REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: IN002B1760

Product name: Cymofil

Chemical active substance:

Cymoxanil, 450 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: August 2022

MS Finalisation date: May 2023 (initial Core Assessment)

September 2023 (final Core Assessment)

April 2024, updated May 2024

(final Core Assessment following the commenting period - 2 nd tour)

Version history

When	What
April 2022	Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS, ~~Malta~~ Poland, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009
May 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
September 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through~~ and shaded.
April 2024	Core Assessment updated following the commenting period 2 nd tour. Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in purple. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
May 2024	Final report (National Assessment updated after the correction of Appendix 4 prepared by the Applicant) In order to facilitate tracking of changes in the Lists of data considered for national authorization (Appendix 4), amendments are highlighted in turquoise, while not agreed use pattern is ~~struck through~~ and shaded.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification
The critical GAPs with respect to consumer intake and risk assessment for the preparation IN002B1760 are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central EU for all crops. In the Central EU potato is the only intended field use, as showed in Part B, Section 0.

Overall conclusion
The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01* mg/kg for potatoes for cymoxanil as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of cymoxanil residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland, the zRMS agrees with the authorization of the intended use.

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

Data gaps
No data gaps were identified.

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	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop) **	F, Fn, Fpn G, Gn, Gpn or I ***	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
~~2~~ 1	~~MT, IT, ES, FR, PT, EL, CY, HR~~ DE, CZ, BE, NL, AT, SI, IE, PL	Potato (0211000)	F	Late blight (*Phythophtora infestans*)	Foliar spray	BBCH 12-95	6	5-10	a) 0.33 b) 1.98	a) 148.5 b) 891	300-500 ~~150-1000~~	7	250-330 g product/ha	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 15 “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

7.1.2 Summary of the evaluation

The preparation IN002B1760 is composed of cymoxanil.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of cymoxanil

Reference value	Source	Year	Value	Study relied upon	Safety factor
Cymoxanil - Parent compound					
ADI	EFSA	2008	0.013 mg/kg bw	1 year dog study	100
ARfD	EFSA	2008	0.08 mg/kg bw/day	developmental NOAEL in the rabbit	100

7.1.2.1 Summary for cymoxanil

Table 7.1-3: 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?
~~2~~ 1	Potatoes	Yes	Yes (4 NEU; ~~4 SEU~~)	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

As residues of cymoxanil do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

7.1.2.2 Summary for IN002B1760

Table 7.1-4: Information on IN002B1760 (KCA 6.8)

Crop	PHI for IN002B1760 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for IN002B1760 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Cymoxanil		
Potatoes	7 days	Yes	7 days	-

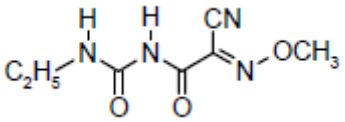
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Cymoxanil

General data on cymoxanil are summarized in the table below (last updated 2021/10/27)

Table 7.2-1: General information on cymoxanil

Active substance (ISO Common Name)	Cymoxanil
IUPAC	*1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea*
Chemical structure	
Molecular formula	$C_7H_{10}N_4O_3$
Molar mass	198.2 g/mol
Chemical group	Cyanoacetamideoxime
Mode of action (if available)	FRAC code 27, unknown mode of action
Systemic	Yes
Company (ies)	DuPont de Nemours SAS Oxon Italia SpA Indofil Industries (Netherlands) B.V.
Rapporteur Member State (RMS)	Austria
Approval status	Approved Date of (01/09/2009) and reference to decision (COMMISSION DIRECTIVE 2008/125/EC; REGULATION (EU) No 2017/195; REGULATION (EU) No 2021/745) Reg. (EU) 2022/708, Reg. (EU) 2023/1446
Restriction (e.g. is restricted to use as "...")	Only uses as fungicide may be authorised
Review Report	SANCO/179/08 – final rev. 1 09/07/2010
Current MRL regulation	~~Regulation (EC) No 832/2018~~ 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
EFSA Journal: conclusion on article 12	Yes – EFSA, 2015, 2019
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Data were available and were evaluated during the review of MRLs according to Art. 12 of Reg. 396/2005 (Evaluation Report prepared by Austria, 2013 and EFSA RO, 2015).
No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Tomato	High water content	≤ 18 months	Austria, 2013
Sunflower seed	High oil content	18 months	Austria, 2013
Grapes	High acid content	24 months	Austria, 2013
Lettuce	High water content	12 months	DAR, 2007
Homogenised potato tuber	High starch content	12.5 months	DAR, 2007
Animal Products			
Not available and not required			

Conclusion on stability of residues during storage
According to the available data, new studies on stability of residues are not needed as stability was proved for high water matrices (tomato) and high acid content (grapes) up to 18 months at -18°C.

zRMS comments:
In DAR on Cymoxanil, Vol. 1 (Austria, 2007) it is stated that *Without significant decrease in the residue level, the storage stability of cymoxanil under frozen conditions (about -20 ºC and darkness) was demonstrated at least for 30 days in homogenised lettuce and 12 months in whole lettuce plant (Oxon). On the above described conditions, potato tuber homogenates were stable at least for 12.5 months (DuPont). A storage stability for whole potato tuber was not performed.*

The residue data are valid with regard to storage stability.
The stability of residues during storage of cymoxanil in potato is sufficiently addressed to support the proposed use of the product IN002B1760. No additional study is required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
Residues in sample extracts were considered to be stable within the time frame of the analytical procedure as the procedural recoveries in the residue studies demonstrate the stability of cymoxanil during storage in extracts prior to analysis.

Conclusion on stability of residues in sample extracts
On the basis of the relevant data, the residues in sample extracts were considered to be stable within the time frame of the analytical procedure for the intended use.
Additional data are considered as not relevant as samples were stored for less than 24 hours after extraction.

Evaluator comments:
Information given by the Applicant is sufficient.
No further data are required.

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
Data were available and were evaluated during the peer review (Austria, 2007) and during the review of MRLs according to Art. 12 of Reg. 396/2005 (Evaluation Report prepared by Austria, 2013 and EFSA RO, 2015).

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Application and sampling details					Reference
		Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data							
Fruits and fruiting vegetable	Tomatoes[a]	Foliar, F	0.63	3	3		Austria, 2013
		Foliar, F	0.24	4	13		Austria, 2013
		Foliar, F	0.14	7	7, 14, 21, 35		Austria, 2013
	Grape[a]	Foliar, F	0.24	4	0, 1, 4 10, 18		Austria, 2013
Root and tuber vegetables	Potatoes[b]	Foliar, F	0.24	8	10		Austria, 2007
		Foliar, F	0.40	3	3		Austria, 2007
Leafy vegetables	Lettuce[b]	Foliar, F	0.24	3	11		Austria, 2007
		Foliar, F	0.84	4	3		Austria, 2007

(a): Studies newly submitted by RMS (Austria, 2013); only the first study is GLP compliant
(b): Studies evaluated during the peer review (Austria, 2007)

Summary of plant metabolism studies reported in the EU

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-W35958, IN-KQ9609 or IN-KP53310) 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 (Austria, 2013). 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.

Primary metabolism was only investigated for foliar treatment but the results of the confined rotational crops studies (see below) are deemed sufficient to conclude that seed treatments would not results in significant residues uptake in edible parts of crops. Therefore, the GAPs for seed treatment on fresh beans (with pods) and pulses (dry) which were reported in this review are deemed covered.

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in primary crops

EFSA, 2015: *The metabolism of cymoxanil has been investigated for foliar treatment in three different crop groups. Studies on the nature of the residues in succeeding crops show that significant residues of cymoxanil are not expected in rotational crops. Based on the available data, EFSA was able to derive a general residue definition for monitoring and risk assessment being cymoxanil, also covering the authorised good agricultural practices (GAPs) for seed treatment.*

Evaluator comments:
The metabolism of cymoxanil has been investigated for foliar treatment in three different crop groups, including potatoes. The metabolism of cymoxanil in plants following foliar treatment applications is sufficiently addressed to support the proposed use of the product IN002B1760. Based on the available data, EFSA was able to derive a

general residue definition for monitoring and risk assessment being cymoxanil.

Plant residue definition for monitoring:
Cymoxanil - EFSA 2019; Reg. (EU) 2022/1363
Plant residue definition for risk assessment:
Cymoxanil – EFSA 2019
No additional study is required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data
Data were available and reviewed at EU level (Austria, 2007).
No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Application and sampling details					Reference
		Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data							
Root and tuber vegetables	Sugar beet	Bare soil	1.2	-	30, 120		Austria, 2007
Leafy vegetables	Letuce	Bare soil	1.2	-	30, 120		Austria, 2007
Cereals	Wheat	Bare soil	1.2	-	30, 120		Austria, 2007

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU
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 (see Appendix A). 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.*

Summary of new plant metabolism studies
No new data submitted in the framework of this application.

Conclusion on metabolism in rotational 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.*

The intended uses could not modify this conclusion.

Evaluator comments:
Studies on the nature of the residues in succeeding crops were reviewed at EU level (Austria, 2007).
Significant residues of cymoxanil were not identified in rotational crops. No additional study is required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

A study on the effects of industrial processing on the nature of the residue was not required and therefore not submitted during the peer review.
No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Not investigated	-
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Not investigated	-
Sterilisation (20 minutes, 120°C, pH 6)	Not investigated	-

Hydrolysis studies were performed with pH 5, 7, 9 at 25°C and pH 4, 7, 9 at 20°C allow to elucidate the metabolic pathway though process (Austria, 2013).

Conclusion on nature of residues in processed commodities

No new data are submitted in the framework of this application and are not required.

Evaluator comments:
Information given by the Applicant is sufficient.
It should be noted that residues of cymoxanil in the assessed crop were found to be below the threshold of 0.01 mg/kg (all residues values are below the LOQ at harvest date). Therefore, processing studies with this active substance are not required.

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

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruit crops (Tomatoes, grapes) Root crops (Potatoes) Leafy crops (Lettuce)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (significant residues of cymoxanil were not identified in rotational crops)
Processed commodities	Not available
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes (tentative)
Plant residue definition for monitoring	Cymoxanil (EFSA, 2015) ** Reg. (EU) 2022/1363
Plant residue definition for risk assessment	Cymoxanil (EFSA, 2015)***
Conversion factor from enforcement to RA	Not applicable

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

Data were available and were reviewed at EU level (EFSA, 2008).

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Application details		N rate/comment	Reference
		Rate (mg/kg feed/d)	Duration (days)		
EU data					
Lactating ruminants	Goat	10	3	>200N/compared to pigs	EFSA, 2008

Summary of plant metabolism studies reported in the EU
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.*

Summary of new animal metabolism studies
No new data submitted in the framework of this application.

Conclusion on metabolism in livestock
The available information is considered sufficient to propose parent cymoxanil as residue definition for monitoring and risk assessment.
The requested uses are considered as covered by the available information.

Evaluator comments:
Information given by the Applicant is sufficient.
EFSA concluded that the previous assessment of residues in livestock (EFSA, 2015) is still valid (EFSA Journal 2019;17(10):5823).
No additional study is required.

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

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
Time needed to reach a plateau concentration in milk and eggs (days)	1
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) Cymoxanil (Reg. (EU) 2022/1363)
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

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

Data are available to the applicant covering the requested use on potato. These data were already positively evaluated for the authorisation of the product Moximate 505 WG (mancozeb 465 g/kg + cymoxanil 40 g/kg) evaluated by zRMS Greece and approved on the 29.04.2014.
Data are also available for grape and new data are available for tomato uses. A detailed assessment of the studies is reported in Appendix 2.
A summary of all the available data is reported in the table below.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of IN002B1760 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	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)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
151000 Grapes	Greece, 2014 R-A7115	N-EU	GAP on which a.s. assessment is based: 5 x 112.5 g as/ha, BBCH 77-81, interval between application 7-10 days, PHI 28d, outdoor E: 4x<0.01 RA: 4x<0.01	N/A				
		S-EU	GAP on which a.s. assessment is based: 5 x 112.5 g as/ha, BBCH 79-83, interval between application 7-10 days, PHI 28d, outdoor E: 4x<0.01 RA: 4x<0.01	N/A				
	Overall supporting data for cGAP	EU	E: 8x<0.01 RA: 8x<0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.3	Yes
211000 Potatoes	Greece, 2014 20074095/E1-FPPO	N-EU	GAP on which a.s. assessment is based: 6 x 120 g as/ha, BBCH 95, interval between application 5-7 days, PHI 7d, outdoor E: 4x<0.01 RA: 4x<0.01	N/A				
	Greece, 2014 20074095/E1-FPPO	S-EU	GAP on which a.s. assessment is based: 6 x 120 g as/ha, BBCH 95, interval between application 5-7 days, PHI 7d, outdoor E: 4x<0.01 RA: 4x<0.01	N/A				
	Overall supporting data for cGAP	EU	E: 8 4x<0.01 RA: 8 4x<0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.3 0.01*	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	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)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
231010 Tomatoes 2a * extrapolated to 231030 Aubergine	New studies GLP STUDY-21-58	S-EU	GAP on which a.s. assessment is based: 5 x 148.5 g as/ha, BBCH 89, interval between application 7 days, PHI 3d, outdoor E: 2x<0.01 RA: 2x<0.01	NA				
	New studies GLP STUDY-21-59	EU	GAP on which a.s. assessment is based: 5 x 148.5 g as/ha, BBCH 89, interval between application 7 days, PHI 3d, indoor E: 2x<0.01 RA: 2x<0.01	NA				
	Overall supporting data for cGAP	S-EU	E: 4x<0.01 RA: 4x<0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	Tomatoes: 0.4 Aubergine: 0.3	Yes

* Source of EU MRL: Reg. 2018/832 Reg. (EU) 2022/1363

7.2.3.2 Conclusion on the magnitude of residues in plants

The present application is intended for the authorisation of a new product containing cymoxanil, a solid formulation (WG) containing 45% of active ingredient. This kind of formulation is widely diffused across Europe and its use is not known to cause problems in terms of residues arising after the applications performed according to the intended GAP.

Crop-by-crop evaluation

~~Grapes: data supporting the intended GAP are available from field trials: 4 trials were carried out in Northern Europe and 4 in Southern Europe; they were reviewed at EU level (Greece, 2014) and positively evaluated, the results indicating an almost zero residue situation.~~

Potato: data supporting the intended GAP are available from field trials: 4 trials were carried out in Northern Europe and 4 in Southern Europe; they were reviewed at EU level (Greece, 2014) and positively evaluated, the results indicating an almost zero residue situation.

~~Tomato: data supporting the intended GAP are available from field trials: 2 trials were carried out in Southern Europe in open field conditions and 2 in protected conditions; data evidenced an almost zero residue situation, as results were always below the Limit of Detection (<LOD).~~

~~According to appendix D of EU guidelines, extrapolation to aubergine is possible with trials on tomato, which is the case here.~~

Conclusions

Data are available by the applicant supporting the intended use on potatoes. For this crop, a situation of non-residues is evidenced.

The data submitted show that no exceedance of the MRL will occur and the proposed uses are considered acceptable.

zRMS comments:

Information given by the Applicant is sufficient and accepted.

Potato is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. When the supervised residue trials show that the residue levels in plants or plant products are lower than the limit of quantification (LOQ), the number of independent trials may be reduced. The number of trials shall not be below the minimum of four per zone for major crops.

The intended GAP for cymoxanil for potato in Central Europe is 6x148.5 g a.s./ha with interval between applications of 5-10 days at BBCH 12-95 with PHI of 7 days.

The study on the magnitude of residue has been submitted by the Applicant in the framework of this application.

A total of 4 supervised residue trials on potato were performed in Northern Europe during 2007/2008.

1. Semrau; 2010, Report no.: 20074095/E1-FPPO - six applications, separated by a 4-6 days interval were made at 120 g ai/ha for cymoxanil. The actual application rate tested in residue trials was no less than ±25 % of the intended maximum application rate.

The trials are supported by valid storage stability data and validated analytical methods.

Results:

In all trials no residues of cymoxanil were found in the treated and untreated field specimens of potato tubers above the limit of detection (0.003 mg/kg).

The residues arising from the proposed use will not exceed the MRL established for cymoxanil for potato of 0.01* mg/kg in Reg. (EU) 2022/1363.

The use is considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The use of the product on potatoes (as well as on the other crops) resulted in a zero-residue situation, consequently no new dietary burden calculation is required.

The dietary burden calculation made by EFSA in the framework of the Art. 12 evaluation can be considered still valid.

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure)

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	0.02	STMR
Beans (dry)	0.02	STMR	0.02	STMR
Lupins (dry)	0.02	STMR	0.02	STMR
Potatoes	0.01	STMR	0.01	HR

Table 7.2-11: Results of the dietary burden calculation (Animal model 2017)

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)
Risk assessment residue definition: cymoxanil					
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	0.029	N

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

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.*

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Data are not available and considered as not required.
No new data were submitted in the framework of this application.

zRMS comments:
In EFSA Journal 2019;17(10):5823 EFSA concluded that *In the context of the EFSA MRL review of cymoxanil in 2015, the dietary burden for livestock was calculated including potatoes and potato by-products; soyabeans and sunflower seeds were not considered in the estimation of the animal intake of cymoxanil residues due to the lack of residue data for cymoxanil in these commodities (EFSA, 2015). EFSA highlighted that this might underestimate the animal intake of the active substance.*
However, there was sufficient evidence to conclude that MRLs for cymoxanil in animal commodities are not required (EFSA, 2015).
The previous assessment of residues in livestock (EFSA, 2015) is still valid.
The use under consideration in the framework of this dossier does not modify the animal exposure due to uses already authorised. There is no risk for MRLs to be exceeded in animal commodities.
No additional data are required.

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

7.2.5.1 Available data for all crops under consideration

Data are available at EU level and were reviewed in the framework of the review of the existing MRL (Austria, 2013).
EFSA, 2015: …*studies investigating the magnitude of residues in processed commodities of wine grapes and tomatoes allowed EFSA to derive tentative processing factors for enforcement and risk assessment in raisins, wine, grape juice, peeled and canned tomatoes, tomatoes sauce, juice and ketchup. A robust peeling factor was derived for cucurbits with inedible peel.*
No new data were submitted in the framework of this application.

Table 7.2-12: Overview of the available processing studies

Processed commodity	**Number of studies[(a)]**	**Processing Factor (PF)**		**Reference**
		Individual values	**Median PF**	
EU data				
Enforcement residue definition: cymoxanil				
Robust processing factors (sufficiently supported by data)				
Cucurbits inedible peel, peeled	15	Derived from melons residue trials where levels are always <LOQ in pulp while significant levels were observed in whole melons	0.1	Austria, 2013
Indicative processing factors (limited dataset and/or uncertainty on the naturee of residues)				
Tomatoes, sauce	1	0.29[(b)]	0.3	Austria, 2013
Wine grapes, juice	1	1.4[(c)]	1.4	Austria, 2013
Tomatoes, ketchup	1	0.69[(b)]	0.7	Austria, 2013

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Residue levels in raw and processed commodities were quantified in one study only; the other studies, where residues were <0.05 mg/kg in raw and processed commodities, were not considered (Austria, 2013).
(c): Residue levels in juice was measured above the LOQ (0.07 mg/kg) while <0.05 mg/kg in raw grapes; another study, where residues were <0.05 mg/kg in raw and processed commodities, was not considered (Austria, 2013).

7.2.5.2 Conclusion on processing studies

According to SANCO/7035/VI/95 rev.5, *Processing studies are not normally necessary if no significant or no analytically determinable residue occur in the plant or plant product which would be processed*, which is here the case because residues in all residue studies are lower than LOQ (< 0.01 mg/kg).
No need for additional data/studies is evidenced.

zRMS comments:
Information given by the Applicant is sufficient. As residues of cymoxanil exceeding 0.1 mg/kg are not expected in the treated crop, there is no need to investigate the effect of industrial and/or household processing.
No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

Potatoes can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

Evaluator comments:
The crops under consideration can be grown in rotation.
Cymoxanil or structurally related metabolites did not account for more than 0.02 mg eq/kg. Significant residues of

cymoxanil are not expected in rotational crops (EFSA, 2015).
A waiting period before sowing or planting of succeeding crops is not required.
No further data are required.

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 IN002B1760. Therefore, other special studies are not needed.

zRMS comments:
Information given by the Applicant is sufficient.
Additionally, according to the SANTE/11956/2016 rev. 9, 14 September 2018, potato has no melliferous capacity, so no further data are required.

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 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

As a worst case, TDMI and IESTI were calculated using the current MRLs (~~Reg. (EU) 2018/832~~ Reg. (EU) 2022/1363).
~~As a second step, for the crop of interest potatoes, STMR coming from the residue trials has been used (i.e. 0.01 mg/kg).~~ For details, please refer to the table below.

~~**Code number**~~	~~**Groups and examples of individual products to which the MRLs apply (a)**~~	~~Reg. (EU) 2018/832~~
~~0100000~~	~~, FRUITS, FRESH or FROZEN; TREE NUTS~~	
~~0110000~~	~~, Citrus fruits~~	~~0.01*~~
~~0120000~~	~~, Tree nuts~~	~~0.01*~~
~~0130000~~	~~, Pome fruits~~	~~0.01*~~
~~0140000~~	~~, Stone fruits~~	~~0.01*~~
~~0150000~~	~~, Berries and small fruits~~	
~~0151000~~	~~, (a) grapes~~	~~0.01 (STMR, HR)~~
~~0151010~~	~~, Table grapes~~	~~0.01 (STMR, HR)~~
~~0151020~~	~~, Wine grapes~~	~~0.01 (STMR, HR)~~
~~0152000~~	~~, (b) strawberries~~	~~0.01*~~
~~0153000~~	~~, (c) cane fruits~~	~~0.01*~~
~~0154000~~	~~, (d) other small fruits and berries~~	~~0.01*~~
~~0160000~~	~~, Miscellaneous fruitswith~~	~~0.01*~~
~~0161000~~	~~, (a) edible peel~~	~~0.01*~~
~~0162000~~	~~, (b) inedible peel, small~~	~~0.01*~~
~~0163000~~	~~, (c) inedible peel, large~~	~~0.01*~~
~~0200000~~	~~, VEGETABLES, FRESH or FROZEN~~	
~~0210000~~	~~, Root and tuber vegetables~~	~~0.01*~~
~~**0211000**~~	~~, (a) potatoes~~	~~**0.01 (STMR, HR)**~~
~~0212000~~	~~, (b) tropical root and tuber vegetables~~	~~0.01*~~
~~0213000~~	~~, (c) other root and tuber vegetables except sugar beets~~	~~0.01*~~
~~0220000~~	~~, Bulb vegetables~~	~~0.01*~~
~~0220010~~	~~, Garlic~~	~~0.01*~~
~~0220020~~	~~, Onions~~	~~0.01*~~
~~0220030~~	~~, Shallots~~	~~0.01*~~
~~0220040~~	~~, Spring onions/green onions and Welsh onions~~	~~0.01*~~
~~0220990~~	~~, Others (2)~~	~~0.01*~~

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EU) 2018/832
0230000	, — Fruiting vegetables	
0231000	, — (a) Solanaceae and Malvaceae	
0231010	, — — Tomatoes	0.01 (STMR, HR)
0231020	, — — Sweet peppers/bell peppers	0.01*
0231030	, — — Aubergines/eggplants	0.01 (STMR, HR)
0231040	, — — Okra/lady's fingers	0.01*
0231990	, — — Others (2)	0.01*
0232000	, — (b) cucurbits with edible peel	0.08
0232010	, — — Cucumbers	0.08
0232020	, — — Gherkins	0.08
0232030	, — — Courgettes	0.08
0232990	, — — Others (2)	0.08
0233000	, — (c) cucurbits with inedible peel	0.4
0233010	, — — Melons	0.4
0233020	, — — Pumpkins	0.4
0233030	, — — Watermelons	0.4
0233990	, — — Others (2)	0.4
0234000	, — (d) sweet corn	0.01*
0239000	, — (e) other fruiting vegetables	0.01*
0240000	, — Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	0.01*
0241000	, — (a) flowering brassica	0.01*
0242000	, — (b) head brassica	0.01*
0243000	, — (c) leafy brassica	0.01*
0244000	, — (d) kohlrabies	0.01*
0250000	, — Leaf vegetables, herbs and edible flowers	
0251000	, — (a) lettuces and salad plants	
0251010	, — — Lamb's lettuces/corn salads	0.01*
0251020	, — — Lettuces	0.03 (ft)
0251030	, — — Escaroles/broad-leaved endives	0.01*
0251040	, — — Cresses and other sprouts and shoots	0.01*
0251050	, — — Land cresses	0.01*
0251060	, — — Roman rocket/rucola	0.01*
0251070	, — — Red mustards	0.01*
0251080	, — — Baby leaf crops (including brassica species)	0.01*
0251990	, — — Others (2)	0.01*
0252000	, — (b) spinaches and similar leaves	
0253000	, — (c) grape leaves and similar species	0.01*
0254000	, — (d) watercresses	0.01*
0255000	, — (e) witloofs/Belgian endives	0.01*
0256000	, — (f) herbs and edible flowers	0.02*
0260000	, — Legume vegetables	
0260010	, — — Beans (with pods)	0.05*
0260020	, — — Beans (without pods)	0.05*
0260030	, — — Peas (with pods)	0.15
0260040	, — — Peas (without pods)	0.05*
0260050	, — — Lentils	0.01*
0260990	, — — Others (2)	0.01*
0270000	, — Stem vegetables	
0300000	, — PULSES	0.05* (ft)
0300010	, — — Beans	0.05* (ft)
0300020	, — — Lentils	0.05* (ft)
0300030	, — — Peas	0.05* (ft)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EU) 2018/832
0300040	,,,,,,Lupins/lupini beans	0,05* (ft)
0300990	,,,,,,Others (2)	0,05*
0400000	,,OILSEEDS AND OIL FRUITS	0,01*
0401000	,,,Oilseeds	0,01*
0402000	,,,Oil fruits	0,01*
0402010	,,,,,,Olives for oil production	0,01*
0402020	,,,,,,Oil palms kernels	0,01*
0402030	,,,,,,Oil palms fruits	0,01*
0402040	,,,,,,Kapok	0,01*
0402990	,,,,,,Others (2)	0,01*
0500000	,,CEREALS	0,01*
0500010	,,,,,,Barley	0,01*
0500020	,,,,,,Buckwheat and other pseudocereals	0,01*
0500030	,,,,,,Maize/corn	0,01*
0500040	,,,,,,Common millet/proso millet	0,01*
0500050	,,,,,,Oat	0,01*
0500060	,,,,,,Rice	0,01*
0500070	,,,,,,Rye	0,01*
0500080	,,,,,,Sorghum	0,01*
0500090	,,,,,,Wheat	0,01*
0500990	,,,,,,Others (2)	0,01*
0600000	,,TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	0,1*
0610000	,,,Teas	0,1*
0620000	,,,Coffee beans	0,1*
0630000	,,,Herbal infusions from	0,1*
0631000	,,,,,(a) flowers	0,1* (ft)
0632000	,,,,,(b) leaves and herbs	0,1*
0633000	,,,,,(c) roots	0,1*
0639000	,,,,,(d) any other parts of the plant	0,1*
0640000	,,,Cocoa beans	0,1*
0650000	,,,Carobs/Saint John's breads	0,1*
0700000	,,HOPS	0,1* (ft)
0800000	,,SPICES	
0810000	,,,Seed spices	0,1*
0850000	,,,Bud spices	0,1*
0850010	,,,,,,Cloves	0,1*
0850020	,,,,,,Capers	0,1*
0850990	,,,,,,Others (2)	0,1*
0860000	,,,Flower pistil spices	0,1*
0860010	,,,,,,Saffron	0,1*
0860990	,,,,,,Others (2)	0,1*
0870000	,,,Aril spices	0,1*
0870010	,,,,,,Mace	0,1*
0870990	,,,,,,Others (2)	0,1*
0900000	,,SUGAR PLANTS	0,01*
0900010	,,,,,,Sugar beet roots	0,01*
0900020	,,,,,,Sugar canes	0,01*
0900030	,,,,,,Chicory roots	0,01*
0900990	,,,,,,Others (2)	0,01*
1000000	,,PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
1010000	,,,Commodities from	0,01*
1011000	,,,,,(a) swine	0,01*

~~Code number~~	~~Groups and examples of individual products to which the MRLs apply (a)~~	~~Reg. (EU) 2018/832~~
~~1011010~~	~~, Muscle~~	~~0,01*~~
~~1011020~~	~~, Fat~~	~~0,01*~~
~~1011030~~	~~, Liver~~	~~0,01*~~
~~1011040~~	~~, Kidney~~	~~0,01*~~
~~1011050~~	~~, Edible offals (other than liver and kidney)~~	~~0,01*~~
~~1011990~~	~~, Others (2)~~	~~0,01*~~
~~1012000~~	~~, (b) bovine~~	~~0,01*~~
~~1012010~~	~~, Muscle~~	~~0,01*~~
~~1012020~~	~~, Fat~~	~~0,01*~~
~~1012030~~	~~, Liver~~	~~0,01*~~
~~1012040~~	~~, Kidney~~	~~0,01*~~
~~1012050~~	~~, Edible offals (other than liver and kidney)~~	~~0,01*~~
~~1012990~~	~~, Others (2)~~	~~0,01*~~
~~1016000~~	~~, (f) poultry~~	~~0,01*~~
~~1016010~~	~~, Muscle~~	~~0,01*~~
~~1016020~~	~~, Fat~~	~~0,01*~~
~~1016030~~	~~, Liver~~	~~0,01*~~
~~1016040~~	~~, Kidney~~	~~0,01*~~
~~1016050~~	~~, Edible offals (other than liver and kidney)~~	~~0,01*~~
~~1016990~~	~~, Others (2)~~	~~0,01*~~
~~1020000~~	~~, Milk~~	~~0,01*~~
~~1020010~~	~~, Cattle~~	~~0,01*~~
~~1020020~~	~~, Sheep~~	~~0,01*~~
~~1020030~~	~~, Goat~~	~~0,01*~~
~~1020040~~	~~, Horse~~	~~0,01*~~
~~1020990~~	~~, Others (2)~~	~~0,01*~~
~~1030000~~	~~, Birds eggs~~	~~0,01*~~
~~1030010~~	~~, Chicken~~	~~0,01*~~
~~1030020~~	~~, Duck~~	~~0,01*~~
~~1030030~~	~~, Geese~~	~~0,01*~~
~~1030040~~	~~, Quail~~	~~0,01*~~
~~1030990~~	~~, Others (2)~~	~~0,01*~~
~~1040000~~	~~, Honey and other apiculture products (7)~~	~~0,05*~~
~~1050000~~	~~, Amphibians and Reptiles~~	~~0,01*~~
~~1060000~~	~~, Terrestrial invertebrate animals~~	~~0,01*~~
~~1070000~~	~~, Wild terrestrial vertebrate animals~~	~~0,01*~~

		Cymoxanil Reg. (EU) 2022/1363 Annex II
Code number	**Groups and examples of individual products to which the MRLs apply (a)**	**Current**
100000	FRUITS, FRESH or FROZEN; TREE NUTS	
110000	Citrus fruits	0.01*
110010	Grapefruits	0.01*
110020	Oranges	0.01*
110030	Lemons	0.01*
110040	Limes	0.01*
110050	Mandarins	0.01*
110990	Others (2)	0.01*
120000	Tree nuts	0.01*
120010	Almonds	0.01*

120020	Brazil nuts	0.01*
120030	Cashew nuts	0.01*
120040	Chestnuts	0.01*
120050	Coconuts	0.01*
120060	Hazelnuts/cobnuts	0.01*
120070	Macadamias	0.01*
120080	Pecans	0.01*
120090	Pine nut kernels	0.01*
120100	Pistachios	0.01*
120110	Walnuts	0.01*
120990	Others (2)	0.01*
130000	Pome fruits	0.01*
130010	Apples	0.01*
130020	Pears	0.01*
130030	Quinces	0.01*
130040	Medlars	0.01*
130050	Loquats/Japanese medlars	0.01*
130990	Others (2)	0.01*
140000	Stone fruits	0.01*
140010	Apricots	0.01*
140020	Cherries (sweet)	0.01*
140030	Peaches	0.01*
140040	Plums	0.01*
140990	Others (2)	0.01*
150000	Berries and small fruits	
151000	(a) grapes	0,05
151010	Table grapes	0,05
151020	Wine grapes	0,05
152000	(b) strawberries	0.01*
153000	(c) cane fruits	0.01*
153010	Blackberries	0.01*
153020	Dewberries	0.01*
153030	Raspberries (red and yellow)	0.01*
153990	Others (2)	0.01*
154000	(d) other small fruits and berries	0.01*
154010	Blueberries	0.01*
154020	Cranberries	0.01*
154030	Currants (black, red and white)	0.01*
154040	Gooseberries (green, red and yellow)	0.01*
154050	Rose hips	0.01*
154060	Mulberries (black and white)	0.01*
154070	Azaroles/Mediterranean medlars	0.01*
154080	Elderberries	0.01*
154990	Others (2)	0.01*
160000	Miscellaneous fruitswith	0.01*
161000	(a) edible peel	0.01*
161010	Dates	0.01*

161020	Figs	0.01*
161030	Table olives	0.01*
161040	Kumquats	0.01*
161050	Carambolas	0.01*
161060	Kaki/Japanese persimmons	0.01*
161070	Jambuls/jambolans	0.01*
161990	Others (2)	0.01*
162000	(b) inedible peel, small	0.01*
162010	Kiwi fruits (green, red, yellow)	0.01*
162020	Litchis/lychees	0.01*
162030	Passionfruits/maracujas	0.01*
162040	Prickly pears/cactus fruits	0.01*
162050	Star apples/cainitos	0.01*
162060	American persimmons/Virginia kaki	0.01*
162990	Others (2)	0.01*
163000	(c) inedible peel, large	0.01*
163010	Avocados	0.01*
163020	Bananas	0.01*
163030	Mangoes	0.01*
163040	Papayas	0.01*
163050	Granate apples/pomegranates	0.01*
163060	Cherimoyas	0.01*
163070	Guavas	0.01*
163080	Pineapples	0.01*
163090	Breadfruits	0.01*
163100	Durians	0.01*
163110	Soursops/guanabanas	0.01*
163990	Others (2)	0.01*
200000	VEGETABLES, FRESH or FROZEN	
210000	Root and tuber vegetables	0.01*
211000	(a) potatoes	0.01* (0.01 mg/kg STMR, HR)
212000	(b) tropical root and tuber vegetables	0.01*
212010	Cassava roots/manioc	0.01*
212020	Sweet potatoes	0.01*
212030	Yams	0.01*
212040	Arrowroots	0.01*
212990	Others (2)	0.01*
213000	(c) other root and tuber vegetables except sugar beets	0.01*
213010	Beetroots	0.01*
213020	Carrots	0.01*
213030	Celeriacs/turnip rooted celeries	0.01*
213040	Horseradishes	0.01*
213050	Jerusalem artichokes	0.01*
213060	Parsnips	0.01*
213070	Parsley roots/Hamburg roots parsley	0.01*
213080	Radishes	0.01*

213090	Salsifies	0.01*
213100	Swedes/rutabagas	0.01*
213110	Turnips	0.01*
213990	Others (2)	0.01*
220000	Bulb vegetables	0.01*
220010	Garlic	0.01*
220020	Onions	0.01*
220030	Shallots	0.01*
220040	Spring onions/green onions and Welsh onions	0.01*
220990	Others (2)	0.01*
230000	Fruiting vegetables	
231000	(a) Solanaceae and Malvaceae	
231010	Tomatoes	0,4
231020	Sweet peppers/bell peppers	0.01*
231030	Aubergines/eggplants	0,3
231040	Okra/lady's fingers	0.01*
231990	Others (2)	0.01*
232000	(b) cucurbits with edible peel	0,08
232010	Cucumbers	0,08
232020	Gherkins	0,08
232030	Courgettes	0,08
232990	Others (2)	0,08
233000	(c) cucurbits with inedible peel	0,4
233010	Melons	0,4
233020	Pumpkins	0,4
233030	Watermelons	0,4
233990	Others (2)	0,4
234000	(d) sweet corn	0.01*
239000	(e) other fruiting vegetables	0.01*
240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	0.01*
241000	(a) flowering brassica	0.01*
241010	Broccoli	0.01*
241020	Cauliflowers	0.01*
241990	Others (2)	0.01*
242000	(b) head brassica	0.01*
242010	Brussels sprouts	0.01*
242020	Head cabbages	0.01*
242990	Others (2)	0.01*
243000	(c) leafy brassica	0.01*
243010	Chinese cabbages/pe-tsai	0.01*
243020	Kales	0.01*
243990	Others (2)	0.01*
244000	(d) kohlrabies	0.01*
250000	Leaf vegetables, herbs and edible flowers	
251000	(a) lettuces and salad plants	
251010	Lamb's lettuces/corn salads	0.01*
251020	Lettuces	0,03

251030	Escaroles/broad-leaved endives	0.01*
251040	Cresses and other sprouts and shoots	0.01*
251050	Land cresses	0.01*
251060	Roman rocket/rucola	0.01*
251070	Red mustards	0.01*
251080	Baby leaf crops (including brassica species)	0.01*
251990	Others (2)	0.01*
252000	(b) spinaches and similar leaves	
252010	Spinaches	0,9
252020	Purslanes	0.01*
252030	Chards/beet leaves	0.01*
252990	Others (2)	0.01*
253000	(c) grape leaves and similar species	0.01*
254000	(d) watercresses	0.01*
255000	(e) witloofs/Belgian endives	0.01*
256000	(f) herbs and edible flowers	0.02*
256010	Chervil	0.02*
256020	Chives	0.02*
256030	Celery leaves	0.02*
256040	Parsley	0.02*
256050	Sage	0.02*
256060	Rosemary	0.02*
256070	Thyme	0.02*
256080	Basil and edible flowers	0.02*
256090	Laurel/bay leaves	0.02*
256100	Tarragon	0.02*
256990	Others (2)	0.02*
260000	Legume vegetables	
260010	Beans (with pods)	0.05*
260020	Beans (without pods)	0.05*
260030	Peas (with pods)	0,15
260040	Peas (without pods)	0.05*
260050	Lentils	0.01*
260990	Others (2)	0.01*
270000	Stem vegetables	
270010	Asparagus	0.01*
270020	Cardoons	0.01*
270030	Celeries	0.01*
270040	Florence fennels	0.01*
270050	Globe artichokes	0.01*
270060	Leeks	0,02
270070	Rhubarbs	0.01*
270080	Bamboo shoots	0.01*
270090	Palm hearts	0.01*
270990	Others (2)	0.01*
280000	Fungi, mosses and lichens	0.01*
280010	Cultivated fungi	0.01*

280020	Wild fungi	0.01*
280990	Mosses and lichens	0.01*
290000	Algae and prokaryotes organisms	0.01*
300000	PULSES	0.01*
300010	Beans	0.01*
300020	Lentils	0.01*
300030	Peas	0.01*
300040	Lupins/lupini beans	0.01*
300990	Others (2)	0.01*
400000	OILSEEDS AND OIL FRUITS	0.01*
401000	Oilseeds	0.01*
401010	Linseeds	0.01*
401020	Peanuts/groundnuts	0.01*
401030	Poppy seeds	0.01*
401040	Sesame seeds	0.01*
401050	Sunflower seeds	0.01*
401060	Rapeseeds/canola seeds	0.01*
401070	Soyabeans	0.01*
401080	Mustard seeds	0.01*
401090	Cotton seeds	0.01*
401100	Pumpkin seeds	0.01*
401110	Safflower seeds	0.01*
401120	Borage seeds	0.01*
401130	Gold of pleasure seeds	0.01*
401140	Hemp seeds	0.01*
401150	Castor beans	0.01*
401990	Others (2)	0.01*
402000	Oil fruits	0.01*
402010	Olives for oil production	0.01*
402020	Oil palms kernels	0.01*
402030	Oil palms fruits	0.01*
402040	Kapok	0.01*
402990	Others (2)	0.01*
500000	CEREALS	0.01*
500010	Barley	0.01*
500020	Buckwheat and other pseudocereals	0.01*
500030	Maize/corn	0.01*
500040	Common millet/proso millet	0.01*
500050	Oat	0.01*
500060	Rice	0.01*
500070	Rye	0.01*
500080	Sorghum	0.01*
500090	Wheat	0.01*
500990	Others (2)	0.01*
600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	0.1*
610000	Teas	0.1*
620000	Coffee beans	0.1*

630000	Herbal infusions from	0.1*
631000	(a) flowers	0.1*
631010	Chamomile	0.1*
631020	Hibiscus/roselle	0.1*
631030	Rose	0.1*
631040	Jasmine	0.1*
631050	Lime/linden	0.1*
631990	Others (2)	0.1*
632000	(b) leaves and herbs	0.1*
632010	Strawberry	0.1*
632020	Rooibos	0.1*
632030	Mate/maté	0.1*
632990	Others (2)	0.1*
633000	(c) roots	0.1*
633010	Valerian	0.1*
633020	Ginseng	0.1*
633990	Others (2)	0.1*
639000	(d) any other parts of the plant	0.1*
640000	Cocoa beans	0.1*
650000	Carobs/Saint John's breads	0.1*
700000	HOPS	0.1*
800000	SPICES	
810000	Seed spices	0.1*
810010	Anise/aniseed	0.1*
810020	Black caraway/black cumin	0.1*
810030	Celery	0.1*
810040	Coriander	0.1*
810050	Cumin	0.1*
810060	Dill	0.1*
810070	Fennel	0.1*
810080	Fenugreek	0.1*
810090	Nutmeg	0.1*
810990	Others (2)	0.1*
820000	Fruit spices	0.1*
820010	Allspice/pimento	0.1*
820020	Sichuan pepper	0.1*
820030	Caraway	0.1*
820040	Cardamom	0.1*
820050	Juniper berry	0.1*
820060	Peppercorn (black, green and white)	0.1*
820070	Vanilla	0.1*
820080	Tamarind	0.1*
820990	Others (2)	0.1*
830000	Bark spices	0.1*
830010	Cinnamon	0.1*
830990	Others (2)	0.1*
840000	Root and rhizome spices	

840010	Liquorice	0.1*
840020	Ginger (10)	
840030	Turmeric/curcuma	0.1*
840040	Horseradish (11)	
840990	Others (2)	0.1*
850000	Bud spices	0.1*
850010	Cloves	0.1*
850020	Capers	0.1*
850990	Others (2)	0.1*
860000	Flower pistil spices	0.1*
860010	Saffron	0.1*
860990	Others (2)	0.1*
870000	Aril spices	0.1*
870010	Mace	0.1*
870990	Others (2)	0.1*
900000	SUGAR PLANTS	0.01*
900010	Sugar beet roots	0.01*
900020	Sugar canes	0.01*
900030	Chicory roots	0.01*
900990	Others (2)	0.01*
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	
1010000	Commodities from	0.01*
1011000	(a) swine	0.01*
1011010	Muscle	0.01*
1011020	Fat	0.01*
1011030	Liver	0.01*
1011040	Kidney	0.01*
1011050	Edible offals (other than liver and kidney)	0.01*
1011990	Others (2)	0.01*
1012000	(b) bovine	0.01*
1012010	Muscle	0.01*
1012020	Fat	0.01*
1012030	Liver	0.01*
1012040	Kidney	0.01*
1012050	Edible offals (other than liver and kidney)	0.01*
1012990	Others (2)	0.01*
1013000	(c) sheep	0.01*
1013010	Muscle	0.01*
1013020	Fat	0.01*
1013030	Liver	0.01*
1013040	Kidney	0.01*
1013050	Edible offals (other than liver and kidney)	0.01*
1013990	Others (2)	0.01*
1014000	d) goat	0.01*
1014010	Muscle	0.01*
1014020	Fat	0.01*
1014030	Liver	0.01*

1014040	Kidney	0.01*
1014050	Edible offals (other than liver and kidney)	0.01*
1014990	Others (2)	0.01*
1015000	(e) equine	0.01*
1015010	Muscle	0.01*
1015020	Fat	0.01*
1015030	Liver	0.01*
1015040	Kidney	0.01*
1015050	Edible offals (other than liver and kidney)	0.01*
1015990	Others (2)	0.01*
1016000	(f) poultry	0.01*
1016010	Muscle	0.01*
1016020	Fat	0.01*
1016030	Liver	0.01*
1016040	Kidney	0.01*
1016050	Edible offals (other than liver and kidney)	0.01*
1016990	Others (2)	0.01*
1017000	(g) other farmed terrestrial animals	0.01*
1017010	Muscle	0.01*
1017020	Fat	0.01*
1017030	Liver	0.01*
1017040	Kidney	0.01*
1017050	Edible offals (other than liver and kidney)	0.01*
1017990	Others (2)	0.01*
1020000	Milk	0.01*
1020010	Cattle	0.01*
1020020	Sheep	0.01*
1020030	Goat	0.01*
1020040	Horse	0.01*
1020990	Others (2)	0.01*
1030000	Birds eggs	0.01*
1030010	Chicken	0.01*
1030020	Duck	0.01*
1030030	Geese	0.01*
1030040	Quail	0.01*
1030990	Others (2)	0.01*
1040000	Honey and other apiculture products (7)	0.05*
1050000	Amphibians and Reptiles	0.01*
1060000	Terrestrial invertebrate animals	0.01*
1070000	Wild terrestrial vertebrate animals	0.01*

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

As a worst case, TDMI and IESTI were calculated using the current MRLs (Reg. (EU) 2018/832): GEMS/Food G06 was the diet with the highest TMDI, reaching 23% ADI, being tomatoes the main contributor with 11% ADI and grapes the third contributor with 2% ADI. As this represent an unrealistic scenario, a second calculation was performed taking into account STMR and HR coming from the residue

trials. According to EFSA PRIMo 3.1, using those data, the diet with the highest rate was NL Toddler reaching 16% ADI, being spinaches the main contributor with 6% and milk (cattle) the second contributor with 5%. According to the performed calculations, no chronic risks for consumers can be identified due to the use of IN002B1760.

Regarding acute exposure, cucurbits with inedible peel are the main contributors both as primary commodities than processed commodities for children and adults, together with spinaches. However, according to the performed calculations, no acute risks for consumers can be identified.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev 3.1	23 % (based on GEMS/Food G06) 1st contributor: tomatoes 11% 2nd contributor: watermelons 3% 3rd contributor: table grapes 2%
IEDI (% ADI) according to EFSA PRIMo rev 3.1	16 % (based on NL toddler) 1st contributor: spinaches 6% 2nd contributor: milk (cattle) 5% 3rd contributor: apples 0.8%
IESTI (% ARfD) according to EFSA PRIMo rev 3.1	Children Primary commodities: Melons 76% Watermelons 61% Processed commodities: Pumpkins/boiled 44% Spinaches / frozen; boiled 17% Adults Primary commodities: Watermelons 20% Melons 20% Processed commodities: Pumpkins/boiled 28% Spinaches / frozen; boiled 10%
NTMDI (% ADI) **	Not necessary
NEDI (% ADI)**	Not necessary
NESTI (% ARfD) **	Not necessary

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

TMDI (% ADI) according to EFSA PRIMo rev 3.1	21% (based on GEMS/Food G06) 1st contributor: tomatoes 11% 2nd contributor: watermelons 3% 3rd contributor: melons 1%
IEDI (% ADI) according to EFSA PRIMo rev 3.1	Not necessary
IESTI (% ARfD) according to EFSA PRIMo rev 3.1	Children Primary commodities: Potatoes 2% Processed commodities: Potatoes / fried 1% Adults Primary commodities: Potatoes 0.05 0.4% Processed commodities: Potatoes / chips 0.1%
NTMDI (% ADI) **	Not necessary
NEDI (% ADI)**	Not necessary
NESTI (% ARfD) **	Not necessary

The proposed uses of cymoxanil in the formulation IN002B1760 do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev.3.1). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018).
Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation

(see section 7.1.2).
Current MRL values for cymoxanil according to the Reg. (EU) 2022/1363 have been taken into account as input values for the chronic assessment. For acute risk assessment, a refined assessment is presented, using the HR in potatoes and MRLS for animal commodities.
All MRLs for cymoxanil are based on the residue definition for monitoring/enforcement of parent cymoxanil only, which is also the residue definition for risk assessment. No Conversion Factor is required to account for the residue definitions, and no processing factors are required.

Long-term consumer intake concerns were not identified for any of the European diets incorporated in the EFSA PRIMo 3.1. The total calculated intake accounted for up to 21% of the ADI (based on GEMS/Food G06), see the following table.

TMDI (% ADI) according to EFSA PRIMo 3.1	21% (based on based on GEMS/Food G06 – tomatoes 11%)
IESTI (% ARfD) according to EFSA PRIMo 3.1	2% (children: Potatoes)

An acute consumer risk was not identified for consumption of potatoes. The acute consumer exposure was calculated to be 2% of the ARfD when potatoes is consumed by children and ~~0.05%~~ 0.4% of the ARfD by adult.
The chronic and the short-term intakes of cymoxanil residues are unlikely to present a public health concern.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

zRMS comments:
Information given by the Applicant is sufficient and accepted.

7.4 References

Austria, 2007. Draft assessment report 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, 2008. Final addendum to the draft assessment report on the active substance cymoxanil prepared by the rapporteur Member State Austria in the framework of Council Directive 91/414/EEC, September 2008

Austria, 2013. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for cymoxanil, July 2013. Available online: www.efsa.europa.eu

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.2008.167r

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, 47 pp. doi:10.2903/j.efsa.2015.4355

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Evaluation of confirmatory data following the Article 12 MRL review for cymoxanil. EFSA Journal 2019;17(10):5823, 23 pp. https://doi.org/10.2903/j.efsa.2019.5823

Appendix 1 Lists of data considered in support of the evaluation

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
KCA 6.3-01	Koenings, I.	2009	Determination of Cymoxanil and Mancozeb Residues in Wine Grapes Following Treatment with WP 4.5/68 or WP 4/46.5 under Open Field Conditions in Northern and Southern Europe, 2007 Doc. No. 632-4003 Anadiag Report no. R A7115 GLP, Unpublished	N	IND
KCA 6.3-02	Semrau J.	2010	Determination of Residues of Cymoxanil and Mancozeb After Six Applications Cymoxanil/Mancozeb 4.5/68 % w/w in Field Potatoes, Northern Europe, 2007/2008 Eurofins Report no.: 20074095/E1-FPPO Doc. No. 634-1105 GLP, Unpublished	N	Indofil Industries Limited IND
KCA 6.3-03	Semrau J.	2010	Determination of Residues of Cymoxanil and Mancozeb After Six Applications of Cymoxanil/Mancozeb 4.5/68 % w/w WP or Cymoxanil/Mancozeb 4/46.5 % w/w WP in Field Potatoes, Southern Europe, 2007/2008 Eurofins Report no.: 20074095/E2-FPPO Doc. No. 634-1106 GLP, Unpublished	N	IND
KCA 6.3-04	Sala A.	2021	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760 (Southern Europe – 2 open field trials year 2021) LabAnalysis Report no.: GLP-STUDY-21-58 GLP, Unpublished	N	IND
KCA 6.3-05	Sala A.	2021	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760 (Southern Europe – 2 greenhouse trials year 2021) LabAnalysis Report no.: GLP-STUDY-21-59 GLP, Unpublished	N	IND

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
Storage stability					
KCA 6.1-01 (from DAR, Vol. 3, Annex B, parte 3, B7)	Freschi G.	2004	Freezer storage stability of cymoxanil residue in lettuce plants Sipcam Research Centre SIP1379 GLP, Unpublished	N	Oxon
KCA 6.1-02 (from DAR, Vol. 3, Annex B, parte 3, B7)	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 time maximum use rates to investigate the need for magnitude of residue data in processed fractions Morse Laboratories Inc.; DuPont Experimental Station AMR 3296-95 GLP, Unpublished	N	DuPont
Nature of residues in plants					
KCA 6.2.1-01 (from DAR, Vol. 3, Annex B, parte 3, B7)	Fox G. C.	1999	Metabolism of [2-^{14}C]cymoxanil in lettuce DuPont Experimental Station, Wilmongton, Delaware, USA AMR 4375-97 GLP, Unpublished	N	DuPont
KCA 6.2.1-02 (from DAR, Vol. 3, Annex B, parte 3, B7)	Melkebeke T., van Noorloos B.	2003a	Metabolism, distribution and expression of cymoxanil residues in lettuce NOTOX B.V., 's-Hertogensbosch, The Netherlands 257794 GLP, Unpublished	N	Oxon
KCA 6.2.1-03 (from DAR, Vol. 3, Annex B, parte 3, B7)	Li Y., Hausman S.M.	1996	Plant metabolism of [2-^{14}C]cymoxanil in potatoes DuPont Experimental Station, Wilmongton, Delaware, USA AMR 3408-95 GLP, Unpublished	N	DuPont
KCA 6.2.1-04 (from DAR, Vol. 3, Annex B, parte 3, B7)	Melkebeke T., van Noorloos B.	2003b	Metabolism, distribution and expression of cymoxanil residues in potatoes NOTOX B.V., 's-Hertogensbosch, The Netherlands 257772 GLP, Unpublished	N	Oxon
Nature of residues in rotational crops					
KCA 6.6.1-01 (from DAR,	Singles S.K., Strek H.J., Sheftic G.D.	1996	Accumulation of residues in confined rotational crps: lettuce, wheat and beets after treatment with [^{14}C]cymoxanil DuPont Experimental Station	N	DuPont

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
Vol. 3, Annex B, parte 3, B7)			AMR 3575-95 GLP, Unpublished		
Nature of residues in livestock					
KCA 6.2.2-01 (from DAR, Vol. 3, Annex B, parte 3, B7)	[redacted]	1996	The distribution of [2-^{14}C]-DPX-T3217 (cymoxanil) in the lactating goat (nature of residue study to EPA guideline) [redacted] GLP, Unpublished	Y	DuPont

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
KCA 6.3-01	Koenings, I.	2009	Determination of Cymoxanil and Mancozeb Residues in Wine Grapes Following Treatment with WP 4.5/68 or WP 4/46.5 under Open Field Conditions in Northern and Southern Europe, 2007 Doc. No. 632-4003 Anadiag Report no. R A7115 GLP, Unpublished	N	IND
KCA 6.3-03	Semrau J.	2010	Determination of Residues of Cymoxanil and Mancozeb After Six Applications of Cymoxanil/Mancozeb 4.5/68 % w/w WP or Cymoxanil/Mancozeb 4/46.5 % w/w WP in Field Potatoes, Southern Europe, 2007/2008 Eurofins Report no.: 20074095/E2-FPPO Doc. No. 634-1106 GLP, Unpublished	N	IND
KCA 6.3-04	Sala A.	2021	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760 (Southern Europe – 2 open field trials year 2021) LabAnalysis Report no.: GLP-STUDY-21-58 GLP, Unpublished	N	IND
KCA 6.3-05	Sala A.	2021	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760 (Southern Europe – 2 greenhouse trials year 2021) LabAnalysis Report no.: GLP-STUDY-21-59	N	IND

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, Unpublished		

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
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Cymoxanil

A 2.1.1 Stability of residues

No studies performed in the framework of this application.

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

No studies performed in the framework of this application.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Grapes

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (a.s. g/ha)	Interval between applications	Growth stage at last application	PHI (days)
cGAP N-EU* (Art. 12, EFSA, 2015)	5	150	7	11-89	28
cGAP S-EU (Art. 12, EFSA, 2015)	4	170	7	15-85	21
Intended cGAP (number**1)	5	121.5	7-10	11-85	28

* Table grapes
**Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.1.1 Study 1

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	KCA 6.3-01
Report	Determination of Cymoxanil and Mancozeb Residues in Wine Grapes Following Treatment with WP 4.5/68 or WP 4/46.5 under Open Field Conditions in Northern and Southern Europe, 2007 Doc. No. 632-4003 Report no. R A7115
Guideline(s):	Yes 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
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 2: Summary of the study 1

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 analyzed	Residues	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				Cymoxanil		
	(a)	(b)				(c)			(mg/kg)	(d)	(e)
Northern Europe											
R A7115 Trial: A7115 BM1 Martigne Briand, Northern France	Grapes / FB1236 Grolleau	1. 1950 2. 08 -18/06/2007 3. 27/09/2007	0.109 0.112 0.112 0.113 0.117	968 995 998 1005 1041	0.011 0.011 0.011 0.011 0.011	18/06/2007 28/06/2007 09/07/2007 19/07/2007 30/07/2007	BBCH 79	Grapes	0.18 <0.01 <0.01 **<0.01** nd	0 7 14 **28** 56	Recovery data: Study R A7184 (Doc N. 432-015) Spiking levels 0.01-0.5 mg/kg: Grapes:79.6±12 % LOQ = 0.01 mg/kg LOD= 0.001 mg/kg N.D. = Not Detectable (Lower than limit of Detection) Formulation: WP 4 or 4.5% Storage time: max 314 days Time between extraction and analysis: max 24 hours
R A7115 Trial: A7115 CT1 Reuilly, Northern France	Grapes / FB1236 Pinot Noir	1. 1969 2. 20/05/ – 10/06/2007 3. 18/09/2007	0.123 0.121 0.116 0.121 0.110	1027 1004 967 1004 915	0.012 0.012 0.012 0.012 0.012	19/06/2007 27/06/2007 05/07/2007 13/07/2007 24/07/2007	BBCH 81	Grapes	0.06 < 0.01 < 0.01 < 0.01 nd	0 7 14 27 55	
R A7115 Trial: A7115 AN1 Frudenheim, Northern France	Grapes / FB1236 Auxerrois	1. 1993 2. 25/05/ – 04/06/2007 3. 03/09/ – 13/09/2007	0.124 0.126 0.120 0.118 0.115	1033 1049 997 979 954	0.012 0.012 0.012 0.012 0.012	14/06/2007 22/06/2007 30/07/2007 09/07/2007 17/07/2007	BBCH 77	Grapes	< 0.01 nd	28 56	
R A7115 Trial: A7115 GE1 Endingen, Germany	Grapes / FB1236 Weissburgunder	1. 1998 2. 20 -29/05/2007 3. 09/ – 20/09/2007	0.119 0.121 0.116 0.117 0.124	991 1005 964 977 1036	0.012 0.012 0.012 0.012 0.012	16/06/2007 23/06/2007 02/07/2007 10/07/2007 18/07/2007	BBCH 79	Grapes	< 0.01 < 0.01	29 55	
Southern Europe											
R A7115 Trial: A7115 IT1 Monleale, Italy	Grapes / FB1236 Barbera	1. 2002 2. 25/05 – 12/06/2007 3. 20/ – 30/09/2007	0.115 0.113 0.113 0.118 0.103	1022 1001 1001 1051 918	0.011 0.011 0.011 0.011 0.011	18/06/2007 27/06/2007 06/07/2007 16/07/2007 26/07/2007	BBCH 81 – 83	Grapes	0.41 0.07 0.02 < 0.01 < 0.01	0 6 21 28 57	Recovery data: Study R A7184 (Doc N. 432-015) Spiking levels 0.01-0.5 mg/kg: Grapes:79.6±12 % LOQ = 0.01 mg/kg LOD= 0.001 mg/kg N.D. = Not Detectable (Lower than limit of Detection) Formulation: WP 4 or 4.5% Storage time: max 314 days
R A7115 Trial: A7115 BD1 Tain l'Hermitage, Southern France	Grapes / FB1236 Syrah	1. 1992 2. 24/05 – 05/06/2007 3. 15/09 – 23/09/2007	0.122 0.116 0.118 0.126	1019 965 984 1048	0.012 0.012 0.012 0.012	15/06/2007 25/06/2007 04/07/2007 13/07/2007	BBCH 79	Grapes	< 0.01 nd	28 56	

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (b)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (c)	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	PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				Cymoxanil (mg/kg)		
R A7115 Trial: A7115 TL1 Fronton, Southern France	Grapes / FB1236 Negrette	1. 1991 2. 11/06 - 21/06/2007 3. 15/09 - 20/09/2007	0.123 0.125 0.125 0.126 0.123	1021 1043 1038 1050 1025	0.012 0.012 0.012 0.012 0.012	14/06/2007 25/06/2007 04/07/2007 13/07/2007 23/07/2007	BBCH 81	Grapes	< 0.01 nd	28 57	Time between extraction and analysis: max 24 hours
R A7115 Trial: A7115 GR1 Polla Nera, Greece	Grapes / FB1236 Syrah	1. 2001 2. 24/05 - 05/06/2007 3. 01/10/2007	0.122 0.117 0.114 0.126 0.113	1016 975 952 1053 943	0.012 0.012 0.012 0.012 0.012	25/06/2007 06/07/2007 16/07/2007 27/07/2007 06/08/2007	BBCH 81	Grapes	0.28 0.02 < 0.01 < 0.01 < 0.01	0 7 14 28 56	

(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 2.1.3.2 Potatoes

Table A 3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (a.s. g/ha)	Interval between applications	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	6	130	5	13-93	7
Intended cGAP (number*2)	6	148.5	5-10	12-95	7

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

A 2.1.3.2.1 Study 2

Comments of zRMS:	Four residue field trials on potatoes were conducted in the Germany, Poland and Northern France during 2007/2008. Cymoxanil/Mancozeb 4.5/68% w/w WP was applied to potatoes. Six applications separated by a 5 ±1 days interval were made at 120 g ai/ha for cymoxanil. Treated samples were taken at 0, 3, 7, 14, 21 and 28 days after application. Results: In all trials no residues of cymoxanil were found in the treated and untreated field specimens of potato tubers above the limit of detection (0.003 mg/kg). Specimens were stored frozen for a maximum period of 280 days from sampling to analysis for cymoxanil. The specimens of potato (tubers) were analysed for cymoxanil using DFG method S 19 (extend revision) with extraction module E 1 and gel permeation chromatography with LOQ of 0.01 mg/kg. The study is acceptable.

Reference:	KCA 6.3-02
Report	Determination of Residues of Cymoxanil and Mancozeb After Six Applications Cymoxanil/Mancozeb 4.5/68 % w/w in Field Potatoes, Northern Europe, 2007/2008; Semrau, J. (2010) Doc. No. 634-1105 Report no.: 20074095/E1-FPPO
Guideline(s):	Yes 1607/VI/95 rev. 2
Deviations:	No
GLP:	Yes
Acceptability:	Yes

~~Reference:~~	~~KCA 6.3-03~~
~~Report~~	~~Determination of Residues of Cymoxanil and Mancozeb After Six Applications of Cymoxanil/Mancozeb 4.5/68 % w/w WP or Cymoxanil/Mancozeb 4/46.5 % w/w WP in Field Potatoes, Southern Europe, 2007/2008~~ ~~Doc. No. 634-1106~~ ~~Report no.: 20074095/E2-FPPO~~
~~Guideline(s):~~	~~Yes~~ ~~1607/VI/95 rev. 2~~
~~Deviations:~~	~~No~~
~~GLP:~~	~~Yes~~
~~Acceptability:~~	~~Yes~~

Table A 4: Summary of the study 1

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 analyzed	Residues	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				Cymoxanil		
	(a)	(b)				(c)			(mg/kg)	(d)	(e)
Northern Europe											
20074095/E1-FPPO Trial: F07W133R Plouhinec, Brittany, Northern France	Potatoes / Ondine	1. 20/04/2007 2. 14/06 – 10/07/2007 3. 16/08/2007	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	18/07/2007 25/07/2007 30/07/2007 02/08/2007 08/08/2007 13/08/2007	95	Tubers	nd nd **nd** nd nd nd	0 3 **7** 14 21 28	Recovery data: Study GAB-0703V (Doc N. 432-018) Spiking levels 0.01-0.1 mg/kg: Potato:101±3.2 % LOQ = 0.01 mg/kg LOD= 0.003 mg/kg N.D. = Not Detectable (Lower than limit of Detection) Formulation: WP 4.5% Storage time: max 280 days Time between extraction and analysis: max 24 hours
20074095/E1-FPPO Trial: G07W344R Blumberg, Brandenburg, Germany	Potatoes / Kormoran	1. 14/04/2007 2. 02/06 – 05/07/2007 3. 09/08/2007	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	13/07/2007 16/07/2007 23/07/2007 26/07/2007 02/08/2007 06/08/2007	97	Tubers	nd nd **nd** nd nd nd	0 3 **7** 14 21 28	
20074095/E1-FPPO Trial: S08-02370-01 Rutesheim-Perouse, Baden-Würrtemberg, Germany	Potatoes / Nicola	1. 30/04/2008 2. na 3. 01/09/2008	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	01/08/2008 07/08/2008 13/08/2008 19/08/2008 25/08/2008 29/08/2008	48	Tubers	nd nd **nd** nd nd nd	0 3 **7** 14 21 28	
20074095/E1-FPPO Trial: PL07W020R Brodziszewo, Wielkopolska, Poland	Potatoes / Pasat	1. 13/04/2007 2. na 3. 09/10/2007	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	11/09/2007 17/09/2007 21/09/2007 26/09/2007 01/10/2007 06/10/2007	49	Tubers	nd nd **nd** nd nd nd	0 3 **7** 14 21 28	
~~Southern Europe~~											

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	PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				Cymoxanil (mg/kg)		
20074095/E2-FPPO Trial: S07W130R Mareny, Valencia, Spain	Potatoes / Martina	1. 03/09/2007 2. na 3. 23/12/2007	0.123 0.118 0.123 0.118 0.122 0.120	419 403 418 403 415 408	0.029 0.029 0.029 0.029 0.029 0.029	26/11/2007 30/11/2007 05/12/2007 10/12/2007 14/12/2007 20/12/2007	48	Tubers	nd nd **nd** nd nd nd	0 3 7 14 21 28	Recovery data: Study GAB-0703V (Doc N. 432-018) Spiking levels 0.01-0.1 mg/kg: Potato:101±3.2 % LOQ = 0.01 mg/kg LOD= 0.003 mg/kg N.D. = Not Detectable (Lower than limit of Detection) Formulation: WP 4.5% Storage time: max 280 days Time between extraction and analysis: max 24 hours
20074095/E2-FPPO Trial: F07W135R Montauban, Midi-Pyrénées, Southern France	Potatoes / Mona Lisa	1. 23/05/2007 2. na 3. 12/08/2007	0.129 0.128 0.128 0.127 0.128 0.124	301 300 300 298 301 290	0.043 0.043 0.043 0.043 0.043 0.043	17/07/2007 20/072007 25/07/2007 30/07/2007 04/08/2007 09/08/2007	47-69	Tubers	nd nd **nd** nd nd nd	0 3 7 14 21 28	
20074095/E2-FPPO Trial: S08-02371-01 Pernes-les-Fontaines, Provence-Alpes-Côte d'Azur, Southern France	Potatoes / Cicero	1. 15/03/2008 2. June – July 2008 3. 11/08/2008	0.134 0.130 0.118 0.118 0.137 0.120	313 304 276 277 321 280	0.043 0.043 0.043 0.043 0.043 0.043	13/07/2008 18/07/2008 23/07/2008 28/07/2008 02/08/2008 08/08/2008	97	Tubers	nd nd **nd** nd nd nd	0 3 7 14 21 28	
20074095/E2-FPPO Trial: S07W131R Villarreal de Huerva, Aragon, Spain	Potatoes / Agria	1. 15/05/2007 2. na 3. 14/09/2007	0.128 0.132 0.132 0.131 0.129 0.129	401 411 413 410 404 402	0.032 0.032 0.032 0.032 0.032 0.032	17/08/2007 22/082007 27/08/2007 31/08/2007 06/09/2007 11/09/2007	47-48	Tubers	nd nd **nd** nd nd nd	0 3 7 14 21 28	

(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 2.1.3.3 Tomatoes, Aubergines

Table A 5: Comparison of intended and critical EU GAPs

Tomatoes

Type of GAP	Number of applications	Application rate per treatment (a.s. g/ha)	Interval between applications	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	4	240	7	15-89	3
Intended cGAP (number*3)	5	148.5	7-10	12-89	3

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

Aubergines

Type of GAP	Number of applications	Application rate per treatment (a.s. g/ha)	Interval between applications	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	5	120	7	15-89	3
Intended cGAP (number*3)	5	148.5	7-10	12-89	3

A 2.1.3.3.1 Study 1

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference: KCA 6.3.04

Report: Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760
(Southern Europe – 2 open field trials year 2021)
Sala A., 2021
Report no.: GLP-STUDY-21-58

Guideline(s): Yes

- Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 11, The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP) OECD ENV/MC/CHEM(98)16.
- Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).
- Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).
- Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.
- Commission of the European Communities Working Document 7029/VI/95 rev.5 Appendix B: "General Recommendations for the Design, Preparation and Realization of Residue Trials, 22 July 1997."
- European Commission, Directorate General Health and Consumer Protection: SANTE/2019/12752 Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin.
- SANTE/2020/12830 Rev.1, dated 24. February 2021: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post approval Control and Monitoring Purposes

Deviations: No

GLP: Yes

Acceptability: Yes

Summary of the study

The objective of this study was the determination of cymoxanil residues in raw agricultural commodity (RAC) tomato samples coming from 2 harvest trials carried out in open field in Southern Europe (Italy).
Five applications of IN002B1760 were carried out.
The analytical determination was carried out using a HPLC-MS/MS method validated and confirmed according to SANTE/2020/12830 Rev.1 dated 24 February 2021 guideline during the study.

Field phase
The trial codes and locations were the following:

- BF 21 03 BPL IT 01: 81047 – Macerata Campania (CE) – ITALY
- BF 21 03 BPL IT 02: 80031 – Brusciano (NA) – ITALY

The formulated product was applied on plot T at a rate of 0.33 kg/ha corresponding to 0.1551 kg/ha of Cymoxanil – each application.
The water volume was selected according to Good Agricultural Practice in the trial area (1000 L/ha).

Actual application timings, rates and deviations from the target rate are reported in the following table:

Table 14: Field Phase – application details

BF 21 03 BPL IT 01	03/08/2021	A1	T	79-81	0.1558	1004	+0.45
	10/08/2021	A2	T	81-83	0.1543	995	-0.55
	17/08/2021	A3	T	83-85	0.1550	1000	-0.05
	24/08/2021	A4	T	85-87	0.1550	1000	-0.05
	31/08/2021	A5	T	87-89	0.1554	1002	+0.20
BF 21 03 BPL IT 02	11/08/2021	A1	T	80-81	0.1551	1000	+0.00
	18/08/2021	A2	T	81-83	0.1560	1006	+0.56
	25/08/2021	A3	T	83-85	0.1555	1003	+0.28
	01/09/2021	A4	T	85-87	0.1547	997	-0.28
	08/09/2021	A5	T	87-89	0.1551	1000	+0.00

Table 15: Field Phase – sampling details

Trial code: BF 21 03 BPL IT 01					
GLP-SMPL-21-845	C	S1	87-89	03/09/2021	3 DALA
GLP-SMPL-21-847	T				

[1]DALA: Days after last application

Trial code: BF 21 03 BPL IT 02					
GLP-SMPL-21-889	C	S1	87-89	11/09/2021	3 DALA
GLP-SMPL-21-891	T				

[1]DALA: Days after last application

Analytical phase
The analyses were carried using an analytical method validated during the study according to SANTE/2020/12830 Rev.1, dated 24. February 2021 guideline.

A summary of the residues found on samples is reported in the following table:

Table 16: Field samples - result summary

BF 21 03 BPL IT 01	GLP SMPL 21 845	C	3 DALA	N.D.[2]
	GLP SMPL 21 847	T		N.D.
BF 21 03 BPL IT 02	GLP SMPL 21 889	C		N.D
	GLP SMPL 21 891	T		N.D

[1]DALA: Day After Last Application
[2]N.D: Non detectable, residue lower than instrumental Limit of Detection (LOD = 0.00216 mg/kg)

Table A 6: Summary of the study 1 GLP-STUDY-21-58

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	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				Cymoxanil (mg/kg)	(d)	(e)
Southern Europe											
Study Code: GLP-STUDY-21-58 Trial No: BF-21-03-BPL-IT-01 81047-Macerata Campania-Italy	Tomato / Elba F1	1. 2021 2. n.a. 3. 03/09/2021	0,1558 0,1543 0,1550 0,1550 0,1554	1004 995 1000 1000 1002	0,01552 0,01551 0,01550 0,01550 0,01551	03/08/2021 10/08/2021 17/08/2021 24/08/2021 31/08/2021	79-80 81-83 83-85 85-87 87-89	Tomato	<LOD	3	Recovery data: Study GLP-STUDY-21-58 Spiking levels 0.01-0.1 mg/kg: Tomato: 98.6±6.6 % LOQ = 0.01 mg/kg LOD= 0.003 mg/kg N.D. = Not Detectable (Lower than limit of Detection) Formulation: WP 45% Storage time: max 66 days Time between extraction and analysis: max 24 hours
Study Code: GLP-STUDY-21-58 Trial No: BF-21-03-BPL-IT-02 80031-Brusciano-Italy	Tomato / Dragone F1	1. 2021 2. n.a. 3. 11/09/2021	0,1551 0,1560 0,1555 0,1547 0,1551	1000 1006 1003 997 1000	0,01551 0,01551 0,01550 0,01552 0,01551	11/08/2021 18/08/2021 25/08/2021 01/09/2021 08/09/2021	80-81 81-83 83-85 85-87 87-89	Tomato	<LOD	3	

(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 2.1.3.3.2 Study 2

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference: KCA 6.3.05

Report: Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760
(Southern Europe – 2 greenhouse trials year 2021)
Sala A, 2021
Report no.: GLP-STUDY-21-59

Guideline(s): Yes

- Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 11, The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP) OECD ENV/MC/CHEM(98)16.
- Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).
- Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).
- Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.
- Commission of the European Communities Working Document 7029/VI/95 rev.5 Appendix B: "General Recommendations for the Design, Preparation and Realization of Residue Trials, 22 July 1997."
- European Commission, Directorate General Health and Consumer Protection: SANTE/2019/12752 Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin.
- SANTE/2020/12830 Rev.1, dated 24. February 2021: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

Deviations: No

GLP: Yes

Acceptability: Yes

Summary of the study

The objective of this study was the determination of cymoxanil residues in raw agricultural commodity (RAC) tomato samples coming from 2 harvest trials carried out in greenhouse in Southern Europe (Italy).
Five applications of IN002B1760 were carried out.
The analytical determination was carried out using a HPLC-MS/MS method validated in the concurrent study GLP-STUDY-21-58 *Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760 (Southern Europe – 2 open field trials year 2021)* test facility LabAnalysis – Study Director Alberto Sala – in compliance with SANTE/2020/12830 Rev.1 dated 24 February 2021 guideline.

Field phase
The trial codes and locations were the following:

- BF 21 03 BPL IT 03: 81047 – Macerata Campania (CE) – ITALY
- BF 21 03 BPL IT 04: 81025 – Marcianise (CE) - ITALY

The formulated product was applied on plot T at a rate of 0.33 kg/ha corresponding to 0.1551 kg/ha of Cymoxanil – each application.

The water volume was selected according to Good Agricultural Practice in the trial area (1000 L/ha).

Actual application timings, rates and deviations from the target rate are reported in the following table:

Table 17: Field Phase – application details

Trial	Actual Application Data						
	Date	Application	Plot	BBCH	Test item rate (kg cymoxanil/ha)	Water (L/ha)	% – deviation from – target rate
BF-21-03-BPL-IT-03	06/07/2021	A1	T	77-79	0.1551	1000	+0.00
	13/07/2021	A2	T	81-83	0.1559	1005	+0.50
	20/07/2021	A3	T	83-85	0.1551	1000	+0.00
	27/07/2021	A4	T	85-87	0.1555	1003	+0.25
	03/08/2021	A5	T	87-89	0.1570	1013	+1.25
BF-21-03-BPL-IT-04	13/07/2021	A1	T	77-79	0.1546	997	-0.31
	20/07/2021	A2	T	81-83	0.1561	1006	+0.63
	27/07/2021	A3	T	83-85	0.1551	1000	+0.0
	03/07/2021	A4	T	85-87	0.1556	1003	+0.31
	10/08/2021	A5	T	87-89	0.1551	1000	+0.0

Table 18: Field Phase – sampling details

Trial code: BF-21-03-BPL-IT-03					
GLP-SMPL-21-849	C	S1	87-89	06/08/2021	3 DALA
GLP-SMPL-21-851	T				

[1]DALA: Days after last application

Trial code: BF-21-03-BPL-IT-04					
GLP-SMPL-21-893	C	S1	87-89	13/08/2021	3 DALA
GLP-SMPL-21-895	T				

[1]DALA: Days after last application

Analytical phase

The analyses were carried using an analytical method validated in the concurrent study GLP-STUDY-21-58, according to -SANTE/2020/12830 Rev.1, dated 24. February 2021 guideline.

A summary of the residues found on samples is reported in the following table:

Table 19: Field samples – result summary

BF-21-03-BPL-IT-03	GLP-SMPL-21-849	C	3 DALA	**N.D.**[2]
	GLP-SMPL-21-851	T		**N.D.**
BF-21-03-BPL-IT-04	GLP-SMPL-21-893	C		**N.D**
	GLP-SMPL-21-895	T		**N.D**

[1]DALA: Day After Last Application

[2]N.D: Non detectable, residue lower than instrumental Limit of Detection (LOD = 0.00216 mg/kg)

Table A 7: Summary of the study 2 – GLP-STUDY-21-59

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	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				Cymoxanil (mg/kg)	(d)	(e)
Southern Europe											
Study Code: GLP-STUDY-21-58 Trial No: BF-21-03-BPL-IT-03 81047-Macerata Campania-Italy	Tomato / Clanio F1	1. 2021 2. n.a. 3. 06/08/2021	0,1551 0,1559 0,1551 0,1550 0,1550	1000 1005 1000 1003 1013	0,01551 0,01551 0,01551 0,01550 0,01550	06/07/2021 13/07/2021 20/07/2021 27/07/2021 03/08/2021	77-79 81-83 83-85 85-87 87-89	Tomato	<LOD	3	Recovery data: Study GLP-STUDY-21-58 Spiking levels 0.01-0.1 mg/kg: Tomato: 98.6±6.6 % LOQ = 0.01 mg/kg LOD= 0.003 mg/kg N.D. = Not Detectable (Lower than limit of Detection) Formulation: WP 45% Storage time: max 96 days Time between extraction and analysis: max 24 hours
Study Code: GLP-STUDY-21-58 Trial No: BF-21-03-BPL-IT-04 81025-Marcianise-Italy	Tomato / Apero F1	1. 2021 2. n.a. 3. 13/08/2021	0,1551 0,1560 0,1555 0,1547 0,1551	1000 1006 1003 997 1000	0,01551 0,01551 0,01550 0,01552 0,01551	11/08/2021 18/08/2021 25/08/2021 01/09/2021 08/09/2021	80-81 81-83 83-85 85-87 87-89	Tomato	<LOD	3	

(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 2.1.4 Magnitude of residues in livestock

No studies performed in the framework of this application.

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

No studies performed in the framework of this application.

A 2.1.6 Magnitude of residues in representative succeeding crops

No studies performed in the framework of this application.

A 2.1.7 Other/Special Studies

No studies performed in the framework of this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo) rev 3.1

A 3.1 TMDI calculations

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	23%	GEMS/Food G06	3,05	11%	Tomatoes	3%	Watermelons	2%	Table grapes	3%	
	22%	NL toddler	2,89	6%	Spinaches	5%	Milk: Cattle	4%	Table grapes	10%	
	15%	RO general	1,97	6%	Tomatoes	4%	Wine grapes	1%	Watermelons	3%	
	14%	DE child	1,80	3%	Table grapes	3%	Tomatoes	2%	Spinaches	5%	
	12%	GEMS/Food G07	1,57	3%	Wine grapes	3%	Tomatoes	0,8%	Table grapes	3%	
	12%	GEMS/Food G15	1,57	4%	Tomatoes	2%	Wine grapes	1%	Watermelons	3%	
	12%	IE adult	1,54	3%	Wine grapes	3%	Melons	1%	Tomatoes	3%	
	12%	NL child	1,52	2%	Table grapes	2%	Spinaches	2%	Milk: Cattle	5%	
	11%	GEMS/Food G08	1,48	4%	Tomatoes	2%	Wine grapes	0,8%	Table grapes	3%	
	11%	GEMS/Food G10	1,45	4%	Tomatoes	1,0%	Wine grapes	0,7%	Table grapes	3%	
	11%	FR child 3 15 yr	1,44	3%	Tomatoes	2%	Milk: Cattle	1%	Melons	5%	
	11%	PT general	1,43	6%	Wine grapes	3%	Tomatoes	0,6%	Table grapes	2%	
	11%	GEMS/Food G11	1,42	3%	Tomatoes	2%	Wine grapes	1,0%	Table grapes	3%	
	10%	FR adult	1,29	5%	Wine grapes	1%	Tomatoes	0,4%	Melons	2%	
	9%	DE women 14-50 yr	1,14	2%	Tomatoes	2%	Wine grapes	1,0%	Milk: Cattle	3%	
	8%	DE general	1,06	2%	Tomatoes	2%	Wine grapes	0,9%	Milk: Cattle	3%	
	8%	FR toddler 2 3 yr	1,06	2%	Milk: Cattle	1%	Tomatoes	1%	Spinaches	5%	
	8%	ES child	1,06	3%	Tomatoes	1,0%	Milk: Cattle	0,6%	Spinaches	3%	
	8%	FI adult	1,02	4%	Coffee beans	2%	Tomatoes	0,7%	Wine grapes	5%	
	7%	IT toddler	0,94	4%	Tomatoes	0,5%	Wheat	0,4%	Spinaches	1%	
	7%	NL general	0,93	1%	Wine grapes	1%	Tomatoes	1%	Spinaches	2%	
	7%	DK child	0,92	2%	Tomatoes	1%	Cucumbers	1,0%	Milk: Cattle	3%	
	7%	SE general	0,90	2%	Tomatoes	1,0%	Milk: Cattle	0,5%	Spinaches	3%	
	7%	ES adult	0,88	2%	Tomatoes	1,0%	Wine grapes	0,6%	Melons	2%	
	7%	IT adult	0,88	4%	Tomatoes	0,7%	Spinaches	0,4%	Melons	0,9%	
	7%	UK toddler	0,86	2%	Tomatoes	2%	Milk: Cattle	0,6%	Table grapes	4%	
	6%	UK infant	0,83	3%	Milk: Cattle	1%	Tomatoes	0,3%	Potatoes	5%	
	6%	DK adult	0,80	2%	Wine grapes	2%	Tomatoes	0,4%	Melons	1%	
	6%	UK vegetarian	0,76	2%	Tomatoes	2%	Wine grapes	0,3%	Spinaches	1%	
	6%	FR infant	0,73	2%	Spinaches	1%	Milk: Cattle	0,5%	Pumpkins	2%	
	6%	FI 3 yr	0,72	2%	Tomatoes	0,8%	Watermelons	0,6%	Cucumbers	1%	
	5%	UK adult	0,70	2%	Wine grapes	1%	Tomatoes	0,2%	Milk: Cattle	1%	
	5%	FI 6 yr	0,60	1%	Tomatoes	0,8%	Watermelons	0,4%	Cucumbers	1%	
	4%	PL general	0,56	3%	Tomatoes	0,7%	Table grapes	0,3%	Potatoes	0,7%	
	3%	LT adult	0,45	2%	Tomatoes	0,3%	Milk: Cattle	0,2%	Potatoes	1%	
	1%	IE child	0,13	0,3%	Milk: Cattle	0,2%	Tomatoes	0,1%	Table grapes	0,6%	

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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	21%	GEMS/Food G06	2,76	11%	Tomatoes	3%	Watermelons	1%	Melons		
	19%	NL toddler	2,42	5%	Spinaches	5%	Milk: Cattle	3%	Tomatoes		
	12%	RO general	1,50	6%	Tomatoes	1%	Watermelons	0,9%	Milk: Cattle		
	11%	DE child	1,43	3%	Tomatoes	2%	Milk: Cattle	1%	Spinaches		
	10%	GEMS/Food G10	1,26	4%	Tomatoes	0,7%	Watermelons	0,6%	Pumpkins		
	9%	NL child	1,23	2%	Milk: Cattle	2%	Spinaches	2%	Tomatoes		
	9%	FR child 3 15 yr	1,23	3%	Tomatoes	2%	Milk: Cattle	1%	Melons		
	9%	GEMS/Food G15	1,23	4%	Tomatoes	1%	Watermelons	0,5%	Milk: Cattle		
	9%	IE adult	1,13	3%	Melons	1%	Tomatoes	0,9%	Spinaches		
	9%	GEMS/Food G08	1,13	4%	Tomatoes	0,6%	Melons	0,5%	Watermelons		
	9%	GEMS/Food G07	1,11	3%	Tomatoes	0,6%	Wine grapes	0,5%	Milk: Cattle		
	8%	GEMS/Food G11	1,05	3%	Tomatoes	0,6%	Spinaches	0,6%	Milk: Cattle		
	8%	ES child	1,02	3%	Tomatoes	1,0%	Milk: Cattle	0,6%	Watermelons		
	8%	FR toddler 2 3 yr	0,98	2%	Milk: Cattle	1%	Tomatoes	1%	Spinaches		
	7%	FI adult	0,92	4%	Coffee beans	2%	Tomatoes	0,2%	Cucumbers		
	7%	IT toddler	0,90	4%	Tomatoes	0,5%	Wheat	0,4%	Spinaches		
	7%	SE general	0,89	2%	Tomatoes	1,0%	Milk: Cattle	0,5%	Spinaches		
	7%	DK child	0,87	2%	Tomatoes	1%	Cucumbers	1,0%	Milk: Cattle		
	7%	DE women 14-50 yr	0,85	2%	Tomatoes	1,0%	Milk: Cattle	0,4%	Sugar beet roots		
	6%	IT adult	0,83	4%	Tomatoes	0,7%	Spinaches	0,4%	Melons		
	6%	UK infant	0,80	3%	Milk: Cattle	1%	Tomatoes	0,3%	Potatoes		
	6%	DE general	0,79	2%	Tomatoes	0,9%	Milk: Cattle	0,4%	Coffee beans		
	6%	UK toddler	0,76	2%	Tomatoes	2%	Milk: Cattle	0,3%	Wheat		
	6%	ES adult	0,75	2%	Tomatoes	0,6%	Melons	0,5%	Spinaches		
	6%	PT general	0,73	3%	Tomatoes	1,0%	Wine grapes	0,4%	Potatoes		
	5%	NL general	0,70	1%	Tomatoes	1%	Spinaches	0,7%	Milk: Cattle		
	5%	FR infant	0,70	2%	Spinaches	1%	Milk: Cattle	0,5%	Pumpkins		
	5%	FR adult	0,67	1%	Tomatoes	0,9%	Wine grapes	0,4%	Melons		
	5%	FI 3 yr	0,66	2%	Tomatoes	0,8%	Watermelons	0,6%	Cucumbers		
	4%	FI 6 yr	0,55	1%	Tomatoes	0,8%	Watermelons	0,4%	Cucumbers		
	4%	DK adult	0,52	2%	Tomatoes	0,4%	Melons	0,4%	Milk: Cattle		
	4%	UK vegetarian	0,52	2%	Tomatoes	0,3%	Wine grapes	0,3%	Milk: Cattle		
	4%	PL general	0,48	3%	Tomatoes	0,3%	Potatoes	0,2%	Apples		
	3%	LT adult	0,45	2%	Tomatoes	0,3%	Milk: Cattle	0,2%	Potatoes		
	3%	UK adult	0,41	1%	Tomatoes	0,4%	Wine grapes	0,2%	Milk: Cattle		
	0,9%	IE child	0,12	0,3%	Milk: Cattle	0,2%	Tomatoes	0,1%	Wheat		

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 3.2 IEDI calculations

Chronic risk assessment: JMPR methodology (IEDI/TMDI)												
				No of diets exceeding the ADI :	---						Exposure resulting from	
	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		MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	16%	NL toddler	2,05	6%	Spinaches	5%	Milk: Cattle	0,8%	Apples		9%	16%
	10%	GEMS/Food G06	1,24	3%	Watermelons	1%	Melons	0,7%	Pumpkins		2%	10%
	8%	DE child	1,01	2%	Spinaches	2%	Milk: Cattle	1,0%	Apples		5%	8%
	8%	NL child	1,00	2%	Spinaches	2%	Milk: Cattle	0,6%	Sugar beet roots		5%	8%
	7%	FR child 3 15 yr	0,90	2%	Milk: Cattle	1%	Melons	0,8%	Spinaches		4%	7%
	7%	IE adult	0,87	3%	Melons	1,0%	Spinaches	0,3%	Milk: Cattle		3%	7%
	6%	FR toddler 2 3 yr	0,81	2%	Milk: Cattle	1%	Spinaches	0,3%	Beans (with pods)		5%	6%
	5%	GEMS/Food G15	0,70	1%	Watermelons	0,5%	Milk: Cattle	0,3%	Wheat		3%	5%
	5%	GEMS/Food G10	0,70	0,7%	Watermelons	0,6%	Pumpkins	0,5%	Melons		3%	5%
	5%	FI adult	0,69	4%	Coffee beans	0,2%	Cucumbers	0,1%	Spinaches		5%	5%
	5%	FR infant	0,68	2%	Spinaches	1%	Milk: Cattle	0,5%	Pumpkins		2%	5%
	5%	UK infant	0,68	3%	Milk: Cattle	0,3%	Potatoes	0,2%	Peas (without pods)		5%	5%
	5%	DK child	0,66	1%	Cucumbers	1,0%	Milk: Cattle	0,8%	Melons		3%	5%
	5%	ES child	0,66	1,0%	Milk: Cattle	0,6%	Spinaches	0,6%	Watermelons		3%	5%
	5%	GEMS/Food G11	0,64	0,7%	Spinaches	0,6%	Milk: Cattle	0,4%	Melons		3%	5%
	5%	GEMS/Food G08	0,62	0,6%	Melons	0,5%	Watermelons	0,4%	Milk: Cattle		3%	5%
	5%	GEMS/Food G07	0,62	0,5%	Milk: Cattle	0,5%	Melons	0,4%	Pumpkins		3%	5%
	5%	RO general	0,61	1%	Watermelons	0,9%	Milk: Cattle	0,4%	Wheat		2%	5%
	4%	SE general	0,58	1,0%	Milk: Cattle	0,5%	Spinaches	0,3%	Bovine: Muscle/meat		2%	4%
	4%	UK toddler	0,55	2%	Milk: Cattle	0,3%	Wheat	0,3%	Beans		3%	4%
	4%	NL general	0,52	1%	Spinaches	0,7%	Milk: Cattle	0,2%	Sugar beet roots		2%	4%
	4%	DE women 14-50 yr	0,52	1,0%	Milk: Cattle	0,4%	Spinaches	0,4%	Sugar beet roots		3%	4%
	4%	DE general	0,49	0,9%	Milk: Cattle	0,4%	Coffee beans	0,4%	Spinaches		3%	4%
	3%	FI 3 yr	0,44	0,8%	Watermelons	0,6%	Cucumbers	0,5%	Spinaches		1,0%	3%
	3%	ES adult	0,43	0,6%	Melons	0,6%	Spinaches	0,4%	Milk: Cattle		2%	3%
	3%	FR adult	0,40	0,4%	Melons	0,4%	Spinaches	0,3%	Milk: Cattle		2%	3%
	3%	FI 6 yr	0,38	0,8%	Watermelons	0,4%	Cucumbers	0,4%	Spinaches		0,8%	3%
	3%	IT adult	0,35	0,7%	Spinaches	0,4%	Melons	0,4%	Watermelons		0,8%	3%
	2%	IT toddler	0,32	0,5%	Wheat	0,4%	Spinaches	0,3%	Melons		1%	2%
	2%	PT general	0,28	0,4%	Potatoes	0,3%	Wheat	0,3%	Melons		1%	2%
	2%	DK adult	0,27	0,4%	Melons	0,4%	Milk: Cattle	0,1%	Cucumbers		1%	2%
	2%	UK vegetarian	0,25	0,3%	Spinaches	0,3%	Milk: Cattle	0,2%	Melons		1%	2%
	2%	UK adult	0,20	0,2%	Milk: Cattle	0,1%	Melons	0,1%	Spinaches		1,0%	2%
	2%	LT adult	0,20	0,3%	Milk: Cattle	0,2%	Potatoes	0,2%	Cucumbers		0,9%	2%
	0,9%	PL general	0,12	0,3%	Potatoes	0,2%	Apples	0,1%	Tomatoes		0,4%	0,9%
	0,7%	IE child	0,10	0,3%	Milk: Cattle	0,1%	Wheat	0,1%	Melons		0,6%	0,7%
	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 - Raw commodities

Unprocessed commodities

Results for children
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)
76%	Melons	0,4 / 0,4	61
61%	Watermelons	0,4 / 0,4	49
28%	Spinaches	1 / 1	23
13%	Pumpkins	0,4 / 0,4	11
7%	Cucumbers	0,08 / 0,08	5,2
5%	Courgettes	0,08 / 0,08	3,7
2%	Potatoes	0,01 / 0,01	1,5
2%	Pears	0,01 / 0,01	1,4
2%	Oranges	0,01 / 0,01	1,3
2%	Milk: Cattle	0,01 / 0,01	1,2
2%	Peas (with pods)	0,15 / 0,15	1,2
1%	Leeks	0,02 / 0,02	1,2
1%	Lettuces	0,03 / 0,03	1,1
1%	Apples	0,01 / 0,01	1,1
1%	Pineapples	0,01 / 0,01	1,0

Expand/collapse list

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

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)
20%	Watermelons	0,4 / 0,4	16
20%	Melons	0,4 / 0,4	16
7%	Pumpkins	0,4 / 0,4	5,9
5%	Spinaches	1 / 1	4,0
3%	Cucumbers	0,08 / 0,08	2,2
2%	Courgettes	0,08 / 0,08	1,9
0,6%	Peas (with pods)	0,15 / 0,15	0,51
0,6%	Gherkins	0,08 / 0,08	0,48
0,5%	Head cabbages	0,01 / 0,01	0,42
0,5%	Beans (with pods)	0,05 / 0,05	0,39
0,5%	Milk: Cattle	0,01 / 0,01	0,39
0,5%	Lettuces	0,03 / 0,03	0,36
0,4%	Swedes/rutabagas	0,01 / 0,01	0,34
0,4%	Table grapes	0,3 / 0,01	0,34
0,4%	Beans	0,05 / 0,05	0,33

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
46%	Melons	0,4 / 0,4	36
37%	Watermelons	0,4 / 0,4	29
28%	Spinaches	1 / 1	23
16%	Table grapes	0,3 / 0,3	13
15%	Tomatoes	0,4 / 0,4	12
8%	Pumpkins	0,4 / 0,4	6,4
6%	Aubergines/egg plants	0,3 / 0,3	4,5
4%	Cucumbers	0,08 / 0,08	3,1
3%	Wine grapes	0,3 / 0,3	2,8
2%	Courgettes	0,08 / 0,08	1,6
2%	Milk: Cattle	0,01 / 0,01	1,2
2%	Peas (with pods)	0,15 / 0,15	1,2
1%	Beans	0,05 / 0,05	0,91
1,0%	Carobs/Staint John's	0,1 / 0,1	0,79
0,9%	Lettuces	0,03 / 0,03	0,69

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Watermelons	0,4 / 0,4	9,7
12%	Melons	0,4 / 0,4	9,4
10%	Tomatoes	0,4 / 0,4	7,7
9%	Wine grapes	0,3 / 0,3	7,1
8%	Table grapes	0,3 / 0,3	6,1
7%	Aubergines/egg plants	0,3 / 0,3	5,8
5%	Spinaches	1 / 1	4,0
4%	Pumpkins	0,4 / 0,4	3,5
2%	Cucumbers	0,08 / 0,08	1,3
1%	Courgettes	0,08 / 0,08	0,96
0,8%	Gherkins	0,08 / 0,08	0,64
0,6%	Peas (with pods)	0,15 / 0,15	0,51
0,6%	Oranges	0,01 / 0,01	0,47
0,5%	Plums	0,01 / 0,01	0,39
0,5%	Beans (with pods)	0,05 / 0,05	0,39

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
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)
2%	Potatoes	0,01 / 0,01	1,5
2%	Milk: Cattle	0,01 / 0,01	1,2
0,3%	Milk: Goat	0,01 / 0,01	0,24
0,2%	Honey and other apiculture	0,05 / 0,05	0,18
0,2%	Poultry: Muscle/meat	0,01 / 0,01	0,17
0,2%	Eggs: Chicken	0,01 / 0,01	0,12
0,2%	Swine: Muscle/meat	0,01 / 0,01	0,12
0,1%	Bovine: Liver	0,01 / 0,01	0,08
0,09%	Bovine: Edible offals (other	0,01 / 0,01	0,07
0,09%	Bovine: Muscle/meat	0,01 / 0,01	0,07
0,09%	Other farmed animals:	0,01 / 0,01	0,07
0,08%	Equine: Muscle/meat	0,01 / 0,01	0,06
0,07%	Sheep: Muscle/meat	0,01 / 0,01	0,05
0,05%	Bovine: Kidney	0,01 / 0,01	0,04
0,04%	Milk: Sheep	0,01 / 0,01	0,04

Expand/collapse list

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

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)
0,5%	Milk: Cattle	0,01 / 0,01	0,39
0,4%	Potatoes	0,01 / 0,01	0,30
0,2%	Milk: Goat	0,01 / 0,01	0,18
0,2%	Milk: Sheep	0,01 / 0,01	0,15
0,1%	Poultry: Muscle	0,01 / 0,01	0,12
0,09%	Honey and other apiculture	0,05 / 0,05	0,07
0,07%	Bovine: Muscle	0,01 / 0,01	0,06
0,07%	Other farmed animals:	0,01 / 0,01	0,06
0,06%	Swine: Muscle/meat	0,01 / 0,01	0,05
0,06%	Equine: Muscle/meat	0,01 / 0,01	0,05
0,06%	Sheep: Muscle/meat	0,01 / 0,01	0,05
0,06%	Poultry: Liver	0,01 / 0,01	0,05
0,05%	Eggs: Chicken	0,01 / 0,01	0,04
0,05%	Bovine: Liver	0,01 / 0,01	0,04
0,04%	Bovine: Edible offals (other	0,01 / 0,01	0,03

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Milk: Cattle	0,01 / 0,01	1,2
0,8%	Potatoes	0,01 / 0,01	0,66
0,3%	Milk: Goat	0,01 / 0,01	0,24
0,2%	Honey and other apiculture	0,05 / 0,05	0,18
0,2%	Poultry: Muscle/meat	0,01 / 0,01	0,17
0,2%	Eggs: Chicken	0,01 / 0,01	0,12
0,2%	Swine: Muscle/meat	0,01 / 0,01	0,12
0,1%	Bovine: Liver	0,01 / 0,01	0,08
0,09%	Bovine: Edible offals (other	0,01 / 0,01	0,07
0,09%	Bovine: Muscle/meat	0,01 / 0,01	0,07
0,09%	Other farmed animals:	0,01 / 0,01	0,07
0,08%	Equine: Muscle/meat	0,01 / 0,01	0,06
0,07%	Sheep: Muscle/meat	0,01 / 0,01	0,05
0,05%	Bovine: Kidney	0,01 / 0,01	0,04
0,04%	Milk: Sheep	0,01 / 0,01	0,04

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,5%	Milk: Cattle	0,01 / 0,01	0,39
0,4%	Potatoes	0,01 / 0,01	0,31
0,2%	Milk: Goat	0,01 / 0,01	0,18
0,2%	Milk: Sheep	0,01 / 0,01	0,15
0,1%	Poultry: Muscle	0,01 / 0,01	0,12
0,09%	Honey and other apiculture products	0,05 / 0,05	0,07
0,07%	Bovine: Muscle	0,01 / 0,01	0,06
0,06%	Other farmed animals: Muscle/meat	0,01 / 0,01	0,06
0,06%	Swine: Muscle/meat	0,01 / 0,01	0,05
0,06%	Equine: Muscle/meat	0,01 / 0,01	0,05
0,06%	Sheep: Muscle/meat	0,01 / 0,01	0,05
0,06%	Poultry: Liver	0,01 / 0,01	0,05
0,05%	Eggs: Chicken	0,01 / 0,01	0,04
0,05%	Bovine: Liver	0,01 / 0,01	0,04
0,04%	Bovine: Edible offals (other than	0,01 / 0,01	0,03

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults				Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
44%	Pumpkins / boiled	0,4 / 0,4	35	28%	Pumpkins / boiled	0,4 / 0,4	22	27%	Pumpkins / boiled	0,4 / 0,4	21	20%	Pumpkins / boiled	0,4 / 0,4	16
17%	Spinaches / frozen; boiled	1 / 1	14	10%	Spinaches / frozen; boiled	1 / 1	8,3	17%	Spinaches / frozen; boiled	1 / 1	14	10%	Spinaches / frozen; boiled	1 / 1	8,3
4%	Courgettes / boiled	0,08 / 0,08	2,8	2%	Courgettes / boiled	0,08 / 0,08	1,8	16%	Wine grapes / juice	0,3 / 0,3	13	8%	Wine grapes / juice	0,3 / 0,3	6,2
2%	Gherkins / pickled	0,08 / 0,08	1,8	0,6%	Peas (with pods) / boiled	0,15 / 0,15	0,51	10%	Tomatoes / juice	0,4 / 0,4	7,6	4%	Tomatoes / sauce/puree	0,4 / 0,4	3,3
1%	Leeks / boiled	0,02 / 0,02	1,1	0,6%	Coffee beans / extraction	0,1 / 0,02	0,48	5%	Tomatoes / sauce/puree	0,4 / 0,4	3,8	4%	Wine grapes / wine	0,3 / 0,3	2,8
1%	Sugar beets (root) / sugar	0,01 / 0,12	1,1	0,5%	Sugar beets (root) / sugar	0,01 / 0,12	0,44	2%	Courgettes / boiled	0,08 / 0,08	1,7	2%	Table grapes / raisins	0,3 / 1,41	1,7
1%	Potatoes / fried	0,01 / 0,01	0,93	0,5%	Cauliflowers / boiled	0,01 / 0,01	0,42	1%	Sugar beets (root) / sugar	0,01 / 0,12	1,1	2%	Courgettes / boiled	0,08 / 0,08	1,3
1%	Witloofs / boiled	0,01 / 0,01	0,89	0,5%	Beetroots / boiled	0,01 / 0,01	0,39	1,0%	Gherkins / pickled	0,08 / 0,08	0,79	0,6%	Peas (with pods) / boiled	0,15 / 0,15	0,51
1,0%	Broccoli / boiled	0,01 / 0,01	0,79	0,4%	Beans / canned	0,05 / 0,05	0,36	0,8%	Leeks / boiled	0,02 / 0,02	0,66	0,6%	Coffee beans / extraction	0,1 / 0,02	0,48
0,9%	Cauliflowers / boiled	0,01 / 0,01	0,70	0,4%	Leeks / boiled	0,02 / 0,02	0,35	0,8%	Beans (with pods) /	0,05 / 0,05	0,63	0,5%	Sugar beets (root) / sugar	0,01 / 0,12	0,44
0,8%	Escaroles/broad-leaved er	0,01 / 0,01	0,66	0,4%	Celeries / boiled	0,01 / 0,01	0,34	0,7%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,4%	Beans / canned	0,05 / 0,05	0,36
0,8%	Beans (with pods) / boiled	0,05 / 0,05	0,63	0,4%	Apples / juice	0,01 / 0,01	0,33	0,7%	Apples / juice	0,01 / 0,01	0,54	0,4%	Apples / juice	0,01 / 0,01	0,33
0,7%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,3%	Beans (without pods) /	0,05 / 0,05	0,26	0,7%	Oranges / juice	0,01 / 0,01	0,53	0,3%	Leeks / boiled	0,02 / 0,02	0,27
0,7%	Apples / juice	0,01 / 0,01	0,54	0,3%	Broccoli / boiled	0,01 / 0,01	0,24	0,6%	Broccoli / boiled	0,01 / 0,01	0,47	0,3%	Beans (without pods) / boiled	0,05 / 0,05	0,26
0,7%	Oranges / juice	0,01 / 0,01	0,53	0,3%	Parsnips / boiled	0,01 / 0,01	0,21	0,6%	Witloofs / boiled	0,01 / 0,01	0,47	0,3%	Cauliflowers / boiled	0,01 / 0,01	0,25
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.

Processed commodities

Results for children				Results for adults				Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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	0,01 / 0,01	0,93	0,1%	Potatoes / chips	0,01 / 0,01	0,08	0,7%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,1%	Potatoes / chips	0,01 / 0,01	0,08
0,7%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,07%	Potatoes / dried (flakes)	0,01 / 0,05	0,06	0,5%	Potatoes / fried	0,01 / 0,01	0,44	0,07%	Potatoes / dried (flakes)	0,01 / 0,05	0,06
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