FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: FEL02

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

Chemical active substances:

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: October 2023; April 2024; June 2024

Version history

When	What
March 2023	Part B-Section 7-Core assessment, Version 01 of applicant
October 2023	dRR version by zRMS
April 2024	The final version of the RR after the commenting period
June 2024	Verification of a list of data considered for national authorization

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7 Metabolism and residue data (KCA section 6)

This dossier is intended for the application for national authorization of the product Copper / Cymoxanil 200 / 40 g/kg WG (Product code: FEL02) according to Article 33 of Regulation (EC) No 1107/2009 in the Central EU Zone with a single use claimed in potato.

The product is already approved since several years in other EU member states, mainly in the South zone (see details in Part A). Some of the studies included in this dossier have already been evaluated as part of these applications.

FEL02 contains Copper (as Bordeaux mixture) 200 g/kg, and Cymoxanil 40 g/kg.

Copper
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 on 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 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.

A next renewal dossier for Copper compounds has been prepared for submission to the RMS Italy in December 2022. It is expected that the evaluation of the current Art. 33 application can be finished before the conclusion on the next renewal dossier is achieved. UPL Europe Ltd. is again a member of the EU CuTF for the upcoming renewal.

The zonal GAP table presented in this dossier has been prepared in compliance with the renewal regulation of the active substance Copper compounds (Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018) and in line with its specific provisions. The total dose for each use must not exceed 28 kg/ha of Copper metal over 7 years (4 kg/ha/year as a median).

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

The RMS and EFSA are held to assess plant protection products according to the existing methodology described in a series of guidance documents (GDs). Those have been developed for synthetic, organic molecules, and are in most cases not applicable to minerals and Copper. This has led to an EFSA conclusion (EFSA, 2018a) 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 Commission, EFSA, the RMS and several MS (see comments from DE and IT in the Peer review Re-port), and this is now fully justified by the documents made available recently by EFSA. 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 conclusion (EFSA, 2018b) 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 does not consider bio-availability; for an essential, ubiquitous micronutrient that is a metal it is indispensable to provide assessment methodologies that consider the bioavailability and the potentially toxic fraction in each real-world exposure scenario. Total concentrations do not result in any meaningful outcome.

Data normalisation to enable comparison of toxicological lab and field data as well as data obtained with different bioavailable fractions is a pre-requisite to allow a realistic assessment of potential risk. Simplistic worst-case scenarios will always indicate a high risk already at naturally occurring concentrations.

For a homeostatically tight controlled essential element the application of assessment factors is meaningless. The question whether an excess exposure or deficiency leads to an adverse disruption of the homeostatic control cannot be approached in this way. Further, the exceptional data richness of the Copper dossier and more than 100 years of experience with the use as fungicide make safety factors unnecessary.

These unique features of Copper are already considered in the assessment of Copper under separate legislation (REACH, 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 (EFSA, 2021a and 2021b). 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.

Cymoxanil

The active substance Cymoxanil was included in Annex I of Directive 91/414/EEC on 1 September 2009 (2008/125/EC), repealed by Regulation 540/2011/EU implementing Regulation 1107/2009/EC. The expiration of approval for Cymoxanil is ~~23 August 2023~~ 15 Auguste 2026 according to Commission Implementing Regulation (EU) ~~2022/707 of 05 May 2022~~ 2023/1446 of 12 July 2023.

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. Where the active substance data is relied upon in the risk assessment of the formulation, this document refers to the conclusions of the original EU-review of Cymoxanil. Studies newly submitted for the purpose of renewal are considered as new studies in the framework of this application.

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.

7.1 Summary and zRMS Conclusion

Copper (Bordeaux mixture)

Stability of Residues

No new data are submitted in the framework of this application.

Copper is an element and is inherently stable as it cannot be transformed into any other material. Therefore, under freezer storage conditions, residues of copper in crop commodities will be stable and copper is not expected to metabolise or to form degradation products.

Metabolism in plant and animal

The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the active substance and renewal procedure. The data evaluated is sufficient to support the proposed uses.

The residue definitions agreed for monitoring and risk assessment:

Total Copper (EFSA 2008, EFSA, 2018a and Reg. (EC) No 149/2008)

Copper is a monoatomic element which cannot be degraded and thus, no metabolites in animals are expected.

No further data are required.

Magnitude of residues in plants

Proposed GAP:

Max. 6 applications, BBCH 21 – 95, 0.60 kg a.s./ha, PHI: 7 (month of application: 04 to 09)

The Applicant refers to following studies:

1. A set of two at harvest supervised residue trials (2008) in the NEU zone (1 in Germany and 1 in Poland) was performed with Copper Oxychloride 37.5 WG formulation.

Trial GAP: 4 x 1.1-1.2 kg Copper/ha, interval = 7 d, PHI = 3 d

Deviations: The trials are overdosed in relation to the application rate per treatment; Number of application are 4 instead of 6.

Studies have been already evaluated in the framework of the Review of the existing maximum residue levels for Copper compounds (EFSA Journal 2018;16(3).

The trials are considered not acceptable to support this use due to the small number of applications.

2. A set of four at harvest supervised residue trials (2006) in the NEU zone (2xAustria, 1xCzech Republic and 1 in Slovakia) was performed with SC formulation Flowbrix (670 g/L of Copper oxychloride).

Trial GAP: 6x1 kg Copper/ha, interval 6-7 d, PHI 14 d

Deviations: PHI is 14 instead of 7

The trials are considered not acceptable to support this use due to the PHI higher than proposed.

3. A set of 12 decline supervised trials in the NEU (10x Germany; climatically different parts) was performed in 1990, 1991 and 1992 with Funguran-OH 50 WP. Trials GAP: 6 x 0.6 kg Copper/ha, PHI = 7 d.

Studies have been already evaluated in the framework of the Review of the existing maximum residue levels for Copper compounds (EFSA Journal 2018;16(3).

The trials are considered acceptable to support this application.

4. New studies on the magnitude of residue have been submitted by the applicant in the framework of this

application.

A set of two supervised at harvest trials in the NEU zone (2020) was performed with BORDEAUX MIXTURE 20 % WG (FAP13) formulation.

Trial GAP: 6 x 1 kg Copper/ha, interval = 5-8 days, PHI = 7-8 days

The trials were performed at a more critical GAP than proposed and represent a worst case The higher PHI of 8 (instead of 7) in one of the trials is considered acceptable, since Copper is an element and is inherently stable.

The trials are considered acceptable to support this application.

The number of trials is sufficient to support the use of copper on potatoes according to the proposed GAP in Central Zone. The data submitted show that no exceedance of the MRL will occur.

Use is accepted.

AT applies for the following additional uses (see section B0): Sweet potato (0212020) and Yams (0212030). According to EU agreed rules, an extrapolation from residues provided on potatoes is possible. In addition, MRLs for potatoes, sweet potatoes and yams are the same for copper (5 mg/kg) and Cymoxanil (0.01 mg/kg). Uses on Sweet potato (0212020) and Yams (0212030) are accepted.

Magnitude of residues in livestock

Regarding available feeding data, there is no risk for animal MRL to be exceeded. Data provided by the Applicant are accepted.

Industrial Processing and/or Household Preparation

No new data were submitted in the framework of this application.

Copper is an element and cannot be transformed into any other substance and it does not hydrolyse, therefore a conversion factor is not applicable. Consequently, the nature of the residue in all processed commodities is “Copper”.

According to the results obtained from the EFSA Primo Model for the calculation of the chronic risk assessment for Copper, the maximum percentage of contribution to the ADI of potato is negligible (highest intake: 2%, PL general).

Therefore, processing studies with potato tubers, the only edible plant part to be processed, are deemed not necessary.

Magnitude of residues in representative succeeding crops

EFSA Journal 2018;16(1):5152: *Based on the scientific literature, the experts agreed that plant would not absorb more than the essential nutritional amount. Therefore, field trials on rotational crops were not deemed necessary and a comprehensive survey on the copper background levels in plant commodities was used as a surrogate to assess the residue levels in all off-label crops (including rotational crops).*

No additional studies are required.

Other / special studies

Copper is non-systemic; therefore it is not likely that residues would be found in pollen or honey. Also, potatoes and also most other root and tuber vegetables have no melliferous capacity.

No further data are required.

Consumer risk assessment

Theoretical Maximum Dietary Intakes (TMDI) were estimated using the EFSA PRIMo model (revision 3.1). Calculations are acceptable.

The proposed uses of copper in the formulation FEL02 do not represent unacceptable acute and chronic risks for the consumer.

Cymoxanil

Stability of Residues

EFSA concluded (EFSA, 2008) that residues of Cymoxanil are stable under frozen condition (about -20°C and darkness) for at least 12 months in frozen potato tuber homogenates.

A new study investigating stability of residues during storage of potato samples has been submitted by the applicant in the framework of this application. Conclusion: cymoxanil residues in potato tuber homogenates are considered stable during storage at about -20°C and darkness for 12 months.

This study was submitted, by the Cymoxanil Task Force, for the first time at EU level for the purpose of the active substance renewal (on-going). The study was not considered in this assessment and not assessed by the zRMS. The stability of residues in potato for Cymoxanil was reviewed during the Annex I inclusion process and still considered adequate to address this endpoint.

No additional studies are required.

Metabolism in plant and animal

The residue definitions agreed for monitoring and risk assessment:

Plant residue definition for monitoring	Cymoxanil (Regulation (EU) No. 2018/832, Reg. (EU) 2022/1363)
Plant residue definition for risk assessment	Cymoxanil (EFSA, 2015)
Animal residue definition for monitoring	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355
Animal residue definition for risk assessment	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355

No further data are required.

Magnitude of residues in plants

Proposed GAP:

Max. 6 applications, BBCH 21 – 95, 0.12 kg a.s./ha, PHI: 7 (month of application: 04 to 09)

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

1. Submitted for the first time at EU level by the applicant for the product authorisation of FDJ03 following the first inclusion of Cymoxanil (Austria, 2013) and submitted for the active substance renewal (Lithuania, 2020).

Trials GAP: 8x 0.112-0.135 kg Cymoxanil/ha, interval= 6-8 d, PHI= 7 - 8 d

E/RA: 2x ND (< 0.002)

LOQ = 0.02 mg/kg

As no residues were detected, the overdosed trials (8 applications instead of 6 applications) can be accepted. These trials are considered relevant for this application.

2. Submitted for the purpose of the active substance renewal (Lithuania, 2020)

- Trials GAP: 6x 0.140-0.155 kg Cymoxanil/ha, interval=4-6 d, PHI=6-7 d

E/RA: 2x < LOQ (0.01)

These trials are considered relevant for this application.

- Trials GAP: 6x 0.106-0.123 kg Cymoxanil/ha, interval=3-7 d, PHI=7 d

E/RA: 4x ND (<0.003)

LOQ = 0.01 mg/kg

These trials are considered relevant for this application.

- Trials GAP: 12x 0.112-0.126 kg Cymoxanil./ha, interval= 5 d, PHI= 0 d

E/RA: 3x ND (< 0.003)

These trials are considered not relevant for this application due to PHI of 0 days. This is not consistent with what is proposed in the intended GAP.

- Trials GAP: 12 x 0.115-0.125 kg Cymoxanil./ha, interval= 5 d, PHI= 0 d

E/RA: 4x ND (< 0.003)

These trials are considered not relevant for this application due to PHI of 0 days. This is not consistent with what is proposed in the intended GAP.

The number of trials is sufficient to support the use of copper on potatoes according to the proposed GAP in Central Zone. The data submitted show that no exceedance of the MRL will occur.

Use is accepted.

AT applies for the following additional uses (see section B0): Sweet potato (0212020) and Yams (0212030). According to EU agreed rules, an extrapolation from residues provided on potatoes is possible. In addition, MRLs for potatoes, sweet potatoes and yams are the same for copper (5 mg/kg) and Cymoxanil (0.01 mg/kg). Uses on Sweet potato (0212020) and Yams (0212030) are accepted.

Magnitude of residues in livestock

No new data were submitted in the framework of this application.

EFSA conclusion, 2008: "livestock feeding studies are regarded as not necessary, because a "non-residue" situation (<0.05 mg Cymoxanil/kg) on potato (relevant feedingstuff) is established.

Industrial Processing and/or Household Preparation

Residue trial studies showed a non-residue situation for the representative use of Cymoxanil on potato tubers, the only edible plant part to be processed; residues of Cymoxanil will not exceed the threshold of 0.01 mg/kg. Therefore, investigation of the magnitude of residues in processed potato is not required.

Magnitude of residues in representative succeeding crops

EFSA, 2015: "Studies on the nature of the residues in succeeding crops show that significant residues of Cymoxanil are not expected in rotational crops. "

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed to support the intended uses of Cymoxanil in the product FEL02 on potatoes.

Other / special studies

~~Copper is non-systemic; therefore it is not likely that residues would be found in pollen or honey. Also~~, Potatoes and also most other root and tuber vegetables have no melliferous capacity.

No further data are required.

Consumer risk assessment

Theoretical Maximum Dietary Intakes (TMDI) were estimated using the EFSA PRIMo model (revision 3.1). Calculations are acceptable.

The proposed uses of cymoxanil in the formulation FEL02 do not represent unacceptable acute and chronic risks for the consumer.

NOTE: according to the SANTE/2019/12752 Rev01 extrapolation from potatoes (0211000) to whole subgroup (b) tropical root and tuber vegetables (0212000) is possible.

Uses on sweet potato and yams is accepted.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAP with respect to consumer intake and risk assessment for the preparation FEL02 is presented in Table 7.1-1. It has been selected from the individual GAPs in the Central zone for the use on potatoes. A list of all intended uses within the Central EU zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 5 mg/kg for Copper on potato, sweet potato and yam as laid down in Reg. (EU) 396/2005 is not expected. An exceedance of the current MRL of 0.01 mg/kg for Cymoxanil on potato as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

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

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11	12
						Formulation		**Application**				**Application rate per treatment**				**Remarks**	
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Type**	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (days)**	**kg product/ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.s. (Cymoxanil + Copper) /ha a) max. rate per appl. b) max. total rate per crop/season**	**water L/ha min max**	**PHI (days)**		**Conclusion**
1	Potatoes 0211000	CEU	FEL02	F	Late blight (*Phytophthora infestans*) Bacteriosis (Pseudomonas spp.; Xanthomo-nas spp.)	WG	200 g/kg Copper 40 g/kg Cymoxanil	Spraying	BBCH 21 - 95	Max. 6	7 - 9	a) 3.0 b) 18	a) 0.12 + 0.60 b) 0.72 + 3.6	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
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** 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

Explanation for Column 12 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

AT applies for the following additional uses (see section B0): Sweet potato (0212020) and Yams (0212030). According to EU agreed rules, an extrapolation from residues provided on potatoes is possible. In addition, MRLs for potatoes, sweet potatoes and yams are the same for copper (5 mg/kg) and Cymoxanil (0.01 mg/kg). Uses on Sweet potato (0212020) and Yams (0212030) are accepted.

7.1.2 Summary of the evaluation

The preparation FEL02 is composed of Copper (as Bordeaux mixture) and Cymoxanil.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Copper and Cymoxanil

Reference value	Source	Year	Value	Study relied upon	Safety factor
Copper					
ADI	EFSA conclusion	2018a	0.15 mg/kg bw/day	Based on human data (WHO value of 0.15 mg Cu/kg bw/day for children)	No SF for human data
ARfD	EFSA conclusion	2018a	Not allocated/not necessary	-	-
Cymoxanil					
ADI	EFSA conclusion	2008	0.013 mg/kg bw/d	1-year dog study	100
ARfD	EFSA conclusion	2008	0.08 mg/kg bw	developmental NOAEL studies in rabbits	100

7.1.2.1 Summary for Copper

Table 7.1-3: Summary for Copper compounds

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potatoes	Yes	Yes (~~16~~ 14 NEU trials)	Yes	NR	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
NR Not required

Copper is an element and is inherently stable as it cannot be transformed into any other material. The effects of processing on the nature of Copper residues have been investigated and considered for risk assessment (EFSA, 2018b). Processing studies with potatoes are not available and deemed not necessary.

Copper occurs naturally in the soil, and levels of approximately 6 to 30 mg total Copper/kg in the soil are essential for normal plant growth and development. 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 (EFSA, 2018b).

7.1.2.2 Summary for Cymoxanil

Table 7.1-4: Summary for Cymoxanil

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potatoes	Yes	Yes (~~15~~ 8 NEU trials)	Yes	Yes	Yes	No	No

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

There is no need to investigate the effect of industrial and/or household processing as a non-residue situation was demonstrated for potatoes, i.e. residues < LOQ (<0.01 mg/kg).

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues will be present in succeeding crops.

The metabolism of Cymoxanil in livestock was sufficiently investigated. There is no evidence of possible residues in livestock after application of the product FEL02 according to intended use on potatoes.

7.1.2.3 Summary for FEL02

Table 7.1-5: Information on FEL02 (KCA 6.8)

Crop	PHI for FEL02 proposed by applicant	PHI sufficiently supported for		PHI for FEL02 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper	Cymoxanil		
Potato	7 days	Yes	Yes		

Assessment

7.2 Copper compounds

General data on Copper (Bordeaux mixture) are summarized in the table below (last updated 2022/09/22)

Table 7.2-1: General information on Copper (Bordeaux mixture)

Active substance (ISO Common Name)	Bordeaux Mixture
IUPAC	Traditional mixture of Copper (II) sulphate and calcium hydroxide
Chemical structure	$Cu_4(OH)_6SO_{4}.3CaSO_{4}.nH_2O$
Molecular formula	$Ca_3Cu_4H_6\ O_{22}S_4.nH_2O$
Molar mass	860 + 18n g/mol where n =1 to 6
Chemical group	Inorganic salt of coper
Mode of action (if available)	Fungicidal and bactericidal
Systemic	No
Company (ies)	UPL Europe Ltd.*
Rapporteur Member State (RMS)	France
Approval status	Approved (01.01.2019) (REGULATION (EU) No 2018/1981)
Restriction	Only for use as a fungicide/bactericide
Review Report	SANTE/10506/2018 Rev. 5 27.11.2018
Current MRL regulation	Regulation (EC) No 149/2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	EFSA, 2018b – see list of references
EFSA Journal : Conclusion on the peer review	EFSA Journal 2018;16(1):5152
EFSA Journal: conclusion on article 12	EFSA Journal 2018;16(3):5212
Current MRL applications on intended use	None

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues during storage

Copper is an element and is inherently stable as it cannot be transformed into any other material. Therefore, under freezer storage conditions, residues of Copper in crop commodities will be stable and Copper is not expected to metabolise or to form degradation products. The analysis for Copper in crop commodities involves quantitation in the atomic state to measure the total Copper content irrespective of its chemical form following aggressive acid digestion to dissolve the residue.

Thus, since Copper is inherently stable and the analytical techniques measure total Copper content irrespective of form, studies to measure the stability of Copper residues in crop or other commodities are not required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Procedural recoveries from experiments carried out concurrently with residue sample analysis were acceptable confirming the stability of residue in sample extracts.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

Copper is an essential micronutrient and is present in all tissues of plants, animals and fungi. It is naturally present in agricultural soils. There is a wealth of published information on the uptake of Copper by plants and its role in plant physiology. Information relevant to the use of Copper as a plant protection product is summarised below.

In plants, Copper is absorbed from soil through the roots. From the roots, Copper is transported to the rest of the plant in the sap bound to nitrogen containing compounds. In plants such as grapes, potatoes, tomatoes, lettuce, spinach, melon, courgette, onion, garlic, shallots and peas, Copper is necessary for a wide range of metabolic processes such as respiration and photosynthesis[1].

Used according to Good Agricultural Practice, Copper is applied as a fungicidal spray post-emergence to the foliage and fruit of grapes, potatoes, tomatoes, lettuce, spinach, melon, courgette, onion, garlic, shallots and peas. Copper is a non-systemic like fungicide. Formulations used commercially contain components to ensure that the Copper remains on the foliage or fruit to exert its fungicidal activity.

Copper is a monoatomic charged element and inherently stable. It cannot be transformed into related degradation products or metabolites. Therefore, once on the leaves or fruit of treated crops it does not metabolise or form degradation products. Therefore, the relevant residue in plant commodities is Copper alone.

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

Supervised trials to address this issue are summarised in Section 7.2.3.

EFSA concluded (EFSA, 2018a): "Copper compounds were discussed at the Pesticides Peer Review Meeting 167 in October 2017. Specific studies investigating metabolism and distribution of residues in plants following the foliar application of Copper are not available. However, the public scientific literature reported by the RMS provided enough information on the uptake, translocation and effects of Copper in plants. In plants, Copper is absorbed from soil through the roots. From the roots, Copper is transported in the sap to the rest of the plant. Upon foliar application, transportation and distribution of Copper in plants are limited.

The experts agreed to consider Copper as a non-systemic-like compound. Copper is a monoatomic element and therefore is considered inherently stable. As no metabolites are expected, the nature of residues in primary crops, rotational crops and processed commodities as well as its stability during storage are considered addressed and specific studies were not required. The relevant residue for monitoring and risk assessment was defined as total Copper, including Copper residues arising from all variants of Copper. This residue definition is expected to cover Copper residues arising from all variants of Copper […] because the analytical methods for enforcement convert them into mineral Copper."

Conclusion on metabolism in primary crops

Metabolism studies were not conducted but sufficient scientific data have been provided to acknowledge the metabolism of Copper in/on primary crops. When used on primary crops, Copper does not metabolise or form degradation products because it is a monoatomic charged element and inherently stable. The residue definition for primary crops for enforcement and risk assessment is Total Copper.

The conclusion on metabolism in primary crops also applies to the intended use of Copper (Bordeaux mixture) in the product FEL02 on potatoes. No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

[1] Linder, M. C. (1991) Biochemistry of Copper, Section 10.4. Plenum Press.

Summary of plant metabolism studies reported in the EU

Copper occurs naturally in soils and levels of approximately 6 to 30 mg total Copper/kg in the soil are essential for normal plant growth and development. Concentrations of total Copper in soil found in two surveys, were 6 to 24 mg Copper/kg (in a range of EU agricultural soils) and 3 to 194 mg/kg, mean of 21 mg/kg, (in 504 soils in France)[2].

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 below. 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 confirms the assumption for this bias and provides lower average values for vineyards, and also shows there is no measurable accumulation for field crops (see Table 7.2-2).

Table 7.2-2: Background levels of Copper present in soil from natural or anthropogenic sources other than the regulated use

Soil	Soil concentration [mg Cu/kg soil DM]	
Background level	**11.5**	
Vineyards	29.5	Overall median 10th percentile value LUCAS data[c]
	26.09	Overall median value LUCAS data
	128.0	Overall median 90th percentile value LUCAS data[d]
	49.26	Overall mean value LUCAS data
Arable fields[b]	7	Overall median 10th percentile value
	13.2	Overall median value
	26	Overall median 90th percentile value
	15	Overall mean value
Orchards[b]	-	Overall median 10th percentile value
	39.8	Overall median value
	58	Overall median 90th percentile value
	23	Overall mean value
Olive groves	24.7	Overall median value LUCAS data
	74.5	Overall median 90th percentile value LUCAS data
	33.5	Overall mean value LUCAS data

a Recently published data from the EU LUCAS program [Copper distribution in European Topsoils: An assessment based on LUCUS soil survey, Ballabio et al., Science of the Total Environment 636 (2018) 282-298] 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. The EUCuTF have therefore used the LUCAS data for their PEC soil calculations.

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].

2 Cetois, A., Quesnoit, M. and Hinsinger, P (2003) Soil Copper mobility and bioavailability – a review.

It should be noted that elevated Copper levels were observed in a proportion of vineyard soils and a much lesser extent in some orchard soils.

Due to the ubiquitous property of Copper, which naturally present in plants as an essential micronutrient, field trials on rotational crops according to the current OECD recommendations would not be helpful to assess residues in rotational crops. These studies are therefore not required (EFSA, 2018b).

Based on several scientific publications reported by the RMS, bioavailable Copper is taken up by the crops according to the plant needs. Therefore, independently from the Copper contamination in soil, plants are not expected to absorb more than the essential nutritional amount. It is highlighted that an excess of Copper absorption by plant may cause phytotoxic effects. Consequently, it is assumed that Copper uptake in succeeding crop is naturally auto regulated by the crop. Considering this, it is concluded that Copper can be present in succeeding crops (annual and permanent) as an endogenous compound, following natural soil absorption as a micronutrient (EFSA, 2018b).

Conclusion on metabolism in rotational crops

No studies were conducted to investigate the nature of residues in rotational crops. The natural background levels in soil are very much greater than the Copper added by the use as an agricultural fungicide. Therefore, it would be not possible to distinguish between the Copper derived from fungicides and the Copper derived from the Copper naturally present in the soil. The metabolism of Copper in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Copper is a monoatomic element and inherently stable. It is not expected to metabolise or to form degradation products (EFSA, 2018b). The analysis for Copper in crop commodities involves quantitation in the atomic state to measure the total Copper content irrespective of its chemical form following aggressive acid digestion to dissolve the residue.

