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REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for cyproconazole in mustard seed and gold of pleasure[1]

European Food Safety Authority[2,]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, France, herewith referred to as the evaluating Member State (EMS), received an application from Syngenta Agro S.A.S. to modify the existing MRLs for the active substance cyproconazole in mustard seed and gold of pleasure. In order to accommodate for the intended use of cyproconazole in France, the EMS proposed to raise the existing MRLs in these crops to 0.4 mg/kg. France drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA, the proposed extrapolation of residue data from rape seed to mustard seed and gold of pleasure is acceptable and a sufficient number of residue trials has been submitted to derive a MRL proposal of 0.4 mg/kg in the crops under consideration. The submitted residue trials data support the NEU use only. Based on the risk assessment results, EFSA concludes that the intended use of cyproconazole on mustard seed and gold of pleasure will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. EFSA emphasizes that the above assessment does not take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment is performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

KEY WORDS

Cyproconazole, seeds of mustard and gold of pleasure, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, triazole fungicide, triazole derivative metabolites (TDM).

[1] On request from European Commission, Question No EFSA-Q-2012-00869, approved on 12 April 2013.
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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005[3], France, herewith referred to as the evaluating Member State (EMS), received an application from Syngenta Agro S.A.S. to modify the existing MRLs for the active substance cyproconazole in mustard seed and gold of pleasure. In order to accommodate for the intended use of cyproconazole in France, the EMS proposed to raise the existing MRLs in these crops to 0.4 mg/kg. France drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 1 October 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS France, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance cyproconazole and conclusions from previous EFSA reasoned opinions on the modification of the existing MRLs for cyproconazole.

The toxicological profile of cyproconazole was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.02 mg/kg bw per day and an ARfD of 0.02 mg/kg bw.

The metabolism of cyproconazole in primary crops was investigated in four different crop groups. From these studies the peer review concluded to establish the residue definition for enforcement as parent cyproconazole (sum of isomers). For risk assessment two separate residue definitions were derived: a) cyproconazole (sum of isomers) and b) triazole derivative metabolites. The second residue definition was set as provisional pending finalisation of a global and harmonised approach for all the active substances of the triazole chemical group. For the use on mustard seed and gold of pleasure, EFSA concludes that the metabolism of cyproconazole is sufficiently addressed and that the derived residue definitions are applicable.

EFSA considers that the proposed extrapolation of residue data from rape seed to mustard seed and gold of pleasure is acceptable and a sufficient number of residue trials has been submitted to derive a MRL proposal of 0.4 mg/kg in the crops under consideration. The submitted residue trials data support the NEU use only. There is evidence that adequate analytical enforcement methods are available to control residues of cyproconazole in plant matrices with high fat content at the LOQ of 0.01 mg/kg.

Studies investigating the nature of cyproconazole residues in processed commodities were assessed in the peer review and showed that the compound is hydrolytically stable under the processing conditions representative for pasteurisation, boiling/baking and sterilisation. Therefore for processed commodities the same residue definitions as for raw agricultural commodities are applicable. The effects of processing on the nature and magnitude of TDMs have not been investigated. Given the low dietary intake of cyproconazole residues via mustard seed and gold of pleasure, specific studies investigating the magnitude of cyproconazole residues in processed commodities are not necessary.

The occurrence of cyproconazole residues in rotational crops was investigated in the framework of the peer review. However, since the available studies showed some deficiencies, no final conclusion on the possible occurrence of cyproconazole related residues in rotational corps was derived. EFSA therefore recommends that before granting authorisations Member States should establish specific restrictions/risk management measures to avoid the occurrence of cyproconazole related residues in rotational crops.

Residues of cyproconazole in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration and/or their by-products are normally not fed to livestock.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on rape seed. These values were used as input values both for mustard seed and gold of pleasure as well as for poppy seed and rape seed. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. As no consumption data are available for the gold of pleasure, the acute exposure assessment was performed only with regard to mustard seed assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the median level as observed in supervised field trials.

The estimated exposure was then compared with the toxicological reference values derived for cyproconazole.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 23.4% of the ADI (UK toddler diet). The contribution of residues in mustard seed to the total consumer exposure accounted for a maximum of 0.002% of the ADI (WHO regional European diet and WHO Cluster diet E). No consumption data are available for gold of pleasure.

No acute consumer risk was identified in relation to the cyproconazole residues in mustard seed (0.03% of the ARfD). No consumption data have been provided for the gold of pleasure. Similarly to mustard seed, gold of pleasure is a very minor crop, and thus the potential acute exposure from the intake of this crop is expected to be low.

EFSA concludes that the intended use of cyproconazole on mustard seed and gold of pleasure will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. EFSA emphasizes that the above assessment does not take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment is performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

Summary table

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Cyproconazole (F)				
0401080	Mustard seed	0.05*	0.4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses. The MRL supports NEU use only.
0401130	Gold of pleasure	0.05*	0.4	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble pesticide. MRL is expressed as mg/kg of fat contained in the whole product

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set or to modify an MRL in accordance with the provisions of Article 7 of that Regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta Agro S.A.S.[6] to modify the existing MRLs for the active substance cyproconazole in mustard seed and gold of pleasure. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 1 October 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00869 and the following subject:

Cyproconazole - Application to modify the existing MRLs in mustard seed and the gold of pleasure.

France proposed to raise the existing MRLs of cyproconazole in mustard seed and gold of pleasure from the limit of quantification (LOQ) of 0.05 mg/kg to 0.4 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

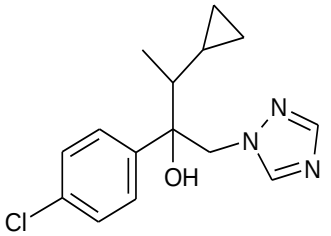
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 1 January 2013.

[4] Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.
[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.
[6] Syngenta AGRO S.A.S., Avenue des Prés 1, CS 10537, Gyancourt cedex, France

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cyproconazole is the ISO common name for (2*RS*,3*RS*;2*RS*,3*SR*)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-ol (IUPAC). Cyproconazole is a 1:1 mixture of the two diastereomeric pairs, each of which is a 1:1 mixture of the enantiomers (*i.e.* all four stereoisomers are present in similar amounts). The chemical structure of the compound is as follows:



Molecular weight: 291.8

Cyproconazole is a broad spectrum fungicide belonging to the triazole group of ergosterol-biosynthesis inhibitors (EBI). The active substance is taken up by the plant and distributed acropetally. Cyproconazole prevents the development of fungi by interfering with the biosynthesis of cell membranes. The active substance has preventative and curative activity and is fat-soluble (Log P_{ow}=3.09).

Cyproconazole was peer reviewed under Council Directive 91/414/EEC with Ireland designated as rapporteur Member State (RMS). The assessment was finalised with the inclusion of cyproconazole in Annex I to Council Directive 91/414/EEC[7,8]. The representative use evaluated for the peer review was the outdoor foliar spraying against fungi in wheat. An EFSA conclusion on the risk assessment of cyproconazole is available (EFSA, 2010).

The EU MRLs for cyproconazole are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). Since the entry into force of this regulation, two EFSA reasoned opinions have been issued on the modification of the existing MRLs for cyproconazole in rape seed (EFSA, 2011b) and in poppy seed (EFSA, 2012). The MRL proposal of 0.4 mg/kg as proposed by EFSA has been implemented for these crops. A CXL of 0.4 mg/kg is set for rape seed only. The MRL review of cyproconazole according to Article 12 of Regulation (EC) No 396/2005 is not yet finalized.

The applicant now intends to apply for the authorisation of cyproconazole on mustard and gold of pleasure in France. The details of the intended GAPs are given in Appendix A.

[7] Commission Implementing Directive 2011/56/EU of 27 April 2011, OJ L 108, 28.4.2011, p. 30–33.

[8] In 2008, following the withdrawal of the support for cyproconazole by the notifier, a decision on non-inclusion of cyproconazole in Annex I was taken (Commission Decision 2008/934/EC) and consequently the authorisations for plant protection products containing that substance had to be withdrawn. The applicant resubmitted the dossier for the inclusion of cyproconazole in Annex I of Directive 91/414/EEC which was evaluated by the RMS in the format of an Additional Report to the DAR (Ireland, 2010).

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2012), Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Ireland, 2006, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance cyproconazole (EFSA, 2010), as well as the conclusions from previous EFSA reasoned opinions on cyproconazole (EFSA, 2011b, 2012). 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[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

The availability of the analytical enforcement methods for the determination of cyproconazole residues in oilseeds has been investigated in the previously issued EFSA reasoned opinions (EFSA, 2011b, 2012). The multi-residue method DFG S19 was found to be applicable for plant matrices with high acid, high water content and dry matrices. The commodity under consideration is a matrix with a high fat content. For this crop group there was evidence that the multi-residue QuEChERS method can be used for enforcement purposes (EFSA, 2011b).

1.2. Methods for enforcement of residues in food of animal origin

Crops under consideration are normally not fed to livestock and thus the availability of analytical enforcement methods for the determination of cyproconazole residues in food commodities of animal origin was not investigated in the framework of the current application.

2. Mammalian toxicology

The toxicological profile of the active substance cyproconazole was assessed in the framework of the peer review under Directive 91/414/EEC (Ireland, 2006, 2010). The data were sufficient to derive toxicological reference values for cyproconazole and the metabolite triazole alanine which are compiled in Table 2-1. It is noted that for the triazole derivative metabolites (TDMs)[10], a group of common metabolites for pesticides belonging to the triazole group, toxicological reference values were derived (EFSA, 2011a) which are also reported in the table below.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Cyproconazole					
ADI	EFSA	2010	0.02 mg/kg bw per day	Rat multigeneration; long-term rat and mouse	100
ARfD	EFSA	2010	0.02 mg/kg bw	Rat multigeneration; rabbit, developmental	100
Metabolites: 1,2,4-triazole, triazole acetic acid and triazole lactic acid [(a)]					
ADI	EFSA	2011	0.02 mg/kg bw per day	Rat, multigeneration study	1000
ARfD	EFSA	2011	0.06 mg/kg bw	Rat, developmental study	500
Metabolite: triazole alanine					

[9] Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.
[10] Triazole derivative metabolites (TDMs): see Appendix D

	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA	2011	0.10 mg/kg bw per day	Rat, developmental study	1000
ARfD	EFSA	2011	0.10 mg/kg bw	Rat, developmental study	1000

(a): For triazole lactic acid the same value as for 1,2,4 triazole was applied in absence of reproductive data (EFSA, 2011a).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of cyproconazole in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (Ireland, 2006; EFSA, 2010) and in the previously issued reasoned opinions (EFSA, 2011b, 2012). Metabolism studies have been performed with apples, grapes, coffee beans, sugar beet, peanuts and wheat, crops representative four crop groups - fruit and fruiting vegetables, root and tuber vegetables, pulses and oilseeds, and cereals. Further details on the plant metabolism can be found in these evaluations.

For the uses on mustard seed and gold of pleasure, EFSA concludes that in line with the conclusions for rape seed (EFSA, 2011b), the following residue definitions derived in the peer review should be applied:

Residue definition for enforcement: cyproconazole (sum of isomers)

Residue definition for risk assessment: a) cyproconazole (sum of isomers) and

b) triazole derivative metabolites (TDMs) (provisional)

3.1.1.2. Magnitude of residues

In support of the MRL application, the applicant provided eight supervised residue trials on rape seed as conducted in 2004 and 2005 in Northern Europe. The samples were analysed for the parent compound cyproconazole only; no residue data have been provided on triazole derivative metabolites (TDMs). EFSA notes that the same residue trials were submitted in the framework of the MRL request for rape seed (The United Kingdom, 2010) and poppy seed (Czech Republic, 2012) and were assessed by EFSA in 2011 (EFSA, 2011b) and 2012 (EFSA, 2012), respectively.

The applicant proposes to extrapolate the results of the rape seed residue trials to mustard seed and gold of pleasure. According to the EU guidance document (EC, 2011) such an extrapolation is acceptable and a sufficient number of residue trials has been submitted. France from a climatic point of view is divided in northern and southern part. According to the above mentioned guidance document, mustard is mainly grown in the northern region, whereas gold of pleasure is grown in the north or in the south. The residue trials on rape seed reflect the residue situation in northern Europe.

EFSA derived a MRL proposal and risk assessment values for the seed of mustard and gold of pleasure for the residue definition as cyproconazole (sum of isomers) (see Table 3-1).

The storage stability of cyproconazole in primary crops was investigated in the DAR under Directive 91/414/EEC (Ireland, 2006). Residues of cyproconazole were found to be stable at ≤ -18°C for up to 40 months in matrices with high fat content. As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated (deep frozen for not more than 9 months), it is concluded that the residue data are valid with regard to storage stability.

The analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for purpose (France, 2012).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.4 mg/kg for the intended use on mustard and gold of pleasure in the NEU.

Table 3-1: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement	Risk assessment					
Enforcement residue definition: cyproconazole (sum of isomers) **Risk assessment residue definition: cyproconazole (sum of isomers)**									
Rape seed → mustard seed, gold of pleasure	NEU	Outdoor	0.01; 3*0.03; 0.04; 0.05, 0.08; 0.23	0.01; 3*0.03; 0.04; 0.05, 0.08; 0.23	0.035	0.23	0.4	1	R_{ber}= 0.15 R_{max}= 0.29 MRL_{OECD} = 0.345/0.4
Enforcement residue definition: cyproconazole (sum of isomers) **Risk assessment residue definition: triazole derivative metabolites (TDMs)**									
Rape seed → mustard seed, gold of pleasure	NEU	Outdoor	0.01; 3*0.03; 0.04; 0.05, 0.08; 0.23	No data	-	-	-	-	-

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of cyproconazole residues was investigated in studies performed at three test conditions representing pasteurization, baking/brewing/boiling and sterilization (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). Cyproconazole is not degraded under standard processing conditions and therefore will be the relevant residue after processing in those primary commodities in which it is the main residue according to metabolism studies (EFSA, 2010).

The effects of processing on the nature and magnitude of TDMs have not been investigated.

No processing studies have been submitted investigating the effects of processing on the magnitude of cyproconazole residues in processed mustard seed and gold of pleasure. Taking into account the low dietary exposure of consumers and the insignificant contribution of residues in the crops under consideration to the total dietary intake such studies are not required. Given the fat-solubility of cyproconazole, an accumulation of residues in oil might be expected.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Both crops under consideration can be grown in a crop rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed.

The available studies demonstrate that the degradation rate of cyproconazole in soil is slow with a maximum DT_{90f} exceeding 1000 days (EFSA, 2010). Studies investigating the nature and magnitude of cyproconazole related residues in rotational crops were assessed in the peer review under Directive 91/414/EEC (Ireland 2006, 2010). These studies gave an indication that the residue pattern in rotational crops is similar to the metabolic pattern observed in primary crops. However, due to deficiencies in the studies (no rotational crop metabolism studies were available with triazole ring labelled cyproconazole, the rotational crop field studies did not investigate plant back intervals less than 430 days), no final conclusions can be derived with regard to the occurrence of cyproconazole related residues in rotational crops.

EFSA reiterates the recommendation derived in the reasoned opinion regarding the MRL request on rape seed (EFSA, 2011b) that Member States when granting authorisations for the use of cyproconazole should take appropriate risk management measures to avoid the occurrence of cyproconazole related residues in rotational crops and/or succeeding crops.

It is also strongly recommended to perform rotational crop metabolism studies with triazole ring labelled cyproconazole and to perform rotational crop studies in which shorter plant back intervals are investigated. These data will be required for the risk assessment of TDMs.

3.2. Nature and magnitude of residues in livestock

Since seed of mustard and gold of pleasure and/or their by-products are not normally fed to livestock, the nature and magnitude of cyproconazole residues in livestock was not assessed in the framework of this application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[11] (EFSA, 2007).

For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on rape seed (see Table 3-1). These values were used as input values both for mustard seed and gold of pleasure as well as for poppy seed and rape seed. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the median level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Cyproconazole				
Mustard seed, gold of pleasure	0.035	Median residue (rape seed) (Table 3-1)	0.035	Median residue (rape seed) (Table 3-1)
Poppy see, rape seed	0.035	Median residue (EFSA, 2011b, 2012)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Other commodities of plant and animal origin	MRL	See Appendix C		

The estimated exposure was then compared with the toxicological reference values derived for cyproconazole (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 23.4% of the ADI (UK toddler diet). The contribution of residues in mustard seed to the total consumer exposure accounted

[11] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

for a maximum of 0.002% of the ADI (WHO regional European diet and WHO Cluster diet E). No consumption data are available for gold of pleasure.

No acute consumer risk was identified in relation to the cyproconazole residues in mustard seed (0.03% of the ARfD). No consumption data have been provided for gold of pleasure. Similarly to mustard seed, gold of pleasure is a very minor crop, and thus the potential acute exposure from the intake of this crop is expected to be low.

EFSA concludes that the intended use of cyproconazole on mustard and gold of pleasure will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

EFSA emphasizes that the above assessment does not take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment is performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of cyproconazole was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.02 mg/kg bw per day and an ARfD of 0.02 mg/kg bw.

The metabolism of cyproconazole in primary crops was investigated in four different crop groups. From these studies the peer review concluded to establish the residue definition for enforcement as parent cyproconazole (sum of isomers). For risk assessment two separate residue definitions were derived: a) cyproconazole (sum of isomers) and b) triazole derivative metabolites. The second residue definition was set as provisional pending finalisation of a global and harmonised approach for all the active substances of the triazole chemical group. For the use on mustard seed and gold of pleasure, EFSA concludes that the metabolism of cyproconazole is sufficiently addressed and that the derived residue definitions are applicable.

EFSA considers that the proposed extrapolation of residue data from rape seed to mustard seed and gold of pleasure is acceptable and a sufficient number of residue trials has been submitted to derive a MRL proposal of 0.4 mg/kg in the crops under consideration. The submitted residue trials data support the NEU use only. There is evidence that adequate analytical enforcement methods are available to control residues of cyproconazole in plant matrices with high fat content at the LOQ of 0.01 mg/kg.

Studies investigating the nature of cyproconazole residues in processed commodities were assessed in the peer review and showed that the compound is hydrolytically stable under the processing conditions representative for pasteurisation, boiling/baking and sterilisation. Therefore for processed commodities the same residue definitions as for raw agricultural commodities are applicable. The effects of processing on the nature and magnitude of TDMs have not been investigated. Given the low dietary intake of cyproconazole residues via mustard seed and gold of pleasure, specific studies investigating the magnitude of cyproconazole residues in processed commodities are not necessary.

The occurrence of cyproconazole residues in rotational crops was investigated in the framework of the peer review. However, since the available studies showed some deficiencies, no final conclusion on the possible occurrence of cyproconazole related residues in rotational corps was derived. EFSA therefore recommends that before granting authorisations Member States should establish specific restrictions/risk management measures to avoid the occurrence of cyproconazole related residues in rotational crops.

Residues of cyproconazole in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration and/or their by-products are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on rape seed. These values were used as input values both for mustard seed and gold of pleasure as well as for poppy seed and rape seed. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. As no consumption data are available for the gold of pleasure, the acute exposure assessment was performed only with regard to mustard seed assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the median level as observed in supervised field trials.

The estimated exposure was then compared with the toxicological reference values derived for cyproconazole.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 23.4% of the ADI (UK

toddler diet). The contribution of residues in mustard seed to the total consumer exposure accounted for a maximum of 0.002% of the ADI (WHO regional European diet and WHO Cluster diet E). No consumption data are available for gold of pleasure.

No acute consumer risk was identified in relation to the cyproconazole residues in mustard seed (0.03% of the ARfD). No consumption data have been provided for the gold of pleasure. Similarly to mustard seed, gold of pleasure is a very minor crop, and thus the potential acute exposure from the intake of this crop is expected to be low.

EFSA concludes that the intended use of cyproconazole on mustard seed and gold of pleasure will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. EFSA emphasizes that the above assessment does not take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment is performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

RECOMMENDATION

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Cyproconazole (F)				
0401080	Mustard seed	0.05*	0.4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses. The MRL supports NEU use only.
0401130	Gold of pleasure	0.05*	0.4	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble pesticide. MRL is expressed as mg/kg of fat contained in the whole product

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Oilseed rape, mustard, gold of pleasure	FRANCE	F	*Alternaria sp., Sclerotinia sp.*	SC	80 g/L	Foliar spray	BBCH 61-70 BBCH 75-80	1-2	15 days		100-500	0.08	42	

Remarks:
(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Cyproconazole			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.02**	ARfD (mg/kg bw):	**0.02**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
3	23
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)
23.3	UK Toddler	11.4	Sugar beet (root)	5.2	Milk and cream,	2.0	Wheat	8.3
21.1	UK Infant	9.7	Milk and cream,	5.0	Sugar beet (root)	1.3	Wheat	12.7
19.7	NL child	7.3	Milk and cream,	3.2	Apples	2.4	Wheat	12.5
19.0	DE child	6.0	Apples	3.6	Milk and cream,	2.1	Wheat	8.0
18.1	FR toddler	9.9	Milk and cream,	1.3	Apples	1.3	Apples	14.9
16.1	WHO Cluster diet B	4.3	Wheat	1.8	Wine grapes	1.2	Maize	6.5
12.8	DK child	3.2	Milk and cream,	2.8	Wheat	2.2	Rye	5.8
12.3	IE adult	1.3	Wine grapes	1.1	Maize	1.1	Maize	6.1
12.0	FR infant	6.4	Milk and cream,	1.3	Apples	1.0	Potatoes	10.0
10.0	WHO cluster diet E	2.0	Wheat	1.6	Wine grapes	1.0	Potatoes	4.2
9.9	ES child	3.1	Milk and cream,	2.2	Wheat	0.6	Apples	6.2
9.5	SE general population 90th percentile	3.1	Milk and cream,	1.6	Wheat	1.0	Potatoes	6.7
9.4	WHO cluster diet D	3.3	Wheat	1.3	Milk and cream,	1.0	Potatoes	4.1
9.0	PT General population	2.5	Wine grapes	2.0	Wheat	1.3	Potatoes	2.6
8.7	FR all population	4.0	Wine grapes	1.6	Wheat	0.7	Milk and cream,	2.3
7.8	WHO Cluster diet F	1.8	Wheat	1.0	Milk and cream,	0.9	Potatoes	3.7
7.6	WHO regional European diet	1.5	Wheat	1.2	Milk and cream,	1.0	Potatoes	4.5
7.3	NL general	1.6	Milk and cream,	1.0	Wheat	0.7	Potatoes	4.0
6.9	UK vegetarian	1.9	Sugar beet (root)	1.0	Wheat	0.8	Milk and cream,	2.4
6.8	IT kids/toddler	3.3	Wheat	0.8	Other cereal	0.4	Apples	1.5
6.6	UK Adult	2.0	Sugar beet (root)	1.1	Wine grapes	0.8	Wheat	2.1
6.0	ES adult	1.2	Milk and cream,	1.2	Wheat	0.4	Wine grapes	3.3
6.0	DK adult	1.4	Wine grapes	1.3	Milk and cream,	1.0	Wheat	2.5
4.9	LT adult	1.0	Milk and cream,	0.9	Apples	0.8	Potatoes	2.5
4.9	IT adult	2.1	Wheat	0.4	Apples	0.4	Other cereal	1.3
4.3	FI adult	1.4	Milk and cream,	0.5	Wheat	0.3	Rye	2.7
3.3	PL general population	1.0	Apples	0.9	Potatoes	0.3	Table grapes	1.7

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Cyproconazole 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 variabilty 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)
	0.03	Mustard seed	0.035 / -	0.0	Mustard seed	0.035 / -	0.0	Mustard seed	0.035 / -	0.0	Mustard seed	0.035 / -
	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)			
	*) 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 Cyproconazole 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.											

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 20/03/2013 14:44)

Code number	Groups and examples of individual products to which the MRLs apply	Cyproconazole (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	0,1
130010	Apples (Crab apple)	0,1
130020	Pears (Oriental pear)	0,1
130030	Quinces	0,1
130040	Medlar	0,1
130050	Loquat	0,1
130990	Others	0,1
140000	(iv) Stone fruit	
140010	Apricots	0,1
140020	Cherries (sweet cherries, sour cherries)	0,1
140030	Peaches (Nectarines and similar hybrids)	0,1
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,2
151010	Table grapes	0,2
151020	Wine grapes	0,2
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes,)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*

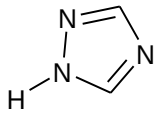
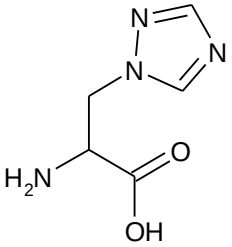
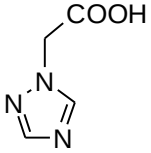
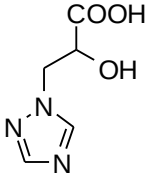
Code number	Groups and examples of individual products to which the MRLs apply	Cyproconazole (F)
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	5.00
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar	0,05*
	(leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,1
270020	Cardoons	0,05*
270030	Celery	0,2
270040	Fennel	0,05*
270050	Globe artichokes	0,1
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,4
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,4
401070	Soya bean	0,07
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,1
500010	Barley	0,1
500020	Buckwheat	0,1
500030	Maize	0,1
500040	Millet (Foxtail millet, teff)	0,1
500050	Oats	0,1
500060	Rice	0,1
500070	Rye	0,1
500080	Sorghum	0,1
500090	Wheat (Spelt Triticale)	0,1
500990	Others	0,1
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,1
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Cyproconazole (F)
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,1
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,5
1011040	Kidney	0,5
1011050	Edible offal	0,5
1011990	Others	0,05*
1012000	(b) Bovine	
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,5
1012040	Kidney	0,5
1012050	Edible offal	0,5
1012990	Others	0,05*
1013000	(c) Sheep	
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,5
1013040	Kidney	0,5
1013050	Edible offal	0,5
1013990	Others	0,05*
1014000	(d) Goat	
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,5
1014040	Kidney	0,5
1014050	Edible offal	0,5
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,5
1015040	Kidney	0,5
1015050	Edible offal	0,5
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,5
1017040	Kidney	0,5
1017050	Edible offal	0,5
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(*) Indicates lower limit of analytical determination

(F): Fat soluble

D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structure
1,2,4-triazole	1*H*-1,2,4-triazole (free triazole) (CAS number 288-88-0)	
Triazole alanine	(RS)-2-amino-3-(1*H*-1,2,4 triazol-1-yl)propanoic acid or 3-(1*H*-1,2,4-triazol-1-yl)-D,L-alanine (CAS number 86362-20-1)	
Triazole acetic acid	1*H*-1,2,4-triazol-1-ylacetic acid (CAS number 28711-29-7)	
Triazole lactic acid or Triazole hydroxy propionic acid	(R,S)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid	

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DT_{90f}	period required for 90 % dissipation (field method)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
Log P_{ow}	partition coefficient between n-octanol and water
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method

RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
UK	The United Kingdom