of 333 mg test item/kg dry weight of soil. The soil treated with test item and untreated (control) were incubated and sampled for analysis after 0, 7, 14, 28, 42, 56, 70, 84 and 98 of incubation.

Material and methods

Test item:	Name: Copper hydroxide 50% WP Batch number: SCL-97561 Production date: 4th April, 2018 Expiry date: 3rd April, 2020
Test design:	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 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 98 days.
Test medium:	The freshly collected agricultural soil was used. The soil was collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna on January 03, 2019. It had not been treated with any plant protection products or organic and inorganic fertilizers for at least 5 years. Soil samples were taken from a depth of 20 cm. They were collected from different parts of the field to obtain a common laboratory sample.
Endpoints:	The concentration of nitrate [mg/kg dry soil] after 0, 7, 14, 28, 42, 56, 70, 84 and 98 days of incubation. The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 – 7, 0 – 14, 0 – 28, 0 – 42, 0 – 56, 0 – 70, 0 – 84, 0 – 98 days. Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 – 7, 0 – 14, 0 – 28, 0 – 42, 0 – 56, 0 – 70, 0 – 84, 0 – 98 days.
Test concentration:	Two concentrations of test item were used for the study - low: 99.9 mg of test item/kg of dry weight soil (i.e. 50.1 mg of the Cu/kg dry weight of soil), - high: 333 mg of test item/kg of dry weight soil (i.e. 167.2 mg of Cu /kg dry weight of soil).
Test conditions:	Temperature: 18.0 – 21.5°C Soil moisture: 45.3% – 50.3% of the maximum water holding capacity Ilumination: incubation in darkness
Statistical analysis:	- Shapiro-Wilk's test on Normal Distribution - Levene's Test on Variance Homogeneity (with Residuals) - Williams Multiple Sequential t-test Procedure.
Validity criteria:	The coefficients of variation (CV) in the control group were 3.6, 14.2, 1.6, 3.8, 4.2, 1.6, 4.4, 2.2 and 3.2%, after 0, 7, 14, 28, 42, 56, 70, 84 and 98 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.

Findings

Sampling interval (Day)	Sample	Mean nitrate content [mg/kg/day]	CV

0	Control	**173.14** ± 6.21	3.6
	Lower concentration	**233.74**+ ± 4.35	1.9
	Higher concentration	**259.51**+ ± 2.67	1.0
7	Control	**127.28** ± 18.14	14.2
	Lower concentration	**217.56**+ ± 7.33	3.4
	Higher concentration	**262.11**+ ± 6.18	2.4
14	Control	**193.86** ± 3.12	1.6
	Lower concentration	**315.96**+ ± 7.90	2.5
	Higher concentration	**404.66**+ ± 4.01	1.0
28	Control	**275.78** ± 10.61	3.8
	Lower concentration	**399.36**+ ± 10.46	2.6
	Higher concentration	**493.05**+ ± 26.13	5.3
42	Control	**326.49** ± 13.75	4.2
	Lower concentration	**426.64**+ ± 11.29	2.6
	Higher concentration	**501.39**+ ± 6.53	1.3
56	Control	**371.02** ± 5.79	1.6
	Lower concentration	**491.52**+ ± 10.73	2.2
	Higher concentration	**590.65**+ ± 12.86	2.2
70	Control	**407.26** ± 17.73	4.4
	Lower concentration	**534.20**+ ± 10.61	2.0
	Higher concentration	**683.36**+ ± 17.62	2.6
84	Control	**518.12** ± 11.45	2.2
	Lower concentration	**633.45**+ ± 54.17	8.6
	Higher concentration	**791.28**+ ± 63.96	8.1
98	Control	**512.05** ± 16.37	3.2
	Lower concentration	**634.05**+ ± 20.25	3.2
	Higher concentration	**790.38**+ ± 19.81	2.5

+ - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, two sided)