Processing studies were evaluated during the EU Review of Copper and the Article 12 MRL review. Article 12 MRL review (EFSA, 2018b: "Among others, robust PFs for enforcement and risk assessment were derived for peeled fruits (oranges, mandarins, kiwi fruits and melons), juices (orange, apples and wine grapes), canned commodities (peaches, cherries, peas without pods), dried fruits (plums and table grapes), olive oil and press cake, strawberries jam and orange marmalade, wines (red and white) and beer"

EFSA (2018b) concluded that "Further processing studies are not required although they could allow to further refine the consumer risk assessment (e.g. for cereal processed commodities) or the dietary burden calculations (e.g. for citrus pomaces and potatoes by-products). If more robust PFs were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed."

Processing studies with potatoes are not available and deemed not necessary.

Conclusion on nature of residues in processed commodities

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

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-3: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Not relevant. Copper is a monoatomic element and inherently stable.
Rotational crops covered	Not relevant. Copper is a monoatomic element and inherently stable.
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Copper is a monoatomic element and inherently stable. Therefore it is not expected to metabolise or to form degradation products.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes, Copper is an element and therefore cannot be metabolised or broken down
Plant residue definition for monitoring	Total Copper (EFSA, 2018a)
Plant residue definition for risk assessment	Total Copper (EFSA, 2018a)
Conversion factor from enforcement to RA	None (EFSA, 2018a)

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Summary of metabolism studies reported in the EU

Copper is a monoatomic element which cannot be degraded and thus, no metabolites are expected.

Copper is an essential micronutrient and is present in all tissues of plants, animals and fungi. In domestic animals, Copper has a fundamental role in many metabolic processes.

Copper is frequently added to the diet of intensively reared species such as poultry along with other minerals and vitamins. Copper absorption, metabolism and excretion are similar in most species of mammals and birds the processes are described in the toxicological Part B6.

Copper compounds are authorized for pesticide use on many crops that might be fed to livestock such as citrus fruits, apples, potatoes, head cabbages and several root crops. Furthermore, many major feed items which are not treated with Copper as a fungicide (e.g. cereals and oilseeds) may also contribute to the livestock dietary burdens. Therefore, the dietary burdens were calculated not only considering residues from the authorized uses, but also including the background residue levels and monitoring data (EFSA, 2018b). The dietary burdens calculated for all groups of livestock were found to highly exceed the trigger value of 0.004 mg/kg bw/d.

Copper is an essential micronutrient for animals and some specific Copper compounds can also be used as a feed additive in animal nutrition, when needed. For that purpose, maximum contents of Copper in feedstuffs are currently in place in the framework of different Feed Regulations. The maximum contents of Copper in feedstuffs defined in these Regulations are reported in the table below (Regulation (EU) 2018/1039[3]):

Table 7.2-4 Currently authorized maximum Copper contents in feed in the European Union

Livestock group	**Maximum Copper content [mg/kg complete feed] [(a)]**
Bovines	
Bovines before the start of rumination	15
Other bovines	30
Ovines	15
Caprines	35
Piglets	
suckling and weaned up to 4 weeks after weaning	150
from 5th week after weaning up to 8 weeks after weaning	100
Crustaceans	50
Other Animals	25

[(a)] according to current Feed Regulation (Regulation (EU) 2018/1039)

A comparison between the maximum dietary burdens calculated (see Section 7.2.4.1) with the currently authorized maximum Copper contents in feed is reported in the table below.

[3] Regulation (EU) 2018/1039; OJ 268, 18.10.2003, p. 29.

Table 7.2-5 Comparison of the maximum dietary burdens with maximum Copper contents to be authorized in complete feed

	Cattle		Sheep		Swine		Poultry		
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing	Broiler	Layer	Turkey
Feed intake [kg dw/day]	12	25	2.5	1.7	6	3	0.12	0.13	0.5
Feed intake [kg fresh weight /day]	13.636	28.409	2.841	1.932	6.818	3.409	0.136	0.148	0.568
Bodyweight [kg]	500	650	75	40	260	100	1.7	1.9	7
Animal Dietary Burden Calculation									
Maximum intake Cu [mg/kg bw/day]	**3.394**	**5.008**	**4.727**	**3.818**	**1.718**	**0.721**	**1.281**	**1.535**	**0.804**
Supplemented Feed									
Cu permitted in Complete feed [mg/kg feed][(a,b)]	30	30	15	15	100	100	25	25	25
Total Cu intake [mg/kg bw day]	**0.818**	**1.311**	**0.568**	**0.724**	**2.622**	**3.409**	**2.005**	**1.944**	**2.029**

a Complete feed containing a moisture content of 12%
[b] Regulation (EU) 2018/1039

Conclusion on metabolism in livestock

It can be seen from the comparison of the animal dietary burden consumption intake to the level of Copper permitted in complete animal feed, that the dietary consumption of calculated maximum dietary burden arising from pesticide residues is greater than that from currently allowed maximum level of Copper in complete feed for cattle and sheep. In practice, results from monitoring programmes of complete animal feed in the EU (EFSA FEEDAP Panel, 2015), demonstrate that this may not often occur. It is highlighted, that the maximum levels of Copper in complete feed are legal limits which are therefore expected to be monitored by feed business operators when completing the feed diets. Consequently, the maximum Copper content in complete feed reported in the Feed Regulations should guarantee that the Copper animal intake remains under these levels. In addition, it should also be noted that the theoretical maximal dietary burdens calculated under Point 7.2.4.1 are not expected to occur in practice because they would anyways not be tolerated by most of the animal species (see also EFSA FEEDAP Panel, 2015). Therefore, specific studies to evaluate the metabolism, distribution and expression of the residue in livestock are not required.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

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

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. The detailed assessment of the studies is presented in Appendix 2. Trial results relevant for the intended use are summarized in Table 7.2-6 below.

A WP formulation instead of a WG formulation was used in one of the studies conducted in the N-EU. As this type of formulation is considered to show similar Copper residue behaviour in potatoes for the intended use, bridging studies are deemed not necessary.

For the purpose of clarity, “Trials UPL” refer to those trials owned exclusively by UPL, while “Trials TF” refer to those trials shared/owned by the members of the European Copper Task Force (EUCuTF), of which UPL is a member.

The EUCuTF has prepared a statement explaining and justifying the approach used for the consumer risk assessment, residue data package and deviations from guidelines in the framework of the review of the existing MRLs for Copper compounds (KCA 6/01). This is the same approach used in this dossier. The main points from this statement and which will help understand the data presented here, are the following:

In an extensive number of residue trials, the 5 defended forms of Copper (hydroxide, oxychloride, oxide, tribasic Copper sulphate and Bordeaux mixture) in their WP, WG and SC formulations were tested on parallel plots on the same trial sites in a high number of permutations. The outcome and conclusion agreed in both the review under Directive 91/414/EEC/ Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 was that no difference in residues is expected whatever form and formulation type is applied. Consequently, the experimental differences found in parallel plots reflect the variability of residue testing. The use of different products with independent application does not constitute as simple replicate trial as per FAO[4], and considering that it was further concluded that no acute consumer risk assessment is required, it is appropriate to use the average of the parallel plots to estimate the STMRs used in PRIMo.

A number of trials had been conducted as residue decline trial design. In the evaluation presented in the RAR, the RMS chose to use the highest residue values from any sampling at or after the PHI regardless of the PHI stipulated in the cGAP. Again, considering that no acute consumer risk assessment is required, it is appropriate to use the residue data from the sampling corresponding to the PHI.

In its initial evaluation of the EUCuTF dossier, the RMS applied the proportionality principle and scaling of residues to the submitted package (residue data generated with 8 kg/ha, renewal dossier submitted for a cGAP of 6 kg/ha). At the same time a restriction to 4 kg/ha was proposed. The subsequent EFSA peer review rejected the use of the proportionality principle and considered residues as a data gap. The implementing Regulation (EU) No 2018/1981 stipulates a flexible dose scheme of 28 kg/7 y. Whilst formally, the conditions for applying the proportionality principle according to the EFSA technical report 2018:EN-1503 are indeed not fulfilled, the variability distribution of Copper contents in both untreated and treated crops is such that the existing residue data without scaling can be used as worst-case scenario, and no further residue data are required.

[4] FAO Plant Production and Protection Paper 225. Submission and evaluation of pesticide residue data for the estimation of maximum residue levels in food and feed, 3rd edition.

Table 7.2-6: Summary of EU reported and new data supporting the intended use of FEL02 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outdoor EU)	Residue levels [mg/kg]	Control residue in trials [mg/kg]	STMR [mg/kg] (a)	HR [mg/kg] (a)	Unrounded OECD calculator MRL [mg/kg] (a)	Current EU MRL* [mg/kg] (b)	MRL compli-ance
Potatoes	New trials[c]	N-EU	~~Trials TF, 2008 (GAP: 4 x 1.1-1.2 kg Copper/ha, interval = 7 d, PHI = 3 d): 0.54, 0.94~~ Trials TF, 1990-1992,(GAP: 6 x 0.6 kg Copper/ha, interval = 7 d, PHI = 7 d: 0.8, 2x 1.2, 3x 1.4, 3x 2.0, 2.4, 2.5, 3.5	0.08 - 3.8					
	New trials	N-EU	Trials UPL, 2020 (GAP: 6 x 1 kg Copper/ha, interval = 5-8 d, PHI = 7 -8 d): 1.07, 1.22						
	Overall supporting data for cGAP	N-EU	E/RA: ~~0.54~~, 0.8, ~~0.94~~, 1.07, 2x 1.2, 1.22, 3x 1.4, 3x2.0, 2.4, 2.5, 3.5		1.4	3.5	4.79	5 (7)	Yes

* Source of EU MRL: Reg. (EC) No 149/2008
(a) Where only one value for different zones is shown, the Mann-whitney U-test showed that populations are statistically similar (have the same distribution)
(b) In parenthesis EFSA's MRL proposal in the framework of the Review of the existing maximum residue levels for Copper compounds according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018b)
(c) Studies might have been already evaluated in the framework of the Review of the existing maximum residue levels for Copper compounds (EFSA, 2018b). However, for the purpose of clarity and since GAPs might differ, they have been re-submitted with this dossier.

7.2.3.2 Conclusion on the magnitude of residues in plants

Potatoes are a major crop and, therefore, require 8 trials per region. Trials conducted in the Northern EU region are considered suitable to support the use of ~~Cymoxani~~l Copper compounds on potatoes in the Central zone. 16 trials are available for the Northern EU region which is sufficient to support the proposed use.

12 trials were performed according to the intended cGAP. 4 trials were conducted at a more critical GAP than proposed due to a higher total application rate; these trials represent a "worst case" compared to the intended GAP. The data submitted show that no exceedance of the MRL will occur.

zRMS:
AT applies for the following additional uses (see section B0): Sweet potato (0212020) and Yams (0212030). According to EU agreed rules, an extrapolation from residues provided on potatoes is possible. In addition, MRLs for potatoes, sweet potatoes and yams are the same for copper (5 mg/kg) and Cymoxanil (0.01 mg/kg). Uses on Sweet potato (0212020) and Yams (0212030) are accepted.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-7: Input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Copper				
Beet sugar, tops *	35.60	STMR	35.60	STMR
Cabbage heads, leaves	0.26	Monitoring data (EFSA,2018b)	0.26	Monitoring data (EFSA,2018b)
Kale leaves	1.24	Monitoring data (EFSA,2018b)	1.24	Monitoring data (EFSA,2018b)
Carrot, culls *	1.08	STMR	1.08	STMR
Potato, culls *	1.60	STMR	1.60	STMR
Swede	0.95	Background data (EFSA,2018b)	0.95	Background data (EFSA,2018b)
Turnip	0.95	Background data (EFSA,2018b)	0.95	Background data (EFSA,2018b)
Barley, grain	4.09	Monitoring data (EFSA,2018b)	4.09	Monitoring data (EFSA,2018b)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Bean, seed	7.21	Monitoring data (EFSA,2018b)	7.21	Monitoring data (EFSA,2018b)
Corn, field, grain	2.40	Background data (EFSA,2018b)	2.40	Background data (EFSA,2018b)
Cotton, delinted seed	12.0	Background data (EFSA,2018b)	12.0	Background data (EFSA,2018b)
Lupin, seed	7.30	Background data (EFSA,2018b)	7.30	Background data (EFSA,2018b)
Millet, grain	4.15	Background data (EFSA,2018b)	4.15	Background data (EFSA,2018b)
Oat, grain	4.15	Background data (EFSA,2018)	4.15	Background data (EFSA,2018)
Rye, grain	3.57	Monitoring data (EFSA,2018b)	3.57	Monitoring data (EFSA,2018b)
Sorghum, grain	4.15	Background data (EFSA,2018b)	4.15	Background data (EFSA,2018b)
Soybean, seed	12.0	Background data (EFSA,2018b)	12.0	Background data (EFSA,2018b)
Wheat, grain	4.13	Monitoring data (EFSA,2018b)	4.13	Monitoring data (EFSA,2018b)
Apple, pomace, wet *	1.23	STMR	1.23	STMR
Beet, sugar *	1.55	STMR	1.55	STMR
Citrus *	0.80	STMR (oranges)	0.80	STMR (oranges)
Flaxseed, linseed, meal	12.96	Monitoring data (EFSA,2018b)	12.96	Monitoring data (EFSA,2018b)
Palm, kernel meal	0.65	Background data (EFSA,2018b)	0.65	Background data (EFSA,2018b)
Peanut, meal	12	Background data (EFSA,2018b)	12	Background data (EFSA,2018b)
Rape, meal	1.20	Background data (EFSA,2018b)	1.20	Background data (EFSA,2018b)
Rice, bran/pollard	2.54	Monitoring data (EFSA,2018b)	2.54	Monitoring data (EFSA,2018b)
Safflower, meal	12.0	Background data (EFSA,2018b)	12.0	Background data (EFSA,2018b)
Sunflower, meal	18.41	Monitoring data (EFSA,2018b)	18.41	Monitoring data (EFSA,2018b)

*	Crops for which a (more critical) GAP is intended for a different UPL Copper formulation. This means, that the risk assessment already takes into account the worst-case residues.

Table 7.2-8: Results of the dietary burden calculation

Animal species	Median dietary burden [mg/kg bw/d]	Maximum dietary burden [mg/kg bw/d]	Highest contributing commodity	Max dietary burden [mg/kg DM]	Trigger exceeded [Y/N]
Copper					
Beef cattle*	3.394	3.394	Potato	141.4	Y
Dairy cattle*	5.008	5.008	Potato	130.2	Y
Ram/ewe	4.727	4.727	Potato	141.8	Y
Lamb	3.818	3.818	Potato	89.8	Y
Breeding swine	1.718	1.718	Potato	74.5	Y
Finishing swine*	0.721	0.721	Soybean	24.0	Y
Broiler poultry	1.281	1.281	Potato	18.2	Y
Layer poultry*	1.535	1.535	Beet, sugar	22.4	Y
Turkey	0.804	0.804	Soybean	11.3	Y

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Copper is used as feed additive for all livestock species. The EFSA Scientific Opinion on the safety and efficacy of Copper compounds (E4) as feed additives for all animal species (EFSA Journal 2016; 14(8):4563) proposed the maximum acceptable levels of Copper in feed as a dietary supplement as summarised in the table below.

Table 7.2-9: Maximum acceptable levels of Copper in feed as a dietary supplement

Livestock group	Maximum Copper content [mg/kg complete feed] [(a)]	Maximum Copper content [mg/kg complete feed DM basis] [(b)]
Bovines		
Bovines before the start of rumination	15	13.2
Other bovines	30	26.4
Ovines	15	13.2
Caprines	35	30.8
Piglets		
suckling and weaned up to 4 weeks after weaning	150	132
from 5th week after weaning up to 8 weeks after weaning	100	88
Crustaceans	50	44
Other Animals	25	22

a Complete feed containing a moisture content of 12%
b Regulation (EU) 2018/1039

A comparison of the results of the maximum intake of Copper resulting from the animal dietary burden calculation compared to that arising from supplemented feed is shown in the table below.

Table 7.2-10: Comparison of the maximum dietary burdens with maximum Copper contents to be authorized in complete feed

	Cattle		Sheep		Swine		Poultry		
	beef	**dairy**	**Ram/Ewe**	**Lamb**	**Breeding**	**Finishing**	**Broiler**	**Layer**	**Turkey**
Feed intake [kg dw/day]	12	25	2.5	1.7	6	3	0.12	0.13	0.5
Feed intake [kg fresh weight /day]	13.636	28.409	2.841	1.932	6.818	3.409	0.136	0.148	0.568
Bodyweight [kg]	500	650	75	40	260	100	1.7	1.9	7
Animal Dietary Burden Calculation									
Maximum intake Cu [mg/kg bw/day]	**3.394**	**5.008**	**4.727**	**3.818**	**1.718**	**0.721**	**1.281**	**1.535**	**0.804**
Supplemented Feed									
Cu permitted in Complete feed [mg/kg feed][(a,b)]	30	30	15	15	100	100	25	25	25
Total Cu intake [mg/kg bw day]	**0.818**	**1.311**	**0.568**	**0.724**	**2.622**	**3.409**	**2.005**	**1.944**	**2.029**

[a] Complete feed containing a moisture content of 12%
[b] Regulation (EU) 2018/1039

It can be seen from the comparison of the animal dietary burden consumption intake to the level of Copper permitted in complete animal feed, that the dietary consumption of calculated maximum dietary burden arising from pesticide residues is greater than that from currently allowed maximum level of Copper in complete feed for cattle and sheep. In practice, results from monitoring programmes of complete animal feed in the EU (EFSA FEEDAP Panel, 2015), demonstrate that this may not often occur. It is highlighted, that the maximum levels of Copper in complete feed are legal limits which are therefore expected to be monitored by feed business operators when completing the feed diets. Consequently, the maximum Copper content in complete feed reported in the Feed Regulations should guarantee that the Copper animal intake remains under these levels. In addition, it should also be noted that the theoretical maximal dietary burdens calculated under Point 7.2.4.1 are not expected to occur in practice because they would anyways not be tolerated by most of the animal species (see also EFSA FEEDAP Panel, 2015).

Although these dietary intake levels do not include Copper derived from drinking water, the level of Copper intake is already much greater than the trigger value of 0.004 mg/kg bw/day set by Regulation (EC) No 1107/2009 for the conduction of livestock feeding studies on the grounds that there may be risks to consumers through consumption of Copper residues in food of animal origin.

In addition, the EFSA Scientific Opinion on the safety and efficacy of Copper compounds (E4) as feed additives for all animal species (EFSA, 2009), concluded that "no concerns for consumer safety are expected from the use of Copper compounds under application in animal nutrition when used up to the maximum EU-authorised levels in feed."
It can be concluded that the livestock dietary burden calculation based on the method in Animal Burden Calculation according to OECD 505 is not suitable for the risk assessment of a micronutrient like Copper. Nevertheless, the use of Copper as a plant protection product can be considered acceptable.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Processing studies with crops other than potatoes have been previously evaluated by EFSA.
EFSA (2018b) concluded that: “Further processing studies are not required although they could allow to further refine the consumer risk assessment (e.g. for cereal processed commodities) or the dietary burden calculations (e.g. for citrus pomaces and potatoes by-products). If more robust PFs were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.”

No new data were submitted in the framework of this application.

Copper is an element and cannot be transformed into any other substance and it does not hydrolyse, therefore a conversion factor is not applicable. Consequently, the nature of the residue in all processed commodities is “Copper”.

Potato and other tuber vegetables are included in the category 2 of procedures for processing commodities according to the guideline OECD 508, a mixture of domestic (or home) and industrial procedures. The types of processing studies for this category, while encouraged, are often considered optional by some regulatory authorities.

Furthermore, according to the results obtained from the EFSA Primo Model for the calculation of the chronic risk assessment for Copper, the maximum percentage of contribution to the ADI of potato is negligible (highest intake: 2%, PL general).

Therefore, processing studies with potato tubers, the only edible plant part to be processed, are deemed not necessary.

7.2.6 Magnitude of residues in representative succeeding crops

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Rotational crops field trials are not required.

EFSA 2018a: “Based on the scientific literature, the experts agreed that plant would not absorb more than the essential nutritional amount. Therefore, field trials on rotational crops were not deemed necessary and a comprehensive survey on the Copper background levels in plant commodities was used as a surrogate to assess the residue levels in all off-label crops (including rotational crops).”

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of FEL02. Therefore, other studies are not needed.

Copper is non-systemic; therefore it is not likely that residues would be found in pollen or honey. Also, potatoes and also most other root and tuber vegetables have no melliferous capacity.

A survey of recent peer-reviewed literature revealed that levels of Copper broadly vary between 0.10 - 15.5 mg/kg, as presented in the table below.

Table 7.2-11: Peer-reviewed literature on Copper content of honey and pollen

Cu in honey or pollen	Comment	Reference
Mean: 0.50 mg/100 g	Content of Copper in honey in Ireland	Downey et al. (2005) Preliminary contribution to the characterisation of artisanal honey produced on the island of Ireland by palynological and physico-chemical data/ Food Chemistry 91 347–354
Mean: 3.22 mg/kg Range: 0.37 - 15.5 mg/kg	Trace and minor elements in Slovenian honey	Golob et al. (2005) Determination of trace and minor elements in Slovenian honey by total reflection X-ray fluorescence spectroscopy / Food Chemistry 91 (2005) 593–600
Mean: 0.37 mg/kg Range: 0.10 - 1.73	Metals found in honey from Canary Islands and non-Canary (range)	Hernandez et al. (2005) Characterization of honey from the Canary Islands: determination of the mineral content by atomic absorption spectrophotometry/ Food Chemistry 93 449–458
Mean: 0.42 mg/kg Range: 0.11 - 0.88	Honey in Czech Republic	Lachman et al. (2007) Analysis of minority honey components: Possible use for the evaluation of honey quality/ Food Chemistry 101, 973–979
Range: 0.23 - 2.41 mg/kg	Honey from different geographic regions of Turkey	Tuzen et al. (2007) Trace element levels in honeys from different regions of Turkey. Food Chemistry 103 (2007) 325–330
Mean: 1.07 mg/kg	Honey in Croatia	Bilandzic et al (2011) Determination of grace elements in Croatian floral honey originating from different regions. Food Chemistry 128 (2011): 1160-1164.
Range: 1.77 - 2.99 mg/kg	Honey from various floral origin	Özcan et al (2012). Mineral and heavy metal contents of different honeys produced in Turkey. Journal of Apicultural Research 51(4): 353-358 (2012)
Mean: 0.31 mg/kg	Honey from different botanical origin in Italy	Conti (2000). Lazio region (central Italy) honeys: a survey of mineral content and typical quality parameters. Food Control 11 (2000) 459-463
Range: 0.67 - 1.94 mg/kg	Honey from Marche Region in Italy, different floral origin.	Conti et al (2007). Characterization of Italian honeys (Marche Region) on the basis of their mineral content and some typical quality parameters. Chemistry Central Journal 2007, 1:14

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see Table 7.1-2). As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

In order to evaluate the potential chronic exposure to Copper residues through the diet, the Theoretical Maximum Dietary Intakes (TMDI) were estimated using the EFSA PRIMo model (revision 3.1). For the evaluation of the chronic exposure the model uses 5 WHO diets relevant to the EU and 22 national diets from 13 different EU Member States.

The calculation of the TMDI was performed by taking into account all the crops to which Copper may be applied as well as natural background or monitoring values in other crops and livestock matrices.
Table 7.2-12 shows the input values for inclusion in the PRIMO model.

The values used in the PRIMo are shown below. The values represent the residue levels present in the edible parts of the RAC and differ from those values in Table 7.2-6 which represent the residues present in the RAC as harvested. Where replicate trials have been conducted on different formulations, the average of the two independent plots has been taken. It has been demonstrated that the formulation type and form of Copper present in the formulation has no effect on the level of the residues in the crops and there is no acute consumer dietary risk calculation, so this approach is considered justified. The residue present at the designated PHI for the crop is also taken, regardless of whether higher residues are present at later time points. Again, the chronic nature of the risk assessment being undertaken justifies this approach.

A two-tier approach has been used to refine the input to the PRIMO model. Residues present in the edible portion of the RAC from the supervised field trials have been used where available. In addition to this, to take into account the presence of Copper in the environment, background and monitoring data has been sought and input to give a fair representation of the total intake of Copper in the diet. Monitoring data has only been used where a significant number of samples (number of samples noted in the table below). The refinement steps taken have been designated as Tier II inputs in Table 7.2-12. This is the same approach for the consumer risk assessment conducted by the European Copper Task Force (EUCuTF) in the framework of the review of the existing MRLs for Copper compounds (KCA 6/01).

