FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: FEL02

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

Chemical active substance:

Copper (Bordeaux mixture), 200 g/kg

Cymoxanil, 40 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Art. 33 authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: March 2023

MS Finalisation date: December 2023, April 2024

Version history

When	What
March 2023	Part B - Section 0 - Core Assessment Central Zone – version 01 of applicant
December 2023	zRMS assessment of dRR
April 2024	The final version of the RR after the commenting period

Table of Contents

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

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 of the approval of Copper compounds as candidates for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009 was agreed.

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.

Generally, the risk assessment is based on the studies, methods and approaches accepted in course of the EU peer review of the active substance Cymoxanil.

This application is intended for the first authorisation of the product FEL02 in the **Central EU zone**.

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 product 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 active substance laid down in Regulation (EC) No 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No 284/2013. Data submitted on the formulated product are owned by the applicant UPL Europe Ltd. A summary of the data is provided in dRR format. Summaries of studies and risk assessments which have not yet been assessed in any EU Member State are included in dRR Part B. Also copies of summaries of studies which have been submitted in the framework of the current process of renewal of approval of Cymoxanil 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.

The technical active substance Cymoxanil used in FEL02 was evaluated during the EU Review for the approval of Cymoxanil. Thus, an assessment of technical equivalence is not required for the current application.

This application follows the data requirements for active substances laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

In addition to the submission of studies as listed in the separate sections of this application, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1.2-1 Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	-	-
Central zone	zRMS Poland (current application): Cuprofix C (no authorisation number yet)	cMS Austria : Cuprofix C Disperss, cMS Ireland : Cuprofix C Disperss, cMS Deutchland : Cuprofix C Disperss cMS Czech Republic : Cuprofix C Disperss
Southern zone	zRMS Italy: Cimoram, 8105 Cuprofix C Disperss, 11637 Coppercim M WG, 12393 Cimoram Blu, 12996 Cimoram Ultra WG, 15101 Vitene R WG, 15102	cMS Spain: Cuprofix C cMS Malta: Cuprofix C Disperss, 2015-09-17 P02
Inter-zonal		

0.1.3 Regulatory history of the active(s)

0.1.3.1 Copper as Bordeaux mixture

Table 0.1.3.1-1 Summary of regulatory history of CAS No: 8011-63-0 (Copper as Bordeaux Mixture)

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2009/37/EC
RMS	France
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2019 (Regulation (EU) 2018/1981)
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2019
Date of final Commission (re-registration) deadline (Step 2)	31.12.2025
Current expiration of approval	The Commission considers that Copper compounds are candidates for substitution for the folowing reasons: • copper compounds are persistent substances (given that the half-life in soil is greater than 120 days) and • toxic substances (given the long-term no-observed effect concentration for aquatic organisms is less than 0.01 mg/L. However, the applicant disagrees with this classification and is challenging the applictaion of the 'P' criteria to inorganic substances under Reg. (EC) No 1107/2009 since it is not applied to such substances under Reg. (EU) 528/2012 or 1278/2008.
Low risk substance or Candidate for Substitution?	Yes

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

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

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

In this overall assessment Member States must pay particular attention to:

- the operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment and other mitigation measures as appropriate;
- the protection of water and non-target organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate;
- the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, do not exceed the minimum necessary to achieve the desired effects and do not cause any unacceptable effect on the environment, taking into account background levels of copper at the applica-

tion site, and, where the information is available, copper input from other sources. Member States may in particular decide to set a maximum annual application rate not exceeding 4 kg/ha of copper.

The SANCO report for copper compounds (SANTE/10506/2018– 27.11.2018) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is available (EFSA Journal 2018;16(1):5152).

Table 0.1.3.1-2 Information on minimum purity of Copper as Bordeaux mixture

EU agreed minimum purity from Inclusion Directive or Implementing regulation
Expressed as total copper content IQV 263 g/kg Saldeco 276 g/kg Isagro 263 g/kg UPL 257 g/kg Manica 270 g/kg

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

Table 0.1.3.1-3 Endpoints used for evaluation

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Dermal penetration	Concentrate: 1% Spray dilution (0.33 g Cu/L): 9%	
Fish - Acute toxicity	Mortality, LC_{50} (96 h) = 0.207 mg/L total (mm); 0.0344 mg/L dissolved (mm)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Fish – Chronic toxicity	Growth, EC_{10} (53-d) = 0.00112 mg/L (dissolved Cu)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Aquatic invertebrate – Acute toxicity	Mortality, LC_{50} (48 h)= 0.0308 mg/L total (mm); 0.0266 mg/L dissolved (mm)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Aquatic invertebrate – Chronic toxicity	Reproduction, NOEC (21 d) = 0.0076 mg/L total (gmm)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Sediment dwelling organism – chronic toxicity (water spike)	NOEC (28 d) = 0.50 mg/L total (nom)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Sediment dwelling organism – chronic toxicity (sediment spike)	NOEC (28 d) = 16.17 mg/kg dry weight normalized to 2.5% OC	SSD-HC5 = 40.4 mg/kg dry weight normalized to 2.5% OC
Algae – Chronic toxicity	Growth rate, E_rC_{50} (72h) = 0.02229 mg/L total (nom)	ETO- $RAC_{sw;ch}$ = 0.0048 mg/L dissolved
Indoor microcosm study	NOEC = 0.0048 mg/L dissolved (mm) (AF = 2 applied)	NOEC = 0.0048 mg/L dissolved (mm) (AF = 1 applied)

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

0.1.3.2 Cymoxanil

Table 0.1.3.2-1 Summary of regulatory history of CAS No: 57966-95-7

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/125/EC
RMS	Austria
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.09.2009 (2008/125/EC)
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01.12.2009
Date of final Commission (re-registration) deadline (Step 2)	30.08.2019
Current expiration of approval	~~31.08.2023~~ 15.08.2026
Low risk substance or Candidate for Substitution?	No

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

In this overall assessment Member States must pay particular attention to:

- the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures such as buffer zones, where appropriate.

The SANCO report for Cymoxanil (SANCO/179/08 – final rev. 1, 9 July 2010) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is available (EFSA Scientific Report (2008) 167, 1-116). In addition, some studies which have been submitted in the framework of the current process of renewal of approval of Cymoxanil (draft Renewal Assessment Report, July 2020) are included in dRR Part B.

Table 0.1.3.2-2 Information on minimum purity of Cymoxanil

EU agreed minimum purity from Inclusion Directive or Implementing regulation
≥970 g/kg

For the purposes of the present submission, the risk assessment for Cymoxanil is performed in line with the provisions for new product authorisations according to Article 33 of Regulation (EC) No 1107/2009. The expiration date

of Cymoxanil Annex I inclusion is ~~31st of August 2023~~ 15th of August 2026 and Cymoxanil is in the process of renewal of approval. New end points have been drafted in a Renewal Assessment Report of July 2020 (but not yet agreed on EU level). A risk assessment for Cymoxanil is performed for the formulation FEL02 as included in this present Registration Report following the registration of FEL02 in Central EU Zone taking into account the current (draft renewed) end points and guidance documents.

Table 0.1.3.1-3 Endpoints used for evaluation

Not applicable

0.1.4 Regulatory history of the product

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

Table Błąd! W dokumencie nie ma tekstu o podanym stylu.**-1: Summary of regulatory history of the product FEL02**

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
FEL02	Cimoram	IT	8105	09/11/1992	18/03/2019
FEL02	Cuprofix C Disperss	IT	11637	14/03/2003	18/03/2019
FEL02	Coppercim WG	IT	12393	27/09/2005	18/03/2019
FEL02	Cimoram Blu	IT	12996	23/01/2006	18/03/2019
FEL02	Cimoram Ultra WG	IT	15101	18/03/2011	18/03/2019
FEL02	CURZATE ERRE EVO	IT	15102	18/03/2011	18/03/2019
FEL02	MOXYL COMBI WG	IT	17375	28/12/2018	18/03/2019
FEL02	Cuprofix C Disperss	MT	2015-09-17 P02	14/03/2003	17/10/2019 (renewed)

The product was not one of the representative products of the EU Review procedure for renewal of approval of the active substance Copper compounds and of the active substance Cymoxanil.

0.2 zRMS conclusion

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

Residues section: 1,2
Fate section: 1,2
Ecotoxicology Section: 1,2

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

Residues section: none
Fate section: none
Ecotoxicology Section: none

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

Residues section: none

Residues section: All uses / GAPs are covered by established MRLs .

zRMS main conclusions:

Section physical-chemical properties: no data gaps.

Section fate: no data gaps.

Section metabolism and residues: uses are accepted.

Section ecotoxicology: A safe use regarding aquatic organisms was only established if specific national risk mitigation available is applied and otherwise, the risk remains open for finalization of the assessment by cMS. The risk for aquatic organism should be considered at MSs level. Risk for sediment dwelling organism should be decided at MSs level. The risk mitigation measures to bees should be decided at MSs level. The risk for birds and mammals should be decided at MSs level with consideration of acceptance WoE approach. Member States may in particular decide to set a maximum annual application rate not exceeding 4 kg/ha of Copper. The requirement of further data to refine the risk for *Folsomia candida* and *Hypoaspis aculeifer* should be dealt at national level.

Updated 04.2024.

There are some studies formulation ATOFEL02 (Batch no:8.335.3). In our opinion - due to the same content of the active substance inside FEL02 and ATOFEL02 (cooper as Bordeaux mixture 200 g/kg and cymoxanil 40 g/kg) and the same type of formulation (water-dispersible granule - WG formulation) it could be used in risk assessment in ecotoxicology point of view. Due to the AT and CZ comments, the Applicant should provide a comparison of the formulations of ATOFEL 02 and FEL02 including Part C (considering the new more strict rules by EFSA also applied at a.s. level). This approach should be considered at MSs level.

Appendix 1 ALL intended uses

GAP rev. , date: dd.mm.yyyy

PPP (product name/code):	**FEL02**	**Formulation type:**	**WG**
Active substance 1:	**Copper as Bordeaux mixture**	**Conc. of a.s. 1:**	**200 g/kg**
Active substance 2:	**Cymoxanil**	**Conc. of a.s. 2:**	**40 g/kg**
Safener:	**-**	**Conc. of safener:**	**-**
Synergist:	**-**	**Conc. of synergist:**	**-**
Applicant:	**UPL Holdings Coöperatief U.A.**	**Professional use:**	☒
Zone(s):	**Central Zone**	**Non professional use:**	☐
Verified by MS:	**Yes**		
Field of use:	**Fungicide**		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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: e.g. g safener/ synergist per ha**
					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**		
1	Central	Potatoes	F	Late blight (*Phytophthora infestans*)	Spraying	(BBCH 21 to 95)	6	7	a) 3.0 b) 18.0	a) 0.120 + 0.600 b) 0.720 + 3.6	100 - 1000	7	Month of application: 04 to 09
2	Central	Sweet potato (IPOBA) and Yams (CXSES/DIUSS)	F	*Phytophthora infestans,*	Foliar spray	From first leaves visible to 50% of leaves brownish (BBCH 10-95) March to October	a) 6 b) 6	7 days	a) 3.0 b) 18.0	a) 0.12 + 0.6 b) 0.72 + 3.60	200-1000	7	Month of application : 04 to 10

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife, International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/L

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For, the crops EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

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

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions