REASONED OPINION

APPROVED: 16 September 2019

doi: 10.2903/j.efsa.2019.5823

Evaluation of confirmatory data following the Article 12 MRL review for cymoxanil

European Food Safety Authority (EFSA),
Maria Anastassiadou, Alba Brancato, Luis Carrasco Cabrera, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

The applicant DuPont de Nemours (Deutschland) GmbH submitted a request to the competent national authority in Austria to evaluate confirmatory data identified for cymoxanil in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 and implemented in the EU MRL Regulation. To address the data gap on table and wine grapes, lettuce and spinach, the applicant submitted new residue trials for cymoxanil on these commodities. The data gap was considered satisfactorily addressed. Confirmatory data on analytical methods for enforcement in hops and herbal infusions (dried flower), and storage stability data in dry matrices were not submitted with the present application. Based on the available information, a revision of the existing MRLs for table and wine grapes, spinach and pulses should be considered by risk managers.

Keywords: cymoxanil, confirmatory data, pesticide, MRL review, risk assessment

Requestor: European Commission

Question number: EFSA-Q-2019-00186

Correspondence: pesticides.mrl@efsa.europa.eu

Suggested citation: 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

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

In 2015, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for cymoxanil according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were identified:

1) a confirmatory analytical method for enforcement in hops and herbal infusions (dried, flower);
2) a study investigating storage stability of cymoxanil in dry matrices;
3) additional residue trials supporting the authorisations on table and wine grapes (southern Europe (SEU) use), lettuce (SEU use), spinach (SEU use), sunflower seed (SEU use) and soyabean (SEU use).

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2016/1785, including footnotes related to data gaps number 1, 2 and 3, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 8 October 2018. The footnote related to data gap number 3 was introduced only for table and wine grapes, lettuces and spinaches. For sunflower seeds and soyabeans, data gap number 3 was not translated into a footnote in the MRL regulation because risk managers decided to set the MRL at the level of limit of quantification (LOQ) for these commodities.

Thus, in the framework of the current assessment, EFSA focused on the confirmatory data gaps number 1, 2 and 3, the latter one for table, wine grapes, lettuces and spinaches only.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, DuPont de Nemours (Deutschland) GmbH submitted an application to the competent national authority in Austria (rapporteur Member State, RMS) to evaluate confirmatory data on table and wine grapes, lettuces and spinaches identified under data gap number 3 during the MRL review. The applicant provided residue trials supporting the SEU uses for these crops. The RMS assessed the new information in an evaluation report which was submitted to the European Commission and forwarded to the EFSA on 11 March 2019. No information on data gaps number 1 and 2 was submitted in the context of the current application.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Cyproxanil				
0151000	Grapes	0.3 (ft 1)	0.05	The data gap identified by EFSA concerning three additional trials from SEU in grapes has been addressed. The SEU residue trials suggest an MRL of 0.02 mg/kg. Considering that MRL proposed in the NEU residue trials for grapes evaluated in the MRL review is higher (0.05 mg/kg), a revision of the existing MRL in table and wine grapes from 0.3 to 0.05 mg/kg would be appropriate; the footnote can be deleted
0151010	Table grapes	0.3 (ft 1)	0.05	
0151020	Wine grapes	0.3 (ft 1)	0.05	
0251020	Lettuces	0.03 (ft 1)	0.03	The data gap identified by EFSA concerning two additional trials from SEU in lettuces has been addressed. The MRL is confirmed and the footnote can be deleted
0252010	Spinaches	1 (ft 1)	0.9	The data gap identified by EFSA concerning four trials from SEU in spinaches has been addressed. The SEU residue trials suggest an MRL of 0.9 mg/kg. Therefore, a revision of the existing MRL in spinaches from 1 to 0.9 mg/kg would be appropriate; the footnote can be deleted

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
0300000	Pulses	0.05* (ft 2)	0.01*	Information on storage stability in dry matrices requested as confirmatory data was not provided. Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on pulses Considering that the validated analytical method assessed in the MRL review reports an LOQ of 0.01 mg/kg for dry matrices, a revision of the existing MRL from 0.05* to 0.01* mg/kg and deletion of the footnote would be appropriate
0300010	Beans	0.05* (ft 2)	0.01*	
0300020	Lentils	0.05* (ft 2)	0.01*	
0300030	Peas	0.05* (ft 2)	0.01*	
0300040	Lupins/lupini beans	0.05* (ft 2)	0.01*	
0631000	Herbal infusions (dried flowers)	0.1* (ft 3)	0.1*	Information on storage stability and analytical methods for enforcement in herbal infusions from flowers requested as confirmatory data was not provided. Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on herbal infusions (dried flowers). A modification of the existing MRL is not required
0631010	Chamomile	0.1* (ft 3)	0.1*	
0631020	Hibiscus/roselle	0.1* (ft 3)	0.1*	
0631030	Rose	0.1* (ft 3)	0.1*	
0631040	Jasmine	0.1* (ft 3)	0.1*	
0631050	Lime/linden	(ft 3)	0.1*	
0700000	Hops (dried)	0.1* (ft 3)	0.1*	Information on storage stability and analytical methods for enforcement in hops requested as confirmatory data was not provided. Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on hops. A modification of the existing MRL is not required

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 3).
ft 2: The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2).
ft 3: The European Food Safety Authority identified some information on storage stability and analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. Footnote related to data gap No 1 and 2).

Table of contents

Assessment

The review of existing maximum residue levels (MRLs) for the active substance cymoxanil according to Article 12 of Regulation (EC) No 396/2005[1] (MRL review) has been performed in 2015 (EFSA, 2015). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of Good Agricultural Practices (GAPs) assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested are listed in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2016/1785[2], including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRLs was requested to address the confirmatory data by 8 October 2018.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016), the applicant, DuPont de Nemours (Deutschland) GmbH, submitted an application to the competent national authority in Austria (designated rapporteur Member State, RMS) to evaluate some of the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided residue trials supporting the southern Europe (SEU) GAPs on table and wine grapes, lettuces and spinaches.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 11 March 2019 (Austria, 2019). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005.

EFSA based its assessment on the evaluation report submitted by the RMS (Austria, 2019), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and an additional assessment on the modification of the existing MRL for cymoxanil in beans without pods performed after the MRL review (EFSA, 2015, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011[3] and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2016/1785 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[4].

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The evaluation report submitted by the RMS (Austria, 2019) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Not relevant for the current assessment.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

[1] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[2] Commission Regulation (EU) 2016/1785 of 7 October 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cymoxanil, phosphane and phosphide salts and sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in or on certain products. OJ L 273, 8.10.2016, p. 10–30.

[3] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[4] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

Data gap number 1 requested a confirmatory method for enforcement in hops and herbal infusions (dried, flower) (EFSA, 2015). No confirmatory method for the above-mentioned commodities was submitted in the context of the current assessment.

1.1.5. Storage stability of residues in plants

Data gap number 2 requested a study investigating storage stability of cymoxanil in dry matrices. No new information was submitted on data gap number 2 in the context of the current assessment.

1.1.6. Proposed residue definitions

The previously derived residue definitions are still applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In order to address data gap number 3, the applicant provided additional residue trials on grapes, lettuces and spinaches.

1.2.1.1. Table and wine grapes

In the MRL review for cymoxanil (EFSA, 2015), three additional residue trials compliant with the southern outdoor GAP on table and wine grapes were requested as confirmatory data.

Four additional residue trials on wine grapes in SEU were submitted to address the data gap identified for this commodity. Samples were stored in compliance with the demonstrated storage conditions and analysed with a sufficiently validated analytical method. Trials were found to be independent and compliant with the SEU critical GAP.

EFSA concluded that the data gap identified for table and wine grapes in the framework of the MRL review was addressed. The SEU residue trials suggest an MRL of 0.02 mg/kg.

Residue trials on table and wine grapes from northern Europe (NEU) have been submitted and assessed in the context of the MRL review (EFSA, 2015). Since the preharvest interval (PHI) for grapes in the SEU GAP (= 21 days) is different from the PHI for grapes in the NEU GAP (= 28 days), the SEU and NEU residue trials cannot be combined. Considering that MRL proposal from the NEU residue trials for grapes evaluated in the MRL review is higher (0.05 mg/kg) than the one from the SEU (0.02 mg/kg), a revision of the existing MRL in table and wine grapes from 0.3 to 0.05 mg/kg would be appropriate.

1.2.1.2. Lettuces

In the framework of the MRL review for cymoxanil (EFSA, 2015), two additional residue trials compliant with the SEU outdoor GAP on lettuce were requested as confirmatory data.

Three additional SEU residue trials on lettuce were submitted to address the data gap identified for this commodity. Samples were stored in compliance with the demonstrated storage conditions and analysed with a sufficiently validated analytical method. Trials were found to be independent and compliant with the critical GAP.

EFSA concluded that the data gap identified for lettuces in the framework of the MRL review was addressed. The estimated MRL for cymoxanil in lettuce was found to be 0.03 mg/kg. Therefore, the MRL set in lettuces is confirmed.

1.2.1.3. Spinaches

In the framework of the MRL review for cymoxanil (EFSA, 2015), four additional residue trials compliant with the SEU outdoor GAP on spinaches were requested as confirmatory data.

Five additional SEU residue trials on spinach were submitted to address the data gap identified for this commodity. Samples were stored in compliance with the demonstrated storage conditions and analysed with a sufficiently validated analytical method. Trials were found to be independent and compliant with the SEU critical GAP.

EFSA concluded that the data gap identified for spinaches in the framework of the MRL review was addressed. The SEU residue trials suggest an MRL of 0.9 mg/kg. Residue trials on spinach from NEU have been submitted and assessed in the context of the MRL review (EFSA, 2015). Since the PHI for spinach in the SEU GAP (= 7 days) is different from the PHI for spinaches in the Northern Europe GAP (= 14 days), the SEU and NEU residue trials cannot be combined. Considering that MRL proposal from the SEU residue trials for spinaches evaluated in the MRL review is higher (0.9 mg/kg) than the one from the NEU (0.07 mg/kg), a revision of the existing MRL in spinaches from 1 to 0.9 mg/kg would be appropriate.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current assessment.

1.2.3. Magnitude of residues in processed commodities

Not relevant for the current assessment.

2. Residues in livestock

Sunflower seeds and soyabeans may be fed to livestock. 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.

3. Consumer risk assessment

EFSA updated the previous risk assessment, taking into account information on beans without pods, submitted in the framework of the modification of the existing MRL for cymoxanil in this commodity (EFSA, 2017) and the new data on grapes, spinaches and lettuces submitted under this application. The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (EFSA, 2007). The toxicological reference values for cymoxanil have not changed since the MRL review (EFSA, 2015).

3.1. Short-term (acute) dietary risk assessment

The short-term risk assessment was performed only for the commodities under assessment and for which new residue trials were submitted: table and wine grapes, lettuces and spinaches. The estimation of the exposure is based on the highest residue (HR) derived from the supervised field trials on the above-mentioned commodities (see Appendix D). The international estimated short-term intake (IESTI) accounted for 13.8% of the acute reference dose (ARfD) in spinaches (BE children), 4.1% of the ARfD in table grapes (DE children), 1.5% of the ARfD in wine grapes (UK adult) and 0.7% of the ARfD in lettuce (DE children).

3.2. Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed based on the existing uses of cymoxanil at EU level. EFSA updated the previous exposure assessment (EFSA, 2017), with the supervised trials median residue value (STMR), derived from the new trials available in grapes, lettuce and spinach (Austria, 2019). The complete list of input values is reported in Appendix D. The contributions of commodities for which no GAP was reported in the framework of the MRL review (EFSA, 2015) or for which the confirmatory data requested remain unavailable (i.e. sunflower seeds, soyabeans, herbal infusions (dried flowers) and hops (dried)) were not included in the calculation.

The estimated long-term exposure to cymoxanil accounted for up to 1.9% of the acceptable daily intake (ADI) for WHO Cluster diet B. The contribution of residues expected in (i) table grapes is up to the 0.5% of the ADI for DE child, (ii) wine grapes up to the 1.5% of the ADI for FR all population, (iii) lettuces up to the 0.04% of the ADI for ES adult and (iv) spinaches up to the 0.1% of the ADI for FR toddler.

4. Conclusion and Recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2015), the following confirmatory data on data gap number 3[5] were submitted by the applicant:

- Four residue trials on wine grapes in SEU to support the authorisations on table and wine grapes;
- Three residue trials on lettuces in SEU and
- Five additional residue trials on spinaches in SEU.

The above data gaps were sufficiently addressed. Based on the available information, a revision of the existing MRLs for table and wine grapes and spinaches would be appropriate. The MRL for lettuces is confirmed.

For sunflower seeds and soyabeans, the data gap number 3 was not translated into footnote in the MRL regulation because risk managers decided to set the MRL at the level of LOQ for these commodities. Thus, these crops are not subject to the current assessment.