Table 7.2-12: Input values for the consumer risk assessment (all crops)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
1	**FRUIT (FRESH OR FROZEN)**										
	Citrus fruit	**20**	**SEU**								
4	Grapefruit		SEU					0.44	0.49	0.80	STMR Oranges (Pulp)
4	Oranges*		SEU	Pulp (BBCH ≥ 84): 0.51, 0.54, 0.56, 0.68, 0.71, 0.8, 0.9, 1.075, 1.28, 1.42, 1.87	0.80	1.9		0.44	0.51	0.80	STMR Oranges (pulp) with BBCH ≥ 84
4	Lemons		SEU					0.44	0.53	0.62	STMR Mandarin (Pulp)
4	Limes		SEU					0.44	-	0.62	STMR Mandarin (Pulp)
4	Mandarins*		SEU	Pulp (BBCH ≥ 84): 0.41, 0.42, 0.49, 0.62 0.78, 1.20, 1.62	0.62	1.6	0.48 – 0.70	0.44	0.59	0.62	STMR Mandarins (pulp) with BBCH ≥ 84
4	Other citrus fruits		SEU						-	0.80	STMR Oranges (Pulp)
2	Tree nuts (shelled or unshelled)*	30	SEU	Almond: 6.735, 10.20, 11.105 Walnuts: 10.63, 12.00, 8.045, 10.615, 14.40	10.6	14.4	7.27-18.3	4.5-13.3	12.64-18.92	10.62	STMR Almond/walnut
4	Almonds							10.7	-	10.62	STMR Almond/walnut
4	Brazil nuts							10.7	18.92	10.62	Extrapolation from Almond/walnut (STMR)
4	Cashew nuts							13.3	-	13.3	Background data (EFSA, 2018b)
4	Chestnuts							10.7	-	10.62	Extrapolation from Almond/walnut (STMR)
4	Coconuts							4.5	-	4.5	Background data (EFSA, 2018b)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [a)]	Background mg/kg[b)]	Monitoring mg/kg [b)]	PRIMo Input mg/kg	Comment / Reference
4	Hazelnuts/cobnuts							10.7	15.13	10.62	Extrapolation from Almond/walnut (STMR)
4	Macadamia							10.7	-	10.62	Extrapolation from Almond/walnut (STMR)
4	Pecans							10.7	-	10.62	Extrapolation from Almond/walnut (STMR)
4	Pine nut kernels							13.3	15.96 (n = 103)	15.96	Monitoring data (EFSA, 2018b)
4	Pistachios							13.3	-	10.62	Extrapolation from Almond/walnut (STMR)
4	Walnuts							10.7	12.64	10.62	Extrapolation from Almond/walnut (STMR)
4	Other tree nuts									10.62	Extrapolation from Almond/walnut (STMR)
2	**Pome fruit**	**5**	**NEU/SEU**								
4	Apples*		SEU	0.985, 1.09, 1.10, 1.235, 1.325, 1.335, 2.63, 2.235, 1.68, 2.80, 1.182, 2.536, 3.44, 4.202, 2.06	1.68	4.20	0.36 – 1.17	0.77	0.5 (n = 128)	Tier I: 1.68 Tier II: 0.5	Tier I: STMR Apples Tier II: Monitoring data (EFSA, 2018b)
4	Pears*		SEU	0.985, 1.09, 1.10, 1.235, 1.325, 1.335, 2.63, 2.235, 1.68, 2.80, 1.182, 2.536, 3.44, 4.202, 2.06	1.68	4.20	1.1 - 1.17	0.77	0.8	1.68	STMR Apples (post-flowering)
4	Quinces		SEU					0.77	< 2	1.68	STMR Apples (post-flowering)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
4	Medlar		SEU					0.77	-	1.68	STMR Apples (post-flowering)
4	Loquat		SEU					0.77	-	1.68	STMR Apples (post-flowering)
4	Other pome fruits		SEU							1.68	STMR Apples (post-flowering)
2	**Stone fruit**	**5**	**NEU/SEU**								
4	Apricots*		SEU	1.205, 2.17, 2.075, 3.075, 1.875, 3.075, 2.18, 3.74, 0.81, 1.773, 1.921, 2.511	2.12	3.74	0.26 - 1.19	1.02	0.76	2.12	STMR peaches and apricots
4	Cherries*		NEU/SEU	3.60, 2.015, 3.19, 1.56, 2.87, 4.31, 1.22	2.87	4.31	0.72 – 0.89	1.02	0.77	2.87	STMR cherries N+S
4	Peaches*		SEU	1.205, 2.17, 2.075, 3.075, 1.875, 3.075, 2.18, 3.74, 0.81, .773, 1.921, 2.511	2.12	3.74	0.26 – 1.19	1.02	0.89	2.12	STMR peaches and apricots
4	Plums*		SEU	0.696, 1.636, 1.368, 0.70, 0.39, 0.775, 0.743, 1.21, 0.88	0.78	1.64	0.23 – 1.15	1.02	0.62	0.78	STMR plum
4	Other stone fruits		SEU					1.02		2.12	STMR peaches and apricots
2	**Berries & small fruits**										
3	Table and wine grapes	50									
4	Table grapes*		NEU/SEU	5.2, 14.5, 33, 4.3, 8.5, 11.0, 3.21, 4.73, 5.98, 8.10, 7.03, 6.47, 1.23, 5.48	6.22	33.0	< 0.08 – 3.2	1.20	1.28 (n = 258)	Tier I: 6.22 Tier II: 1.28	Tier I: STMR all regions Tier II: Monitoring data (EFSA, 2018b)
4	Wine grapes*		NEU/SEU	5.2, 14.5, 33, 4.3, 8.5, 11.0, 3.21, 4.73, 5.98, 8.10, 7.03, 6.47, 1.23, 5.48	6.22	33.0	< 0.08 – 3.2	1.20	0.26	Tier I: 6.22 Tier II: 1.28	Tier I: STMR all regions Tier II: Monitoring data (EFSA, 2018b)
3	Strawberry*	5	All	0.47, 0.97, 0.70, 0.865,	1.44	5.95	0.14 – 1.23	0.43	0.37 (n =	Tier I:	Tier I:

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
				1.755, 0.945, 3.12, 0.815, 2.935, 3.275, 1.745, 1.195, 1.08, 3.275, 0.505, 2.34, 4.37, 1.44, 1.355, 1.43, 0.469, 2.685, 1.185, 3.57, 5.165, 5.945					193)	1.44 Tier II: 0.37	STMR all regions Tier II: Monitoring data (EFSA, 2018b)
3	Cane fruit	5									
4	Blackberries							1.4	0.95	1.00	Extrapolation raspberries/currant STMR
4	Dewberries							1.4	0.79	1.00	Extrapolation raspberries/currant STMR
4	Raspberries*		NEU	0.77, 0.95, 1.04, 1.08	1.00	1.08	0.62 - 1.22	1.4	0.61	1.00	STMR raspberries/currant
4	Other Cane fruits									1.00	Extrapolation raspberries/currant STMR
3	Other small fruits & berries	5									
4	Blueberries							1.4	0.6	1.00	Extrapolation raspberries/currant STMR
4	Cranberries							1.4	< 2	1.00	Extrapolation raspberries/currant STMR
4	Currants (red, black, white)*		NEU	0.77, 0.95, 1.04, 1.08	1.00	1.08	0.62 - 1.22	1.4	0.78	1.00	STMR raspberries/currant
4	Gooseberries							1.4	0.77	1.00	Extrapolation raspberries/currant STMR
4	Rose hips							1.4	-	1.00	Extrapolation raspberries/currant STMR
4	Mulberries							1.4	-	1.00	Extrapolation raspberries/currant STMR
4	Azarole							1.4	-	1.00	Extrapolation

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
											raspberries/currant STMR
4	Elderberries							1.4	-	1.00	Extrapolation raspberries/currant STMR
4	Other small fruits & berries								-	1.00	Extrapolation raspberries/currant STMR
2	**Miscellaneous fruit**										
3	Miscellaneous fruit (edible peel)										
4	Dates	20						0.86	1.73	0.86	Background data (EFSA, 2018b)
4	Figs	20						0.86	7.85	7.85	Monitoring data (EFSA, 2018b)
4	Table olives*	30	SEU	6.80, 7.20, 2.63, 4.58, 4.13, 5.26, 6.55, 7.80, 11.04, 4.76, 4.24, 3.38, 4.23, 4.20, 2.08	4.58	11.04	0.95 – 3.19	2.28	2.95	4.58	STMR olive
4	Kumquats	20						0.86	< 2	0.86	Background data (EFSA, 2018b)
4	Carambola	20						0.86	-	0.86	Background data (EFSA, 2018b)
4	Persimmon	20						0.86	0.22	0.86	Background data (EFSA, 2018b)
4	Jambolan (java plum)	20						0.86	-	0.86	Background data (EFSA, 2018b)
4	Other miscellaneous fruits (edible peel)	20						0.86	-	0.86	Background data (EFSA, 2018b)
3	Miscellaneous fruit (inedible peel, small)	20									
4	Kiwi*			5.470, 7.016, 6.871, 11.235, 4.18, 3.34, 3.79, 5.53	5.5	11.24	1.03 – 1.73	1.48	1.54	2.42	STMR Kiwi × PF (0.44)
4	Lychee (Litchi)							1.48	2.72	1.48	Background data (EFSA, 2018b)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [a]	Background mg/kg[b]	Monitoring mg/kg [b]	PRIMo Input mg/kg	Comment / Reference
4	Passion Fruit							1.48	3.55	1.48	Background data (EFSA, 2018b)
4	Prickly pear (cactus fruit)							1.48	-	1.48	Background data (EFSA, 2018b)
4	Star apple							1.48	-	1.48	Background data (EFSA, 2018b)
4	American persimmon							1.48	-	1.48	Background data (EFSA, 2018b)
4	Other misc. fruit (inedible peel, small)										
3	Miscellaneous fruit (inedible peel, large)	20									
4	Avocados							0.96	2.9	0.96	Background data (EFSA, 2018b)
4	Bananas							0.96	1.08	0.96	Background data (EFSA, 2018b)
4	Mangoes							0.96	0.6	0.96	Background data (EFSA, 2018b)
4	Papaya							0.96	0.39	0.96	Background data (EFSA, 2018b)
4	Pomegranate							0.96	1.44	0.96	Background data (EFSA, 2018b)
4	Cherimoya							0.96	-	0.96	Background data (EFSA, 2018b)
4	Guava							0.96	0.74	0.96	Background data (EFSA, 2018b)
4	Pineapple							0.96	0.88	0.96	Background data (EFSA, 2018b)
4	Bread fruit							0.96	-	0.96	Background data (EFSA, 2018b)
4	Durian							0.96	-	0.96	Background data (EFSA, 2018b)
4	Soursop							0.96	-	0.96	Background data (EFSA, 2018b)
4	Other misc. fruit (inedible peel,									0.96	Background data (EFSA, 2018b)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
	large)										
1	**VEGETABLES (FRESH OR FROZEN)**										
	Root and tuber vegetables incl. potatoes	5									
3	Potatoes	5	NEU	0.54, 0.8, 0.94, 1.07, 2x 1.2, 1.22, 3x 1.4, 3x2.0, 2.4, 2.5, 3.5	1.74	3.5	0.08 – 3.8	1.06	0.86 (n = 572)	Tier I: 1.74 Tier II: 0.86	Tier I: STMR tubers, NEU+SEU combined Tier II: Monitoring data (EFSA, 2018b)
			SEU	1.2, 1.66, 1.74, 6x2							
3	Tropical root and tuber vegetables	5									
4	Cassava							1.51	-	1.51	Background data (EFSA, 2018b)
4	Sweet potatoes							1.51	0.68	1.51	Background data (EFSA, 2018b)
4	Yams							1.51	-	1.51	Background data (EFSA, 2018b)
4	Arrowroot							1.51	-	1.51	Background data (EFSA, 2018b)
3	Other tropical root and tuber vegetables	5						1.51	-	1.51	Background data (EFSA, 2018b)
4	Beetroot							0.95	0.77	0.95	Background data (EFSA, 2018b)
4	Carrots*		NEU/SEU	0.55, 1.215, 0.87, 0.485, 0.87, 1.69, 1.32, 1.80, 0.937, 2.14, 0.82, 0.86, 1.48, 1.44, 0.867, 1.79, 1.46, 0.815	1.08	2.14	0.29 – 1.99	0.95	0.46 (n = 125)	Tier I: 1.08 Tier II: 0.46	Tier I: STMR Carrot Tier II: Monitoring data (EFSA, 2018b)
4	Celeriac							0.95	1.16	1.16	Monitoring data (EFSA, 2018b)
4	Horseradish							0.95	-	0.95	Background data (EFSA, 2018b)
4	Jerusalem arti-							0.95	-	0.95	Background data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [a)]	Back-ground mg/kg[b)]	Monitoring mg/kg [b)]	PRIMo Input mg/kg	Comment / Reference
	chokes										(EFSA, 2018b)
4	Parsnips							0.95	1.02	0.95	Background data (EFSA, 2018b)
4	Parsley root							0.95	1.46	0.95	Background data (EFSA, 2018b)
4	Radishes							0.95	0.17 (n = 76)	0.17	Monitoring data (EFSA, 2018
4	Salsify							0.95	1.3	0.95	Background data (EFSA, 2018b)
4	Swedes							0.95	< 2	0.95	Background data (EFSA, 2018b)
4	Turnips							0.95	-	0.95	Background data (EFSA, 2018b)
4	Other root and tuber vegetables							0.95	-	0.95	Background data (EFSA, 2018b)
2	**Bulb vegetables**	**5**									
4	Garlic							2.24	1.93 (n = 56)	1.93	Monitoring data (EFSA, 2018b)
4	Onions*		NEU SEU	0.74, 0.57, 0.63, 0.53, 0.53, 0.49, 0.46, 0.47, 0.37, 0.46, 0.615, 0.81, 1.14, 1.40, 0.28, 0.20, 0.88	0.53	1.40	0.37-1.49	0.56	0.55	0.53	STMR Onion NEU+SEU
4	Shallots									0.53	STMR onion
	Spring onions							0.83	0.51	0.83	Background data (EFSA, 2018b)
4	Other bulb vegetables									0.83	Background data (EFSA, 2018b)
2	**Fruiting vegetables**										
3	Solanaceae	5									
4	Tomatoes*		NEU SEU GH	1.8, 2.0, 2.9, 1.7, 1.5, 2.2, 1.5, 1.9, 2.4, 1.0, 1.0, 0.92, 1.0, 2.0, 2.0, 1.6, 2.0	1.8	2.9	0.47-1.2	0.75	0.37	1.8	STMR SEU
4	Peppers*		NEU SEU GH	2.20, 3.07, 1.465, 1.25, 1.58, 2.97, 2.855, 2.22, 2.585, 3.37, 4.68, 1.27, 1.345, 1.985, 2.875,	2.59	4.68	0.14-0.81	0.75	0.56	2.59	STMR NEU+SEU+GH

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Back-ground mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
				2.96, 0.985, 1.315, 3.175, 3.405							
4	Aubergines (egg-plant)							0.75	0.46	1.8	Extrapolation from Tomato (STMR)
4	Okra, lady's fingers							0.94	-	0.94	Background data (EFSA, 2018b)
4	Other Solanaceae								-	0.94	Extrapolation from Okra
3	Cucurbits (edible peel)	5									
4	Cucumbers*		NEU SEU GH	0.37, 0.51, 0.515, 0.63, 0.745, 0.955, 1.24, 1.35, 0.61, 0.495, 0.425, 0.465, 0.87, 0.76, 0.59, 0.625, 0.35, 0.54, 0.545, 0.635, 0.67, 0.93, 1.255, 1.775	0.63	1.78	0.21-0.58	0.37	0.31	0.63	STMR NEU+SEU+GH
4	Gherkins									0.63	Extrapolation from cucumber (STMR)
4	Courgettes									0.63	Extrapolation from cucumber (STMR)
4	Other cucurbits (edible peel)									0.63	Extrapolation from cucumber (STMR)
3	Cucurbits (inedible peel)	5									
4	Melon*		SEU	Whole fruit: 0.34, 0.53, 0.69, 1.05, 1.19, 1.22, 1.54, 1.6, 1.9, 1.94, 2.02, 2.15, 2.6, 2.6 Pulp: 0.29, 0.31, 0.39, 0.41, 0.5, 0.6, 0.73, 0.73, 0.87, 1.02, 1.28, 1.42, 1.49, 1.57	1.7 (pulp: 0.405)	5	0.11 – 1.65 (pulp)	0.42	0.47	0.405	STMR SEU+GH Pulp
			GH	Whole fruits: 0.79, 1.2, 1.8, 2, 2, 5							

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
				Pulp: 0.34, 0.4, 0.4, 0.4, 0.7, 0.9							
4	Pumpkin									0.405	Extrapolation from melon (STMR Pulp)
4	Watermelon									0.405	Extrapolation from melon (STMR Pulp)
4	Other cucurbits (inedible peel)									0.405	Extrapolation from melon (STMR Pulp)
3	Sweet corn	10						0.48	0.88 (n = 84)	0.88	Monitoring data (EFSA, 2018b)
3	Other fruiting vegetables	5									
2	**Brassica vegetables**	**20**									
3	Flowering brassica										
4	Broccoli*		NEU/SEU	0.526, 0.781, 2.76, 0.533, 0.216, 0.293, 0.335, 0.247, 1.92, 0.865, 0.915, 1.11, 0.375, 0.225, 0.35, 2.785	0.53	2.79	0.23-0.85	0.41	0.52	0.53	STMR
4	Cauliflower*		NEU/SEU	0.526, 0.781, 2.76, 0.533, 0.216, 0.293, 0.335, 0.247, 1.92, 0.865, 0.915, 1.11, 0.375, 0.225, 0.35, 2.785	0.53	2.79	0.23-0.85	0.41	0.28	0.53	STMR
4	Other flowering brassica									0.53	STMR
3	Head brassica										
4	Brussels sprout							0.41	0.42 (n = 162)	0.42	Monitoring data (EFSA, 2018b)
4	Head cabbage*		SEU	0.26, 0.33, 0.34, 1.55	0.33	1.55	0.20 - 0.38	0.41	0.26 (n = 81)	0.33	STMR
4	Other head brassica									0.42	Monitoring data (EFSA, 2018b)
3	Leafy brassica										

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
4	Chinese cabbage							0.56	0.37	0.56	Background data (EFSA, 2018b)
4	Kale							0.56	1.24 (n = 127)	1.24	Monitoring data (EFSA, 2018b)
4	Other leafy brassica									1.24	Monitoring data (EFSA, 2018b)
3	Kohlrabi							0.56	0.28	0.28	Monitoring data (EFSA, 2018b)
2	**Leaf vegetables & fresh herbs**										
3	Lettuce and other salad plants incl. Brassicaceae	100									
4	Lamb's lettuce							0.83	-	Tier I: 20.20 Tier II: 2.57	Extrapolation lettuce
4	Lettuce*		GH / SEU	53.95, 43.2, 7.09, 20.2, 31.05, 11.3, 3.22, 2.03, 5.49, 3.28, 2.03, 36.0, 20.2, 64.6, 35.4, 17.5, 16.3, 25.3, 34.2	20.20	64.6	0.29-8.92	0.83	2.57 (n = 166)	Tier I: 20.20 Tier II: 2.57	Tier I: STMR GH+SEU Tier II: Monitoring data (EFSA, 2018b)
4	Escarole (broad-leave endive)							0.56	0.44	Tier I: 20.20 Tier II: 2.57	Extrapolation lettuce
4	Cress							0.83	-	Tier I: 20.20 Tier II: 2.57	Extrapolation lettuce
4	Land cress							0.83	-	Tier I: 20.20 Tier II: 2.57	Extrapolation lettuce
4	Rocket, Rucola							0.83	0.81 (n = 61)	0.81	Monitoring data (EFSA, 2018b)
4	Red mustard							0.83	-	Tier I: 20.20 Tier II:	Extrapolation lettuce

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [a)]	Background mg/kg[b)]	Monitoring mg/kg [b)]	PRIMo Input mg/kg	Comment / Reference
										2.57	
4	Leaves and sprouts of *Brassica* spp							0.56	-	Tier I: 20.20 Tier II: 2.57	Extrapolation lettuce
4	Other lettuce and other salad plants									Tier I: 20.20 Tier II: 2.57	Extrapolation lettuce
3	Spinach & similar (leaves)	20									
4	Spinach							0.83	1.59	1 Tier I: 20.20 Tier II: 2.57	Extrapolation lettuce
4	Purslane							0.83	-	0.83	Extrapolation lettuce
4	Beet leaves							0.83	< 2	0.83	Extrapolation lettuce
4	Other spinach and similar						1.1	0.83	-	0.83	Extrapolation lettuce
3	Vine leaves (grape leaves)	20					4.2	4.15	64	4.15	Background data (EFSA, 2018b)
3	Water cress	20					0.8	0.1	1.25	0.1	Background data (EFSA, 2018b)
3	Witloof	20					0.5	0.51	0.51	0.51	Background data (EFSA, 2018b)
3	Herbs and edible flowers						4.2	1.20	1.85 (n = 530)	1.85	Monitoring data (EFSA, 2018b)
4	Cervil	20									
	Chives	20									
	Celey leaves	50									
	Parsley	20									
	Sage	20									
	Rosemary	20									
	Thyme	20									
	Basil and edible flowers	20									
	Laurel/bay leaves	20									

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [a)]	Background mg/kg[b)]	Monitoring mg/kg [b)]	PRIMo Input mg/kg	Comment / Reference
	Taragon	20									
	Others	20									
2	**Legume vegetables (fresh)**	**20**									
4	Beans (whole pods)*		SEU/NEU	1.76, 1.84, 2.26, 3.27, 3.29, 3.66, 1.395, 1.605, 2.405, 2.63, 3.125, 3.765, 4.89, 5.93, 4.36, 3.90	3.20	5.93	0.38-4.26	0.48	0.78	3.20	STMR NEU+SEU beans + peas (with pods)
	Beans (without pods)*		SEU/NEU	1.495, 1.79, 2.03, 2.44, 2.445, 2.585, 1.55, 1.97, 2.47, 6.26, 2.85, 5.61, 3.38, 6.82, 2.46, 2.76	2.47	6.82	1.18 - 6.23	3.18	-	2.47	STMR NEU+SEU beans + peas (without pods)
4	Peas (with pods)*		SEU/NEU	1.76, 1.84, 2.26, 3.27, 3.29, 3.66, 1.395, 1.605, 2.405, 2.63, 3.125, 3.765, 4.89, 5.93, 4.36, 3.90	3.20	5.93	0.38-2.27			3.20	STMR NEU+SEU beans + peas (with pods)
	Peas (without pods)*		SEU/ NEU	1.495, 1.79, 2.03, 2.44, 2.445, 2.585, 1.55, 1.97, 2.47, 6.26, 2.85, 5.61, 3.38, 6.82, 2.46, 2.76	2.47	6.82	1.18 - 5.2	1.76	1.42	2.47	STMR NEU+SEU beans + peas (without pods)
4	Lentils (fresh)									3.18	Background data (EFSA, 2018b)
4	Other legume vegetables (fresh)									3.18	Background data (EFSA, 2018b)
2	**Stem veg. (fresh)**										
4	Asparagus	5						0.65	0.79 (n = 73)	0.79	Monitoring data (EFSA, 2018b)
4	Cardoons	20						0.65	-	0.65	Background data (EFSA, 2018b)
4	Celery	20						0.65	0.24	0.65	Background data (EFSA, 2018b)
4	Fennel	20						0.65	0.7	0.65	Background data (EFSA, 2018b)
4	Globe artichokes*	20	SEU	3.84, 4.73, 8.25, 11.31	6.49	11.31	0.66-1.53	0.65	-	6.49	STMR
4	Leek*	20	SEU	3.94, 7.75, 14.2, 25.25	10.98	25.25	0.49-2.8	0.65	0.38	10.98	STMR

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
4	Rhubarb	20						0.65	0.35	0.65	Background data (EFSA, 2018b)
4	Bamboo shoots	20						0.65	-	0.65	Background data (EFSA, 2018b)
4	Palm hearts	20						0.65	-	0.65	Background data (EFSA, 2018b)
4	Other stem vegetables	20								6.49	Extrapolation from Globe artichoke
2	**Fungi**	**20**									
4	Cultivated fungi							2.86	2.2 (n = 229)	2.2	Monitoring data (EFSA, 2018b)
4	Wild fungi							2.86	5.39	2.86	Background data (EFSA, 2018b)
4	Other fungi							2.86		2.86	Background data (EFSA, 2018b)
2	Seaweeds									1.8	Background HR
1	**PULSES, DRY**	**20**									
4	Beans							7.3	7.21 (n = 100)	7.21	Monitoring data (EFSA, 2018b)
4	Lentils							7.3	9.19 (n = 211)	9.19	Monitoring data (EFSA, 2018b)
4	Peas							7.3	6.11 (n = 117)	6.11	Monitoring data (EFSA, 2018b)
4	Lupins							7.3	-	7.3	Background data (EFSA, 2018b)
4	Other pulses, dry									9.19	Monitoring data (EFSA, 2018b)
1	**OILSEEDS AND OILFRUITS**										
2	**Oilseeds**										
4	Linseeds	30						12.0	12.96 (n = 96)	12.96	Monitoring data (EFSA, 2018b)
4	Peanuts	30						12.0	-	12	Background data (EFSA, 2018b)
4	Poppy seeds	30						12.0	16.05 (n = 80)	16.05	Monitoring data (EFSA, 2018b)
4	Sesame seed	30						12.0	16.11	12	Background data (EFSA, 2018b)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [a)]	Back-ground mg/kg[b)]	Monitoring mg/kg [b)]	PRIMo Input mg/kg	Comment / Reference
4	Sunflower seed	40						12.0	18.41 (n = 101)	18.41	Monitoring data (EFSA, 2018b)
4	Rape seed	30						12.0	-	1.2	12.0 (x PF oil)
4	Soya bean	40						12.0	-	12	Background data (EFSA, 2018b)
4	Mustard seed	30						12.0	6.17	12	Background data (EFSA, 2018b)
4	Cotton seed	30						12.0	-	12	Background data (EFSA, 2018b)
4	Pumpkin seed	30						12.0	11.35	12	Background data (EFSA, 2018b)
4	Safflower	30						12.0	-	12	Background data (EFSA, 2018b)
4	Borage	30								12	Extrapolated from Linseed
4	Gold of pleasure	30								12	Extrapolated from Linseed
4	Hemp seed	30								12	Extrapolated from Linseed
4	Castor bean	30								12	Extrapolated from Linseed
4	Other oilseeds	30								12	Extrapolated from Linseed
2	**Oil fruits**	**30**									
4	Olives for oil production			See table olives	4.58	11.04		2.28	-	0.46	STMR * PF (0.1)
4	Oil palm kernels									4.54	From literature [c)]
4	Oil palm fruits									3.34	From literature [d)]
4	Kapok									4.54	Extrapolation from Palm nuts
4	Other oil fruits									4.54	Extrapolation from Palm nuts
1	**CEREALS**	**10**									
4	Barley							4.15	4.09 (n = 83)	4.09	Monitoring data (EFSA, 2018b)
4	Buckwheat							8.42	6.68	8.42	Background data (EFSA, 2018b)
4	Maize							4.15	2.4	2.4	Median monitoring data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
											(EFSA, 2018b)
4	Millet							4.15	6.73	4.15	Background data (EFSA, 2018b)
4	Oats							4.15	5.09	4.15	Background data (EFSA, 2018b)
4	Rice							4.15	2.54 (n = 264)	2.54	Monitoring data (EFSA, 2018b)
4	Rye							4.15	3.57 (n = 157)	3.57	Monitoring data (EFSA, 2018b)
4	Sorghum							4.15	-	4.15	Background data (EFSA, 2018
4	Wheat							4.15	4.13 (n = 351)	4.13	Monitoring data (EFSA, 2018b)
4	Other cereals									4.15	Extrapolation from cereals
1	**TEA, COFFEE, HERBAL INFUSIONS AND COCOA**										
2	**Tea, dry leaves and stalks**	**40**						0.25	2.46 (n = 176)	2.46	Monitoring data (EFSA, 2018b)
2	**Coffee beans**	**50**						16.3	14.03 (n = 115)	14.03	Monitoring data (EFSA, 2018b)
2	**Herbal infusions**	**100**						0.3	0.17 (n = 74)	0.17	Monitoring data (EFSA, 2018b)
2	**Cocoa (fermented beans)**	**50**						1.5	-	1.5	Background data (EFSA, 2018b)
2	**Carob (St. John's bread)**	**20**						5.71	-	5.71	Background data (EFSA, 2018b)
1	**HOPS (dried cone)***	**1000**		163, 178, 192, 250	184.86	249.5	6.3-56.4	-	149.8 (n = 8)	184.86	STMR
1	**SPICES**	**40**								11.3	Background (EFSA, 2018b)
1	**SUGAR PLANTS**	**5**									
4	Sugar beet (root)*		NEU/ SEU	0.785, 1.20, 1.82, 1.905, 1.15, 1.37, 1.53, 1.56, 1.63, 1.85, 1.125, 1.145, 1.60, 1.66, 0.473, 0.816, 1.85, 2.48	1.55	2.48	0.16-3.45	1.25	-	1.55	STMR NEU+SEU
4	Sugar cane							0.69	-	0.69	Background data (EFSA, 2018b)
4	Chicory roots							1.09	-	1.09	Background data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
											(EFSA, 2018b)
4	Other sugar plants									1.55	Extrapolation from Sugar beet
1	**PRODUCT OF ANIMAL ORIGIN**										
2	**MEAT, etc.**										
3	SWINE										
4	Meat	5						0.88	0.68	0.88	Background data (EFSA, 2018b)
4	Fat	5						0.41		0.41	Background data (EFSA, 2018b)
4	Liver	30						11.6	9.71	11.6	Background data (EFSA, 2018b)
4	Kidney	30						7.28		7.28	Background data (EFSA, 2018b)
4	Edible offal	30								-	
4	Other products	5								-	
3	BOVINE										
4	Meat	5						0.9	2.03	0.9	Background data (EFSA, 2018b)
4	Fat	5						0.39		0.39	Background data (EFSA, 2018b)
4	Liver	30						64.3	86.68 (n = 206)	86.7	Monitoring data (EFSA, 2018b)
4	Kidney	30						4.61	3.45	4.61	Background data (EFSA, 2018b)
4	Edible offal	30								-	
4	Other products	5								-	
3	**SHEEP**										
4	Meat	5						1.25	1.03	1.25	Background data (EFSA, 2018b)
4	Fat	5						0.3		0.3	Background data (EFSA, 2018b)
4	Liver	30						90		90	Background data (EFSA, 2018b)
4	Kidney	30						3.85		3.85	Background data (EFSA, 2018b)
4	Edible offal	30						-		-	

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [a]	Back-ground mg/kg[b]	Monitoring mg/kg [b]	PRIMo Input mg/kg	Comment / Reference
4	Other products	5						-		-	
3	**GOAT**										
4	Meat	5						1.25	1.03	1.25	Background data (EFSA, 2018b)
4	Fat	5						0.3		0.3	Background data (EFSA, 2018b)
4	Liver	30						90		90	Background data (EFSA, 2018b)
4	Kidney	30						3.85		3.85	Background data (EFSA, 2018b)
4	Edible offal	30								-	
4	Other products	5								-	
3	HORSES, ASSES, MULES. HINNIES										
4	Meat	5						0.9	2.1	0.9	Background data (EFSA, 2018b)
4	Fat	5						0.39		0.39	Background data (EFSA, 2018b)
4	Liver	30						64.3		64.3	Background data (EFSA, 2018b)
4	Kidney	30						4.61		4.61	Background data (EFSA, 2018b)
4	Edible offal	30								-	
4	Other products	5								-	
3	POULTRY										
4	Meat	5						0.65	3.47 (n = 144)	3.47	Monitoring data (EFSA, 2018b)
4	Fat	5						0	3.2	0	Background data (EFSA, 2018b)
4	Liver	30						6.9	-	6.9	Background data (EFSA, 2018b)
4	Kidney	30								-	
4	Edible offal	30								-	
4	Other products	5								-	
3	OTHER FARM ANIMALS										
4	Meat	5							1.84 (n = 392)	1.84	Monitoring data (EFSA, 2018b)
4	Fat	5									

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg a)	Background mg/kg b)	Monitoring mg/kg b)	PRIMo Input mg/kg	Comment / Reference
4	Liver	30									
4	Kidney	30									
4	Edible offal	30									
4	Other products	5									
2	**MILK AND CREAM**	**2**									
4	Cattle							0.1	0.24 (n = 433)	0.24	Monitoring data (EFSA, 2018b)
4	Sheep							0.1	0.24 (n = 433)	0.24	Monitoring data (EFSA, 2018b)
4	Goat							0.1	0.24 (n = 433)	0.24	Monitoring data (EFSA, 2018b)
4	Horse							0.1	0.24 (n = 433)	0.24	Monitoring data (EFSA, 2018b)
4	Other products							0.1	0.24 (n = 433)	0.24	Monitoring data (EFSA, 2018b)
2	**BIRDS EGGS**	**2**									
4	Chicken							0.62	0.58 (n = 145)	0.58	Monitoring data (EFSA, 2018b)
4	Duck							0.62	0.58 (n = 145)	0.58	Monitoring data (EFSA, 2018b)
4	Goose							0.62	0.58 (n = 145)	0.58	Monitoring data (EFSA, 2018b)
4	Qual							0.62	0.58 (n = 145)	0.58	Monitoring data (EFSA, 2018b)
4	Other eggs							0.62	0.58 (n = 145)	0.58	Monitoring data (EFSA, 2018b)
2	**Honey**									0.53	ANSES background values
2	**Amphibian and Reptiles**									2.5	ANSES background values
2	**Terrestrial invertebrate animals**									4.00	ANSES background values
2	**Wild terrestrial animal**							-	1.72 (n = 184)	1.72	Monitoring data (EFSA, 2018b)

* Crops for which a (more critical) GAP is intended for a different UPL Copper formulation. This means, that the risk assessment already takes into account the worst-case residues.
a) Control samples from Magnitude of Residue trials
b) EFSA Journal 2018;16(3):5212
c) Aigberua et al., EC Nutrition 11.6 (2017): 244-252

d) Akpakpan et al., International Journal of Modern Chemistry, 2012, 2(1):20-27

If all crops for which a defined MRL under 396/2005 are included, the diet with the highest IEDI for Copper is the “NL Toddler” with 122% of ADI. For this diet, the highest contributor is apples with 12% of ADI. The second highest TMDI for Copper is the “GEMS/Food G11” with 86% of ADI where soybean is the major contributor with 30% of the ADI.

Refinement of the inputs into the PRIMo model were made to take into account data generated by background monitoring of Copper in crops throughout the UK, and also monitoring results (France, 2016). Using this refined Tier II input, the diet with the highest IEDI for Copper is the “NL Toddler” with 94% of ADI. For this diet, the highest contributors were maize/corn and wheat, representing 11% of ADI, each.

Copper levels in drinking water (EFSA, 2009 and EFSA, 2015) were determined from monitoring studies conducted in Sweden, Germany, France, The Netherlands, Greece and Ireland. Median daily intake of Copper from drinking water in children aged 9 – 21 months was estimated to be 0.46 mg in Uppsala and 0.26 mg in Malmö. In Berlin (Germany), Copper concentrations in random daytime samples of tap water ranged between > 0.01 and 3.0 mg/L, with a median of 0.03 mg/L. The typical concentrations reported in the VRAR were 0.11 mg/L. Typical drinking water concentrations in flushed tap water range from 0.01 to 0.5 mg/L, which on an average would contribute to the ADI to less than 5%. It is therefore determined that the exceedance of the ADI of Copper is unlikely.

Dietary surveys

Model calculations as estimated above, based on STMR residue values are typically worst-case as they assume that all of the food commodities contain residues. Even with this assumption, the intakes of Copper found on treated commodities are within the ADI of 0.15 mg/kg bw/day. The standard model (PRIMo) estimates that the highest dietary intake for Copper is for the “NL Toddler” at 94% of the ADI, i.e. an intake of 1.44 mg/day for a 10.2 kg toddler. For the next highest dietary intake group, “GEMS/Food G11” with 74% of ADI, for a 60 kg adult, this equates to an intake level of 6.66 mg/day.

In addition, several dietary surveys (EFSA, 2015) were conducted and the results are summarised in Table 7.2-13 below. These surveys indicate that the European median intakes of Copper via the diet are in fact in the range of 0.39 – 1.46 mg/day across different age groups for both males and females. This is a more realistic estimate of Copper intake levels.

Therefore, it can be concluded that the risk to consumers from the use of Copper as a plant protection product is acceptable.

Table 7.2-13: Results of European Surveys on the European dietary intake of Copper (Germany, Finland, UK, Italy, France, Netherlands, Latvia, Sweden)

Age class	Sex	Number of individuals surveyed	Range of median intake levels [mg Cu/day]	Overall median intake level [mg Cu/day]
Infant	Male	1039	0.39–0.49	0.39
	Female	1005	0.34–0.49	0.38
1 to < 3	Male	1209	0.62–0.84	0.67
	Female	1174	0.54–0.81	0.63
3 to < 10	Male	1843	0.95–1.41	0.95
	Female	1808	0.78–1.27	0.89
10 to < 18	Male	1796	1.12–1.48	1.26
	Female	1943	0.96–1.39	1.10
18 to < 65	Male	5429	13.7–1.59	1.46
	Female	7472	1.11–1.37	1.25
65 to < 75	Male	601	1.29–1.48	1.46
	Female	763	1.12–1.27	1.23
≥ 75	Male	241	1.07–1.40	1.30
	Female	359	1.02–1.27	1.14

Chambers et al (2010) [5] concluded that the optimal intake of Copper is 2.6 mg/day. This means that from the results of the surveys, in the main, adults are more likely to be deficient in their normal dietary intake of Copper rather than under threat from excess Copper in the diet.

EFSA (2015) 6 derived adequate intakes for Copper to 1.6 mg/day for men and 1.3 mg/day for woman. The diets with the lowest IEDI for Copper are, therefore, not providing sufficient Copper, e.g. for the PL adults.

A position paper (KCA 6/01) has been prepared on behalf of the EUCuTF examining the effect of Copper intake from natural sources as well as fungicide use. Copper is not a typical pesticide; it is an essential micronutrient required in many biochemical processes. Copper deficiency or excess can lead to adverse effects, and therefore the human body has an efficient homeostatic mechanism that tightly controls bioavailable Copper concentrations to the required normal levels. Copper excess is rare and is seen mainly in genetic diseases such as Wilson's disease, idiopathic Copper toxicosis and childhood cirrhosis.

The impact of the increased risk from fungicide use of this essential micronutrient is assessed against the variability of natural Copper background levels and shown that the non-systemic nature of Copper compounds does not lead to any increase of the Copper content in many crops (e.g. root and tuber crops, fruit and vegetables with non-edible peel, etc.). The natural variability found in Copper consumed in food is managed by all populations by adapting the absorption rate and the homeostatic control.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

The IEDI estimates for the various diets were found 6 - 94% of ADI. The highest IEDI was calculated for the NL Toddler. For this diet, maize/corn and wheat were the highest contributors to the residue intake, representing 11% of ADI, each.

Table 7.2-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	-
IEDI (% ADI) according to EFSA PRIMo rev.3.1	Tier I: 122% (NL Toddler Diet) Tier II: 94% (NL Toddler Diet)
IESTI (% ARfD) according to EFSA PRIMo	Not calculated, as ARfD not applicable
NESTI (% ARfD)	Not applicable

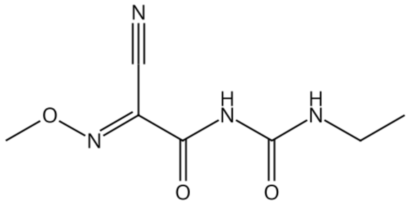
The proposed use of Copper in the formulation FEL02 do not represent unacceptable acute and chronic risks for the consumer.

[5] Chambers, A., Krewski, D., Birkett, N., Plunkett., Hertzberg, R., Danzeisen, R., Aggett, PJ., Starr, TB., Baker, S., Dourson., PJ., Keen, CL., Meek, R and Slob, W. (2010). An exposure-response curve for Copper excess and deficiency. J. Toxicol. and Environ. Health, Part B **13**: 546–578

7.3 Cymoxanil

General data on Cymoxanil are summarized in the table below (last updated 2022/07/27).

Table 7.3-1: General information on Cymoxanil

Active substance (ISO Common Name)	Cymoxanil
IUPAC	1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea
Chemical structure	 E/Z ratio min 99:1
Molecular formula	$C_7H_{10}N_4O_3$
Molar mass	198.18
Chemical group	aliphatic nitrogen
Mode of action (if available)	Fungicide
Systemic	Yes (contact and local systemic activity)
Company (ies)	UPL Europe Ltd, Sipcam Oxon SpA, Belchim Crop Protection NV/SA, Agria S.A., Corteva Agriscience, Indofil Industries Limited, and Sipcam Inagra S.A.*
Rapporteur Member State (RMS)	Austria
Approval status	Approved on 01/09/2009 by Commission Directive 2008/125/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.
Restriction	Only for use as fungicide
Review Report	SANCO/179/08 – final rev. 1 09/07/2010
Current MRL regulation	~~Regulation (EC) No 2018/832~~ Reg. (EU) 2022/1363
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2008- see list of reference)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2015- see list of reference)
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

The stability of residues in potato for Cymoxanil was reviewed during the Annex I inclusion process and still considered adequate to address this endpoint.

A new study investigating stability of residues during storage of potato samples has been submitted by the applicant in the framework of this application. The study results are summarized in the Table below. The detailed assessment of this study is presented in Appendix 2.

Studies on the storage stability of samples of animal commodities are not required since no livestock feeding study has been conducted.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (plant product)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Potato	Potato tuber homogenate (~~High water content commodity~~) (high starch content commodity)	12 months	Austria, 2007, EFSA, 2008
New data			
Potato	Homogenised potato tuber (~~High water content commodity~~) (high starch content commodity)	12 months	Weber H., 2011

RMS conclusion in DAR (Austria, 2007): "Despite a formal deficiency in the storage stability design (tested fortification level of 0.250 mg Cymoxanil/kg potato sample was about 4.5 times higher and not 10 times higher than the LOQ = 0.056 mg/kg as regarded by DG Sanco doc. 7032/VI/95, rev. 5, 22/7/97, Storage stability of residue samples) there was demonstrated a storage stability on frozen potato tuber homogenate (stored at about -20°C and darkness) at least for 12.5 months."

EFSA concluded (EFSA, 2008) that residues of Cymoxanil are stable under frozen condition (about -20°C and darkness) for at least 12 months in frozen potato tuber homogenates.

Conclusion on stability of residues during storage

Cymoxanil residues in potato tuber homogenates are considered stable during storage at about -20°C and darkness for 12 months.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

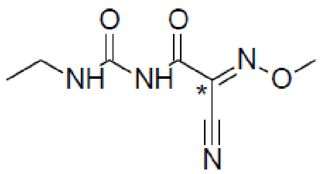
No new data submitted in the framework of this application. Specific studies to determine the stability of residues in stored sample extracts have not been conducted because the stability is adequately demonstrated by the acceptable procedural recovery efficiencies obtained in the residue trials.

Conclusion on stability of residues in sample extracts

Residues in the analysed sample extracts, which were used to support the intended use of Cymoxanil in the product FEL02 on potatoes, are considered stable during the respective time of storage.

7.3.2 Nature of residues in plants, livestock and processed commodities

The metabolism of Cymoxanil was investigated using 14C-labelled Cymoxanil, labelled at the C2 position (interchangeably described as [acetyl-2-14C]Cymoxanil, [cyanoacetamide-2-14C]Cymoxanil or [2-^{14}C]Cymoxanil). Chemical structure and the position of the radiolabel:



* denotes the position of the [^{14}C] radiolabel

Due to the double bond in the imino functional group at the C2 position, Cymoxanil can exist as two stereoisomers having (E) and (Z) configurations. Cymoxanil is manufactured as the (E) isomer. The available data do not indicate that the (Z) isomer is formed by metabolic process in plant and livestock matrices.

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Studies on the metabolism of Cymoxanil in root and leafy crops (potatoes and lettuce) were submitted for the first inclusion of Cymoxanil into Annex I of Council Directive 91/414/EEC and reviewed under uniform principles. Additional studies investigating the metabolism of Cymoxanil in grapes, tomatoes and potatoes were submitted by the applicant for the purpose of authorisation of the product FDJ03 (Cymoxanil: 450 g/kg) following the first inclusion of Cymoxanil and assessed according to Uniform Principles (Austria, 2013). These additional studies have also been evaluated in the framework of the article 12 MRL review (EFSA, 2015).

EFSA, 2015: "During the peer review, the metabolism of Cymoxanil has been investigated for foliar treatment in two different crop groups: root crops and leafy crops. The reported studies indicated a rapid and extensive degradation of the parent compound. Cymoxanil was rapidly degraded over intermediates (metabolites IN-W3595, IN-KQ960 or IN-KP533) to glycine, which was further conjugated or incorporated in natural substances (carbohydrates, peptides or proteins). None of these metabolites was considered as toxicologically relevant (EFSA, 2008).

In the framework of the present MRL review, the RMS submitted four additional studies investigating the metabolism of Cymoxanil in fruit crops (tomatoes and grapes), hereby covering a third crop group […].

According to the RMS, these studies were also considered acceptable during the zonal assessment (central EU) of plant protection products containing Cymoxanil. Although only one of these studies is GLP compliant, all results corroborate the metabolic pattern depicted in root and leafy crops.

The parent compound is also extensively degraded in fruits. It was quantified at levels of 0.01 mg/kg in tomatoes (PHI 3 days) and 0.05 mg/kg in grapes (PHI 18 days). Apart from glycine, significant metabolites were not identified. Major part of the non-extracted radioactivity was characterised as polar metabolites, conjugates or incorporated into plant constituents as well."

For the purpose of active substance renewal, two additional crop metabolism studies were provided: one in grapes and one in lettuce. As the intended use of FEL02 is only on potatoes, the RMS Lithuania conclusion is provided as supplementary information in support of this application. dRAR Volume 1 (Lithuania, 2020): "In these new studies, some of the known photolytic and hydrolytic degradants of cymoxanil were able to be detected, more so than in the earlier studies. These metabolites were almost exclusively found in the surface wash fraction rather than in the plant extracts, confirming their probable abiotic origin. This was exaggerated in the new grape study in which the grapevines were grown under protection between the final spray and harvest which is not normal agronomic practice for grapes, and which may have impeded normal photolysis and weathering processes. This may also explain why the TRRs in the grapes in this grape study were ~10 times higher than might have been expected when compared to the TRRs seen in the other plant metabolism studies considering the relative rate of [2-14C]cymoxanil being applied, and thus why the metabolites were able to be detected in this study and at relatively significant amounts compared to the previous findings. However, these newer studies do not alter the overall conclusion that once absorbed into the plant tissues, cymoxanil is very rapidly degraded to glycine which then enters the metabolic pool and is naturally incorporated. Generally, little cymoxanil or structurally related metabolites were seen in the plant extracts in these new studies."

A summary of the metabolism studies relevant for the intended use on potatoes is given in the table below.

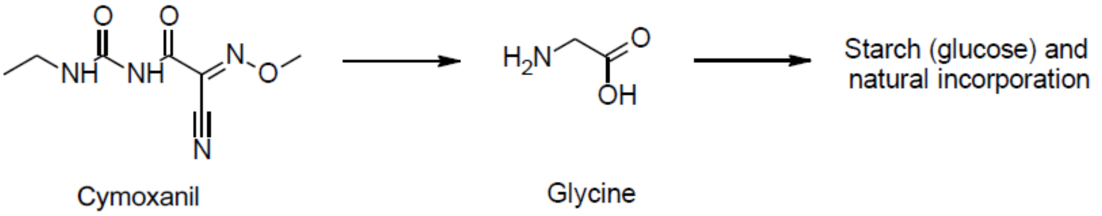
Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	**Rate (kg Cymoxanil/ha)**	**No**	**Sampling (DAT)**	**Remarks**	
EU data								
Root and tuber vegetables	Potatoes	[2-^{14}C]	foliar treatment, F	0.40	3	3		Austria, 2007
	Potatoes	[2-^{14}C]	foliar treatment, F	0.24	8	10		Austria, 2007
	Potatoes	[2-^{14}C]	foliar treatment, F	0.21	5	10		Austria, 2013, EFSA, 2015

Summary of plant metabolism studies reported in the EU

<u>Metabolism study in potatoes (Li Y. and Hausmann S.M., 1996)</u>
GAP: 3x0.40 kg a.s./ha, PHI 3 d. The total application rate was 1.7 N compared to the intended cGAP.

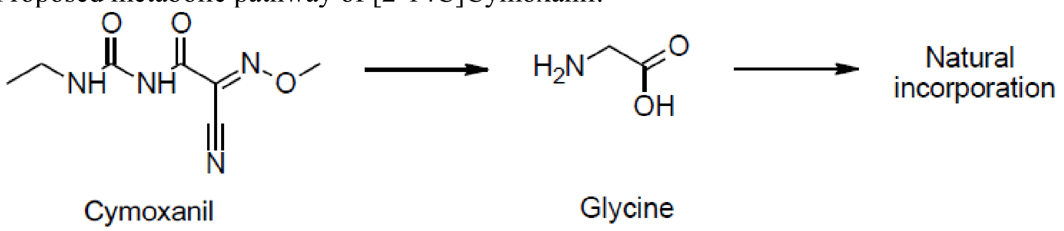
Proposed metabolic pathway of [2-14C]Cymoxanil:



RMS conclusion (Austria, 2007): "The parent compound was not detected in mature potato tuber (variety Red Pontiac). As main metabolite in the mature potato tuber homogenate glycine was identified (after acid hydrolysis and protease digestion of aqueous fraction: 78.5 % of TRR or 0.54 mg eq/kg). A significant amount of glucose (8.1 % of TRR or 0.06 mg eq/kg) was released from the starch in the pellet of mature potato tuber homogenate after acid hydrolysis. No other structurally related metabolites of 14C-Cymoxanil have been detected in mature potato tuber. This study indicates an extensively metabolism of 14C-Cymoxanil resulting to glycine and incorporation of radioactivity in natural compounds (like carbohydrates, peptides or proteins)."

<u>Metabolism study in potatoes (Melkebeke T., van Noorloos B., 2003)</u>
GAP: 8x0.24 kg a.s./ha, PHI 10 d. The total application rate was 2.7 N compared to the intended cGAP.

Proposed metabolic pathway of [2-14C]Cymoxanil:



RMS conclusion (Austria, 2007): "No parent compound was detected in mature potato tubers (variety Bild Star). Metabolism of Cymoxanil resulted in conjugated glycine (about 27% TRR or 0.282 mg eq/kg) as the main identified metabolite in mature potato tuber. The majority of the unidentified radioactive residue was characterized as polar metabolites or material incorporated in natural compounds".

<u>Metabolism studies in potatoes, tomatoes and grapes (Belasco I.J. et al, 1981)</u>
Austria, 2013: "It has been shown that labelled Cymoxanil is rapidly metabolised by grapes, potatoes and tomatoes, resulting primarily in the formation of [14C]glycine with subsequent reincorporation of the radiolabel into other naturally occurring compounds closely associated with the metabolism of glycine. These results support the EU reviewed studies on potatoes and lettuce (available in the DAR of Cymoxanil). Although the additional submitted study (Belasco I.J. et al, 1981) was not performed according to GLP and actual guidelines, it can be clearly shown that the metabolism of Cymoxanil is comparable in all plant matrices tested. Therefore the study additionally provided by the applicant is acceptable for supplementary information."

Conclusion on metabolism in primary crops

No new studies were conducted for the purpose of this application because the metabolism of Cymoxanil in primary crops was sufficiently investigated. Once adsorbed into the plant tissue, Cymoxanil rapidly degrades to glycine which then leads to natural incorporation into endogenous biomolecules such that significant residues of parent cymoxanil or structurally-related metabolites are not expected in plant commodities. This also applies to the intended uses of Cymoxanil in the product FEL02 on potatoes.

The residue definition for primary crops for both enforcement and risk assessment is Cymoxanil.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

A confined rotational crop metabolism study was submitted for the first inclusion of Cymoxanil into Annex I and reviewed under uniform principles. The metabolism of [2-14C]Cymoxanil was investigated following one pre-plant application at 1212 g a.s./ha, which was 1.7 N rate compared to the intended GAP on potatoes, on bare soil and subsequent sowing of sugar beet, lettuce and wheat 30 and 120 days later. The study was concluded to be acceptable.

Summary of plant metabolism studies reported in the EU

Table 7.3-4: TRR values in rotational crops after application of [2-^{14}C] Cymoxanil to bare soil

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate of labelled Cymoxanil (kg a.s./ha)	Rotational Crop Interval (RCI)** (days)	DASST*** (days)	TRR**** [mg eq/kg]	
EU data								
Leafy vegetables	Lettuce /heads	[2-^{14}C]	G	1.212	30	76	< 0.01	Austria, 2007
					120	167	< 0.01	
Root and tuber vegetables	Sugar beet /foliage				30	132	0.02	
					120	210	< 0.01	
	Sugar beet /roots				30	132	0.01	
					120	210	< 0.01	
Cereals	Spring wheat /forage				30	57	0.07	
					120	152	0.01	
	Spring wheat /straw				30	132	0.14	
					120	210	0.12	
	Spring wheat /grain				30	132	0.04	
					120	210	0.05	

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)
** RCI … rotational crop interval, time between single soil application of ^{14}C-Cymoxanil and crop planting
*** DASST … days after single soil treatment,
**** total radioactive residue (TRR) expressed as mg ^{14}C-Cymoxanil equivalents/kg (mg eq/kg) fresh weight of raw agricultural commodity (RAC)-determined by total combustion

RMS (Austria, 2007) concluded that a supplementary rotational field crop study performed in Europe is not required as there is no evidence of possible residues in the tested rotational crops after application of Cymoxanil according to intended uses.

Article 12 MRL review (EFSA, 2015): "A rotational crop study investigating residues uptake in lettuce, sugar beet and wheat for two different plants back intervals (30-days PBI and 120-days PBI) was evaluated during the peer review. The application rate used in this study (1.2 kg a.s./ha on bare soil) covers the maximal application rates authorised for non-perennial crops within the EU. […]. At final harvest, total radioactivity was not significant (<0.01 mg eq/kg) in lettuce heads and was only of 0.01 mg eq/kg in sugar beet roots from the 30-days plant back interval. Significant amounts of total radioactive residue (TRR) were only detected in wheat grain (0.04-0.05 mg eq/kg) and in wheat straw (0.12-0.14 mg eq/kg) for both PBI. In cereals where TRR was more than 0.01 mg eq/kg, the radioactivity was further analysed. Cymoxanil or structurally related metabolites were not identified and individual components accounting for more than 0.02 mg eq/ha were not detected. Based on this study it was concluded that significant residues of Cymoxanil are not expected in practice in rotational crops (EFSA, 2008). This conclusion is still relevant in the framework of the present review."

Conclusion on metabolism in rotational crops

No new studies were conducted because the metabolism of Cymoxanil in rotational crops was sufficiently investigated in the study submitted for the Annex I inclusion. The study showed that no significant residues of Cymoxanil are expected in practice in rotational crops. There is no evidence of possible residues in rotational crops after application of Cymoxanil according to intended use on potatoes. No risk mitigation measurements are required.

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

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application. No study investigating the nature of residues in processed commodities is required as a "non residue" situation was demonstrated for potatoes in the trial studies: residues < LOQ (< 0.01 mg/kg) and even < LOD (0.002 or 0.003 mg/kg) for the majority of samples.

Conclusion on nature of residues in processed commodities

The intended use of Cymoxanil on potato is not expected to result in residues of Cymoxanil at or above 0.01 mg/kg. Therefore a study to investigate the effect of processing on the nature of the residue is not required.

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.3-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (Potatoes)
Rotational crops covered	Leaf vegetables (lettuce) Sugar plants (sugar beet) Cereals (Spring wheat) A “non residue” situation in rotational crops is established, therefore no further investigations were done on these crops (EFSA, 2008)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (significant residues of Cymoxanil were not identified in rotational crops (EFSA, 2015))
Processed commodities	not applicable (“non residue” situation in potato; human TMDI < 10% of ADI, no processing studies are regarded necessary) (EFSA, 2008)
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes (tentative) (EFSA, 2015)
Plant residue definition for monitoring	Cymoxanil (Regulation n°2018/832, EFSA, 2015)
Plant residue definition for risk assessment	Cymoxanil (EFSA 2015)
Conversion factor from enforcement to RA	Not applicable (EFSA, 2015)

7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

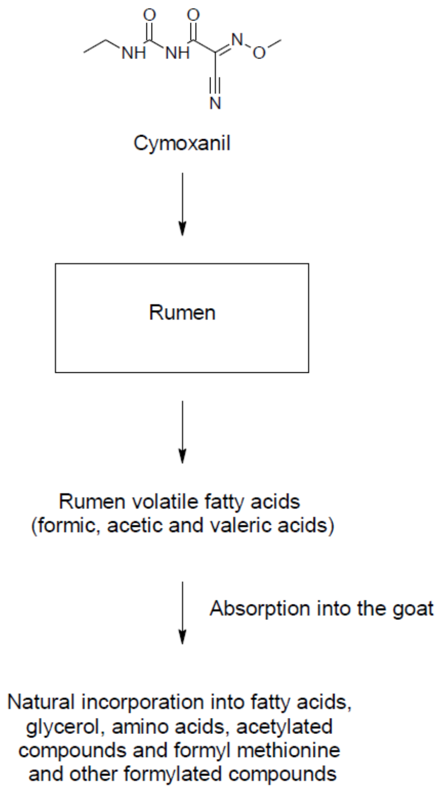
No new data submitted in the framework of this application.

A study on the metabolism of Cymoxanil in livestock was submitted for the first inclusion of Cymoxanil into Annex I of Council Directive 91/414/EEC. The metabolism of [2-14C] Cymoxanil was investigated in the lactating goat after administration of a daily dose of 10 mg/kg/day in the feed for 3 consecutive days. The study was reviewed under uniform principles and deemed to be acceptable.

Table 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[2-^{14}C]	1	10	3	Milk	twice daily	Austria, 2007
						Urine and faeces	twice daily	
						Tissues	at sacrifice	

Proposed metabolic pathway of [2-^{14}C]Cymoxanil in the goat following oral administration:



Summary of metabolism studies reported in the EU

RMS conclusion (Austria, 2007): "14C-Cymoxanil dosed over 3 consecutive days, equivalent to 10 mg 14C-Cymoxanil per kg diet and day, was metabolised by one tested lactating goat essentially to natural products including fatty acids, glycerol, glycine and other amino acids, lactose and hydrolysable formyl and acetyl group. 14C-Methan was hypothesised as a metabolite. Neither 14C-Cymoxanil nor structurally related metabolites were detected in any tissue, milk or in the urine (radioactivity in faeces was not further determined) of the goat.

Additionally, an in vitro bovine rumen fluid test was performed. An initial metabolism of 14C-Cymoxanil was mediated by rumen (micro)organisms, which metabolised 14C Cymoxanil primarily to polar natural products like formic, acetic and valeric acid and incorporated the resulted metabolites into natural products (e.g. lipids, sugars, proteins or others). "

EFSA, 2008: "A goat metabolism study was evaluated indicating that Cymoxanil is rapidly and extensively metabolised essentially to natural products. The parent compound Cymoxanil was proposed as residue definition for ruminant only. An overall animal residue definition cannot be proposed as no laying hen study was submitted."

EFSA, 2015: "Cymoxanil is authorised for use on potatoes, dry pulses, sunflower seed and soya bean that might be fed to livestock. Although the calculated dietary burdens (max 0.045 mg/kg DM) may have been slightly underestimated (missing data for oilseeds), the calculated intake was sufficiently low (compared to the trigger value of 0.1 mg/kg DM) to conclude that MRLs for cymoxanil in animal commodities are not required. Nevertheless, if a residue definition for ruminant and pig commodities would be needed in the future, the available metabolism study would be sufficient to propose parent cymoxanil as a residue definition for monitoring and risk assessment in ruminants and pigs."

Conclusion on metabolism in livestock

No new studies were conducted because the metabolism of Cymoxanil in livestock was sufficiently investigated in a study with lactating goats submitted for the Annex I inclusion. The study indicates that Cymoxanil is rapidly and extensively metabolised essentially to natural products. In none of the animal commodities Cymoxanil residues (or its metabolites) were detected (no residue situation). There is no evidence of possible residues in livestock after application of the product FEL02 according to intended use on potatoes.

There is no livestock residue definition (both enforcement and risk assessment).

7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.3-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
Time needed to reach a plateau concentration	After 1 day in milk
Animal residue definition for monitoring	Residue definition in animal commodities is not needed but could be set as Cymoxanil (for ruminant and pigs) if needed in the future.(EFSA, 2015)
Animal residue definition for risk assessment	Residue definition in animal commodities is not needed but could be set as Cymoxanil (for ruminant and pigs) if needed in the future. (EFSA, 2015)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 Summary of European data and new data supporting the intended uses

New studies

Two at harvest supervised residue trials, conducted in 2010, were submitted for the first time at EU level by the applicant for the purpose of authorisation of the product FDJ03 (WG formulation with 45 g/kg of Cymoxanil) following the first inclusion of Cymoxanil and assessed according to Uniform Principles (Austria, 2013). This study was also submitted for the purpose of the active substance renewal (Lithuania, 2020); assessed by RMS Lithuania and reviewed by Co-RMS Finland before submission to EFSA (On-going peer-review process). These 2 trials are considered relevant for this application.

14 additional supervised residue trials, conducted in 2006, 2007 and 2010 in the N-EU, were submitted by the applicant for the purpose of the active substance renewal (Lithuania, 2020) of which 13 trials are considered relevant for this application. Presumably, these studies have also been evaluated in the framework of the Art. 12 review of Cymoxanil (EFSA, 2015). The study results are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Available data but not relied on

Residue trial studies with Cymoxanil on potatoes were submitted for the first inclusion of Cymoxanil into Annex I of Council Directive 91/414/EEC and reviewed under uniform principles (Austria, 2007, EFSA, 2008). Ten of these trials were conducted in the N-EU:

Trial GAP: 4 x 0.118-0.128 kg Cymoxanil/ha, interval: 7-10 d, PHI 7 d. (4 trials, 2002, applicant Oxon)
Trial GAP: 11-12 x 0.176-0.235 kg Cymoxanil/ha, interval: 7-10 d, PHI 14 d. (6 trials, 1996, applicant DuPont)

In none of these trials, residues at or above the LOQ of 0.05 mg/kg were determined.

The N-EU trial GAPS didn’t match with the intended GAP for potatoes in the C-EU. Furthermore, as the LOQ in these studies (0.05 mg/kg) is not compatible with the current MRL for potatoes (0.01 mg/kg) and LOD was not stated, these study results could not be used in the risk assessment.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of FEL02 and conformity to existing MRL

Commodity	Source	Residue zone	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Calculated MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Potato	EFSA, 2015	NEU	GAP on which EU MRL a.s. assessment is based: 6 x 0.13 kg as/ha, interval= min. 5 d, PHI 7 d E/RA**: 17 x <0.01; 14x <0.05	N/A				
	New trials [a,] (KCA 6.3/05, Jonchere F., 2011)	NEU	Trials GAP: 8x 0.112-0.135 kg Cymoxanil/ha, interval= 6-8 d, PHI= 7 - 8 d E/RA**: 2x ND (< 0.002)					
	New trials, [b] (KCA 6.3/06, Tetuan B., 2011)	NEU	Trials GAP: 6x 0.140-0.155 kg Cymoxanil/ha, interval=4-6 d, PHI=6-7 d E/RA**: 2x < LOQ (0.01)					
	New trials, [b] (KCA 6.3/07, Semrau J., 2010)	NEU	Trials GAP: 6x 0.106-0.123 kg Cymoxanil/ha, interval=3-7 d, PHI=7 d E/RA**: 4x ND (<0.003)					
	~~New trials, [b] (KCA 6.3/08, Old J., Hansford R., 2007)~~	~~NEU~~	~~Trials GAP: 12x 0.112-0.126 kg Cymoxanil./ha, interval= 5 d, PHI= 0 d~~ ~~E/RA**: 3x ND (< 0.003)~~					
	~~New trials [b] (KCA 6.3/09, Livingstone K., Haigh I. M, 2008)~~	~~NEU~~	~~Trials GAP: 12 x 0.115-0.125 kg Cymoxanil./ha, interval= 5 d, PHI= 0 d~~ ~~E/RA**: 4x ND (< 0.003)~~					
	Overall supporting data for cGAP	N-EU	E/RA: 2 x < 0.01; ~~11~~ 4x < 0.003; 2 < 0.002	<0.01	<0.01	0.01[c]	0.01*	Yes

* Source of EU MRL: ~~Regulation (EC) No 2018/832~~ Reg. (EU) 2022/1363

** Trials compliant with GAP and/or performed at a more critical GAP

a Submitted for the first time at EU level by the applicant for the product authorisation of FDJ03 following the first inclusion of Cymoxanil (Austria, 2013) and submitted for the active substance renewal (Lithuania, 2020).

b Submitted for the purpose of the active substance renewal (Lithuania, 2020)

c No OECD MRL calculation was conducted. The MRLis proposed at the Limit of Quantification.

7.3.3.2 Conclusion on the magnitude of residues in plants

Trials conducted in the Northern EU region are considered suitable to support the use of Cymoxanil on potatoes in the Central zone.

The current MRL for Cymoxanil in root and tuber vegetables is 0.01 mg/kg (EC No 2018/832), based on the limit of analytical quantification.

Two relevant supervised residue trials are available in which an analytical method was used with an LOQ of 0.02 mg/kg and LOD of 0.002 mg/kg13 supervised residue trials are available in which an analytical method was used with an LOQ of 0.01 mg/kg and LOD of 0.003 mg/kg. 4 of the 15 trials were performed according to the intended cGAP. The other trials represent a worst case compared to the intended GAP, since the total application rate is higher than the intended 0.72 kg Cymoxanil per ha and/or the PHI is less than 7. As no residues were detected, rescaling using the proportionality approach is deemed not necessary. These trials were all conducted in Northern Europe and considered relevant for this application.

As no residues were detected in any of the samples analysed, it is a non residue situation for the intended use on potatoes. The trial results do not provide evidence that the actual MRL of 0.01 mg/kg has to be modified. No new MRL is proposed.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues of cymoxanil will be present in succeeding crops.

Potatoes are a major crop, therefore eight trials are required. Since a non residue situation has been demonstrated, four trials are acceptable. With 15 N-EU trials, sufficient trials are available to support the proposed use.

The results of the 15 N-EU trials confirm that the intended use of Cymoxanil on potatoes in the CEU is acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Cymoxanil is authorised for use on potatoes, dry pulses, sunflower seed and soya bean that might be fed to livestock (EFSA, 2015). In the Art. 12 MRL review (EFSA, 2015), livestock dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (European Commission, 1996). The input values for all relevant commodities had been selected according to the recommendations of JMPR (FAO, 2009).

Table 7.3-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Cymoxanil				
Peas (dry)	0.02	STMR (EFSA, 2015)	0.02	STMR (EFSA, 2015)
Beans (dry)	0.02	STMR (EFSA, 2015)	0.02	STMR (EFSA, 2015)
Lupins (dry)	0.02	STMR (EFSA, 2015)	0.02	STMR (EFSA, 2015)
Potatoes	0.01 *	STMR (EFSA, 2015)	0.01*	HR (EFSA, 2015)

* Indicates that the input value is proposed at the limit of quantification.
STMR: supervised trials median residue; HR: highest residue

Table 7.3-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded * (Y/N)
Dairy ruminants	0.0009	0.0009	Potatoes	0.025	N
Meat ruminants	0.0019	0.0019	Potatoes	0.045	N
Poultry	0.0013	0.0013	Potatoes	0.020	N
Pigs	0.0020	0.0020	Potatoes	0.049	N

* The current dossier for the authorisation of a new product is submitted before the date of renewal of the approval of the active substance Cymoxanil. Hence, the old active substance data requirements still apply; trigger value 0.1 mg/kg DM.

Article 12 MRL review (EFSA, 2015): "Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary. Nevertheless, it is highlighted that for soya bean and sunflower seed, no residue data were available. The animal intake of Cymoxanil residues via these commodities has therefore not been assessed and may have been underestimated. Nevertheless, considering the large margin between the highest calculated dietary burden (0.045 mg/ kg DM) and the trigger value of 0.1 mg/ kg DM, and considering that contribution for oilseeds grains is restricted to the median value of the data set, the trigger value is not expected to be exceeded.

Consequently, EFSA is of the opinion that MRLs for Cymoxanil in animal commodities are not required. Nevertheless, if a residue definition for ruminant and pig commodities would be needed in the future, the metabolism study performed on lactating goat evaluated during the peer review would be sufficient to conclude. Based on this study, parent Cymoxanil would be applicable for monitoring and risk assessment in ruminant and pig commodities (EFSA, 2008)."

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new data were submitted in the framework of this application.

~~There is no need to investigate the effect of industrial and/or household processing because the newly submitted trials studies with potatoes demonstrated a non-residue situation (< LOQ of 0.01 mg/kg).~~

EFSA conclusion, 2008: "livestock feeding studies are regarded as not necessary, because a "non-residue" situation (<0.05 mg Cymoxanil/kg) on potato (relevant feedingstuff) is established. Additionally, according to the goat metabolism study no Cymoxanil (< 0.05 mg/kg) or structurally related metabolites were detected in any got tissue (e.g. milk, liver, kidney, muscles or fat)."

7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

No data/information on processing studies was reviewed during the approval of the active substance.

No new data were submitted in the framework of this application.

Residue trial studies showed a non-residue situation for the representative use of Cymoxanil on potato tubers, the only edible plant part to be processed; residues of Cymoxanil will not exceed the threshold of 0.01 mg/kg. Therefore, investigation of the magnitude of residues in processed potato is not required. Specific processing factors for enforcement of processed commodities are not calculated and proposed.

7.3.6 Magnitude of residues in representative succeeding crops

The crop under consideration can be grown in rotation.

EFSA, 2015: "Studies on the nature of the residues in succeeding crops show that significant residues of Cymoxanil are not expected in rotational crops. "

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed to support the intended uses of Cymoxanil in the product FEL02 on potatoes.

7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of FEL02. Therefore, other special studies are not needed.

According to document SANTE/11956/2016 rev.9 of 14 September 2018 "Technical guidance for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey" potatoes do not have melliferous capacity. Additionally, all residue levels found in the residue trials presented to support the intended uses of Cymoxanil in the product FEL02 on potatoes are below the LOQ ranging from 0.01 to 0.05 mg/kg. Consequently, there is no reasonable expectation of residues in pollen or any other bee product. Therefore, studies on residues in pollen and bee products are not necessary.

7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see Table 7.1-2).

7.3.8.1 Input values for the consumer risk assessment

A dietary risk assessment using revision 3.1 of EFSA PRIMO was performed. For the chronic consumer risk assessment, all uses of Cymoxanil at EU level were taken into consideration; the contributions of commodities for which no GAP was reported in the framework of the MRL review (EFSA, 2015) or for which the confirmatory data requested remain unavailable (EFSA, 2019) were not included in the calculation. For the acute consumer risk assessment only the intended use on potatoes was taken into consideration. Due to the non-residue situation for Cymoxanil in the supervised trials, the actual MRL of 0.01 mg/kg, which was based on the LOQ of 0.01 mg/kg, was used as input value (STMR/HR) for potatoes.

Table 7.3-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition : Cymoxanil				
Table grapes	0.05	STMR (EFSA, 2019)		
Wine grapes	0.05	STMR (EFSA, 2019)		
Lettuces	0.01	STMR (EFSA, 2019)		
Spinaches	0.02	STMR (EFSA, 2019)		
Potatoes	0.01*	STMR NEU trials	0.01*	HR (EFSA, 2015)
Garlic	0.01*	STMR (EFSA, 2015)		
Onions	0.01*	STMR (EFSA, 2015)		
Tomatoes	0.01*	STMR (EFSA, 2015)		
Aubergines (egg plants)	0.05	STMR (EFSA, 2015)		
Cucumbers	0.01*	STMR (EFSA, 2015)		
Gherkins	0.01*	STMR (EFSA, 2015)		
Courgettes	0.01*	STMR (EFSA, 2015)		
Melons	0.002	STMR x PF (EFSA, 2015)		
Pumpkins	0.002	STMR x PF (EFSA, 2015)		
Watermelons	0.002	STMR x PF (EFSA, 2015)		
Broccoli	0.01*	STMR (EFSA, 2015)		
Cauliflower	0.01*	STMR (EFSA, 2015)		
Beans (fresh, with pods)	0.05	STMR (EFSA, 2015)		
Beans (fresh, without pods)	0.05	STMR (EFSA, 2017)		
Peas (fresh, with pods)	0.05	STMR (EFSA, 2015)		
Peas (fresh, without pods)	0.05	STMR (EFSA, 2015)		
Globe artichokes	0.01*	STMR (EFSA, 2015)		
Leek	0.01*	STMR (EFSA, 2015)		
Beans (dry)	0.02	STMR (EFSA, 2015)		
Lentils (dry)	0.02	STMR (EFSA, 2015)		
Peas (dry)	0.02	STMR (EFSA, 2015)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Lupins (dry)	0.02	STMR (EFSA, 2015)		

* indicates that the input value is proposed at the limit of quantification

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3. The chronic risk assessment ranges from 0.1% to 2% of ADI.

Table 7.3-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	Not calculated
IEDI (% ADI) according to EFSA PRIMo rev.3.1	2% (based on PT general)
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	Potatoes: 2% (based on children) Potatoes: 0.4% (based on adults)

The proposed uses of Cymoxanil in the formulation FEL02 on potatoes do not represent unacceptable acute and chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

7.5 References

Copper

Aigberua, A.O., Ovuru, K.F. and Izah, S.C., Evaluation of Heavy Metals in Palm Oil Sold in Some Markets in Yenagoa Metropolis, Bayelsa State, Negeria, E C Nutrition 11.6(2017):244-252

Akpakpan, A.E., Eduok, U.M., Udiong, D.S., Udo, I.E. and Ntukuyoh, A.I., Level of Metals in Kernels and Shells of Oil Palm and Coconut Fruits, International Journal of Modern Chemistry, 2012, 2(1): 20-27

Bilandžić, N., Đokić, M., Sedak, M., Kolanović, B.Z., Varenina, I., Končurat, A., Rudan,N. (2011) Determination of trace elements in Croatian floral honey originating from different regions. Food Chemistry 128 (2011): 1160-1164.

Commission Regulation (EC) 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residues levels for products covered by Annex I thereto

Conti, M. E, (2000). Lazio region (central Italy) honeys: a survey of mineral content and typical quality parameters. Food Control 11 (2000) 459-463

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Downey, G., Hussey, K., Kelly, J.D., Walshe, T.F. Martin, P.G. (2005) Preliminary contribution to the characterisation of artisanal honey produced on the island of Ireland by palynological and physico-chemical data/ Food Chemistry 91 347–354

EFSA (2009). Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on Copper(II) oxide as a source of Copper added for nutritional purposes to food supplements following a request from the European Commission. The EFSA Journal 1089, 1-15

EFSA (2015). Scientific Opinion on Dietary Reference Values for Copper. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal 2015: 13(10):4253

EFSA (European Food Safety Authority), 2008. Conclusion on pesticide peer review. Conclusion regarding the peer review of the pesticide risk assessment of the active substance. Copper (I), Copper (II) variants namely Copper hydroxide, Copper oxychloride, tribasic Copper sulfate, Copper (I) oxide, Bordeaux mixture. EFSA Scientific Report (2008) 187, 1-101.

EFSA (European Food Safety Authority), 2013. Conclusion on pesticide peer review. Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance Copper (I), Copper (II) variants namely Copper hydroxide, Copper oxychloride, tribasic Copper sulfate, Copper (I) oxide, Bordeaux mixture. EFSA Scientific Report (2013) 11(6), 3235.

EFSA (European Food Safety Authority), 2018a. Conclusion on pesticide peer review. 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.

EFSA (European Food Safety Authority), 2018b. Reasoned Opinion on the review of the existing maximum residue levels for Copper compounds according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(3):5212, 135 pp.

EFSA (European Food Safety Authority), 2021a. 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). EFSA Journal 2021;19(3):6498

EFSA (European Food Safety Authority), 2021b. 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). EFSA Journal 2021;18(3):EN-6501.

France, 2016. Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009. COPPER COMPOUNDS, Volume 3 – B.7 (AS), December 2016.

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Lachman, J., Kolihová, D., Miholová, D., Košata, J., Titěra, D., Kult, K. (2007) Analysis of minority honey components: Possible use for the evaluation of honey quality. Food Chemistry 101 973–979

Özcan, M., Ölmez, C., Arslan, D. and Dursun, N. (2012). Mineral and heavy metal contents of different honeys producted in Turkey. Journal of Apicultural Research 51(4): 353-358 (2012)

Tuzen, M., Silici, S., Mendil, D., Soylak, M. (2007) Trace element levels in honeys from different regions of Turkey. Food Chemistry 103 (2007) 325–330

Cymoxanil

Austria, 2007. Draft Assessment Report (DAR) on the active substance Cymoxanil prepared by the rapporteur Member State Austria in the framework of Council Directive 91/414/EEC, June 2007. Available online: www.efsa.europa.eu

Austria, 2013, Registration report for FDJ03 (Cymoxanil: 450 g/kg) prepared by the zonal rapporteur Member State Austria in the framework of product authorization following active substance approval. Central Zone. Evaluator: AGES, Institute for Plant Protection Products, January 2013.

Commission Regulation (EU) 2018/832 of 05 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, Cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products.

EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance Cymoxanil. EFSA Scientific Report (2008) 167, 1-116, doi:10.2903/j.efsa.2008.167.

EFSA (European Food Safety Authority), 2015. Reasoned Opinion on the review of the existing maximum residue levels for Cymoxanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(12):4355. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2017. Reasoned opinion on the modification of the existing maximum residue level for Cymoxanil in beans without pods. EFSA Journal 2017;15(12):5066, 19 pp. https://doi.org/10.2903/j.efsa.2017.5066

EFSA (European Food Safety Authority), 2019. Evaluation of confirmatory data following the Article 12 MRL review for Cymoxanil. EFSA Journal 2019;17(10):5823. Available online: www.efsa.europa.eu

Lithuania, 2020. Combined Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009 and Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008, Volume 3-B.7 (AS), February 2020. Available online: www.efsa.europa.eu

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate. 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
Copper					
KCA 6.1/01	Long, E., Weidenauer, L.	2019	CROP RESIDUE DATA AND CONSUMER RISK ASSESSMENT FOR COPPER COMPOUNDS - A CRITICAL ANALYSIS EU Copper Task Force, not available not available GLP/GEP: no Published: no	no	EUCuTF(*)
KCA 6.3/01	Sicbaldi, F., Soddu, R., Riccelli, S.	2009	Copper residues in potato after four applications of Copper Oxychloride 37.5 WG. Two Harvest Trials in Northern Europe (Germany and Poland) in 2008 Isagro S.p.A., RA.08.26 Isagro, Ricerca Srl GLP: yes Published: no	no	ISA (Isagro S.p.A)(*)
KCA 6.3/02	Klimmek, S., Gizler, A.	2007	Magnitude of Residues of Copper in/on Potato Following Six Applications of Flowbrix - Austria, Czech Republic and Slovakia, Season 2006 Kwizda Agro GmbH, Austria, G06-0074, KWI-0601 Eurofins Analytik GmbH, Dr. Specht Laboratorien, Hamburg, Germany GLP: yes Published: no	no	KWI (Kwizda Agro GmbH, Austria)(*)

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
KCA 6.3/03	Steffen, M.	1992	Application for registration of FUNGURAN-OH 50 WP (50% Copper as Copper hydroxide) EU Copper Task Force, not stated not available GLP: yes Published: no	no	EUCuTF(*)
KCA 6.3/04	Schneider, E.	2021	Determination of Copper Residues in Potato Raw Agricultural Commodity Following Foliar Applications with BORDEAUX MIXTURE 20 % WG (FAP13) under Field Conditions in Northern Europe in 2020, Report No. R CO233 Upl Europe Ltd., C0233 Anadiag, France GLP: yes Published: no	N	UPL (E.I. Du Pont de Nemours and Company)(*)
Cymoxanil					
KCA 6.1/02	Weber H.	2011	Storage stability of Residues of Cymoxanil, Mancozeb and ETU in Potato Samples. Report number: GAB-0704 Eurofins – Dr. Specht GLP GLP: Yes Published: No	N	Indofil Industries Limited and Belchim Crop Protection(*)
KCA 6.3/05	Jonchere F.	2011b	Determination of Cymoxanil residues in potatoes following applications of the formulated product FAZ02 (50 g/kg Cymoxanil + 680 g/kg mancozeb WG) under field conditions in Northern Europe – 2010, report no B0163 Anadiag, France GLP: yes Published: no	N	Société Financière de Pontarlier (SFP)(*)
KCA 6.3/06	Tetuan B.	2011	Determination of residues at harvest in potatoes, following six broadcast applications of Harpon WG, under field conditions – Northern Europe – Season 2010 - Report number: 10 F PT GW P/A (PROMO/ZOX-CM/10.01) PROMO-VERT Promo-Vert	N	Gowan Comercio Internacional & Servicos Ltda(*)

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
			GLP: Yes Published: No		
KCA 6.3/07	Semrau J.	2010a	Determination of residues of Cymoxanil and mancozeb after six applications Cymoxanil/Mancozeb 4.5/68% w/w WP in field potatoes, Northern Europe 2007/2008. Report number: 20074095/E1-FPPO Eurofins agroscience services GLP: Yes Published: No	N	Belchim Crop Protection NV and Indofil Industries Limited(*)
~~KCA 6.3/08~~	~~Old J., Hansford R.~~	~~2007~~	~~Magnitude of residues of Cymoxanil in potatoes following applications of Cymoxanil 60WG – Northern Europe,~~ ~~Season 2006~~ ~~Report number: DuPont-20033~~ ~~Charles River Laboratories~~ ~~GLP: Yes~~ ~~Published: No~~	~~N~~	~~E. I. du Pont de Nemours and Company(*)~~
~~KCA 6.3/09~~	~~Livingstone K., Haigh I. M.~~	~~2008~~	~~Magnitude of residues of Cymoxanil in potatoes following applications of Cymoxanil 60WG – Northern Europe,~~ ~~Season 2007.~~ ~~Report number: DuPont-22006~~ ~~Charles River Laboratories~~ ~~GLP: Yes~~ ~~Published: No~~	~~N~~	~~E. I. du Pont de Nemours and Company(*)~~

EUCuTF = European Union Copper Task Force
UPL = UPL Europe Ltd
(*) 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
Cymoxanil					
KCA 6.1/01	Nathan E.C.	1996	Magnitude of residues of Cymoxanil in potatoes following application of Curzate M-8 fungicide at maximum label rates and at five times maximum use rates to investigate the need for magnitude of residue data in processed fractions. Report number: AMR 3296-95 Morse Laboratories Inc. GLP: Yes Published: No	N	E. I. du Pont de Nemours & Co., Inc.
KCA 6.2.1/01	Li Y. and Hausmann	1996	Plant Metabolism of [2-^{14}C]Cymoxanil in Potatoes Report number: AMR 3408-95 E. I. du Pont de Nemours & Co., Inc. GLP: Yes Published: No	N	E. I. du Pont de Nemours & Co., Inc.
KCA 6.2.1/02	Melkebeke T., van Noorloos B.	2003	METABOLISM, DISTRIBUTION, AND EXPRESSION OF CYMOXANIL RESIDUES IN POTATOES Report number: 257772 NOTOX GLP: Yes Published: No	N	OXON Italia SpA
KCA 6.2.1/03	Belasco, I. J., et al	1981	Metabolism of [^{14}C] Cymoxanil in Grapes, Potatoes and Tomatoes Report number: Pestic. Sci. 1981, 12, 355-364 E. I. du Pont de Nemours & Co., Inc. GLP: No Published: Yes	N	N/A (Published Literature)
KCA 6.2.3/01	[redacted]	1996	The Distribution of [2-^{14}C] DPX-T3217 (Cymoxanil) in the Lactating Goat (Nature of Residue Study to EPA Guidelines) Report number: AMR 2084-91	N	E. I. du Pont de Nemours &

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
Cymoxanil					
			E. I. du Pont de Nemours & Co., Inc. GLP: Yes Published: No		Co., Inc.
KCA 6.6.1/01	Koch Singles A., Strek H. J. & Sheftic G. D.	1996	Accumulation of Residues in Confined Rotational Crops: Lettuce, Wheat, and Beets After Treatment with [^{14}C]Cymoxanil Report number: AMR 3575-95 E. I. du Pont de Nemours & Co., Inc. GLP: Yes Published: No	N	E. I. du Pont de Nemours & Co., Inc.

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 No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner
KCA 6.3/08	Old J., Hansford R.	2007	Magnitude of residues of Cymoxanil in potatoes following applications of Cymoxanil 60WG – Northern Europe,	N	E. I. du Pont de

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
			Season 2006 Report number: DuPont-20033 Charles River Laboratories GLP: Yes Published: No		Nemours and Company(*)
KCA 6.3/09	Livingstone K., Haigh I. M.	2008	Magnitude of residues of Cymoxanil in potatoes following applications of Cymoxanil 60WG – Northern Europe, Season 2007. Report number: DuPont-22006 Charles River Laboratories GLP: Yes Published: No	N	E. I. du Pont de Nemours and Company(*)

List of data relied on and 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 No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Copper compounds

A 2.1.1 Stability of residues

No new studies submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

No new studies submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Potatoes

Table A 2.1- 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment [kg Copper/ha]	Interval between application [days]	Growth stage at last application	PHI [days]
cGAP NEU (Art. 12, EFSA, 2018b)	4	0.7	7	BBCH 37-91	14
Intended cGAP CEU (Use no. 1)	6	0.6	7	BBCH 21-95	7

A 2.1.3.1.1 Study 1

A set of two at harvest supervised residue trials (2008) in the NEU zone (1 in Germany and 1 in Poland) was performed with Copper Oxychloride 37.5 WG formulation.

Trial GAP: 4 x 1.1-1.2 kg Copper/ha, interval = 7 d, PHI = 3 d

The trials were performed at a more critical GAP than proposed; the study is considered acceptable to support this application as “worst case”.

Comments of zRMS:	The trials are considered not acceptable to support this use due to the small number of applications (4 instead of 6).

Reference:	KCA 6.3/01
Report:	Sicbaldi, F., Soddu, R., Riccelli, S., 2009 Copper residues in potato after four applications of Copper Oxychloride 37.5 WG. Two harvest in trials in northern Europe (Germany and Poland) in 2008. Report No: RA.08.26
Guideline(s):	Yes Commission Directive 96/68/EC (amending Council Directive 91/414/EC)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Analytical method Renolab MA RES 002 was described in the Analytical Phase report (Maccaferri, 2009) attached to the study report: FAAS at 324.8 nm after acidic digestion.
Validation meets the requirements of SANCO/3029/99 rev.4 and SANCO/825/00 rev. 8.1.

Table A 2.1- 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues Copper [mg/kg]	PHI [days]	Details on trial
			kg a.s./ ha	Water [L/ha]	g a.s./hL						
	(a)	(b)				(c)				(d)	(e)
RA.08.26 1H Germany NEU 2008	Potato Karlena	1. 30 Apr 2008 2. 20 June - 10 Jul 2008 3. 07 Aug 2008	-	-	-	-	-	Tuber	0.88	3	Control
			1.069 1.172 1.172 1.138	380.00 416.67 416.67 403.33	281 281 281 282	1. 14 Jul 2008 2. 21 Jul 2008 3. 28 Jul 2008 4. 04 Aug 2008	71 79 81 85	Tuber	0.94	3	Copper Oxychloride 37.5 WG
RA.08.26 2H Poland NEU 2008	Potato Pasat	1. 02 May 2008 2. 20 June - 04 Jul 2008 3. 25 Sep 2008	-	-	-	-	-	Tuber	0.48	3	Control
			1.134 1.116 1.144 1.153	403.33 396.67 406.67 410.00	281 281 281 281	1. 02 Sep 2008 2. 09 Sep 2008 3. 16 Sep 2008 4. 22 Sep 2008	94 94 94 96	Tuber	0.54	3	Copper Oxychloride 37.5 WG

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Results of studies conducted according to the GAP are underlined.

A 2.1.3.1.2 Study 2

A set of four at harvest supervised residue trials (2006) in the NEU zone (2xAustria, 1xCzech Republic and 1 in Slovakia) was performed with SC formulation Flowbrix (670 g/L of Copper oxychloride).
Trial GAP: 6x1 kg Copper/ha, interval 6-7 d, PHI 14 d

Note: The trials were not conducted according to the intended cGAP.

Comments of zRMS:	The trials are considered not acceptable to support this use due to the PHI higher than proposed.

Reference:	KCA 6.3/02
Report:	Klimmek, S., Gizler, A., 2007 Magnitude of Residues of Copper in/on Potato Following Six Applications of Flowbrix – Austria, Czech Republic and Slovakia, Season 2006 Report No: KWI-0601
Guideline(s):	Yes Commission Directive 96/68/EC (amending Council Directive 91/414/EC)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Analytical method: Specht method (Report KWI-0602V, S. Klimmek, 2007): ICP-OES after acid digestion. The LOQ was 1 mg/kg.

Procedural recoveries during analysis of the field samples: mean (n=2) recovery of 82.5% (fortification levels of 1 and 10 mg/kg).

Control samples: c=0.84-1.1 mg/kg of Copper; indicating the natural content of Copper

Table A 2.1- 3: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues Copper [mg/kg]	PHI [days]	Details on trial
			kg a.s./ ha	Water [L/ha]	g a.s./hL						
	(a)	(b)				(c)				(d)	(e)
F-06-K-098-01 Austria NEU 2006	Potato Hermes	1. 18 Apr 2006 2. July 3. 18 Aug 2006	-	-	-	-	-	Tuber	1.0	14	Control
			0.977 0.987 0.999 0.977 1.007 1.001	403 407 412 403 415 413	243 243 243 243 243 242	1. 29 June 2006 2. 06 Jul 2006 3. 13 Jul 2006 4. 20 Jul 2006 5. 26 Jul 2006 6. 04 Aug 2006	63 65 67 71 73 75	Tuber	1.2	14	Copper Oxychlo-ride 670 g/L SC
F-06-K-098-02 Austria NEU 2006	Potato Valisa	1. 08 May 2006 2. early-mid Jul 3. 05 Sep 2006	-	-	-	-	-	Tuber	1.1	14	Control
			0.938 0.944 1.009 0.944 0.944 0.944	290 292 312 292 292 292	323 323 323 323 323 323	1. 18 Jul 2006 2. 26 Jul 2006 3. 02 Aug 2006 4. 08 Aug 2006 5. 16 Aug 2006 6. 22 Aug 2006	69 71-79 85 85 93 93	Tuber	1.0	14	Copper Oxychlo-ride 670 g/L SC
F-06-K-098-03 Czech Repub-lic NEU 2006	Potato Dalli	1. 25 Apr 2006 2. early-mid Jul 3. 31 Aug 2006	-	-	-	-	-	Tuber	0.84	14	Control
			1.019 0.994 0.982 1.001 0.908 1.011	420 410 405 413 383 417	243 243 242 242 237 242	1. 11 Jul 2006 2. 19 Jul 2006 3. 26 Jul 2006 4. 03 Aug 2006 5. 10 Aug 2006 6. 16 Aug 2006	65-67 69 69-71 71-73 73-75 75	Tuber	1.1	14	Copper Oxychlo-ride 670 g/L SC
F-06-K-098-01 Slovakia NEU 2006	Potato Bernadet	1. 29 Mar 2006 2. July 3. 16 Aug 2006	-	-	-	-	-	Tuber	0.98	14	Control
			0.986 0.929 0.999 0.989 0.975 0.939	415 383 412 408 402 387	238 243 243 243 243 243	1. 28 June 2006 2. 06 Jul 2006 3. 12 Jul 2006 4. 18 Jul 2006 5. 25 Jul 2006 6. 01 Aug 2006	67 69 71 73 73-75 75-78	Tuber	1.0	14	Copper Oxychlo-ride 670 g/L SC

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

A 2.1.3.1.3 Study 3

A set of 12 decline supervised trials in the NEU (10x Germany; climatically different parts) was performed in 1990, 1991 and 1992 with Funguran-OH 50 WP. Trial GAP was conform the intended cGAP: 6 x 0.6 kg Copper/ha, interval = 7 d; the study is considered acceptable to support this application.

Comments of zRMS:	Studies have been already evaluated in the framework of the Review of the existing maximum residue levels for Copper compounds (EFSA Journal 2018;16(3). The trials are considered acceptable to support this application.

Reference:	KCA 6.3/03
Report:	Steffen, M., 1992 Application for registration of FUNGURAN-OH 50 WP (50% Copper as Copper hydroxide). Report on supervised trial for residue analysis. Report No: 15585, 15586, 16348, 16349, 16350, 16351, 16356, 16357, SPI03855, SPI03881; SPI03954, SPI03955
Guideline(s):	Yes Commission Directive 96/68/EC (amending Council Directive 91/414/EC)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

There was no decline of the Copper content (0, 4, 14, 21 DALA)

Analytical method: FAAS after acidic digestion. Test facility: Norddeutsche Affinerie AG, Hamburg, Germany (additional information for the method are not available)

Table A 2.1- 4: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analysed	Residues Copper [mg/kg]	PHI [days]	Details on trial
			kg a.s./ ha	Water [L/ha]	g a.s./hL						
	(a)	(b)				(c)				(d)	(e)
15585 Germany NEU 1992	Potato Forelle	1. mid Apr 1992 2. N/D 3. 27 Aug 1992	-	-	-	-	-	Tuber	1.60	14	Control
			0.600	500	120	1. 25 Jun 1992	N/D	Tuber			Funguran-OH 300SC
			0.600	500	120	2. 06 Jul 1992	N/D		1.0	0	
			0.600	500	120	3. 16 Jul 1992	N/D		2.4	7	
			0.600	500	120	4. 23 Jul 1992	N/D		2.2	14	
			0.600	500	120	5. 30 Jul 1992	N/D		2.4	21	
			0.600	500	120	6. 06 Aug 1992	79/81				
15586 Germany NEU 1992	Potato Indira	1. mid Apr 1992 2. N/D 3. 26 Aug 1992	-	-	-	-	-	Tuber	0.7	14	Control
			0.600	500	120	1. 17 Jun 1992	N/D	Tuber			Funguran-OH 300SC
			0.600	500	120	2. 24 Jun 1992	N/D		1.0	0	
			0.600	500	120	3. 01 Jul 1992	N/D		0.8	7	
			0.600	500	120	4. 16 Jul 1992	N/D		0.9	14	
			0.600	500	120	5. 29 Jul 1992	N/D		0.8	21	
			0.600	500	120	6. 05 Aug 1992	79				
16348 Germany NEU 1990	Potato Hansa	1. 17 Apr 1990 2. N/D 3. 23 Aug 1990	-	-	-	-	-	Tuber	1.6	14	Control
			0.600	500	120	1. 19 Jun 1990	N/D	Tuber			Funguran OH-50WP
			0.600	500	120	2. 28 Jun 1990	N/D		2.4	0	
			0.600	500	120	3. 05 Jul 1990	N/D		1.4	7	
			0.600	500	120	4. 12 Jul 1990	N/D		1.4	14	
			0.600	500	120	5. 23 Jul 1990	N/D		1.6	21	
			0.600	500	120	6. 02 Aug 1990	70				
16349 Germany NEU 1990	Potato Hansa	1. 09 Apr 1990 2. N/D 3. 05 Sep 1990	-	-	-	-	-	Tuber	1.3	14	Control
			0.600	500	120	1. 25 Jun 1990	N/D	Tuber			Funguran OH-50WP
			0.600	500	120	2. 12 Jul 1990	N/D		1.4	0	
			0.600	500	120	3. 20 Jul 1990	N/D		2.0	7	
			0.600	500	120	4. 26 Jul 1990	N/D		1.6	14	
			0.600	500	120	5. 02 Aug 1990	N/D		2.7	21	
			0.600	500	120	6. 15 Aug 1990	70				
16350 Germany NEU 1990	Potato Hansa	1. 17 Apr 1990 2. N/D 3. 23 Aug 1990	-	-	-	-	-	Tuber	1.4	14	Control
			0.600	500	120	1. 19 Jun 1990		Tuber			Funguran-OH 300SC
			0.600	500	120	2. 28 Jun 1990			1.7	0	
			0.600	500	120	3. 05 Jul 1990			2.0	7	
			0.600	500	120	4. 12 Jul 1990			2.0	14	
			0.600	500	120	5. 23 Jul 1990			1.8	21	
			0.600	500	120	6. 02 Aug 1990					

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment kg a.s./ ha	Water [L/ha]	g a.s./hL	Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analysed	Residues Copper [mg/kg]	PHI [days]	Details on trial
	(a)	(b)				(c)				(d)	(e)
16351 Germany NEU 1990	Potato Hansa	1. 09 Apr 1990 2. N/D 3. 05 Sep 1990	-	-	-	-	-	Tuber	1.8	14	Control
			0.600 0.600 0.600 0.600 0.600 0.600	500 500 500 500 500 500	120 120 120 120 120 120	1. 25 Jun 1990 2. 12 Jul 1990 3. 20 Jul 1990 4. 26 Jul 1990 5. 02 Aug 1990 6. 15 Aug 1990		Tuber	1.7 2.0 2.3 1.9	0 7 14 21	Funguran-OH 300SC
16356 Germany NEU 1991	Potato Indira	1. N/D 2. N/D 3. 04 Sep 1991	-	-	-	-	-	Tuber	1.0	14	Control
			0.600 0.600 0.600 0.600 0.600 0.600	500 500 500 500 500 500	120 120 120 120 120 120	1. 04 Jul 1991 2. 17 Jul 1991 3. 24 Jul 1991 4. 31 Jul 1991 5. 07 Aug 1991 6. 14 Aug 1991		Tuber	1.3 1.2 1.4 1.1	0 7 14 21	Funguran OH-50WP
16357 Germany NEU 1991	Potato Indira	1. N/D 2. N/D 3. 04 Sep 1991	-	-	-	-	-	Tuber	1.4	14	Control
			0.600 0.600 0.600 0.600 0.600 0.600	500 500 500 500 500 500	120 120 120 120 120 120	1. 04 Jul 1991 2. 17 Jul 1991 3. 24 Jul 1991 4. 31 Jul 1991 5. 07 Aug 1991 6. 14 Aug 1991		Tuber	1 1.2 1.1 1.1	0 7 14 21	Funguran-OH 300SC
SPI 03885 Germany NEU 1990	Potato Selma	1. 03 Apr 1990 2. 18 Jun – 09 Jul 1990 3. 09 Aug 1990	-	-	-	-	-	Tuber	1.1	14	Control
			0.600 0.600 0.600 0.600 0.600 0.600	400 400 400 400 400 400	150 150 150 150 150 150	1. 28 May 1990 2. 05 Jun 1990 3. 18 Jun 1990 4. 28 Jun 1990 5. 09 Jul 1990 6. 19 Jul 1990	N/D N/D N/D N/D N/D 81/83	Tuber	1.7 1.4 1.6 1.8	0 7 14 21	Funguran OH-50WP
SPI 03881 Germany NEU 1990	Potato Tomensa	1. 03 Apr 1990 2. 18 Jun – 09 Jul 1990 3. 09 Aug 1990	-	-	-	-	-	Tuber	0.9	14	Control
			0.600 0.600 0.600 0.600 0.600 0.600	400 400 400 400 400 400	150 150 150 150 150 150	1. 28 May 1990 2. 05 Jun 1990 3. 18 Jun 1990 4. 28 Jun 1990 5. 09 Jul 1990 6. 19 Jul 1990	N/D N/D N/D N/D N/D 75	Tuber	1.5 1.4 1.3 1.1	0 7 14 21	Funguran-OH 300SC

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analysed	Residues Copper [mg/kg]	PHI [days]	Details on trial
			kg a.s./ ha	Water [L/ha]	g a.s./hL						
	(a)	(b)				(c)				(d)	(e)
SPI 03954 Germany NEU 1990	Potato Tomensa	1. 10 Apr 1990 2. 12 – 30 Jun 1990 3. 15 Aug 1990	-	-	-	-	-	Tuber	3.5	14	Control
			0.600 0.600 0.600 0.600 0.600 0.600	400 400 400 400 400 400	150 150 150 150 150 150	1. 25 May 1990 2. 08 Jun 1990 3. 19 Jun 1990 4. 29 Jun 1990 5. 13 Jul 1990 6. 25 Jul 1990	N/D N/D N/D N/D N/D 75	Tuber	2.3 2.5 2.4 2.9	0 7 14 21	Funguran-OH 300SC
SPI 03955 Germany NEU 1990	Potato Tomensa	1. 10 Apr 1990 2. 12-30 Jun 1990 3. 15 Aug 1990	-	-	-	-	-	Tuber	3.8	14	Control
			0.600 0.600 0.600 0.600 0.600 0.600	400 400 400 400 400 400	150 150 150 150 150 150	1. 25 May 1990 2. 08 Jun 1990 3. 19 Jun 1990 4. 29 Jun 1990 5. 13 Jul 1990 6. 25 Jul 1990		Tuber	3.0 3.5 3.1 3.6	0 7 14 21	Funguran OH-50WP

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N/D not determined
Note: although it is a decline study, residue value at higher PHI were not selected when they were higher than at PHI 7 d. A justification for this deviation is provided in Section 7.2.3.1.