Time interval [d]	**Lower concentration** **99.9 mg of test item/kg dry weight soil**	**Higher concentration** **333 mg of test item/kg of dry weight soil**
0 – 7	**64.7**	**105.7**
0 – 14	**-297.0**	**-600.8**
0 – 28	**-61.4**	**-127.5**
0 – 42	**-25.8**	**-57.7**
0 – 56	**-30.3**	**-67.4**
0 – 70	**-28.3**	**-81.0**
0 – 84	**-15.9**	**-54.2**

Conclusions

On the basis of the results, it was concluded that Copper hydroxide 50% WP at the concentration 99.9 mg of test item/kg of dry weight soil (i.e. 50.1 mg of Cu/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Comments of zRMS:	The study is considered valid. All validity criteria were met. **Agreed endpoints:** It was concluded that Copper hydroxide 50% WP at the concentrations corresponding to PEC: 99.9 mg of test item/kg dry weight soil (i.e. 50.1 mg of Cu/kg dry

	weight of soil) and upper PEC: 333 mg of test item/kg dry weight soil (i.e. 167.2 mg of the Cu/kg dry weight of soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

Reference:	KCP 10.5.2
Report	"Copper hydroxide 50% WP. Soil Microorganisms: Carbon Transformation Test". Paweł XXX, Feb, 2019, G/93/18.
Guideline(s):	OECD Guideline No. 217 (2000) / EU Method C.22
Deviations:	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 KFoc > 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. The deviation did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Materials

Test item:	
Description:	Copper hydroxide 50% WP
Production batch:	SCL- 97561
Active ingredients content:	50.2% w/w
Test system:	
Species:	Microorganisms
Source:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Experimental conditions:	
Temperature:	18.0 – 20.0°C
Humidity:	45.6 – 50.1% 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: 99.9 mg of test item/kg dry weight soil (i.e. 50.1 mg of the Cu/kg dry weight of soil), upper PEC: 333 mg of test item/kg dry weight soil (i.e. 167.2 mg of the Cu/kg dry weight of soil).

Statistics: In order to determine significance of differences between the control and the treated groups, the Shapiro-Wilk's Test on Normal Distribution, the 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: 99.9 mg of test item/kg dry weight soil (i.e. 50.1 mg of Cu/kg dry weight of soil) and upper PEC: 333 mg of test item/kg dry weight soil (i.e. 167.2 mg of Cu/kg dry weight of soil) did not exceed 25% on 28 day of analysis.

Oxygen (O_2) consumption - deviations from the control [%]:

Day	**PEC** 99.9 mg of test item/kg dry weight soil (i.e. 50.1 mg of Cu/kg dry weight of soil)	**5 x PEC** 333 mg of test item/kg of dry weight soil (i.e. 167.2 mg of the Cu/kg dry weight of soil)
0	5.9	15.9
7	-0.1	-16.3
14	26.1	35.5
28	-2.5	-2.5

"-" 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 hydroxide 50% WP at the concentrations corresponding to PEC: 99.9 mg of test item/kg dry weight soil (i.e. 50.1 mg of the Cu/kg dry weight of soil) and upper PEC: 333 mg of test item/kg dry weight soil (i.e. 167.2 mg of the Cu/kg dry weight of soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

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,
100.0% – pea,
100.0% – corn,

100.0% – white mustardt,
100.0% – radish,
100.0% – toamto,

- 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.

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 hydroxide 50% WP: ER_{50}, and NOER values.

Endpoint value		**Soybean (*Glycine max*)**	**Corn (*Zea mays*)**	**Pea (*Pisum sativum*)**	**White mustard (*Sinapis alba*)**	**Radish (*Raphanus sativus*)**	**Tomato (*Solanum lycopersicon*)**
Plant number at the end of the experiment							
ER_{50}	Kg/ha [a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha [a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008
Shoot length (plants without roots)							
ER_{50}	Kg/ha [a]	>16	>16	>16	>16	>16	>16
	Kg/ha [a]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	g Cu/ha [b]	4.0	4.0	4.0	4.0	4.0	4.0
		2008	2008	2008	2008	2008	2008
Plant dry weight (plants without roots)							
ER_{50}	Kg/ha [a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha [a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008

: value for the test item, expressed as kg/ha
b: value for the active substance

Phytotoxicity:

<u>**Soybean**</u>

Application rate Kg/ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]		Symptoms	Mean effect [%]		Symptoms
	R1	0			0		
	R2	0			0		
	R3	0			0		
0	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
1	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
2	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
4	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
8	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
16	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		

N: normal, C: chlorosis, Ld: leaf deformation, Sd: stem deformation,Ne:Necrosis, W-Wilting
*: lack of plants

Corn:

Application rate Kg /ha	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effect [%]		Symptoms	Mean effect [%]		Symptoms
	R1	0			0		
	R2	0			0		
	R3	0			0		
0	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
1	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
2	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
4	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
8	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
16	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		

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
	R1	0			0		
	R2	0			0		
	R3	0			0		
0	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
1	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
2	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
4	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
8	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
16	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	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
	R1	0			0		
	R2	0			0		
	R3	0			0		
0	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
1	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
2	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
4	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
8	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
16	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		

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
	R1	0			0		
	R2	0			0		
	R3	0			0		
0	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
1	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
2	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
4	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
8	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	R7	0			0		
	R1	0			0		
	R2	0			0		
	R3	0			0		
16	R4	0	0.00	N	0	0.00	N
	R5	0			0		
	R6	0			0		
	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 hydroxide 50% WP on Seedling Emergence and Seedling Growth of Terrestrial Plants".
S. XXX, 5700/2019, 2020,Bioscience Research Foundation

Guideline(s): OECD No. 208 (2006)

Deviations: Deviation from the Study Plan: The study finished in June 2020, not in November 2019, as it had been planned. This deviation did not affect the study results

GLP: Yes

Acceptability: Yes

Duplication: No
(if vertebrate study)

Summary

The study, aimed at evaluating the effect of Copper hydroxide 50% WP 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 on 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 60ºC, and weighed.

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER_{10}, ER_{25}, ER_{50}, and NOER.

Material and methods

Test item:	Copper hydroxide 50% WP Batch number: SCL-98802 Production date: April 4, 2018 Expiry date: April 3, 2020
Test species::	Soybean (*Glycine max*), Corn, (*Zea mays*), Radish (*Raphanus sativus*), Pea (*Pisum sativum*), Tomato (*Solanum lycopersicon*) and White mustard (*Sinapis alba)*
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. 502, 1004, 2008, 4016 and 8032 g Cu/ha)
Soil:	sandy loam containing 1.2% organic carbon
Endpoints:	ER_{10}, ER_{25}, ER_{50}, NOER
Test conditions:	Temperature: 21.7– 22.8°C Humidity: 58.2 – 69.4% Photoperiod – 16h day:8h night Light intensity: 323– 400 µE/m^2/s Carbon dioxide concentration: 336– 355 ppm
Statistical analysis:	The endpoints 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, 100.0% – pea, 100.0% – corn, 100.0% – white mustardt,

100.0% – radish,
100.0% – toamto,
- 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.

Number of seeds per pot

The number of seeds per pot and the total number of seeds per application ratewere as follow:

- 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 hydroxide 50% WP: ER_{50}, and NOER values.

Endpoint value		**Soybean (*Glycine max*)**	**Corn (*Zea mays*)**	**Pea *(Pisum sativum)***	**White mustard (*Sinapis alba*)**	**Radish *(Raphanus sativus*)**	**Tomato *(Solanum lycopersicon)***
Plant number at the end of the experiment							
ER_{50}	Kg/ha	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008
Shoot length (plants without roots)							
ER_{50}	Kg/ha	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha	4.0	4.0	4.0	4.0	4.0	4.0
	g/ha	2008	2008	2008	2008	2008	2008
Plant dry weight (plants without roots)							
ER_{50}	Kg/ha	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008

a: value for the test item, expressed as kg/ha
b: value for the active substance

ZRMS comments:

