REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: **Nordox 75 WG**

Chemical active substance(s):

Copper (I) oxide (Cu_2O), 750 g/kg

Interzonal

NATIONAL ASSESSMENT

Poland

(Authorization in accordance to Art. 43)

Applicant: Nordox AS

Submission date: 31/01/2022

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).

0 Product background, regulatory context and GAP information

0.1 Introduction

This document reviews information related to data on application of the plant protection product Nordox 75 WG containing the active substance Copper (I) oxide.
This dossier is presented to support the approval of the product Nordox 75 WG under the Commission Regulation (EU) No 284/2013. The product Nordox 75 WG was the representative formulation in the EU evaluation.
The EFSA Report of Copper (EFSA Journal 2018;16(1):5152) is considered to provide the relevant review information or a reference to where such information can be found.

Appendix 1 of this document contains the list of all intended uses

Information on the detailed composition of Nordox 75 WG can be found in the confidential dossier of this submission (Registration Report - Part C).

0.1.1 Reason for application

This document reviews information related to the authorization in accordance to Art. 43 on application of the plant protection product Nordox 75 WG containing the active substance Copper (I) oxide.
This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.
In addition to the submission of studies as listed in the separate sections of this application, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	PL, Nordox 75 WG, authorization no.: R-173/2015	-

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of CAS No: 1317-39-1

Status	
Approved in EU	Yes
Original Inclusion Directive	Commission Directive 2009/37/EC
RMS	France
Date of renewal of Approval of Active Substance	01.01.2019 (Regulation (EU) 2018/1981)
Date of deadline for renewal of authorization (renewal)	01.04.2019
Current expiration of approval of Active Substance	31.12.2025
Low risk substance or Candidate for Substitution?	The Commission considers that copper compounds are candidates for substitution for the folowing reasons: • copper compounds are persistent substances (given that the half-life in soil is greater than 120 days) and • toxic substances (given the long-term no-observed effect concentration for aquatic organisms is less than 0.01 mg/L. However, the applicant disagrees with this classification and is challenging the applictaion of the 'P' criteria to inorganic substances under Reg 1107/2009 since it is not applied to such substances under Regs. (EU) 528/2012 or 1278/2008.

Issues that need to be considered as part of the EU approval are listed below.

Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the conclusions of the review report on copper compounds and in particular Appendices I and II thereto, shall be taken into account.

In their overall assessment Member States shall pay particular attention to:

– the operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment and other mitigation measures as appropriate;
– the protection of water and non-target organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate;
– the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, do not exceed the minimum necessary to achieve the desired effects and do not cause any unacceptable effect on the environment taking into account background levels of copper at the application site, and, where the information is available, copper input from other sources. Member States may in particular decide to set a maximum annual application rate not exceeding 4 kg/ha of copper

The SANCO report for copper compounds (SANTE/10506/2018– 27/11/2018) is considered to provide the

relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is available (EFSA Journal 2018;16(1):5152).

Table 0.1-3: Information on minimum purity of Copper (I) oxide

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
858 g/kg	Not different

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).
**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Table 0.1-4: Endpoints used in this submission that differ from the EU agreed endpoint

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Dermal penetration	Concentrate: 1% Spray dilution (0.33 g Cu/L): 9%	Concentrate: 0.1% Spray dilution: 0.5%
Fish - Acute toxicity	Mortality, LC_{50} (96 h) = 0.207 mg/L total (mm); 0.0344 mg/L dissolved (mm)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Fish – Chronic toxicity	Growth, EC_{10} (53-d) = 0.0012 mg/L (dissolved Cu)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Aquatic invertebrate – Acute toxicity	Mortality, LC_{50} (48 h)= 0.0308 mg/L total (mm); 0.0266 mg/L dissolved (mm)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Aquatic invertebrate – Chronic toxicity	Reproduction, NOEC (21 d) = 0.0076 mg/L total (gmm)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Sediment dwelling organism – chronic toxicity (water spike)	NOEC (28 d) = 0.50 mg/L total (nom)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Sediment dwelling organism – chronic toxicity (sediment spike)	NOEC (28 d) = 16.17 mg/kg dry weight normalized to 2.5% OC	~~SSD HC5 = 40.4 mg/kg dry weight normalized to 2.5% OC~~ NOEC (28 d) = 16.17 mg/kg dry weight normalized to 2.5% OC
Algae – Chronic toxicity	Growth rate, E_rC_{50} (72h) = 0.02229 mg/L total (nom)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Indoor microcosm study	NOEC = 0.0048 mg/L dissolved (mm) (AF = 2 applied)	NOEC = 0.0048 mg/L dissolved (mm) ~~(AF = 1 applied)~~ (AF = 2 applied)