A 2.1.3.1.4 Study 4

A set of two supervised at harvest trials in the NEU zone (2020) was performed with BORDEAUX MIXTURE 20 % WG (FAP13) formulation.

Trial GAP: 6 x 1 kg Copper/ha, interval = 5-8 days, PHI = 7-8 days

The trials were performed at a more critical GAP than proposed and represent a worst case The higher PHI of 8 (instead of 7) in one of the trials is considered acceptable, since Copper is an element and is inherently stable.

Comments of zRMS:	The trials are considered acceptable to support this application.

Reference:	KCA 6.3/04 (Schneider, E., 2021)
Report	Determination of Copper Residues in Potato Raw Agricultural Commodity Following Foliar Applications with BORDEAUX MIXTURE 20 % WG (FAP13) under Field Conditions in Northern Europe in 2020, Schneider, E., 2021, Report No. R CO233
Guideline(s):	Yes, OECD TG 509 (2009), SANCO 7525/VI/95 rev. 10.3 (2017)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The method was successfully validated for the matrices Carrot, Plum, Sugar Beet, Pome Fruit, Kiwi Fruit, Grape, Field Strawberries and Flowering Brassica plant. Sugar beet and carrot belong to the same group, Root and tuber vegetables, as potatoes. LOQ of the analytical method was 832 ppb Cu for sugar beet roots and 1111 ppb Cu for carrot roots. The analytical method was concluded to meet the requirements of the SANCO/3029/99 rev. 4 and SANCO/825/00 rev 8.1 guidance. Acceptable procedural recoveries for potatoes demonstrated that the method can be used for potatoes too.

Table A 2.1- 5: Summary of the study 04 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment*			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha (Copper)	Water (l/ha)	g a.s./hl				Copper		
C0233 ND1 Hazebrouck, 59190, France (North) 2020	Potato / ARTEMIS	Planting: 16 April 2020 Flowering: 28 June to 15 July 2020 Harvest: 16 Sep 2020 to 20 Sep 2020	1000 955.6 966.7 966.7 988.9 988.9	600 573 580 580 593 593	166.7 166.8 166.7 166.7 16.8 166.8	22 Jul 2020 29 Jul 2020 04 Aug 2020 12 Aug 2020 19 Aug 2020 26 Aug 2020	BBCH 49	Tubers	<u>1.07</u>	<u>7</u>	Report reference: Schneider, E., 2021, Report No. R CO233 Analytical method: ICP-MS after acid digestion (Falconer D., 2019 (ANADIAG reference MC668) Date of analysis: 16 Mar 2021; Sample storage : frozen for 6 months Storage of final extracts at room temp.: <. 24 h Acceptable procedural recoveries of 107.5% and 105.3% at levels of 1 and 10 mg/kg, respectively. Conc in untreated sample: c=1.13 mg/kg
C0233 CZ1 Černíkovice, 51601, Czech Republic NEU 2020	Potato / LAURA	Planting: 15 April 2020 Harvest: 11 Sep 2020 to 21 Sep 2020	986.7 968.9 1044.4 1013.3 986.7 968.9	740 727 783 760 740 727	133.3 133.3 133.4 133.3 133.3 133.3	30 Jul 2020 06 Aug 2020 13 Aug 2020 21 Aug 2020 28 Aug 2020 03 Sep 2020	BBCH 49	Tubers	<u>1.22</u>	<u>8</u>	Conc in untreated sample: c=1.24 mg/kg

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
* Medium volume spraying/broadcast spraying
Note: BBCH49 corresponding to BBCH96 of growth plant
Results of studies conducted according to the GAP are underlined.

A 2.1.4 Magnitude of residues in livestock

No new study is submitted for the evaluation of this new product.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new study is submitted for the evaluation of this new product.

A 2.1.5.2 Processing studies on a core set of representative processes

No new study is submitted for the evaluation of this new product.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new study is submitted for the evaluation of this new product.

A 2.1.7 Other/Special Studies

No new study is submitted for the evaluation of this new product.

A 2.2 Cymoxanil

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

A 2.2.1.1.1.1 Study 1

Introduction

This study was submitted, by the Cymoxanil Task Force, for the first time at EU level for the purpose of the active substance renewal (on-going).

RMS Lithuania concluded in the dRAR (Lithuania, 2020): " Residues of Cymoxanil were sufficiently stable for 12 months for homogenised potato tubers when stored at approximately -18°C. This period covers the longest time period for which samples were stored in the field trials provided by Task force.

Acceptable example chromatograms and calibration graphs, Cymoxanil analytical standard analysis and GLP certificates were provided. Study is considered acceptable and used for evaluation.

At 9 month time point the recovery was below 70 % (65 %) and the recovery for fresh fortified sample was quite high (90 %) that could imply the degradation of Cymoxanil during storage. However, the RMS is of the opinion that Cymoxanil is stable for 12 months, since at 12 months time point the recovery was 72 %.

The following deviations from OECD 506 (adopted 16 October 2007) were observed: None."

Summary

Comments of zRMS:	This study was submitted, by the Cymoxanil Task Force, for the first time at EU level for the purpose of the active substance renewal (on-going) Study was not assessed by the zRMS. The stability of residues in potato for Cymoxanil was reviewed during the Annex I inclusion process and still considered adequate to address this endpoint.

Reference:	CA 6.1/02: Weber H. (2011)
Report	Storage stability of Residues of Cymoxanil, Mancozeb and ETU in Potato Samples, Weber, H, 2011, Report no: GAB-0704
Guideline(s):	EU directive 91/414/EEC, EU commission working document 1607/VI/97, Appendix H: storage stability 7032/VI/95 rev 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Executive summary

A deep-freezer storage stability study was conducted to investigate the stability of Cymoxanil, mancozeb and ETU during storage at ≤ -18°C.

The storage stability testing for Cymoxanil was performed with homogenised sample material of whole potato tubers. A set of samples was fortified with 0.20 mg/kg of Cymoxanil. The specimens were stored in coloured (brown) glass jars with screw caps. Stored fortified and stored control samples of homogenised potato (tuber) were analysed at day 0 and after 1, 2, 3, 6, 9, and 12 months.

The specimens were analysed for residue of Cymoxanil using DFG Method S19 (extended revision) with extraction module E1, gel permeation chromatography and analysis by LC-MS/MS.
The recoveries of the stored samples show that Cymoxanil is stable at -18°C or below for at least 12 months.

Materials and methods

Test item: Cymoxanil (Batch 6306X, 99.1% pure)
Test commodity: Homogenised potato tuber

For the analysis for Cymoxanil untreated potatoes (whole tubers) were homogenised using a cutter in the presence of dry ice. A set of samples (50 g) was fortified with 0.20 mg/kg of Cymoxanil. The specimens were stored in coloured (brown) glass jars with screw caps. For the analysis all samples were extracted directly.

Stored fortified and stored control samples of homogenised potato (tuber) were analysed at day 0 and after 1, 2, 3, 6, 9, and 12 months. Freshly fortified samples were prepared and analysed together with the stored fortified samples. At each time point after day 0, one control sample and two stored fortified samples containing Cymoxanil were analysed together with one freshly fortified sample containing Cymoxanil.

The specimens were analysed for residues of Cymoxanil using DFG Method S19 (extended revision) with extraction module E1 and gel permeation chromatography (GPC). Samples are extracted with acetone using a homogeniser. Water is added beforehand in an amount that takes into account the natural water content of the specimen so that during extraction the acetone/water ratio remains constant at 2/1 (v/v). This method has been validated in the report DuPont-35769 (Lakaschus, S., Gizler, A., 2013); please refer to B5 for details. The limit of quantification (LOQ) of the validated method was 0.01 mg/kg for Cymoxanil. The limit of detection (LOD) was 0.003 mg/kg.

Results and discussions

Procedural recoveries

Table below presents an overview on the procedural recoveries for Cymoxanil freshly spiked in homogenised potato tubers. Procedural recoveries at each sampling time were within acceptable limits (in the range 70 to 110%).

Table A 2.2- 1: Summary of concurrent recoveries of Cymoxanil from potato matrix.

Matrix	Spike level (mg/kg)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Potato tubers (homogenised)	0.2 mg a.s./kg	6	78 – 95	87.2 ± 6.4

At 6 time points (1, 2, 3, 6, 9 and 12 months) 1 fortified sample each were analysed.

All recoveries of Cymoxanil residues in homogenised potato tubers were 71 % or greater (72 % when normalised for procedural recovery efficiency), showing that Cymoxanil residues were stable in a freezer for 12 months at approximately -18°C prior to analysis, as shown below. Only the 9 months storage sample was recovered below 70 % (at 64 % and 65 %).

Table A 2.2- 2: Overview on degradation data for Cymoxanil in potato matrices from storage samples fortified with 0.2 mg Cymoxanil/kg

Crop commodity	Storage interval (months)	Results in stored samples after fortification of 0.2 mg/kg				Procedural analysis	
		Residue level after storage (mg/kg)	% Initial level	% Mean Recovery ± RSD%*	% Mean Recovery (Corrected)**	Individual fresh fortifications (mg/kg)	% Mean Recovery
Potatoes (homogenised tuber)	0	0.171, 0.157, 0.180	86, 79, 90	85 ± 7	100	-	-
	1	0.181, 0.169	91, 85	88	102	0.172	86
	2	0.170, 0.164	85, 82	84	88	0.189	95
	3	0.159, 0.157	80, 79	80	92	0.173	87
	6	0.148, 0.151	74, 76	75	96	0.155	78
	9	0.130, 0.127	65, 64	65	72	0.180	90
	12	0.141, 0.144	71, 72	72	83	0.173	87

* - No RSD is calculated as n= 1 or 2
** - Corrected for the procedural recovery of freshly fortified sample in the same set.

Conclusion

The recoveries of the stored samples show that Cymoxanil in potato (tuber) is stable at -18°C or below for at least 12 months. A trend curve was constructed for corrected and for uncorrected recovery in storage samples. In both cases, a time period of 12 months was obtained with recoveries above the 70 % margin.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

No new studies submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Potatoes

Table A 2.2- 3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment kg a.s./ha	Interval between application [days]	Growth stage at last application	PHI (days)
cGAP N-EU -supported by applicant Oxon (DAR, Austria, 2007 and EFSA conclusion, 2008)	4	0.120	7-10	BBCH 95	7
cGAP N-EU -supported by applicant DuPont (DAR, Austria, 2007 and EFSA conclusion, 2008)	6-8	0.175	7-10	BBCH 21 -95	14
cGAP N-EU (Art. 12, EFSA, 2015)	6	0.13	5	BBCH 95	7
Proposed cGAP N-EU-supported by applicant (dRAR, lithuania, 2020)	5	0.15	5	BBCH 95	7
Intended cGAP CEU (use no. 1)	6	0.12	7	BBCH 95	7

A 2.2.3.1.1 Study 01

Introduction

A set of two at-harvest supervised residue trials (2010) in the NEU zone (1 in Northern France and 1 in Poland) was performed with WG formulation FAZ02 containing 50 g/kg Cymoxanil and 680 g/kg mancozeb.

This study has already been assessed according to Uniform Principles and considered acceptable (Austria, 2013). The study has also been submitted for the purpose of the active substance renewal (on-going peer-review). According to RMS in dRAR (Lithuania, 2020) the "study was performed in accordance to OECD 509 and suitable for evaluation."

The trials were performed at a more critical GAP than proposed and represent a worst case. As no residues were detected, rescaling using the proportionality approach is deemed not necessary.
Trials GAP: 8x 0.112-0.135 kg Cymoxanil/ha, interval: 6-8 d, BBCH up to 94-96, PHI= 7 - 8 d

Summary

Comments of zRMS:	Submitted for the first time at EU level by the applicant for the product authorisation of FDJ03 fol-lowing the first inclusion of Cymoxanil (Austria, 2013) and submitted for the active substance re-newal (Lithuania, 2020). As no residues were detected, the overdosed trials (8 applications instead of 6 applications) can be accepted. These trials are considered relevant for this application.

Reference:	KCA 6.3/05, Jonchere F., 2011
Report	Determination of Cymoxanil residues in potatoes following applications of the formulated product FAZ02 (50 g/kg Cymoxanil + 680 g/kg mancozeb WG) under field conditions in Northern Europe – 2010, Jonchere F., 2011, report no R B0163.
Guideline(s):	1607/VI/95 rev. 2 7029/VI/95 rev. 5 (Appendix B) from July 1997 SANCO 3029/99 rev. 4, SANCO 825/00 rev. 7 ENV/JM/MONO(2007)17 SANCO/7525/VI/95 rev.8
Deviations:	At the application No.1 the volume applied was 450 L/ha instead of 400 L/ha (±10%), leading to a deviation of +12.5% of the dose rate. This deviation is considered to have no substantial impact on the study as it concerns the first of the 8 applications
GLP:	Yes
Acceptability:	Yes

Residues were extracted from homogenized specimen with acetonitrile in the presence of magnesium sulfate, sodium chloride and buffering citrate salts. An aliquot of the organic extract was cleaned up by dispersive SPE with PSA and magnesium sulfate. The extract obtained after centrifugation was analysed by QuEChERS LC-MS/MS.

Table A 2.2- 4: Summary of the study 01 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			kg a.s./ ha (Cymoxanil)	Water (l/ha)	kg a.s./hl				Cymoxanil		
B0163 AN1/ Northern France/ NEU/ 2010	Potato/ Nautile	1. 21/04/2010 2. 20/06/ - 03/07/2010 3. 02/08/2010	0.122 0.116 0.124 0.128 0.114 0.126 0.112 0.126	610 581 619 638 571 629 562 629	0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02	17 Jun 2010 23 Jun 2010 29 Jun 2010 05 Jul 2010 13 Jul 2010 20 Jul 2010 26 Jul 2010 03 Aug 2010	BBCH 47/49	Tubers	< 0.02 (NDR < 0.002)	7	Report reference: Jonchere F. 2011 Analytical method: MA726-01; QuEChERS LC-MS/MS after solvent extraction (Richter, S. 2009, Report P/B 1668G) The analytical method was successfully validated (SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 7). LOQ=0.02 mg/kg LOD=0.002 mg/kg. Specimens were frozen within 4h15min after sampling. The samples were stored for up to 182 days from sample to analysis and for <1 day from extraction to analysis, therefore covered by storage stability. Acceptable procedural recoveries: 101% and 105% at levels of 20 and 200 µg/kg during residue analysis for Cymoxanil in potato tubers.
B0163 PL1 Poland NEU 2010	Potato/ Denar	1. 14/04/2010 2. not relevant 3. 21/08/2010	0.135 0.113 0.129 0.125 0.122 0.128 0.126 0.126	450 375 430 415 405 425 420 420	0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03	25 Jun 2010 02 Jul 2010 09 Jul 2010 16 Jul 2010 23 Jul 2010 29 Jul 2010 06 Aug 2010 13 Aug 2010	BBCH 48	Tubers	< 0.02 (NDR < 0.002)	8	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: No detectable residues at harvest (residues below the limit of detection)
Results of studies conducted according to the GAP are underlined.

A 2.2.3.1.2 Study 02

Introduction

Two independents at harvest residue trials were conducted with HARPON WG containing 33% Cymoxanil and 33% zoxamide in Northern Europe (2 trials in Germany) during 2010.

The study has been submitted for the purpose of the active substance renewal (on-going). According to RMS in dRAR (Lithuania, 2020) the "study was performed in accordance to OECD 509 and suitable for evaluation."

The trials were performed at a more critical GAP than proposed and represent a worst case. As no residues were detected, rescaling using the proportionality approach is deemed not necessary.
Trials GAP: 6 x 0.140-0.155 kg a.s./ha, interval= 4-6 d, BBCH 81-89, PHI=6-7 d

Summary

Comments of zRMS:	These trials are considered acceptable and relevant for this application.

Reference:	KCA 6.3/06 (Tetuan B., 2011)
Report	Determination of residues at harvest in potatoes, following six broadcast applications of Harpon WG, under field conditions – Northern Europe – Season 2010 -, Tetuan B., 2011, Report No: 10 F PT GW P/A (PROMO/ZOX-CM/10.01)
Guideline(s):	OECD, ENV/JM/MONO(99)22; OECD, ENV/JM/MONO(2202)9; OECD, ENV/MC/CHEM(98)17
Deviations:	Deviation no 1. Sheet 14 (year 2011) During the preparation of specimens (internal reference: 11-0247 (study specimen reference: 101GWP021SH-001) and internal reference: 11-0245 (study specimen reference: 101GWP011SH-001)), the two control specimens packaging were identified by the same reference. The person, who prepared specimens, made a transcription error. No impact on the study as no residues were found in the specimens.
GLP:	Yes
Acceptability:	Yes.

Table A 2.2- 5: Summary of the study 02 trials

Trial No/ Location/ EU zone/ Year	Commodity/ Variety (a)	Dates of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Method of application	Application rate per treatment			Dates of application, (interval in days) (c)	Growth stage at treatment (BBCH)	Portion analysed	Residues (mg/kg)	PHI (days) (d)	Details on trial s (e)
				kg a.s./ha (Cymoxanil)	Water (l/ha)	kg as/hl				Cymoxanil		
10 F PT GW P01/ Motterwitz, Saxony, D-04668 Germany/ NEU/ 2010	Potato / Alegria	1. 26.May.2010 2. 10-20.Jul.2010 3. 06.Oct.2010	Foliar spray	0.155 0.140 0.151 0.149 0.147 0.154	420 380 408 404 400 420	0.037 0.037 0.037 0.037 0.037 0.037	05/08/10 10/08/10 (5) 16/08/10 (6) 20/08/10 (4) 25/08/10 (5) 30/08/10 (5)	81 81 85 85 85 89	Potato	<0.01	7	Report reference: Tetuan B., 2011 Analytical method: QuEChERS LC-MS/MS after extraction with acetonitrile/2% potassium bicarbonate aqueous solution (80/20, v/v) mixture (Tetuan B., 2011, Report No, 10 F PT GW P/A (PROMO/ZOX-CYM/10.01) The analytical method was fully validated according to SANCO/2020/12830 rev. 1. LOQ = 0.01 mg/kg LOD: not specified Samples were deep frozen within 3.5 hours after sampling at the latest.The samples were stored for up to a maximum of 150 days, therefore covered by storage stability. Acceptable recoveries of 101% (n=5) and 110% (n=5) at levels of 0.01 and 0.1 mg/kg, resp.
10 F PT GW P02/ Kassow, Mecklenburg-West Pomerania, D-18258 Germany/ NEU/ 2010	Potato / Albatros	1. 20.Apr.2010 2. 12-24.Jul.2010 3. 23.Sep.2010	Foliar spray	0.147 0.149 0.150 0.146 0.152 0.147	400 404 408 396 412 400	0.037 0.037 0.037 0.037 0.037 0.037	04/08/10 09/08/10 (5) 15/08/10 (6) 20/08/10 (5) 25/08/10 (5) 29/08/10 (4)	81 81 81-85 85 85 85	Potato	<0.01	6	

(a) According to EEC and Codex class classification;
(b) Only if relevant; (c) Year must be indicated
(d) Days after last application (underline label PHI)
(e) Remarks may include; climatic conditions, reference to analytical methods and LOQ

A 2.2.3.1.3 Study 03

Introduction

Four independent decline supervised trials were conducted with Cymoxanil/mancozeb 4.5/68% w/w WP in Northern Europe (2 trials in Germany, 1 trial in Poland and N. France) during 2007-2008.

The study has been submitted for the purpose of the active substance renewal (on-going). According to RMS in dRAR (Lithuania, 2020) the “study was performed in accordance to OECD 509 and suitable for evaluation.”

The decline trials were performed at a GAP comparable with the intended cGAP.
Trials GAP: 6x 0.106-0.123 g a.s./ha, interval= 3-7 d, BBCH 45-97, (sampling at 0, 3, 7, 14, 21 and 28 DALA).

Summary

Comments of zRMS:	These trials are considered acceptable and relevant for this application.

Reference:	KCA 6.3/07 (Semrau J., 2010)
Report	Determination of residues of Cymoxanil and mancozeb after six applications Cymoxanil/Mancozeb 4.5/68% w/w WP in field potatoes, Northern Europe 2007/2008, Semrau J., 2010. Report No: 20074095/E1-FPPO
Guideline(s):	EU (1999), IVA (1992)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 2.2- 6: Summary of the study 03 trials

Trial No/ Location/ EU zone/ Year	Commodi-ty/ Variety (a)	Dates of 1. Sowing or plant-ing 2. Flowering 3. Harvest (b)	Method of application	Application rate per treatment			Dates of appli-cation, (inter-val in days) (c)	Growth stage at treatment (BBCH)	Portion analysed	Residues (mg/kg)	PHI (days) (d)	Details on trial s (e)
				kg a.s./ha (Cy-moxan-il)	Water (l/ha)	kg as/hl				Cymoxanil		
F07W133R/ F-56680 Plouhinec, Bretagne, France/ NEU/ 2007	Potato / Ondine	1. 20.Apr.2007 2. 14.Jun-10.Jul.2007 3. 16.Aug.2007	Foliar spray	0.123 0.115 0.113 0.117 0.123 0.115	315 295 288 297 315 295	0.039 0.039 0.039 0.039 0.039 0.039	18/07/07 25/07/07 (7) 30/07/07 (5) 02/08/07 (3) 08/08/07 (6) 13/08/07 (5)	73 81 91 91 93 97	Potato Potato Potato Potato Potato Potato	N.D. N.D. N.D. N.D. N.D. N.D.	0 3 7 14 21 28	Report reference: Semrau J., 2010 Analytical method: DFG S19 (extended revision) with extrac-tion E1 and GPC, LC-MS/MS (Weber H., 2008, GAB-0703V)
G07W344R/ D-16356 Blumberg, Brandenburg, Germany/ NEU/ 2007	Potato / Kormoran	1. 17.Apr.2007 2. 02.Jun-05.Jul .2007 3. 09.Aug.2007	Foliar spray	0.115 0.117 0.122 0.118 0.122 0.119	294 299 311 300 313 304	0.039 0.039 0.039 0.039 0.039 0.039	13/07/07 16/07/07 (3) 23/07/07 (7) 26/06/07 (3) 02/08/07 (6) 06/08/07 (4)	719 95 95-97 95-97 95-97 97	Potato Potato Potato Potato Potato Potato	N.D. N.D. N.D. N.D. N.D. N.D.	0 3 7 14 21 28	The analytical method was fully validated according to SAN-CO/3029/99 rev. 4. LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
PL07W020R/ PL-64-500 Brodziszewo Wielkopolska, Poland/ NEU/ 2007	Potato / Pasat	1. 13.Apr.2007 2. NA 3. 09.Oct.2007	Foliar spray	0.109 0.117 0.109 0.110 0.122 0.123	279 298 279 281 312 313	0.039 0.039 0.039 0.039 0.039 0.039	11/09/07 17/09/07 (6) 21/09/07 (4) 26/09/07 (5) 01/10/07 (5) 06/10/07 (5)	49 49 49 49 49 49	Potato Potato Potato Potato Potato Potato	N.D. N.D. N.D. N.D. N.D. N.D.	0 3 7 14 21 28	Samples were deep frozen within 4.5 hours after sampling at the latest. Samples from these trials were stored frozen for maximum of 280 days, therefore covered by storage stability.
S08-02370-01/ D-71277 Rutesheim-Perouse, Baden-Wurttemberg, Germany/ NEU/2008	Potato / Nicola	1. 30.Apr.2008 2. NA 3. 01.Sep.2008	Foliar spray	0.111 0.106 0.121 0.116 0.108 0.120	283 270 308 295 275 305	0.039 0.039 0.039 0.039 0.039 0.039	01/08/08 07/08/08 (6) 13/08/08 (6) 19/08/08 (6) 25/08/08 (6) 29/08/08 (4)	45 46 47 48 48 48	Potato Potato Potato Potato Potato Potato	N.D. N.D. N.D. N.D. N.D. N.D.	0 3 7 14 21 28	Acceptable procedural recoveries of 87-99% (n=4) and 89-1030% (n=4) at levels of 0.01 and 0.1 mg/kg, resp.

(a) According to EEC and Codex class classification
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (underline label PHI)
(e) Remarks may include; climatic conditions, reference to analytical methods and LOQ

A 2.2.3.1.4 Study 04

Introduction

Four at harvest supervised residue trials (2006) were conducted with DPX-T3217-213 (Cymoxanil 60 WG) containing 60 % Cymoxanil) in northern Europe (2 in UK, 1 in The Netherlands and 1 in Germany).

The study has been submitted for the purpose of the active substance renewal (on-going). According to RMS in dRAR (Lithuania, 2020) the "study was performed in accordance to OECD 509 and suitable for evaluation."