No new information was submitted on data gap number 1 requesting a confirmatory analytical method for enforcement in hops and herbal infusions (dried, flower). Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on hops and herbal infusions (dried flowers). A modification of the existing MRLs is not required.

No new information was submitted on data gap number 2 requesting a study investigating storage stability of cymoxanil in dry matrices. Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on pulses. Considering that the validated analytical method assessed in the MRL review reports an LOQ of 0.01 mg/kg for dry matrices, a revision of the existing MRL from 0.05* mg/kg to 0.01* mg/kg and deletion of the footnote would be appropriate. The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

References

Austria, 2019. Evaluation report on the modification of MRLs for cymoxanil in grapes, lettuce and spinach. January 2019, 44 pp.

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance cymoxanil. EFSA Journal 2008;6(10):167r, 116 pp. https://doi.org/10.2903/j.efsa.2008.167r

EFSA (European Food Safety Authority), 2015. 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, 48 pp. https://doi.org/10.2903/j.efsa.2015.4355

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Reasoned opinion on the modification of the existing maximum residue level for cymoxanil in beans without pods. EFSA Journal 2017;15(12):5066, 19 pp. https://doi.org/10.2903/j.efsa.2017.5066

European Commission, 2016. Commission staff working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 17 June 2016. SANTE/E4/VW 10235/2016 - Rev. 2, 3 pp., Brussels, 17 June 2016.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)

[5] Additional residue trials supporting the authorisations on table and wine grapes (SEU use), lettuce (SEU use), spinach (SEU use), sunflower seed (SEU use) and soyabean (SEU use).

Eq	residue expressed as a.s. equivalent
GAP	Good Agricultural Practice
GC-NPD	gas chromatography with nitrogen/phosphorous detector
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
NEU	northern Europe
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
WG	water-dispersible granule
WHO	World Health Organization
WP	wettable powder

Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

Code	Crop name	Region/ country	Outdoor/ indoor[a]	Pests controlled	Active substance (a.s.)	Formulation type[b]	a.s. conc. in formulation (g/kg)	Appl. method	Growth stage[c]	No of appl.	Interval (days) Minim.	Water amount (L/ha)	Max. appl. rate (g a.s./ ha)	PHI (days)[d]	Comments
151010	Table grapes	NEU/AT	Outdoor	Plasmopara viticola, Downy mildew	Cymoxanil	WG	45	Foliar treatment – broadcast spraying	BBCH 11–71	1–4	10	Not specified	90	28	
151010	Table grapes	SEU/IT	Outdoor	Plasmopara viticola, Phomopsis viticola	Cymoxanil	WP	200	Foliar treatment – broadcast spraying	BBCH 15–85	1–4	7	Not specified	170	21	Assessed for confirmatory data
151020	Wine grapes	NEU/DE	Outdoor	Plasmopara viticola	Cymoxanil	WG	330	Foliar treatment – broadcast spraying	BBCH 14–89	1–5	7	Not specified	150	28	
151020	Wine grapes	SEU/IT	Outdoor	Plasmopara viticola, Phomopsis viticola	Cymoxanil	WP	200	Foliar treatment – broadcast spraying	BBCH 15–85	1–4	7	Not specified	170	21	Assessed for confirmatory data
251020	Lettuces	SEU/IT	Outdoor	Bremia lactucae	Cymoxanil	WP	200	Foliar treatment – broadcast spraying	BBCH 19–49	1–4	5	Not specified	240	7	Assessed for confirmatory data
252010	Spinaches	NEU/BE	Outdoor	Downy mildew	Cymoxanil	WG	250	Foliar treatment – broadcast spraying	N/A	1–2	10	Not specified	150	14	

Code	Crop name	Region/ country	Outdoor/ indoor[a]	Pests controlled	Active substance (a.s.)	Formul-ation type[b]	a.s. conc. in formul-ation (g/kg)	Appl. method	Growth stage[c]	No of appl.	Interval (days) Minim.	Water amount (L/ha)	Max. appl. rate (g a.s./ ha)	PHI (days)[d]	Comments
252010	Spinaches	SEU/IT	Outdoor	Downy mildew	Cymoxanil	WP	200	Foliar treatment – broadcast spraying	BBCH 19–49	1–4	7	Not specified	180	7	Assessed for confirmatory data

NEU: northern European Union; SEU: southern European Union; MS: Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Tomatoes	Foliar, 3 × 0.63 kg a.s./ha	3	EFSA (2015)
		Tomatoes	Foliar, 4 × 0.24 kg a.s./ha	13	EFSA (2015)
		Tomatoes	Foliar, 7 × 0.14 kg a.s/ha	7, 14, 21, 35	EFSA (2015)
		Grapes	Foliar, 8 × 0.21 kg a.s./ha	0, 1, 4, 10, 18	EFSA (2015)
	Root crops	Potatoes	Foliar, 8 × 0.24 kg a.s./ha	10	EFSA (2008)
		Potatoes	Foliar, 3 × 0.40 kg a.s./ha	3	EFSA (2008)
	Leafy crops	Lettuces	Foliar, 3 × 0.24 kg a.s./ha	11	EFSA (2008)
		Lettuces	Foliar, 4 × 0.84 kg a.s./ha	3	EFSA (2008)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/source**
	Root/tuber crops	Sugar beet	Bare soil, 1.2 kg a.s./ha	30, 120	A 'no residue' situation in rotational crops was established (EFSA, 2008)
	Leafy crops	Lettuces	Bare soil, 1.2 kg a.s./ha	30, 120	A 'no residue' situation in rotational crops was established (EFSA, 2008)
	Cereal (small grain)	Wheat	Bare soil, 1.2 kg a.s./ha	30, 120	A 'no residue' situation in rotational crops was established (EFSA, 2008)
	Other	–	–	–	–
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/source**
	Pasteurisation (20 min, 90°C, pH 4)		Not investigated		In the context of the MRL review for cymoxanil, a study investigating the nature of residues in processed commodities through standard hydrolytic conditions was considered desirable but not essential (EFSA, 2015)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Not investigated		
	Sterilisation (20 min, 120°C, pH 6)		Not investigated		
	Other processing conditions		Not investigated		

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Not applicable
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring (RD-Mo)	Cymoxanil
Plant residue definition for risk assessment (RD-RA)	Cymoxanil
Conversion factor (monitoring to risk assessment)	Not applicable.
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	High water and acidic content: • HPLC–MS/MS, 0.01 mg/kg (EFSA, 2015) • GC-NPD, 0.05 mg/kg (incl. IVL) (EFSA, 2008) High oil content: • HPLC–MS/MS, 0.01 mg/kg (ILV not required for DFG S19 method) (EFSA, 2015) Dry content: • HPLC–MS/MS, 0.01 mg/kg (EFSA, 2015) • HPLC–MS/MS, 0.01 mg/kg (ILV not required for DFG S19 method) (EFSA, 2015) Hops (also applicable to herbal infusions, dried flowers): GC-NPD, 0.1 mg/kg; A confirmatory method for enforcement in hops and herbal infusions (dried flowers) was requested in the framework of the MRL review under Article 12 of Reg. (EC) No 396/2005 (EFSA, 2015), but was not provided

DAT: days after treatment; a.s: active substance; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation; GC-NPD: gas chromatography with nitrogen/phosphorous detector; MRL: maximum residue level.

B.1.1.2. Storage stability

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compound covered**	**Comment/source**
				Value	**Unit**		
	High water content	Tomatoes	−18	≤ 18	Months	cymoxanil	Study performed on several crops investigating storage periods of up to 873 days. However, an unexplained decline of residues was observed in tomatoes between 18 and 24 months. (EFSA, 2015)
	High acid content	Grapes	−18	24	Months	cymoxanil	
	High oil content	Sunflower seed	−18	18	Months	cymoxanil	

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compound covered**	**Comment/source**
				Value	**Unit**		
	Dry content	–	–	–	–	–	A confirmatory study investigating storage stability of cymoxanil in dry matrices was requested in the framework of the MRL review under Article 12 of Reg. (EC) No 396/2005 (EFSA, 2015), but was not provided

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)
Table and wine grapes	NEU	EFSA (2015): 2 × < 0.001; 6 × < 0.01; < 0.04; 14 × < 0.05	Residue trials on wine grapes compliant with GAP. Extrapolation to table grapes for which the GAP is less critical is possible because residue levels are < LOQ (EFSA, 2015)	**0.05***	0.05	0.05
	SEU	EFSA (2015): 4 × < 0.01; 0.015 Austria (2019): 4 × < 0.01	Residue trials on wine grapes compliant with GAP. Extrapolation to table grapes is possible (EFSA, 2015)	0.02	0.015	0.01
Lettuces	SEU	EFSA (2015): 4 × < 0.01; 0.01; 0.02 Austria, (2019): 3 × < 0.01	Residue trials on lettuces compliant with GAP	**0.03**	0.02	0.01
Spinaches	NEU	EFSA (2015): 4 × < 0.02; 0.04	Residue trials on spinaches compliant with GAP	0.07	0.04	0.02
	SEU	EFSA (2015): Unscaled residues: 2 × < 0.01; 0.01; 0.02; 0.04; 0.05; 0.65 Scaled residues (sf 0.75): 2 × < 0.01; 0.0075; 0.15; 0.03; 0.0375; 0.488 Austria (2019): 2 × < 0.01; 0.021; 0.049; 0.47	Residue trials on spinaches compliant with GAP. Trials evaluated in the framework of the MRL review (EFSA, 2015) were overdosed (240 g a.s./ha instead of 180 g a.s./ha). A scaling factor (sf) of 0.75 was applied to derive the scaled residue values for these trials which were used in the present assessment	**0.9**	0.49	0.02

*: Indicates that the MRL is proposed at the limit of quantification (EFSA, 2015). Values in bold are the final MRL proposals.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Supervised trials median residue according to the residue definition for monitoring.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Study was performed, although the DT90 values were below 100 days. Study confirmed that significant residues of cymoxanil are not expected in rotational crops (EFSA, 2008)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Not available and not required (EFSA, 2015)

B.1.1.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

No additional data were submitted on sunflower seeds and soyabeans which may be fed to livestock; grapes, lettuces and spinaches are not expected to be fed to livestock.

B.3. Consumer risk assessment

ARfD	0.08 mg/kg bw (EFSA, 2008)
Highest IESTI, according to EFSA PRIMo	Spinaches: 13.8% of ARfD (BE children) Table grapes: 4.1% of ARfD (DE children) Wine grapes: 1.5% of ARfD (UK adult) Lettuce: 0.7% of ARfD (DE children)
Assumptions made for the calculations	The calculation was performed with revision 2 of the EFSA PRIMo. It is based on the highest residue levels expected in the commodities under assessment, i.e. table and wine grapes, lettuces and spinaches

ADI	0.013 mg/kg bw per day (EFSA, 2008)
Highest IEDI, according to EFSA PRIMo	1.9 % ADI (WHO Cluster diet B) Wine grapes: 1.5% of ADI (FR all population) Table grapes: 0.5% of ADI (DE child) Spinach: 0.1% of ADI (FR toddler) Lettuce: 0.04% of ADI (ES adult)
Assumptions made for the calculations	The calculation was performed with revision 2 of the EFSA PRIMo. It is based on the median residue levels in the raw agricultural commodities, except for cucurbits with inedible peel, where the relevant peeling factor was applied The previous exposure estimate (EFSA, 2017) was updated with the confirmatory data available on grapes, spinach and lettuce. The contributions of commodities for which no GAP was reported in the framework of the MRL review (2015) or for which the confirmatory data requested remain unavailable (i.e. sunflower seed, soyabean, herbal infusions(dried flowers) and hops(dried)), were not included in this calculation

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; GAP: Good Agricultural Practice.

B.4. Recommended MRLs

Code[a]	Commodity	Existing MRL[b]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Cyproxanil				
0151000	Grapes	0.3 (ft 1)	0.05	The data gap identified by EFSA concerning three additional trials from SEU in grapes has been addressed. The SEU residue trials suggest an MRL of 0.02 mg/kg. Considering that MRL proposed in the NEU residue trials for grapes evaluated in the MRL review is higher (0.05 mg/kg), a revision of the existing MRL in table and wine grapes from 0.3 mg/kg to 0.05 mg/kg would be appropriate; the footnote can be deleted
0151010	Table grapes	0.3 (ft 1)	0.05	
0151020	Wine grapes	0.3 (ft 1)	0.05	
0251020	Lettuces	0.03 (ft 1)	0.03	The data gap identified by EFSA concerning two additional trials from SEU in lettuces has been addressed. The MRL is confirmed and the footnote can be deleted
0252010	Spinaches	1 (ft 1)	0.9	The data gap identified by EFSA concerning four trials from SEU in spinaches has been addressed. The SEU residue trials suggest an MRL of 0.9 mg/kg. Therefore, a revision of the existing MRL in spinaches from 1 to 0.9 mg/kg would be appropriate; the footnote can be deleted
0300000	Pulses	0.05* (ft 2)	0.01*	Information on storage stability in dry matrices requested as confirmatory data was not provided. Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on pulses Considering that the validated analytical method assessed in the MRL review reports an LOQ of 0.01 mg/kg for dry matrices, a revision of the existing MRL from 0.05* mg/kg to 0.01* mg/kg and deletion of the footnote would be appropriate
0300010	Beans	0.05* (ft 2)	0.01*	
0300020	Lentils	0.05* (ft 2)	0.01*	
0300030	Peas	0.05* (ft 2)	0.01*	
0300040	Lupins/lupini beans	0.05* (ft 2)	0.01*	
0631000	Herbal infusions (dried flowers)	0.1* (ft 3)	0.1*	Information on storage stability and analytical methods for enforcement in herbal infusions from flowers requested as confirmatory data was not provided. Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on herbal infusions (dried flowers). A modification of the existing MRL is not required
0631010	Chamomile	0.1* (ft 3)	0.1*	
0631020	Hibiscus/ roselle	0.1* (ft 3)	0.1*	
0631030	Rose	0.1* (ft 3)	0.1*	
0631040	Jasmine	0.1* (ft 3)	0.1*	
0631050	Lime/linden	0.1* (ft 3)	0.1*	
0700000	Hops (dried)	0.1* (ft 3)	0.1*	Information on storage stability and analytical methods for enforcement in hops requested as confirmatory data was not provided. Since the data gap was not addressed, risk management action would be appropriate, e.g. revocation of the existing uses on hops. A modification of the existing MRL is not required

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 3).
ft 2: The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 2).

ft 3: The European Food Safety Authority identified some information on storage stability and analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it (footnote related to data gaps No 1 and 2).

Appendix C – Pesticide Residue Intake Model (PRIMo)

Cymoxanil			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per 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

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	0 – 2
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
1.9	WHO Cluster diet B	0.7	Wine grapes	0.2	Tomatoes	0.2	Potatoes	
1.8	FR all population	1.5	Wine grapes	0.1	Potatoes	0.1	Beans (with pods)	
1.8	PT General population	1.0	Wine grapes	0.4	Potatoes	0.1	Table grapes	
1.4	WHO cluster diet E	0.6	Wine grapes	0.3	Potatoes	0.1	Beans (with pods)	
1.4	IE adult	0.5	Wine grapes	0.2	Potatoes	0.1	Aubergines (egg plants)	
1.4	FR toddler	0.4	Beans (with pods)	0.4	Potatoes	0.1	Peas (without pods)	
1.4	NL child	0.5	Potatoes	0.3	Table grapes	0.2	Beans (with pods)	
1.0	DE child	0.5	Table grapes	0.2	Potatoes	0.1	Tomatoes	
1.0	FR infant	0.3	Beans (with pods)	0.3	Potatoes	0.1	Peas (without pods)	
0.9	WHO regional European diet	0.3	Potatoes	0.1	Peas (with pods)	0.1	Wine grapes	
0.9	NL general	0.2	Wine grapes	0.2	Potatoes	0.1	Beans (with pods)	
0.8	DK adult	0.5	Wine grapes	0.1	Potatoes	0.0	Peas (without pods)	
0.8	WHO cluster diet D	0.3	Potatoes	0.1	Wine grapes	0.1	Tomatoes	
0.7	WHO Cluster diet F	0.3	Potatoes	0.2	Wine grapes	0.1	Tomatoes	
0.7	UK Toddler	0.3	Potatoes	0.1	Beans	0.1	Peas (without pods)	
0.7	UK Adult	0.4	Wine grapes	0.1	Potatoes	0.0	Peas (without pods)	
0.7	UK vegetarian	0.3	Wine grapes	0.1	Potatoes	0.1	Beans	
0.7	SE general population 90th percentile	0.3	Potatoes	0.1	Tomatoes	0.0	Onions	
0.6	UK Infant	0.3	Potatoes	0.2	Peas (without pods)	0.1	Beans	
0.6	ES adult	0.2	Wine grapes	0.1	Beans (with pods)	0.1	Potatoes	
0.5	PL general population	0.3	Potatoes	0.1	Table grapes	0.1	Tomatoes	
0.5	ES child	0.1	Potatoes	0.1	Beans (with pods)	0.1	Tomatoes	
0.5	DK child	0.2	Potatoes	0.1	Cucumbers	0.1	Table grapes	
0.4	IT kids/toddler	0.1	Tomatoes	0.1	Potatoes	0.0	Table grapes	
0.4	IT adult	0.1	Tomatoes	0.1	Beans (with pods)	0.1	Table grapes	
0.4	LT adult	0.2	Potatoes	0.0	Tomatoes	0.0	Cucumbers	
0.3	FI adult	0.1	Wine grapes	0.1	Potatoes	0.0	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Cymoxanil is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS, with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
13.8	Spinach	0.49/-	13.8	Spinach	0.49/-	5.5	Spinach	0.49/-	5.5	Spinach	0.49/-
4.1	Table grapes	0.05/-	4.1	Table grapes	0.05/-	2.0	Table grapes	0.05/-	2.0	Table grapes	0.05/-
0.7	Lettuce	0.02/-	0.5	Wine grapes	0.05/-	1.5	Wine grapes	0.05/-	1.5	Wine grapes	0.05/-
0.5	Wine grapes	0.05/-	0.4	Lettuce	0.02/-	0.3	Lettuce	0.02/-	0.2	Lettuce	0.02/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---		
		***)			***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
5.0	Tomato juice	0.23/-		0.5	Tomato (preserved-	0.23/-
0.6	Grape juice	0.015/-		0.1	Wine	0.015/-
0.2	Potato puree (flakes)	0.01/-		0.0	Potato uree (flakes)	0.01/-
0.0	Fried potatoes	0.01/-		0.0	Fried potatoes	0.01/-
0.0	Wine	0.015/-		0.0	Raisins	0.015/-

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Cymoxanil, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

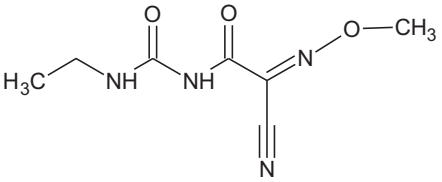
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Table grapes	0.05	STMR	0.05	HR
Wine grapes	0.05	STMR	0.05	HR
Lettuces	0.01	STMR	0.02	HR
Spinaches	0.02	STMR	0.49	HR
Potatoes	0.01	STMR (EFSA, 2015)	Acute risk assessment only for the crops under consideration	
Garlic	0.01	STMR (EFSA, 2015)		
Onions	0.01	STMR (EFSA, 2015)		
Tomatoes	0.01	STMR (EFSA, 2015)		
Aubergines (egg plants)	0.05	STMR (EFSA, 2015)		
Cucumbers	0.01	STMR (EFSA, 2015)		
Gherkins	0.01	STMR (EFSA, 2015)		
Courgettes	0.01	STMR (EFSA, 2015)		
Melons	0.002	STMR x PF (EFSA, 2015)		
Pumpkins	0.002	STMR x PF (EFSA, 2015)		
Watermelons	0.002	STMR x PF (EFSA, 2015)		
Broccoli	0.01	STMR (EFSA, 2015)		
Cauliflower	0.01	STMR (EFSA, 2015)		
Beans (fresh, with pods)	0.05	STMR (EFSA, 2015)		
Beans (fresh, without pods)	0.05	STMR (EFSA, 2017)		
Peas (fresh, with pods)	0.05	STMR (EFSA, 2015)		
Peas (fresh, without pods)	0.05	STMR (EFSA, 2015)		
Globe artichokes	0.01	STMR (EFSA, 2015)		
Leek	0.01	STMR (EFSA, 2015)		
Beans (dry)	0.02	STMR (EFSA, 2015)		
Lentils (dry)	0.02	STMR (EFSA, 2015)		
Peas (dry)	0.02	STMR (EFSA, 2015)		
Lupins (dry)	0.02	STMR (EFSA, 2015)		
Sunflower seeds	–	Not considered in the risk assessment since the confirmatory data requested in the framework of the MRL review (EFSA, 2015) remain unavailable		
Soyabeans	–			
Herbal infusions (dried, flowers)	–			
Hops (dried), including hop pellets and unconcentrated powder	–			

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation[a]	Structural formula[a]
cymoxanil	1-[(*EZ*)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea N#C\C(=N\OC)C(=O)NC(=O)NCC PSOONIQXVGMYIU-JIBDQCPFSA-N	

(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).