

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: FEL02

Product name(s): Cuprofix C/Cuprofix C Disperss

Chemical active substance(s):

Copper (Bordeaux mixture), 200 g/kg

Cymoxanil, 40 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Art. 33 new authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: March 2023

MS Finalisation date: November 2023; April 2024

Version history

When	What
March 2023	Part B - Section 8 - Core Assessment, Version 01 of applicant
November 2023	dRR version by zRMS
April 2024	The final version of the RR after the commenting period

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8 Fate and behaviour in the environment (KCP 9)

This dossier is intended for the application for the national authorisation of the product FEL02 according to Article 33 of Regulation (EC) No 1107/2009. The product FEL02 is based on the active substances Copper (as Bordeaux mixture), 200 g/kg, and Cymoxanil, 40 g/kg.

The active substance Copper compounds was first included in Annex I of Directive 91/414/EEC on 1 December 2009 (Commission Directive 2009/37/EC of 23 April 2009). The original rapporteur Member State France provided a Monograph in April 2007 and an Addendum in July 2008. A list of endpoints agreed at the original approval can be found in the Review Report on Copper compounds (SANCO/150/08 final 26 May 2009).

With Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, the active substance Copper compounds was included in the list of approved active substances according to Regulation (EC) No 1107/2009.

The renewal of approval of Copper compounds (Copper hydroxide, Copper oxychloride, Copper oxide, Bordeaux mixture, tribasic Copper sulphate) according to Regulation (EC) No 1107/2009 was confirmed with Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018, coming into force by 1 January 2019. The rapporteur Member State for the renewal of the EU Review, France, prepared a Renewal Assessment Report in December 2016, with updates in September and November 2017. The conclusion of the Peer Review can be found in EFSA Journal 2018;16(1):5152. The renewal the approval of Copper compounds as candidates for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009 was agreed.

The product (FEL02) was not one of the representative products of the EU Review procedure for renewal of approval of Copper compounds, however, the applicant UPL Europe Ltd. is a member of the European Union Copper Task Force, (EUCuTF) and was one of the notifiers of the renewal procedure. UPL Europe Ltd. has full access to the active substance data package submitted to the rapporteur Member State France.

The active substance Cymoxanil was first included in Annex I of Directive 91/414/EEC on 1 September 2009 (Commission Directive 2008/125/EC of 19 December 2008). The original rapporteur Member State Austria provided a Monograph in June 2007. A list of endpoints agreed at the original approval can be found in the Review Report on Cymoxanil (SANCO/179/08 final 9 July 2010).

With Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, the active substance Cymoxanil was included in the list of approved active substances according to Regulation (EC) No 1107/2009.

Cymoxanil is in the process of renewal of approval according to Regulation (EC) No 1107/2009. The rapporteur Member State for the renewal of the EU Review, Lithuania, prepared a Renewal Assessment Report in July 2020, and the public consultation was finished in October 2020.

The product (FEL02) is not one of the representative products of the EU Review procedure for renewal of approval of cymoxanil, however, the applicant UPL Europe Ltd. is a member of the Cymoxanil Task Force and was one of the notifiers of the renewal procedure. UPL Europe Ltd. has full access to the active substance data package submitted to the rapporteur Member State Lithuania.

This application follows the data requirements for the plant protection product laid down in Regulation (EC) No 284/2013. Data submitted on the formulated product are owned by the applicant UPL Europe Ltd. A summary of the data is provided in dRR format. Only summaries of studies and risk assessments which have not yet been assessed in any EU Member State are included in dRR Part B.

The technical active substance Copper (Bordeaux mixture) used in FEL02 was evaluated during the EU Review for the renewal of approval of Copper compounds. Thus, an assessment of technical equivalence is not required for the current application.

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 conclusion¹ 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. The inappropriateness of current guidelines for the assessment of Copper compounds has been recognised by the EU

¹ EFSA Journal 2018;16(1):5152

Commission, EFSA, the RMS and several MS (see comments from DE and IT in the Peer review Report), and this is now fully justified by the documents made available recently by EFSA^{2,3}. Those documents confirm that the approaches and methodology suggested by the EUCuTF already during the EU renewal and also presented by its members for Art. 43 and Art. 33 authorizations can be used for transition metals like copper. In addition, and noticeably, the use of the EUCuTF approach is a prerequisite to enable a meaningful assessment and avoid conservative outcomes for copper products.

The applicant UPL Europe Ltd. presents several statements explaining and justifying the risk assessment approach and deviations from the EU agreed endpoints in the present dossier and in line with the EU dossier submitted for the renewal. The statements are referred to in the dossier where applicable.

The present submission and its evaluation by MS are due before this GD will be available, explaining and justifying the risk assessment approach herein proposed.

The current EFSA conclusion⁴ 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 bioavailability; 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, BPR).

Therefore, applicants as well as zRMS are required to deviate from the LoEP and the standard procedures described in the GD. This can now be fully justified by the documents made available recently by EFSA^{5,6}. Those documents confirm that the approaches and methodology suggested by the EUCuTF already during the EU renewal and also presented by its members for Art. 43 and Art. 33 authorizations will find their way into the evaluation system and can be used for transition metals.

² Statement of the PPR Panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products (PPP) | European Food Safety Authority (europa.eu)

³ Outcome of the Public Consultation on the draft statement of the PPR Panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products (PPP) - - 2021 - EFSA Supporting Publications - Wiley Online Library

⁴ *Ibidem*

⁵ EFSA Journal 2021;19(3):6498

⁶ EFSA Journal 2021;18(3):EN-6501

8.1 Critical GAP and overall conclusions

The formulated product FEL02 is proposed to be applied as a fungicide up to 6 times per season to potatoes. The maximum application rates (per application) are 0.12 kg Cymoxanil/ha and 0.60 kg Copper/ha (equivalent to 3 kg product/ha) with a minimum application interval of 7 days.

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

PPP (product name/code)	FEL02	Formulation type:	WG
Active substance 1	Cymoxanil	Conc. of a.s. 1:	40 g/kg
Active substance 2	Copper as Bordeaux mixture	Conc. of a.s. 2:	200 g/kg
Safener	-	Conc. of safener:	-
Synergist	-	Conc. of synergist:	-
Applicant:	UPL Holdings Coöperatief U.A.	Professional use	<input checked="" type="checkbox"/>
Zone:	Central	Non-professional use	<input type="checkbox"/>
Verified by MS:	Yes/No		

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:	Conclusion
					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.s./ha a) max. rate per appl. b) max. total rate per crop / season	Water L/ha min / max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	EU Central Zone	Potato	F	Late blight (<i>Phytophthora infestans</i>)	Spraying	From first basal side shoot visible to 50% of the leaves brownish (BBCH 21 to 95)	6	7	a) 3.0 b) 18.0	a) 0.12 + 0.60 b) 0.72 + 3.60	100 / 1000	7	Month of application: 04 to 09	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

N/A: Not available

Explanation for column 15 "Conclusion"

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

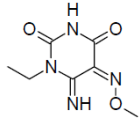
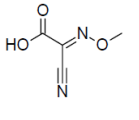
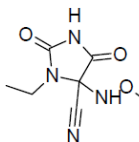
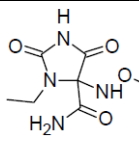
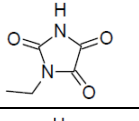
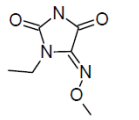
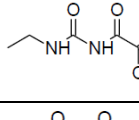
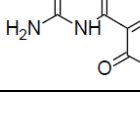
zRMS comments:

The dRR was prepared by applicant. All comments and conclusions of the zRMS are presented in grey and yellow after commenting. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.

8.2 Metabolites considered in the assessment

8.2.1 Metabolites of Cymoxanil (active substance 1)

Table 8.2-1: Metabolites of Cymoxanil relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IN-U3204	198.2		- Soil: 24.7% - Surface water: 24.7% - Sediment: 0.5%	Exposure assessments (PECsoil, PECgw and PECsw/sed) not covered by EU assessment
IN-W3595	128.1		- Soil: 10.1% - Surface water: 26.1% - Sediment: 2.3%	Exposure assessments (PECsoil, PECgw and PECsw/sed) not covered by EU assessment
IN-JX915	198.2		- Soil: 10.9% - Surface water: 52.6% - Sediment: 1.2%	Exposure assessments (PECsoil, PECgw and PECsw/sed) not covered by EU assessment
IN-KQ960	216.2		- Soil: 6.3% - Surface water: 13.0% - Sediment: 5.5%	Exposure assessments (PECgw and PECsw/sed) not covered by EU assessment
IN-T4226	142.1		- Soil: 1.7% - Surface water: 11.1% - Sediment: 1.0%	Exposure assessment (PECsw/sed) not covered by EU assessment
IN-R3273	171.2		- Soil: 2.4% - Surface water: 35.4% - Sediment: 0.5%	Exposure assessment (PECsw/sed) not covered by EU assessment
IN-KP533	160.1		- Soil: 2.7% - Surface water: 20.5% - Sediment: 6.5%	Exposure assessment (PECsw/sed) not covered by EU assessment
Metabolite fraction M5	198.2		- Soil: 0.0% - Surface water: 22.9% - Sediment: 0.0%	Exposure assessment (PECsw/sed) not covered by EU assessment

8.2.2 Metabolites of Copper (active substance 2)

Copper is an element and therefore cannot be transformed into related metabolites or degradation products.

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 substances.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Cymoxanil (active substance 1) and its metabolites

Aerobic degradation in soil is discussed in detail in the EFSA conclusion report on Cymoxanil (EFSA Scientific Report (2008) 167, 1-116) and under point B.8 of the respective Draft Assessment Report on Cymoxanil (2007) where the study references can be found.

The endpoints relevant for risk assessment of Cymoxanil and its metabolites are summarised in the following tables. It is noted here that new information (post-approval) on soil aerobic degradation has become available and is discussed in section 8.8.1.1 and in Appendix 2.

Table 8.3-1: Summary of aerobic degradation rates for Cymoxanil - laboratory studies

Cymoxanil, Laboratory studies, aerobic conditions							
Soil type	pH ^a	t. °C / % MWHC	DT50 / DT90 (days)	DT50 (d) 20°C and pF2 ^b	Chi ² (%)	Kinetic model	Evaluated on EU level
Sandy loam, UK	6.0 ¹	20°C / 40%	0.1 / 0.5	0.2	1.4	FOMC	y / LoEP ^c
Sandy loam, US	6.4 ¹	25°C / 75%	1.2 / 18.8	5.8	17.6	FOMC	y / LoEP ^c
Sandy clay loam, J	6.8 ¹	25°C / 50%	0.2 / 0.8	0.4	5.9	FOMC	y / LoEP ^c
Sandy loam, DE	6.5 ¹	20°C / 50%	2.3 / 13.1	3.1	6.9	FOMC	y / LoEP ^c
Sandy loam, F	7.8 ¹	20°C / 50%	0.7 / 2.3	0.6	16.7	FOMC	y / LoEP ^c
Sandy clay loam, UK	5.7 ¹	20°C / 50%	2.5 / 33.3	7.3	6.5	FOMC	y / LoEP ^c
Silt loam, UK	4.3 ²	20°C / 40%	4.3 / 23.7	6.1	4.3	FOMC	y / LoEP ^c
Silt loam, UK	6.4 ²	20°C / 40%	0.9 / 3.1	0.8	2.6	SFO	y / LoEP ^c
Clay loam, UK	7.5 ²	20°C / 40%	0.2 / 0.8	0.2	5.7	SFO	y / LoEP ^c
Geometric mean (n=9)				1.2			
pH-dependence, Yes or No:				Yes ^d			
Silt loam, UK	6.5 ²	10°C / 40%	1.4 / 4.7	-	2.8	SFO	y / LoEP ^c

a Measured in matrix (1) unknown or (2) CaCl₂ solution

b Q10=2.2 used for temperature correction of soil DT50 values

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

d Soil DT50 significantly ($p < 0.05$) depending on soil pH (lower under acidic conditions). This was taken into consideration in the assessment of leaching potential.

Table 8.3-2: Summary of aerobic degradation rates for metabolite IN-U3204 - laboratory studies

Metabolite IN-U3204, Laboratory studies, aerobic conditions								
Soil type	pH ^a	t. °C / % MWHC	DT50 / DT90 (days)	f.f. (from parent)	DT50 (d) 20°C and pF2 ^b	Chi² (%)	Kinetic model	Evaluated on EU level
Sandy clay loam, J	6.8 ¹	25°C / 50%	0.6 / 1.9	0.48	0.9	11.0	P _{SFO} → M _{SFO}	y / LoEP ^c

Metabolite IN-U3204, Laboratory studies, aerobic conditions								
Soil type	pH ^a	t. °C / % MWHC	DT50 / DT90 (days)	f.f. (from parent)	DT50 (d) 20°C and pF2 ^b	Chi² (%)	Kinetic model	Evaluated on EU level
Silt loam, UK	6.4 ²	20°C / 40%	0.4 / 1.3	0.24	0.3	0.88	P _{SFO} → M _{SFO}	y / LoEP ^c
Clay loam, UK	7.5 ²	20°C / 40%	0.2 / 0.6	0.36	0.2	0.95	P _{SFO} → M _{SFO}	y / LoEP ^c
Arithmetic mean (n=3)				0.36				
Geometric mean (n=3)					0.4			
pH-dependence, Yes or No:					No			

Table 8.3-3: Summary of aerobic degradation rates for metabolite IN-W3595 - laboratory studies

a Measured in matrix (1) unknown or (2) CaCl₂ solution
b Q10=2.2 used for temperature correction of soil DT50 values
c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Metabolite IN-JX915, Laboratory studies, aerobic conditions								
Soil type	pH ^a	t. °C / % MWHC	DT50 / DT90 (days)	f.f. (from parent)	DT50 (d) 20°C and pF2 ^b	Chi² (%)	Kinetic model	Evaluated on EU level
Sandy clay loam, J	6.8 ¹	25°C / 50%	0.6 / 1.9	0.10	1.0	27	P _{SFO} → M _{SFO}	y / LoEP ^c

Table 8.3-5: Summary of aerobic degradation rates for metabolite IN-KQ960 - laboratory studies

Metabolite IN-KQ960, Laboratory studies, aerobic conditions

Soil type	pH ^a	t. °C / % MWHC	DT50 / DT90 (days)	f.f. (from M1) ^b	DT50 (d) 20°C and pF2 ^c	Chi ² (%)	Kinetic model ^b	Evaluated on EU level
Sandy clay loam, J	6.8 ¹	25°C / 50%	7.6 / 25.2	0.16	11.2	19.2	P _{SFO} → M1 _{SFO} → M2 _{SFO}	y / LoEP ^d

a Measured in matrix (1) unknown or (2) CaCl₂ solution

b M1 = IN-U3204; M2 = IN-KQ960

c Q10=2.2 used for temperature correction of soil DT50 values

d LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

8.3.1.2 Copper (active substance 2)

The rate of degradation in soil was evaluated during Annex I renewal as published in EFSA Journal 2018;16(1):5152⁷.

As outlined in the EFSA conclusion, Copper is an inorganic metallic compound and therefore cannot be degraded. The (rate of) degradation in soil as a measure of laboratory tests on carbon-based organic molecules is not applicable to Copper. 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 solubility 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.

⁷ EFSA (European Food Safety Authority), Arena et al., 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance copper compounds copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture. EFSA Journal 2018;16(1):5152, 25 pp.
<https://doi.org/10.2903/j.efsa.2018.5152>

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.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

8.3.2.1 Cymoxanil (active substance 1) and its metabolites

A study was not required nor provided during the Annex I Inclusion of Cymoxanil.

8.3.2.2 Copper (active substance 2)

Please refer to point 8.3 above.

8.4 Field studies (KCP 9.1.1.2)

Field studies with the formulation were not performed since it is possible to extrapolate from data obtained with the active substance.

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

8.4.1.1 Cymoxanil (active substance 1) and its metabolites

A study was not required nor provided during the Annex I Inclusion of Cymoxanil.

8.4.1.2 Copper (active substance 2)

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. Following the assessment of confirmatory data by EFSA, the approval has been amended by Commission Implementing Regulation (EU) No 2015/232/EC concerning monitoring programmes for contamination by Copper in order to conclude on the environmental risk assessment (EFSA, 2018)⁸.

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. The values suitable for use in soil exposure assessments are summarised below.

Soil	Soil concentration [mg Cu/kg soil DM]	Comment
Background level	11.5	
Vineyards ^a	28 66.4 160 73	Overall median 10 th percentile value Overall median value Overall median 90 th percentile value Overall mean value
Vineyards	29.5 26.09 128.0 49.26	Overall median 10 th percentile value LUCAS data ^e Overall median value LUCAS data Overall median 90 th percentile value LUCAS data ^d Overall mean value LUCAS data
Arable fields ^b	7 13.4 26 15.9	Overall median 10 th percentile value Overall median value Overall median 90 th percentile value Overall mean value
Orchards ^b	- 39.8 58 23	Overall median 10 th percentile value Overall median value Overall median 90 th percentile value Overall mean value
Olive groves	24.7 74.5 33.5	Overall median value LUCAS data Overall median 90 th percentile value LUCAS data Overall mean value LUCAS data

⁸ EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for copper compounds copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture in light of confirmatory data. EFSA supporting publication 2018:EN-1486. 25 pp. doi:10.2903/sp.efsa.2018.EN-1486

- a Recently published data from the EU LUCAS program (Copper distribution in European Topsoils: An assessment based on LUCAS soil survey (Ballabio *et al.* 2018⁹) 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.
- b Includes new data from the EU LUCAS program.
- c Calculated from the standard deviation of the set of data in the paper described in ^a.
- d Calculated from the standard deviation of the set of data in the paper described in ^a.

It can be seen following an extensive review of European monitoring programs a median soil concentration of 13.4 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 (Ballabio *et al.* 2018) 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 the extend the data set and to refine the values presented in the LoEP for their PECsoil calculations.~~

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

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

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
	15	Overall mean value
Orchards	-	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

⁹ Cristiano Ballabio, Panos Panagos, Emanuele Lugato, Jen-How Huang, Alberto Orgiazzi, Arwyn Jones, Oihane Fernández-Ugalde, Pasquale Borrelli, Luca Montanarella. Copper distribution in European topsoils: An assessment based on LUCAS soil survey. Science of The Total Environment Volume 636, 15 September 2018, Pages 282-298

8.4.2.1 Cymoxanil (active substance 1) and its metabolites

A study was not required nor provided during the Annex I Inclusion of Cymoxanil.

8.4.2.2 Copper (active substance 2)

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

Please refer to point 8.4 above for a summary of EU monitoring programs and to point 8.7 below for PEC_{accumulation} 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 extrapolate from data obtained with the active substances.

8.5.1 Laboratory studies

8.5.1.1 Cymoxanil (active substance 1) and its metabolites

Sorption behaviour in laboratory studies is discussed in detail in the EFSA conclusion report on Cymoxanil (EFSA Scientific Report (2008) 167, 1-116) and under point B.8 of the respective Draft Assessment Report on Cymoxanil (2007) where the study references can be found.

The endpoints relevant for risk assessment of Cymoxanil and its metabolites are summarised in the following tables. It is noted here that new information (post-approval) on adsorption/desorption has become available and is discussed in section 8.8.1.1 and in Appendix 2.

Table 8.5-1: Summary of soil adsorption/desorption for Cymoxanil

Cymoxanil						
Soil type	OC (%)	pH ^a	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level
Silt loam, DE	0.59	6.9	0.090	15.1	0.88	y / LoEP ^b
Sandy loam, US	1.0	5.7	0.910	87.1	0.87	y / LoEP ^b
Loamy sand, UK	1.6	8.1	0.462	28.9	0.81	y / LoEP ^b
Clay, UK	2.0	7.2	0.856	43.4	0.87	y / LoEP ^b
Arithmetic mean (n=4)				43.6	0.86	
pH-dependence, Yes or No:				No		

a Measured in matrix unknown

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.5-2: Summary of soil adsorption/desorption for metabolite IN-U3204

Metabolite IN-U3204								
Soil type	OC (%)	pH ^a	K _d (mL/g)	K _{oc} (mL/g)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level

Table 8.5-2: Summary of soil adsorption/desorption for metabolite IN-U3204

Metabolite IN-U3204								
Soil type	OC (%)	pH ^a	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level
HPLC method	--	--	--	27.9	--	--	1.0 ^b	y / LoEP ^c
pH-dependence, Yes or No:				n.a.				

a Measured in matrix unknown

b PRAPeR 32 agreed default value

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.5-3: Summary of soil adsorption/desorption for metabolite IN-W3595

Metabolite IN-W3595								
Soil type	OC (%)	pH ^a	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level
Loamy sand, US	2.3	4.6	0.63	27.4	--	--	--	y / LoEP ^c
Sandy loam, US	0.99	7.6	0.026	2.6	--	--	--	y / LoEP ^c
Silt loam, US	3.2	7.8	0.074	2.3	--	--	--	y / LoEP ^c
Sandy loam, US	0.46	6.4	0.020	4.3	--	--	--	y / LoEP ^c
Arithmetic mean (n=4)				9.2			1.0 ^b	
pH-dependence, Yes or No:				Yes				
Koc-acid				33.3				
Koc-base				2.3				
pKa				5.2				

a Measured in matrix unknown

b PRAPeR 32 agreed default value

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.5-4: Summary of soil adsorption/desorption for metabolite IN-JX915

Metabolite IN-JX915								
Soil type	OC (%)	pH ^a	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level
Loamy sand, US	2.3	4.6	0.13	5.4	--	--	--	y / LoEP ^c
Sandy loam, US	0.99	7.6	0.34	34.3	--	--	--	y / LoEP ^c
Silt loam, US	3.2	7.8	0.66	20.6	--	--	--	y / LoEP ^c
Sandy loam, US	0.46	6.4	0.021	4.4	--	--	--	y / LoEP ^c
Arithmetic mean (n=4)				16.2			1.0 ^b	
pH-dependence, Yes or No:				No				

a Measured in matrix unknown

b PRAPeR 32 agreed default value

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.5-5: Summary of soil adsorption/desorption for metabolite IN-KQ960

Metabolite IN-KQ960								
Soil type	OC (%)	pH ^a	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level
HPLC method	--	--	--	21.6	--	--	1.0 ^b	y / LoEP ^c
pH-dependence, Yes or No:				n.a.				

a Measured in matrix unknown

b PRAPeR 32 agreed default value

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.5-6: Summary of soil adsorption/desorption for metabolite IN-T4226

Metabolite IN-T4226								
Soil type	OC (%)	pH ^a	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level
HPLC method	--	--	--	17.7	--	--	1.0 ^b	y / LoEP ^c
pH-dependence, Yes or No:				n.a.				

a Measured in matrix unknown

b PRAPeR 32 agreed default value

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.5-7: Summary of soil adsorption/desorption for metabolite IN-R3273

Metabolite IN-R3273								
Soil type	OC (%)	pH ^a	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level
Loamy sand, US	2.3	4.6	0.59	25.7	--	--	--	y / LoEP ^c
Sandy loam, US	0.99	7.6	0.49	49.5	--	--	--	y / LoEP ^c
Silt loam, US	3.2	7.8	1.5	46.9	--	--	--	y / LoEP ^c
Sandy loam, US	0.46	6.4	0.21	45.7	--	--	--	y / LoEP ^c
Arithmetic mean (n=4)				42.0			1.0 ^b	
pH-dependence, Yes or No:				Yes				

a Measured in matrix unknown

b PRAPeR 32 agreed default value

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.5-8: Summary of soil adsorption/desorption for metabolite IN-KP533

Metabolite IN-KP533								
Soil type	OC (%)	pH ^a	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level
HPLC method	--	--	--	12.9	--	--	1.0 ^b	y / LoEP ^c
pH-dependence, Yes or No:				n.a.				

Table 8.5-8: Summary of soil adsorption/desorption for metabolite IN-KP533

Metabolite IN-KP533								
Soil type	OC (%)	pH ^a	K _d (mL/g)	K _{oc} (mL/g)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level

a Measured in matrix unknown

b PRAPeR 32 agreed default value

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

8.5.1.2 Copper (active substance 2)

The adsorption/desorption in soil 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_{d_{oc}} value for soil at pH 4 - 5 of 19509.9 L/kg was selected as a generic K_{d_{oc}} value for soil for a first tier exposure assessment. The geomean K_{d_{oc}} value 33918.3 mL/g oc derived from pH range 5.5 - 6.5 was used for PEC_{SW} simulations. A summary of soil adsorption data is presented in the following table.

Table 8.5-9 Summary of soil adsorption for Copper (EFSA Journal 2018;16(1):5152)

Copper							
Soil type	OC [%]	pH [CaCl ₂]	K _d [mL/g]	K _{d_{oc}} [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	-	-	-
Geometric mean			-	pH 4-5: 19509.9 pH 5.5-6.5: 33918.3	-	-	-
pH-dependency			Yes				

8.5.2 Column leaching (KCP 9.1.2.1)

Column leaching studies with the formulation were not performed since it is possible to extrapolate from data obtained with the active substances.

8.5.2.1 Cymoxanil (active substance 1) and its metabolites

A study was not required nor provided during the Annex I Inclusion of Cymoxanil.

8.5.2.2 Copper (active substance 2)

Column leaching in soil was evaluated during Annex I renewal as published in 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 overestimation 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 Cymoxanil (active substance 1) and its metabolites

Lysimeter studies are discussed in detail in the EFSA conclusion report on Cymoxanil (EFSA Scientific Report (2008) 167, 1-116) and under point B.8 of the respective Draft Assessment Report on Cymoxanil (2007) where the study references can be found.

Data from lysimeter studies are not used in exposure/risk assessment of Cymoxanil or its metabolites.

8.5.3.2 Copper (active substance 2)

A review of the existing monitoring programmes 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 Cymoxanil (active substance 1) and its metabolites

A study was not required nor provided during the Annex I Inclusion of Cymoxanil.

8.5.4.2 Copper (active substance 2)

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 aerobic mineralisation in surface water and degradation in (irradiated) 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 Cymoxanil (active substance 1) and its metabolites

Degradation in water/sediment systems is discussed in detail in the EFSA conclusion report on Cymoxanil (EFSA Scientific Report (2008) 167, 1-116) and under point B.8 of the respective Draft Assessment Report on Cymoxanil (2007) where the study references can be found.

A summary of the observed metabolites and their maximum occurrence is given in the following tables.

Table 8.6-1: Summary of observed metabolites

Metabolite	Maximum occurrence	Evaluated on EU level
IN-U3204	Max. 24.7 % (whole system; water/sediment study)	y / LoEP ^a
IN-W3595	Max. 27.5 % (whole system; water/sediment study)	y / LoEP ^a
IN-KQ960	Max. 14.3 % (whole system; water/sediment study)	y / LoEP ^a
IN-JX915	Max. 52.6 % (water; aquatic photolysis study) ^b	y / LoEP ^a
IN-T4226	Max. 12.0 % (whole system; water/sediment study)	y / LoEP ^a
IN-R3273	Max. 35.4 % (water; aquatic photolysis study) ^c	y / LoEP ^a
IN-KP533	Max. 26.0 % (whole system; water/sediment study)	y / LoEP ^a
Metabolite fraction M5	Max. 22.9 % (whole system; water/sediment study)	y / LoEP ^a

^a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

^b Value from aquatic photolysis study used in a worst case assessment. In water/sediment studies IN-JX915 was found at max. 8.5% of AR (whole system).

^c Value from aquatic photolysis study used in a worst case assessment. In water/sediment studies IN-R3273 was found at max. 5.0% of AR (whole system).

The endpoints relevant for risk assessment of Cymoxanil and its metabolites (i.e. those derived from the non-irradiated water/sediment study) are summarised in the following tables.

Table 8.6-2: Summary of degradation in water/sediment of Cymoxanil

Cymoxanil (max. in sediment 3.9% AR after 1 d)							
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	Kinetic fit	DT50 / DT90 (d) sed.	Evaluated on EU level
Sand	7.4 / 7.0 ¹	0.5 / 1.7	SFO	0.5 / 1.7	SFO	n.c.	y / LoEP ^b
Sand	5.3 / 5.1 ¹	1.6 / 5.3	SFO	1.5 / 5.0	SFO	n.c.	y / LoEP ^b
Silty clay loam	8.3 / 7.5 ²	0.1 / 0.2	SFO	0.1 / 0.2	SFO	n.c.	y / LoEP ^b

Cymoxanil (max. in sediment 3.9% AR after 1 d)							
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	Kinetic fit	DT50 / DT90 (d) sed.	Evaluated on EU level
Silt loam	8.3 / 7.5 ²	0.2 / 0.5	SFO	0.2 / 0.5	SFO	n.c.	y / LoEP ^b
Geometric mean (n=4)		0.3 / 1.0		0.3 / 1.0		--	

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Metabolite IN-U3204 (max. in water 24.7% AR after 0.13 d, max. in sediment 0.5 % AR after 3 d)						
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level
Sand	7.4 / 7.0 ¹	0.6 / 2.0	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silty clay loam	8.3 / 7.5 ²	0.2 / 0.5	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silt loam	8.3 / 7.5 ²	0.5 / 1.7	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Geometric mean (n=3)		0.4 / 1.2		--	--	

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Metabolite IN-W3595 (max. in water 26.1 % AR after 0.25 d, max. in sediment 2.3 % AR after 1 d)						
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level
Sand	7.4 / 7.0 ¹	3.6 / 12.1	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silty clay loam	8.3 / 7.5 ²	2.7 / 9.0	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silt loam	8.3 / 7.5 ²	2.7 / 8.9	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Geometric mean (n=3)		3.0 / 9.9			--	

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

<p>Metabolite IN-KQ960 (max. in water 13.0 % AR after 1 d, max. in sediment 5.5 % AR after 30 d)</p>
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Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level y/n/ Reference
Sand	7.4 / 7.0 ¹	154 / 521	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Sand	5.3 / 5.1 ¹	45.4 / 151	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silt loam	8.3 / 7.5 ²	15.2 / 50.5	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Geometric mean (n=3)		47.4 / 158			--	

n.c.: not conducted

a pH of sediment measured in matrix unknown (1) or CaCl₂ solution (2)

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.6-6: Summary of degradation in water/sediment of metabolite IN-JX915

Metabolite IN-JX915 (max. in water 7.2% AR after 1 d, max in sediment 1.2% AR after 1 d)						
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level
Sand	7.4 / 7.0 ¹	2.5 / 8.3	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Sand	5.3 / 5.1 ¹	1.1 / 3.7	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silty clay loam	8.3 / 7.5 ²	2.1 / 7.1	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silt loam	8.3 / 7.5 ²	1.5 / 5.1	P _{SFO} → M _{SFO}	n.c.	n.c.	y / LoEP ^b
Geometric mean (n=4)		1.7 / 5.8		--	--	

n.c.: not conducted

a pH of sediment measured in matrix unknown (1) or CaCl₂ solution (2)

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.6-7: Summary of degradation in water/sediment of metabolite IN-T4226

Metabolite IN-T4226 (max. in water 11.1 % AR after 3 d, max. in sediment 1.0 % AR after 8 d)						
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level
Sand	7.4 / 7.0 ¹	3.9 / 12.9	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Sand	5.3 / 5.1 ¹	5.4 / 17.9	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Geometric mean (n=2)		4.6 / 15.2		--	--	

n.c.: not conducted

a pH of sediment measured in matrix unknown (1) or CaCl₂ solution (2)

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.6-8: Summary of degradation in water/sediment of metabolite IN-R3273

Metabolite IN-R3273 (max. in water 5.0 % AR after 3 d, max. in sediment 0.5 % AR after 3 d)						
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level

Table 8.6-8: Summary of degradation in water/sediment of metabolite IN-R3273

Metabolite IN-R3273 (max. in water 5.0 % AR after 3 d, max. in sediment 0.5 % AR after 3 d)						
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level
Sand	7.4 / 7.0 ¹	6.0 / 19.9	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Sand	5.3 / 5.1 ¹	6.7 / 22.2	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Geometric mean (n=2)		6.3 / 21.0		--	--	

n.c.: not conducted

a pH of sediment measured in matrix unknown (1) or CaCl₂ solution (2)

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.6-9: Summary of degradation in water/sediment of metabolite IN-KP533

Metabolite IN-KP533 distribution (max. in water 20.5 % AR after 10 d, max. in sediment 6.5 % AR after 1 d) ^a						
Water / sediment system (aerobic)	pH wat./sed. ^b	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level
Sand	7.4 / 7.0 ¹	2.3 / 7.5	M _{SFO}	n.c.	n.c.	y / LoEP ^c
Sand	5.3 / 5.1 ¹	3.0 / 10.0	M _{SFO}	n.c.	n.c.	y / LoEP ^c
Geometric mean (n=2)		2.6 / 8.7		--	--	

n.c.: not conducted

a Worst-case assessment, individual amounts of IN-KP533 in two of four water/sediment systems not known (in two systems maximal 8.0 % of AR in the entire system)

b pH of sediment measured in matrix unknown (1) or CaCl₂ solution (2)

c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.6-10: Summary of degradation in water/sediment of metabolite ‘Metabolite fraction M5’

Metabolite fraction M5 distribution (max. in water 22.9 % AR after 1 d, max. in sediment 0.0 % AR)						
Water / sediment system (aerobic)	pH wat./sed. ^a	DegT50 / DegT90 (d) whole system	Kinetic fit	DT50 / DT90 (d) water	DT50 / DT90 (d) sed.	Evaluated on EU level
Silty clay loam	8.3 / 7.5 ²	1.2 / 4.0	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Silt loam	8.3 / 7.5 ²	1.6 / 5.2	M _{SFO}	n.c.	n.c.	y / LoEP ^b
Geometric mean (n=2)		1.4 / 4.6				

a pH of sediment measured in matrix unknown (1) or CaCl₂ solution (2)

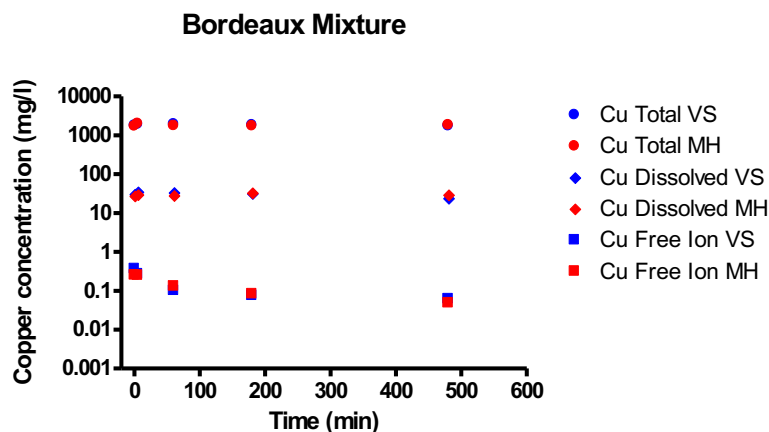
b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

8.6.2 Copper (active substance 2)

Data on the behaviour of Copper in water/sediment systems was evaluated during Annex I renewal 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 Blust and Joosen study (see RAR, Vol. 3, B8, CP 9.2.3/01. Blust and Joosen, 2016) 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 $\mu g\ Cu/L$) DT_{50} values were ± 1 day while at lower concentrations (24, 12 and 2.5 $\mu g\ Cu/L$) 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 (Blust and Joosen, 2016). Any free Copper ions also dissipate with < 1 day (Ma, see RAR, Vol. 3, B8, CP 9.2/02. Ma *et al.*, 1999). 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 (PECsoil) (KCP 9.1.3)

8.7.1 Justification for new endpoints

8.7.1.1 Cymoxanil (active substance 1)

No deviation from EU agreed endpoints.

8.7.1.2 Copper (active substance 2)

No deviation from EU agreed endpoints.

8.7.2 Active substance(s) and relevant metabolite(s)

No specific studies have been prepared by the applicant for PECsoil calculation (please refer below for further modelling details).

The formulated product FEL02 is proposed to be applied as a fungicide up to 6 times per season to potatoes with a minimum application interval of 7 days. The maximum application rates (per application) are 0.12 kg Cymoxanil/ha and 0.6 kg Copper/ha (equivalent to 3 kg product/ha).

The application window is from April up to and including September.

Table 8.7-1: Input parameters related to application for PECsoil calculations

Use No.	1
Crop	Potato
Application rate (g as/ha)	Cymoxanil (active substance 1): 0.12 kg/ha Copper (active substance 2): 3.6 kg/ha ^a
Number of applications/interval	6 annual applications / 7-day interval ^a
Crop interception (%)	Cymoxanil (active substance 1): 60% (see section 8.7.2.1) Copper (active substance 2): 0% (see section 8.7.2.2)
Depth of soil layer (cm)	PECsoil _{initial} : 5 cm PECsoil _{accumulation} : 20 cm (tillage) ^b
Soil density	1.5 g/cm ³

a For copper the calculations were performed with a single season's application (annual dose) i.e. 6 x 0.6 kg/ha (see section 8.7.2.2 for further detail).

b PECsoil_{accumulation} is relevant only for copper

8.7.2.1 Cymoxanil (active substance 1) and its metabolites

For Cymoxanil and the metabolites IN-U3204, IN-W3595 and IN-JX915 calculations were performed for 6 annual applications with a 7-day interval based on a simple first tier approach (Excel sheet) assuming even distribution of the compound in upper 0-5 cm soil layer and a standard soil density of 1.5 g/cm³. A crop interception of 60% was assumed for all applications in a worst case approach (early application scenario).

The PECsoil calculations for Cymoxanil and its metabolites were performed based on SFO kinetics according to the FOCUS document 'Soil persistence models and EU registration' (FOCUS, 1997).

The input parameters used in PECsoil calculations for Cymoxanil and metabolites relevant for soil risk assessment are summarised in the following table.

Table 8.7-2: Input parameter for Cymoxanil and relevant metabolites for PECsoil calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days) ^a	Values in accordance to EU endpoint
Cymoxanil	198.2	--	7.3 d (SFO kinetics) ^b	y / LoEP ^c
IN-U3204	198.2	24.7	0.9 d (SFO kinetics)	y / LoEP ^c
IN-W3595	128.1	10.1	2.5 d (SFO kinetics)	y / LoEP ^c
IN-JX915	198.2	10.9	1.0 d (SFO kinetics)	y / LoEP ^c

Table 8.7-2: Input parameter for Cymoxanil and relevant metabolites for PECsoil calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days) ^a	Values in accordance to EU endpoint
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- a Worst case laboratory values normalised for moisture and temperature (in accordance with EFSA LoEP)
b SFO-DT50 re-calculated from lab FOMC-DT90 by division with 3.32. In accordance with the EFSA LoEP, the pseudo SFO-DT50 was used in PECsoil calculations
c LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

First the concentration in soil immediately after a single application was calculated:

$$\text{Initial PECsoil, single application} = A \cdot (1 - f_{\text{int}}) / (100 \cdot d \cdot \rho)$$

Where:

- A = application rate [g/ha]
f_{int} = fraction intercepted by plant cover
d = depth of the soil layer = 5 cm for spray applications
ρ = bulk density = 1.5 g/cm³

For multiple applications the concentration in soil immediately after n applications, spaced i days apart, was calculated as:

$$\text{Initial PECsoil, n applications} = \text{Initial PECsoil, single application} \cdot (1 - \exp(-n \cdot k \cdot i)) / (1 - \exp(-k \cdot i))$$

Where:

- n = number of applications
k = rate constant [d⁻¹]
i = interval between applications [d]

The actual PECsoil at a particular point in time t days after application (single and/or multiple), was calculated as:

$$\text{Actual PECsoil} = \text{Initial PECsoil} \cdot \exp(-k \cdot t)$$

Where:

- k = rate constant [d⁻¹]
t = time period concerned [d]

Finally, the time weighted average (TWA) concentration over a period of t days after application (single and/or multiple) was calculated as:

$$\text{PECsoil, TWA} = \text{Initial PECsoil} \cdot (1 - \exp(-k \cdot t)) / k \cdot t$$

Where:

- k = rate constant [d⁻¹]
t = time period concerned [d]

Considering that the DT90 values for Cymoxanil and its metabolites were all well below 1 year, no PECsoil,plateau concentrations were calculated.

The PECsoil values for Cymoxanil and its metabolites are listed in the following tables.

Table 8.7-3: PECsoil for Cymoxanil on potato

PECsoil (mg/kg)	Potato			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.064	-	0.129	-

Short term	24h	0.058	0.061	0.118	0.123
	2d	0.053	0.058	0.107	0.118
	4d	0.044	0.053	0.088	0.108
Long term	7d	0.033	0.047	0.067	0.095
	14d	0.017	0.035	0.034	0.072
	21d	0.009	0.028	0.018	0.056
	28d	0.004	0.022	0.009	0.045
	50d	0.001	0.013	0.001	0.027
	100d	0.000	0.007	0.000	0.014
Plateau concentration		n.r.	-	n.r.	-

n.r.: not relevant (DT90 << 1 year)

Table 8.7-4: PEC_{soil} for metabolite IN-U3204 on potato

PEC _{soil} (mg/kg)		Potato			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.016	-	0.016	-
Short term	24h	0.007	0.011	0.007	0.011
	2d	0.003	0.008	0.003	0.008
	4d	0.001	0.005	0.001	0.005
Long term	7d	0.000	0.003	0.000	0.003
	14d	0.000	0.001	0.000	0.001
	21d	0.000	0.001	0.000	0.001
	28d	0.000	0.001	0.000	0.001
	50d	0.000	0.000	0.000	0.000
	100d	0.000	0.000	0.000	0.000
Plateau concentration		n.r.	-	n.r.	-

n.r.: not relevant (DT90 << 1 year)

Table 8.7-5: PEC_{soil} for metabolite IN-W3595 on potato

PEC _{soil} (mg/kg)		Potato			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.004	-	0.005	-
Short term	24h	0.003	0.004	0.004	0.004
	2d	0.002	0.003	0.003	0.004
	4d	0.001	0.003	0.002	0.003
Long term	7d	0.001	0.002	0.001	0.002
	14d	0.000	0.001	0.000	0.001

	21d	0.000	0.001	0.000	0.001
	28d	0.000	0.001	0.000	0.001
	50d	0.000	0.000	0.000	0.000
	100d	0.000	0.000	0.000	0.000
Plateau concentration		n.r.	-	n.r.	-

n.r.: not relevant (DT90 << 1 year)

Table 8.7-6: PECsoil for metabolite IN-JX915 on potato

PEC _{soil} (mg/kg)		Potato			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.007	-	0.007	-
Short term	24h	0.003	0.005	0.004	0.005
	2d	0.002	0.004	0.002	0.004
	4d	0.000	0.002	0.000	0.002
Long term	7d	0.000	0.001	0.000	0.001
	14d	0.000	0.001	0.000	0.001
	21d	0.000	0.000	0.000	0.000
	28d	0.000	0.000	0.000	0.000
	50d	0.000	0.000	0.000	0.000
	100d	0.000	0.000	0.000	0.000
Plateau concentration		n.r.	-	n.r.	-

n.r.: not relevant (DT90 << 1 year)

8.7.2.2 Copper (active substance 2)

For Copper calculations were performed for a single season's application (annual dose) based on a simple first tier approach (Excel sheet) assuming even distribution of the compound in upper 0-5 cm soil layer and a standard soil density of 1.5 g/cm³. 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.

In addition to the levels of Copper arising from the regulated use, natural background levels of Copper originating from geogenic Copper and previous anthropogenic Copper inputs from a variety of sources in the soil exposure assessment were included. 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.

The input parameters used in PEC_{soil} calculations for Copper are summarised in the following table.

Table 8.7-7: Input parameter for Copper for PECsoil calculation

Compound	DT ₅₀	Value in
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	[days]	accordance to EU endpoint
Copper	No degradation expected ^a	y / LoEP ^b

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

^b LoEP = list of endpoints, EFSA Journal 2018;16(1):5152

Following one application, the initial PEC_{soil} value immediately after application is calculated according to the following formula ¹⁰ :

$$\text{Initial PEC}_{\text{soil, single application}} = A \cdot (1 - f_{\text{int}}) / (100 \cdot d \cdot \rho)$$

Where:

A = application rate [g/ha]
f_{int} = fraction intercepted by plant cover
d = depth of the soil layer = 5 cm for spray applications
ρ = bulk density = 1.5 g/cm³

Afterwards, accumulated PEC_{soil} values were 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), 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 of potatoes are summarised below and are taken from Appendix A of 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.

Soil	Soil concentration [mg Cu/kg soil DM]	Comment
Background level	11.5	
Arable fields ^a	7	Overall median 10 th percentile value
	13.4	Overall median value
	26	Overall median 90 th percentile value
	15.9	Overall mean value

^a Includes new data from the EU LUCAS program (Copper distribution in European Topsoils: An assessment based on LUCAS soil survey, (Ballabio et al. 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)	
Arable fields	32	EFSA (2013)
	7	Overall 10 th percentile value
	13	Overall median value
	26	Overall 90 th percentile value
	15	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. The EUCuTF stated in their monitoring report that

¹⁰ European Commission, Directorate for Agriculture, VI B II. 1, 09.08.99, Guidance Document on the Calculation of Predicted Environmental Concentration Values (PEC) of Plant Protection Products for Soil, Ground Water, Surface Water and Sediment, 7193/VI/99 rev. 0, DRAFT Working Document

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 extend the data set and to refine the values presented in the LoEP for their PEC soil calculations.

Findings:

The calculated initial PECsoil values for Copper in soil following a single season's application (annual appl. rate) are summarised in the following table. As Copper does not degrade, PECsoil values with time are not relevant.

Table 8.7-8: PECsoil_{initial} for total Copper

Individual Crop	Rate per Season [g a.s. /ha]	Soil depth [cm]	PECsoil _{initial} [mg/kg]
Potato	1 × 3600	5	4.80

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

Table 8.7-9: PECsoil_{accumulation} for total Copper over seven-year registration

Individual Crop	Rate per Season [g a.s. /ha]	PECsoil _{accumulation} calculation			Background Monitoring Value [mg/kg] ^b	Overall PECsoil _{accumulation} [mg/kg] ^c
		Soil depth [cm]	No. of years	C _{low} ^a [mg/kg]		
Potato	1 × 3600	20	6	7.2	7	19
					13.4	25.4
					26	38

Note: Copper is an element so DT₅₀ value is not relevant

a — C_{low} = PECsoil_{initial} at 20 cm × 6

b — 10th percentile value, median value and 90th percentile value in European arable soils

c — Overall PECsoil_{accumulation} over 7 years = Background monitoring value + C_{low} + PECsoil_{initial} at 5 cm

8.7.2.3 PECsoil of formulation

The calculation of PECsoil for the formulation is considered not relevant.

zRMS comments:

Cymoxanil

zRMS agree with PECs calculations performed for cymoxanil and its metabolites.

Copper

The PECsoil values were re-calculated by zRMS due to fact that the applicant used differ from those of the pertinent List of Endpoints (EFSA Journal 2018; 16(1):5152). PECs was calculated with new mean values including data from the LUCAS database.

However, there is neither a guidance nor a harmonized approach on how to use these data or how to implement them in evaluation procedures. Therefore, zRMS is of the opinion that the applicant's data should not be used but instead the background values of the LoEP (see table above).

The PEC soil calculations for copper take into account the Cu added to soil as plant protection product only.
PEC_{soil} accumulation for total copper over x years registration for potatoes (1 x 3600 g/ha)

PEC _{soil} accumulation for total copper over x years registration for potatoes (1 x 3600 g/ha)										
Individual Crop	Rate per Season	PEC _{soil} accumulation calculation					Background Monitoring Value ^B	Overall PEC _{soil} , accumulation _n ^C	Overall PEC _{soil} , accumulation _n ^D	Overall PEC _{soil} , accumulation _n ^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]						
Potatoes	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

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.

In opinion zRMS, publication Ballabio 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.

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

8.8.1 Justification for new endpoints

8.8.1.1 Cymoxanil (active substance 1)

PEC_{gw} calculations were performed for the active substance Cymoxanil, and the metabolites IN-W3595, IN-U3204, IN-JX915, and IN-KQ960 which were in the EFSA conclusion of 2008 determined to be relevant for groundwater risk assessment. For the parent substance and for the metabolites IN-W3595, IN-U3204, IN-JX915 there are no deviations from EU agreed endpoints. For IN-KQ960 however, new information (post-approval) has become available and is used in the groundwater risk assessment. An overview of the alternative information used for modelling is listed in the following table.

Table 8.8-1: New information (post-approval) used for groundwater risk assessment of metabolite IN-KQ960

Endpoint	EU agreed value	Value used for modelling	Justification
Koc	21.6 L/kg	5.34 L/kg	New data available from a study by Ford (2009). This information was also used in a risk assessment performed in 2013 for authorisation of the product FDJ03, which also contains Cymoxanil as active substance, and was at the time reviewed by zRMS Austria. In the registration report for FDJ03, the RMS concluded that in accordance with the guidance document on the evaluation of new active substance data post-approval (SANCO, 2012), the new information ' <i>presents the case of adverse effects</i> ' and consequently the alternative Koc value was used for groundwater risk assessment (see Appendix 2 for further detail).
DT50 soil	11.2 d	1.0 d	New data from a study by Völkel (2011). This new information was also used in the risk assessment of FDJ03 and reviewed by zRMS Austria. In the registration report for FDJ03, the RMS concluded that in accordance with the guidance document on the evaluation of new active substance data post-approval (SANCO, 2012), ' <i>since the metabolite IN-KQ960 was calculated to be over the trigger value of 0.1 µg/L in the groundwater risk assessment</i> ' [...] ' <i>no safe use is guaranteed</i> ' [...] and ' <i>the new DT50 value of 1.0 day could be taken into consideration</i> ' for groundwater risk assessment (see Appendix 2 for further detail). For FEL02 also, the PEC _{gw} values modelled with the new Koc of 5.34 L/kg were not all <0.1 µg/L for all scenarios (see Koomen (2022a)) and therefor the same reasoning applies.

8.8.1.2 Copper (active substance 2)

Table 8.8-2: New information used for groundwater risk assessment of copper

Endpoint	EU agreed value	Value used for modelling	Justification
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Koc	Kd _{oc} = 19509.9 L/kg	Kd = 1643 L/kg	A median Kd value of 1643 mL/g (see RAR, Vol. 3, B8, CA 7.1.3.1.1/01. Oorts, 2015) was used in the groundwater modelling, whereas EFSA recommended that a value of Kd _{oc} = 19509.9 mL/g should be used. As the value used is far more conservative than the value recommended by EFSA but still results in Copper concentrations in groundwater that were predicted to be < 0.001 µg/L in all of the relevant FOCUS scenarios (see results below) and never approach the legal limit of 2 mg/L set by the European Drinking water directive (98/83/EC) for groundwater, the data has not been modelled with the EFSA value.
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8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

A FOCUS GW calculation for the product FEL02 was performed in order to predict the concentration of residues in groundwater (PEC_{gw}). The procedures followed and the input parameters selected were in accordance with the generic guidance for FOCUS groundwater scenarios (FOCUS, 2021) and the working document of the central zone (Anonymous, 2018).

The formulated product FEL02 is proposed to be applied as a fungicide up to 6 times per season to potatoes with a minimum application interval of 7 days. The maximum application rates of the active substances (per application) are 0.12 kg Cymoxanil/ha and 0.6 kg Copper/ha (equivalent to 3 kg product/ha).

The application window is from April up to and including September. Considering the 6-month application window, two separate simulations were performed, one for early applications and one for late applications. For each scenario the tool AppDate (v3.06) was used to determine the appropriate dates of application. For the early applications scheme, the first date of application was set at BBCH 21 (“first basal side shoot visible”). For the late applications scheme, the last date of application was set at BBCH 90 (“harvest”) minus one week to take into account the pre-harvest interval (PHI) of 7 days. The application dates per scenario are listed in Table 8.8-3.

According to the working document of the central zone (Anonymous, 2018), for the central zone groundwater simulations are to be performed for at least the FOCUS scenarios Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, and Porto. However, for reasons of completeness, simulations were performed and reported also for the remaining scenarios Jokioinen, Sevilla, and Thiva. First, the PEC_{gw} calculations were performed using the FOCUS model PEARL 5.5.5. Depending on the outcome of the calculations performed in PEARL, additional calculations were performed using the FOCUS models PELMO 6.6.4 and MACRO 5.5.4¹¹.

Input parameters related to application of the product FEL02 are presented in the following table.

Use No.	1
Crop / FOCUS crop	Potato / Potato
Application rate (g as/ha)	Cymoxanil (active substance 1): 0.12 kg/ha Copper (active substance 2): 0.6 kg/ha ^a
Number of applications/interval (d)	6 annual applications / 7-day interval
Application date(s)	Application dates are entered as absolute application dates and vary per scenario (see Table 8.8-2)
Crop interception (%)	Cymoxanil (active substance 1): 60-85% (see section 8.8.2.1) Copper (active substance 2): 0% (see section 8.8.2.2)
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v5.5.5

a For copper calculations were performed with a single season's application (annual dose) i.e. 6 x 0.6 kg/ha (see section

¹¹ According to the working document of the central zone, with respect to the use of both the models PEARL and PELMO: ‘if the results of one of these models show the PEC_{gw} results to be <0.001 µg/L in all relevant scenarios for all substances triggering groundwater assessment, it is not necessary to perform simulation runs with the other model’ and ‘No MACRO simulations are necessary if the PEC_{gw} values calculated with FOCUS PEARL and FOCUS PELMO are <0.001 µg/L for all substances which trigger groundwater assessment’.

8.7.2.2 for further detail).

Table 8.8-3: Application dates used for groundwater risk assessment

Crop	Scenario	Application dates (absolute) ^a	
		Early application ^b	Late application ^c
Potato	Châteaudun	13 May	25 August
	Hamburg	30 May	8 September
	Jokioinen	29 June	18 September
	Kremsmünster	30 May	8 September
	Okehampton	22 May	25 August
	Piacenza	2 May	3 September
	Porto	6 April	8 June
	Sevilla	1 April	24 May
	Thiva	1 April	23 July

a Based on AppDate Version 3.06 (June 2019) for respective FOCUS crop in conjunction with the intended growth stages.

b Based on BBCH 21. According to the GAP table the month of application is 04-09 (i.e. April up to and including September). In case AppDate proposes an application timing before April for BBCH 21, April 1 was selected as the first date of application.

c Based on BBCH 90 taking into account a pre-harvest interval (PHI) of 7 days.

8.8.2.1 Cymoxanil (active substance 1) and its metabolites

For Cymoxanil and the metabolites IN-W3595, IN-U3204, IN-JX915, and IN-KQ960 PECgw calculations were performed on the basis of 6 annual applications with a 7-day interval between applications (Koomen, 2022a). Crop interception values were determined for each location based on the application dates using AppDate Version 3.06 (June 2019). For potatoes, the crop interception was set at 60% for growth stages BBCH 20-39 and at 85% for growth stages BBCH 40-89 based on the FOCUS document 'Generic guidance for Tier 1 FOCUS groundwater assessments' (FOCUS, 2021). The application was set to 'to the soil surface' and the application rate was manually corrected for interception, thereby disabling the internal interception routines in the models. The effective application rates entered into the models were 48 g Cymoxanil/ha in case of 60% interception and 18 g Cymoxanil/ha in case of 85% interception.

In line with the approach taken in the EFSA conclusion, two different sets of calculations were performed for Cymoxanil. First, in a standard approach, the PECgw were calculated using the soil geometric mean DT50 of 1.2 days (normalised). Second, in order to take into account the pH-dependent degradation of Cymoxanil, the PECgw were calculated using a worst-case DT50 of 7.3 days (normalised) which is representative for acidic soils. For the relevant metabolites, the PECgw values were calculated within the assessment for the parent compound using the transformation scheme option incorporated in the model. This means that the degradation rate of the parent substance will also affect the timing and magnitude of formation of metabolites, and therefore for the metabolites the PECgw values were also calculated using both the geomean and the conservative DT50 values for Cymoxanil.

The input parameters used in PECgw calculations for Cymoxanil and metabolites relevant for groundwater risk assessment are summarised in the following tables.

Table 8.8-4: Input parameters related to Cymoxanil for PECgw calculations

Parameter ^a	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Physical-chemical parameters		
Molecular weight	198.2 g/mol	
Vapor pressure	1.5E-04 Pa (20°C)	y / LoEP ^b .
Water solubility	782 mg/L (20°C)	y / LoEP ^b .
Degradation in soil		
DT50 soil	1.2 days	y / LoEP ^b . Geometric mean of experimental data (n=9; normalised to pF2 and 20°C (Q10=2.2)).
	7.3 days	y / LoEP ^b . Representative worst-case value of

		experimental data (normalised to pF2 and 20°C (Q10=2.2)) taking into account the pH-dependent degradation of Cymoxanil ^c .
Temperature correction function: - Q10 - Molar activation energy	2.2 54 kJ/mol	y / LoEP ^b . In accordance with the working document of the central zone (2018; v1-rev.1) the Q10 value used to normalise the DT50 for soil was used in the models.
Sorption to soil		
pH-dependent sorption (yes/no)	no	y / LoEP ^b .
Koc	43.6 L/kg	y / LoEP ^b . Arithmetic mean of experimental data (n=4).
Kom	25.3 L/kg	y / LoEP ^b (calculated as Koc/1.724).
Freundlich exponent 1/n	0.86	y / LoEP ^b . Arithmetic mean of experimental data (n=4).
Crop-related parameters		
Crop uptake factor	0.5	y / LoEP ^b .

- a All substance parameters not explicitly mentioned in this table were set at the default values recommended by the FOCUS guidance for groundwater assessment (2021) and/or model related user manuals (July 2022).
- b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116
- c In the EFSA Scientific Report (2008) it is stated that in a “highly conservative risk assessment” [...] ‘an additional simulation (FOCUS PEARL) was performed, and agreed by the experts, [...] with a worst case pseudo SFO DT50 value of 7.3 days’.

Table 8.8-5: Input parameters related to metabolite IN-W3595 for PECgw calculations

Parameter ^a	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Physical-chemical parameters		
Molecular weight	128.1 g/mol	
Vapor pressure	0 Pa	y / LoEP ^b .
Water solubility	782 mg/L (20°C)	y / LoEP ^b . Parent value
Degradation in soil		
DT50 soil	2.5 days	y / LoEP ^b . Worst case of experimental data (n=2; normalised to pF2 and 20°C (Q10=2.2)).
Temperature correction function: - Q10 - Molar activation energy	2.2 54 kJ/mol	y / LoEP ^b . In accordance with the working document of the central zone (2018; v1-rev.1) the Q10 value used to normalise the DT50 for soil was used in the models.
Formation fraction Source → sink relation	0.15 P → IN-W3595	y / LoEP ^b . Worst case of experimental data (n=2). PECgw calculations were performed within the assessment for the parent compound using the transformation scheme option incorporated in PEARL.
Sorption to soil		
pH-dependent sorption (yes/no)	yes	y / LoEP ^b . The reported arithmetic mean of experimental data (n=4) is 9.2 L/kg.
Koc-acid Koc-base pKa	33.3 L/kg 2.3 L/kg 5.2	y / LoEP ^b . The reported arithmetic mean of experimental data (n=4) is 9.2 L/kg
Kom-acid Kom-base	19.3 L/kg 1.33 L/kg	y / LoEP ^b (calculated as Koc/1.724).
Freundlich exponent 1/n	1	y / LoEP ^b . A value of 1 is used in a worst case approach.
Crop-related parameters		
Crop uptake factor	0	y / LoEP ^b .

- a All substance parameters not explicitly mentioned in this table were set at the default values recommended by the FOCUS guidance for groundwater assessment (2021) and/or model related user manuals (July 2022).
- b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.8-6: Input parameters related to metabolite IN-U3204 for PECgw calculations

Parameter ^a	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Physical-chemical parameters		
Molecular weight	198.2 g/mol	

Vapor pressure	0 Pa	y / LoEP ^b .
Water solubility	782 mg/L (20°C)	y / LoEP ^b . Parent value
Degradation in soil		
DT50 soil	0.4 day	y / LoEP ^a . Geometric mean of experimental data (n=3; normalised to pF2 and 20°C (Q10=2.2)).
Temperature correction function: - Q10 - Molar activation energy	2.2 54 kJ/mol	y / LoEP ^b . In accordance with the working document of the central zone (2018; v1-rev.1) the Q10 value used to normalise the DT50 for soil was used in the models.
Formation fraction Source → sink relation	0.36 P → IN-U3204	y / LoEP ^b . Arithmetic mean of experimental data (n=3). PECgw calculations were performed within the assessment for the parent compound using the transformation scheme option incorporated in PEARL.
Sorption to soil		
pH-dependent sorption (yes/no)	no	y / LoEP ^b .
Koc	27.9 L/kg	y / LoEP ^b . HPLC method (n=1).
Kom	16.2 L/kg	y / LoEP ^b (calculated as Koc/1.724).
Freundlich exponent 1/n	1	y / LoEP ^b . A value of 1 is used in a worst case approach.
Crop-related parameters		
Crop uptake factor	0	y / LoEP ^b .

a All substance parameters not explicitly mentioned in this table were set at the default values recommended by the FOCUS guidance for groundwater assessment (2021) and/or model related user manuals (July 2022).

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.8-7: Input parameters related to metabolite IN-JX915 for PECgw calculations

Parameter ^a	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Physical-chemical parameters		
Molecular weight	198.2 g/mol	
Vapor pressure	0 Pa	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^b . Parent value
Degradation in soil		
DT50 soil	1.0 day	y / LoEP ^b . Experimental data (n=1; normalised to pF2 and 20°C (Q10=2.2)).
Temperature correction function: - Q10 - Molar activation energy	2.2 54 kJ/mol	y / LoEP ^b . In accordance with the working document of the central zone (2018; v1-rev.1) the Q10 value used to normalise the DT50 for soil was used in the models.
Formation fraction Source → sink relation	0.10 P → IN-JX915	y / LoEP ^b . Experimental data (n=1). PECgw calculations were performed within the assessment for the parent compound using the transformation scheme option incorporated in PEARL.
Sorption to soil		
pH-dependent sorption (yes/no)	no	y / LoEP ^b .
Koc	16.2 L/kg	y / LoEP ^b . Arithmetic mean of experimental data (n=4).
Kom	9.4 L/kg	y / LoEP ^b (calculated as Koc/1.724).
Freundlich exponent 1/n	1	y / LoEP ^b . A value of 1 is used in a worst case approach.
Crop-related parameters		
Crop uptake factor	0	y / LoEP ^b .

a All substance parameters not explicitly mentioned in this table were set at the default values recommended by the FOCUS guidance for groundwater assessment (2021) and/or model related user manuals (July 2022).

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.8-8: Input parameters related to metabolite IN-KQ960 for PECgw calculations

Parameter ^a	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Physical-chemical parameters		
Molecular weight	216.2 g/mol	

Vapor pressure	0 Pa	y / LoEP ^b .
Water solubility	782 mg/L (20°C)	y / LoEP ^b . Parent value
Degradation in soil		
DT50 soil	1.0 day	n / New data (post-approval) from a study by Völkel (2011) were used in a refined assessment. Geometric mean of new data (n=3) and data in the LoEP (n=1), EFSA conclusion (2008). See text above and Appendix 2 for further detail on the study and justification of use.
Temperature correction function: - Q10 - Molar activation energy	2.2 54 kJ/mol	y / LoEP ^b . In accordance with the working document of the central zone (2018; v1-rev.1) the Q10 value used to normalise the DT50 for soil was used in the models.
Formation fraction Source → sink relation	0.16 P → IN-U3204 → IN-KQ960	y / LoEP ^b . Arithmetic mean of experimental data (n=1). PECgw calculations were performed within the assessment for the parent compound using the transformation scheme option incorporated in PEARL.
Sorption to soil		
pH-dependent sorption (yes/no)	no	y / LoEP ^b .
Koc	5.34 L/kg	n / New data (post-approval) from a study by Ford (2009). Arithmetic mean of experimental data (n=4). See text above and Appendix 2 for further detail on the study and justification of use.
Kom	3.10 L/kg	n / calculated as Koc/1.724 on the basis of new data
Freundlich exponent 1/n	1	y / LoEP ^b .
Crop-related parameters		
Crop uptake factor	0	y / LoEP ^b .

a All substance parameters not explicitly mentioned in this table were set at the default values recommended by the FOCUS guidance for groundwater assessment (2021) and/or model related user manuals (July 2022).

b LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

The PECgw values for Cymoxanil and its metabolites as calculated using the geomean DT50 for cymoxanil of 1.2 days (standard approach) are listed in the following tables.

Table 8.8-9: PECgw for Cymoxanil following use on potato (FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PECgw at 1 m Soil Depth (µg/L)	
		Early applications	Late applications
Potato	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	(Jokioinen) ^a	(<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) ^a	(<0.001)	(<0.001)
	(Thiva) ^a	(<0.001)	(<0.001)

a According to the working document of the central zone the scenarios Jokioinen, Sevilla and Thiva are not required for groundwater risk assessment in the central zone.

Table 8.8-10: PECgw for metabolite IN-W3595 following use on potato (FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PECgw at 1 m Soil Depth (µg/L)
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		Early applications	Late applications
Potato	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	(Jokioinen) ^a	(<0.001)	(0.005)
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	(Sevilla) ^a	(<0.001)	(<0.001)
	(Thiva) ^a	(<0.001)	(<0.001)

a According to the working document of the central zone the scenarios Jokioinen, Sevilla and Thiva are not required for groundwater risk assessment in the central zone.

Table 8.8-11: PEC_{gw} for metabolite IN-U3204 following use on potato (FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Early applications	Late applications
Potato	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	(Jokioinen) ^a	(<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) ^a	(<0.001)	(<0.001)
	(Thiva) ^a	(<0.001)	(<0.001)

a According to the working document of the central zone the scenarios Jokioinen, Sevilla and Thiva are not required for groundwater risk assessment in the central zone.

Table 8.8-12: PEC_{gw} for metabolite IN-JX915 following use on potato (FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Early applications	Late applications
Potato	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	(Jokioinen) ^a	(<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) ^a	(<0.001)	(<0.001)

	(Thiva) ^a	(<0.001)	(<0.001)
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a According to the working document of the central zone the scenarios Jokioinen, Sevilla and Thiva are not required for groundwater risk assessment in the central zone.

Table 8.8-13: PECgw for metabolite IN-KQ960 following use on potato (FOCUS PEARL 5.5.5) ^a

Crop	Scenario	80 th Percentile PECgw at 1 m Soil Depth (µg/L)	
		Early applications	Late applications
Potato	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	(Jokioinen) ^b	(<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) ^b	(<0.001)	(<0.001)
	(Thiva) ^b	(<0.001)	(<0.001)

a PECgw calculated using new data (post-approval) on adsorption and soil aerobic degradation of metabolite IN-KQ960. See section 8.8.1.1 and Appendix 2 for further detail on these studies and justification of use.

b According to the working document of the central zone the scenarios Jokioinen, Sevilla and Thiva are not required for groundwater risk assessment in the central zone.

As for Cymoxanil and the metabolites relevant for groundwater assessment the PECgw values calculated in FOCUS PEARL 5.5.5 were <0.001 µg/L for all scenarios, according to the working document of the central zone no additional runs using FOCUS PELMO or FOCUS MACRO were required.

The PECgw values for Cymoxanil and its metabolites using the worst-case DT50 for cymoxanil of 7.3 days in order to account for pH-dependent degradation of Cymoxanil (highly conservative approach performed using FOCUS PEARL only), are listed in the following table.

Table 8.8-14: Additional runs in FOCUS PEARL using a worst case DT50 of 7.3 days for Cymoxanil (highly conservative risk assessment taking into account pH-dependent degradation of Cymoxanil)

Crop	Scenario	80 th Percentile PECgw at 1 m Soil Depth (µg/L)					
		Cymoxanil		IN-W3595		IN-U3204	
		Early appl.	Late appl.	Early appl.	Late appl.	Early appl.	Late appl.
Potato	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	0.004 ^a	<0.001	<0.001
	(Jokioinen) ^b	(<0.001)	(<0.001)	(0.006)	(0.015)	(<0.001)	(<0.001)
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	0.002 ^a	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	(Sevilla) ^b	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)
	(Thiva) ^b	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)			
		IN-JX-915		IN-KQ960	
		Early appl.	Late appl.	Early appl.	Late appl.
Potato	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	(Jokioinen) ^b	(<0.001)	(<0.001)	(<0.001)	(0.0027)
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
	(Sevilla) ^b	(<0.001)	(<0.001)	(<0.001)	(<0.001)
	(Thiva) ^b	(<0.001)	(<0.001)	(<0.001)	(<0.001)

a In line with the approach taken in the EFSA conclusion (2008), considering that use of the DT50 value for Cymoxanil of 7.3 days is 'highly conservative', no additional calculations with the FOCUS models PELMO and MACRO were performed.

b According to the working document of the central zone the scenarios Jokioinen, Sevilla and Thiva are not required for groundwater risk assessment in the central zone.

8.8.2.2 Copper (active substance 2)

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 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/EC) for groundwater. Furthermore, the Copper concentrations are generally below the threshold values established for Copper in European Member States as reported by the commission (Brussels, 5.3.2010 C(2010) 1096 final; and sec (2010) 166 final)¹² 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

¹² European Commission: Report from the commission in accordance with Article 3.7 of the Groundwater Directive 2006/118/EC on the establishment of groundwater threshold values. Brussels, 5.3.2010 C(2010) 1096 final.

Member state	Threshold value	Unit	GWB at risk	GWB at poor status
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	mg Cu/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:	KCP 9.2.4/01, Demetriades, A. <i>et al</i>, 2012
Title:	European Ground Water Geochemistry Using Bottled Water as a Sampling Medium
Report No.:	Not applicable
Guidelines:	Not applicable
Deviations:	No
GLP:	No
Published	Literature
Comment:	-

In this 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.

PECgw modelling:

In addition to the above presented information, PECgw values were calculated using FOCUS PEARL 4.4.4 The substance input parameters and calculated PECgw values presented below are based on the results obtained from the study by Bradatsch (2019).

Considering that Copper is not degraded, the application rate was entered in the model as a single season's application of 3.6 kg (annual dose). 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. Therefore, for Copper, crop interception was assumed to be zero.

The substance input parameters used in PECgw calculations for Copper are summarised in the following table.

Table 8.8-15: Input parameters related to Copper for PECgw calculations

Parameter ^a	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Physical-Chemical parameters		
Molecular weight	63.54 g/mol	-
Water solubility	500 mg/L (20°C)	y / LoEP ^b . at 20°C, pH 5.6 LoEP EFSA Journal 2018; 16(1):5152
Vapour pressure	0 Pa (20°C)	y / LoEP ^b . Not applicable as expected to be negligible
Degradation in soil		
DT ₅₀ soil [d]	1000000	y / LoEP ^b . Conservative default, no degradation expected.
Temperature correction function: - Q10 - Molar activation energy	2.58 54 kJ/mol	EFSA recommendation
Sorption to soil		
Kd	1643 L/kg	n / Median value (n = 450), (see RAR, Vol. 3, B8, CA 7.1.3.1.1/01. Oorts K, 2015b)
Freundlich exponent 1/n	1	y / LoEP ^b . Conservative default
Crop/ Management related parameters		
Crop uptake factor	0	y / LoEP ^b .

a All substance parameters not explicitly mentioned in this table were set at the default values recommended by the FOCUS guidance for groundwater assessment (2021) and/or model related user manuals (July 2022).

b LoEP = list of endpoints, EFSA Journal 2018;16(1):5152

The PECgw values for Copper are listed in the following table.

Table 8.8-16: PECgw for Copper following use on potato (FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PECgw at 1 m Soil Depth (µg/L)	
		Early applications	Late applications
Potato	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	(Jokioinen) ^a	(<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) ^a	(<0.001)	(<0.001)
	(Thiva) ^a	(<0.001)	(<0.001)

a According to the working document of the central zone the scenarios Jokioinen, Sevilla and Thiva are not required for groundwater risk assessment in the central zone.

The applicant would like to reiterate that FOCUS modelling is not designed or validated to predict the behaviour of metals in the environment, and thus is not suitable for Copper predictions and was only carried out for completeness.

Nevertheless, following the simulations for the early and late uses on potatoes, the maximum PEC_{gw} values as calculated with FOCUS PEARL 4.4.4 were below 0.001 µg/L for all scenarios. According to the working document of the central zone no additional runs using FOCUS PELMO or FOCUS MACRO are required.

In concordance with the EFSA conclusion on Copper, these predicted groundwater concentrations are far below the legal limit of 2 mg/L set by the European Drinking Water Directive (98/83/EC) for groundwater¹³.

The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by Copper must not be expected following GAP use of FEL02.

zRMS comments:

Cymoxanil

The submitted PEC_{gw} assessment was accepted for proposed pattern use.

Cymoxanil and the metabolites relevant for groundwater were assessed in FOCUS PEARL 5.5.5 were <0.001 µg/L for all scenarios, according to the working document of the central zone no additional runs using FOCUS PELMO or FOCUS MACRO were required.

Cymoxanil and IN-U3204, IN W3595, IN-JX915 and IN-KQ960 are not found in significant amounts in the percolate at 1.0 m soil depth (i.e. < 0.1 µg/L) indicating that the compounds do not leach in soil. This can mainly be explained by the very fast degradation of Cymoxanil and its metabolites IN-U3204, IN W3595, IN-JX915 and IN-KQ960.

Copper

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 were lower than to the regulatory threshold 0.1 µg/L in groundwater at 1 m depth in all scenario with PEARL.

However, the groundwater monitoring UE 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/EC) 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.

¹³ The council of the European union: Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. Official Journal of the European Communities (5.12.98).

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

8.9.1 Justification for new endpoints

8.9.1.1 Cymoxanil (active substance 1)

PEC_{sw}/sed calculations were performed for the active substance Cymoxanil, and metabolites IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533, and 'metabolite fraction M5' which were in the EFSA conclusion of 2008 determined to be relevant for risk assessment of surface water and sediment. For the parent substance and for all metabolites except IN-KQ960 there are no deviations from EU agreed endpoints. For IN-KQ960 however, new information (post-approval) has become available and is used in risk assessment. An overview of the alternative information used for modelling is listed in the following table.

Table 8.9-1: New information (post-approval) used for surface water and sediment risk assessment of metabolite IN-KQ960

Endpoint	EU agreed value	Value used for modelling	Justification
Koc	21.6 L/kg	5.34 L/kg	New data available from a study by Ford (2009). This information was also used in a risk assessment performed in 2013 for authorisation of the product FDJ03, which also contains Cymoxanil as active substance, and was at the time reviewed by zRMS Austria. In the registration report for FDJ03, the RMS concluded that in accordance with the guidance document on the evaluation of new active substance data post-approval (SANCO, 2012), the new information ' <i>presents the case of adverse effects</i> ' and consequently the alternative Koc value was used for risk assessment of surface water and sediment (see Appendix 2 for further detail).

8.9.1.2 Copper (active substance 2)

No deviation from EU agreed endpoints.

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

A FOCUS SW calculation for the product FEL02 was performed in order to predict the concentration of residues in surface water (PEC_{sw}) and sediment (PEC_{sed}).

For Cymoxanil and Copper the PEC_{sw} and PEC_{sed} calculations were performed using the model STEPS 1-2 in FOCUS v.3.2. The procedures followed and the input parameters selected were in accordance with the generic guidance for FOCUS surface water scenarios (FOCUS, 2015) and the working document of the central zone (Anonymous, 2018).

The formulated product FEL02 is proposed to be applied as a fungicide up to 6 times per season to potatoes with a minimum application interval of 7 days. The maximum application rates of the active substances (per application) are 0.12 kg Cymoxanil/ha and 0.6 kg Copper/ha (equivalent to 3 kg product/ha).

The application window is from April up to and including September. The seasons Mar-May and Jun-Sep were assessed in combination with both the regions 'North Europe' and 'South Europe'.

Input parameters related to application of the product FEL02 are presented in the following table.

Table 8.9-2: Input parameters related to application for PECsw/sed calculations (STEPS1-2)

Use No.	1
Crop	Potato
Application rate (kg as/ha)	Cymoxanil (active substance 1): 0.12 kg/ha Copper (active substance 2): 0.6 kg/ha
Number of applications/interval (d)	6 annual applications / 7-day interval ^a
FOCUS regions (Step 2)	North Europe and South Europe
Application timing (Step 2)	Early: Mar-May Late: Jun-Sep
Application method (Step 2)	Spraying
Crop interception (Step 2)	Cymoxanil (active substance 1): 50-70% (see section 8.9.2.1) Copper (active substance 2): 0% (see section 8.9.2.2)
Models used for calculation	FOCUS STEPS1-2

^a For copper the PECsw calculations were based on a single application scenario (1 x 0.6 kg/ha) and the PECsed calculations were based on an annual dose scenario (6 x 0.6 kg/ha) (see section 8.9.2.2 for further detail).

8.9.2.1 Cymoxanil (active substance 1) and its metabolites

For Cymoxanil, PECsw/sed calculations were performed on the basis of 6 annual applications with a 7-day interval between applications (Koomen, 2022b). For early applications (Mar-May) ‘average crop cover’ was selected which is associated with a crop interception of 50% for potatoes. For late applications (Jun-Sep) ‘full canopy’ was selected which is associated with a crop interception of 70%.

The input parameters used in PECsw/sed calculations for Cymoxanil and metabolites relevant for surface water/sediment risk assessment are summarised in the following tables.

Table 8.9-3: Input parameters related to Cymoxanil relevant for PECsw/sed calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Water solubility	782 mg/L	y / LoEP ^a . Value at 20°C.
DT50 sediment/water system	0.30 day	y / LoEP ^a . Geometric mean of experimental data (n=4)
DT50 water	0.30 day	Whole system value used
DT50 sediment	0.30 day	Whole system value used
DT50 soil	1.20 days	y / LoEP ^a . Geometric mean of experimental data (n=9), normalised to pF2 and 20°C (Q10=2.2)).
Koc	43.6 L/kg	y / LoEP ^a . Arithmetic mean of experimental data (n=4).

^a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-4: Input parameters related to metabolite IN-U3204 relevant for PECsw/sed calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	198.2 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	24.7%	y / LoEP ^a .
DT50 sediment/water system	0.4 day	y / LoEP ^a . Geometric mean of experimental data (n=3)

DT50 water	0.4 day	Whole system value used
DT50 sediment	0.4 day	Whole system value used
Maximum occurrence in soil	24.7%	y / LoEP ^a .
DT50 soil	0.4 day	y / LoEP ^a . Geometric mean of experimental data (n=3, normalised to pF2 and 20°C (Q10=2.2)).
Koc	27.9 L/kg	y / LoEP ^a . HPLC method (n=1)

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-5: Input parameters related to metabolite IN-W3595 relevant for PEC_{sw/sed} calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	128.1 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	27.5%	y / LoEP ^a .
DT50 sediment/water system	3.0 days	y / LoEP ^a . Geometric mean of experimental data (n=3)
DT50 water	3.0 days	Whole system value used
DT50 sediment	3.0 days	Whole system value used
Maximum occurrence in soil	10.1%	y / LoEP ^a .
DT50 soil	2.5 days	y / LoEP ^a . Worst case of experimental data (normalised to pF2 and 20°C (Q10=2.2)).
Koc	9.2 L/kg	y / LoEP ^a . Arithmetic mean of experimental data (n=4)

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-6: Input parameters related to metabolite IN-KQ960 relevant for PEC_{sw/sed} calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	216.2 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	14.3%	y / LoEP ^a .
DT50 sediment/water system	47.4 days	y / LoEP ^a . Geometric mean of experimental data (n=3)
DT50 water	47.4 days	Whole system value used
DT50 sediment	47.4 days	Whole system value used
Maximum occurrence in soil	6.3%	y / LoEP ^a .
DT50 soil	11.2 days	y / LoEP ^a . Experimental data (n=1, normalised to pF2 and 20°C (Q10=2.2)).
Koc	5.34 L/kg ¹	New data (post-approval) from a study by Ford (2009). Arithmetic mean of experimental data (n=4). See text above and Appendix 2 for further detail on the study and justification of use.

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-7: Input parameters related to metabolite IN-JX915 relevant for PEC_{sw/sed} calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	198.2 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	52.6%	y / LoEP ^a .
DT50 sediment/water system	1.7 days	y / LoEP ^a . Geometric mean of experimental data (n=4)

DT50 water	1.7 days	Whole system value used
DT50 sediment	1.7 days	Whole system value used
Maximum occurrence in soil	10.9%	y / LoEP ^a .
DT50 soil	1.0 day	y / LoEP ^a . Experimental data (n=1, normalised to pF2 and 20°C (Q10=2.2)).
Koc	16.2 L/kg	y / LoEP ^a . Arithmetic mean of experimental data (n=4)

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-8: Input parameters related to metabolite IN-T4226 relevant for PEC_{sw/sed} calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	142.1 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	12.0%	y / LoEP ^a .
DT50 sediment/water system	4.6 days	y / LoEP ^a . Geometric mean of experimental data (n=2)
DT50 water	4.6 days	Whole system value used
DT50 sediment	4.6 days	Whole system value used
Maximum occurrence in soil	1.7%	y / LoEP ^a .
DT50 soil	1000 days	y / LoEP ^a . Worst case value (no data available)
Koc	17.7 L/kg	y / LoEP ^a . HPLC method (n=1)

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-9: Input parameters related to metabolite IN-R3273 relevant for PEC_{sw/sed} calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	171.2 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	35.4%	y / LoEP ^a .
DT50 sediment/water system	6.3 days	y / LoEP ^a . Geometric mean of experimental data (n=2)
DT50 water	6.3 days	Whole system value used
DT50 sediment	6.3 days	Whole system value used
Maximum occurrence in soil	2.4%	y / LoEP ^a .
DT50 soil	1000 days	y / LoEP ^a . Worst case value (no data available)
Koc	42.0 L/kg	y / LoEP ^a . Arithmetic mean of experimental data (n=4)

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-10: Input parameters related to metabolite IN-KP533 relevant for PEC_{sw/sed} calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	160.1 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	26.0%	y / LoEP ^a .
DT50 sediment/water system	2.6 days	y / LoEP ^a . Geometric mean of experimental data (n=2)
DT50 water	2.6 days	Whole system value used
DT50 sediment	2.6 days	Whole system value used
Maximum occurrence in soil	2.7%	y / LoEP ^a .

DT50 soil	1000 days	y / LoEP ^a . Worst case value (no data available)
Koc	12.9 L/kg	LoEP, EFSA conclusion (2008). HPLC method (n=1)

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

Table 8.9-11: Input parameters related to metabolite ‘Metabolite fraction M5’ relevant for PEC_{sw/sed} calculations STEPS 1-2

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
Molecular weight	198.2 g/mol	y / LoEP ^a .
Water solubility	782 mg/L	y / LoEP ^a . Parent value used
Maximum occurrence in water/sediment	22.9%	y / LoEP ^a .
DT50 sediment/water system	1.4 days	y / LoEP ^a . Geometric mean of experimental data (n=3)
DT50 water	1.4 days	Whole system value used
DT50 sediment	1.4 days	Whole system value used
Maximum occurrence in soil	0.0% ^b	y / LoEP ^a .
DT50 soil	1000 days	y / LoEP ^a . Worst case value (no data available)
Koc	9.2 L/kg	y / LoEP ^a . Value of IN-W3595 used

a LoEP = list of endpoints, EFSA Scientific Report (2008) 167, 1-116

b As ‘Metabolite fraction M5’ is not identified in soil, the region/season scenario ‘no Runoff/Drainage’ was selected.

The PEC_{sw} and PEC_{sed} values for Cymoxanil and its metabolites as calculated using STEPS 1-2 in FOCUS are listed in the following tables.

Table 8.9-12: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sed} for Cymoxanil following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1				
Potato	---	38.9	1.01	16.5
Step 2				
Potato: Northern Europe	March-May	1.10*	0.052*	0.167
	Jun-Sep	1.10*	0.044*	0.100
Potato: Southern Europe	March-May	1.10*	0.072*	0.333
	Jun-Sep	1.10*	0.050*	0.150

* single application

Table 8.9-13: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sed} for metabolite IN-U3204 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1				
Potato	---	19.3	0.635	5.32

Table 8.9-13: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite IN-U3204 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 2				
Potato: Northern Europe	March-May	0.273*	0.015*	0.027
	Jun-Sep	0.273*	0.013*	0.016
Potato: Southern Europe	March-May	0.273*	0.020*	0.054
	Jun-Sep	0.273*	0.014*	0.024

* single application

Table 8.9-14: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite IN-W3595 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 1				
Potato	---	58.8	12.0	5.30
Step 2				
Potato: Northern Europe	March-May	0.232*	0.048*	0.019
	Jun-Sep	0.196*	0.061*	0.013*
Potato: Southern Europe	March-May	0.398	0.082	0.035
	Jun-Sep	0.217*	0.044*	0.018

* single application

Table 8.9-15: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite IN-KQ960 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 1				
Potato	---	54.6	47.0	2.86
Step 2				
Potato: Northern Europe	March-May	1.074	0.924	0.057
	Jun-Sep	0.825	0.706	0.043
Potato: Southern Europe	March-May	1.698	1.461	0.090
	Jun-Sep	1.012	0.870	0.053

* single application

Table 8.9-16: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite IN-JX915 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 1				
Potato	---	25.4	2.98	4.03
Step 2				
Potato: Northern Europe	March-May	0.581*	0.101*	0.050*
	Jun-Sep	0.581*	0.088*	0.041*
Potato: Southern Europe	March-May	0.581*	0.0006*	0.087*
	Jun-Sep	0.581*	0.097*	0.046*

* single application

Table 8.9-17: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite IN-T466 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 1				
Potato	---	23.6	7.14	4.08
Step 2				
Potato: Northern Europe	March-May	0.362	0.110	0.061
	Jun-Sep	0.236	0.071	0.039
Potato: Southern Europe	March-May	0.677	0.205	0.117
	Jun-Sep	0.330	0.100	0.056

* single application

Table 8.9-18: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite IN-R3273 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 1				
Potato	---	76.2	29.7	31.7
Step 2				
Potato: Northern Europe	March-May	0.810	0.314	0.308
	Jun-Sep	0.577	0.224	0.216
Potato: Southern Europe	March-May	1.391	0.541	0.552
	Jun-Sep	0.751	0.292	0.284

* single application

Table 8.9-19: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite IN-KP533 following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 1				
Potato	---	56.1	10.0	7.06
Step 2				
Potato: Northern Europe	March-May	0.646	0.116	0.081
	Jun-Sep	0.409	0.073	0.050
Potato: Southern Europe	March-May	1.236	0.221	0.157
	Jun-Sep	0.587	0.105	0.073

* single application

Table 8.9-20: FOCUS STEPS 1-2 PEC_{sw} and PEC_{sd} for metabolite 'Metabolite fraction M5' following multiple applications of FEL02 to potato

Scenario FOCUS	Season of application	Max PEC _{sw} (µg/L)	21-d TWA PEC _{sw} (µg/L)	Max PEC _{sd} (µg/kg)*
Step 1				
Potato	---	9.30	0.901	0.833
Step 2				
Potato: No Runoff/Drainage	n.a.	0.253*	0.025*	0.009*

* single application

8.9.2.2 Copper (active substance 2)

A review of the existing monitoring programmes 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 10000 µg/L, with a median value of 1.97 µg/L, (n = 104254 samples). Dissolved 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 notifier would like to reiterate that all interested parties had previously agreed that the FOCUS models are not appropriate for predicting the behaviour of metals such as Copper. In the FOCUS models substance sorption to soil or sediment is described solely by interaction with organic material and thus are not suitable to predict the behaviour of Copper reaching surface water bodies from run-off and drainage. 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. Furthermore, important binding processes for the Cu²⁺ ion, such as adsorption to clay and mineral oxides can occur in soil and sediment. Therefore, it is noted here that FOCUS modelling was only carried out for completeness. The applicant would like to request that more suitable assessment protocols are used for minerals such as Copper.

PEC in surface water

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

As described above, the spray drift scenario starts with a non-equilibrium phase during which total Copper dissipates with a DT₅₀ of < 1 day (see RAR, Vol. 3, B8, CP 9.2.3/01. Blust and Joosen, 2016). Any free Copper ions also dissipate with < 1 day (see RAR, Vol. 3, B8, CP 9.2/02. Ma *et al.*, 1999). 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.33 evaluations.

The applicant would like to point out that on page 15 of the EFSA conclusion that they are pleased to see that EFSA recognises that due to the very rapid dissipation of Copper (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.

PEC in sediment

The PEC_{sed} values calculated according to the above approach are for information only and not presented at this point. These values should not be used for the risk assessment. Indeed, the sediment input from the soil column in a single year would be overestimated due to the assumption at Step 1-2 (which is independent of K_{oc}). PEC tools are not available for calculating accumulation from repeated uses over the years in a realistic way.

To calculate the PEC sediment accumulation and in line with the EFSA conclusion, the FOCUS Step 2 PEC sediment values (FOCUS Steps 1-2 v3.2) via runoff/drainage are added to a median **background level of Copper in European sediments of 17 mg/kg** and also considering a K_d of 10000 mg/L. In addition, runoff mitigation may require the implementation of a vegetated buffer zone of 10 m or 20 m and thus, PEC_{sed} reduction of 60% and 80% were considered, respectively.

In case of spray drift, initial PEC_{sed} values for Copper were calculated using the following equation, in line with the RAR and EFSA conclusion:

$$\begin{aligned} \text{PEC}_{\text{sed, total}} &= \frac{\text{Annual AR} \times f_{\text{drift}} \times 10^6 \times 30}{30,000 \times 100 \times 100 \times 0.8} \\ &= \frac{\text{Annual AR} \times f_{\text{drift}} \times 37.5}{300} \end{aligned}$$

Where:

PEC_{sed, total}: Predicted environmental concentration in sediment (µg/kg)

Annual AR: annual application rate (g/ha)

f_{drift}: % drift rate

These values were then converted from µg/kg to mg/kg by dividing by a factor of 1000. PEC_{sed} values for Copper are provided as mg/kg of total Copper.

Drift rates are based on Step 3 drift values and were taken from the Drift calculator v.1.1 as incorporated in FOCUS SWASH v. 5.3. Where the implementation of no-spray buffer zones would be necessary, reduced drift rates corresponding to the respective buffer zone were considered. All drift rates were selected on basis of a single application as a (first tier) worst-case assumption. Please refer to **Table 8.9-27** below for details regarding Step 3 drift values used for PEC_{sed} calculations.

Calculations were performed with one annual maximum dose (representing multiple applications) repeated for seven years, assuming no degradation. See GAP table under point 8.1 for full details.

Table 8.9-21: Input parameters related to active substance Copper for PEC_{sw/sed} calculations with FOCUS Steps 1-2 (v3.2)

Parameter	Value	Value in accordance with EU endpoint (y/n). Additional remark(s).
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Molecular weight	63.54 g/mol	-
Saturated vapour pressure	0 Pa	y / LoEP ^a . Not applicable; inorganic solid with negligible volatility
Water solubility	500 mg/L	y / LoEP ^a . Value at 20°C, pH 7
K _d _{oc}	33918.3 L/kg (for PEC _{sw}) 10000 L/kg (for PEC _{sed})	y / LoEP ^a . Geometric mean calculated from soils pH range 5.5 - 6.5 Conservative default
DT _{50,soil}	1000 d	y / LoEP ^a . Conservative default
DT _{50,water}	1000 d	y / LoEP ^a . Conservative default
DT _{50,sed}	1000 d	y / LoEP ^a . Conservative default
DT _{50,whole system}	1000 d	y / LoEP ^a . Conservative default
Background Copper level in sediment	17 mg/kg	y / LoEP ^a . Median value

a LoEP = EFSA Journal 2018; 16(1):5152

Findings: PEC in surface water

Results from FOCUS Steps 1-2 (v3.2) PEC_{sw} modelling are presented in the following table. Representative simulation files can be found in appendix 2.2.

Table 8.9-22: Standard FOCUS Step 1-2 maximum PEC_{sw} for active substance Copper following a single application to potato (all entry routes to water bodies considered, TOTAL Copper)

Crop	Application pattern	Season of application	Region	Step 1	Step 2
				Maximum PEC _{sw} actual [µg/L]	Maximum PEC _{sw} actual [µg/L]
Potato	1 × 600 g/ha	Mar - May	N	9.845	5.518
			S		5.518
		Jun - Sep	N	9.845	5.518
			S		5.518

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 study by Blust and Joosen (Blust and Joosen, 2016, see RAR, Vol. 3, B8, CP 9.2.3/01) have demonstrated that in a realistic water/sediment scenario the total Copper declines very rapidly in the water phase while dissolved Copper was at least a factor of 10 lower. This study describes best the speciation and kinetic behaviour of Copper in an aquatic environment following a spray drift event. Despite, the EUCuTF has proposed a more conservative total/dissolved value of 3 for use in the risk assessment, based on the measurements in the mesocosm study. The EFSA evaluation used a total/dissolved ratio of 1, which suggests that all Copper is dissolved. This is against all observations in the monitoring studies and studies from the dossier cited above. The Art.33 evaluation should apply a total to dissolved Copper ratio of at least 3.

Therefore, the following table presents the dissolved PEC_{sw}, which were used for ecotoxicological risk assessment.

Table 8.9-23: Standard FOCUS Step 1-2 maximum PEC_{sw} for active substance Copper following a single application to potato (all entry routes to water bodies considered, DISSOLVED Copper)

Crop	Application pattern	Season of application	Region	Step 1	Step 2
				Maximum PEC _{sw} actual [µg/L]	Maximum PEC _{sw} actual [µg/L]
Potato	1 × 600 g/ha	Mar - May	N	3.282	1.839
			S		1.839
		Jun - Sep	N	3.282	1.839
			S		1.839

Findings: PEC in sediment

Results from FOCUS Steps 1-2 (v3.2) PECsed modelling are presented in the following table. Representative simulation files can be found in appendix 2.2.

The PECsed results for runoff/drainage as route of entry are presented in **Table 8.9-24**.

Table 8.9-24: Maximum accumulated PECsed for Copper (seven-year period) for the entry route runoff/drainage following uses on potatoes considering background concentration and risk mitigation (FOCUS evaluation step 2)

Crop	Application pattern	Season	Region	PECsed [mg/kg]	PECsed accumulation (7 years) + background	PECsed accumulation (7 years) + background 60% mitigation ^a	PECsed accumulation (7 years) + background 80% mitigation ^b
					[mg/kg]	[mg/kg]	[mg/kg]
Potato	1 × 3600 g/ha	Mar - May	N	1.67	28.69	21.68	19.34
			S	3.34	40.38	26.35	21.68
		Jun - Sep	N	1.67	28.69	21.68	19.34
			S	2.5	34.5	24.00	20.50

N = Northern EU, S = Southern EU

a Equal to 10 m vegetated buffer

b Equal to 20 m vegetated buffer

The drift input values for different no-spray buffer-zones and the results for spray drift as route of entry are presented in and **Tables 8.9-25 and 8.9-26**, respectively.

Table 8.9-25: Step 3 drift values for different no-spray buffer-zones used for calculation of PECsed,accumulation values following spray drift as route of entry

Crop	Application pattern	No-spray buffer zone [m]	Drift [%] ^a
Potato	1 × 3600 g/ha	Standard distance	1.594
		5	0.522
		10	0.277

a areic mean for single applications (ditch) as worst-case

Table 8.9-26: Maximum accumulated PECsed for Copper (seven-year period) for the entry route spray drift following uses on potatoes-considering background concentration and risk mitigation (FOCUS evaluation step 2)

Crop	Application pattern	PECsed [mg/kg]	PECsed accumulation (7 years) + background + no-spray buffer [mg/kg]		
			Standard	5 m	10 m
Potato	1 × 3600 g/ha	0.717	22.02	18.64	17.87

N = Northern EU, S = Southern EU

The quantity of Copper in sediments has also been investigated experimentally in stream sediments taken from a stream in southern Germany next to an ongoing field trial treated with Copper to show that the level of Copper in stream sediments is low. The study is summarized below.

Reference:	KCP 9.2.5/01, Axmann, S., 2019
Title:	A field study to determine Copper residues in stream sediments
Report No.:	S17-04438

Guidelines:	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements
Deviations:	No
GLP:	Yes
Published	No
Comment:	-

Executive Summary

The objective of the study was to determine the Copper contents in stream sediments close to a field trial that had previously been treated with Copper. Sediment samples were taken from four sectors in the stream. Two sectors (1a and 1b) which were located upstream from the field site and represented controls without any possible Copper input from the field site and two further sectors 2 and 3 which were located close to the field site and represented areas potentially exposed to Copper from treatments on the adjacent field trial.

Two samples were taken per sector – one sample from the surface (actual) sediment layer and one from the deeper (older) sediment layer(s). The layers were identified visually (i.e. colour, structure). Samples were taken with a spade to avoid disturbance of sediments before sampling, sampling direction was always downstream to upstream.

The trial site is part of an ongoing study S13-02262 “A Field Study to Evaluate the Effects of Copper on Earthworm Fauna in Central Europe” (Olaf Klein), Eurofins Agroscience Services Ecotox GmbH, Eutinger Str.24, 75233 Niefern-Öschelbronn, Germany). The study started in the autumn of 2003 and had been treated with (Copper hydroxide) at three different treatment rates, 4 kg/ha/year (T1), 8 kg/ha/year (T2) and 40 kg/ha/year (T3). The last treatment was at 40 kg/ha/year (T3) in March 2009. Annual Copper treatments from 2003 until November 2017 resulted in total amounts of 56 kg/ha (T1), 112 kg/ha (T2) and 240 kg/ha (T3).

From 2003 to 2017 there were no flood events recorded or data on flood events available. Intense rain events were recorded twice in 2013. Several rain events were indicated as possible intense rain events. The inclination of the trial site is low (0.6°) and directed north-northwest towards the stream Stunzach. The available data on area surface, the fluvial system of the stream Stunzach and precipitation data do not indicate intense runoff of Copper from the trial site into the waterbody of the trial S17-04438-01 by surface water (TOPPS, 2015).

The dried and homogenised sediment was extracted using a mixture of strong acids in a suitable heat extraction system. Final analysis of total Copper was done with ICP-OES (inductively coupled plasma with optical emission spectrometry).

Procedural recoveries run concurrently with test specimen at levels of 4 mg/kg, 10 mg/kg, 20 mg/kg and 100 mg/kg gave an overall mean recovery of $85.6 \pm 6.7\%$.

Copper concentrations below 10 mg/kg dry sediment, were found in the samples from sector 1a, 12 (surface) and 17.4 (deeper) mg/kg dry sediment in sector 1b which both represent a control without any possible Copper input from the field site. This was in the range of geogenic Copper background in sediments of 17 mg/kg (RAR 2018). Copper concentrations in the samples of the potentially exposed sectors 2 and 3 were below 13 mg/kg except for the deeper, older sediment layer of sector 3 with a Copper residue concentration of (21.8 mg/kg dry sediment).

In sectors 1b, 2 and 3 the concentration of Copper in deeper (older) sediment was up to 74% higher than in the surface sediment layer. In sector 1a the Copper concentration in both sediment layers was at the same level.

Despite of 15 years of Copper application on the adjacent field no increase of the Copper concentration in the upper 5 cm sediment layer was observed.

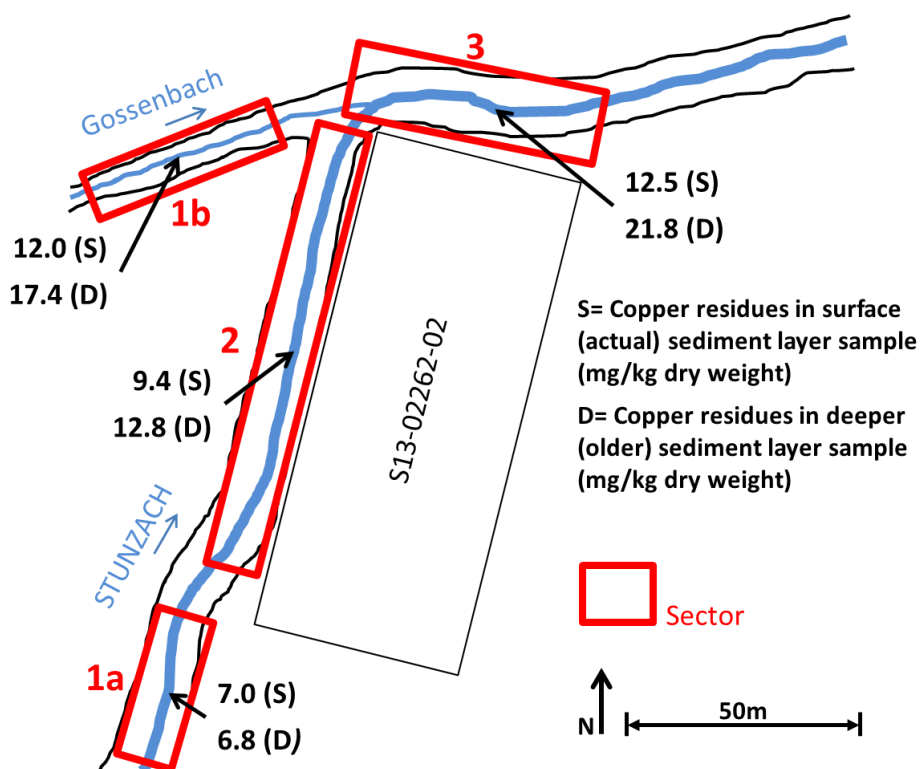


Figure 8.9.2-1 Sampling/Site information (Sampling from 15 Nov 2017)

Table 8.9-27: Summary of Copper Residues in Sediment

Sample code	Sector	Sediment layer	Mean Copper Residue [mg/kg dry sediment]
S17-04438-01-1a-1	1a	Surface (actual)	7.0
S17-04438-01-1a-2	1a	Deeper (older)	6.8
S17-04438-01-1b-1	1b	Surface (actual)	12.0
S17-04438-01-1b-2	1b	Deeper (older)	17.4
S17-04438-01-2-1	2	Surface (actual)	9.4
S17-04438-01-2-2	2	Deeper (older)	12.8
S17-04438-01-3-1	3	Surface (actual)	12.5
S17-04438-01-3-2	3	Deeper (older)	21.8

I. MATERIALS AND METHODS

The field phase was carried out in Southern Germany at the field site of the study S13-02262 (trial -02). Sediment samples were taken from four sectors. Two sectors (1a, 1b) were located upstream from the field site and represented the control without any possible Copper input from the field site. Sectors 2 and 3 were located close to the field site and represented possible Copper (passive-) treated areas. Two samples per sector were taken – one sample from the surface (actual) sediment layer and one sample from deeper (older) sediment layer(s).

The field trial S13-02262-02 is part of the ongoing study S13-02262 “A Field Study to Evaluate the Effects of Copper on Earthworm Fauna in Central Europe” (Klein, Eurofins Agroscience Services Ecotox GmbH, Eutinger Str.24, 75233 Niefern-Öschelbronn, Germany). The study started on 01 Oct 2013. Before the initiation of the study S13-02262 the field site was the trial G03N047N of the study 20031343/G1-NFEW (Klein, 2015): A Field Study to Evaluate the Effects of Copper on Earthworm Fauna in Central Europe; see RAR, Vol. 3, B8, CA 7.1.2.2.2/01), which had been running 10 years from autumn 2003 until autumn 2013. Both studies were conducted on grassland.

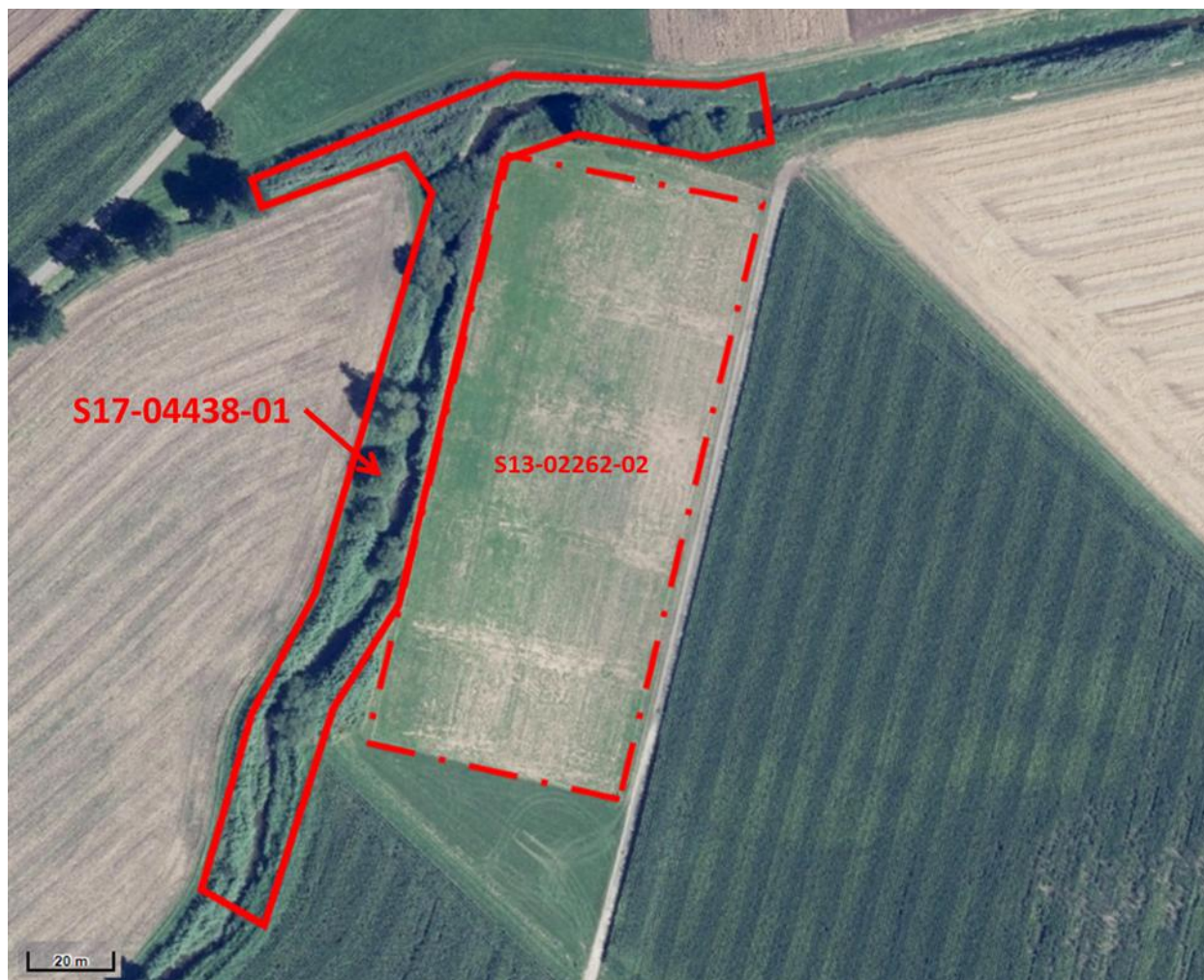


Figure 8.9.2-2 Location of the sampling-site

The study started on 01 Oct 2013 and had been treated with (Copper hydroxide) at three different treatment rates, 4 kg/ha/year (T1), 8 kg/ha/year (T2) and 40 kg/ha/year (T3). The last treatment was at 40 kg/ha/year (T3) in March 2009. Annual Copper treatments from 2003 until November 2017 resulted in total amounts of 56 kg/ha (T1), 112 kg/ha (T2) and 240 kg/ha (T3).

Table 8.9-28: Summary of test item Copper hydroxide applied (target) in studies 20031343/G1-NFEw and S13-02262

Study/trial	Period	Total amount of test item applied*
20031343 / G1-NFEw / G03N047N	Autumn 2003 - autumn 2013 **(T3 from autumn 2003 - spring 2009)	40 kg/ha (T1) 80 kg/ha (T2) 240 kg/ha (T3)**
S13-02262 / S13-02262-02	01 Oct 2013 - 15 Nov 2017	16 kg/ha (T1) 32 kg/ha (T2)
Total	Autumn 2013 - 15 Nov 2018	56 kg/ha (T1) 112 kg/ha (T2) 240 kg/ha(T3)**

*according to target application mode in studies 20031343/G1-NFEw and S13-02262

** (T3 from autumn 2003 – spring 2009)

Sediment sampling took place on 15 Nov 2017. Sediment samples were taken from four sectors. Two samples per sector were taken – one sample from the surface (actual) sediment layer and one sample from deeper (older) sediment layer(s). Samples were taken with a spade to avoid disturbing the sediments. The sampling direction order was from downstream to upstream (sector 3 → sector 2 → sector 1a / sector 1b). In each sector the surface sediment layer sample was taken before the deeper sediment layer sample.

Sampling was done in four stream sectors near to trial site -02 of the study S13-02262. The sectors 1a and 1b represent stream areas without any possible Copper input from the trial site, sectors 2 and 3 were areas with possible passive Copper input from the trial site.

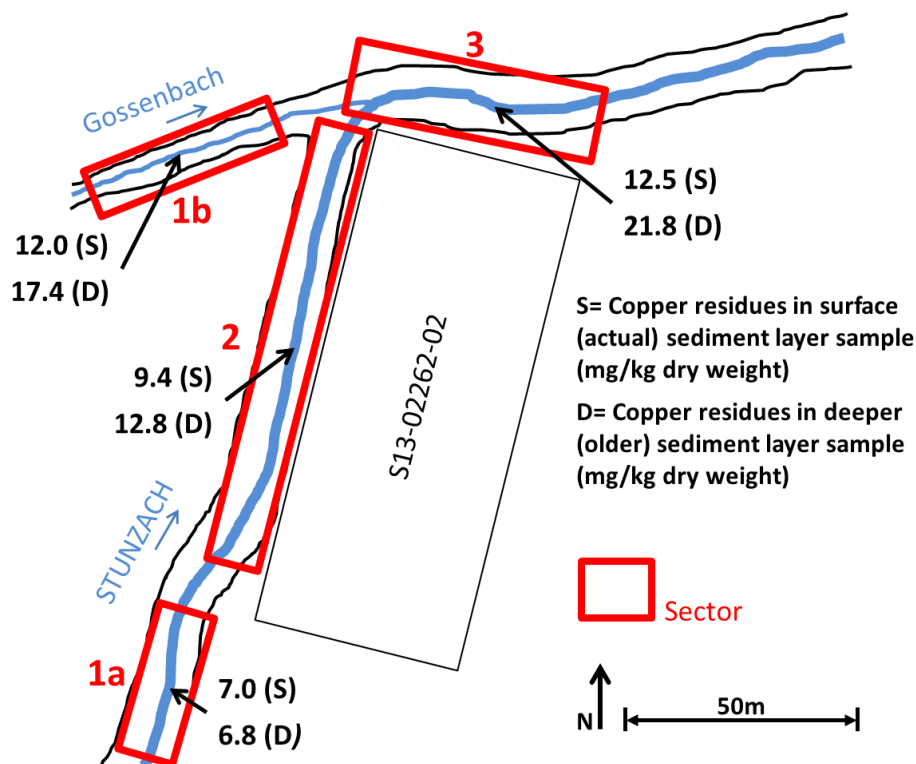


Figure 8.9.2-3 Sampling/Site information (Sampling from 15 Nov 2017)

The dried and homogenised sediment was extracted using a mixture of strong acids in a suitable heat extraction system. Final analysis of total Copper was done with ICP-OES (inductively coupled plasma with optical emission spectrometry). Appropriate dilutions were prepared to meet the respective working range of the ICP-OES.

Procedural recoveries run concurrently with test specimen at levels of 4 mg/kg, 10 mg/kg, 20 mg/kg and 100 mg/kg gave an overall mean recovery of $85.6 \pm 6.7\%$.

II. RESULTS AND DISCUSSION

The Copper residues in the samples from sector 1a were low when compared to possible natural Copper content in soil 40-60 mg/kg (Scheffer & Schachtschabel, 2002). Slightly higher, but still low Copper residues were found in the samples from sector 1b and sector 3. The maximum Copper residue (21.8 mg/kg dry sediment) was found in the deeper sediment layer sample from sector 3 (Table 8.9-32).

In sectors 1b, 2 and 3 the concentration of Copper in deeper (older) sediment was up to 74% higher than in the surface sediment layer. In sector 1a the Copper concentration in both sediment layers was at the same level.

Table 8.9-29: Summary of Copper Residues in Sediment

Sample code	Sector	Sediment layer	Mean Copper Residue (mg/kg dry sediment)
S17-04438-01-1a-1	1a	Surface (actual)	7.0
S17-04438-01-1a-2	1a	Deeper (older)	6.8
S17-04438-01-1b-1	1b	Surface (actual)	12.0
S17-04438-01-1b-2	1b	Deeper (older)	17.4
S17-04438-01-2-1	2	Surface (actual)	9.4
S17-04438-01-2-2	2	Deeper (older)	12.8
S17-04438-01-3-1	3	Surface (actual)	12.5

S17-04438-01-3-2	3	Deeper (older)	21.8
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III. CONCLUSIONS

Despite 15 years of Copper application on the adjacent field no increase of the Copper concentration in the upper 5 cm sediment layer was observed.

8.9.2.3 PEC_{sw}/sed of formulation

The calculation of PEC_{sw}/sed for the formulation is considered not relevant.

zRMS comments:

Cymoxanil

PEC_{sw}/sed are accepted for risk assessment.

Copper

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.

Based on the results of the study of Blust R and Joosen S (2016; 9d.2.3-1), the correction factor of 3 cannot be agreed by the RMS.” (RAR-copper compounds- Volume 3 – B.8 (PPP).

The final report of monitoring study was submitted but no used by zRMS.

The copper content in stream sediments was examined in field trials including copper treated plots with different application rate 4.0 to 40.0 kg Cu/ha. The sampling points were located close to the field site and represented areas potentially exposed to copper from the treatments on the adjacent field trial.

The meteorological data were collected. The Cu content in stream sediments was examined (Table 8.9.2.9). Sediment was analyzed for residues of copper using the analytical methods reported in the GLP compliant studies. The report was used only for additional information.

PL:

The PEC_{sw} have been calculated by applicant 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.

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 potatoes for exposure via spray drift and run-off. The PEC_{sw} and PEC_{sed} concentrations of copper were determined using the following assumptions:

PEC_{sw} values for active substance copper following a single application to 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)	10m NSZ µg/L)	20m NSZ µg /L)

Potatoes 1x 600g Cu /ha	0.552	0.0552	0.552	0.055	0.0232
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Sum PECsw (drift and runoff) values for active substance copper following a single application to 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
Potatoes 1x 600g Cu /ha	0.023	---

Sum PECsed (drift and runoff) values for active substance copper following a single application annual dose for 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	
Potatoes 90% runoff reduction 20m	3600 g Cu /ha	0.28	2.02	2.8	5.6	19.02

The PECsw and PECsed values may be used in the aquatic 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.

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

8.10.1 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

8.10.1.1 Cymoxanil (active substance 1) and its metabolites

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Cymoxanil
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	0.0052 / 0.00058 (n = 2)
Photochemical oxidative degradation in air	DT50: 21.3 hrs (Atkinson's method, OH- concentration of $1.5 \times 10^6 \text{ cm}^{-3}$ (12-hrs day))
Vapour pressure (Pa):	$1.50 \times 10^{-4} \text{ Pa}$ (20 °C, 99.9%)
Henry's Law Constant (Pa.m ³ /mol):	$3.8 \times 10^{-5} \text{ Pa m}^3 \text{ mol}^{-1}$ at 20°C, pH 7
Volatilisation	Not studied – no data requested
Metabolites	Not studied – no data requested

Summary:

The fate and behaviour in air of Cymoxanil was evaluated during the Annex I Inclusion. No additional studies have been performed. Because of the vapour pressure of $1.5 \times 10^{-4} \text{ Pa}$ (20 °C) being $> 10^{-5} \text{ Pa}$ the behaviour in air has to be considered with respect to short-range and long-range transport potential and adverse effects to the environment.

Short-range transport

- Risk assessment for terrestrial organisms is covered by in-field-risk assessments.
- For risk assessment for aquatic organisms transport of Cymoxanil via volatilisation and successive deposition has only to be taken into account at FOCUS Step 4. As an acceptable risk for aquatic organisms can be demonstrated via FOCUS Step 2 PEC values, it is not necessary to consider short-range transport into surface in aquatic risk assessments.

Long-range transport potential and adverse effects to the environment:

- As the DT50 in air according to Atkinson is below the trigger of 2 days, no long-range transport potential or adverse effects to the environment are expected for Cymoxanil.

8.10.1.2 Copper (active substance 2)

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. Data are therefore not required.

zRMS comments:

Information on the fate and behaviour of cymoxanil and copper in the air provided by the Applicant is in line with the EU agreed data For this active substances.

Appendix 1 Lists of data considered in support of the evaluation

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Demetriades , A., Reimann, C., Birke M., the Eurogeosurveys Geochemistry EGG Team	2012	EUROPEAN GROUND WATER GEOCHEMISTRY USING BOTTLED WATER AS A SAMPLING MEDIUM not available, not applicable Springer Science + Business Media, Inc., 115-139 GLP/GEP: no Published: yes	N	-
KCP 9.2.4.1/01	Koomen, B.	2022a	FEL02: ESTIMATIONS OF PEC _{GW} FOR THE ACTIVE SUBSTANCE CYMOXANIL AND RELEVANT SOIL METABOLITES AFTER USE ON POTATO IN THE EU (CENTRAL ZONE) Report No.: 20291840A Source: Charles River Laboratories GLP/GEP: no Published: no	N	UPL EU
KCP 9.2.4.1/01	Bradatsch, C.	2019	CALCULATION OF PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER (PEC _{GW}) FOR THE ACTIVE SUBSTANCE COPPER USING THE MODEL SOFTWARE FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 AND FOCUS MACRO 5.5.4 - PRODUCT FEL02 - Report No.: 1181686-CP-090204-02-SU GAB Consulting GmbH, Stade, Germany GLP/GEP: no Published: no	N	UPL EU
KCP	Koomen, B.	2022b	FEL02: ESTIMATIONS OF PEC _{SW} AND PEC _{SED} FOR THE ACTIVE SUBSTANCE CYMOXANIL		UPL EU

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
9.2.5/01			AND RELEVANT METABOLITES AFTER USE ON POTATO IN THE EU (CENTRAL ZONE) Company Report No.: 20291840B Source: Charles River Laboratories GLP/GEP: no Published: no		
KCP 9.2.5/01	Axmann, S.	2019	A FIELD STUDY TO DETERMINE COPPER RESIDUES IN STREAM SEDIMENTS EU Copper Task Force, S17-04438 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH GLP: yes Published: no	N	EUCuTF(*)

UPL EU = UPL Europe Ltd.; EUCuTF = EU Copper Task Force

(*) UPL is a full member of the EU Copper Task Force, UPL Europe Ltd has a full access to all the studies included in the AIR dossier submitted for the EU renewal of copper compounds
UPL is a full member of the Cymoxanil AIR4 Task Force, UPL Europe Ltd has a full access to all the studies included in the AIR dossier submitted for the EU renewal of cymoxanil

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/01	Blust, R., Steven Joosen, S.	2016	KINETICS AND SPECIATION OF COPPER IN COPPER BASED FUNGICIDE FORMULATIONS USED IN CROP PROTECTION European Copper Task Force, Petit-Lancy, Switzerland, F-Cu 2016-2 Department of Biology, University of Antwerp, Belgium GLP/GEP: no Published: no	N	EUCuTF
KCP 9.2/02	Ma, H., Kim, S.D., Cha, D.K., Allen, H.E.	1999	EFFECT OF KINETICS OF COMPLEXATION BY HUMIC ACID ON TOXICITY OF COPPER TO CERIODAPHNIA DUBIA not available, not applicable Environmental Toxicology and Chemistry, 18(5), 828-837 GLP/GEP: no Published: yes	N	EUCuTF
KCP 9.2.5/01	Blust, R., Steven Joosen, S.	2016	KINETICS AND SPECIATION OF COPPER IN COPPER BASED FUNGICIDE FORMULATIONS USED IN CROP PROTECTION European Copper Task Force, Petit-Lancy, Switzerland, F-Cu 2016-2 Department of Biology, University of Antwerp, Belgium GLP/GEP: no Published: no Submitted in: KCP 9.2/01	N	EUCuTF
KCP 9.2.5/02	Ma, H., Kim, S.D., Cha, D.K., Allen, H.E.	1999	EFFECT OF KINETICS OF COMPLEXATION BY HUMIC ACID ON TOXICITY OF COPPER TO CERIODAPHNIA DUBIA not available, not applicable Environmental Toxicology and Chemistry, 18(5), 828-837 GLP/GEP: no Published: yes Submitted in: KCP 9.2/02	N	EUCuTF

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

List of data relied on not submitted by the applicant but necessary for evaluation

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

Appendix 2 Detailed evaluation of the new Annex II studies

For Cymoxanil new Annex II data on the adsorption and soil aerobic degradation is submitted for PECgw and PECsw/sed assessments of the metabolite IN-KQ960. These new endpoints were also used in a risk assessment performed in 2013 for authorisation of the product FDJ03, which also contains Cymoxanil as active substance, and was at the time reviewed by zRMS Austria. The summaries of these studies and the comments/conclusions by the zRMS are integrally taken over in Appendix A 2.1.

For Copper new data related to PECsw/sed calculations (Steps 1-2) are presented in Appendix A 2.2.

Justification for use of new data (post approval) for metabolite IN-KQ960 as presented in the Registration Report Part B.5 for the product FDJ03 of 2013 (zRMS Austria):

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information
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Reference:	KHIA1 9.1/02; IN-KQ960, a Metabolite of Cymoxanil – Rate of Degradation in Three Soils
Author(s), year:	Völkel, W., 2011
Report/Doc. number:	20110084
Guideline(s):	OECD Test Guideline 307 (April 2002)
GLP:	Yes
Deviations:	None
Validity:	considered acceptable

Material and methods: The Cymoxanil metabolite IN-KQ960 was applied to three soils with an application rate of 29.65 µg per 100g soil. The following soils were used: Speyer 5M (sandy loam), Am Fischteich (silt loam) and Speyer 2.2 (loamy sand). Microbial soil biomass was determined of untreated soil samples before incubation. Soil samples were incubated in the dark at 20°C. The experiment was performed in an open gas-flow system with ventilation of moistened air. Duplicate samples were taken on five additional days to day 0. Samples were extracted with an acetonitrile/water solution and afterwards analysed with LC-MS to determine the amount of IN-KQ960. DT₅₀ and DT₉₀ values were calculated according to FOCUS Kinetics (2006) and with KinGUI 1.1.

In order to evaluate the efficiency of the analytical methods, untreated soil samples fortified with the test item (fortification levels 20%, 50%, 70% and 80% of the initial amount) at the expected concentration were worked up and analysed the same way as the treated samples, at every sampling interval and for each soil.

Findings: IN-KQ960 degraded rapidly in all three soils. After 0.71 days of incubation, degradation of at least half of the material could be detected. The DT₉₀ was reached within 3 days with 1.7% of initial IN-KQ960 in the Speyer 5M-soil, 6.7% in the Am Fischteich-sample and 6.1% in the Speyer 2.2-soil. In the Am Fischteich-sample degradation was slightly slower; therefore, an additional extraction was performed after 8 days of incubation. For the other two samples, the incubation was determined after 3 days. Degradation kinetics and half-life values are given in table 9.1-2.

Table 9.1-2 DT₅₀ and DT₉₀ values calculated for IN-KQ960 in three soils

IN-KQ960	Speyer 5M		Am Fischteich		Speyer 2.2
Kinetic Model	SFO	FOMC*	SFO	FOMC*	SFO*
DT ₅₀ [d]	0.35	0.27	0.62	0.47	0.42
DT ₉₀ [d]	1.15	1.50	2.05	2.88	1.39
Chi ² Error [%]	10.2	7.1	9.3	7.0	13.5
r ²	0.976	0.986	0.980	0.989	0.955

* Best fit model

For the samples fortified with IN-KQ960, mean recoveries of 85%, 95.8% and 89.8% of the soils Speyer 5M, Am Fischteich and Speyer 2.2 were obtained.

Conclusion: For the Speyer 5M and the Am Fischteich-soil, FOMC kinetic are chosen to be best fit model with DT₅₀ values of 0.27 days and 0.47 days. For the sample from the Speyer 2.2 soil, the DT₅₀ was taken from SFO kinetics with a value of 0.42 days.

Comments (zMS): No mass balance or rate of recovery is given for the soil samples. Only for the fortified control samples, a recovery rate was established from 85%- 95%. Quantification of released CO₂ and eventually other volatile compounds would have been required in order to identify losses through CO₂ from the system. The study is considered acceptable, since only the rate of degradation was used for further evaluation and it was a replication of an already in the DAR evaluated degradation pathway.

For the further modelling the SFO degradation values have been taken. Including the DT₅₀ of the LoEP (11.2 days, EFSA conclusion Sept. 2005), a geometric mean value of 1.0 days was taken for PEC_{GW} calculations. According to the guidance document SANCO/10328/2004-rev. 8, new Annex II date will only be accepted if no safe use is guaranteed. Since the metabolite IN-KQ960 was calculated to be over the trigger value of 0.1 µg/L in the groundwater risk assessment, the new DT₅₀ value of 1.0 days could be taken into consideration. However, the soil and the surface water/sediment risk assessments were done as given in the EFSA conclusion.

Reference:	KHIA1 9.3/01; [14C]-Cymoxanil: Adsorption/desorption on soil
Author(s), year:	Ford G., 2009
Report/Doc. number:	Report No.: AGC/06, Reference No.: QBR102749
Guideline(s):	OECD Test Guideline 106 (2000)
GLP:	Yes
Deviations:	None
Validity:	considered acceptable

Material and methods: The stock solution of Cymoxanil (¹⁴C-Cymoxanil and unlabelled Cymoxanil) was prepared in acetonitrile (conc. in final dilutions < 0.1%). Aliquots were mixed in centrifuge tubes with portions of air dried soil (4 different UK soils) which was pre-equilibrated in 0.01M CaCl₂. For Cymoxanil the following concentrations were tested: 0.04, 0.4, 2.0 and 5.0 mg/L. For the metabolites IN-U3204 and IN-KQ960 a single concentration of 5.0 mg/L was tested. For IN-T4226 and IN-KP533 the single concentration was 1.0 mg/L, respectively. In a 2:1 ratio of solution to soil, the tubes were shaken at 20°C in the darkness for 4 hours. Duplicates were done of each sample and the control, except for the highest concentration for which the test was run in triplicates. After the incubation time, each sample was centrifuged, the supernatant removed, the volume measured and the concentration of the radioactivity in the solution was determined by LSC. The concentration of radioactivity in soil was calculated by the difference. Following the adsorption, desorption of Cymoxanil was done with a calcium chloride solution. The mixture was shaken again the same way as done before and afterwards separated by centrifugation. The desorption process was carried out twice and after each centrifugation the radioactivity was measured in the supernatant solution by LSC. For the soils with the application of 5.0 mg/L, solvents were extracted after desorption and the radioactivity of the extracts and the insoluble residues was measured.

Findings: Radioactivity during the course of the study ranged from 86.0% AR to 94.0% AR for adsorption and desorption samples at 5.0 mg/L. Adsorption water radioactivity ranged from 34.4% AR (0.04 mg/L) to 79.2% AR (2.0 mg/L). Values were generally lower with increasing soil organic matter. Radioactivity in the desorption waters ranged from 10.8% to 18.8% AR for desorption water 1 and 2.5% to 8.3% AR for desorption water 2. After desorption the soils were solvent extracted and the radioactivity/compound content of the extracts was < 1% AR and insoluble residue were measured to be 1.6 to 17.1% AR. For the metabolites, the recovery in the adsorption and desorption solution (sum of all solutions) ranged from 80 to 98% for IN-U3204, from 99 to 104% for IN-KQ960, from 70 to 117% for IN-T4226 and from 22 to 64% for IN-KP533. Calculated Koc values are given in table 9.3-2 for Cymoxanil and in table 9.3-3 for the metabolites.

Table 9.3-2 Adsorption/Desorption parameters for [¹⁴C]-Cymoxanil

Soil	ADSORPTION				DESORPTION			
	K _d [L/kg]	K _{d,oc} [L/kg]	1/n _s	r ₂	K _d [L/kg]	K _{d,oc} [L/kg]	1/n _s	r ₂
1	0.0135	2.70	0.9240	0.9976	1.152	230.40	0.9510	0.9990
2	0.1020	5.37	0.9572	0.9999	0.9248	48.67	0.9914	0.9999
3	0.2392	14.07	0.9244	0.9999	0.8518	50.11	1.0408	0.9979
4	0.6668	16.26	0.9301	0.9999	0.7794	19.01	1.0014	0.9978

K_d = coefficient of adsorption

K_{d,oc} = coefficient of desorption

K_{d,oc} = K_d adjusted for % organic carbon content of soil

K_{d,oc} = K_d adjusted for % organic carbon content of soil

K_{d,om} = K_d adjusted for % organic matter content of soil

Table 9.3-3 Adsorption of metabolites IN-U3204, IN-KQ960, IN-T4226 and IN-KP533

Soil	IN-U3204		IN-KQ960		IN-T4226		IN-KP533	
	K _d [L/kg]	K _{oc} [L/kg]	K _d [L/kg]	K _{oc} [L/kg]	K _d [L/kg]	K _{oc} [L/kg]	K _d [L/kg]	K _{oc} [L/kg]
1	0.193	38.6	0.008	1.6	n.c.	n.c.	1.509	301.8
3	0.294	17.29	0.155	9.12	0.857	50.41	8.0	470.6
4	0.786	19.17	0.217	5.29	0.083	2.02	1.448	35.32
arith. mean		25.02		5.34		26.22		269.24

n.c. = not calculated

All results for IN-KP533 are considered as overestimates due to the apparent instability of the metabolites and the presence of a component believed to be oxamic/oxalic acid in samples.

Conclusion: The mean Koc value of Cymoxanil was 9.6 L/kg (based on Freundlich isotherms) and of the metabolites IN-U3204, IN-KQ960, IN-T4226 and IN-KP533 the mean Koc values (based in Kd values) were 25.0 L/kg, 5.34 L/kg, 26.2 L/kg and 269.2 L/kg, respectively.

Comments (zMS): The K_a (and analogous K_d) values of Cymoxanil were obtained from the log-transformation of the concentration of the radioactive Cymoxanil in the adsorption water and in the soil, adequately assuming that $\log x (x/m) = 1/n_a \times \log (C_e) + K_a$. Whereas x/m is the concentration of test substance in solution ($\mu\text{g/L}$) at equilibrium, $1/n_a$ is the exponential constant or slope, C_e is the concentration of test substance in solution ($\mu\text{g/L}$). However, $\log(K_a)$ was used as K_a instead of calculating K_a as 10 to the power of $\log(K_a)$. The K_a and also the K_{aoc} values have been recalculated by the zRMS and are given in table 9.3-4.

Table 9.3-4 Recalculated Adsorption/Desorption parameters for [^{14}C]-Cymoxanil

Soil	ADSORPTION				DESORPTION			
	K_a [L/kg]	K_{aoc} [L/kg]	$1/n_a$	r_2	K_d [L/kg]	K_{doc} [L/kg]	$1/n_d$	r_2
1	1.032	206	0.9240	0.9976	14.207	2841	0.9510	0.9990
2	1.265	67	0.9572	0.9999	8.375	441	0.9914	0.9999
3	1.735	102	0.9244	0.9999	7.084	417	1.0408	0.9979
4	4.643	113	0.9301	0.9999	5.984	146	1.0014	0.9978
arith. mean		112				961		

According to the guidance document SANCO/10328/2004-rev. 8, new Annex II date will only be accepted if no safe use is guaranteed or if adverse effects are created. In this case, the input parameter of IN-KQ960 could be changed due to a non safe use for PEC_{GW} calculations which were discovered during the Annex I inclusion process. However, the new K_{oc} value of IN-KQ960 (5.34 L/kg) rather presents the case of adverse effects and therefore will be used further on in the risk assessment.

A 2.1 KCP 9.2.5 Predicted Environmental Concentrations in surface water (PEC_{sw}) – Simulation files

A 2.2.1 PEC_{sw} - All entry routes to water bodies considered, TOTAL Copper

A 2.2.1.1 FOCUS Step 1

Potato, 1 × 600 g/ha

STEPS 1-2 in FOCUS FOCUS Surface water Tool for Exposure Predictions Step 1

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 14/12/2022, 15:21:18

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: Copper (UPL)

Active substance:	COP PEC _{sw}
Application rate (g/ha) of a.i.:	600.00
Application/crop type:	potatoes
Number of applications per season:	1.00
Water solubility (mg/L):	500.00
KOC compound(L/kg):	33918.30
DT50 water/sediment (d):	1000.00

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Equivalent app. rate for drift (g/ha):	600.00
Equivalent app. rate for runoff/drainage(g/ha):	600.00
Equivalent app. rate for runoff/drainage(g/ha) of parent:	0.00E+00
Loading to water body via drift (mg/m ²):	1.6554
Loading to water body via runoff/drainage(mg/m ²):	60.0000
fraction of substance entering water body in water phase:	0.0216
fraction of substance entering water body in sediment phase:	0.9784

Table: Calculated Concentrations in the water body

Time (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	9.8447		1.47E+03	
1	4.4430	7.1439	1.51E+03	1.49E+03
2	4.4399	5.7927	1.51E+03	1.5E+03
4	4.4338	5.1148	1.5E+03	1.5E+03
7	4.4246	4.8209	1.5E+03	1.5E+03
14	4.4032	4.6174	1.49E+03	1.5E+03
21	4.3818	4.5424	1.49E+03	1.5E+03
28	4.3606	4.4996	1.48E+03	1.49E+03
42	4.3185	4.4463	1.46E+03	1.49E+03
50	4.2946	4.4239	1.46E+03	1.48E+03
100	4.1484	4.3225	1.41E+03	1.46E+03

A 2.2.1.2 FOCUS Step 2

Potato, 1 × 600 g/ha, North Europe - Mar-May

STEPS 1-2 in FOCUS FOCUS Surface water Tool for Exposure Predictions Step 2

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 14/12/2022, 15:23:31

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: Copper (UPL)

Active substance:	COP PECsw
Application rate (g/ha) of a.i.:	600.00
Crop Interception:	no interception (0 %)
Application/crop type:	potatoes
Number of applications per season:	1
Region and season of application:	North Europe, Mar. - May
Water solubility (mg/L):	500.00
KOC assessed compound(L/kg):	33918.30
KOC parent compound(L/kg):	0.00E+00
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	1000.00

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	600.00
Equivalent application rate for runoff/drainage(g/ha):	600.00
Loading to water body per drift event(mg/m²):	1.6554
Loading to water body via runoff/drainage (mg/m²):	11.9668
fraction of substance entering water body in water phase:	0.0216
fraction of substance entering water body in sediment:	0.9784
Total Loading to water body via drift (mg/m²):	1.6554 (12.1522%)
Total Loading to water body via water phase(mg/m²):	0.2589 (1.9005%)
Total Loading to water body via sediment phase (mg/m²):	11.7079 (85.9473%)
Maximum PECsw (µg/L):	5.5180
Maximum PECsw occurring on day:	0
Maximum PECsed (µg/kg dry sediment):	332.8441
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	5.5180	---	332.8441	---
1	1.9176	3.7178	332.6134	332.7287
2	0.7441	2.5243	332.3830	332.6135
4	1.0998	1.5831	331.9225	332.3831
7	0.9800	1.3334	331.2330	332.0379
14	0.9752	1.1555	329.6297	331.2343
21	0.9705	1.0946	328.0342	330.4333
28	0.9658	1.0630	326.4465	329.6349
42	0.9565	1.0290	323.2939	328.0458
50	0.9512	1.0170	321.5062	327.1424
100	0.9188	0.9759	310.5545	321.5706

A 2.2.3 PEC_{SED} - Entry via runoff/drainage only (no drift)

Potato, 1 × 3600 g/ha, North Europe - Mar-May

STEPS 1-2 in FOCUS FOCUS Surface water Tool for Exposure Predictions Step 2

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 14/12/2022, 15:29:49

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: Copper (UPL)

Active substance:	COP PECsed runoff-drainage
Application rate (g/ha) of a.i.:	3600.00
Crop Interception:	no interception (0 %)
Application/crop type:	no drift (incorp or seed trtmt)
Number of applications per season:	1
Region and season of application:	North Europe, Mar. - May
Water solubility (mg/L):	500.00
KOC assessed compound(L/kg):	10000.00
KOC parent compound(L/kg):	0.00E+00
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	1000.00

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	0.0000
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	3600.00
Equivalent application rate for runoff/drainage(g/ha):	3600.00
Loading to water body per drift event(mg/m²):	0.0000
Loading to water body via runoff/drainage (mg/m²):	71.8007
fraction of substance entering water body in water phase:	0.0698
fraction of substance entering water body in sediment:	0.9302
Total Loading to water body via drift (mg/m²):	0.0000 (0.0000%)
Total Loading to water body via water phase(mg/m²):	5.0093 (6.9767%)
Total Loading to water body via sediment phase (mg/m²):	66.7913 (93.0233%)
Maximum PEC _{SW} (µg/L):	16.6978
Maximum PEC _{SW} occurring on day:	4
Maximum PEC _{sed} (µg/kg dry sediment):	1.67E+03
Maximum PEC _{sed} occurring on day:	4

Table: Calculated Concentrations in the water body

Time after max. peak(d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	16.6978	---	1.67E+03	---
1	16.6863	16.6920	1.67E+03	1.67E+03
2	16.6747	16.6863	1.67E+03	1.67E+03
4	16.6516	16.6747	1.67E+03	1.67E+03
7	16.6170	16.6574	1.66E+03	1.67E+03
14	16.5366	16.6171	1.65E+03	1.66E+03
21	16.4565	16.5769	1.65E+03	1.66E+03
28	16.3769	16.5368	1.64E+03	1.65E+03
42	16.2187	16.4571	1.62E+03	1.65E+03
50	16.1290	16.4118	1.61E+03	1.64E+03
100	15.5796	16.1323	1.56E+03	1.61E+03