The trials were performed at a more critical GAP than proposed and represent a worst case. As no residues were detected, rescaling using the proportionality approach is deemed not necessary.
Trials GAP: 12 x 0.112-0.126 kg a.s./ha, interval= 5 d, BBCH 33-99, Sampling at 0 DALA

Trials No 1 and 4 were conducted at the locations less than 3 km distance from each other with applications made 15 days apart, these two trials are not considered independent. Therefore three residue values (underlined in table, all <LOQ) were used in the risk assessment.

Summary

Comments of zRMS:	These trials are considered not relevant for this application due to PHI of 0 days. This is not consistent with what is proposed in the intended GAP.

Reference:	KCA 6.3/08 (Old J., Hansford R., 2007)
Report	Magnitude of residues of Cymoxanil in potatoes following applications of Cymoxanil 60WG – Northern Europe, Season 2006, Old J., Hansford R., 2007, report no DuPont-20033.
Guideline(s):	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Cymoxanil is extracted from homogenized samples with acetone. Water is added beforehand in an amount that takes into account the natural water content of the tomato specimen so that during extraction the acetone:water ratio remains constant at 2/1 (v/v). After addition of NaCl and ethyl-acetate/cyclohexane and repeated homogenization, the organic phase containing Cymoxanil is allowed to separate from the aqueous layer. The extract is concentrated and subjected to gel permeation chromatography (GPC). The GPC eluate is concentrated and fractionated on Bio Beads S-X3 (polystyrene gel) using a mixture of ethyl acetate and cyclohexane. Cymoxanil is determined by LC-MS/MS.
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Table A 2.2- 7: Summary of the study 04 trials

Trial No/ Location/ EU zone/ Year	Commodi-ty/ Variety (a)	Dates of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Method of application	Application rate per treatment			Dates of appli-cation, (inter-val in days) (c)	Growth stage at treatment (BBCH)	Portion analysed	Residues (mg/kg)	PHI (days) (d)	Details on trials (e)
				kg a.s./ha (Cy-moxan-il)	Water (l/ha)	kg as/hl				Cymoxanil		
Trial No 1 Ramsey, Harwich, Essex, CO12 5DN UK NEU/ 2006	Potato / Maris Bard	1. 21.Mar.2006 2. NA 3. 10.Aug.2006	Foliar spray	0.122 0.121 0.121 0.122 0.122 0.121 0.121 0.121 0.119 0.121 0.124 0.122	407 404 402 406 404 402 402 400 397 403 412 404	0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030	15/06/06 21/06/06 (6) 26/06/06 (5) 30/06/06 (4) 05/07/06 (5) 10/07/06 (5) 14/07/06 (4) 20/07/06 (6) 25/07/06 (5) 31/07/06 (6) 04/08/06 (4) 10/08/06 (6)	67 70 72 80 82 83 84 85 86 87 88 89	Potato	ND	0	Report reference: Old J., Hansford R., 2007 Analytical method:. DFG S19 (extended revision) with extraction E1 and GPC, LC-MS/MS (Lakaschus, 2004, report DuPont-15026) The analytical method was fully validated according to SANCO/3029/99 rev. 4. Potatoes: LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Samples were deep frozen within 5.5 hours after sampling at the latest. Specimens from these trials were stored frozen for 195 days, therefore covered by storage stability. Extracts were stored for up to 5 days before analysis. Acceptable procedural recover-ies of 81-85% (n=2) and 79-81% (n=2) at levels of 0.01 and 0.1 mg/kg, resp.
Trial No 2/ Goch-Nierswalde, North Rhine-Westphalia, D-47574 Germany/ NEU/ 2006	Potato / Estima	1. 04.Mar.2006 2. NA 3. 17.Aug.2006	Foliar spray	0.117 0.112 0.117 0.123 0.126 0.125 0.118 0.125 0.125 0.125 0.120 0.125	389 370 389 407 419 415 391 415 415 415 400 415	0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030	28/06/06 03/07/06 (6) 07/07/06 (5) 13/07/06 (4) 17/07/06 (5) 24/07/06 (5) 27/07/06 (4) 02/08/06 (6) 08/08/06 (5) 11/08/06 (6) 17/08/06 (4) 22/08/06 (6)	33 39 61 61 69 43 44 44 45 45 47 49	Potato	ND	0	
Trial No 3/ ME Ottersum, Limburg, NL-6595 The Netherlands/ NEU/ 2006	Potato / Bintje	1. 11.Apr.2006 2. NA 3. 22.Aug.2006	Foliar spray	0.119 0.118 0.122 0.122 0.117 0.118 0.121	397 393 407 407 390 392 402	0.030 0.030 0.030 0.030 0.030 0.030 0.030	28/06/06 03/07/06 (5) 07/07/06 (4) 13/07/06 (6) 17/07/06 (4) 24/07/06 (7) 27/07/06 (3)	61 65 65 69 43 43 44	Potato	ND	0	

				0.122	407	0.030	02/08/06 (6)	44				
				0.120	400	0.030	07/08/06 (5)	44				
				0.121	403	0.030	11/08/06 (4)	45				
				0.120	400	0.030	17/08/06 (6)	47				
				0.121	403	0.030	22/08/06 (5)	49				
Trial No 4/	Potato /	1. 23.Mar.2006	Foliar spray	0.122	406	0.030	30/06/06	67	Potato	ND	0	
Ramsey, Harwich,	Desiree	2. NA		0.119	397	0.030	05/07/06 (5)	69				
Essex, CO12 5LH		3. 25.Aug.2006		0.121	402	0.030	10/07/06 (5)	72				
UK/				0.122	404	0.030	14/07/06 (4)	76				
NEU/				0.119	394	0.030	20/07/06 (6)	80				
2006				0.122	405	0.030	25/07/06 (5)	84				
				0.123	408	0.030	31/07/06 (6)	86				
				0.124	412	0.030	04/08/06 (4)	87				
				0.124	412	0.030	10/08/06 (6)	88				
				0.122	404	0.030	15/08/06 (5)	89				
				0.121	402	0.030	19/08/06 (4)	90				
				0.120	399	0.030	25/08/06 (6)	90-99				

(a) According to EEC and Codex class classification
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (underline label PHI)
(e) Remarks may include; climatic conditions, reference to analytical methods and LOQ
ND: Not detected
NA: Not available

A 2.2.3.1.5 Study 05

Introduction

Four at harvest supervised residue trials were conducted with DPX-T3217-213 (Cymoxanil 60 WG) containing 60 % Cymoxanil in northern Europe (2 in UK, 1 in The Netherlands and 1 in Germany) during 2007.

The study has been submitted for the purpose of the active substance renewal (on-going). According to RMS in dRAR (Lithuania, 2020) the "study was performed in accordance to OECD 509 and suitable for evaluation."

The trials were performed at a more critical GAP than proposed and represent a worst case. As no residues were detected, rescaling using the proportionality approach is deemed not necessary.
Trials GAP: 12 x 0.115-0.125 kg a.s./ha, interval= 5 d, BBCH 55-98, Sampling at 0 DALA

Summary

Comments of zRMS:	These trials are considered not relevant for this application due to PHI of 0 days. This is not consistent with what is proposed in the intended GAP.

Reference:	KCA 6.3/09 (Livingstone K., Haigh I. M, 2008)
Report	Magnitude of residues of Cymoxanil in potatoes following applications of Cymoxanil 60WG – Northern Europe, Season 2007, Livingstone K., Haigh I. M, 2008. Document no.: DuPont-22006
Guideline(s):	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Cymoxanil is extracted from homogenized samples with acetone. Water is added beforehand in an amount that takes into account the natural water content of the tomato specimen so that during extraction the acetone:water ratio remains constant at 2/1 (v/v). After addition of NaCl and ethyl-acetate/cyclohexane and repeated homogenization, the organic phase containing Cymoxanil is allowed to separate from the aqueous layer. The extract is concentrated and subjected to gel permeation chromatography (GPC). The GPC eluate is concentrated and fractionated on Bio Beads S-X3 (polystyrene gel) using a mixture of ethyl acetate and cyclohexane. Cymoxanil is determined by LC-MS/MS.

Table A 2.2- 8: Summary of the study 05 trials

Trial No/ Location/ EU zone/ Year	Commodi-ty/ Variety	Dates of 1. Sowing or planting 2. Flowering 3. Harvest	Method of application	Application rate per treatment			Dates of appli-cation, (inter-val in days)	Growth stage at treatment (BBCH)	Portion analysed	Residues (mg/kg)	PHI (days)	Details on trials
	(a)	(b)		kg a.s./ha (Cy-moxan-il)	Water (l/ha)	kg as/hl	€		(a)	Cy-moxanil	(d)	€
Trial No 1/ Ramsey, Har-wich, Essex, CO12 5LH UK NEU/ 2007	Potato / Desiree	1. 10.Mar.2007 2. NA 3. 17.Aug.2007	Foliar spray	0.121 0.119 0.119 0.125 0.119 0.119 0.122 0.123 0.121 0.122 0.123 0.124	403 394 397 414 397 397 406 409 400 404 408 410	0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030	21/06/07 26/06/07 (5) 01/07/07 (5) 07/07/07 (6) 11/07/07 (4) 16/07/07 (5) 21/07/07 (5) 26/07/07 (5) 31/07/07 (5) 05/08/07 (5) 10/08/07 (5) 17/08/07 (7)	69 71 73 75 81 91 91 92 91 91 98 98	Potato tuber	<u>ND</u>	<u>0</u>	Report reference: (Livingstone K., Haigh I. M, 2008) Analytical method:. DFG S19 (ex-tended revision) with extraction E1 and GPC, LC-MS/MS (Lakaschus, 2004, report DuPont-15026) The analytical method was fully validated according to SAN-CO/3029/99 rev. 4. LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Samples were deep frozen within 12 hours after sampling. Specimens from these trials were stored frozen for 211 days, therefore covered by storage stability. Extracts were stored for up to 4 days before analysis Acceptable procedural recoveries of 82-93% (n=2) and 82-85% (n=2) at levels of 0.01 and 0.1 mg/kg, resp.
Trial No 2 Clacton-on-sea, Essex, CO16 0AR UK NEU/ 2007	Potato / Estima	1. 04.Mar.2007 2. NA 3. 17.Aug.2007	Foliar spray	0.121 0.122 0.121 0.122 0.124 0.123 0.125 0.123 0.121 0.122 0.121 0.122	401 404 400 406 411 408 415 409 401 406 400 406	0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030	21/06/07 26/06/07 (5) 01/07/07 (5) 07/07/07 (6) 11/07/07 (4) 16/07/07 (5) 21/07/07 (5) 26/07/07 (5) 31/07/07 (5) 05/08/07 (5) 10/08/07 (5) 17/08/07 (7)	55 57 57 67 77 90 90 91 91 91 95 98	Potato tuber	<u>ND</u>	<u>0</u>	
Trial No 3 MS Ottersum, Limburg, NL-6595 The Netherlands NEU 2007	Potato / Kardal	1. 27.Apr.2007 2. NA 3. 10.Aug.2007	Foliar spray	0.120 0.117 0.122 0.123 0.117 0.121 0.117 0.121 0.121	400 390 407 410 390 403 390 403 403	0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030	15/06/07 20/06/07 (5) 25/06/07 (5) 30/06/07 (5) 05/07/07 (5) 10/07/07 (5) 15/07/07 (5) 20/07/07 (5) 25/07/07 (5)	55 59 59 61 65 67 67 67 67	Potato tubers	<u>ND</u>	<u>0</u>	

				0.118 0.124 0.115	393 413 383	0.030 0.030 0.030	30/07/07 (5) 04/08/07 (5) 10/08/07 (6)	67 79 87				
Trial No 4 D-47574 Goch- Nierswalde, North Rhine, NL- 6595 Germany NEU 2007	Potato / Kardal	1. 21.Apr.2007 2. NA 3. 10.Aug.2007	Foliar spray	0.119 0.120 0.125 0.120 0.125 0.116 0.116 0.115 0.121 0.123 0.117 0.116	397 400 417 400 417 387 387 383 403 410 390 387	0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030 0.030	15/06/07 20/06/07 (5) 25/06/07 (5) 30/06/07 (5) 05/07/07 (5) 10/07/07 (5) 15/07/07 (5) 20/07/07 (5) 25/07/07 (5) 30/07/07 (5) 04/08/07 (5) 10/08/07 (6)	55 59 59 61 65 67 67 67 67 67 79 85	Potato tubers	ND	0	

(a) According to EEC and Codex class classification
(b) Only if relevant
€ Year must be indicated
(d) Days after last application (underline label PHI)
€ Remarks may include; climatic conditions, reference to analytical methods and LOQ
ND: Not detected

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new studies submitted

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.2.5.1 Distribution of the residue in peel/pulp

No new studies submitted

A 2.2.5.2 Processing studies on a core set of representative processes

No new studies submitted

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies submitted

A 2.2.7 Other/Special Studies

No new studies submitted

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Not calculated

A 3.2 IEDI calculations

Copper -Tier I

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Copper			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0,15	ARfD (mg/kg bw):	insert valid entry
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2012	Year of evaluation:	

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
122%	NL toddler	183,60	12%	Apples	11%	Maize/corn	11%	Wheat		
86%	GEMS/Food G11	128,68	30%	Soyabeans	10%	Wheat	5%	Potatoes		
82%	GEMS/Food G07	122,53	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		
81%	GEMS/Food G10	122,07	26%	Soyabeans	11%	Wheat	4%	Lettuces		
76%	NL child	113,37	11%	Wheat	9%	Sugar beet roots	6%	Apples		
76%	GEMS/Food G06	113,30	20%	Wheat	10%	Soyabeans	4%	Table grapes		
75%	GEMS/Food G08	112,34	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		
72%	GEMS/Food G15	107,66	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		
67%	DE child	99,80	14%	Apples	12%	Wheat	6%	Table grapes		
66%	FI adult	98,33	52%	Coffee beans	2%	Lettuces	2%	Rye		
64%	IE adult	96,39	14%	Sheep: Liver	6%	Wheat	5%	Wine grapes		
56%	FR child 3 15 yr	84,00	13%	Wheat	4%	Sugar beet roots	4%	Milk: Cattle		
51%	RO general	76,99	14%	Wheat	8%	Sunflower seeds	7%	Wine grapes		
50%	DK child	75,64	13%	Rye	12%	Wheat	3%	Oat		
47%	FR toddler 2 3 yr	70,41	8%	Wheat	5%	Milk: Cattle	4%	Apples		
47%	PT general	70,21	11%	Wheat	10%	Wine grapes	6%	Potatoes		
44%	ES child	65,35	12%	Wheat	6%	Lettuces	3%	Poultry: Muscle/meat		
42%	NL general	63,20	5%	Wheat	3%	Sugar beet roots	3%	Potatoes		
41%	UK infant	61,78	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		
41%	DE women 14-50 yr	60,82	6%	Wheat	5%	Sugar beet roots	4%	Coffee beans		
40%	DE general	60,25	5%	Wheat	4%	Coffee beans	4%	Sugar beet roots		
40%	UK toddler	59,27	11%	Wheat	4%	Potatoes	4%	Beans		
39%	IT toddler	58,06	18%	Wheat	4%	Other cereals	4%	Lettuces		
38%	FR adult	57,32	10%	Wine grapes	6%	Wheat	4%	Coffee beans		
35%	SE general	53,17	9%	Wheat	5%	Lettuces	5%	Potatoes		
33%	ES adult	49,34	7%	Lettuces	6%	Wheat	2%	Wine grapes		
31%	IT adult	46,02	11%	Wheat	5%	Lettuces	2%	Other lettuce and other salad plants		
27%	FI 3 yr	40,04	5%	Potatoes	4%	Oat	3%	Wheat		
23%	FR infant	34,50	4%	Spinaches	3%	Milk: Cattle	2%	Potatoes		
23%	UK vegetarian	34,44	6%	Wheat	3%	Wine grapes	2%	Lettuces		
22%	UK adult	33,23	5%	Wheat	4%	Wine grapes	2%	Potatoes		
22%	FI 6 yr	32,63	5%	Potatoes	3%	Wheat	2%	Oat		
20%	LT adult	30,49	4%	Potatoes	3%	Wheat	3%	Rye		
20%	DK adult	29,65	4%	Wine grapes	3%	Wheat	1%	Potatoes		
12%	PL general	17,84	4%	Potatoes	2%	Apples	1%	Table grapes		
7%	IE child	11,03	3%	Wheat	0,7%	Potatoes	0,6%	Milk: Cattle		

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 122,4 % of the ADI.
For 1 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Copper-Tier II

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Copper

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0,15**	ARfD (mg/kg bw):	**insert valid entry**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2012**	Year of evaluation:	

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
94%	NL toddler	141,30	11%	Maize/corn	11%	Wheat	10%	Milk: Cattle		
74%	GEMS/Food G11	110,51	30%	Soyabeans	10%	Wheat	3%	Coffee beans		
71%	GEMS/Food G10	106,89	26%	Soyabeans	11%	Wheat	3%	Poultry: Muscle/meat		
69%	GEMS/Food G07	103,30	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		
68%	GEMS/Food G06	101,66	20%	Wheat	10%	Soyabeans	4%	Tomatoes		
63%	GEMS/Food G08	94,81	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		
63%	GEMS/Food G15	94,05	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		
61%	FI adult	91,59	52%	Coffee beans	2%	Rye	1%	Oat		
60%	NL child	90,40	11%	Wheat	9%	Sugar beet roots	5%	Sunflower seeds		
55%	IE adult	81,99	14%	Sheep: Liver	6%	Wheat	4%	Sweet potatoes		
48%	FR child 3 15 yr	72,60	13%	Wheat	4%	Sugar beet roots	4%	Milk: Cattle		
46%	DE child	69,31	12%	Wheat	4%	Apples	3%	Milk: Cattle		
44%	DK child	66,36	13%	Rye	12%	Wheat	3%	Oat		
42%	RO general	62,50	14%	Wheat	8%	Sunflower seeds	2%	Tomatoes		
40%	FR toddler 2 3 yr	59,77	8%	Wheat	5%	Milk: Cattle	3%	Sugar beet roots		
37%	UK infant	55,61	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		
35%	ES child	53,20	12%	Wheat	3%	Poultry: Muscle/meat	2%	Milk: Cattle		
34%	UK toddler	51,42	11%	Wheat	4%	Beans	3%	Sugar beet roots		
33%	NL general	48,89	5%	Wheat	3%	Sugar beet roots	3%	Coffee beans		
32%	PT general	48,30	11%	Wheat	4%	Sunflower seeds	3%	Potatoes		
32%	DE general	47,78	5%	Wheat	4%	Coffee beans	4%	Sugar beet roots		
32%	DE women 14-50 yr	47,56	6%	Wheat	5%	Sugar beet roots	4%	Coffee beans		
31%	IT toddler	47,17	18%	Wheat	4%	Other cereals	2%	Tomatoes		
26%	FR adult	39,45	6%	Wheat	4%	Coffee beans	2%	Wine grapes		
26%	SE general	39,28	9%	Wheat	3%	Bovine: Muscle/meat	2%	Potatoes		
23%	ES adult	34,44	6%	Wheat	1%	Poultry: Muscle/meat	1%	Barley		
21%	IT adult	32,23	11%	Wheat	2%	Other cereals	1%	Tomatoes		
21%	FI 3 yr	30,94	4%	Oat	3%	Wheat	3%	Potatoes		
17%	FR infant	25,05	3%	Milk: Cattle	2%	Wheat	2%	Leeks		
17%	UK vegetarian	24,79	6%	Wheat	2%	Beans	0,8%	Potatoes		
16%	FI 6 yr	24,53	3%	Wheat	2%	Oat	2%	Potatoes		
16%	LT adult	24,16	3%	Wheat	3%	Rye	2%	Potatoes		
16%	UK adult	23,36	5%	Wheat	1%	Beans	1,0%	Poultry: Muscle/meat		
13%	DK adult	19,66	3%	Wheat	1%	Rye	0,8%	Milk: Cattle		
7%	PL general	10,32	2%	Potatoes	1%	Tomatoes	0,7%	Apples		
6%	IE child	9,51	3%	Wheat	0,6%	Milk: Cattle	0,5%	Rice		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Copper is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Cymoxanil

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Cymoxanil

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,013	ARfD (mg/kg bw):	0,08
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	PT general	0,23	1,0%	Wine grapes	0,4%	Potatoes	0,1%	Table grapes		1%
2%	NL toddler	0,22	0,6%	Table grapes	0,3%	Potatoes	0,3%	Beans (with pods)		1%
1%	RO general	0,18	0,6%	Wine grapes	0,3%	Potatoes	0,1%	Tomatoes		1%
1%	IE adult	0,18	0,5%	Wine grapes	0,2%	Potatoes	0,1%	Aubergines/egg plants		1%
1%	GEMS/Food G07	0,17	0,6%	Wine grapes	0,3%	Potatoes	0,1%	Table grapes		1%
1%	GEMS/Food G06	0,17	0,4%	Table grapes	0,3%	Tomatoes	0,2%	Potatoes		1%
1%	FR adult	0,16	0,9%	Wine grapes	0,1%	Beans (with pods)	0,1%	Potatoes		1%
1%	GEMS/Food G11	0,15	0,4%	Wine grapes	0,3%	Potatoes	0,2%	Table grapes		0,9%
1%	GEMS/Food G08	0,14	0,4%	Wine grapes	0,3%	Potatoes	0,1%	Table grapes		0,8%
1%	GEMS/Food G15	0,14	0,4%	Wine grapes	0,3%	Potatoes	0,1%	Table grapes		0,8%
1%	DE child	0,13	0,5%	Table grapes	0,2%	Potatoes	0,1%	Tomatoes		0,8%
1,0%	NL child	0,13	0,4%	Table grapes	0,3%	Potatoes	0,1%	Beans (with pods)		0,7%
0,9%	FR child 3 15 yr	0,12	0,2%	Beans (with pods)	0,1%	Wine grapes	0,1%	Table grapes		0,8%
0,8%	GEMS/Food G10	0,11	0,2%	Potatoes	0,2%	Wine grapes	0,1%	Table grapes		0,6%
0,8%	FR toddler 2 3 yr	0,10	0,3%	Beans (with pods)	0,1%	Potatoes	0,1%	Wine grapes		0,6%
0,8%	NL general	0,10	0,2%	Wine grapes	0,2%	Potatoes	0,1%	Table grapes		0,6%
0,7%	UK toddler	0,09	0,3%	Potatoes	0,1%	Beans	0,1%	Peas (without pods)		0,5%
0,7%	UK adult	0,09	0,4%	Wine grapes	0,1%	Potatoes	0,0%	Peas (without pods)		0,6%
0,7%	UK vegetarian	0,09	0,3%	Wine grapes	0,1%	Potatoes	0,1%	Beans		0,6%
0,7%	DE women 14-50 yr	0,09	0,3%	Wine grapes	0,1%	Table grapes	0,1%	Potatoes		0,6%
0,7%	FI 3 yr	0,09	0,4%	Potatoes	0,1%	Table grapes	0,1%	Cucumbers		0,3%
0,7%	SE general	0,09	0,3%	Potatoes	0,1%	Tomatoes	0,0%	Onions		0,4%
0,7%	DK adult	0,09	0,4%	Wine grapes	0,1%	Potatoes	0,1%	Table grapes		0,6%
0,7%	DE general	0,09	0,3%	Wine grapes	0,1%	Table grapes	0,1%	Potatoes		0,6%
0,6%	UK infant	0,08	0,3%	Potatoes	0,2%	Peas (without pods)	0,1%	Beans		0,4%
0,6%	ES adult	0,07	0,2%	Wine grapes	0,1%	Beans (with pods)	0,1%	Potatoes		0,5%
0,6%	FI 6 yr	0,07	0,3%	Potatoes	0,1%	Table grapes	0,1%	Cucumbers		0,3%
0,5%	PL general	0,07	0,3%	Potatoes	0,1%	Table grapes	0,1%	Tomatoes		0,3%
0,5%	FR infant	0,07	0,2%	Beans (with pods)	0,1%	Potatoes	0,0%	Spinaches		0,4%
0,5%	ES child	0,07	0,1%	Potatoes	0,1%	Beans (with pods)	0,1%	Tomatoes		0,4%
0,5%	DK child	0,06	0,2%	Potatoes	0,1%	Cucumbers	0,1%	Table grapes		0,3%
0,4%	IT toddler	0,05	0,1%	Tomatoes	0,1%	Potatoes	0,0%	Table grapes		0,3%
0,4%	IT adult	0,05	0,1%	Tomatoes	0,1%	Beans (with pods)	0,1%	Table grapes		0,4%
0,4%	LT adult	0,05	0,2%	Potatoes	0,0%	Tomatoes	0,0%	Cucumbers		0,1%
0,4%	FI adult	0,05	0,1%	Wine grapes	0,1%	Potatoes	0,0%	Tomatoes		0,3%
0,1%	IE child	0,02	0,0%	Potatoes	0,0%	Beans (without pods)	0,0%	Table grapes		0,1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Cymoxanil is unlikely to present a public health concern.

A 3.3 IESTI calculations

Copper

Not required as an ARfD for Copper has not been set.

Cymoxanil

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Potatoes	0 / 0,01	1,5	0,4%	Potatoes	0 / 0,01	0,30

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Potatoes / fried	0 / 0,01	0,93	0,1%	Potatoes / dried (flakes)	0 / 0,05	0,06
0,7%	Potatoes / dried (flakes)	0 / 0,05	0,59	0,0%	Potatoes / chips	0 / 0,01	0,03

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Cymoxanil is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

None.