

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 9800 A

Product name: COBRANZA

Chemical active substance:

Copper oxychloride, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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8 Fate and behaviour in the environment (KCP 9)

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

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

~~The RMS and EFSA are held to assess plant protection products according to the existing methodology described in a series of guidance documents (GDs). Those have been developed for synthetic, organic molecules, and are in most cases not applicable to minerals and copper. This has led to an EFSA conclusion that indicated a number of critical concerns, or assessments that could not be finalized, which do not reflect any realistic risk, but rather illustrate the inappropriateness of the current GDs for the assessment of copper. This can easily be seen in a number of endpoints that suggest a high risk exists at concentrations below natural background of this essential micronutrient. This has been recognized by EFSA, the RMS and several MS (see comments from DE and IT in the Peer review Report), and the EU Commission has mandated EFSA with the development with a copper specific guidance (xxxx 2019-0036).~~

~~Art.43 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.~~

zRMS comment:

The applicant's claim is in opposition to the EU assessment of copper and was not considered in the risk assessment. EFSA conclusion gives the current state of the of the risk assessment for copper PPPs and represents the basis for the Annex I inclusion of copper compounds until further guidance or alternative models are available.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion Groundwater
					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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	Grapevine	F	Downy mildew (<i>Plasma- para viticola</i>)	Foliar Spray	BBCH 15-85	a) 4 b) 4	10-12	a) 2.0 b) 8.0	a) 1.0* b) 4.0*	800-1000	21	* Ex- pressed as Cu	A
2	CEU	Potato	F	Late blight (<i>Phytophthora infestans</i>)	Foliar Spray	BBCH 15-85	a)-4 3 b)-4 3	10-12	a) 2.0-2.4 b) 7.2-8.0	a) 1.0-1.2* b) 3.6-4.0*	500-1000	14	* Ex- pressed as Cu 3 applica- tions for the dose of 2.4 kg/ha, 4 applications for the dose of 2.0 kg/ha	A
3	CEU	Solanaceous fruits (Tomato, aubergine)	F	Late blight (<i>Phytophthora infestans</i>)	Foliar Spray	BBCH 15-85	a) 3 b) 3	10-12	a) 1.5-2.4 b) 4.5-7.2	a) 0.75-1.2* b) 2.25- 3.6*	500-1000	3	* Ex- pressed as Cu	A
4	CEU	Pome fruit (apple, pear, quince)	F	Scab (<i>Venturia spp.</i>)	Foliar Spray	BBCH 15-85	a) 3-5 b) 3-5	10-12	a) 1.15-2.4 b) 5.75-7.2	a) 0.575-1.2* b) 2.875- 3.6*	800-1000	14	* Ex- pressed as Cu 3 applica- tions for the dose of 2.4 kg/ha, 5 applications for the dose of 1.15	A

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of Copper oxychloride

As copper is an elementary atomic particle there are no relevant metabolites for copper.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Copper oxychloride

Copper is an elementary atomic particle and therefore cannot be degraded. In the absence of a route and consequently a rate of degradation, the distribution of the different forms of copper in soil is the important factor influencing the environmental fate of copper and bio-availability to plants and soil organisms.

The mobile, active and toxicologically significant substance is the free copper²⁺ ion present in the soil solution. It is a highly reactive species and consequently most of the copper in the soil is strongly bound to a wide range of soil substances, therefore limiting the amount of free copper²⁺ ions in the soil solution. The strongest interactions are formed with organic matter and oxides of manganese and iron, whilst clay minerals although adsorbing less strongly also contribute significantly because they are present throughout the soil profile. These strong interactions with soil particles result in the majority of soil copper (typically > 99% of the total) being present as a bound residue. A small proportion of soil copper is located in the soil solution as hydrated copper ([Cu(H₂O)₆]²⁺) and as soluble inorganic or organic complexes. The levels of copper in the soil solution are small, usually representing < 1% of the total soil copper, whilst the levels of the free copper²⁺ ion in the soil solution are very small (usually < 0.1% of the total soil copper) due to rapid complexation.

The amount of free copper²⁺ ion in the soil solution is controlled primarily by pH and the amount of dissolved organic carbon in the soil. In acid soils (pH < 6) the concentration of copper²⁺ ions in the soil solution will be greater than at neutral or alkaline pH. This is because the [Cu(H₂O)₆]²⁺ ion can exist at low pH, but as alkalinity increases reactions with inorganic anions result in the formation of sparingly soluble salts and these remove copper²⁺ ions from solution by precipitation. The stability of copper-organic matter complexes also increases as pH is raised. These complexes are formed by the interaction of copper with organic functional groups such as carboxylic acids which are protonated at low pH and consequently have less affinity for copper²⁺ ions.

Under anaerobic conditions the level of copper²⁺ ions in solution is controlled by the formation and precipitation of sparingly soluble sulphides and changes in redox potential do not significantly affect the level of copper²⁺ ions in solution.

Maintaining an alkaline soil pH and abundant supply of organic matter in the soil are therefore important means of regulating the level of bio-available copper. The addition of lime and low copper compost materials are methods to achieve these aims and can be conducted routinely as part of normal farming practice.

Soil copper concentrations are given in terms of total soil copper, however as previously described the vast majority of copper in soil is bound to solid components and consequently not available to

plant and soil organisms. The concentration of free copper²⁺ ions (the toxicologically significant form) in the soil solution, or of poorly adsorbed copper forms which can easily be released as free copper²⁺ in the soil solution, is more relevant. Simple measurements of total copper in the soil should not be used as a means of assessing exposure risk without taking these important facts into account.

In laboratory studies, copper added to soil became bound primarily to inorganic and organic matter and to oxide fractions within the soil. Measurement of the concentration of copper in bio-available fractions (exchangeable and soil solution) showed that levels did not change substantially, even in soils containing already elevated levels of copper. These studies were performed using exaggerated application rates up to 500 mg copper/kg and 24.3 kg copper/ha and over a very short time which may not have allowed true equilibrium to be established. Ageing processes are important for copper because over time residues become increasingly bound and consequently less available. Indeed, care should be taken when considering the results obtained from spiking experiments because the solubility and therefore the bioavailability of added copper may be overestimated under these artificial conditions. Where field (aged) soil samples are compared to freshly spiked soil samples, it was found that bioavailability was increased for the spiked soils and this was related to a much greater soluble copper concentration at any given level of total soil copper.

A generic lab-to-field (L/F) factor of 4 is proposed in order to correct for higher toxicity observed in standard tests with laboratory-spiked soils compared to tests in soils affected by long-term use of Cu-based plant protection products. This factor is based on a comprehensive comparison of Cu toxicity in 11 vineyard soils with high Cu concentrations because of the application of Cu fungicides and corresponding reference soils spiked with CuCl₂. This correction factor should be performed when comparing toxicity data from freshly spiked soils with total exposure concentrations measured in field-contaminated soils.

The degradation of copper in soil under aerobic conditions was evaluated during Annex I renewal as published in EFSA Journal 2018; 16(1):5152.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Copper oxychloride

The degradation of copper in soil under anaerobic conditions was evaluated during Annex I renewal as published in EFSA Journal 2018; 16(1):5152.

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Copper oxychloride

The dissipation rate of copper in soil under field conditions was evaluated during Annex I renewal as published in EFSA Journal 2018; 16(1):5152.

In 2003, the European Copper Task Force (EUCuTF) initiated a 10 year earthworm field monitoring study. After 10 years of treatment with copper the NOEC of the study was the dose rate T2 (8 kg copper/ha/year). Soil total copper concentrations at this treatment rate in the top soil layer (0-5 cm) at Niefern increased from an initial value of around 28 mg/kg up to a maximum value of 130.8 mg/kg dry weight at sampling 32 (Mar 2013). At Heiligenzimmern, concentrations in the top soil layer at the 8 kg copper/ha/year treatment rate increased from an initial value of around 32 mg/kg

dry weight up to a maximum value of 132.9 mg/kg dry weight at sampling 29 (Nov 2011, after 25th application). In the deeper soil layer (5-30 cm) at both sites the total copper content did not increase significantly.

'Bioavailable' copper content (as defined by CaCl₂ extraction) were very low throughout the ten years of the study at all treatment levels and soil depths. Levels were ≤ 2.6 mg/kg dry weight, with the exception of the highest copper treatment rate (40 kg copper/ha/year) in 2009 where a maximum value of 4.8 mg copper/kg dry weight at sampling 24 (after 18th application) was detected.

In addition, a review of the existing monitoring programmes and published literature on copper levels in European agricultural soils has been conducted, with the aim of identifying a concentration suitable for use in soil exposure assessments for various crops. No convincing evidence for accumulation of copper in arable fields was found, but elevated copper levels were observed in a proportion of vineyard soils and to a much lesser extent in some orchard soils.

It can be seen in the following table (Appendix A EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152) that following an extensive review of European monitoring programs a median soil concentration of 11 mg Cu/kg has been found for top soil across Europe and is considerably lower than the very conservative value of 32 considered by EFSA in 2013.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Copper oxychloride

The accumulation potential of copper in soil under field conditions was evaluated during Annex I renewal as published in Appendix A EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152.

A review of European monitoring programs was used to identify levels of copper present in soil from natural or anthropogenic sources other than the regulated use for the soil exposure assessments. The values suitable for use in soil exposure assessments are summarised below.

Soil	Soil concentration (mg Cu/kg soil-DM)	
Background level	11.5	
Vineyards ^a	28	Overall median 10 th percentile value
	66.4	Overall median value
	160	Overall median 90 th percentile value
	73-77.5	Overall mean value
Vineyards	29.5	Overall median 10 th percentile value
	26.09	Overall median value
	128.0	LUCAS data ^e
	49.26	Overall median value LUCAS data
		Overall median 90 th percentile value LUCAS data ^d
		Overall mean value LUCAS data
Arable fields ^b	32	Overall median 10 th percentile value
	7	Overall median value
	13.2-4	Overall median 90 th percentile value
	26	Overall mean value
	15.9	
Orchards ^b	-	Overall median 10 th percentile value
	39.8-48.3	Overall median value
	58	Overall median 90 th percentile value
	23-22.5	Overall mean value
Olive groves	24.7	Overall median value LUCAS data
	74.5	Overall median 90 th percentile value LUCAS data
	33.5	Overall mean value LUCAS data

^aRecently published data from the EU LUCAS program [Copper distribution in European Topsoils: An assessment based on LUCAS soil survey, xxxx et al., Science of the Total Environment 636 (2018) 282–298] confirms the assumption that the data for vineyards in the LOEP values are biased towards the higher end as they are mainly based on published literature, which focusses mainly on contaminated sites.

^bIncludes new data from the EU LUCAS program.

^cCalculated from the standard deviation of the set of data in the paper described in ^a.

^dCalculated from the standard deviation of the set of data in the paper described in ^a.

A comprehensive review of European monitoring programs was used to identify levels of copper present in soil from natural or anthropogenic sources other than the regulated use for the soil exposure assessments. The values suitable for use in soil exposure assessments are summarised below and are taken from Appendix A EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152 of the revised list of endpoints of the updated RAR August 2018.

Summary of measured background values of total copper contents in different agricultural soils in the EU from European monitoring data (EU-LoEP 2018)

Soil	Soil concentration (mg Cu/kg soil DM)	
Vineyards	28	Overall 10 th percentile value
	72	Overall median value
	160	Overall 90 th percentile value
	67	Overall mean value
Arable fields	32	EFSA (2013)
	7	Overall 10 th percentile value
	13	Overall median value
	26	Overall 90 th percentile value
Orchards	15	Overall mean value
	-	Overall 10 th percentile value
	48	Overall median value
	58	Overall 90 th percentile value
	22	Overall mean value

(see EU-LoEP in Appendix A, EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152)

A review of monitoring programs for copper in soil was carried out in 2018 and was used to identify ‘background levels’ of copper present in soil from natural or anthropogenic sources other than the regulated use for use in soil exposure assessments. The results taken from the LoEP (Appendix A EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152) are summarised in the table above.

It can be seen following an extensive review of European monitoring programs a median soil concentration of 13.2 mg Cu/kg has been found for arable soil across Europe and is considerably lower than the very conservative value of 32 considered by EFSA in 2013.

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

Recently published data from the EU LUCAS program [Copper distribution in European Topsoils: An assessment based on LUCAS soil survey, xxx et al., Science of the Total Environment 636 (2018) 282–298] confirms the assumption for this bias and provides lower average values for vineyards, and also shows there is no measurable accumulation for field crops. The EUCuTF have used the LUCAS data set to extend the data set and to refine the values presented in the LoEP for their PEC soil calculations.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapo-

late from data obtained with the active substance.

8.5.1 Copper oxychloride

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The adsorption/desorption of copper was evaluated during Annex I renewal as published in EFSA Journal 2018; 16(1):5152. A survey of adsorption K_d in European arable and grazing land soils was selected as the key study for assessing copper distribution between the aqueous phase and soil. The soils were representative for the variability in physico-chemical properties of soils in Europe and K_d values were measured at relevant doses and realistic conditions. It was concluded that copper exhibited medium mobility to immobility in soil and that the adsorption of copper was pH dependent. The geometric K_{doc} value for soil at pH 4-5 of 19509.9 L/kg was selected as a generic K_{doc} value for soil for a first tier exposure assessment.

The geometric K_{doc} value 33918.3 mL/goc derived from pH range 5.5-6.5 was used for PEC_{sw} simulations.

Parent							
Soil Type	OC %	Soil pH ^{a)}	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
494 topsoil samples from arable land and grass land across Europe	0.5-48.0	3.28-4.00	-	2300.0-35202.4	-	-	-
	0.6-49.0	4.01-4.99	-	908.7-337000	-	-	-
	0.7-36.0	5.08-5.48	-	1727.8-505444.4	-	-	-
	0.5-42.0	5.53-6.50	-	350.0-430400.0	-	-	-
	0.5-22.0	6.51-7.98	-	5163.3-1062833.3	-	-	-
Median value (if not pH dependent)			-	-	-	-	-
Geometric mean (if not pH dependent) [‡]			-	pH 4-5: 19509.9 pH 5.5-6.5: 33918.3	-	-	-
Arithmetic mean (if not pH dependent)			-	-	-	-	-
pH dependence, <i>Yes or No</i>			Yes				

^{a)} Measured in CaCl₂

8.5.2 Column leaching (KCP 9.1.2.1)

8.5.2.1 Copper oxychloride

Discussion of the soil mobility of copper (soil adsorption/desorption and aged soil column leaching) can be found in the EFSA Journal 2018; 16(1):5152. A summary of the information provided is included below:

Mobility of copper in soil is influenced significantly by all components of the soil and by different physical, chemical and biological parameters whose relative importance are not well known. For

these reasons, standard laboratory sorption tests have not been performed. If these tests had been conducted the resulting K_{oc} values obtained would considerably underestimate adsorption and overestimate the movement of copper because K_{oc} is a function of the soil organic carbon content only.

Tests performed to determine the extent of copper adsorption showed that humic acids, manganese and iron oxides and clay particles all contribute significantly to adsorption, with humic acids and manganese oxides showing the highest propensity for binding. Adsorption to these materials is in agreement with the Langmuir adsorption equation and is pH dependent, with increased adsorption observed as soil pH is increased. Although adsorption to iron oxides and clays was less strong compared to organic matter and manganese oxides their abundance throughout the soil profile will mean that their overall adsorption will be at least as great as organic matter and manganese oxides and will not be restricted to surface layers as is the case for organic matter interactions.

Investigations into copper mobility were performed using column leaching experiments conducted under laboratory conditions with standard Speyer soils (2.1, 2.2 and 2.3) at application rates up to 18 kg/ha (2.25 times the maximum annual rate according to the EU GAP). After leaching with 370 to 393 mL of water over a period of 48 hours, the levels of copper detected in the leachate did not differ from those observed in control leachate. Movement through the leaching column was minimal, with applied copper located almost exclusively in the upper most soil segment (0-6 cm).

In these studies, column leaching was performed without ageing, which could have led to an over-estimation of the leaching potential as the degree of copper binding increases with time. Despite these worst case conditions the results of the test showed that copper applied to the column did not leach.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

8.5.3.1 Copper oxychloride

A review of the existing monitoring programs and published literature on copper levels in groundwater has been conducted which confirms the limit of 2 mg/L for copper will not be exceeded following the regulated use of copper as a fungicide as published in EFSA Journal 2018; 16(1):5152.

Generally natural levels of copper in groundwater were low, with background concentrations ranging from <0.63 to 25 µg/L, with the exception of volcanic aquifers. In the upper soil layers, typical copper concentrations in soil water and leachate from field leaching and lysimeter studies ranged from 1 to 90 µg/L, with a peak concentration of 164.2 µg/L detected at a depth of 25 cm. A review of copper levels in groundwater aquifers with possible anthropogenic inputs detected a range of concentrations from <LOD to 39 µg/L, with a peak concentration of 90 µg/L. Typical concentrations in ranged from < 0.1 to 18 µg/L which is within the range of natural background levels copper concentrations never approach the legal limit of 2 mg/L set by the European Drinking Water Directive (98/83/EC7) for groundwater.

8.5.4 Field leaching studies (KCP 9.1.2.3)

8.5.4.1 Copper oxychloride and its metabolites

Not used in exposure/risk assessment.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

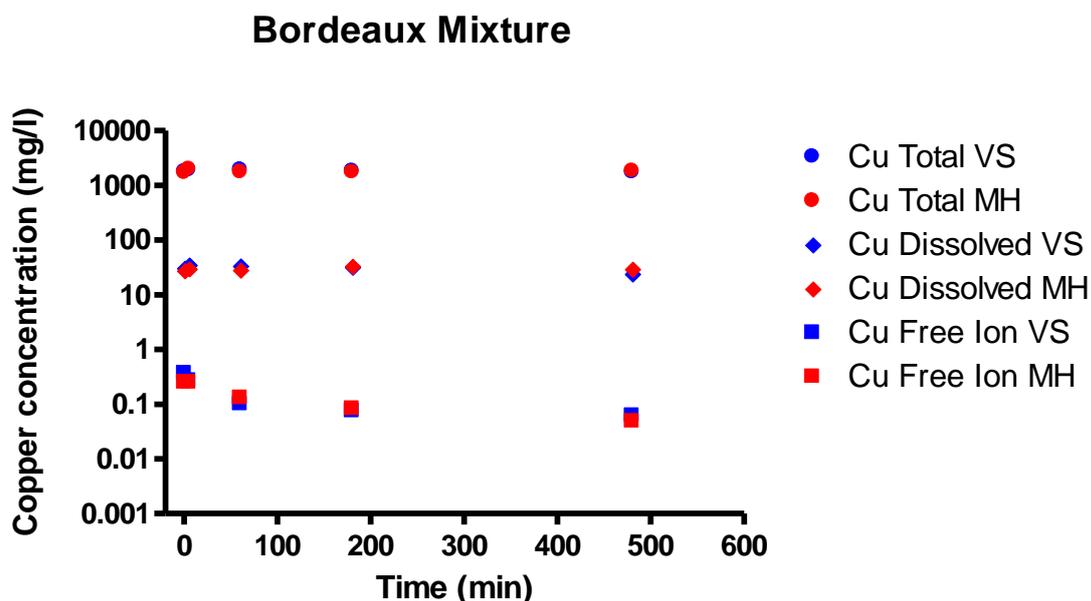
Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1 Copper oxychloride

Data on the behaviour of copper in water sediment systems was evaluated during Annex I renewal inclusion as published in EFSA Journal 2018; 16(1):5152.

No regulatory study was conducted to assess the behaviour of the formulated product or copper compounds in water/sediment system. However a laboratory microcosm study was conducted and the results used for determination of the relevant parameters to be used for risk assessment purposes. Dissipation times based on total copper concentrations in the microcosm study varied between 4 and 30.5 days (mean 9 days, n =18). Also, representative literature studies are provided as complementary data to illustrate the dissipation of copper from surface water under field and laboratory conditions.

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 xxxx 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 this, 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.

Based on a very large body of literature, the order of toxic potential is $Me^{2+} > \text{inorganic complexes} > \text{organic complexes}$. Copper toxicity to aquatic biota is primarily due to dissolved cupric ion (Cu^{2+}). Assessment of the dissipation time based on the toxic copper species, i.e. free cupric ion Cu^{2+} , revealed much lower dissipation times. At the highest concentrations in the microcosm study (120 and 240 μg Cu/L) DT_{50} values were ± 1 day while at lower concentrations (24, 12 and 2.5 μg

Cu/L) no changes in free cupric ion concentrations are observed, therefore indicating $DT_{50} \ll 1$ day.

As described above, the spray drift scenario starts with a non-equilibrium phase during which total copper dissipates with a DT_{50} of < 1 day (xx 2016). Any free copper ions also dissipate with < 1 day (xx 2008). The system will reach an equilibrium stage within ca. 24 hours, and the resulting dissolved copper concentration will be a function of the water chemistry (pH, DOC, hardness, etc.).

Therefore a DT_{50} of < 1 day is appropriate and the single application scenario shall be presented as the worst-case scenario.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

8.7.1.1 Copper oxychloride

EU agreed endpoints (EFSA Journal 2018; 16(1):5152 & 10.2903/sp.efsa.2018.EN-1486) are used for the risk assessment.

8.7.2 Active substance and relevant metabolites

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1*	2	3	4
Crop	Grapevine	Potato	Solanaceous fruits (tomato, aubergine)**	Pome fruits (apple, pear, quince)
Application rate (g Cu/ha)	Copper oxychloride: 1000	Copper oxychloride: 1200		
Number of applications/interval	4/10	3/10		
Crop interception (%)	60	45	50	60
	(0 as worst case for all uses)			
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)	20 cm (tillage)		5 cm (no tillage)

* Worst case for PEC_{soil} calculations

**Surrogate crops proposed to calculate the interception percentage

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Copper oxychloride	-	-	(1 x 10 ¹⁰ d used for calculations)	Y EFSA Journal 2018;

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
				16(1):5152

8.7.2.1 Copper oxychloride

Calculations were based on a simple first tier approach (Excel sheet) assuming even distribution of the compound in upper 0-5 cm soil layer following a single season's application. The long-term potential accumulation for copper was estimated following repeated annual applications for a 20 cm depth of soil in the case of arable crops and for 5cm soil depth in case of permanent crops. A standard soil density of 1.5 g/cm³ was assumed for all calculations.

In addition to the levels of copper arising from the regulated use, 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. This requirement to include sources other than the regulated use is specific to copper and so a standard soil exposure assessment is not possible. European monitoring programs provided a comprehensive overview of copper levels in agricultural soils. No convincing evidence for accumulation of copper in arable fields was found, but elevated copper levels were observed in a proportion of vineyard soils. Concentrations suitable for use in soil exposure assessments, including sources other than the regulated use, were identified.

Crop interception data, which correspond to the intended growth stages, are taken from the FOCUS groundwater guidance paper (FOCUS 2002). Crop interception will reduce the amount of a compound reaching the soil and therefore this would normally be taken into account depending on the growth stage at application. For copper, the estimation of PEC_{soil} has assumed that there is no crop interception. Although foliar application to crops will involve, at later growth stages, high levels of interception, the assumption has been made that since copper is a contact fungicide with no systemic activity, all the copper applied will eventually be deposited to the soil either by mechanical action (as a consequence of prevailing wind) or be washed off by rain.

The PEC_{soil} has been calculated according to the following equations:

For single application:

$$\text{Initial PECs} = \text{application rate} \times (1 - (\% \text{interception} / 100)) / (100 \times \text{soil depth} \times \text{soil density})$$

Where:

$$\text{Soil depth} = 5 \text{ cm}$$

$$\text{Soil density} = 1.5 \text{ g/cm}^3$$

An accumulated PEC_{soil} value was calculated for repeated annual applications. For copper, which is not degraded, this value comprised the predicted accumulated concentration in the soil after repeated applications for six years in 20 cm depth of soil for arable crops and 5 cm depth of soil for permanent crops, plus the concentration arising from the final years' application in 5 cm depth of soil, plus the concentration arising from copper already present in the soil.

A comprehensive review of European monitoring programs was used to identify levels of copper present in soil from natural or anthropogenic sources other than the regulated use for the soil exposure assessments. The values suitable for use in soil exposure assessments are summarised below and are taken from Appendix A EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152 of the revised list of endpoints of the updated RAR August 2018.

A review of monitoring programs for copper in soil was carried out in 2018 and was used to identify 'background levels' of copper present in soil from natural or anthropogenic sources other than

the regulated use for use in soil exposure assessments. The results taken from the LoEP (Appendix A EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152) are summarised in the table above. ~~The EUCuTF stated in their monitoring report that these values are most likely biased towards the higher end as they are mainly based on published literature, which focusses mainly on contaminated sites.~~

~~Recently published data from the EU LUCAS program confirms the assumption for this bias and provides lower average values for vineyards, and also shows there is no measurable accumulation for field crops. The EUCuTF have used the LUCAS data set to refine the values presented in the LoEP for their PEC soil calculations.~~

Findings: The PEC_{soil initial} values for total copper in soil following a single season's application are summarised below in Table 8.7-. As copper does not degrade PEC_{soil} values with time are not relevant.

Table 8.7-3: PEC_{soil initial} for total copper

Individual Crop	Rate per Season	Soil depth	PEC _{soil, initial}
	[g Cu/ha]	[cm]	[mg/kg]
Vines (0% interception)	1 x 4000	5	5.3
Potato (0% interception)	1 x 3600	5	4.8
Solanaceous fruits (tomato, aubergine) (0% interception)	1 x 3600	5	4.8
Pome fruits (apple, pear, quince) (0% interception)	1 x 3600	5	4.8

PEC_{soil} accumulation values which consider different values of the soil background level (e.g. 90th percentile value, median value, 10th percentile value) are provided below. The calculations are based on a worst case assumption that the maximum dose is applied for each year of the period authorization is requested for (7 years) and PEC_{soil} values for copper do not consider any dissipation routes, with no degradation or other losses considered for this time period.

Table 8.7-4: PEC_{soil} accumulation for total copper over seven year registration

Individual Crop	Rate per Season	DT ₅₀ ^A	PEC _{soil} accumulation calculation					Background Monitoring Value ^B	Overall PEC _{soil, accumulation} ^C	Overall PEC _{soil, accumulation} ^D	Overall PEC _{soil, accumulation} ^F
			Soil depth	DT ₅₀ ^A	C _{low} 7 of years	C _{low} 10 of years	C _{low} 20 of years				
	[g Cu/ha]		[cm]	[mg/kg]			[mg/kg]				
Vines	1 x 4000	Not relevant	5	Not relevant	37.1	53	106	72	109.1	125	178
								160	197.1	213	266
								67	104.1	120	173

^A Copper is an element so DT₅₀ value is not relevant

^B overall median value, 90th percentile, overall mean value in European vines

^C Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 7 years

^D Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 10 years

^F Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 10years

8.7.2.2 PEC_{soil} of COBRANZA

Table 8.7-3: PEC_{soil} for COBRANZA on grapevine (0% interception as worst case)

Active substance/ preparation	Application rate (g/ha)	PEC _{act} (mg/kg)	Tillage depth (cm)
Copper oxochloride/ COBRANZA	2000 x 4	10.67	5

zRMS comments:

The calculations of PECs for copper are acceptable.

The PEC soil calculations for copper take 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' period was considered and additionally, the natural copper background (median and 90th percentile values) 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.

zRMS agrees with opinion DE concerning publication xxx et al. (2018). Due to no data 10th and 90th percentile concentration in the publication and the suggested percentile copper concentrations from the applicant (and how they have been derived) are not comprehensible. Therefore have not used in PECs calculations.

The calculations cover proposed uses in GAP.

Modelling results are acceptable and are appropriate to be used for the subsequent risk assessment for soil organisms.

Below PECs calculated by zRMS after comments cRMS.

The calculations cover proposed uses in GAP.

Individual Crop	Rate per Season	PEC _{soil} accumulation calculation					Background Monitoring Value ^B	Overall PEC _{soil} , accumulation ^C	Overall PEC _{soil} , accumulation ^D	Overall PEC _{soil} , accumulation ^F
		Soil depth	DT ₅₀ ^A	C _{low} 7 of years	C _{low} 10 of years	C _{low} 20 of years				
	[gCu./ha]	[cm]		[mg/kg]			[mg/kg]			
Potato	1 x 3600	5	Not relevant	33.6	48	96	13	46.6	61	109
							26	59.6	74	122
							15	48.6	63	78

^A Copper is an element so DT₅₀ value is not relevant

^B overall median value, 90th percentile, overall mean value in European arable

^C Overall PEC_{soil}, accumulation = Background monitoring value + C_{low} + PEC_{soil}, initial over 7 years

^D Overall PEC_{soil}, accumulation = Background monitoring value + C_{low} + PEC_{soil}, initial over 10 years

^F Overall PEC_{soil}, accumulation = Background monitoring value + C_{low} + PEC_{soil}, initial over 10years

Individual Crop	Rate per Season	PEC _{soil} accumulation calculation					Background Monitoring Value ^B	Overall PEC _{soil} , accumulation ^C	Overall PEC _{soil} , accumulation ^D	Overall PEC _{soil} , accumulation ^F
		Soil depth	DT ₅₀ ^A	C _{low} 7 of years	C _{low} 10 of years	C _{low} 20 of years				

	[gCu./ha]	[cm]		[mg/kg]			[mg/kg]			
Solanaceous fruits (tomato, aubergine)	1 x 3600	5	Not relevant	33.6	48	96	13	46.6	61	109
							26	59.6	74	122
							15	48.6	63	78

^A Copper is an element so DT₅₀ value is not relevant
^B overall median value, 90th percentile, overall mean value in European arable
^C Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 7 years
^D Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 10years
^F Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 20years

Individual Crop	Rate per Season	PEC _{soil} accumulation calculation					Background Monitoring Value ^B	Overall PEC _{soil, accumulation} ^C	Overall PEC _{soil, accumulation} ^D	Overall PEC _{soil, accumulation} ^F
		Soil depth	DT ₅₀ ^A	C _{low} 7 of years	C _{low} 10 of years	C _{low} [20 of years]				
				[mg/kg]						
Pome fruits (apple, pear, quince)	1 x 3600	5	Not relevant	33.6	48	96	48	81.6	96	144
							58	91.6	106	154
							22	55.6	70	118

^A Copper is an element so DT₅₀ value is not relevant
^B overall median value, 90th percentile, overall mean value in European orchards
^C Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 7 years
^D Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 10years
^F Overall PEC_{soil, accumulation} = Background monitoring value + C_{low} + PEC_{soil, initial} over 20years

Modelling results are acceptable and are appropriate to be used for the subsequent risk assessment for soil organisms.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

EU agreed endpoints are used for the risk assessment.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1	2	3	4
Crop	Grapevine	Potato	Solanaceous fruits	Pome fruits (apple, pear, quince)
Scenario	Vines	Potatoes	Tomato	Apple
Application rate (g Cu /ha)	Copper- oxychloride : 4000		Copper oxychloride : 3600	

Number of applications/interval (d)	4/10		3/10	
Crop interception (%)	60	±5	50	60
	0 (For calculations)			
Frequency of application	annual			
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3			

Table 8.8-2: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)*			
	Vines (BBCH 15)	Potatoes (BBCH 15)	Tomatoes (BBCH 15)	Apple (BBCH 15)
Châteaudun	22/04	07/05	19/05	09/04
Hamburg	14/05	20/05	-	26/04
Jokioinen	-	17/06	-	13/05
Kremsmünster	14/05	20/05	-	26/04
Okehampton	-	10/05	-	05/04
Piacenza	22/04	26/04	19/05	09/04
Porto	08/04	05/03	31/03	29/03
Sevilla	14/04	08/02	23/04	26/03
Thiva	03/04	09/03	19/04	29/03

*According to AppDate v3.05 (30 April 2019)

8.8.2.1 Copper oxychloride

In FOCUS groundwater models substance sorption to soil is described solely by interaction with organic material. The adsorption properties of the Cu²⁺ ion is not limited to organic carbon binding and other significant processes occur, many of which are effectively irreversible. Many of the copper species formed are only sparingly soluble and are therefore less likely to be affected by any downward movement of water in the soil. Furthermore, important binding processes for the Cu²⁺ ion, such as adsorption to clay and mineral oxides can occur at all depths in the soil column and not just at the surface layer as is the case for organic matter interactions.

It should be noted that the FOCUS models are not designed or validated to predict the behaviour of metals in the environment. Nevertheless an assessment of the potential for copper to reach groundwater according to standard FOCUS modelling has been conducted and is shown below.

A review of the existing monitoring programmes and published literature on copper levels in groundwater has been conducted (EFSA Journal 2018; 16(1):5152.). Generally natural levels of copper in groundwater were low, with background concentrations ranging from <0.63 to 25 µg/L, with the exception of volcanic aquifers. In the upper soil layers, typical copper concentrations in soil water and leachate from field leaching and lysimeter studies ranged from 1 to 90 µg/L, with a peak concentration of 164.2 µg/L detected at a depth of 25 cm.

A review of copper levels in groundwater aquifers with possible anthropogenic inputs detected a range of concentrations from <LOD to 39 µg/L, with a peak concentration of 90 µg/L. Typical

concentrations in ranged from < 0.1 to 18 µg/L which is within the range of natural background levels. Copper concentrations never approach the legal limit of 2 mg/L set by the European Drinking Water Directive (98/83/EC7) for groundwater. Furthermore the copper concentrations are generally below the threshold values established for copper in European Member States as reported by the commission in the following report Brussels, 5.3.2010 C(2010) 1096 final; and sec (2010) 166 final except for Finland and partly the UK see table below. It should be noted that in this context 29 out of the 33 groundwater bodies considered by member states to be at risk with regard to copper have no (Finland) or only very limited (UK, grapes only) uses of copper as a plant protection product. Overall concentrations of copper in groundwater are not of concern and are the result of natural background or sources other than copper fungicides.

Member state	Threshold value	Unit	GWB at risk	GWB at poor status
Austria	2	mg/L	no	no
Belgium	100	µg/L	1	no
Bulgaria	2	mg/L	1	no
Cyprus	No threshold value			
Czech Republic	No threshold value			
Denmark	No threshold value			
Estonia	No threshold value			
Finland	20	µg/L	3	2
France	No threshold value			
Germany	No threshold value			
Greece	No threshold value			
Hungary	No threshold value			
Ireland	1500	µg/L	no	no
Italy	No threshold value			
Latvia	No threshold value			
Lithuania	No threshold value			
Luxembourg	No threshold value			
Malta	1	mg/L	no	no
The Netherlands	No threshold value			
Poland	0.2	mgCu/L	1	no
Portugal	No threshold value			
Romania	No threshold value			
Slovak Republic	500.2 - 504.5	µg/L	no	no
Slovenia	No threshold value			
Spain	2	mg/L	1	-
Sweden	No threshold value			
United Kingdom	10.1 - 1500	µg/L	26	14

GWB = ground water bodies

An additional study has looked at the levels of copper in bottled drinking water across Europe as being representative of ground water across Europe and has been summarised below.

Reference:	CP 9.2.4/01, xxxx, A. et al , 2012
Title:	European Ground Water Geochemistry Using Bottled Water as a Sampling Medium
Report No.:	Clean Soil and Safe Water
Guidelines:	Not Applicable
Deviations:	No
GLP:	No
Published	Literature
Comment:	-

In a further study a total of 1785 bottled waters were purchased from supermarkets in 40 European countries that represented 1247 wells/drill holes/springs at 884 locations and were representative of groundwater across Europe. Each of the bottled waters were analysed for 72 parameters which included the concentration of copper at the laboratories of the Federal Institute for Geosciences and Natural Resources (BGR) in Germany.

	Minimum	Median	Maximum
Copper at µg/L	<0.1	0.27	100

The levels of copper in the bottled water purchased from across Europe and deemed to be representative of the ground water from where they had been sampled was found to be between < 0.1 and 100 µg/L.

Table 8.8-3: Input parameters related to active substance Copper oxychloride for PEC_{gw} calculations

Parameter	Unit	Total Copper	Comment
Molar mass	[g/mol]	63.54	-
Water solubility	[mg/L]	500	at 20°C, pH 5.6 LoEP EFSA Journal 2018; 16(1):5152
Vapour Pressure	[Pa]	0	Not applicable inorganic solid with negligible volatility.
K _{foc} /K _{fom}	[mL/g]	19509.9	Geometric mean calculated from soils pH range 4-5 LoEP EFSA Journal 2018; 16(1):5152
K _d		1643 used in modelling	Median value M-CA Section 7, Point 7.1.3.1.1
Freundlich Exponent	[-]	1	Conservative default value
DT ₅₀	[days]	1000000	Appropriate value to simulate no degradation LoEP EFSA Journal 2018; 16(1):5152
Plant uptake factor	[-]	0	Assumed non systemic

A K_d and 1/n values of 1643 and 1 respectively throughout the soil profile were used in the kinetic groundwater modelling, EFSA recommended that a value of 19509.9 should be used. As the value used was far more conservative than the value recommended by EFSA but still resulted in copper concentrations in groundwater that were predicted to be < 0.001 µg/L in all of the relevant FOCUS scenarios and never approach the legal limit of 2 mg/L set by the European Drinking water directive (98/83/EC7) for groundwater the data has not been remodel with the EFSA value.

The notifier 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. Nevertheless there are no concerns for groundwater from use of copper in accordance with the use pattern for the current formulations. Copper concentrations in groundwater were predicted to be < 0.001 µg/L in all of the relevant FOCUS scenarios and never approach the legal limit of 2 mg/L set by the European Drinking water directive (98/83/EC7) for groundwater. Should MS require modelling instead of argumentation by monitoring data they should provide appropriate models to applicants for Art.43 submissions.

Table 8.8-4: Adsorption data for Copper used in the FOCUS modelling

Scenario	Horizon	Depth (cm)	Kd (mL/kg)	1/n	Degradation transformation factor
Châteaudun	1	0-25	1643	1	1.0
	2	25-50			0.5
	3	50-60			0.5
	4	60-100			0.3
	5	100-120			0.0
	6	120-190			0.0
	7	190-260			0.0
Hamburg	1	0-30			1.0
	2	30-60			0.5
	3	60-75			0.3
	4	75-90			0.3
	5	90-100			0.3
	6	100-200			0.0
Jokioinen	1	0-30			1.0
	2	30-60			0.5
	3	60-75			0.3
	4	75-90			0.3
	5	90-100			0.0
	6	100-200			0.0
Kremsmünster	1	0-30			1.0
	2	30-50			0.5
	3	50-60			0.5
	4	60-100			0.3
	5	100-200			0.0
Okehampton	1	0-25			1.0
	2	25-55	0.5		
	3	55-85	0.3		
	4	85-100	0.3		
	5	100-150	0.0		
Piacenza	1	0-30	1.0		
	2	30-40	0.5		
	3	40-60	0.5		
	4	60-80	0.3		
	5	80-100	0.3		
	6	100-170	0.0		
Porto	1	0-35	1.0		
	2	35-60	0.5		
	3	60-100	0.3		
	4	100-120	0.0		
Sevilla	1	0-10	1.0		
	2	10-30	1.0		
	3	30-60	0.5		

	4	60-100			0.3
	5	100-120			0.0
	6	120-180			0.0
Thiva	1	0-30			1.0
	2	30-45			0.5
	3	45-60			0.5
	4	60-85			0.3
	5	85-100			0.3
	6	100-200			0.0

Table 8.8-5: PEC_{gw} for Copper oxychloride on vine with FOCUS PEARL 4.4.4 and PELMO 5.5.3 (1 x 4000 g/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		PEARL	PELMO
Vines	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8-6: PEC_{gw} for Copper oxychloride on potatoes with FOCUS PEARL 4.4.4 and PELMO 5.5.3 (1 x 3600 g/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		PEARL	PELMO
Potatoes	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8-7: PEC_{gw} for Copper oxychloride on tomatoes with FOCUS PEARL 4.4.4 and PELMO 5.5.3 (1 x 3600 g/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		PEARL	PELMO
Tomato	Châteaudun	< 0.001	< 0.001

	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8-8: PEC_{gw} for Copper oxychloride on apple with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 (1 x 3600 g/ha)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		PEARL	PELMO
Apple	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

zRMS comments:

The submitted PEC_{gw} assessment was accepted for proposed pattern use. The used endpoints are consistent with LoEP (EFSA 2018) and the worst case was considered (interception 0%).

The predicted concentrations for copper on application to potato, vines, apples and tomato were lower than to the regulatory threshold 0.1 µg/L in groundwater at 1 m depth in all scenario with PELMO model and PEARL. The groundwater monitoring data set provides evidence, that measured copper concentrations in groundwater are usually higher than 0.1 µg/L but not exceed the legal limit of 2 mg/L set by the European Drinking Water Directive (98/83/EC7) for groundwater. PEC_{gw} for all crop in the GAP for all scenarios are below the legal limit of 2 mg/L. The calculations cover proposed uses in GAP.

zRMS recommends to Member States to consider the monitoring data, if available, at the national level.

Member States must take account of the occurrence of peak levels (monitoring) that may cause adverse effects on human health.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

EU agreed endpoints are used for the risk assessment.

8.9.2 Active substance, relevant metabolites and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for PEC_{SW/SED} calculations

Use No.	1	2	3	4
Crop	Grapevine	Potato	Solanaceous fruits	Pome fruits (apple, pear, quince)
Scenario	Vines	Potatoes	Fruiting vegetables	Apple
Application rate (g asCu/ha)	Copper oxychloride : 1000	Copper oxychloride : 1000		
Number of applications/interval (d)	4/10	3/10		
Crop interception	Minimal			
	No interception for calculations			
Application window	March-May (early) Oct-Feb (late)	March-May		March-May (early) June-Sep (late)
Application method	Foliar spray			
CAM (Chemical application method)	-			
Soil depth (cm)	-			
Models used for calculation	FOCUS STEPS 1-2 v3.1			

8.9.2.1 Copper oxychloride

A review of the existing monitoring programs and published literature on copper levels in surface water has been conducted (EFSA Journal 2018; 16(1):5152. & 10.2903/sp.efsa.2018.EN-1486). Generally natural levels of dissolved copper in surface water ranged over two orders of magnitude, from <0.08 to 14.6 µg/L, with a median value of 0.88 µg/L (807 samples). An additional review of monitoring data conducted during 2014 to 2016 by JRC showed that dissolved copper concentrations in inland surface waters ranged from 0.01 to 10,000 µg/L, with a median value of 1.97 µg/L, (n = 104254 samples). Dissolve copper concentrations in vineyard catchments ranged from 0 to 117 µg/L (n = 326 samples) and from agricultural catchments ranged from <LOQ to 9.77 µg/L (n = 139 samples).

The applicant would firstly 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.

Predicted concentration in surface water has been calculated for copper as follows:

Standard FOCUS Step 1 and 2 PEC_{sw} values are described below and have been calculated as prescribed by EFSA in the (EFSA Journal 2018; 16(1):5152. & 10.2903/sp.efsa.2018.EN-1486) for vines late application as worst case covering all field crops also:

PEC_{sw} without spray drift mitigation:

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

PEC_{sw} with spray drift mitigation:

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

- 1) Focus Step 1 and 2 values were firstly calculated with the no spray drift option to derive the PEC from runoff and drainage only. Mitigation measures for 5, 10, 15 or 20 m of vegetative buffer strip (40%, 60%, 70% or 80% of reduction for surface water) 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 applicants would like to point out that on page 15 of the EFSA conclusion that they are pleased to see that EFSA recognizes that due to the very rapid dissipation of copper (Cu²⁺ 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.

As described above, the spray drift scenario starts with a non-equilibrium phase during which total copper dissipates with a DT₅₀ of < 1 day (xxx 2016). Any free copper ions also dissipate with < 1 day (xx 2008). The system will reach an equilibrium stage within ca. 24 hours, and the resulting dissolved copper concentration will be a function of the water chemistry (pH, DOC, hardness, etc.).

Therefore a DT₅₀ of < 1 day is appropriate and the single application scenario shall be presented as the worst-case scenario in Art.43 33 evaluations.

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 xxx 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.43 33 evaluation should apply a total to dissolved copper ratio of at least 3.

Table 8.9-2: Input parameters related to active substance Copper oxychloride for PEC_{sw/sed} calculations STEP 1/2

Compound	Copper oxychloride	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	63.54	EFSA Journal 2018;16(1):5152
Vapour pressure (Pa)	0	
Water solubility (mg/L)	500 at 20°C, pH 4 to 6	
K _{foc} (mL/g)	33918.3 (geomean, from soils)	

Compound	Copper oxychloride	Value in accordance to EU endpoint y/n/ Reference
	pH 5.5-6.5, used on PEC _{sw} calculations) 10000 (For PEC _{sed} calculations)	
DT _{50,soil} (d)	1000 (maximum value accepted by model)	
DT _{50,water} (d)		
DT _{50,sed} (d)		
DT _{50,whole system} (d)		
Maximum occurrence observed (% molar basis with respect to the parent)	60% in water 50% in sediment	
Background copper level in sediment	17 mg/kg	

PEC_{sw/sed}

~~Due to ecotox Polish expert requirements new calculations have been carried out only for dissolved Copper.~~

~~Table 8.9-3: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to vines early application (all entry routes to water bodies considered)~~

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	—	16.21	All routes	7.56	2510
Step 2					
Southern Europe	March-May	9.00	All routes	3.00	1040
Northern Europe				1.81	553.28

~~Table 8.9-4: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to vines early application (only entry routes by runoff/drainage to water bodies considered)~~

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	—	7.21	Runoff / drainage	7.16	2450
Step 2					
Southern Europe	March-May	2.88	Runoff / drainage	2.86	975.66

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Northern Europe		1.44		1.43	487.83

Table 8.9-5: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to vines early application (only entry routes by drift to water bodies considered)

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step-1	—	16.21	Drift	7.56	2510
Step-2					
Southern Europe	March-May	9.00	Drift	0.69	64.97
Northern Europe					

Table 8.9-6: FOCUS Step 2 maximum drift values for active substance copper following a single application to vines early application (drift mitigation considered)

Uses	Buffer (m)		
	3	5	10
Vines-BBCH 15 Early drift rates	2.1372	1.0244	0.3606

Table 8.9-7: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to vines early application (drift mitigation considered)

Distance (m)	PEC _{sw} (µg/L)	Nozzles reduction		
		50%	75%	90%
3	7.12	3.56	1.78	-
5	3.41	1.71	-	-
10	1.20	-	-	-

Table 8.9-8: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to vines early application (runoff/drainage plus spray drift with mitigation measures)

Distance (m)	PEC _{sw} (µg/L) (considering Run-off/drainage only)	PEC _{sw} (µg/L) (considering drift only)	Nozzles reduction		PEC _{sw} (µg/L) (Total)
			50%	75%	
3	2.88*	7.12	-	1.78	4.66
5		3.41	1.71	-	4.59
10		1.20	-	-	4.08

*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 xxx 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.43 33 evaluation should apply a total to dissolved copper ratio of at least 3.

Table 8.9-9: FOCUS Step 2 PEC_{sw} values for active substance DISSOLVED copper following a single application to vines early application without mitigation measures considering all entry routes

Max dissolved PEC _{sw} (considering only drift route) (µg/L)	Max dissolved PEC _{sw} (considering only runoff and drainage routes) (µg/L)
3.00	0.96*

*Worst case from Southern calculations

Max dissolved PEC _{sw} (considering all entry routes) (µg/L)
3.00

Table 8.9-9 bis: Drift values from FOCUS Drift calculator v1.1 for Vines early and single application

Buffer (m)											
5	10	14	20	30	40	50	60	70	80	90	100
1.024	0.360	0.214	0.122	0.064	0.041	0.028	0.021	0.016	0.013	0.011	0.031

Table 8.9-9 bis 1: Mitigation measures for active substance DISSOLVED copper following a single application to vines early application (runoff/drainage (5m-of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
5	1.71	0.857	0.429	0.171	0.086
10	0.98	0.488	0.244	0.098	0.049
14	0.81	0.407	0.204	0.081	0.041
20	0.71	0.356	0.178	0.071	0.036
30	0.65	0.324	0.162	0.065	0.032
40	0.62	0.311	0.155	0.062	0.031
50	0.61	0.304	0.152	0.061	0.030

60	0.60	0.300	0.150	0.060	0.030
70	0.50	0.297	0.149	0.059	0.030
80	0.50	0.296	0.148	0.059	0.030
90	0.50	0.294	0.147	0.059	0.029
100	0.50	0.293	0.147	0.059	0.029

Table 8.9.9 bis 2: — Mitigation measures for active substance DISSOLVED copper following a single application to vines early application (runoff/drainage (10m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
10	0.78	0.392	0.196	0.078	0.039
14	0.62	0.311	0.156	0.062	0.031
20	0.52	0.260	0.130	0.052	0.026
30	0.46	0.228	0.114	0.046	0.023
40	0.43	0.215	0.107	0.043	0.021
50	0.42	0.208	0.104	0.042	0.021
60	0.41	0.204	0.102	0.041	0.020
70	0.40	0.201	0.101	0.040	0.020
80	0.40	0.200	0.100	0.040	0.020
90	0.40	0.198	0.099	0.040	0.020
100	0.39	0.197	0.099	0.039	0.020

Table 8.9.9 bis 3: — Mitigation measures for active substance DISSOLVED copper following a single application to vines early application (runoff/drainage (15m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
14	0.43	0.215	0.108	0.043	0.022
20	0.33	0.164	0.082	0.033	0.016
30	0.26	0.132	0.066	0.026	0.013
40	0.24	0.119	0.059	0.024	0.012
50	0.22	0.112	0.056	0.022	0.011
60	0.22	0.108	0.054	0.022	0.011
70	0.21	0.105	0.053	0.021	0.011
80	0.21	0.104	0.052	0.021	0.010
90	0.20	0.102	0.051	0.020	0.010
100	0.20	0.101	0.051	0.020	0.010

Table 8.9.9 bis 4: — Mitigation measures for active substance DISSOLVED copper following a single application to vines early application (runoff/drainage (20m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes	Nozzles %			
		50	75	90	95

	($\mu\text{g/L}$)				
20	0.28	0.140	0.070	0.028	0.014
30	0.22	0.108	0.054	0.022	0.011
40	0.19	0.095	0.047	0.019	0.009
50	0.18	0.088	0.044	0.018	0.009
60	0.17	0.084	0.042	0.017	0.008
70	0.16	0.081	0.041	0.016	0.008
80	0.16	0.080	0.040	0.016	0.008
90	0.16	0.078	0.039	0.016	0.008
100	0.15	0.077	0.039	0.015	0.008

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 10000 mL/g values are added to a median background level of copper in European sediments of 17 mg/kg.

Table 8.9-10: FOCUS Step 1 PEC_{sed} values for active substance copper following a single application to vines early application considering all entry routes without mitigation measures

PEC _{sed} (mg/kg)	PEC _{sed, accu} (7 years accumulation) (mg/kg)	Background (mg/kg)	PEC _{sed-TOTAL} (mg/kg)
2.39	16.73	17.0	33.73

Table 8.9-11: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to vines late application (worst case) (all entry routes to water bodies considered)

Scenario	Waterbody	Max PEC _{sw} ($\mu\text{g/L}$)	Dominant entry route	21-d-PEC _{sw, twa} ($\mu\text{g/L}$)	Max PEC _{sed} ($\mu\text{g/kg}$)
FOCUS					
Step-1	—	33.97	All routes	8.36	2640
Step-2					
Southern Europe	Oct-Feb	26.76	All routes	4.22	1170
Northern Europe				3.03	683.17

Table 8.9-12: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to vines late application (worst case) (only entry routes by runoff/drainage to water bodies considered)

Scenario	Waterbody	Max PEC _{sw} ($\mu\text{g/L}$)	Dominant entry route	21-d-PEC _{sw, twa} ($\mu\text{g/L}$)	Max PEC _{sed} ($\mu\text{g/kg}$)
FOCUS					
Step-1	—	7.21	Runoff/Drainage	7.16	2450
Step-2					
Southern Europe	Oct-Feb	2.88	Runoff/Drainage	2.86	975.66

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Northern Europe		3.60		3.57	1220

Table 8.9-13: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to vines late application (worst case) (only entry routes by drift to water bodies considered)

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	—	33.97	Drift	8.36	2640
Step 2					
Southern Europe	Oct-Feb	26.76	Drift	2.07	193.24
Northern Europe					

Table 8.9-14: FOCUS Step 2 maximum drift values for active substance copper following a single application to vines late application (worst case) (drift mitigation considered)

Uses	Buffer (m)					
	3	5	10	14	20	30
Vines BBCH 85						0.2134
Late drift rates – BBCH 85 onwards	6.3955	3.1278	1.1329	0.6833	0.3974	0.0648
						0.2189

Table 8.9-15: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to vines late application (worst case) (drift mitigation considered)

Distance (m)	PEC _{sw} (µg/L)	Nozzles reduction		
		50%	75%	90%
3	21.32	10.66	5.33	2.13
5	10.43	5.22	2.61	1.04
10	3.78	1.89	0.95	-
14	2.28	1.14	-	-
20	1.32 (94%)	0.66	-	-

Table 8.9-16: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to vines late application (worst case) (runoff/drainage plus spray drift with mitigation measures)

Distance (m)	PEC _{sw} (µg/L) (considering Run-off/drainage only)	PEC _{sw} (µg/L) (considering drift only)	Nozzles reduction			PEC _{sw} (µg/L) (Total)
			50%	75%	90%	
3	3.60*	21.32	-	-	2.13	5.73
5		10.43	-	-	1.04	4.64
10		3.78	-	0.95	-	4.55

14		2.28	1.14	-	-	4.74
20		1.32	0.66	-	-	4.26

*Worst case from Northern calculations

Table 8.9-17: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to vines late application (worst case) (runoff/drainage with 60% of reduction (10m of vegetative strip buffer) plus spray drift with mitigation measures)

PEC _{sw} (µg/L) (considering Runoff/drainage only)	PEC _{sw} (µg/L) (considering 10m of vfs)	Distance (m)	PEC _{sw} (µg/L) (considering drift only)	Nozzles reduction			PEC _{sw} (µg/L) (Total)
				50%	75%	90%	
3.60*	1.44	10	3.78	1.89	-	-	3.33
		14	2.28	-	-	-	3.72
		20	1.32	-	-	-	2.76

*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 xxxx 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.43 33 evaluation should apply a total to dissolved copper ratio of at least 3.

Table 8.9-18: FOCUS Step 2 PEC_{sw} values for active substance DISSOLVED copper following a single application to vines late application without mitigation measures considering all entry routes

Max dissolved PEC _{sw} (considering only drift route) (µg/L)	Max dissolved PEC _{sw} (considering only runoff and drainage routes) (µg/L)
8.92	1.20*

*Worst case from Northern calculations

Table 8.9-18: FOCUS Step 2 PEC_{sw} values for active substance DISSOLVED copper following a single application to vines late application (worst case)

Max dissolved PEC _{sw} (considering all en- try routes) (µg/L)	Max dissolved PEC _{sw} (considering only drift) (µg/L)			Max dissolved PEC _{sw} (considering only run-off/drainage) (µg/L)
	Distance (m)	%Nozzles	PEC _{sw}	
8.92	3	50	3.55	1.20*
	5	50	1.74	
	10	-	1.26	

*From Northern calculations (worst case)

Table 8.9-18 bis: Drift values from FOCUS Drift calculator v1.1 for Vines late and single application

Buffer (m)											
5	10	14	20	30	40	50	60	70	80	90	100
3.1278	1.1320	0.6833	0.3974	0.2134	0.1369	0.0969	0.0731	0.0575	0.0467	0.0389	0.0330

Table 8.9-18 bis 1: Mitigation measures for active substance DISSOLVED copper following a single application to vines late application (runoff/drainage (5m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
5	4.20	2.098	1.049	0.420	0.210
10	1.08	0.980	0.495	0.198	0.099
14	1.48	0.740	0.370	0.148	0.074
20	1.16	0.581	0.290	0.116	0.058
30	0.96	0.470	0.230	0.096	0.048
40	0.87	0.436	0.218	0.087	0.044
50	0.83	0.414	0.207	0.083	0.041
60	0.80	0.401	0.200	0.080	0.040
70	0.78	0.392	0.196	0.078	0.039
80	0.77	0.386	0.193	0.077	0.039
90	0.76	0.382	0.191	0.076	0.038
100	0.76	0.378	0.189	0.076	0.038

Table 8.9-18 bis 2: Mitigation measures for active substance DISSOLVED copper following a single application to vines late application (runoff/drainage (10m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
10	1.74	0.869	0.435	0.174	0.087
14	1.24	0.620	0.310	0.124	0.062
20	0.92	0.461	0.230	0.092	0.046
30	0.72	0.359	0.179	0.072	0.036
40	0.63	0.316	0.158	0.063	0.032
50	0.59	0.294	0.147	0.059	0.029
60	0.56	0.281	0.140	0.056	0.028
70	0.54	0.272	0.136	0.054	0.027
80	0.53	0.266	0.133	0.053	0.027
90	0.52	0.262	0.131	0.052	0.026
100	0.52	0.258	0.129	0.052	0.026

Table 8.9-18 bis 3: Mitigation measures for active substance DISSOLVED copper following a single application to vines late application (runoff/drainage (15m-of vegetative-buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
14	1.00	0.500	0.250	0.100	0.050
20	0.68	0.341	0.170	0.068	0.034
30	0.48	0.239	0.119	0.048	0.024
40	0.39	0.196	0.098	0.039	0.020
50	0.35	0.174	0.087	0.035	0.017
60	0.32	0.161	0.080	0.032	0.016
70	0.30	0.152	0.076	0.030	0.015
80	0.29	0.146	0.073	0.029	0.015
90	0.28	0.142	0.071	0.028	0.014
100	0.28	0.138	0.069	0.028	0.014

Table 8.9-18 bis 4: Mitigation measures for active substance DISSOLVED copper following a single application to vines late application (runoff/drainage (20m-of vegetative-buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
20	0.62	0.311	0.155	0.062	0.031
30	0.42	0.209	0.104	0.042	0.021
40	0.33	0.166	0.083	0.033	0.017
50	0.29	0.144	0.072	0.029	0.014
60	0.26	0.131	0.065	0.026	0.013
70	0.24	0.122	0.061	0.024	0.012
80	0.23	0.116	0.058	0.023	0.012
90	0.22	0.112	0.056	0.022	0.011
100	0.22	0.108	0.054	0.022	0.011

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 10000 mL/g values are added to a median background level of copper in European sediments of 17 mg/kg.

Table 8.9-19: FOCUS Step 1 PEC_{sed} values for active substance copper following a single application to vines late application (worst case) considering all entry routes without mitigation measures

PEC _{sed} (mg/kg)	PEC _{sed, accu} (7-years accumulation) (mg/kg)	Background (mg/kg)	PEC _{sed} TOTAL (mg/kg)
2.51	17.57	17.0	34.57

Table 8.9-20: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to potatoes and solanaceous (fruiting vegetables) (all entry routes to water bodies considered)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	—	19.69	All routes	9.08	3010
Step 2					
Southern Europe	March-May	11.04	All routes	3.62	1250
Northern Europe				2.19	665.69

Table 8.9-21: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to potatoes and solanaceous (fruiting vegetables) (only entry routes by runoff/drainage to water bodies considered)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	—	8.65	Runoff/drainage	8.59	2940
Step 2					
Southern Europe	March-May	3.45	Runoff/drainage	3.43	1170
Northern Europe		1.73		1.71	585.39

Table 8.9-22: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to potatoes and solanaceous (fruiting vegetables) (only entry routes by drift to water bodies considered)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	—	19.69	Drift	9.08	3010
Step 2					
Southern Europe	March-May	11.04	Drift	0.85	79.69
Northern Europe					

Table 8.9-23: FOCUS Step 2 maximum drift values for active substance copper following a single application to potato and solanaceous (fruiting vegetables) (drift mitigation considered)

Uses	Buffer (m)		
	3	5	10

Potatoes	0.8160	0.5224	0.2711
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~~Table 8.9-24: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to potatoes and solanaceous (fruiting vegetables) (drift mitigation considered)~~

Distance (m)	PEC _{sw} (µg/L)	Nozzles reduction		
		50%	75%	90%
3	3.264	1.632	0.816	-
5	2.090	1.045	-	-
10	1.108	-	-	-

~~Table 8.9-26: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to potatoes and solanaceous (fruiting vegetables) (runoff/drainage plus spray drift with mitigation measures)~~

Distance (m)	PEC _{sw} (µg/L) (considering Runoff/drainage only)	PEC _{sw} (µg/L) (considering drift only)	Nozzles reduction			PEC _{sw} (µg/L) (Total)
			50%	75%	90%	
3	3.45*	3.264	-	0.816	-	4.27
5		2.090	1.045	-	-	4.50
10		1.108	-	-	-	4.56

*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 xxx 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.43 [33](#) evaluation should apply a total to dissolved copper ratio of at least 3.

~~Table 8.9-27: FOCUS Step 2 PEC_{sw} values for active substance DISSOLVED copper following a single application to potatoes and solanaceous (fruiting vegetables) without mitigation measures considering all entry routes~~

Max-dissolved PEC _{sw} (considering only drift route) (µg/L)	Max-dissolved PEC _{sw} (considering only runoff and drainage routes) (µg/L)
3.68	4.15*

*Worst case from Southern calculations

Max dissolved PEC _{sw} (considering all entry routes) (µg/L)

3.68

Table 8.9-27 bis: Drift values from FOCUS Drift calculator v1.1 for field crops single application

Buffer (m)											
5	10	14	20	30	40	50	60	70	80	90	100
0.5224	0.2771	0.202	0.144	0.0976	0.074	0.0596	0.05	0.043	0.0378	0.0337	0.0304

Table 8.9-27 bis 1: Mitigation measures for active substance DISSOLVED copper following a single application to potatoes and solanaceous (fruiting vegetables) (runoff/drainage (5m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (ug/L)	Nozzles %			
		50	75	90	95
5	1.39	0.693	0.347	0.139	0.069
10	1.06	0.530	0.265	0.106	0.053
14	0.96	0.480	0.240	0.096	0.048
20	0.88	0.441	0.220	0.088	0.044
30	0.82	0.410	0.205	0.082	0.041
40	0.79	0.394	0.197	0.079	0.039
50	0.77	0.385	0.192	0.077	0.038
60	0.76	0.378	0.189	0.076	0.038
70	0.75	0.374	0.187	0.075	0.037
80	0.74	0.370	0.185	0.074	0.037
90	0.73	0.367	0.184	0.073	0.037
100	0.73	0.365	0.183	0.073	0.037

Table 8.9-27 bis 2: Mitigation measures for active substance DISSOLVED copper following a single application to potatoes and solanaceous (fruiting vegetables) (runoff/drainage (10m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (ug/L)	Nozzles %			
		50	75	90	95
10	0.82	0.415	0.207	0.082	0.041
14	0.73	0.365	0.182	0.073	0.036
20	0.65	0.326	0.163	0.065	0.033
30	0.59	0.295	0.148	0.059	0.030
40	0.56	0.279	0.140	0.056	0.028
50	0.54	0.270	0.135	0.054	0.027
60	0.53	0.263	0.132	0.053	0.026
70	0.52	0.259	0.129	0.052	0.026
80	0.51	0.255	0.128	0.051	0.026
90	0.50	0.252	0.126	0.050	0.025
100	0.50	0.250	0.125	0.050	0.025

Table 8.9-27 bis 3: Mitigation measures for active substance DISSOLVED copper following a single application to potatoes and solanaceous (fruiting vegetables) (runoff/drainage (15m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
14	0.50	0.250	0.125	0.050	0.025
20	0.42	0.211	0.105	0.042	0.021
30	0.36	0.180	0.090	0.036	0.018
40	0.33	0.164	0.082	0.033	0.016
50	0.31	0.155	0.077	0.031	0.015
60	0.30	0.148	0.074	0.030	0.015
70	0.29	0.144	0.072	0.029	0.014
80	0.28	0.140	0.070	0.028	0.014
90	0.27	0.137	0.069	0.027	0.014
100	0.27	0.135	0.068	0.027	0.014

Table 8.9-27 bis 4: Mitigation measures for active substance DISSOLVED copper following a single application to potatoes and solanaceous (fruiting vegetables) (runoff/drainage (20m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
20	0.36	0.182	0.091	0.036	0.018
30	0.30	0.151	0.076	0.030	0.015
40	0.27	0.136	0.068	0.027	0.014
50	0.25	0.126	0.063	0.025	0.013
60	0.24	0.120	0.060	0.024	0.012
70	0.23	0.115	0.057	0.023	0.011
80	0.22	0.111	0.056	0.022	0.011
90	0.22	0.109	0.054	0.022	0.011
100	0.21	0.107	0.053	0.021	0.011

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 10000 mL/g values are added to a median background level of copper in European sediments of 17 mg/kg.

Table 8.9-28: FOCUS Step 1 PEC_{sed} values for active substance copper following a single application to potatoes and solanaceous (fruiting vegetables) considering all entry routes without mitigation measures

PEC _{sed} (mg/kg)	PEC _{sed, accu} (7 years accumulation) (mg/kg)	Background (mg/kg)	PEC _{sed} TOTAL (mg/kg)
2.87	20.09	17.0	37.09

Table 8.9-29: ~~FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to apple early application (worst case) (all entry routes to water bodies considered)~~

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	—	125.44	All routes	13.82	3790
Step 2					
Southern Europe	March-May	116.79	All routes	10.89	2020
Northern Europe				9.46	1440

Table 8.9-30: ~~FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to apple early application (worst case) (only entry routes by runoff/drainage to water bodies considered)~~

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	—	8.65	Runoff / drainage	8.59	2940
Step 2					
Southern Europe	March-May	3.45	Runoff / drainage	3.43	1117
Northern Europe		1.73		1.71	585.39

Table 8.9-31: ~~FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to apple early application (worst case) (only entry routes by drift to water bodies considered)~~

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	—	125.44	Drift	13.82	3790
Step 2					
Southern Europe	March-May	116.79	Drift	9.02	843.36

Table 8.9-32: ~~FOCUS Step 2 maximum drift values for active substance copper following a single application to apple early application (worst case) (drift mitigation considered)~~

Uses	Buffer (m)					
	3	5	10	14	20	25
Apple-BBCH 15 Early drift rates	26.1192	18.5428	11.3873	6.0208	2.6039	1.5356

Table 8.9-33: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to apple early application (worst case) (drift mitigation considered)

Distance (m)	PEC _{sw} (µg/L)	Nozzles reduction		
		50%	75%	90%
3	104.48	52.24	26.12	10.45
5	74.17	37.09	18.54	7.42
10	45.55	22.78	11.39	4.56
14	24.08	12.04	6.02	2.41
20	10.42	5.21	2.61	1.04
25	6.14 (94.7%)	3.07	1.54	0.61

Table 8.9-34: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to apple early application (worst case) (run-off/drainage plus spray drift with mitigation measures)

Distance (m)	PEC _{sw} (µg/L) (considering Run-off/drainage only)	PEC _{sw} (µg/L) (considering drift only)	Nozzles reduction			PEC _{sw} (µg/L) (Total)
			50%	75%	90%	
20	3.45*	10.42	-	-	1.04	4.49
25		6.14	-	-	0.61	4.06

*Worst case from Southern calculations

Table 8.9-35: FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to vines late application **apple early application** (worst case) (runoff/drainage with 60% of reduction (10m of vegetative strip buffer) plus spray drift with mitigation measures)

PEC _{sw} (µg/L) (considering Runoff/drainage only)	PEC _{sw} (µg/L) (considering 10m of vfs)	Distance (m)	PEC _{sw} (µg/L) (considering drift only)	Nozzles reduction			PEC _{sw} (µg/L) (Total)
				50%	75%	90%	
3.45*	1.38	20	10.42	-	2.61	-	3.99
		25	6.14	3.07	-	-	4.45

*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 xxx 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.43 evaluation should apply a total to dissolved copper ratio of at least 3.

Table 8.9-36: FOCUS Step 2 PEC_{sw} values for active substance DISSOLVED copper following a single application to apple early application (worst case)

Max dissolved PEC _{sw} (considering only drift route) (µg/L)	Max dissolved PEC _{sw} (considering only runoff and drainage routes) (µg/L)
38.93	1.15*

*Worst case from Southern calculation.

Max dissolved PEC _{sw} (considering all entry routes) (µg/L)	Max dissolved PEC _{sw} (considering only drift) (µg/L)			Max dissolved PEC _{sw} (considering only run-off/drainage) (µg/L)
	Distance (m)	%Nozzles	PEC _{sw}	
38.93	3	90	3.48	1.15*
	5	90	2.47	
	10	90	1.52	
	14	75	2.01	
	20	-	3.47	

Table 8.9-36 bis: Drift values from FOCUS Drift calculator v1.1 for Apple early and single application

Buffer (m)											
5	10	14	20	30	40	50	60	70	80	90	100
18.542	11.387	6.020	2.603	0.995	0.501	0.294	0.1	0.131	0.095	0.071	0.055
g	g	g	g	g	g	g	g	g	g	g	g

Table 8.9-36 bis-1: Mitigation measures for active substance DISSOLVED copper following a single application to apple early application (runoff/drainage (5m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
5	25.41	12.707	6.353	2.541	1.271
10	15.87	7.937	3.968	1.587	0.794
14	9.72	4.859	2.179	0.872	0.436
20	4.16	2.081	1.040	0.416	0.208
30	2.02	1.009	0.504	0.202	0.101
40	1.36	0.679	0.340	0.136	0.068
50	1.08	0.541	0.271	0.108	0.054
60	0.94	0.472	0.236	0.094	0.047
70	0.86	0.432	0.216	0.086	0.043
80	0.82	0.408	0.204	0.082	0.041
90	0.79	0.393	0.196	0.079	0.039
100	0.76	0.380	0.191	0.076	0.038

Table 8.9-36 bis 2: Mitigation measures for active substance DISSOLVED copper following a single application to apple early application (runoff/drainage (10m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
10	15.64	7.822	3.911	1.564	0.782
14	8.49	4.244	2.122	0.849	0.424
20	3.93	1.966	0.983	0.393	0.197
30	1.79	0.894	0.447	0.179	0.089
40	1.13	0.564	0.282	0.113	0.056
50	0.85	0.426	0.213	0.085	0.043
60	0.71	0.357	0.178	0.071	0.036
70	0.63	0.317	0.159	0.063	0.032
80	0.59	0.293	0.147	0.059	0.029
90	0.56	0.278	0.139	0.056	0.028
100	0.53	0.267	0.134	0.053	0.027

Table 8.9-36 bis 3: Mitigation measures for active substance DISSOLVED copper following a single application to apple early application (runoff/drainage (15m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
14	8.26	4.129	2.064	0.826	0.413
20	3.70	1.851	0.925	0.370	0.185
30	1.56	0.779	0.389	0.156	0.078
40	0.90	0.449	0.225	0.090	0.045
50	0.62	0.311	0.156	0.062	0.031
60	0.48	0.242	0.121	0.048	0.024
70	0.40	0.202	0.101	0.040	0.020
80	0.36	0.178	0.089	0.036	0.018
90	0.33	0.163	0.081	0.033	0.016
100	0.30	0.152	0.076	0.030	0.015

Table 8.9-36 bis 4: Mitigation measures for active substance DISSOLVED copper following a single application to apple early application (runoff/drainage (20m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
20	3.64	1.822	0.911	0.364	0.182
30	1.50	0.750	0.375	0.150	0.075
40	0.84	0.421	0.210	0.084	0.042
50	0.56	0.282	0.141	0.056	0.028
60	0.43	0.213	0.106	0.043	0.021
70	0.35	0.174	0.087	0.035	0.017

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles %			
		50	75	90	95
30	0.30	0.150	0.075	0.030	0.015
90	0.27	0.134	0.067	0.027	0.013
100	0.25	0.123	0.062	0.025	0.012

To calculate the PEC sediment accumulation over seven years, the FOCUS Step 1 sediment via spray drift and run off /drainage with a K_{dec} 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.

Table 8.9-37: FOCUS Step 2 PEC_{sed} values for active substance copper following a single application to apple early application (worst case) considering all entry routes without mitigation measures

PEC _{sed} (mg/kg)	PEC _{sed, accu} (7 years accumulation) (mg/kg)	Background (mg/kg)	PEC _{sed} TOTAL (mg/kg)
1.92*	13.44	17.0	30.44

*From Southern calculations (worst case)

Table 8.9-38: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to apple late application (all entry routes to water bodies considered)

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	—	71.55	All routes	11.41	3390
Step 2					
Southern Europe	March-May	62.90	All routes	6.47	1340
Northern Europe				5.76	1040

Table 8.9-39: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to apple late application (only entry routes by runoff/drainage to water bodies considered)

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21-d-PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	—	8.65	Runoff / drainage	8.59	2940
Step 2					
Southern Europe	March-May	2.59	Runoff / drainage	2.57	878.09
Northern Europe		1.73		1.71	585.39

Table 8.9-40: ~~FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for Copper oxychloride following single application of COBRANZA to apple late application (only entry routes by drift to water bodies considered)~~

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d-PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	—	71.55	Drift	11.41	3390
Step 2					
Southern Europe	March-May	62.90	Drift	4.86	454.22
Northern Europe					

Table 8.9-41: ~~FOCUS Step 2 maximum drift values for active substance copper following a single application to apple late application (drift mitigation considered)~~

Uses	Buffer (m)				
	3	5	10	14	20
Apple BBCH 60 onwards Late drift rates	13.1415	7.5124	3.3569	1.9063	1.0359

Table 8.9-42: ~~FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to apple late application (drift mitigation considered)~~

Distance (m)	PEC _{sw} (µg/L)	Nozzles reduction		
		50%	75%	90%
3	52.57	26.29	13.14	5.26
5	30.05	15.03	7.51	3.01
10	13.43	6.72	3.36	1.34
14	7.63	3.82	1.91	-
20	4.14 (93.4%)	2.07	-	-

Table 8.9-43: ~~FOCUS Step 2 PEC_{sw} values for active substance copper following a single application to apple late application (runoff/drainage plus spray drift with mitigation measures)~~

Distance (m)	PEC _{sw} (µg/L) (considering Run-off/drainage only)	PEC _{sw} (µg/L) (considering drift only)	Nozzles reduction			PEC _{sw} (µg/L) (Total)
			50%	75%	90%	
10	2.59 ²	13.43	-	-	1.34	3.93
14		7.63	-	1.91	-	4.50
20		4.14	2.07	-	-	4.66

²Worst 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 xxx 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.43-33 evaluation should apply a total to dissolved copper ratio of at least 3.

Table 8.9-44: FOCUS Step 2 PEC_{sw} values for active substance DISSOLVED copper following a single application to apple late application

Max-dissolved PEC _{sw} (considering only drift route) (µg/L)	Max-dissolved PEC _{sw} (considering only runoff and drainage routes) (µg/L)
20.97	0.86*

*Worst case from Southern calculations

Max-dissolved PEC _{sw} (considering all entry routes) (µg/L)	Max-dissolved PEC _{sw} (considering only drift) (µg/L)			Max-dissolved PEC _{sw} (considering only run-off/drainage) (µg/L)
	Distance (m)	%Nozzles	PEC _{sw}	
20.97	3	90	1.75	0.86*
	5	75	2.50	
	10	50	2.24	
	14	-	2.54	

*From Southern calculations (worst case)

Table 8.9-44 bis: Drift values from FOCUS Drift calculator v1.1 for Apple late and single application

Buffer (m)											
5	10	14	20	30	40	50	60	70	80	90	100
7.5124	3.3569	1.9063	1.0359	0.5147	0.3124	0.2119	0.1542	0.1178	0.0933	0.0759	0.0634

Table 8.9-44 bis 1: Mitigation measures for active substance DISSOLVED copper following a single application to apple late application (runoff/drainage (5m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles-%			
		50	75	90	95
5	10.53	5.266	2.633	1.053	0.527
10	4.99	2.496	1.248	0.499	0.250
14	3.06	1.529	0.764	0.306	0.153
20	1.90	0.949	0.474	0.190	0.095
30	1.20	0.601	0.301	0.120	0.060
40	0.93	0.466	0.233	0.093	0.047
50	0.80	0.399	0.200	0.080	0.040
60	0.72	0.361	0.180	0.072	0.036
70	0.67	0.337	0.168	0.067	0.034
80	0.64	0.320	0.160	0.064	0.032
90	0.62	0.309	0.154	0.062	0.031
100	0.60	0.300	0.150	0.060	0.030

Table 8.9-44 bis 2: Mitigation measures for active substance DISSOLVED copper following a single application to apple late application (runoff/drainage (10m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles-%			
		50	75	90	95
10	4.82	2.410	1.205	0.482	0.241
14	2.89	1.443	0.721	0.289	0.144
20	1.73	0.863	0.431	0.173	0.086
30	1.03	0.515	0.258	0.103	0.052
40	0.76	0.380	0.190	0.076	0.038
50	0.63	0.313	0.157	0.063	0.031
60	0.55	0.275	0.137	0.055	0.027
70	0.50	0.251	0.125	0.050	0.025
80	0.47	0.234	0.117	0.047	0.023
90	0.45	0.223	0.111	0.045	0.022
100	0.43	0.214	0.107	0.043	0.021

Table 8.9-44 bis 3: Mitigation measures for active substance DISSOLVED copper following a single application to apple late application (runoff/drainage (15m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles-%			
		50	75	90	95
10	2.71	1.357	0.678	0.271	0.136
20	1.55	0.777	0.388	0.155	0.078
30	0.86	0.429	0.215	0.086	0.043
40	0.59	0.294	0.147	0.059	0.029
50	0.45	0.227	0.114	0.045	0.023
60	0.38	0.189	0.094	0.038	0.019
70	0.33	0.165	0.082	0.033	0.016
80	0.30	0.148	0.074	0.030	0.015
90	0.27	0.137	0.068	0.027	0.014
100	0.26	0.128	0.064	0.026	0.013

Table 8.9-44 bis 4: Mitigation measures for active substance DISSOLVED copper following a single application to apple late application (runoff/drainage (20m of vegetative buffer strip) plus spray drift)

Distance (m)	PEC _{sw} due to all routes (µg/L)	Nozzles-%			
		50	75	90	95
20	1.51	0.755	0.378	0.151	0.076
30	0.82	0.408	0.204	0.082	0.041
40	0.55	0.273	0.136	0.055	0.027
50	0.41	0.206	0.103	0.041	0.021
60	0.33	0.167	0.084	0.033	0.017
70	0.29	0.143	0.072	0.029	0.014
80	0.25	0.127	0.063	0.025	0.013
90	0.23	0.115	0.058	0.023	0.012
100	0.21	0.107	0.053	0.021	0.011

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 10000 mL/g values are added to a median background level of copper in European sediments of 17 mg/kg.

Table 8.9-45: FOCUS Step 2 PEC_{sed} values for active substance copper following a single application to apple late application considering all entry routes without mitigation measures

PEC _{sed} (mg/kg)	PEC _{sed, accu} (7 years accumulation) (mg/kg)	Background (mg/kg)	PEC _{sed} TOTAL (mg/kg)
1.65*	11.55 25.20	17.0	28.55

*From Southern calculations (worst case)

8.9.2.2 PEC_{sw/sed} of COBRANZA

The PEC_{sw} for COBRANZA was calculated using the following equation:

$$PEC_{sw} (\mu g/L) = \frac{\% \text{ Drift}_{90th\%ile} \times \text{Application rate (g/ha)}}{\text{Water depth (cm)} \times 10}$$

The application of COBRANZA is 8 kg/ha for the use on grapevine and 7.2 kg/ha for the use on potatoes, solanaceous and apple. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC_{sw} value is presented in the table 8.9-46.

Table 8.9-46: PEC_{sw} for COBRANZA

Crop		Distance (m)	Drift (%)	Max PEC _{sw} (µg/L)
Grapevine	Early	3	2.7	72.00
	Late		8.02	213.87
Potatoes		1	2.77	73.87
Solanaceous				66.48
Apple	Early	3	29.2	700.80
	Late		15.73	377.52

The PEC_{sed} for COBRANZA was calculated using the following equation:

$$PEC_{sed} (\mu g/kg dw) = \frac{\% \text{ Drift}_{90th\%ile} \times \text{Application rate (g/ha)} \times \% \text{ active substance in sediment}}{1000 \times \text{sediment density (g/cm}^3) \times \text{sediment height (cm)}}$$

The application of COBRANZA is 8 kg/ha for the use on grapevine and 7.2 kg/ha for the use on potatoes, solanaceous and apple. The 100% of copper in sediment has been used for calculations as worst case. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.5 g/cm³. The resulting maximum instantaneous PEC_{sed} value is presented in the table 8.9-47.

Table 8.9-47: PEC_{sed} for COBRANZA following single application to grapevines and vegetables

Crop		Distance (m)	Drift (%)	Max PEC _{sed} (µg/kg)
Grapevine	Early	3	2.7	332.31
	Late		8.02	987.08
Potatoes		1	2.77	340.92
Solanaceous				306.83
Apple	Early	3	29.2	3234.46
	Late		15.73	1742.40

zRMS comments:

The endpoints used for surface water exposure assessment are consistent with list of EFSA journal (2018)

The application rate used in the calculations was determined assuming the GAP.

The supplemented calculations presented by the Applicant were not accepted due to insufficient data on the following assumptions used to refine the PEC_{sw};

- was not specified what maximum reduction in exposure were used for vegetated buffer zone 5m and 15m. According to the FOCUS Landscape and Mitigation document (FOCUS, 2007) reduction of runoff has been verified for 10-12m and 18-20 m VFS,
- the use of drift-reducing techniques to reduce 95% drift together with spray buffer zone can causes that acceptable limit drift to be exceeded,
- was not indicated in the tables concerning refine which one PEC_{sw} was used (Step1 or Step2).

The Applicant's calculations in strike-through mode are presented in raport transparency should not be used for the risk assessment.

All PEC_{sw} are based on a single application scenario and a total copper as concluded at the EU level, the total/dissolved ratio of 3 is not accepted for the risk assessment.

In opinion zRMS further calculations provided by the Applicant should be considered at the level of the Member States due to the need to apply risk mitigation measures to aquatic organisms.

The PEC_{sw} have been calculated by zRMS taking into account the protection zones (WBZ and NSZ and the use of appropriate anti-drift techniques.

For the entry via drift into water bodies, zRMS 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 calculation of PEC_{sw} values.

Predicted environmental concentrations in surface water bodies (PEC_{sw} and PEC_{sed}) 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:

PEC_{sw} and PEC_{sed} 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					
	PEC _{sw} (runoff and drainage) STEP2 unmitigated µg/L)	PEC _{sw} with 90% reduction runoff (20 m VBZ) µg/L)	PEC _{sw} (drift) STEP2 unmitigated µg/L)	PEC _{sw} (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	1.01	0.101	11.04	1.10	0.11	0.058	0.039	0.029

(Solanaceous fruit) 1x 1200g Cu/ha								
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	1.34	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	-

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

Crop	Application (g/ha)	PECsed (mg/kg)				7 years accumulation + background concentration 17 mg/kg
		1 year	7 years accumulation	Total after 10 years	Total after 20 years	
Vine early	4000 g Cu /ha	4.84	33.88	48.4	96.8	50.88
Vine early 90% runoff reduction 20m	4000 g Cu /ha	0.48	3.36	4.8	9.6	26.6
Vine late	4000 g Cu/ha	4.84	33.88	48.4	96.8	50.88
Vine late 90% runoff reduction 20m	4000 g Cu/ha	0.48	3.36	4.8	9.6	26.6

Potatoes	3600 g Cu/ha	1.44	10.08	14.4	28.8	27.08
Potatoes 90% runoff reduction 20m	3600 g Cu/ha	0.14	1.08	1.77	2.88	18.08
Tomato, aubergine (Solanaceous fruit)	3600 g Cu/ha	4.04	28.28	40.4	80.8	45.28
Tomato, aubergine (Solanaceous fruit) 90% runoff reduction	3600 g Cu/ha	0.40	2.83	4.04	8.08	19.83
Apple, pear, quince early	3600 g Cu/ha	5.8	40.6	58.00	116	57.6
Apple, pear, quince early 90% runoff reduction	3600 g Cu/ha	0.58	4.06	5.80	11.6	28.6
Apple, pear, quince Late	3600 g Cu/ha	1.2	8.4	12.00	24.00	25.4
Apple, pear, quince Late 90% runoff reduction 20m	3600 g Cu/ha	0.12	0.84	1.20	2.4	17.84

In opinion zRMS further calculations provided by the Applicant should be considered at the level of the Member States due to the need to apply risk mitigation measures to aquatic organisms.
 The PEC_{sw} and PEC_{sed} values may be used in the aquatic risk assessment.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

8.10.1.1 Copper oxychloride

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Copper oxychloride
Direct photolysis in air	-
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	-
Volatilisation	Not relevant

zRMS comments:

Information on the fate and behaviour of copper oxychloride in the air provided by the Applicant is in line with the EU agreed data reported in EFSA Journal 2018; 16(1):5152,119.
 Due to its properties copper oxychloride is not expected to pose an unacceptable risk to the atmosphere following application of Cobranza according to the intended use pattern.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1.2.2/01	xxx	2018	Title Copper distribution in European topsoils: An assessment based on LUCAS soil survey Company Report No N/A Source Science of the Total Environment Non GLP Published	N	Literature Paper
KCP 9.2.3/01	xxx	2015	Title Kinetics and speciation of copper in copper based fungicide formulations used in crop protection Company Report No N/A Source Company Report F-Cu 2015-7 Non GLP Unpublished	N	EuCu Task Force
KCP 9.2.4/01	xxx	2012	Title European Ground Water Geochemistry Using Bottled Water as a Sampling Medium Company Report No Source Clean Soil and Safe Water Non GLP Published	N	Literature Paper
KCP 9.2.5/01	xxx	2019	Title A field study to determine copper residues in stream sediments Company Report No S17-04438 Source N/A GLP Unpublished	N	EuCu Task Force

Appendix 2 Detailed evaluation of the new Annex II studies

Not relevant. No new Annex II study.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

All the input and output data of the used models are provided in K documents.