The study is considered valid. All 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 (*Glycine max*)**	**Corn (*Zea mays*)**	**Pea (*Pisum sativum*)**	**White mustard (*Sinapsis alba*)**	**Radish (*Raphanus sativus*)**	**Tomato (*Solanum lycopersicon*)**
Plant number							
ER_{50}	Kg/ha[a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha[a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008
Shoot length (plants without roots)							
ER_{50}	Kg/ha[a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha[a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008
Plant dry weight (plants without roots)							
ER_{50}	Kg/ha[a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha[a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008

a: value for the test item, expressed as kg/ha
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
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
0	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
1	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
2	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
4	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
8	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
16	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		

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
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
0	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
1	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
2	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
4	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
8	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
16	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead
*: all plantsdead

Pea:

Application rate kg/ha	Replicate	Phytotoxic effects Day 7 Mean effect [%]		Day 7 Symptoms	Day 14 Mean effect [%]		Day 14 Symptoms	Day 21 Mean effect [%]		Day 21 Symptoms
0	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.00	N	0	0.00	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
1	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
2	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
4	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
8	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
16	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		

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 Mean effect [%]		Day 7 Symptoms	Day 14 Mean effect [%]		Day 14 Symptoms	Day 21 Mean effect [%]		Day 21 Symptoms
0	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.00	N	0	0.00	N	0	0.00	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
1	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
2	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
4	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
8	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
16	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		

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 Mean effect [%]		Day 7 Symptoms	Day 14 Mean effect [%]		Day 14 Symptoms	Day 21 Mean effect [%]		Day 21 Symptoms
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
0	R4	0	0.00	N	0	0.00	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
1	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
2	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
4	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
8	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		
	R1	0			0			0		
	R2	0			0			0		
	R3	0			0			0		
16	R4	0	0.0	N	0	0.0	N	0	0.0	N
	R5	0			0			0		
	R6	0			0			0		
	R7	0			0			0		

N: normal, C: chlorosis, Ne: necrosis, W: wilting, Ld: leaf deformation, Sd: stem deformation, D: dead
*: all plants dead

Reference:	KCP 10.6.2-02
Report	"Effect of Copper hydroxide 50% WP on vegetative vigour of terrestrial plants". Dr. S. XXX, 2020, Report number 5701/2019. Bioscience Research Foundation
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	Deviation from the Study Plan: The study finished in June 2020, not in December 2019, as it had been planned. This deviation did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Copper hydroxide 50% WP; Batch Number SCL-98802; active substance content: 50.2% (w/w)
Test species:	Soybean (*Glycine max*), Corn (*Zea mays*), radish (*Raphanus sativus*), pea (*Pisum sativum*), tomato (*Solanum lycopersicon*) and white mustard (*Sinapsis alba*)
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: 323 – 400 µE/m²/s, carbon dioxide concentration: 336 – 355 ppm.
Statistical analysis:	The ER_{10}, ER_{25}, ER_{50} 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:	EC_{10}, EC_{25}, EC_{50} and NOEC

No of seeds:

- 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 hydroxide 50% WP 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 1 to 16 kg test item/ha. The phytotoxic symptoms for all plant species tested were observed at all the rates of the test item used. The following phytotoxic symptoms were not 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 (*Glycine max*)**	**Corn (*Zea mays*)**	**Pea (*Pisum sativum*)**	**White mustard (*Sinapsis alba*)**	**Radish (*Raphanus sativus*)**	**Tomato (*Solanum lycopersicon*)**
Plant number							
ER_{50}	Kg/ha[a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha[a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008
Shoot length (plants without roots)							
ER_{50}	Kg/ha[a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha[a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008
Plant dry weight (plants without roots)							
ER_{50}	Kg/ha[a]	>16	>16	>16	>16	>16	>16
	g Cu/ha [b]	>8032	>8032	>8032	>8032	>8032	>8032
NOER	Kg/ha[a]	4.0	4.0	4.0	4.0	4.0	4.0
	g Cu/ha [b]	2008	2008	2008	2008	2008	2008

a: value for the test item, expressed as kg/ha
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