* See relevant section for a detailed explanation
(nom) nominal concentration; (mm) mean measured concentration; (gmm) geometric mean measured concentration

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-5: Summary of regulatory history of the product Nordox 75 WG

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
-	**NORDOX 75 WG**	**PL**	R-173/2015	09.03.2004	20.10.2015

The product Nordox 75 WG was the representative formulation during the EU review of Copper.

0.2 zRMS conclusion

Identity, physical and chemical properties and further information:

The two-year shelf life can be granted for the PPP.

Efficacy:

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.

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.

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. The risk of developing resistance to NORDOX 75WG is low, however, given that for some GAP diseases the inherent risk from the target disease e.g. *Plasmopara viticola* and *Venturia inadequacies* appears to be high, the overall risk of resistance for the product NORDOX 75WG is assessed as low with the potential to increase to medium. Overall the applicant's resistance risk assessment is acceptable.

Toxicology and health risk:

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.

Taking into account the dermal absorption 0.1% for concentrate and 1% for dilution the potential expo-

sures 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) estimated with EFSA AOEM model 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 of 1% from concentrate and 9% from the dilution 9%) is assumed 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.

There is no need to assess a risk for residents and bystanders when the product is used in the greenhouse as intended.

Metabolism and Residues:

The data available are considered sufficient for risk assessment. For strawberry and pepper the current MRL exceedance is expected. An exceedance of the current MRLs of Copper as laid down in Reg. (EU) 396/2005 for the intended uses for which the approval can be done is not expected. 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 **greenhouse uses**.

Fate and behaviour:

In accordance with proposed pattern use in greenhouses, an exposure assessment for the formulation of Nordox 75 WG was submitted.

Ecotoxicology:

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of Nordox 75 WG as a fungicide on arable crops (strawberry, tomato, eggplant, pepper, lettuce, scarole and cucumber) poses an acceptable risk to non-target organisms, if applied according to the recommended use pattern in greenhouses.

Uses to be considered safe on the basis of EU methodology:

Section 7: 5 (except pepper), 7, 8

Other sections: 4, 5, 7, 8

Uses to be considered non-safe on the basis of EU methodology:

None

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

None

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Appendix 1 ALL intended uses

GAP rev. 01, date: 2021-01-31

PPP (product name/code):	Nordox 75 WG	Formulation type:	WG
Active substance 1:	Copper (I) oxide	Conc. of as 1:	750 (c)
Safener:	safener	Conc. of safener:	conc. (c)
Synergist:	synergist	Conc. of synergist:	conc. (c)
Applicant:	Nordox AS	Professional use:	☒
Zone(s):	Interzonal	Non professional use:	☐
Verified by MS:	yes		

Field of use: Fungicide and bactericide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
~~4~~	~~PL~~	~~Strawberry~~	~~G~~	~~*Marssonina fragariae, Zythia fragariae Mycosphaerella, bacterial disease, Colletotrichum sp.*~~	~~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	*Phytophtora spp., Alternaria, Colletotrichum, Bacterial disease (Pseudomonas spp., Xanthomonas spp.).*	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	
7	PL	Lettuce Scarole	G	*Alternaria, Bremia lactucae Bacterial disease: Erwinia spp., Pseudomonas spp. Xanthomonas spp.*	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	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha[f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
8	PL	Cucumber	G	*Alternaria, Antracnosis, Phytophtora spp.*,	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/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions