

REGISTRATION REPORT

**Part A**

**Risk Management**

Product code: **Nordox 75 WG**

Chemical active substance(s):

Copper (I) oxide (Cu<sub>2</sub>O), 750 g/kg

Interzonal

NATIONAL ASSESSMENT

Poland

(Authorization in accordance to Art. 43)

Applicant: Nordox AS

Submission date: 31/03/2021

Evaluation date: December 2022

MS Finalisation date: March 2023

## Version history

When	What
31/01/2022	Original version from the applicant Nordox AS for Art. 43 submission. All new data and information are marked in yellow.
12/2022	Version evaluated by RMS PL
03/2023	Version amended by RMS PL after comments.

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

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

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

Art.43 submissions and their evaluation by MS are unfortunately due before this GD will be available. The current EFSA conclusion and list of endpoints could at best be considered as a first tier, and applicants as well as MS are required to deviate from the standard procedures described in the GD for the following reasons:

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

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

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

**General observation:** Copper compounds should not be considered as Candidate for Substitution (CfS).

The implementing Regulation (EU) 2018/1981 is renewing the approval of the active substance Copper compounds as candidate for substitution (CfS), in accordance with Regulation (EC) 1107/2009. Whereas (12) considers that Copper compounds are persistent and toxic in accordance with points 3.7.2.1 and 3.7.2.3 of Annex II to Regulation (EC) 1107/2009 (PBT assessment), and fulfil the condition set in the second indent of point 4 of Annex II to Regulation (EC) 1107/2009.

The EUCuTF disagrees with the approval as CfS. The conditions in Annex to Regulation (EC) 1107/2009 lack the exemption of inorganic compounds like Copper minerals from the PBT assessment as it has been established under other chemical legislations like REACH and BPD. As laid down in those legislations, the term persistence is meaningless for an element or mineral, due to its natural occurrence. Persistence per se is therefore not a relevant parameter and consequently a PBT assessment is not carried out for inorganic compounds under REACH and BPD. The recent mandate from COM to EFSA directs the development of a guidance towards methods and procedures available under those legislations better adapted for the assessment of inorganic compounds, where the relevant parameter is their bioavailability. This should include an exempt statement regarding the PBT assessment to harmonize the assessment of the same compounds under different legislations.

It should be noted that persistence of minerals is considered not relevant for being categorized as low-risk active substance according to Regulation (EU) 2017/1432. This is clearly not compatible with the same parameter leading to a classification as CfS under the same Regulation (EC) 1107/2009.

The EUCuTF is of the opinion that Copper compounds should not be considered CfS, and have lodged an action for annulment against Regulation (EU) 2018/1981 and renewing the approval of the active substance Copper compounds as candidate for substitution (case number T-153/19 European Union Task Force v. European Commission).

# **PART A**

## **RISK MANAGEMENT**

This document describes the acceptable use conditions required for the registration of Nordox 75 WG containing the active substance Copper (I) oxide in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in Registration Report, Part B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Nordox 75 WG where that data has not been considered in the EU review. Otherwise assessments for the safe use of Nordox 75 WG have been made using endpoints agreed in the EU review of Copper (EFSA Journal 2018;16(1):5152).

### **1 Details of the application**

#### **1.1 Application background**

This application was submitted by Nordox AS.

The application was for approval of Nordox 75 WG, an WG formulation type (Water dispersible granule) containing 750 g/kg Copper (I) oxide for use as a fungicide and bactericide.

#### **1.2 Letters of Access**

The Copper Task Force, grants the right to refer to the Copper Annex II data package to the applicant.

For efficacy trials a letter of access is available from Certis Europe B.V. and Masso S.A.

For the Letter of Access, please refer to Appendix 3.

#### **1.3 Justification for submission of tests and studies**

All tests and studies were prepared and submitted in support of the assessment as required according to 284/2013 EU.

