REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: **Nordox 75 WG**

Chemical active substance(s):

Copper (I) oxide (Cu2O), 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: dd/mm/yyyy

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

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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).

10 Relevance of metabolites in groundwater

10.1 General information

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.

10.2 Relevance assessment

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.

10.2.1 STEP 1: Exclusion of degradation products of no concern

Not relevant.

10.2.2 STEP 3: Hazard assessment – identification of relevant metabolites

Not relevant.

10.2.2.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.2.2.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.2.2.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.2.3 STEP 4: Exposure assessment – threshold of concern approach

Not relevant.

10.2.4 STEP 5: Refined risk assessment

Not relevant.

The zRMS agrees with submitted justification.

Appendix 1 Lists of data considered in support of the evaluation

Not relevant.

Appendix 2 Additional information

Not relevant.