#### **1.4 Data protection claims**

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	Nordox 75 WG
Product name in MS	
Authorization number	
Function	Fungicide and bactericide
Applicant	Nordox AS
Active substance(s) (incl. content)	750 g/kg Copper (I) oxide
Formulation type	Water dispersible granule [Code: WG]
Packaging	Paper lined multi-layer sacks for 1, 10, 25 kg bags
Coformulants of concern for national authorizations	--
Restrictions related to identity	--
Mandatory tank mixtures	--
Recommended tank mixtures	--

### 2.2 Conclusion

The evaluation of the application for Nordox 75 WG resulted in the decision to grant the authorization except strawberry and pepper (section 7).

### 2.3 Substances of concern for national monitoring

Not relevant.

### 2.4 Classification and labelling

#### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Pictograms:	GHS09
Signal word:	Warning
Hazard statement:	H400 - Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:	P273 - Avoid release to the environment. P391 - Collect spillage P501 - Dispose of contents/container to a hazardous or special waste collection point

**See Part C for justifications of the classification and labelling proposals.**

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

Please refer to point 2.4.1.

## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Not relevant.

## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
--	--
Worker protection:	
--	--
Integrated pest management (IPM)/sustainable use:	
--	--
Environmental protection	
Aquatic	--
Other specific restrictions	
--	Max. 28 kg as/ha in 7 years Max. 5 kg as/ha from February -October (bird breeding season)

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
--	--

### 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
Respective code if available	--	--
Environmental protection:		Relevant for use no.
--	--	--

## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Nordox 75 WG  
Active substance 1: Copper (I) oxide  
Safener: safener  
Synergist: synergist  
Applicant: Nordox AS  
Zone(s): Interzonal  
Verified by MS: yes/no

GAP rev. 01, date:  
Formulation type: WG  
Conc. of as 1: 750 <sup>(c)</sup>  
Conc. of safener: conc. <sup>(c)</sup>  
Conc. of synergist: conc. <sup>(c)</sup>  
Professional use:   
Non professional use:

Field of use: Fungicide and bactericide

1 Use-No. <sup>(e)</sup>	2 Member state(s)	3 Crop and/or situation  (crop destination / purpose of crop)	4 F, Fn, Fpn G, Gn, Gpn or I	5 Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	6-9 Application				10-12 Application rate			13 PHI (days)	14 Remarks: e.g. safener/synergist per ha <sup>(f)</sup>
					6 Method / Kind	7 Timing / Growth stage of crop & season	8 Max. number a) per use b) per crop/season	9 Min. interval between applications (days)	10 kg product / ha a) max. rate per appl. b) max. total rate per crop/season	11 kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	12 Water L/ha min / max		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
4	PL	Strawberry	G	<i>Marssonina fragariae</i> , <i>Zythia fragariae</i> <i>Mycosphaerella</i> , bacterial disease, <i>Colletotrichum sp.</i>	Foliar spray	BBCH 13 - BBCH 85	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-800	3	
5	PL	Tomato Eggplant Pepper	G	<i>Phytophthora spp.</i> , <i>Alternaria</i> , <i>Colletotrichum</i> , Bacterial disease ( <i>Pseudomonas spp.</i> , <i>Xanthomonas spp.</i> ).	Foliar spray	BBCH 15 - BBCH 51	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	10	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. <sup>(e)</sup>	Member state(s)	Crop and/or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
7	PL	Lettuce Scarole	G	<i>Alternaria</i> , <i>Bremia lactucae</i> Bacterial disease: <i>Erwinia spp.</i> , <i>Pseudomonas spp.</i> <i>Xanthomonas spp.</i>	Foliar spray	BBCH12 - BBCH49	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	300-1000	3-7	
8	PL	Cucumber	G	<i>Alternaria</i> , <i>Antracnosis</i> , <i>Phytophthora spp.</i>	Foliar spray	BBCH 15 - BBCH 89	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3	

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
 (c) g/kg or g/l  
 (d) Select relevant  
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

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

### 3 Background of authorization decision and risk management

#### 3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a red-brown free flowing granule free from foreign matter with a vanilla odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 234 °C. In aqueous solution, it has a pH value around 7.1 at 21°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium laminate sachets. Its technical characteristics are acceptable for a Water dispersible granule (WG) formulation.

**Nature and characteristics of the packaging:** Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

#### 3.2 Efficacy (Part B, Section 3)

The present Part A is submitted in the framework of the authorization in accordance to Art. 43 with no GAP changes. For the efficacy please refer to the original registration.

#### 3.3 Efficacy data

The dossier has been submitted to support the renewal of NORDOX 75WG in Poland (PL) which belongs to the North-East EPPO Climatic Zone and Hungary (HU) and Slovenia (SI) which belongs to the South-East EPPO Climatic Zone, according to Art. 43 of Regulation (EC) No. 1107/2009, following the renewal of Copper compounds (Copper oxide) as active substances under Regulation (EC) No. 1107/2009.

This core assessment concerns the renewal of authorization of the uses of the protectant fungicide/bactericide, which is currently authorized under product names NORDOX 75WG in Poland (PL) which belongs to the North-East EPPO Climatic Zone and Hungary (HU) and Slovenia (SI) which belongs to the South-East EPPO Climatic Zone. NORDOX 75WG is formulated as a Wettable Granule (WG) and contains 86.2% of copper oxide i.e 750 g/kg of copper (as metal). The product is currently authorised for use as protectant fungicide/bactericide which prevents infection on plants, being active against a broad spectrum of plant pathogenic fungi.

The basis for renewal is an unchanged product (the formulation of the product remains the same) and an unchanged GAP and national label. The applicant provided a statement that this is the case for all CMS's. However, only an in-depth check has been performed for the PL uses in the GAP and the Polish label. Based on this check zRMS confirms that the PL-GAP has remained unchanged indeed. For all other cMS, it is left up to check and confirm if the submitted GAP and national label have remained unchanged indeed. In the case the GAP of an individual cMS has been changed, it is left up to the particular cMS to confirm zRMS conclusions on a national level.

The evaluation for renewal focuses on the resistance section. For evaluation of efficacy, reference can be made to evaluation and experience with the product in the past. Therefore efficacy does not need to be evaluated again. If no resistance has developed, it can be expected that the efficacy of the product is unchanged.

### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

### **3.3.2 Adverse effects on treated crops**

### **3.3.3 Observations on other undesirable or unintended side-effects**

## **3.4 Methods of analysis (Part B, Section 5)**

Analytical methods for determination of Copper, impurities and relevance of CIPAC methods in Nordox 75 WG were evaluated in Part B, Section 5.

### **3.4.1 Analytical method for the formulation**

CIPAC methods are available for the determination of total Copper in formulations:

- CIPAC method 44/WP/M/ (Copper in wettable powder formulation)
- CIPAC method 44/DP/M/ (Copper in dustable powder formulation)

### **3.4.2 Analytical methods for residues**

All information and validation data were provided in the EU review of Copper compounds and were considered adequate.

## **3.5 Mammalian toxicology (Part B, Section 6)**

### **3.5.1 Acute toxicity**

The acute toxicity tests were performed on Nordox 75 WG, one of the representative formulations in the EU review of Copper compounds. The acute toxicity studies for Nordox 75 WG were evaluated during the review and were considered adequate.

**Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Nordox 75 WG**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat (OECD 401)	3165 mg/kg bw	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
LD <sub>50</sub> dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
LC <sub>50</sub> inhalation, rat (OECD 403)	> 5 mg/L air	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
Eye irritation, rabbits (US EPA equivalent to EC method B5)	Non-irritant	Yes	None	xxx (1999) EU agreed dRAR, Vol.3, B6 (2016)
Skin sensitisation, guinea pig (OECD 406, M&K)	Non-sensitising	Yes	None	xxxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
Supplementary studies for combinations of plant protection products	No data – not required			

### 3.5.2 Operator exposure

For Copper, an AOEL of 0.08 mg/kg bw/d was set.

An AAOEL was not allocated during the peer review for the renewal of approval of Copper. Therefore, estimates of the acute exposure to operators has not been conducted.

The proposed dermal absorption rates for Copper of 0.1 % for the concentrate and 1.0 % for the dilution are based on dermal absorption studies on a formulation containing Copper hydroxide. It has already been established during the EU peer review that, given the nature of the active sub-stance (Cu<sup>2+</sup>), dermal penetration factors for both concentrate and in-use spray dilutions from these studies are justifiably relevant to all forms of Copper (oxide, hydroxide, oxychloride, tribasic sulphate and Bordeaux Mixture) and all formulation types (WP, WG, and SC).

The risk assessment was performed with the ECPA greenhouse model (calculator version: 23/12/2010) and the Dutch greenhouse model (Van Golstein Brouwers, Y.G.C., Marquart, J. and Van Hemmen, J.J. (1996)).

The risks posed to operators from the application of Nordox 75 WG are considered to be acceptable.

**Implications for the labelling:** None.

**zRMS:**

Dermal absorption of copper (as copper (I) oxide) from a product Nordox 75 WG determined in this registration report according to the Triple pack' approach based on acceptable studies and interpreted in line with current EU guidelines to be used for risk assessment are: 0.1% for the concentrate and 1% for the dilution. This approach is considered valid for determination of dermal absorption in case of this application of Nordox 75 WG therefore these endpoints are used for exposure estimation

Taking into account dermal absorption 0.1% for concentrate and 1% for dilution the potential exposures to copper (as copper (I) oxide), estimated with Dutch greenhouse model, of operator applying Nordox 75 WG in the greenhouse on strawberry, tomato, eggplant, pepper, lettuce, scarole or cucumber at rate of 1.0 kg a.s./ha, downward spraying, are all below AOEL, thus these applications do not cause unacceptable risk for operator for not wearing any PPE. In case operator is wearing work wear covering arms, body legs and protective gloves the exposure and risk are lower.

When the higher dermal absorption of 1% from concentrate and 9% from the dilution (9%) is assumed then the exposure of operator is below AOEL for all these applications foreseen in GAP only when operator is wearing work wear covering arms, body and legs during mixing/loading and application and protective gloves during mixing/loading.

### 3.5.3 Worker exposure

The risk assessment was performed with the EFSA AOEM model according to the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

The risks posed to workers re-entering areas treated with Nordox 75 WG are considered to be acceptable providing normal work-wear is worn.

**Implications for the labelling:** None.

**zRMS:**

Taking into account the dermal absorption 0.1% for concentrate and 1% for dilution the potential exposures estimated with EFSA AOEM model to copper (as copper (I) oxide), of worker entering for 8 hour for various tasks a greenhouse with crops treated with Nordox 75 WG as foreseen in GAP (strawberry, tomato, eggplant, pepper, lettuce, scarole or cucumber at rate of 1.0 kg a.s./ha, downward spraying) are all below AOEL. Thus these applications do not cause unacceptable risk for worker entering greenhouse for 8 hours to performed various tasks on treated plants. In case the worker is wearing workwear and protective gloves the exposure and risk is further reduced

When the higher dermal absorption is assumed of 1% from concentrate and 9% from the dilution (9%) then the exposure of worker, estimated with EFSA AOEM model, to copper (as copper (I) oxide) is only below AOEL when worker is wearing a work wear covering arms, body and legs and protective gloves and is entering a greenhouse with strawberry, tomato, eggplant, pepper, lettuce, scarole or cucumber treated with Nordox 75 WG at application rate 3 x 1.0 kg a.s./ha, downward spraying. Therefore the risk of workers wearing a workwear covering arms, body and legs and protective gloves is acceptable.

### 3.5.4 Bystander and resident exposure

Calculation needs to be conducted only for field uses, since bystanders and residents should not be affected by application in greenhouses. Therefore, no risk assessment is conducted.

#### zRMS:

There is no exposure of residents and bystanders in case a plant protection product is used in greenhouse.

### 3.6 Residues and consumer exposure (Part B, Section 7)

Although the applicant states that “trials used for the calculations (resulted in an unrounded MRL exceeding the existing MRL of 5 mg/kg) are identical to those evaluated under Art. 12 of regulation (EC) No. 396/2005 (EFSA, 2018), in which a MRL of 15 mg/kg is proposed for strawberries” and that “EU Indoor is the worst case zone with higher residue values on the same GAP (proposed MRL 15) compare to the outdoor data (N+S-EU)”, the fact is that the MRL currently in force according to the trials results can be expected to be exceeded. Thus, strawberry until the MRL change cannot be approved.

For tomatoes (eggplants) (DAR 2007) and peppers trials results were below the relevant MRLs (5 mg/kg). No cucumber and courgettes in the DAR 2007, however the existing relevant residue data are unprotected as submitted in EU in 2011 on the renewal and available then in the RAR (reference EFSA 2018 in table 7.2-3 is misleading; see RAR 2016 for CA 6.3.5-01-02, Kreke N., 2011, see References here). Thus, the approval can be granted. Also, the trials submitted here for lettuce are sufficient. An exceedance of the current MRL of Copper as laid down in Reg. (EU) 396/2005 for lettuces etc. and intended Cucurbitaceae is not expected.

The data available are considered sufficient for risk assessment.

The chronic and the short-term intakes of Copper residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses consistently with the GAP in table of paragraph 2.6.

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

Noticed data gaps are: none

#### 3.6.1 Residues

Since Copper does not degrade in plants and since transportation and distribution of Copper in plants following application as a plant protection product is limited compared to the Copper already present in the plant arising from uptake from the soil, specific studies to evaluate the metabolism, distribution and expression of the residue in plants following application as a plant protection product have not been conducted and are not required. The critical issue is the magnitude of residues of Copper in the edible portions of grapes following applications of Copper as a plant protection product.

The metabolism of Copper in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

Since Copper is known to be inherently stable and cannot degrade into any other material and since the analytical techniques measure total Copper content irrespective of form, studies to measure the effects of industrial processing or household preparation on the nature of the residue are not required.

Copper is an element and will not be metabolized. The chemical fate of Copper in mammals is well documented and no new information will be produced by conducting metabolism studies in livestock, consequently none have been conducted.

Studies on the magnitude of residues in tomato and melons has been submitted and are already EU evaluated (DAR 2007, RAR 2016). Studies on strawberry, pepper, lettuce were submitted 2016 to France (France 2016).

No new study has been submitted in the framework of this application. According to the available data, the intended uses are considered acceptable even all crops exceeding the current MRLs. However, during the EFSA MRL review (Art. 12, EFSA 2018) new tentative MRLs were proposed. All calculated MRLs are below the new tentative proposed MRLs by EFSA.

Crop	Sufficient residue trials?	MRL compliance
Strawberry	Yes (8x)	No**
Tomato, eggplant	Yes* (4x EU + 9x NEU + 5x SEU)	No** Yes
Pepper, orka/lady's finger	Yes (9x pepper)	No**
Cucurbits (edible peel)	Yes (4 x cucumber, 8x courgettes)	Yes
Cucurbits (non-edible peel)	Yes (6x melon: <LOQ)	No** Yes
Lettuce and similars	Yes (8x lettuce)	No** Yes

\*Because of identical GAPs and comparable results for indoor, north and south trials overall calculations and conclusion were done and used for consumer risk assessments.

\*\*During the EFSA MRL review (Art. 12, EFSA 2018) new tentative MRLs were proposed. All calculated MRLs are below the new tentative proposed MRLs by EFSA, except potatoes.

The MRL compliant uses are considered acceptable. The non-compliant uses can't be approved.

### 3.6.2 Consumer exposure

Copper is used as feed additive for all livestock species. Therefore, dietary burden calculations were performed.

But it can be concluded that the livestock dietary burden calculation based on the method in Animal Burden Calculation according to OECD 505 is not suitable for the risk assessment of a micronutrient like Copper. Nevertheless, the use of Copper as a plant protection product can be considered acceptable.

The TMDI estimates for the various diets were found 93 – 6 % of ADI. The highest TMDI was calculated for the “NL Toddler”. For this diet, maize and wheat were the highest contributors to the residue intake, representing 11 % of ADI for both. It should be noted that the biggest contributors (cereal) are not supported uses for Copper compounds.

The NESTI was not calculated as no ARfD was set.

TMDI (% ADI) according to EFSA PRIMo	93 % (NL Toddler Diet)
IEDI (% ADI) according to EFSA PRIMo	Not calculated, not necessary
NEDI (% ADI)**	--
IESTI (% ARfD) according to EFSA PRIMo*	Not calculated
NESTI (% ARfD) **	--

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

\*\* if national model is available

The proposed uses of Copper in the formulation do not represent unacceptable acute and chronic risks for the consumer.

### 3.7 Environmental fate and behaviour (Part B, Section 8)

Concentrations of Nordox 75 WG in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment groundwater and air are provided. The long-term concentrations are based on results obtained for the active substance contained in the formulation.

#### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

PEC<sub>soil</sub> values were calculated for the active substance Copper following a single season's application according to FOCUS and considering a soil depth of 5 cm. For Copper, the estimation of PEC<sub>soil</sub> has assumed that there is no crop interception.

The resulting PEC<sub>soil</sub> values were added to the natural background concentrations reported from the LUCAS data.

Details are given in Part B, core assessment, Section 8, chapter 8.7.

#### 3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

The PEC<sub>gw</sub> calculations are performed for the FOCUS crop scenario tomato with an application amount of 3000 g a.s./ha. It should be noted that the 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 results of the PEC<sub>gw</sub> calculations, based on these worst-case assumptions, lead to PEC<sub>gw</sub> values < 0.001 µg/L. No unacceptable contamination is to be expected.

#### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

##### PEC<sub>sw</sub> calculations – Greenhouse use

According to the List of Endpoints of Copper, the “Dutch Model” was used for the PEC<sub>sw</sub> greenhouse calculations.

For the surface water risk assessment for greenhouse use, some drift from the greenhouse towards a static water body has to be taken into account. Following the “Dutch Model”, the maximum instantaneous PEC<sub>sw</sub>

value was calculated from entry through spray drift that occurred immediately after the last application, considering a drift of 0.1 % of the application rate from the glasshouse.

Details are given in Part B Section 8, chapter 8.9.

The results for  $PEC_{sw}$  for the active substance were used for the eco-toxicological risk assessment.

### **3.7.4 Predicted environmental concentrations in air ( $PEC_{air}$ )**

Copper is not volatile at environmentally relevant temperatures and will therefore not be present in air. Furthermore, Copper cannot be transformed into related metabolites or degradation products and degradation processes likely to occur in air will have no action on Copper.

## **3.8 Ecotoxicology (Part B, Section 9)**

A full risk assessment according to Uniform Principles for the plant protection product Nordox 75 WG in its intended uses is documented in detail in the core assessment.

### **3.8.1 Effects on terrestrial vertebrates**

Since application is intended for indoor/greenhouse use, no risk of exposure to Nordox 75 WG is to be expected for birds, mammals and terrestrial vertebrate wildlife.

### **3.8.2 Effects on aquatic species**

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

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

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

In conclusion, acceptable risk to aquatic organisms from the use of Nordox 75 WG was demonstrated for the greenhouse uses.

### **3.8.3 Effects on bees**

The evaluation of the risk for bees was performed in accordance with the new Bee Guidance Document EFSA (2013). The refined risk assessment of the effects of Copper oxide indicates no unacceptable risk to bees after exposure to Nordox 75 WG. No risk mitigation measures are required.

### **3.8.4 Effects on other arthropod species other than bees**

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

First tier risk assessment demonstrated a low risk for non-target arthropods other than bees when the product is applied according to GAP.

### **3.8.5 Effects on soil organisms**

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

For non-target soil meso- and macrofauna a higher tier risk assessment was presented, demonstrating an acceptable risk for application rates of up to 8 kg Cu/ha/year. Thus, there is no unacceptable risk for non-target soil meso- and macrofauna after exposure to Nordox 75 WG when applied according to GAP.

Additionally, based on laboratory and field data it was concluded that an annual application of 3.00 kg Cu/ha, in the form of Nordox 75 WG is not expected to cause adverse effects on soil microbial function and so the risks following the proposed use of Nordox 75 WG are acceptable.

### **3.8.6 Effects on non-target terrestrial plants**

The evaluation of the risk is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

There is no unacceptable risk for non-target terrestrial plants after exposure to Nordox 75 WG.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not relevant.

## **3.9 Relevance of metabolites (Part B, Section 10)**

An estimation of the concentration of metabolites in groundwater is not required because, as an element, Copper cannot be transformed into metabolites or degradation products.

**4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

Not relevant.

**5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

Not relevant.

## **Appendix 1 Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.

## **Appendix 2 Copy of the product label**

The product label will be provided separately by the applicant.

## **Appendix 3 Letter of Access**

### **Studies owned by the Copper Task Force**

xxx

**Efficacy trials owned by Certis**

XXXX

**Efficacy trials owned by Masso**

xxx

## Appendix 4 Lists of data considered for national authorization

### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.12/01	Grall, E.	2011	Nordox 75 WG , Copper Oxychloride 37.5 NC WG, Flowbrix SC, Copper hydroxide 40% WG, Copper hydroxide 25% DF, Bordoflow New Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009 Company Report No: C48301 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.12/02	Grall, E.	2011	Funguran-OH 50 WP, Bordeaux Mixture RSR Disperss, Copper Oxychloride 37.5 NC WG, Cuproxat flüssig: Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under protected greenhouse conditions in northern and southern Europe in 2010. Company Report No: C91297 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.12/03	Grall, E.	2011	Copper oxychloride 50% WP, Flowbrix SC (Copper oxychloride SC), Bordoflow New, Copper hydroxide 25% DF, Cuproxat flüssig, Bordeaux Mixture 20 NC WG, CA2491 (Champion 50 WG) Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under protected greenhouse conditions in northern and southern Europe in 2009 Company Report No: C48290 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.19/01	Kreke, N.	2012	Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Copper hydroxide 25% DF, Bordoflow New, Flowbrix SC (Copper oxychloride SC), Bordeaux Mixture 20 NC WG; Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2010 Company Report No: C91051 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.19/02	Kreke, N.	2011	Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Funguran-OH 50 WP, Cuproxat Flüssig Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2009 Company Report No: C48097 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.19/03	Kreke, N.	2011	Kreke, N. (2011) Copper hydroxide 25% DF, Bordoflow New Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern Europe in 2011, Company Report No. D35590 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.21/01	Kreke, N.	2011	Bordeaux Mixture 20% WG, Copper hydroxide 25% DF, Flowbrix SC (Copper oxychloride SC), Cuproxat flüssig Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2009 Company Report No: C48053 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.21/02	Kreke, N.	2012	ATOFAP17, CA2112 (CHAMP FLO), Copper oxychloride 50 WP (SU), Bordoflow New: Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2010 Company Report No: C91038 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCP 1.2/01	Mercedes, P. M.	2021	CONFIDENTIAL INFORMATION please refer to Part C				
KCP 1.2/02	Mercedes, P. M.	2021	CONFIDENTIAL INFORMATION please refer to Part C				
KCP 1.4.2/01	Anonymous	2018	Safety Data Sheet. Nordox 75 WG Version 1.0 Revision 05.10.2018 No GLP, published	N	N	--	--
KCP 1.4.3/01-03			CONFIDENTIAL INFORMATION please refer to Part C				
KCP 2.3.3/01	Baker, D.	2003	Regulatory testing on a sample of Cuprous Oxide Technical Report No. 14603 revision 1 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCP 2.7.1/01	Seaman, G. D.	2012	Physical and Chemical Properties of Nordox 75 WG: Storage Stability for up to 2 weeks at 54°C. Report No. XN/12/001/1 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<b>KCP 2.7.5/01</b>	Seaman, G. D.	2014	Physical and Chemical Properties of Nordox 75 WG: Storage Stability for up to 104 weeks at 20°C. Report No. XN/12/001/2 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
<b>KCP 5.1.1/01</b>	Pardo Martinez, M.	2021	Nordox Agro Grade: Validation of the Analytical Method for the Determination of the Copper Active Ingredient Content Company Report No.: 0093/2021 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
<b>KCP 5.1.1/02</b>	Pardo Martinez, M.	2021	Nordox Agro Grade: Validation of the Analytical Method for the Determination of the Sulphate and Chloride Significant Impurities Content Company Report No.: 0094/2021 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
<b>KCP 5.1.1/03</b>	Pardo Martinez, M.	2021	Nordox Agro Grade: Validation of the Analytical Method for the Determination of the Metallic Impurities Content (Arsenic, Cadmium, Lead, Nickel, Chromium, Cobalt, Antimony and Mercury) Company Report No.: 0095/2021 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/01	Riccelli S.	2017	Method Validation for the determination of Copper in/on dry and oily matrices and Matrix Effect evaluation on dry, oily, high water and acid matrices Company Report No RA.17.02 Isagro – Centro di Saggio BPL GLP Published	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 5.2/02	Pardo Martinez M.	2018	Validation of the Analytical Method for the determination of Copper residues in Air Company Report No: CH-657/2017 ChemService GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 7.3/01	xxx	2016	<i>In vitro</i> percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8WG (35% as metallic copper), through human skin Du-Pont-42821 xxx, The Netherlands GLP: Y Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 7.3/02	xxx	2016	<i>In vitro</i> percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8WG (35% as metallic copper), through rat skin Du-Pont-42649 xxx, The Netherlands GLP: Y Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.3/03	xxx	2016	<i>In vivo</i> percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8WG (35% as metallic copper), in rats Du-Pont-42648 xxx, The Netherlands GLP: Y Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 7.3/04	xxx	2020	The fate of test item residues in the skin membranes in <i>in vitro</i> dermal absorption studies; impact on the risk assessment of inorganic copper salts n.a. xxx GLP: N Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 9.2.4/01	Demetriades, A. et al	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	N	--	Literature Paper
KCP 10.2/01	Van Sprang, P.	2019	Response to EFSA comments on the aquatic effects assessment for Cu – extension GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.2/02	Oorts, K. and Verdonek, F.	2019	Relevance of Standard Assessment Factors for Risk Assessment of the Essential Element Copper CuPPP20170705 GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/03	Janssen, S.D., Viaene, K., Van Sprang, P., Deschampselaere, K.	2019	Modelling of the Funguran-OH Effects on <i>Onchorhynchus mykiss</i> Populations GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.2/04	Vangheluwe, M.	2019	Revised PNEC sediment Copper for the sediment effects assessment for Cu: extending the database with additional species GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.3.1.2/01	Colli, M.	2018	Chronic oral effects of Copper oxychloride 50% WP to adult worker honeybees <i>Apis mellifera</i> L., 10-day feeding laboratory test BT215/17 Biotechnologie BT srl, Italy GLP: Y Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.3.1.2/02	Colli, M.	2017	Effects of Copper oxychloride 50% WP to honeybees <i>Apis mellifera</i> L. Larval toxicity test, repeated exposure. BT216/17 Biotechnologie BT srl, Italy GLP: Y Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<b>KCP 10.4/01</b>	Wagenhoff, E.	2018	Laboratory Study on the Sensitivity of Field-Caught Earthworms <i>Aporrectodea caliginosa</i> (Annelida, Lumbricidae) to Copper in Grassland Soils Collected at two Field Sites in South-Western Germany: a Crossover Experiment Report no. S18-00119 GLP: Y Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
<b>KCP 10.4/02</b>	Klein, O.	2019	Addendum to Final Report: A Field Study to Evaluate the Effects of Copper on the Earthworm Fauna in Central Europe: Statistical Analysis of a long term earthworm field study. 20031343/G1-NFEw Eurofins Agrosience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
<b>KCP 10.4/03</b>	Amossé et al.	2018	Short-term effects of two fungicides on enchytraeid and earthworm communities under field conditions. Ecotoxicology GLP: N Published: Yes, DOI <a href="https://doi.org/10.1007/s10646-018-1895-7">https://doi.org/10.1007/s10646-018-1895-7</a>	N	N	--	Literature Paper
<b>KCP 10.4/04</b>	Caetano et al.	2015	Copper toxicity in a natural reference soil: ecotoxicological data for the derivation of preliminary soil screening values. Ecotoxicology GLP: N Published: Yes, DOI <a href="https://doi.org/10.1007/s10646-015-1577-7">10.1007/s10646-015-1577-7</a>	N	N	--	Literature Paper

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4/05	Oorts K. and Peeters B.	2019	Distribution of RAC values for effect of Cu to soil invertebrates in Eu-rope. ARCHE Consulting, Belgium. Research report submitted to the European Copper Task Force. GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF