European Food Safety Authority

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REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for propiconazole according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance propiconazole. In order to assess the occurrence of propiconazole residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

KEY WORDS

propiconazole, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, triazole, fungicide

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SUMMARY

Propiconazole was included in Annex I to Directive 91/414/EEC on 01 June 2004, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Finland, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 04 May 2010 and, after having considered several comments made by EFSA, the RMS provided on 23 May 2012 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 28 May 2014 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 22 August 2014 were considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of propiconazole was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.04 mg/kg bw per d and 0.3 mg/kg bw, respectively.

Primary crop metabolism of propiconazole was investigated in five different crop groups following foliar applications. Based on these studies, EFSA proposes parent propiconazole (sum of isomers) as residue definition for enforcement. For risk assessment, EFSA tentatively proposes to define the residue in all plant commodities as propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers). Tentative conversion factors of 10 for forage and straw and of 3 for all other food and feed commodities are proposed, in order to express the residue levels according to the residue definition for risk assessment. For the post-harvest uses on citrus fruit, considering that it is unlikely that propiconazole metabolites are formed between treatment and sampling, a tentative conversion factor of 1 is proposed for risk assessment. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg in high water content, high fat content, acidic and dry commodities but a fully validated method for enforcement of propiconazole in tea is still required.

Regarding the magnitude of residues in primary crops, for almonds, cherries, plums, strawberries, currants, gooseberries, peppers, cucumbers, globe artichokes, peanuts and tea, the available data were insufficient to derive MRLs. For all other commodities the available residues data are considered sufficient to derive only tentative MRL proposals and risk assessment values.

The hydrolysis studies demonstrated that under pasteurisation, baking/boiling/brewing and sterilisation conditions, propiconazole remained stable in processed commodities. Studies investigating the magnitude of residues in processed products of oranges, apples, plums, table and wine grapes, peanuts, barley grain, rice grain and wheat grain are available. With regard to the risk assessment of propiconazole, further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

During the peer review the potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, sweet potato, carrot, sugar beet, cabbage, peanut, maize and wheat. This study showed comparable metabolic patterns in primary and succeeding crops. Significant residues of parent propiconazole in rotational crops are not expected considering the application rates proposed in the framework of this MRL review. Nevertheless, triazole derivative metabolites might be

of concern in rotational crops and this situation will be reconsidered as soon as a global approach on TDMs will be defined.

Based on the uses reported by the RMS, significant intakes were calculated for ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement was defined as propiconazole (sum of isomers). For risk assessment, EFSA tentatively proposed to define the residue as propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers). The available livestock feeding studies on lactating cows and laying hens allowed EFSA to estimate the magnitude of residues in ruminants, poultry and pig products and to derive MRLs and conversion factors in these commodities. It is therefore concluded that MRLs can be set at the LOQ for all animal commodities except for ruminant and pig tissues. All these MRLs can only tentatively be derived. A validated analytical method for enforcement of these MRLs is available with an LOQ of 0.01 mg/kg in milk, eggs and animal tissues.

Chronic and acute consumer exposure resulting from the uses supported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied for the tentative conversion factors for an indicative calculation. The highest chronic exposure represented 11.2 % of the ADI (British toddler) and the highest acute exposure amounted to 15.3 % of the ARfD (bovine liver).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for propiconazole. Additional calculations of the consumer exposure, considering these CXLs were therefore performed. The highest chronic exposure represented 15.2 % of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 43.5 % of the ARfD (peaches).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see summary table below). All MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, certain tentative MRLs or existing EU MRLs still need to be confirmed by the following data:

- a validated analytical method for enforcement of the residue in tea;
- further investigation on the toxicological properties of the metabolites convertible to 2,4-dichlorobenzoic acid;
- clarifications on the European GAPs for almonds (SEU), strawberries (NEU), currants (NEU), gooseberries (NEU) and peppers (NEU);
- additional trials supporting the authorisations on citrus fruits, almonds, apples, peaches, apricots, cherries, plums, grapes, strawberries, currants, gooseberries, bananas, peppers, cucumbers, sweet corn, globe artichokes, peanuts, rapeseed, maize, barley, oats, rice, wheat, rye, tea, sugar beet and grass, including analysis of parent and metabolites convertible to 2,4-dichlorobenzoic acid in accordance with the proposed residue definition for risk assessment.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- a metabolism study on citrus fruits following post-harvest treatment;
- storage stability study in acidic commodities (may became a major gap in case new trials with samples stored for longer period would be submitted).

Moreover EFSA emphasises that the available metabolism studies do not investigate the possible impact of plant and livestock metabolism on the isomer ratio of propiconazole and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also highlights that the above assessment does not yet 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 should be 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.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: propiconazole (sum of isomers) (F)					
110010	Grapefruit	6	-	5	Further consideration needed [a]
110020	Oranges	6	9	9	Further consideration needed [b]
110030	Lemons	6	-	5	Further consideration needed [a]
110040	Limes	6	-	5	Further consideration needed [a]
110050	Mandarins	6	-	5	Further consideration needed [a]
120010	Almonds	0.05*	-	0.05	Further consideration needed [c]
130010	Apples	0.15	-	0.15	Further consideration needed [a]
120080	Pecans	0.05*	0.02*	0.02	Further consideration needed [d]
140010	Apricots	0.2	-	0.15	Further consideration needed [a]
140020	Cherries	0.05*	-	0.05	Further consideration needed [c]
140030	Peaches	0.2	5	5	Further consideration needed [b]
140040	Plums	0.05*	0.6	0.6	Further consideration needed [e]
151000	Table and wine grapes	0.3	-	0.3	Further consideration needed [a]
152000	Strawberries	0.05*	-	0.05	Further consideration needed [c]
154020	Cranberries	0.05*	0.3	0.3	Further consideration needed [d]
154030	Currants (red, black and white)	0.05*	-	0.05	Further consideration needed [c]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
154040	Gooseberries	0.05*	-	0.05	Further consideration needed [c]
163020	Bananas	0.1	0.1	0.15	Further consideration needed [f]
163080	Pineapples	0.05*	0.02*	0.02	Further consideration needed [d]
231010	Tomatoes	0.05*	3	3	Further consideration needed [d]
231020	Peppers	0.05*	-	0.05	Further consideration needed [c]
232010	Cucumbers	0.05*	-	0.05	Further consideration needed [c]
234000	Sweet corn	0.05*	0.05	0.05	Further consideration needed [b]
270050	Globe artichokes	0.05*	-	0.05	Further consideration needed [c]
401020	Peanuts	0.2	-	0.2	Further consideration needed [c]
401060	Rape seed	0.1*	0.02	0.05	Further consideration needed [f]
401070	Soya bean	0.1*	0.07	0.07	Further consideration needed [d]
500010	Barley grain	0.2	0.2	0.3	Further consideration needed [f]
500030	Maize grain	0.05*	0.05	0.05	Further consideration needed [f]
500050	Oats grain	0.2	-	0.3	Further consideration needed [a]
500060	Rice grain	0.7	-	1.5	Further consideration needed [a]
500070	Rye grain	0.05*	0.02*	0.04	Further consideration needed [f]
500090	Wheat grain	0.05*	0.02*	0.04	Further consideration needed [f]
610000	Tea	0.1*	-	0.1	Further consideration needed [c]
620000	Coffee beans	0.1*	0.02	0.02	Further consideration needed [d]
900010	Sugar beet (root)	0.05*	0.02	0.15	Further consideration needed [f]
900020	Sugar cane	0.05*	0.02*	0.02	Further consideration needed [d]
1011010	Swine muscle	0.01*	0.01*	0.05	Further consideration needed [f]
1011020	Swine fat (free of lean meat)	0.01*	0.01*	0.05	Further consideration needed [f]
1011030	Swine liver	0.01*	0.01*	0.15	Further consideration needed [f]
1011040	Swine kidney	0.01*	0.01*	0.05	Further consideration needed [f]
1012010	Bovine muscle	0.05	0.01*	0.05	Further consideration needed [f]
1012020	Bovine fat	0.05	0.01*	0.07	Further consideration needed [f]
1012030	Bovine liver	0.1	0.01*	0.5	Further consideration needed [f]
1012040	Bovine kidney	0.05	0.01*	0.05	Further consideration needed [f]
1013010	Sheep muscle	0.05	0.01*	0.05	Further consideration needed [f]
1013020	Sheep fat	0.05	0.01*	0.07	Further consideration needed [f]
1013030	Sheep liver	0.1	0.01*	0.5	Further consideration needed [f]
1013040	Sheep kidney	0.05	0.01*	0.05	Further consideration needed [f]
1014010	Goat muscle	0.05	0.01*	0.05	Further consideration needed [f]
1014020	Goat fat	0.05	0.01*	0.07	Further consideration needed [f]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1014030	Goat liver	0.1	0.01*	0.5	Further consideration needed (f)
1014040	Goat kidney	0.05	0.01*	0.05	Further consideration needed (f)
1016010	Poultry muscle	0.01*	0.01*	0.01*	Further consideration needed (f)
1016020	Poultry fat	0.01*	0.01*	0.01*	Further consideration needed (f)
1016030	Poultry liver	0.01*	-	0.01*	Further consideration needed (a)
1020010	Cattle milk	0.01*	0.01*	0.01*	Further consideration needed (f)
1020020	Sheep milk	0.01*	0.01*	0.01*	Further consideration needed (f)
1020030	Goat milk	0.01*	0.01*	0.01*	Further consideration needed (f)
1030000	Birds' eggs	0.01*	0.01*	0.01*	Further consideration needed (f)
-	Other products of plant and animal origin	See App. C.1	See App. C.2	-	Further consideration needed (g)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Indicates that the residue definition is fat soluble.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).
(b): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(d): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(e): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the CXL (combination C-V in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As propiconazole was included in Annex I to the above mentioned directive on 01 June 2004, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-612 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residue Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

Finland, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for propiconazole. The requested information was submitted to EFSA on 04 May 2010 and subsequently checked for completeness. On 23 May 2012, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 28 May 2014 and submitted to Member States (MS) for commenting. All MS comments received by 22 August 2014 were considered by EFSA for finalisation of the reasoned opinion.

[4] Regulation (EC) No 396/2005 of the European 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.

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1−32.

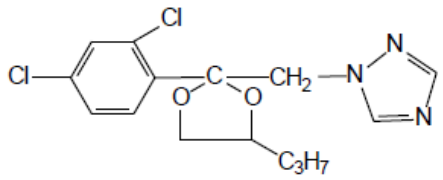
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Propiconazole is the ISO common name for (2*RS*,4*RS*;2*RS*,4*SR*)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole (IUPAC).



Propiconazole is a systemic fungicide belonging to the class of triazoles. It is a racemic mixture of 4 stereoisomers which are separated into cis- and trans-diastereomers, both exerting biological activity. The compound acts as an ergosterol biosynthesis inhibitor (EBI). The lack of normal sterol production slows or stops the growth of the fungus, preventing further infection of host tissues. The active substance is used against several fungal pathogens in a number of agricultural crops.

Propiconazole was evaluated in the framework of Directive 91/414/EEC with Finland being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process include foliar applications to cereals, sugar beets, stone fruits and grass. Following the peer review a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2003/70/EC,[6] entering into force on 01 June 2004. According to Regulation (EU) No 540/2011,[7] propiconazole is deemed to have been approved under Regulation (EC) No 1107/2009.[8] This approval is restricted to uses as fungicide only. As EFSA was not yet involved in the peer review of propiconazole, a conclusion of EFSA on this active substance is not available.

The EU MRLs for propiconazole are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for table & wine grapes, apples, stone fruit, rice and citrus fruit (EFSA, 2010, 2011,

[6] Commission Directive 2003/70/EC of 17 July 2003 amending Council Directive 91/414/EEC to include mecoprop, mecoprop-P and propiconazole as active substances. OJ L 184, 23.7.2003, p. 9−12.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1−186.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1−50.

2012) which were legally implemented in Regulations (EU) No 524/2011/EC,[9] 270/2012/EC[10] and 500/2013/EC.[11] All existing EU MRLs, which are established for the parent compound only, are summarized in Appendix C.1 to this document. CXLs for propiconazole were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs also refer to parent compound only.

For the purpose of this MRL review, the uses of propiconazole currently authorized within the EU as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile (see Appendix A). According to the reported GAPs, propiconazole is applied outdoor on a wide range of crops by foliar spraying up to 14 days before harvest. Additionally post-harvest uses on citrus fruit are authorised. Import tolerances on bananas, peanuts, rape seed and tea were also reported.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Finland, 1998, 2002), the Review Report on propiconazole (EC, 2003), the JMPR Evaluation report (FAO, 2007), the previous reasoned opinions on propiconazole (EFSA, 2010, 2011, 2012) as well as the evaluation reports submitted during the consultation of Member States (Finland, 2014; France, 2014; Germany, 2014; Hungary, 2014; Italy, 2014; Netherlands, 2014; United Kingdom, 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[12] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011 and OEDC, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, analytical methods were evaluated for the determination of propiconazole in plant matrices but cannot be considered fully validated as validation data are not in accordance with the current guidelines (EC, 2010b).

In addition, after Annex I inclusion, an analytical method using LC-MS/MS and its ILV were evaluated and validated for the determination of propiconazole with an LOQ of 0.01 mg/kg in high water content (leek), high oil content (oilseed rape), acidic (lemon) and dry (cereal grain)

[9] Commission Regulation (EU) No 524/2011 of 26 May 2011 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 biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products. OJ L 142, 28.5.2011, p. 1−56.

[10] Commission Regulation (EU) No 270/2012 of 26 March 2012 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 amidosulfuron, azoxystrobin, bentazone, bixafen, cyproconazole, fluopyram, imazapic, malathion, propiconazole and spinosad in or on certain products. OJ L 89, 27.3.2012, p. 5−63.

[11] Commission Regulation (EU) No 500/2013 of 30 May 2013 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European parliament and of the Council as regards maximum residue levels for acetamiprid, Adoxophyes orana granulovirus strain BV-0001, azoxystrobin, clothianidin, fenpyrazamine, heptamaloxyloglucan, metrafenone, Paecilomyces lilacinus strain 251, propiconazole, quizalofop-P, spiromesifen, tebuconazole, thiamethoxam and zucchini yellow mosaik virus - weak strain in or on certain products. OJ L 151, 4.6.2013, p. 1−32.

[12] 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, 11.06.2011, p. 127−175.

commodities (France, 2014). As the method is validated for two mass transitions, it is considered highly specific.

The multi-residue QuEChERS method in combination with HPLC-MS/MS is also available to analyse propiconazole with an LOQ of 0.01 mg/kg in high water content (cucumber), high oil content (avocado), acidic (lemon) and dry (oat) commodities (Table 1-1). A detailed description of the QuEChERS method is reported by CEN (2008).

Table 1-1: Recovery data for the analysis of propiconazole in different crop groups using the QuEChERS method in combination with LC-MS/MS (EURL, 2012)

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
Acidic	0.01 0.10	93.6 102.7	10.1 4.8	10 10	2
Dry (cereals, pulses)	0.01 0.10	100.2 93.8	7.1 9.7	5 5	1
Fatty (avocado)	0.01 0.10	90.2 93.6	4.0 3.6	5 5	1
High water content	0.01 0.10	97.6 104.3	11.5 3.1	15 10	2

Hence it is concluded that propiconazole can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities. A fully validated analytical method for the determination of propiconazole in tea is not available and is required.

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-MS was evaluated and validated for the determination of propiconazole in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs (Finland, 2002). Nevertheless, an ILV is missing.

In addition, after Annex I inclusion, the RMS evaluated an HPLC-MS/MS method and its ILV which were validated for the determination of propiconazole with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs (France, 2014). As the method is validated for two mass transitions, it is considered as highly specific.

Hence it is concluded, that propiconazole can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs.

2. Mammalian toxicology

The toxicological assessment of propiconazole was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2003). These toxicological reference values are summarized in Table 2-1.

Metabolism studies in both mammalians and plants have shown that active substances belonging to the chemical class of triazoles are metabolized to common metabolites known as triazole derivative

metabolites (TDMs), the major ones being the metabolites 1,2,4-triazole,[13] triazole alanine,[14] triazole lactic acid[15] and triazole acetic acid.[16] The toxicological properties of TDMs were discussed by the EFSA Pesticide Risk Assessment Peer Review Expert Meeting on mammalian toxicology of January 2007 (PRAPeR 14); the agreed toxicological reference values are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Propiconazole					
ADI	EC	2003	0.04 mg/kg bw per d	2-year rat	100
ARfD	EC	2003	0.3 mg/kg bw	Rat developmental	100
Metabolites: 1,2,4-triazole, triazole acetic acid and triazole lactic acid [(a)]					
ADI	PRAPeR 14	2007	0.02 mg/kg bw per d	Rat, multigeneration study	1000
ARfD	PRAPeR 14	2007	0.06 mg/kg bw	Rat, developmental study	500
Metabolite: triazole alanine					
ADI	PRAPeR 14	2007	0.10 mg/kg bw per d	Rat, developmental study	1000
ARfD	PRAPeR 14	2007	0.10 mg/kg bw	Rat, developmental study	1000

(a): EFSA PRAPeR Expert Meeting 14 concluded to apply the same toxicological reference values established for 1,2,4 triazole in absence of reproductive toxicity data on triazole acetic acid and triazole lactic acid.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of propiconazole was investigated for foliar application on cereals (winter & spring wheat, rice), on fruits and fruiting vegetables (grapevines, tomatoes), on pulses and oilseeds (peanuts), on root and tuber vegetables (carrots) and on leafy vegetables (celery), using ^{14}C-triazole and ^{14}C-phenyl-labelled propiconazole and ^{14}C-triazole-labelled 1,2,4 triazole (FAO, 2007; Finland, 1998, 2002). The characteristics of these studies are summarized in Table 3-1.

[13] 1,2,4-triazole: 1H-[1,2,4]-triazole. See Appendix E.
[14] triazole alanine: 3-(1H-1,2,4-triazol-1-yl)-DL-alanine. See Appendix E.
[15] triazole lactic acid: (2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propanoic acid. See Appendix E.
[16] triazole acetic acid: 1H-1,2,4-triazol-1-ylacetic acid. See Appendix E.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Method, F or G [(a)]	Application details			
				Rate	No	Sampling (DAT)	Remarks
Studies on propiconazole evaluated by the peer review (Finland, 1998, 2002) and by JMPR (FAO, 2007)							
Fruits and fruiting vegetables	Grapevines	^{14}C-triazole ^{14}C-phenyl	Foliar, F	0.0025 kg a.s/hL	4	30, 63	Interval between applications: 14 - 18 d
Pulses and oilseeds	Peanuts	^{14}C-triazole ^{14}C-phenyl	Foliar, G	0.34 kg a.s./ha	3	14	Applications at 5, 12 and 17 weeks post-planting
		^{14}C-triazole	Foliar, F	0.17 kg a.s./ha	8	14	Interval between applications: 14 d
		^{14}C-triazole	Foliar, G	2.5 kg a.s./ha	8	14	Interval between applications: 7 - 14 d
Cereals	Winter wheat	^{14}C-triazole	Over-top spraying, F	0.125 kg a.s./ha	1	0, 11, 25, 49	Application at BBCH 51
		^{14}C-phenyl				0, 11, 25, 41	
	Spring wheat	phenyl-^{14}C	Foliar, G	0.112 kg a.s./ha	1	12, 77	-
				0.561 kg a.s./ha			
	Rice	^{14}C-triazole	Over-top spraying, G	0.25 kg a.s./ha	2	0, 42	Applications at BBCH 40 – 49 and at BBCH 59 (15 d interval)
Studies on propiconazole evaluated by JMPR (FAO, 2007)							
Root and tuber vegetables	Carrots	^{14}C-phenyl	Foliar, G	0.12 kg a.s./ha or 1.26, 1.20, 1.21 and 1.30 kg a.s./ha	4	14	Interval between applications: 7 d
Leafy vegetables	Celery	^{14}C-phenyl	Foliar, G	0.56 kg a.s./ha	1	7	-
				1.4 kg a.s./ha	2	61	Interval between applications: 16 d
Studies on 1,2,4-triazole evaluated by the peer review (Finland, 1998, 2002) and by JMPR (FAO, 2007)							
Fruits and fruiting vegetables	Tomatoes	^{14}C-triazole	Injection	20-30 mg/kg	1	n.a.	-

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

In whole grapes at harvest, the residues of propiconazole accounted for 16 % to 22.7 % TRR (triazole labelling) and 21 % to 22.7 % TRR (phenyl labelling), while in grape leaves, the parent compound amounted for up to 18 % TRR. Only the triazole labelled fractions were further characterized. In the whole grapes, the ketone metabolite CGA 91304,[17] resulting from the hydrolysis of the dioxolane ring, represented 33 % TRR (0.013 mg eq./kg). 1,2,4-triazole alanine represented 10 % TRR. The alkanol derivative metabolite CGA 91305[18] was recovered free (4.9 % TRR) and as O-glucoside conjugate (7 % TRR). Isomers of the β- hydroxy alcohol CGA 118244,[19] free or conjugated, were also identified: altogether, they represented 12.5 % TRR. The rest of the recovered radioactivity in whole grapes remained unidentified.

In peanuts at harvest (PHI 14 d), unchanged parent compound and non-polar metabolites conjugated with sugars represented up to 69 % TRR in stalks, 61 % TRR in shells and 95 % TRR in kernels. The major metabolic pathway of propiconazole was through hydroxylation of β-carbon of the n-propyl side chain of the dioxolane ring to form the β-hydroxy alcohol CGA 118244 followed by further sugar conjugation. Cleavage of the bridge between the phenyl and triazole rings seemed to occur in the developing kernels. Additional data on greenhouse-peanut confirmed that the major metabolite recovered in the kernels was the 1,2,4-triazole alanine conjugate (50 % TRR).

In winter wheat from the triazole label study, parent compound in the immature upper plant parts decreased from 92.6 % TRR (5 hours after application) to 9.8 % TRR (25 days after application), with a gradual increase of polar metabolites (up to 70 % TRR, 25 days after application), characterized as water soluble sugar conjugates. At harvest (PHI 49 d), the parent compound was not detected in grain (<0.01 mg/kg) and accounted for 12.7 % TRR (0.18 mg/kg) in straw. In grain, acidic compounds represented a high proportion of the TRR (76.2 % TRR, 0.30 mg eq./kg), among them the 1,2,4-triazole alanine was identified (54 % TRR, 0.21 mg eq./kg). In straw, several isomers of the β-hydroxy alcohol CGA 118244 metabolite, in the free or conjugated form were identified: they represented altogether 32.3 % TRR (0.46 mg eq./kg). The alkanol derivative metabolite CGA 91305 was also recovered, representing 10.6 % TRR (0.15 mg eq./kg). In spring wheat grown under greenhouse conditions, propiconazole was recovered at low levels in forage (up to 9 % TRR, 1.5 mg/kg) and mature grains (up to 0.8 % TRR, <0.01 mg/kg). In forage, several conjugates of β-hydroxy alcohol CGA 118244 and γ-hydroxy alcohol CGA 118245[20] were identified: altogether, they represented up to 44.6 % TRR. The other metabolites recovered in grain and forage represented low proportions of the TRR. In grain and forage, 92.4 and 37 % TRR, respectively, remained unextracted.

In rice at harvest (PHI 42 d), radioactive residue levels reached 5.2 mg eq./kg in stalks, 2.8 mg eq./kg in husks and 0.29 mg eq./kg in grains. Unchanged propiconazole accounted for 27.6 % TRR (1.45 mg/kg), 46.8 % TRR (1.33 mg/kg) and 27.7 % TRR (0.08 mg/kg) in stalks, husks and grains, respectively. The major metabolite in grain was identified as the 1,2,4-triazole acetic acid (35 % TRR, 0.10 mg eq./kg). A route of degradation was the hydroxylation of the aliphatic side chain of the parent molecule that gives free and sugar conjugated β-hydroxy isomers (CGA 118244). An alternative pathway was the cleavage of the dioxolane ring to generate first the intermediate ketone CGA 91304 and then the alkanol derivative CGA 91305 that was detected either as free or sugar conjugates. All the metabolites resulting from these pathways represented low proportions of the TRR in grain. The residual radioactivity was characterized mainly as polar compounds and represented up to 14.5 % TRR in grain, while 17.9 % TRR remained unextracted in grain.

[17] CGA 91304: 1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)ethanone. See Appendix E.
[18] CGA 91305: (1RS)-1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)ethanol. See Appendix E.
[19] CGA 118244: 1-[[2-(2,4-dichlorophenyl)-4-(2-hydroxypropyl)-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole. See Appendix E.
[20] CGA 118245: 3-[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]propan-1-ol. See Appendix E.

In carrots at harvest (PHI 14 d), propiconazole was the major identified component of the total residues, accounting for 56 to 75 % TRR in roots and 61.7 to 91.2 % TRR in leaves. Metabolite β-hydroxy alcohol CGA 118244 reached up to 12.1 % TRR in leaves. Minor metabolites were also detected at levels below 3 % TRR in roots and below 5 % TRR in leaves. The fate of the triazole moiety was not investigated.

In celery at harvest, total radioactive residues accounted for 0.85 and 3.12 mg eq./kg at the low and at the high application rate respectively. Propiconazole was the major identified component of the total residues (88.6 to 94.6 % TRR) with minor metabolites detected at very low levels. The fate of the triazole moiety was not investigated.

A metabolism study on greenhouse-grown tomatoes injected with the metabolite ^{14}C-1,2,4-triazole at 20 - 30 mg/kg was also available. No free triazole was found in any sample and the major identified metabolite was the 1,2,4-triazole alanine conjugate (80 % TRR).

Overall, the metabolism was qualitatively similar in all tested crops and proceeded along three basic pathways:

- hydroxylation of the aliphatic side-chain to the β-hydroxy alcohol CGA 118244 with further glucoside conjugation;
- hydrolysis of the dioxolane ring to form the ketone CGA 91304 followed by reduction to the alkanol derivative CGA 91305 and glucoside conjugation;
- cleavage of the phenyl-triazole linkage to form the free 1,2,4-triazole which is further conjugated with endogenous serine to generate the 1,2,4-triazole alanine which can be converted into 1,2,4-triazole-acetic acid and triazole lactic acid.

At harvest, propiconazole was a significant compound in all edible parts of the tested crops with the exception of winter wheat grain, where it was not detected. In particular, parent compound was the major component of the total radioactive residues in carrots (roots and leaves) and celery. In the other crop parts (except wheat and rice grain) metabolites containing the dichlorophenyl-moiety and convertible to the 2,4-dichlorobenzoic acid (2,4-DCBA)[21] (CGA 91304 (ketone), CGA 91305 (alkanol), CGA 118244 (β- hydroxy alcohol isomers) and CGA-118245 (γ-hydroxy alcohol), free and/or conjugated) contributed altogether to a significant part of the radioactivity. During the peer review these metabolites were considered covered by the toxicological profile of propiconazole. However, since specific data are not available, EFSA is of the opinion that their toxicological properties should be further investigated. Such data have been provided in the supplementary dossier for the renewal of approval of propiconazole (AIR 3) submitted to the RMS in July 2014. This issue will therefore be considered in the framework of the AIR process.

Consequently, for risk assessment, EFSA proposes to tentatively define the residue in all plant commodities after foliar treatment as propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers). The residue for enforcement in all plant commodities after foliar treatment is defined as parent propiconazole only (sum of isomers). Validated analytical methods for enforcement of the proposed residue definition are available, except for tea (see also section 1.1). It is highlighted that propiconazole is also authorised for post-harvest treatments on citrus fruits, for which no representative metabolism study is available. Nevertheless, given the results of the available metabolism studies conducted with short PHI intervals, a more extensive metabolism of propiconazole is unlikely in post-harvest treatment of citrus fruits. Therefore, the residue definitions for enforcement and risk assessment derived for foliar treatment are

[21] 2,4-dichlorobenzoic acid: see Appendix E.

also applicable for post-harvest treatment and an additional metabolism study on citrus fruits following post-harvest treatment is only desirable.

Considering that the available metabolism studies were not sufficient to derive reliable conversion factors from enforcement to risk assessment for all metabolism groups, conservative conversion factors of 3 for plant commodities and of 10 for forage and straw, tentatively derived from the metabolism studies, were applied for risk assessment. For the post-harvest uses on citrus fruit, considering that it is unlikely that propiconazole metabolites are formed between treatment and sampling, a tentative conversion factor of 1 is proposed for risk assessment. The conclusions reached by EFSA reflect the views of the JMPR (FAO, 2007) but it is noted that a different residue definition for risk assessment was derived in the framework of the peer review (Finland, 1998). However, the residue definition previously derived by the RMS, which includes parent compound only, is no longer considered appropriate.

In addition, EFSA notes that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of propiconazole and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

Finally, EFSA emphasises that the above residue definitions do not yet take into consideration triazole derivative metabolites (TDMs) which were identified as the predominant compounds of the total residues in cereal grain and in oilseed kernels. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be 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.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance propiconazole is authorised in northern and southern Europe and in third countries for foliar application and for post-harvest treatment in a large number of crops, both under outdoor and indoor conditions (see Appendix A).

To assess the magnitude of propiconazole residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (Finland, 1998) or in the framework of previous MRL applications (EFSA, 2010, 2011, 2012) and additional data submitted during the consultation of Member States (Finland, 2014; France, 2014; Germany, 2014; Hungary, 2014; Italy, 2014; Netherlands, 2014; United Kingdom, 2014). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarized in Table 3-2.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). In all available residue trials (except for trials supporting the import tolerance GAP on rape seed), samples were analysed for parent propiconazole only. Consequently residue trials analysing the sum of parent and all the metabolites convertible to the 2,4-dichlorobenzoic acid in accordance with the proposed residue definition for risk assessment are still required for all the GAPs under assessment, except for the import tolerance on rapeseed. Meanwhile only tentative MRLs and risk assessment values could be derived. According to the RMS, new residue trials on banana, barley (NEU, SEU), maize (NEU, SEU), rice (SEU), wheat (NEU, SEU) and sugar beet (NEU, SEU),

performed according to the proposed residue definitions, will be provided in the framework of the AIR3 and post-AIR 3 of propiconazole.

The following considerations were also made by EFSA:

- Almonds: the number of applications was not reported in the southern outdoor GAP and no residue trials were available. A clarification on the GAP authorised in southern Europe, together with 4 supporting residue trials, are still required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Apricots, peaches: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for these crops (at least 4 trials should be performed on apricots). Indeed, 8 trials are available, comprising 4 trials on peaches, 2 trials on nectarines and 2 trials on apricots. EFSA considers that the available data package is only sufficient to derive tentative MRL and risk assessment values for both crops and 2 additional trials on apricots compliant with the southern GAP are still required.

- Strawberries, currants and gooseberries: the application method was not reported in the northern outdoor GAPs for these crops and no residue trials were available. A clarification on the GAPs authorised in northern Europe together with the supporting complete datasets are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Cherries, cucumbers, globe artichoke: no residue trials are available to support the southern uses. Considering that they are minor crops in southern Europe, 4 residue trials compliant with the southern outdoor GAP are required for each crop. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Bananas: the available residue trials are not compliant with the import tolerance GAP on bananas (aerial treatments by plane at 10 × 100 g ai/ha). Indeed, 7 trials were performed with a direct foliar application at application rates of 13 × 100 g ai/ha or 7 × 200 g ai/ha and only 1 trial performed by aerial treatment is available. Consequently, EFSA considers that the available data package is only sufficient to derive tentative MRL and risk assessment values and 7 additional trials representative of the aerial treatment of bananas are still required.

- Sweet corn: the available residue trials on immature maize supporting the northern and the southern outdoor GAPs on sweet corn were performed with 2 applications instead of 1. Nevertheless, as all results were below the LOQ, the available data package is considered acceptable and further residue trials are not required.

- Plums: no residue trials are available to support the southern use. Considering that it is a major crop in southern Europe, 8 residue trials compliant with the southern outdoor GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Peppers: number of applications, growth stage at last treatment and PHI were not reported in the northern outdoor GAP. A clarification on the GAP together with 8 supporting residue trials, are required for this crop. Meanwhile, neither MRL nor risk assessment values can be derived.

- Peanuts: 10 residue trials compliant with the import tolerance GAP on peanuts are available (FAO, 2007). Nevertheless, as residue levels were determined as "total propiconazole" (all compounds convertible to 2,4-DCBA), they cannot be used to derive an MRL. Therefore, 8 residue trials compliant with the import tolerance GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Rape seed: the number of residue trials supporting the import tolerance GAP is not compliant with the data requirements for this crop (5 trials instead of 8) and trials were performed with a higher application rate (250 g ai/ha instead of 125 g ai/ha). However, as all results were below the LOQ, available trials are considered acceptable and further residue trials are not required. In addition, no residue trials compliant with the northern outdoor GAP are available. Although appropriate MRL and risk assessment values can be derived from the import tolerance GAP, 8 trials compliant with the northern GAP are still required.

- Tea: no residue trials are available to support the import tolerance. Considering that it is a minor crop, 4 residue trials compliant with the import tolerance GAP are required. Meanwhile, neither MRL nor risk assessment values can be derived.

- Maize grain: the number of residue trials supporting northern and southern outdoor GAPs is not compliant with the data requirements for this crop (4 trials instead of 8 in each zone) and trials were performed with 2 applications instead of 1. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

- Rice grain: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (6 trials instead of 8). Although tentative MRL and risk assessment values can be derived, 2 additional trials compliant with the southern GAP are still required.

- Sugar beet: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (3 instead of 8 for root and 4 for tops). Moreover, the available trials were performed with 3 applications instead of 2 at an application rate of 75 g ai/ha instead of 99 g ai/ha. Therefore, although MRL and risk assessment values can be derived from the northern data, 8 trials compliant with the southern GAP on sugar beet root and 4 trials compliant with the southern GAP on sugar beet tops are still required.

- Grass: no residue trials are available to support the northern use. Considering that it is a minor crop in northern Europe, 4 residue trials compliant with the northern outdoor GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Maize forage: the available residue trials are not compliant with the northern and southern outdoor GAP on maize forage. Indeed, they were performed with 2 applications instead of 1. Although tentative MRL and risk assessment values can be derived from the northern data, 4 trials in each zone compliant with the northern and the southern GAPs are still required.

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of propiconazole was demonstrated for a period of 6 months at ≤ -18 °C in commodities with high oil content (soya bean) and 12 months at ≤ -18 °C in dry commodities (cereal grain) and straw (Finland, 1998). Storage stability of propiconazole in high water content commodities was also evaluated by the RMS after Annex I inclusion; these studies demonstrated that propiconazole is stable for up to 9 months (sugar beet leaves) at or below - 20 °C (Finland, 2014). Storage stability for "total residues" determined as 2,4-DCBA was demonstrated for 36 months in high oil content matrices (Finland, 2002). Moreover it is noted that storage stability studies on acidic commodities have not been performed. However, considering that citrus samples were stored for only 4 months prior analysis, it is unlikely that significant degradation of propiconazole had occurred and a storage stability study on acidic commodities is only desirable in the framework of this review. Apart from citrus fruits, rapeseed and maize, the storage conditions for the available residues trials were not reported by the RMS. Considering that storage stability of parent

propiconazole in commodities with high oil content was only demonstrated for 6 months, this information would be desirable in order to confirm the validity of the residues trials on high oil content commodities reported. Degradation of residues during storage of the trial samples is not expected in other commodities. It is noted that, in 2 trials on rape seed and in the southern trials on maize, samples were stored longer than the demonstrated storage stability time for parent compound in high oil content and dry matrices (8.5 and 16 months, respectively). Nevertheless, as residue levels of propiconazole were below the LOQ in all rape seed and maize grain (NEU, SEU) samples, degradation of the residue is not expected to have occurred in samples stored longer.

Consequently, for almonds, cherries, plums, strawberries, currants, gooseberries, peppers, cucumbers, globe artichokes, peanuts and tea, the available data were insufficient to derive MRLs and risk assessment values. For all other commodities, considering that in almost all residue trials, samples were not analysed according to the residue definition for risk assessment and the data gap on the toxicological properties of the metabolites convertible to the 2,4-dichlorobenzoic acid, the available residue data are considered sufficient to derive only tentative MRL proposals and risk assessment values (see also Table 3-2). In case where several uses are supported for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. Tentative MRLs were also derived for feed crops (maize forage, cereal straw, sugar beet tops) in view of the future need to set MRLs in feed items.

Table 3-2: 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
			Enforcement	Risk assessment					
Enforcement residue definition: propiconazole **Risk assessment residue definition:** propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)									
Citrus fruits	EU	Indoor	Oranges: 1.46; 1.6; 1.63; 1.74 Mandarins: 1.31; 1.65; 1.73; 2.31	-	1.64	2.31	5 (tentative) [e]	1.0	Combined dataset on oranges and mandarins compliant with GAP for citrus fruits (EFSA, 2012). MRL_{OECD} = 5.04 R_{ber}= 3.47 R_{max}= 2.61
Almonds	SEU	Outdoor	-	-	-	-	-	-	No trials available.
Apples	NEU	Outdoor	2 × 0.03; 0.031; 0.033; 0.04; 0.05; 2 × 0.07	-	0.04	0.07	0.15 (tentative) [e]	3.0	Trials compliant with GAP (EFSA, 2010). MRL_{OECD} = 0.13 R_{ber} = 0.13 R_{max} = 0.10
Apricots Peaches	SEU	Outdoor	Peaches: 2 × 0.02; 0.03; 0.07 Nectarines: 2 × 0.02 Apricots: 0.02; 0.06	-	0.02	0.07	0.15 (tentative) [e]	3.0	Combined dataset on peaches, nectarines and apricots compliant with GAP (EFSA, 2010). MRL_{OECD} = 0.11 R_{ber} = 0.11 R_{max} = 0.10
Cherries	SEU	Outdoor	-	-	-	-	-	-	No residue trials available.
Plums	SEU	Outdoor	-	-	-	-	-	-	No residue trials available.

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
			Enforcement	Risk assessment					
Table and wine grapes	SEU	Outdoor	3 × 0.02; 0.03; 0.05; 0.07; 0.15; 0.16	-	0.04	0.16	0.3 (tentative) [e]	3.0	Trials compliant with GAP. MRL_{OECD} = 0.3 R_{ber} = 0.26 R_{max} = 0.25
Strawberries Currants (red, black and white) Gooseberries	NEU	Outdoor	-	-	-	-	-	-	Method of application, growth stage at last treatment and PHI not reported in the GAPs.
Bananas	Import (CR)	Outdoor	<0.02; 0.02; 3 × 0.03; 0.03 [f]; 0.04; 0.05; 0.08	-	0.03	0.08	0.15 (tentative) [e]	3.0	Trials performed on bagged and unbagged bananas. Results in whole fruit. MRL_{OECD} = 0.11 R_{ber} = 0.09 R_{max} = 0.09
Peppers	NEU	Outdoor	-	-	-	-	-	-	No residue trials available. Number of applications, growth stage at last treatment and PHI not reported in the GAP.
Cucumbers	SEU	Outdoor	-	-	-	-	-	-	No residue trials available.
Sweet corn	NEU	Outdoor	4 × <0.01	-	0.01	0.01	0.01* (tentative) [e]	3.0	Overdosed trials on immature maize acceptable (Hungary, Netherlands, 2014).
	SEU	Outdoor	4 × <0.01	-	0.01	0.01	0.01* (tentative) [e]	3.0	Overdosed trials on immature maize acceptable (Italy, 2014).
Globe artichokes	SEU	Outdoor	-	-	-	-	-	-	No residue trials available.

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
			Enforcement	Risk assessment					
Peanuts	Import (US)	Outdoor	-	-	-	-	-	-	No residue trials available.
Rape seed	NEU	Outdoor	-	-	-	-	-	-	No residue trials available.
	Import (CA)	Outdoor	5 × <0.05	5 × <0.05	0.05	0.05	0.05 (tentative) [g]	1.0	Trials on canola performed with a higher application rate than the authorised one (250 g ai/ha instead of 125 g ai/ha) (Finland, 2014).
Maize grain	NEU	Outdoor	4 × <0.01	-	0.01	0.01	0.01* (tentative) [e]	3.0	Trials on maize performed with 2 applications instead of 1 (Hungary, Netherlands, United Kingdom, 2014).
	SEU	Outdoor	4 × <0.01	-	0.01	0.01	0.01* (tentative) [e]	3.0	Trials on maize performed with 2 applications instead of 1 (Italy, 2014).
Barley grain Oats grain	NEU	Outdoor	9 × <0.02; 2 × 0.02; 4 × 0.03; 2 × 0.04; 2 × 0.05; 2 × 0.06; 0.10; 0.11; 0.15	-	0.03	0.15	0.2 (tentative) [e]	3.0	Trials on barley compliant with GAP for barley and oat (France, 2014). MRL_{OECD} = 0.18 R_{ber} = 0.10 R_{max} = 0.12
	SEU	Outdoor	3 × <0.02; 2 × 0.02; 2 × 0.04; 2 × 0.05; 2 × 0.07; 0.13; 0.15	-	**0.04**	**0.15**	**0.3 (tentative)** [e]	**3.0**	Trials on barley compliant with GAP for barley and oat. MRL_{OECD} = 0.22 R_{ber} = 0.14 R_{max} = 0.17

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
			Enforcement	Risk assessment					
Barley straw Oats straw	NEU	Outdoor	0.02; 0.05; 0.07; 0.08; 0.11; 0.12; 0.13; 2 × 0.15; 0.23; 0.29; 2 × 0.34; 0.36; 0.42; 0.44; 0.50; 0.83	-	0.19	0.83	1.5 (tentative) [e]	10	Trials on barley compliant with GAP for barley and oat (France, 2014). MRL_{OECD} = 1.08 R_{ber} = 0.75 R_{max} = 0.76
	SEU	Outdoor	0.05; 0.14; 0.16; 0.17; 0.27; 0.28; 0.34; 0.64; 1.02; 1.03; 1.46; 1.74; 1.82	-	**0.34**	**1.82**	**4 (tentative) [e]**	**10**	Trials on barley compliant with GAP for barley and oat. MRL_{OECD} = 3.26 R_{ber} = 2.49 R_{max} = 2.41
Wheat grain Rye grain	NEU	Outdoor	16 × <0.02; 2 × 0.02; 0.023	-	**0.02**	**0.02**	**0.04 (tentative) [e]**	**3.0**	Trials on wheat compliant with GAP for wheat and rye. MRL_{OECD} = 0.03 R_{ber} = 0.04 R_{max} = 0.02
	SEU	Outdoor	11 × <0.02	-	0.01	0.01	0.01* (tentative) [e]	3.0	Trials on wheat compliant with GAP for wheat and rye (France, 2014).
Wheat straw Rye straw	NEU	Outdoor	0.07; 0.11; 0.13; 0.15; 0.29; 0.30; 0.40; 0.43; 0.54; 0.54; 0.65; 0.78; 0.80; 0.81; 0.89	-	**0.43**	0.89	**2 (tentative) [e]**	**10**	Trials on wheat compliant with GAP for wheat and rye. MRL_{OECD} = 1.59 R_{ber} = 1.56 R_{max} = 1.18
	SEU	Outdoor	<0.05; 2 × 0.05; 0.10; 0.19; 0.30; 0.38; 0.58; 0.96	-	0.19	**0.96**	1.5 (tentative) [e]	10	Trials on wheat compliant with GAP for wheat and rye (France, 2014). MRL_{OECD} = 1.53 R_{ber} = 0.96 R_{max} = 1.23

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
			Enforcement	Risk assessment					
Rice grain	SEU	Outdoor	2 × <0.02; 0.19; 0.25; 0.49; 0.71	-	0.22	0.71	1.5 (tentative) [e]	3.0	Trials compliant with GAP. MRL_{OECD} = 1.37 R_{ber} = 1.09 R_{max} = 1.29
Tea	Import (ID)	Outdoor	-	-	-	-	-	-	No residue trials available.
Sugar beet (root)	NEU	Outdoor	3 × <0.01; 3 × <0.02; 4 × <0.05; 2 × 0.07	-	**0.04**	**0.07**	**0.15 (tentative)** [e]	**3.0**	Trials compliant with GAP. MRL_{OECD} = 0.13 R_{ber} = 0.10 R_{max} = 0.10
	SEU	Outdoor	3 × <0.01	-	0.01	0.01	0.01* (tentative) [e]	3.0	Trials performed at 3 × 75 g ai/ha, PHI 21d (Finland, 2014).
Sugar beet (tops)	NEU	Outdoor	3 × 0.01; <0.04; 0.06; 0.07; <0.1; 0.1; 0.2; 3 × 0.3	-	**0.09**	**0.30**	**0.7 (tentative)** [e]	**3.0**	Trials compliant with GAP. MRL_{OECD} = 0.6 R_{ber} = 0.55 R_{max} = 0.45
	SEU	Outdoor	0.05; 0.06; 0.07	-	0.06	0.07	0.2 (tentative) [e]	3.0	Trials performed at 3 × 75 g ai/ha, PHI 21d. MRL_{OECD} = 0.18 R_{ber} = - R_{max} = 0.14
Grass	NEU	Outdoor	-	-	-	-	-	-	No residue trials available.

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
			Enforcement	Risk assessment					
Maize forage	NEU	Outdoor	0.31; 1.1; 1.8; 1.9	-	**1.45**	**1.90**	**5** (tentative) [e]	**10**	Trials on maize performed with 2 applications instead of 1 (Germany, Hungary, Netherlands, United Kingdom, 2014). MRL_{OECD} = 4.22 R_{ber} = 3.75 R_{max} = 5.07
	SEU	Outdoor	0.39; 1.1; 1.5; 1.6	-	1.30	1.60	4 (tentative) [e]	10	Trials on maize performed with 2 applications instead of 1 (Italy, 2014). MRL_{OECD} = 3.44 R_{ber} = 3.15 R_{max} = 3.97

(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): Residue data were sufficient to derive a reliable CF for rape seed only. Tentative conversion factors for enforcement to risk assessment of 3 for all other plant commodities and of 10 for forage and straw were derived from the plant metabolism studies. For post-harvest uses on citrus fruit, a tentative CF of 1 is used (see also section 3.1.1.1).
(e): The MRL proposal can only be tentatively derived considering the absence of residue data on metabolites convertible to the 2,4-dichlorobenzoic acid and the tentative residue definition for risk assessment.
(f): Result from a trial performed by aerial applications (by plane).
(g): The MRL proposal can only be tentatively derived considering the tentative residue definition for risk assessment.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of propiconazole was not investigated in the framework of the peer review. Nevertheless, after the Annex I inclusion, the RMS assessed a study investigating the effect of processing on the nature of propiconazole simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90 °C, pH 4), boiling/brewing/baking (60 minutes at 100 °C, pH 5) and sterilisation (20 minutes at 120 °C, pH 6). From this study, it was concluded that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues in matrices of plant origin (Finland, 2014). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops. As for the RAC, tentative conversion factors of 3 and 1 are proposed in order to express the residue levels in processed commodities according to the residue definition for risk assessment (see also section 3.1.1.1).

Specific studies investigating the magnitude of propiconazole residues in processed commodities of oranges, apples, peaches, plums, table and wine grapes, peanuts, barley grain, rice grain and wheat grain were reported in different sources. An overview of all available processing studies is available in Table 3-3. For some commodities, considering the limited number of processing studies (a minimum of 3 processing studies is normally required), no robust processing factors for enforcement and risk assessment could be derived and consequently the corresponding processing factors reported in Table 3-3 should therefore be considered as indicative only.

Nevertheless, further processing studies on the magnitude of residues are not required in this case as they are not expected to affect the outcome of the risk assessment. If more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: propiconazole				
Processing factors recommended (sufficiently supported by data)				
Oranges, pasteurized juice	4	0.013	1.0	PF derived on oranges extrapolated to citrus fruits (EFSA, 2012).
Oranges, marmalade	4	0.48	1.0	EFSA, 2012
Oranges, peeled	4	0.01	1.0	PF derived on oranges extrapolated to citrus fruits (EFSA, 2012).
Apples, juice	3	0.11	3.0	EFSA, 2010
Apples, sauce	3	0.44	3.0	
Peaches, canned	3	0.05	3.0	
Barley, brewing malt	4	1.00	3.0	Finland, 2002
Barley, beer	4	0.50	3.0	
Rice, unpolished and cooked	4	1.10	3.0	EFSA, 2011
Rice, polished	4	0.80	3.0	
Rice, polished and cooked	4	0.43	3.0	

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Wine grapes, must	3	0.13	3.0	Based on the TRR at harvest (metabolism study with ^{14}C propiconazole) (Finland, 1998).
Wine grapes, white wine	3	0.22	3.0	
Plums, dried (prunes)	3	-	3.0	In two trials, residue levels in dried plums were same than in fresh fruits (<0.05). In one trial, the residue level in dried plums was 0.07 mg/kg. It is not clear whether residues were determined as total residues (2,4-DCBA) or as parent propiconazole (Finland, 1998).
Indicative processing factors (limited dataset)				
Table grapes, dried (raisins)	2	1.89	3.0	-
Wine grapes, juice	1	0.05	3.0	Based on the TRR at harvest (metabolism study with ^{14}C propiconazole) (Finland, 1998).
Wine grapes, press cake	1	0.95	3.0	
Apples, dry pomace	1	8.67	3.0	EFSA, 2010
Apples, wet pomace	1	3.07	3.0	
Wheat, white flour	1	-	3.0	No residues above the LOQ (0.01 mg/kg) were found in samples of grain, flour and bran.
Wheat, bran	1	-	3.0	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The tentative conversion factor for enforcement to risk assessment was derived from the results of the plant metabolism studies (except for the post-harvest uses on citrus fruit, see also section 3.1.1.1).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration, except permanent crops (almonds, citrus fruits, orchards and vineyards), may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of propiconazole are expected to range between 192 - 2099 days which is higher than the trigger value of 100 days (EC, 2003). According to the European guidelines on rotational crops (EC, 1997c), further investigation of residues in rotational crops is therefore required.

3.1.2.2. Nature of residues

The metabolism of propiconazole in rotational crops – lettuce, carrot, peanut, maize, wheat – has been evaluated during the peer review (Finland, 1998). Three confined and one field rotational crop studies investigating the nature of residues following different plant-back intervals are available. The characteristics of these studies are summarised in Table 3-4.

Table 3-4: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals	Harvest Intervals	Remarks
Leafy vegetables	Lettuce	^{14}C-triazole	Foliar + soil, F	8 × 0.17 + 2 × 0.42	42 weeks	50, 55 weeks	Peanut treated as primary crop
Root and tuber vegetables	Carrot	^{14}C-triazole	Foliar + soil, F	8 × 0.17 + 2 × 0.42	42 weeks	55, 62 weeks	Peanut treated as primary crop
Pulses and oilseeds	Peanut	^{14}C-phenyl, ^{14}C-triazole	Soil, G	1.681	14 DAT	151 DAT	-
Cereals	Maize	^{14}C-triazole	Foliar + soil, F	8 × 0.17 + 2 × 0.42	42 weeks	55, 62 weeks	Peanut treated as primary crop
		^{14}C-phenyl, ^{14}C-triazole	Soil, G	1.681	151 DAT	252 DAT	-
	Winter wheat	^{14}C-triazole	Foliar + soil, F	8 × 0.17 + 2 × 0.42	17 weeks	25, 42, 47 weeks	Peanut treated as primary crop
		^{14}C-phenyl, ^{14}C-triazole	Soil, G	1.681	151 DAT	290 DAT	-
	Spring wheat	^{14}C-triazole	Soil, G	3.7 mg a.s./kg soil	0 DAT	3, 4, 7, 13, 25 DAT	-
		^{14}C-triazole	Soil, G	2 × 0.625	0 DAT	31, 59, 94 DAT	-
		1H-[3,5-^{14}C]-1,2,4-triazole	Soil, G	0.75 mg a.s./kg soil	0 DAT	3, 4, 7, 13, 25 DAT	-

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

Metabolism was more extensive in rotational crops than in primary crops. The major non-polar metabolites (β-hydroxy alcohol CGA 118244, γ-hydroxy alcohol CGA 118245, alkanol CGA 91305) and their conjugates found in the primary crops were present only at very low levels in the rotational crops. The major metabolites in rotational crops were polar and identified as conjugates of 1,2,4-triazole, i.e. triazolyl alanine and triazolyl acetic acid. As an example, in spring wheat grain, 42 % TRR was identified as triazolyl alanine and 32 % as triazolyl acetic acid; in addition, in spring wheat straw, 40 % TRR was identified as triazolyl lactic acid and 22 % as triazolyl acetic acid. It is concluded that a more extensive cleavage of the triazole-phenyl bridge occurred in rotational crops than in primary crops (parent was not detected in rotational crops) and that uptake of polar soil degradation products occurred in rotational crops.

Consequently, it can be concluded that metabolism in primary and rotational crops is similar and that a specific residue definition for rotational crops is not deemed necessary.

3.1.2.3. Magnitude of residues

In addition to the confined rotational crop study, several rotational crop field trials were evaluated by JMPR (FAO, 2007). Propiconazole was applied on soya bean or rice at 0.25, 0.49, 0.31 or 0.63 kg a.s./ha and the magnitude of residues was investigated on several succeeding crops (winter wheat, maize, sorghum, sweet potatoes, sugar beets, lettuce, cabbage) sown at different plant-back intervals (0.25, 1, 2, 5, 6, 8, 8.5 and 9 months). Propiconazole was also applied on bare soil at a rate of 0.25 kg a.s./ha and the magnitude of residues was investigated on rape seed and sugar beet sown 30 DAT. At harvest, propiconazole residues were below the LOQ (0.05 mg/kg) in all mature plant parts. No information was provided on TDMs residues.

Considering the application rates proposed in the framework of this MRL review and taking into account that a part of the applied substance is intercepted by the treated crops, it is concluded that significant levels of propiconazole are not expected in rotational crops provided that propiconazole is applied according to GAP reported in Appendix A. Nevertheless, the studies on the nature and magnitude of propiconazole residues in rotational crops indicate that TDMs might be of concern in rotational crops. Therefore, further investigation on TDMs in rotational crops is in principle still required.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Propiconazole is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 3-5. For cereal bran, citrus pomace, rape seed meal and maize silage, default processing factors of 8, 2.5, 2 and 1, respectively have been included in the calculation in order to consider potential concentration of residues in these commodities. For apples pomace, the indicative processing factor derived in section 3.1.1.3 has been used. The (tentative) conversion factors from enforcement to risk assessment were also considered. It is noted that for peanuts and grass, no residue data were available: the animal intake of propiconazole residues via these commodities has therefore not been assessed and may have been underestimated. However, this is not expected to have a major impact on the outcome of the dietary burden considering the high contribution of maize silage.

Table 3-5: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)				
Sugar beet leaves	0.26	Median residue × CF	0.90	Highest residue × CF
Maize silage	14.5	Median residue × CF × 1	19	Highest residue × CF × 1
Citrus fruit pomace	4.1	Median residue × CF × 2.5	4.1	Median residue × CF × 2.5
Apple pomace	0.34	Median residue × CF × PF	0.34	Median residue × CF × PF

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat & rye grain	0.06	Median residue × CF	0.06	Median residue × CF
Barley & oats grain	0.12	Median residue × CF	0.12	Median residue × CF
Maize grain	0.03	Median residue × CF	0.03	Median residue × CF
Wheat & rye bran	0.48	Median residue × CF × 8	0.48	Median residue × CF × 8
Wheat & rye straw	4.30	Median residue × CF	9.6	Highest residue × CF
Barley & oats straw	3.40	Median residue × CF	18.2	Highest residue × CF
Sugar beets	0.11	Median residue × CF	0.21	Highest residue × CF
Rape seed meal	0.1	Median residue × CF × 2	0.1	Median residue × CF × 2

The results of the calculations are reported in Table 3-6. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-6: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)					
Dairy ruminants	2.64	3.45	Maize silage	96.0	Y
Meat ruminants	3.11	4.07	Maize silage	94.7	Y
Poultry	0.014	0.020	Sugar beets	0.32	Y
Pigs	0.45	0.60	Maize silage	15.0	Y

3.2.2. Nature of residues

The nature of propiconazole residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Finland, 1998) and by JMPR (FAO, 2007). Reported metabolism studies include three studies in lactating goats and two studies in laying hens using ^{14}C-triazole and ^{14}C-phenyl-labelled propiconazole. The characteristics of these studies are summarized in Table 3-7.

Lactating goats were dosed with 0.13 and 1.15 mg/kg bw per d of ^{14}C-triazole labelled propiconazole and 3.1 mg/kg bw per d of ^{14}C-phenyl labelled propiconazole, corresponding to approximately 0.03, 0.3 and - 0.8 times the exposure of meat ruminant. Laying hens were dosed with 3.16 mg/kg bw per d of ^{14}C-triazole labelled propiconazole and 2.98−6.58 mg/kg bw per d of ^{14}C-phenyl labelled propiconazole, corresponding to approximately 149−329 times the exposure of poultry.

The ruminant and poultry studies demonstrate that most of the administered radioactivity (73 to 96 %) was eliminated in urine and faeces or excreta. Tissues, eggs and milk exhibited low levels of

^{14}C-residues. In goats, highest levels were found in liver and kidney from the high dose group (3.8 and 2.5 mg eq./kg, respectively). In milk, a plateau was reached on day 4 (0.015 and 0.22 mg eq./kg for low and high doses, respectively). In hens, highest levels were also found in liver and kidney from the high dose group (4.2 and 3.9 mg eq./kg, respectively). In eggs, no plateau was reached (1.2 and 1.7 mg eq./kg for low and high doses, respectively).

Table 3-7: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	^{14}C-triazole	1	0.13	10	Milk	Twice daily
						Urine and faeces	Daily
						Tissues	At sacrifice
		^{14}C-phenyl	2	3.08 – 3.11	4	Milk	Daily
						Urine and faeces	Daily
						Tissues	At sacrifice
		^{14}C-triazole	2	1.12 – 1.15	7	Milk	Twice daily
						Urine and faeces	Daily
						Tissues	At sacrifice
Laying poultry	Hens	^{14}C-phenyl ^{14}C-triazole	2[(a)]	2.98 – 3.16	16	Eggs	Daily
						Excreta	Daily
						Tissues	At sacrifice
		^{14}C-phenyl	4	5.35 – 6.58	8	Eggs	Daily
						Excreta	Daily
						Tissues	At sacrifice

(a): One animal per label.

Propiconazole is efficiently degraded in farm animals and is only found at significant levels in goat liver (12 % TRR, ^{14}C-phenyl study) and fat (20 % TRR, ^{14}C-phenyl study), in hen skin/fat (40 % TRR,^{14}C-phenyl 8 days-long study) and in eggs (12 % TRR in yolk, 28 % TRR in white,^{14}C-phenyl 8 days-long study). Lower amounts are also present in other edible tissues and milk (< 7 % TRR). In goat tissues, the major metabolites are β-hydroxy alcohol CGA 118244 and alkanol CGA 91305 (19/14 % TRR in liver, 9/17 % TRR in kidney, 16/36 % TRR in muscle, 33/31 % TRR in fat, 24 % TRR in milk, respectively, ^{14}C-phenyl study) and the free 1,2,4-triazole CGA 71019 (23 % TRR in kidney, 59 % TRR in muscle, 17 % TRR in fat, 66 % TRR in milk, ^{14}C-triazole 7 days-long study). In hen edible tissues and eggs, the major metabolites were alkanol CGA 91305 (59 % TRR in liver, 44 % TRR in kidney, 85 % TRR in muscle, 43 % TRR in fat, 51 % TRR in egg yolk, 18 % TRR in egg white, ^{14}C-phenyl 8 days-long study) and β-hydroxy alcohol CGA 118244 (52 % TRR in egg white, ^{14}C-phenyl 8 days-long study).

The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. 1,2,4-triazole, the major residue in milk, is not specific for propiconazole since it can be derived from other triazole pesticides and it is therefore not a good indicator for propiconazole use.

Consequently, EFSA proposes to change the current residue definition for risk assessment in all products of animal origin, including parent propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers). For enforcement, the residue is defined as parent propiconazole only (sum of isomers). Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.2). EFSA notes that no livestock metabolism study is available with administration of the metabolites included in the plant residue definition for risk assessment. Nevertheless, such studies are not required, as the risk assessment residue definition in livestock commodities already takes into account all the metabolites which could be expected in animal commodities (except the TDMs).

The conclusions reached by EFSA are also in line with those of the JMPR (FAO, 2007) but it is noted that a different residue definition for risk assessment was derived in the framework of the peer review (Finland, 1998). However, the residue definition previously derived by the RMS, which includes parent compound only, is no longer considered appropriate.

Since log $P_{o/w}$ of propiconazole is higher than 3 (EC, 2003), EFSA concludes that the residue in commodities of animal origin is fat soluble.

EFSA also notes that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of propiconazole and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

Finally, EFSA emphasises that the above residue definitions do not yet 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 should be 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.

3.2.3. Magnitude of residues

During the peer review under Directive 91/414/EEC, the magnitude of propiconazole residues in ruminants and poultry was investigated in two feeding studies with lactating cows and laying hens (Finland, 1998). Three groups of lactating cows, each consisting of three animals were dosed for 28 consecutive days with propiconazole at levels of 15, 75 and 150 mg/kg in the diet (equivalent to 0.59, 2.95 and 6.10 mg/kg bw). Three groups of laying hens, each consisting of 15 animals, were dosed for 28 consecutive days with propiconazole at levels 7.5, 37.5 and 75 mg/kg in the diet (equivalent to 3.9, 19.7 and 39.4 mg/kg bw). The samples were analysed for parent propiconazole and for total residues containing the 2,4-DCBA moiety. Results of both livestock feeding studies are summarised in Table 3-8. In milk and eggs, a plateau level was reached after 14 and 7 days of exposure, respectively.

The storage stability of propiconazole and all metabolites containing the 2,4-DCBA moiety residues in animal products was evaluated by JMPR (FAO, 2007). Studies demonstrated storage stability of propiconazole and all metabolites containing the 2,4-DCBA moiety for up to 5 months in eggs, 7 months in fat, 9.5 months in muscle and 16−17 months in liver, kidney and milk when stored deep frozen. In the cow and hen feeding studies, samples were stored respectively for a maximum 3 months

and 5 months until analysis. Degradation of residues during storage of samples is therefore not expected.

Consequently, the available data are considered sufficient for deriving MRLs in ruminants, pigs and hens. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarized in Table 3-8. Significant residues in ruminant and pig tissues are expected and MRLs for these commodities can be proposed. In poultry tissues, in eggs and in milk, significant residues are not expected and MRLs for these commodities can be established at the LOQ. All these MRLs can only tentatively be derived, due to the data gaps identified in section 3.1.1, resulting in a tentative dietary burden calculation (see also section 3.2.1).

Finally, based on the available livestock feeding studies, EFSA also derived conversion factors of 2.3, 4.5, 12.5 and 96 in pig and ruminant meat, fat, liver and kidney, respectively and a conversion factor of 4 for milk.

Table 3-8: Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	MRL proposal (mg/kg)[c]	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: propiconazole (sum of isomers) **Risk assessment residue definition:** sum of propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)												
Pig muscle	0.45	0.60	0.59	3	<0.05	<0.05	<0.05	<0.05	0.04	0.05	0.05 (tentative)	2.3
			2.95	3	<0.05	<0.05	0.08	0.11				
			6.10	3	<0.05	<0.05	0.14	0.18				
Pig fat			0.59	3	<0.05	<0.05	<0.05	<0.05	0.04	0.05	0.05 (tentative)	4.5
			2.95	3	<0.05	<0.05	0.15	0.23				
			6.10	3	0.06	0.08	0.21	0.26				
Pig liver			0.59	3	0.08	0.14	0.63	0.81	0.11	0.14	0.15 (tentative)	12.5
			2.95	3	0.22	0.34	3.70	4.30				
			6.10	3	0.42	0.66	5.20	5.60				
Pig kidney			0.59	3	<0.05	<0.05	0.60	0.63	0.04	0.05	0.05 (tentative)	96
			2.95	3	<0.05	<0.05	3.80	4.70				
			6.10	3	<0.05	<0.05	5.70	6.50				
Ruminant muscle	3.11	4.07	0.59	3	<0.05	<0.05	<0.05	<0.05	0.05	0.05	0.05 (tentative)	2.3
			2.95	3	<0.05	<0.05	0.08	0.11				
			6.10	3	<0.05	<0.05	0.14	0.18				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	MRL proposal (mg/kg)[c]	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Ruminant fat	3.11	4.07	0.59	3	<0.05	<0.05	<0.05	<0.05	0.05	0.06	0.07 (tentative)	4.5
			2.95	3	<0.05	<0.05	0.15	0.23				
			6.10	3	0.06	0.08	0.21	0.26				
Ruminant liver			0.59	3	0.08	0.14	0.63	0.81	0.36	0.45	0.5 (tentative)	12.5
			2.95	3	0.22	0.34	3.70	4.30				
			6.10	3	0.42	0.66	5.20	5.60				
Ruminant kidney			0.59	3	<0.05	<0.05	0.60	0.63	0.05	0.05	0.05 (tentative)	96
			2.95	3	<0.05	<0.05	3.80	4.70				
			6.10	3	<0.05	<0.05	5.70	6.50				
Poultry muscle	0.014	0.020	3.90	15	<0.05	n.r.	<0.05	n.r.	<0.01	<0.01	0.01* (tentative)	1.0
			19.70	15	<0.05	n.r.	<0.05	n.r.				
			39.40	15	<0.05	n.r.	0.07	n.r.				
Poultry fat			3.90	15	0.05	n.r.	<0.05	n.r.	<0.01	<0.01	0.01* (tentative)	1.0
			19.70	15	0.05	n.r.	<0.05	n.r.				
			39.40	15	0.05	n.r.	0.11	n.r.				
Poultry liver			3.90	15	0.05	n.r.	<0.10	n.r.	<0.01	<0.01	0.01* (tentative)	1.0
			19.70	15	0.05	n.r.	0.16	n.r.				
			39.40	15	0.05	n.r.	0.47	n.r.				
Eggs			3.90	93	<0.05[d]	n.a.	<0.05[d]	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			19.70	93	<0.05[d]	n.a.	0.11[d]	n.a.				
			39.40	93	<0.05[d]	n.a.	0.27[d]	n.a.				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	MRL proposal (mg/kg)[c]	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Milk	2.64	3.46	0.59	12	<0.01[e]	n.a.	<0.01[e]	n.a.	<0.01	<0.01	0.01* (tentative)	4.0
			2.95	12	<0.01[e]	n.a.	0.04[e]	n.a.				
			6.10	12	<0.01[e]	n.a.	0.10[e]	n.a.				

n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk and eggs.
n.r.: Not reported.
(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(c): The median conversion factor for enforcement to risk assessment.
(d): Mean residue level from day 1 until day 28 (15 hens 3 sampling days (1, 3, 7); 12 hens, 2 sampling days (10, 14); 9 hens, 2 sampling days (17, 21); 6 hens, 1 sampling day (28)).
(e): Mean residue level from day 1 until day 28 (3 cows, 3 sampling days (1, 7, 14); 2 cows, 1 sampling day (21); 1 cow, 1 sampling day (28)).
(*): Indicates that the MRL is set at the limit of analytical quantification.

4. Consumer risk assessment

In the framework of this review, only the uses of propiconazole reported by the RMS in Appendix A were considered, however the use of propiconazole was previously also assessed by the JMPR (FAO, 2007). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops supported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarized in Table 4-1. The tentative median and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3. The (tentative) conversion factors derived under sections 3.1.1 and 3.2.3 were included in the calculation, as well as the peeling factor for citrus fruits calculated in section 3.1.1.3. For those commodities where data were insufficient to derive an MRL in section 3, EFSA considered the existing EU MRL multiplied for the tentative conversion factors for an indicative calculation. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation.

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)				
Citrus fruits	0.02	Median × PF × CF (tentative) [a]	0.02	Highest × PF × CF (tentative) [a]
Almonds	0.15	EU MRL × CF [b]	0.15	EU MRL × CF [b]
Apples	0.11	Median × CF (tentative) [a]	0.21	Highest × CF (tentative) [a]
Apricots	0.06	Median × CF (tentative) [a]	0.21	Highest × CF (tentative) [a]
Cherries	0.15	EU MRL × CF [b]	0.15	EU MRL × CF [b]
Peaches	0.06	Median × CF (tentative) [a]	0.21	Highest × CF (tentative) [a]
Plums	0.15	EU MRL × CF [b]	0.15	EU MRL × CF [b]
Table & wine grapes	0.12	Median × CF (tentative) [a]	0.48	Highest × CF (tentative) [a]
Strawberries	0.15	EU MRL × CF [b]	0.15	EU MRL × CF [b]
Currants (red, black and white), Gooseberries	0.15	EU MRL × CF [b]	0.15	EU MRL × CF [b]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Gooseberries	0.15	EU MRL × CF [(b)]	0.15	EU MRL × CF [(b)]
Bananas	0.09	Median × CF (tentative) [(a)]	0.24	Highest × CF (tentative) [(a)]
Peppers	0.15	EU MRL × CF [(b)]	0.15	EU MRL × CF [(b)]
Cucumbers	0.15	EU MRL × CF [(b)]	0.15	EU MRL × CF [(b)]
Sweet corn	0.03	Median × CF (tentative) [(a)]	0.03	Highest × CF (tentative) [(a)]
Globe artichokes	0.15	EU MRL × CF [(b)]	0.15	EU MRL × CF [(b)]
Peanuts	0.60	EU MRL × CF [(b)]	0.60	EU MRL × CF [(b)]
Rape seed	0.05	Median residue × CF (tentative) [(a)]	0.05	Highest residue × CF (tentative) [(a)]
Barley and oats grain	0.12	Median × CF (tentative) [(a)]	0.45	Highest × CF (tentative) [(a)]
Maize grain	0.03	Median × CF (tentative) [(a)]	0.03	Highest × CF (tentative) [(a)]
Rice grain	0.66	Median × CF (tentative) [(a)]	2.13	Highest × CF (tentative) [(a)]
Rye grain	0.06	Median × CF (tentative) [(a)]	0.07	Highest × CF (tentative) [(a)]
Wheat grain	0.06	Median × CF (tentative) [(a)]	0.07	Highest × CF (tentative) [(a)]
Tea	0.30	EU MRL × CF [(b)]	0.30	EU MRL × CF [(b)]
Sugar beet (root)	0.11	Median × CF (tentative) [(a)]	0.21	Highest × CF (tentative) [(a)]
Swine meat	0.11	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) [(d)]	0.14	0.8 × Highest muscle + 0.2 × Highest fat × CF (tentative) [(c)]
Swine fat	0.17	Median × CF (tentative) [(c)]	0.23	Highest × CF (tentative) [(c)]
Swine liver	1.34	Median × CF (tentative) [(c)]	1.76	Highest × CF (tentative) [(c)]
Swine kidney	3.7	Median × CF (tentative) [(c)]	4.8	Highest × CF (tentative) [(c)]
Ruminant meat	0.14	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) [(c)]	0.15	0.8 × Highest muscle + 0.2 × Highest fat × CF (tentative) [(c)]
Ruminant fat	0.23	Median × CF (tentative) [(c)]	0.27	Highest × CF (tentative) [(c)]
Ruminant liver	4.5	Median × CF (tentative) [(c)]	5.7	Highest × CF (tentative) [(c)]
Ruminant kidney	4.8	Median × CF (tentative) [(c)]	4.8	Highest × CF (tentative) [(c)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry meat	0.01*	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) (c)	0.01*	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) (c)
Poultry fat	0.01*	Median residue × CF (tentative) (c)	0.01*	Highest residue × CF (tentative) (c)
Poultry liver	0.01*	Median residue × CF (tentative) (c)	0.01*	Highest residue × CF (tentative) (c)
Ruminant milk	0.04	Median residue × CF (tentative) (c)	0.04	Median residue × CF (tentative) (c)
Birds' eggs	0.01*	Median residue × CF (tentative) (c)	0.01*	Median residue × CF (tentative) (c)

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(b): Use reported by the RMS is not supported by data; the existing EU MRL multiplied by a conversion factor for risk assessment is used for indicative exposure calculations.
(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for propiconazole (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1. The highest chronic exposure was calculated for British toddler, representing 11.2 % of the ADI, and the highest acute exposure was calculated for bovine liver, representing 15.3 % of the ARfD.

Based on the above calculations, EFSA concludes that major uncertainties remain due to the data gaps identified in section 3 but considering tentative MRLs and the existing EU MRLs in the exposure calculation did not indicate a risk to consumers.

EFSA notes that the above studies do not investigate the possible impact of plant and livestock metabolism on the isomer ratio of propiconazole and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA emphasises that the above assessment does not yet 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 should be 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.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. These CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarized in Table 4-2. For the

CXLs on oranges, peaches, plums and tomatoes which were derived from a post-harvest use (degradation of the parent not expected to occur) a CF of 1 was tentatively used. For the CXLs on the other plant commodities, the tentative conversion factors proposed in section 3.1.1 were applied. For products of animal origin, it is noted that when including the CXLs in the EU risk assessment, there is no need to consider the CXLs that have been established for horses and other farm animals because there are no agreed extrapolations for commodities of animal origin at EU level (except for pigs). Also the CXLs established for other edible offals should not be considered because this commodity is not appropriately defined at EU level.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)				
Oranges	0.03	Median × PF × CF (CXL) (tentative) [a]	0.05	Highest × PF × CF (CXL) (tentative) [a]
Other citrus fruits	0.02	Median × PF × CF (tentative) [b]	0.02	Highest × PF × CF (tentative) [b]
Almonds	0.15	EU MRL × CF [c]	0.15	EU MRL × CF [c]
Pecans	0.06	Median × CF (CXL) (tentative) [a]	0.06	Highest × CF (CXL) (tentative) [a]
Apples	0.11	Median × CF (tentative) [b]	0.21	Highest × CF (tentative) [b]
Apricots	0.06	Median × CF (tentative) [b]	0.21	Highest × CF (tentative) [b]
Cherries	0.15	EU MRL × CF [c]	0.15	EU MRL × CF [c]
Peaches	1.55	Median × CF (CXL) (tentative) [a]	2.20	Highest × CF (CXL) (tentative) [a]
Plums	0.19	Median × CF (CXL) (tentative) [a]	0.22	Highest × CF (CXL) (tentative) [a]
Table & wine grapes	0.12	Median × CF (tentative) [b]	0.48	Highest × CF (tentative) [b]
Strawberries	0.15	EU MRL × CF [c]	0.15	EU MRL × CF [c]
Cranberries	0.17	Median × CF (CXL) (tentative) [a]	0.39	Highest × CF (CXL) (tentative) [a]
Currants (red, black and white), Gooseberries	0.15	EU MRL × CF [c]	0.15	EU MRL × CF [c]
Gooseberries	0.15	EU MRL × CF [c]	0.15	EU MRL × CF [c]
Bananas	0.09	Median × CF (tentative) [b]	0.24	Highest × CF (tentative) [b]
Pineapples	0.06	Median × CF (CXL) (tentative) [a]	0.06	Highest × CF (CXL) (tentative) [a]
Tomatoes	0.72	Median × CF (CXL) (tentative) [a]	1.76	Highest × CF (CXL) (tentative) [a]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peppers	0.15	EU MRL × CF [(c)]	0.15	EU MRL × CF [(c)]
Cucumbers	0.15	EU MRL × CF [(c)]	0.15	EU MRL × CF [(c)]
Sweet corn	0.15	Median × CF (CXL) (tentative) [(a)]	0.15	Highest × CF (CXL) (tentative) [(a)]
Globe artichokes	0.15	EU MRL × CF [(c)]	0.15	EU MRL × CF [(c)]
Peanuts	0.60	EU MRL × CF [(c)]	0.60	EU MRL × CF [(c)]
Rape seed	0.05	Median residue × CF (tentative) [(b)]	0.05	Highest residue × CF (tentative) [(b)]
Soya bean	0.03	Median × CF (CXL) (tentative) [(a)]	0.15	Highest × CF (CXL) (tentative) [(a)]
Barley grain	0.12	Median × CF (tentative) [(b)]	0.45	Highest × CF (tentative) [(b)]
Maize grain	0.15	Median × CF (CXL) (tentative) [(a)]	0.15	Highest × CF (CXL) (tentative) [(a)]
Oats grain	0.12	Median × CF (tentative) [(b)]	0.45	Highest × CF (tentative) [(b)]
Rice grain	0.66	Median × CF (tentative) [(b)]	2.13	Highest × CF (tentative) [(b)]
Rye grain	0.06	Median × CF (tentative) [(b)]	0.07	Highest × CF (tentative) [(b)]
Wheat grain	0.06	Median × CF (tentative) [(b)]	0.07	Highest × CF (tentative) [(b)]
Tea	0.30	EU MRL × CF [(c)]	0.30	EU MRL × CF [(c)]
Coffee beans	0.06	Median × CF (CXL) (tentative) [(a)]	0.06	Highest × CF (CXL) (tentative) [(a)]
Sugar beet (root)	0.11	Median × CF (tentative) [(b)]	0.21	Highest × CF (tentative) [(b)]
Sugar cane	0.03	Median × CF (CXL) (tentative) [(a)]	0.03	Highest × CF (CXL) (tentative) [(a)]
Swine meat	0.11	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) [(d)]	0.14	0.8 × Highest muscle + 0.2 × Highest fat × CF (tentative) [(d)]
Swine fat	0.17	Median × CF (tentative) [(d)]	0.22	Highest × CF (tentative) [(d)]
Swine liver	1.34	Median × CF (tentative) [(d)]	1.76	Highest × CF (tentative) [(d)]
Swine kidney	3.7	Median × CF (tentative) [(d)]	4.8	Highest × CF (tentative) [(d)]
Ruminant meat	0.14	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) [(d)]	0.15	0.8 × Highest muscle + 0.2 × Highest fat × CF (tentative) [(d)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Ruminant fat	0.23	Median × CF (tentative) (d)	0.27	Highest × CF (tentative) (d)
Ruminant liver	4.5	Median × CF (tentative) (d)	5.7	Highest × CF (tentative) (d)
Ruminant kidney	4.8	Median × CF (tentative) (d)	4.8	Highest × CF (tentative) (d)
Poultry meat	0.01*	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) (d)	0.01*	0.8 × Median muscle + 0.2 × Median fat × CF (tentative) (d)
Poultry fat	0.01*	Median residue × CF (tentative) (d)	0.01*	Highest residue × CF (tentative) (d)
Poultry liver	0.01*	Median residue × CF (tentative) (d)	0.01*	Highest residue × CF (tentative) (d)
Ruminant milk	0.04	Median residue × CF (tentative) (d)	0.04	Median residue × CF (tentative) (d)
Birds' eggs	0.01*	Median residue × CF (tentative) (d)	0.01*	Median residue × CF (tentative) (d)

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): CXL is not sufficiently supported by data; the corresponding risk assessment values are used for indicative exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Use reported by the RMS is not supported by data; the existing EU MRL multiplied by a conversion factor for risk assessment is used for indicative exposure calculations.
(d): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference values derived for propiconazole (see Table 2-1); detailed results of the calculations are presented as the EU/Codex scenario 1 in Appendix B.2. The highest chronic exposure was calculated for WHO Cluster diet B, representing 15.2 % of the ADI, and the highest acute exposure was calculated for peaches, representing 43.5 % of the ARfD.

For all CXLs, uncertainties remain as they are not well supported by data (further information on the toxicological profiles of the metabolites included in the residue definition for risk assessment are still required, samples from residue trials were analysed only for parent compound or for metabolites convertible to the 2,4-dichlorobenzoic and tentative conversion factors derived from metabolism study were applied). Nevertheless, based on the above calculations, EFSA concludes that inclusion of these CXLs in the exposure calculation did not indicate any risk to European consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of propiconazole was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.04 mg/kg bw per d and 0.3 mg/kg bw, respectively.

Primary crop metabolism of propiconazole was investigated in five different crop groups following foliar applications. Based on these studies, EFSA proposes parent propiconazole (sum of isomers) as residue definition for enforcement. For risk assessment, EFSA tentatively proposes to define the residue in all plant commodities as propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers). Tentative conversion factors of 10 for forage and straw and of 3 for all other food and feed commodities are proposed, in order to express the residue levels according to the residue definition for risk assessment. For the post-harvest uses on citrus fruit, considering that it is unlikely that propiconazole metabolites are formed between treatment and sampling, a tentative conversion factor of 1 is proposed for risk assessment. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg in high water content, high fat content, acidic and dry commodities but a fully validated method for enforcement of propiconazole in tea is still required.

Regarding the magnitude of residues in primary crops, for almonds, cherries, plums, strawberries, currants, gooseberries, peppers, cucumbers, globe artichokes, peanuts and tea, the available data were insufficient to derive MRLs. For all other commodities the available residues data are considered sufficient to derive only tentative MRL proposals and risk assessment values.

The hydrolysis studies demonstrated that under pasteurisation, baking/boiling/brewing and sterilisation conditions, propiconazole remained stable in processed commodities. Studies investigating the magnitude of residues in processed products of oranges, apples, plums, table and wine grapes, peanuts, barley grain, rice grain and wheat grain are available. With regard to the risk assessment of propiconazole, further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

During the peer review the potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, sweet potato, carrot, sugar beet, cabbage, peanut, maize and wheat. This study showed comparable metabolic patterns in primary and succeeding crops. Significant residues of parent propiconazole in rotational crops are not expected considering the application rates proposed in the framework of this MRL review. Nevertheless, triazole derivative metabolites might be of concern in rotational crops and this situation will be reconsidered as soon as a global approach on TDMs will be defined.

Based on the uses reported by the RMS, significant intakes were calculated for ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement was defined as propiconazole (sum of isomers). For risk assessment, EFSA tentatively proposed to define the residue as propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers). The available livestock feeding studies on lactating cows and laying hens allowed EFSA to estimate the magnitude of residues in ruminants, poultry and pig products and to derive MRLs and conversion factors in these commodities. It is therefore concluded that MRLs can be set at the LOQ for all animal commodities except for ruminant and pig tissues. All these MRLs can

only tentatively be derived. A validated analytical method for enforcement of these MRLs is available with an LOQ of 0.01 mg/kg in milk, eggs and animal tissues.

Chronic and acute consumer exposure resulting from the uses supported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied for the tentative conversion factors for an indicative calculation. The highest chronic exposure represented 11.2 % of the ADI (British toddler) and the highest acute exposure amounted to 15.3 % of the ARfD (bovine liver).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for propiconazole. Additional calculations of the consumer exposure, considering these CXLs were therefore performed. The highest chronic exposure represented 15.2 % of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 43.5 % of the ARfD (peaches).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see summary table below). All MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, certain tentative MRLs or existing EU MRLs still need to be confirmed by the following data:

- a validated analytical method for enforcement of the residue in tea;
- further investigation on the toxicological properties of the metabolites convertible to 2,4-dichlorobenzoic acid;
- clarifications on the European GAPs for almonds (SEU), strawberries (NEU), currants (NEU), gooseberries (NEU) and peppers (NEU);
- additional trials supporting the authorisations on citrus fruits, almonds, apples, peaches, apricots, cherries, plums, grapes, strawberries, currants, gooseberries, bananas, peppers, cucumbers, sweet corn, globe artichokes, peanuts, rapeseed, maize, barley, oats, rice, wheat, rye, tea, sugar beet and grass, including analysis of parent and metabolites convertible to 2,4-dichlorobenzoic acid in accordance with the proposed residue definition for risk assessment.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- a metabolism study on citrus fruits following post-harvest treatment;
- storage stability study in acidic commodities (may became a major gap in case new trials with samples stored for longer period would be submitted).

Moreover EFSA emphasises that the available metabolism studies do not investigate the possible impact of plant and livestock metabolism on the isomer ratio of propiconazole and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also highlights that the above assessment does not yet 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 should be 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.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: propiconazole (sum of isomers) (F)					
110010	Grapefruit	6	-	5	Further consideration needed [a]
110020	Oranges	6	9	9	Further consideration needed [b]
110030	Lemons	6	-	5	Further consideration needed [a]
110040	Limes	6	-	5	Further consideration needed [a]
110050	Mandarins	6	-	5	Further consideration needed [a]
120010	Almonds	0.05*	-	0.05	Further consideration needed [c]
130010	Apples	0.15	-	0.15	Further consideration needed [a]
120080	Pecans	0.05*	0.02*	0.02	Further consideration needed [d]
140010	Apricots	0.2	-	0.15	Further consideration needed [a]
140020	Cherries	0.05*	-	0.05	Further consideration needed [c]
140030	Peaches	0.2	5	5	Further consideration needed [b]
140040	Plums	0.05*	0.6	0.6	Further consideration needed [e]
151000	Table and wine grapes	0.3	-	0.3	Further consideration needed [a]
152000	Strawberries	0.05*	-	0.05	Further consideration needed [c]
154020	Cranberries	0.05*	0.3	0.3	Further consideration needed [d]
154030	Currants (red, black and white)	0.05*	-	0.05	Further consideration needed [c]
154040	Gooseberries	0.05*	-	0.05	Further consideration needed [c]
163020	Bananas	0.1	0.1	0.15	Further consideration needed [f]
163080	Pineapples	0.05*	0.02*	0.02	Further consideration needed [d]
231010	Tomatoes	0.05*	3	3	Further consideration needed [d]
231020	Peppers	0.05*	-	0.05	Further consideration needed [c]
232010	Cucumbers	0.05*	-	0.05	Further consideration needed [c]
234000	Sweet corn	0.05*	0.05	0.05	Further consideration needed [b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
270050	Globe artichokes	0.05*	-	0.05	Further consideration needed [c]
401020	Peanuts	0.2	-	0.2	Further consideration needed [c]
401060	Rape seed	0.1*	0.02	0.05	Further consideration needed [f]
401070	Soya bean	0.1*	0.07	0.07	Further consideration needed [d]
500010	Barley grain	0.2	0.2	0.3	Further consideration needed [f]
500030	Maize grain	0.05*	0.05	0.05	Further consideration needed [f]
500050	Oats grain	0.2	-	0.3	Further consideration needed [a]
500060	Rice grain	0.7	-	1.5	Further consideration needed [a]
500070	Rye grain	0.05*	0.02*	0.04	Further consideration needed [f]
500090	Wheat grain	0.05*	0.02*	0.04	Further consideration needed [f]
610000	Tea	0.1*	-	0.1	Further consideration needed [c]
620000	Coffee beans	0.1*	0.02	0.02	Further consideration needed [d]
900010	Sugar beet (root)	0.05*	0.02	0.15	Further consideration needed [f]
900020	Sugar cane	0.05*	0.02*	0.02	Further consideration needed [d]
1011010	Swine muscle	0.01*	0.01*	0.05	Further consideration needed [f]
1011020	Swine fat (free of lean meat)	0.01*	0.01*	0.05	Further consideration needed [f]
1011030	Swine liver	0.01*	0.01*	0.15	Further consideration needed [f]
1011040	Swine kidney	0.01*	0.01*	0.05	Further consideration needed [f]
1012010	Bovine muscle	0.05	0.01*	0.05	Further consideration needed [f]
1012020	Bovine fat	0.05	0.01*	0.07	Further consideration needed [f]
1012030	Bovine liver	0.1	0.01*	0.5	Further consideration needed [f]
1012040	Bovine kidney	0.05	0.01*	0.05	Further consideration needed [f]
1013010	Sheep muscle	0.05	0.01*	0.05	Further consideration needed [f]
1013020	Sheep fat	0.05	0.01*	0.07	Further consideration needed [f]
1013030	Sheep liver	0.1	0.01*	0.5	Further consideration needed [f]
1013040	Sheep kidney	0.05	0.01*	0.05	Further consideration needed [f]
1014010	Goat muscle	0.05	0.01*	0.05	Further consideration needed [f]
1014020	Goat fat	0.05	0.01*	0.07	Further consideration needed [f]
1014030	Goat liver	0.1	0.01*	0.5	Further consideration needed [f]
1014040	Goat kidney	0.05	0.01*	0.05	Further consideration needed [f]
1016010	Poultry muscle	0.01*	0.01*	0.01*	Further consideration needed [f]
1016020	Poultry fat	0.01*	0.01*	0.01*	Further consideration needed [f]
1016030	Poultry liver	0.01*	-	0.01*	Further consideration needed [a]
1020010	Cattle milk	0.01*	0.01*	0.01*	Further consideration needed [f]
1020020	Sheep milk	0.01*	0.01*	0.01*	Further consideration needed [f]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1020030	Goat milk	0.01*	0.01*	0.01*	Further consideration needed (f)
1030000	Birds' eggs	0.01*	0.01*	0.01*	Further consideration needed (f)
-	Other products of plant and animal origin	See App. C.1	See App. C.2	-	Further consideration needed (g)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Indicates that the residue definition is fat soluble.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).
(b): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(d): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(e): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the CXL (combination C-V in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on propiconazole prepared by the rapporteur Member State Finland in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 04 May 2010. Last updated on 23 May 2012.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	NEU	Outdoor	PL	Podosphoaera leucotricha (Ell et), Venturia inaequalis	EC	250.0	g/L	Foliar treatment - spraying			1	2	10	14		75.00	g a.i./ha	14	Application: up to 72 h after infestation, after flowering. Source: EFSA, 2010.
Strawberries	*Fragaria x ananassa*	NEU	Outdoor	DK	fungi								2				125.00	g a.i./ha		Application: after harvest, latest 1st October. Another GAP on strawberries is authorised in Romania (RO) (foliar treament - spraying, 5 g ai/hl).
Currants (red, black and white)	*Ribes nigrum, rubrum*	NEU	Outdoor	DK	fungi								2				125.00	g a.i./ha		Application: after harvest, latest 1st October. Another GAP on currants is authorised in Romania (RO) (foliar treament - spraying, 5 g ai/hl).
Gooseberries	*Ribes uva-crispa*	NEU	Outdoor	DK	fungi								2				125.00	g a.i./ha		Application: after harvest, latest 1 October
Peppers	*Capsicum annuum, var grossum and var. longum*	NEU	Outdoor	RO	Leveillula taurica	EC	250.0	g/L	Foliar treatment - spraying								5.00	g a.i./hL		
Sweet corn	*Zea mays var. sacharata*	NEU	Outdoor	HU, NL	Helminthosporium turcicum	SE	122.4	g/L	Foliar treatment - spraying	30	69		1				122.40	g a.i./ha	21	
Rape seed	*Brassica napus*	NEU	Outdoor	UK	fungi	EC	250.0	g/L	Foliar treatment - spraying				1				125.00	g a.i./ha	28	
Barley	*Hordeum spp.*	NEU	Outdoor	FR	Erysiphe graminis sp.hordei, Peronospora spp., Puccinia hordei, Puccinia striiformis, Rhyncosporium secalis	EC	250.0	g/L	Foliar treatment - spraying		69		2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials. Corresponding GAP is registered in many MSs with small modifications.
Maize	*Zea mays*	NEU	Outdoor	DE, HU, NL, UK	Helminthosporium turcicum, Kabatiella zeae, Puccinia sorghi	SE	122.4	g/L	Foliar treatment - spraying	30	69		1				122.40	g a.i./ha	n.a.	
Oats	*Avena fatua*	NEU	Outdoor	FR	Erysiphe graminis sp. Avenae, Puccinia coronata sp. avenae	EC	250.0	g/L	Foliar treatment - spraying		69		2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials. Corresponding GAP is registered in many MSs with small modifications.
Rye	*Secale cereale*	NEU	Outdoor	FR	Erysiphe graminis, Puccinia spp.	EC	250.0	g/L	Foliar treatment - spraying		71		2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials. Corresponding GAP is registered in many MSs with small modifications.
Wheat	*Triticum aestivum*	NEU	Outdoor	FR	Erysiphe graminis, Puccinia recondita, Puccinia striiformis, Septoria spp.	EC	250.0	g/L	Foliar treatment - spraying		71		2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials. Corresponding GAP is registered in many MSs with small modifications.
Sugar beet	*Beta vulgaris*	NEU	Outdoor	LV	Cercospora beticola, Erysiphe betae, Ramularia beticola, Uromyces betae	EC	250.0	g/L	Foliar treatment - spraying				2	14	28	100.00	125.00	g a.i./ha	28	
Grass	*not specified*	NEU	Outdoor	IE	Drechslera spp., Erysiphe graminis, Puccinia coronata sp, Rhyncosporium spp.	EC	250.0	g/L	Foliar treatment - spraying				1				125.00	g a.i./ha	28	Grass used for ensiling
Maize (for forage)	*Zea mays*	NEU	Outdoor	DE, HU, NL, UK	Helminthosporium turcicum, Kabatiella zeae, Puccinia sorghi	SE	122.4	g/L	Foliar treatment - spraying	30	69		1				122.40	g a.i./ha	n.a.	

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Almonds	*Prunus dulcis*	SEU	Outdoor	EL	Monilinia laxa	EC	250.0	g/L	Foliar treatment - spraying							50.00	150.00	g a.i./ha	35	
Apricots	*Prunus armeniaca*	SEU	Outdoor	IT, GR, SP	Powdery mildew	EC	250.0	g/L	Foliar treatment - spraying	75	85		3	10	12		150.00	g a.i./ha	14	Source: EFSA, 2010
Cherries	*Prunus cerasus, Prunus avium*	SEU	Outdoor	IT	Monilinia fructigena	EC	250.0	g/L	Foliar treatment - spraying			1	2				6.00	g a.i./hL	14	
Peaches	*Prunus persica*	SEU	Outdoor	IT, GR, SP	Powdery mildew	EC	250.0	g/L	Foliar treatment - spraying	75	85		3	10	12		150.00	g a.i./ha	14	Source: EFSA, 2010
Plums	*Prunus domestica*	SEU	Outdoor	IT	Monilinia fructigena	EC	250.0	g/L	Foliar treatment - spraying			1	2				6.25	g a.i./hL	14	
Table grapes	*Vitis euvitis*	SEU	Outdoor	ES, IT, EL, SI	Guignardia bidwellii, Uncinula necator	EC	100.0	g/L	Foliar treatment - spraying	20	85	4	5	10	12		50.00	g a.i./ha	14	
Wine grapes	*Vitis euvitis*	SEU	Outdoor	ES, IT, EL, SI	Guignardia bidwellii, Uncinula necator	EC	100.0	g/L	Foliar treatment - spraying	20	85	4	5	10	12		50.00	g a.i./ha	14	
Cucumbers	*Cucumis sativus*	SEU	Outdoor	ES	Sphaerotheca spp.	EC	100.0	g/L	Foliar treatment - spraying			3	4	10	20	3.00	5.00	g a.i./hL	15	Application: fruiting
Sweet corn	*Zea mays var. sacharata*	SEU	Outdoor	IT	Helminthosporium turcicum, Puccinia sorghi, Kabatiella zeae	SE	122.4	g/L	Foliar treatment - spraying	30	69		1				122.40	g a.i./ha	21	
Globe artichokes	*Cynara scolymus*	SEU	Outdoor	IT	Leveillula taurica	EC	250.0	g/L	Foliar treatment - spraying			3	4	12	14		50.00	g a.i./ha	14	
Barley	*Hordeum spp.*	SEU	Outdoor	FR	Erysiphe graminis, Puccinia spp, Septoria spp.	EC	250.0	g/L	Foliar treatment - spraying		61		2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials.Corresponding GAP is registered in many MSs with small modifications. Actual cGAP in HU: 2 x 125 g/as ha, PHI of 21 days.
Maize	*Zea mays*	SEU	Outdoor	IT	Helminthosporium turcicum, Puccinia sorghi, Kabatiella zeae	SE	122.4	g/L	Foliar treatment - spraying	30	69		1				122.40	g a.i./ha	n.a.	
Oats	*Avena fatua*	SEU	Outdoor	FR	Erysiphe graminis, Puccinia spp, Septoria spp.	EC	250.0	g/L	Foliar treatment - spraying		61		2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials.Corresponding GAP is registered in many MSs with small modifications. Actual cGAP in HU: 2 x 125 g/as ha, PHI of 21 days.
Rice	*Oryza sativa*	SEU	Outdoor	IT	Pyrenophora teres	EC	250.0	g/L	Foliar treatment - spraying	51			2	10	12		150.00	g a.i./ha	21	
Rye	*Secale cereale*	SEU	Outdoor	FR	Erysiphe graminis, Puccinia spp, Septoria spp.	EC	250.0	g/L	Foliar treatment - spraying		71	1	2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials.Corresponding GAP is registered in many MSs with small modifications. Actual cGAP in HU: 2 x 125 g/as ha, PHI of 21 days.
Wheat	*Triticum aestivum*	SEU	Outdoor	FR	Erysiphe graminis, Puccinia spp, Septoria spp.	EC	250.0	g/L	Foliar treatment - spraying		71	1	2	21	42		125.00	g a.i./ha	40	This is the supported use patterns of the notifier which is also supported by residue trials.Corresponding GAP is registered in many MSs with small modifications. Actual cGAP in HU: 2 x 125 g/as ha, PHI of 21 days.
Sugar beet	*Beta vulgaris*	SEU	Outdoor	IT	Cercospora spp., Erysiphe betae	EC	90.0	g/L	Foliar treatment - spraying	10	39		2	14	16		99.00	g a.i./ha	21	In the mixture with prochloraz
Maize (for forage)	*Zea mays*	SEU	Outdoor	IT	Helminthosporium turcicum, Puccinia sorghi, Kabatiella zeae	SE	122.4	g/L	Foliar treatment - spraying	30	69		1				122.40	g a.i./ha	n.a.	

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Grapefruit	*Citrus paradisi*	NEU/SEU	Indoor	ES	Penicillium sp, Geotrichum candidum spp	EC	100.0	g/L	Post-harvest treatment - drenching	n.a.	n.a.		1				0.06	kg a.i./hL	n.a.	The dose rate corresponds to 4.2 g a.s./t of fruits. The application is done mantaining the treatment for 30 seconds using about 40 tons of fruits. Source: EFSA, 2012.
Oranges	*Citrus sinensis*	NEU/SEU	Indoor	ES	Penicillium sp, Geotrichum candidum spp	EC	100.0	g/L	Post-harvest treatment - drenching	n.a.	n.a.		1				0.06	kg a.i./hL	n.a.	The dose rate corresponds to 4.2 g a.s./t of fruits. The application is done mantaining the treatment for 30 seconds using about 40 tons of fruits. Source: EFSA, 2012.
Lemons	*Citrus limon*	NEU/SEU	Indoor	ES	Penicillium sp, Geotrichum candidum spp	EC	100.0	g/L	Post-harvest treatment - drenching	n.a.	n.a.		1				0.06	kg a.i./hL	n.a.	The dose rate corresponds to 4.2 g a.s./t of fruits. The application is done mantaining the treatment for 30 seconds using about 40 tons of fruits. Source: EFSA, 2012.
Limes	*Citrus aurantifolia*	NEU/SEU	Indoor	ES	Penicillium sp, Geotrichum candidum spp	EC	100.0	g/L	Post-harvest treatment - drenching	n.a.	n.a.		1				0.06	kg a.i./hL	n.a.	The dose rate corresponds to 4.2 g a.s./t of fruits. The application is done mantaining the treatment for 30 seconds using about 40 tons of fruits. Source: EFSA, 2012.
Mandarins	*Citrus reticulata*	NEU/SEU	Indoor	ES	Penicillium sp, Geotrichum candidum spp	EC	100.0	g/L	Post-harvest treatment - drenching	n.a.	n.a.		1				0.06	kg a.i./hL	n.a.	The dose rate corresponds to 4.2 g a.s./t of fruits. The application is done mantaining the treatment for 30 seconds using about 40 tons of fruits. Source: EFSA, 2012.

Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Bananas	*Musa x paradisica*	non-EU	Outdoor	Costa Rica	fungi	EC	250.0	g/L	Foliar treatment - general (see also comment field)			8	10		28		100.00	g a.i./ha	0	Application method: aerial foliar treatment (by plane). FR GAP (overseas) less critical : 3x100 g a.s./ha; PHI 1d.
Peanuts	*Arachis hypogaea*	non-EU	Outdoor	USA	fungi	EC			Foliar treatment - spraying				4	10	14		125.00	g a.i./ha	14	Application; 35-40 days after planting or at first sign of disease
Rape seed	*Brassica napus*	non-EU	Outdoor	Canada	Blackleg	EC	250.0	g/L	Foliar treatment - spraying				1				125.00	g a.i./ha	56	The PHI is 60 days. Growth stage at application: rosette stage (between 2nd true leaf and bolting).
Tea	*Camellia sinensis*	non-EU	Outdoor	Indonesia	Exobasidium vexans	EC	250.0	g/L	Foliar treatment - spraying				3	10	14		150.00	g a.i./ha	14	

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU/Codex scenario including demonstrated safe EU MRL proposals and all CXLs

APPENDIX B.1 – EU SCENARIO INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Propiconazole			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,04**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2003**	Year of evaluation:	**2003**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 11
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)
11,2	UK Toddler	6,0	Sugar beet (root)	2,1	Milk and cream,	0,9	Rice	0,0
10,5	UK Infant	3,9	Milk and cream,	2,6	Sugar beet (root)	1,0	Rice	0,0
9,7	NL child	2,9	Milk and cream,	1,7	Apples	0,8	Bovine: Liver	0,0
8,1	DE child	3,3	Apples	1,4	Milk and cream,	0,6	Wheat	0,0
7,2	WHO Cluster diet B	1,3	Wheat	0,9	Bovine: Kidney	0,9	Rice	0,0
7,0	FR toddler	4,0	Milk and cream,	0,7	Apples	0,6	Rice	0,0
6,2	IE adult	2,5	Sheep: Liver	0,4	Wine grapes	0,4	Barley	0,0
6,2	DK child	1,4	Bovine: Liver	1,3	Milk and cream,	0,8	Wheat	0,0
5,0	ES child	1,3	Milk and cream,	0,8	Rice	0,7	Wheat	0,1
4,2	FR infant	2,6	Milk and cream,	0,7	Apples	0,2	Bovine: Meat	0,0
4,0	WHO cluster diet D	1,0	Wheat	0,9	Rice	0,5	Milk and cream,	0,0
3,7	WHO cluster diet E	0,6	Wheat	0,5	Wine grapes	0,3	Rice	0,0
3,5	SE general population 90th percentile	1,2	Milk and cream,	0,7	Rice	0,5	Wheat	0,0
3,4	PT General population	1,3	Rice	0,7	Wine grapes	0,6	Wheat	
3,4	WHO Cluster diet F	0,5	Wheat	0,4	Milk and cream,	0,3	Rice	0,0
3,2	NL general	0,7	Milk and cream,	0,3	Apples	0,3	Wheat	0,0
3,2	WHO regional European diet	0,5	Milk and cream,	0,4	Wheat	0,4	Bovine: Meat	0,0
3,1	UK Adult	1,0	Sugar beet (root)	0,6	Rice	0,3	Wine grapes	0,0
3,1	UK vegetarian	1,0	Sugar beet (root)	0,6	Rice	0,3	Milk and cream,	0,0
2,9	FR all population	1,2	Wine grapes	0,5	Wheat	0,3	Milk and cream,	0,0
2,9	DK adult	0,6	Bovine: Liver	0,5	Milk and cream,	0,4	Wine grapes	0,0
2,8	ES adult	0,5	Milk and cream,	0,4	Rice	0,4	Wheat	0,0
2,5	LT adult	0,5	Apples	0,4	Milk and cream,	0,4	Rice	0,0
2,0	IT kids/toddler	1,0	Wheat	0,3	Rice	0,2	Apples	
1,5	FI adult	0,6	Milk and cream,	0,2	Rice	0,1	Wheat	0,0
1,5	IT adult	0,6	Wheat	0,3	Rice	0,2	Apples	
0,9	PL general population	0,6	Apples	0,1	Table grapes	0,1	Plums	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Propiconazole 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)
15,3	Bovine: Liver	5,67403628117	15,3	Bovine: Liver	5,67403628117	5,3	Rice	2,13 / -	5,3	Rice	2,13 / -
10,5	Table grapes	0,48 / -	10,5	Table grapes	0,48 / -	5,1	Bovine: Liver	5,67403628117	5,1	Bovine: Liver	5,67403628117
9,0	Rice	2,13 / -	9,0	Rice	2,13 / -	5,1	Table grapes	0,48 / -	5,1	Table grapes	0,48 / -
6,9	Apples	0,21 / -	6,0	Bovine: Kidney	4,8 / -	3,8	Wine grapes	0,48 / -	3,8	Wine grapes	0,48 / -
6,7	Bananas	0,24 / -	5,1	Apples	0,21 / -	2,7	Bovine: Kidney	4,8 / -	2,7	Bovine: Kidney	4,8 / -
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)	
5,3	Grape juice	0,48 / -		0,6	Wine	0,48 / -	
3,6	Apple juice	0,21 / -		0,5	Apple juice	0,21 / -	
1,3	Peach juice	0,21 / -		0,1	Peach preserved with	0,21 / -	
0,7	Plums juice	0,15 / -		0,1	Bread/pizza	0,069 / -	
0,5	Cuurant juice	0,15 / -		0,1	Orange juice	0,0231 / -	

*) 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 Propiconazole 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 B.2 – EU/CODEX SCENARIO INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLS

Propiconazole			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,04**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2003**	Year of evaluation:	**2003**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
2	15
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)
15,2	WHO Cluster diet B	5,6	Tomatoes	1,6	Peaches	1,3	Wheat	0,0
12,6	UK Toddler	6,0	Sugar beet (root)	2,1	Milk and cream,	1,1	Tomatoes	0,0
11,7	UK Infant	3,9	Milk and cream,	2,6	Sugar beet (root)	1,0	Rice	0,0
11,6	NL child	2,9	Milk and cream,	1,7	Apples	1,1	Tomatoes	0,0
11,0	DE child	3,3	Apples	1,7	Tomatoes	1,4	Milk and cream,	0,0
9,9	IE adult	2,5	Sheep: Liver	2,2	Peaches	0,9	Maize	0,0
8,5	FR toddler	4,0	Milk and cream,	1,4	Tomatoes	0,7	Apples	0,0
7,6	DK child	1,4	Bovine: Liver	1,3	Milk and cream,	1,0	Tomatoes	0,0
7,6	ES child	1,8	Tomatoes	1,3	Milk and cream,	0,8	Rice	0,1
6,6	PT General population	1,6	Tomatoes	1,4	Peaches	1,3	Rice	
6,2	WHO cluster diet D	1,8	Tomatoes	1,0	Wheat	0,9	Rice	0,0
6,1	WHO regional European diet	2,0	Tomatoes	0,8	Peaches	0,5	Milk and cream,	0,0
5,9	IT kids/toddler	2,6	Tomatoes	1,4	Peaches	1,0	Wheat	
5,5	SE general population 90th percentile	1,4	Tomatoes	1,2	Milk and cream,	0,7	Rice	0,0
5,5	WHO cluster diet E	0,9	Tomatoes	0,6	Wheat	0,5	Peaches	0,0
5,1	ES adult	1,4	Tomatoes	0,8	Peaches	0,5	Milk and cream,	0,0
5,0	WHO Cluster diet F	1,2	Tomatoes	0,5	Wheat	0,4	Milk and cream,	0,0
5,0	IT adult	2,1	Tomatoes	1,5	Peaches	0,6	Wheat	
4,8	FR infant	2,6	Milk and cream,	0,7	Apples	0,3	Tomatoes	0,0
4,4	UK vegetarian	1,1	Tomatoes	1,0	Sugar beet (root)	0,6	Rice	0,0
4,3	NL general	0,8	Tomatoes	0,7	Milk and cream,	0,3	Apples	0,0
4,2	FR all population	1,2	Wine grapes	0,8	Tomatoes	0,5	Peaches	0,0
4,1	UK Adult	1,0	Sugar beet (root)	0,8	Tomatoes	0,6	Rice	0,0
4,0	DK adult	0,7	Tomatoes	0,6	Bovine: Liver	0,5	Milk and cream,	0,0
3,6	LT adult	1,1	Tomatoes	0,5	Apples	0,4	Milk and cream,	0,0
2,7	PL general population	1,6	Tomatoes	0,6	Apples	0,2	Peaches	
2,4	FI adult	0,8	Tomatoes	0,6	Milk and cream,	0,2	Rice	0,0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Propiconazole 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)
43,5	Peaches	2,2 / -	31,9	Peaches	2,2 / -	12,8	Peaches	2,2 / -	9,9	Peaches	2,2 / -
34,1	Tomatoes	1,76 / -	24,7	Tomatoes	1,76 / -	8,9	Tomatoes	1,76 / -	7,2	Tomatoes	1,76 / -
15,3	Bovine: Liver	5,67403628117	15,3	Bovine: Liver	5,67403628117	5,3	Rice	2,13 / -	5,3	Rice	2,13 / -
10,5	Table grapes	0,48 / -	10,5	Table grapes	0,48 / -	5,1	Bovine: Liver	5,67403628117	5,1	Bovine: Liver	5,67403628117
9,0	Rice	2,13 / -	9,0	Rice	2,13 / -	5,1	Table grapes	0,48 / -	5,1	Table grapes	0,48 / -
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)
13,1	Peach juice	2,2 / -		1,5	Peach preserved with	2,2 / -
10,2	Tomato juice	1,76 / -		1,1	Tomato (preserved-fresh)	1,76 / -
5,3	Grape juice	0,48 / -		0,6	Wine	0,48 / -
3,6	Apple juice	0,21 / -		0,5	Apple juice	0,21 / -
1,0	Plums juice	0,22 / -		0,2	Orange juice	0,049 / -

*) 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 Propiconazole 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 C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs (File created on 16/05/2014 16:02)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propiconazole
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	6
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	6
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	6
110030	Lemons (Citron, lemon)	6
110040	Limes	6
110050	Mandarins (Clementine, tangerine and other hybrids)	6
110990	Others	6
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	
130010	Apples (Crab apple)	0.15
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	
140010	Apricots	0.2
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0.2
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0.3
151010	Table grapes	0.3
151020	Wine grapes	0.3
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	
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	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.1
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 (a)	Propiconazole
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	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
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 (leaves)	0,05*
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	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0.1
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	0,1*
401020	Peanuts	0.2
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	
500010	Barley	0.2
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0.2
500060	Rice	0.7
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propiconazole
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propiconazole
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
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	0,01*
1011010	Meat	0,01*
1011020	Fat free of lean meat	0,01*
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0,05
1012020	Fat	0,05
1012030	Liver	0,1
1012040	Kidney	0,05
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	
1013010	Meat	0,05
1013020	Fat	0,05
1013030	Liver	0,1

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propiconazole
1013040	Kidney	0,05
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0,05
1014020	Fat	0,05
1014030	Liver	0,1
1014040	Kidney	0,05
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Meat	0,01*
1015020	Fat	0,01*
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*
1016010	Meat	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017010	Meat	0,01*
1017020	Fat	0,01*
1017030	Liver	0,01*
1017040	Kidney	0,01*
1017050	Edible offal	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propiconazole
1017990	Others	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,01*
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
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	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen)	0,01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products	0,01*

(*) Indicates the limit of analytical determination

APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for propiconazole in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
110020	Oranges	Propiconazole (sum of isomers)	9	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	2.950	4.900	3	n.c.	2.950	4.900	n.k.	1	2013	No	Trials performed in the USA according to the GAP (dip/post-harvest). PF of 0.11 derived for orange juice.
120080	Pecans	Propiconazole (sum of isomers)	0.02 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.02	0.02	1	n.c.	0.02	0.02	n.a.	3		No	Trials conducted in the USA according to GAP. Residues expected <LOQ - STMR and HR for both total and parent residues estimated as <0.02.
140030	Peaches	Propiconazole (sum of isomers)	5	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	1.550	2.200	3	n.c.	1.550	2.200	n.a.	1	2013	No	Trials performed in the USA according to the GAP (dip/post-harvest).
140040	Plums	Propiconazole (sum of isomers)	0.6	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.185	0.220	3	n.c.	0.185	0.220	n.a.	1	2013	No	Trials performed in the USA according to the GAP (dip/spray/post-harvest).
154020	Cranberries	Propiconazole (sum of isomers)	0.3	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.058	0.13	1	n.c.	0.058	0.13	n.a.	3	2006	No	All trials conducted in the USA according to GAP. JMPR stated STMR and HR based on definition of parent only for RA. The actual STMR and HR were 0.225 and 0.59 based on total residue from 2,4-
163020	Bananas	Propiconazole (sum of isomers)	0.1	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.06	0.087	3	n.c.	0.025	0.052	0.4	3	2007	No	Trials conducted in Honduras according to GAP. Residues in whole fruit were estimated.
163080	Pineapples	Propiconazole (sum of isomers)	0.02 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.02	0.02	3	n.c.	0.02	0.02	n.a.	3	2007	No	All trials were conducted outside of the EU according to non-EU GAP. All residues were <LOQ, no MPF is required. STMR and HR for both total and parent residues estimated as <0.02.
231010	Tomatoes	Propiconazole (sum of isomers)	3	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.720	1.760	3	n.c.	0.720	1.760	n.a.	1	2013	No	Trials performed in the USA according to the GAP (dip/drench/spray/post-harvest). Dietary correction factor of 5.
234000	Sweet corn	Propiconazole (sum of isomers)	0.05	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	n.c.	3	n.c.	0.05	0.05	n.a.	3	2007	No	Trials conducted outside of the EU according to non-EU GAP. Residues expected <LOQ - STMR and HR for both total and parent residues estimated as <0.05.
401060	Rape seed	Propiconazole (sum of isomers)	0.02	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.06	n.c.	1	n.c.	0.02	0.02	n.a.	3	2007	No	Trials conducted in Canada according to GAP. Residues measured as parent - JMPR estimate RA STMR as 3 x parent.
401070	Soya bean	Propiconazole (sum of isomers)	0.07	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.03	n.c.	1	n.c.	0.01	0.05	n.a.	3	2007	No	Trials conducted in USA according to GAP. Residues measured as parent - JMPR estimate RA STMR as 3 x parent.
500010	Barley grain	Propiconazole (sum of isomers)	0.2	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.0675	n.c.	1	n.c.	0.0225	0.11	n.a.	3	2007	Yes	Trials conducted in France, Switzerland and Germany according to French GAP. Residues measured as parent - JMPR estimate RA STMR as 3 x parent.
500030	Maize grain	Propiconazole (sum of isomers)	0.05	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	n.c.	3	n.c.	0.05	0.05	n.a.	3	2007	No	Trials conducted outside of the EU according to non-EU GAP. Residues expected <LOQ - STMR and HR for both total and parent residues estimated as <0.05.
500070	Rye grain	Propiconazole (sum of isomers)	0.02 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.06	n.c.	1	n.c.	0.02	0.02	n.a.	3	2007	Yes	Wheat, rye and tritcale residues combined into a single data set. All trials conducted in the EU according to the French GAP. Residues measured as parent - JMPR estimate RA STMR as 3 x parent.

m302045: Default conversion factor derived by JMPR based on metabolism data.

Summary of CXLs for propiconazole in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
500090	Wheat grain	Propiconazole (sum of isomers)	0.02	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.06	n.c.	1	n.c.	0.02	0.02	n.a.	3	2007	Yes	Wheat, rye and tritcale residues combined into a single data set. All trials conducted in the EU according to the French GAP. Residues measured as parent - JMPR estimate RA STMR as 3 x parent.
620000	Coffee beans	Propiconazole (sum of isomers)	0.02	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.06	n.c.	1	n.c.	0.02	0.02	n.a.	3	2007	No	All trials conducted outside of the EU according to non-EU GAP. Residues measured as parent - JMPR estimate RA STMR as 3 x
900010	Sugar beet (root)	Propiconazole (sum of isomers)	0.02	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.06	n.c.	1	n.c.	0.02	0.05	n.a.	3	2007	No	All trials conducted in the EU according to appropriate GAP. Residues measured as parent - JMPR estimate RA STMR as 3 x parent.
900020	Sugar cane	Propiconazole (sum of isomers)	0.02 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0	n.c.	1	n.c.	0.01	0.01	n.a.	3	2007	No	Based on metabolism study. No TRR >0.01 mg/kg in any plant parts.

(*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

n.k.: not known

Summary of CXLs for propiconazole in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1011020	Swine fat (free of lean meat)	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	
1011030	Swine liver	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	No propiconazole was detected. The 'total-DCBA-residue' for liver and kidney was 0.81 and 0.63 (max) and 0.63 and 0.60 (mean) respectively at a slightly exaggerated feeding rate. STMR and HR values are as stated by the JMPR for risk assessment.
1011040	Swine kidney	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1011050	Swine edible offal	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1012010	Bovine meat	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1012020	Bovine fat	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	
1012030	Bovine liver	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	No propiconazole was detected. The 'total-DCBA-residue' for liver and kidney was 0.81 and 0.63 (max) and 0.63 and 0.60 (mean) respectively at a slightly exaggerated feeding rate. STMR and HR values are as stated by the JMPR for risk assessment.
1012040	Bovine kidney	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1012050	Bovine edible offal	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1013010	Sheep meat	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1013020	Sheep fat	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	
1013030	Sheep liver	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	No propiconazole was detected. The 'total-DCBA-residue' for liver and kidney was 0.81 and 0.63 (max) and 0.63 and 0.60 (mean) respectively at a slightly exaggerated feeding rate. STMR and HR values are as stated by the JMPR for risk assessment.
1013040	Sheep kidney	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1013050	Sheep edible offal	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1014010	Goat meat	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1014020	Goat fat	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	

Summary of CXLs for propiconazole in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1014030	Goat liver	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	No propiconazole was detected. The 'total-DCBA-residue' for liver and kidney was 0.81 and 0.63 (max) and 0.63 and 0.60 (mean) respectively at a slightly exaggerated feeding rate. STMR and HR values are as stated by the JMPR for risk assessment.
1014040	Goat kidney	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1014050	Goat edible offal	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1015010	Horses, asses, mules or hinnies meat	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1015020	Horses, asses, mules or hinnies fat	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	
1015030	Horses, asses, mules or hinnies liver	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	No propiconazole was detected. The 'total-DCBA-residue' for liver and kidney was 0.81 and 0.63 (max) and 0.63 and 0.60 (mean) respectively at a slightly exaggerated feeding rate. STMR and HR values are as stated by the JMPR for risk assessment.
1015040	Horses, asses, mules or hinnies kidney	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1015050	Horses, asses, mules or hinnies edible offal	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1016010	Poultry meat	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1016020	Poultry fat	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	
1017010	Other farm animals meat	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1017020	Other farm animals fat	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	
1017030	Other farm animals liver	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	No propiconazole was detected. The 'total-DCBA-residue' for liver and kidney was 0.81 and 0.63 (max) and 0.63 and 0.60 (mean) respectively at a slightly exaggerated feeding rate. STMR and HR values are as stated by the JMPR for risk assessment.
1017040	Other farm animals kidney	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1017050	Other farm animals edible offal	Propiconazole (sum of isomers)	n.a.	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.6	0.8	2007	no	
1020010	Cattle milk	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.01	0.01	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.01) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.
1020020	Sheep milk	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.01	0.01	2007	no	
1020030	Goat milk	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.01	0.01	2007	no	
1020040	Horse milk	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.01	0.01	2007	no	

Summary of CXLs for propiconazole in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1030000	Birds' eggs	Propiconazole (sum of isomers)	yes	0.01 *	Propiconazole and all the metabolites convertible to the 2.4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	0.05	0.05	2007	no	No propiconazole was detected. No 'total-DCBA-residue' (<0.05) was found at the relevant rate of feeding. STMR and HR values are as stated by the JMPR for risk assessment.

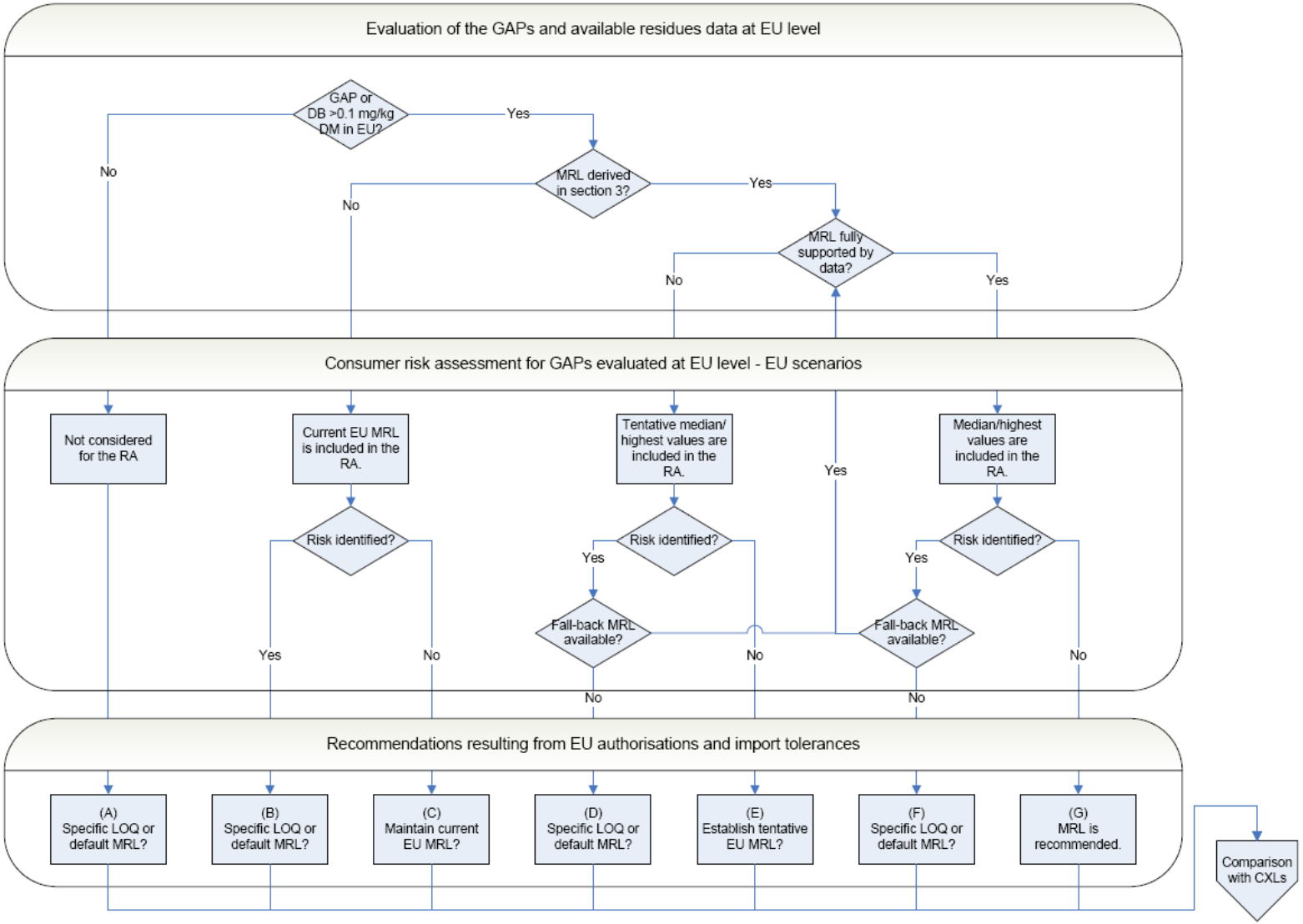
(*) Indicates the lower limit of analytical quantification.

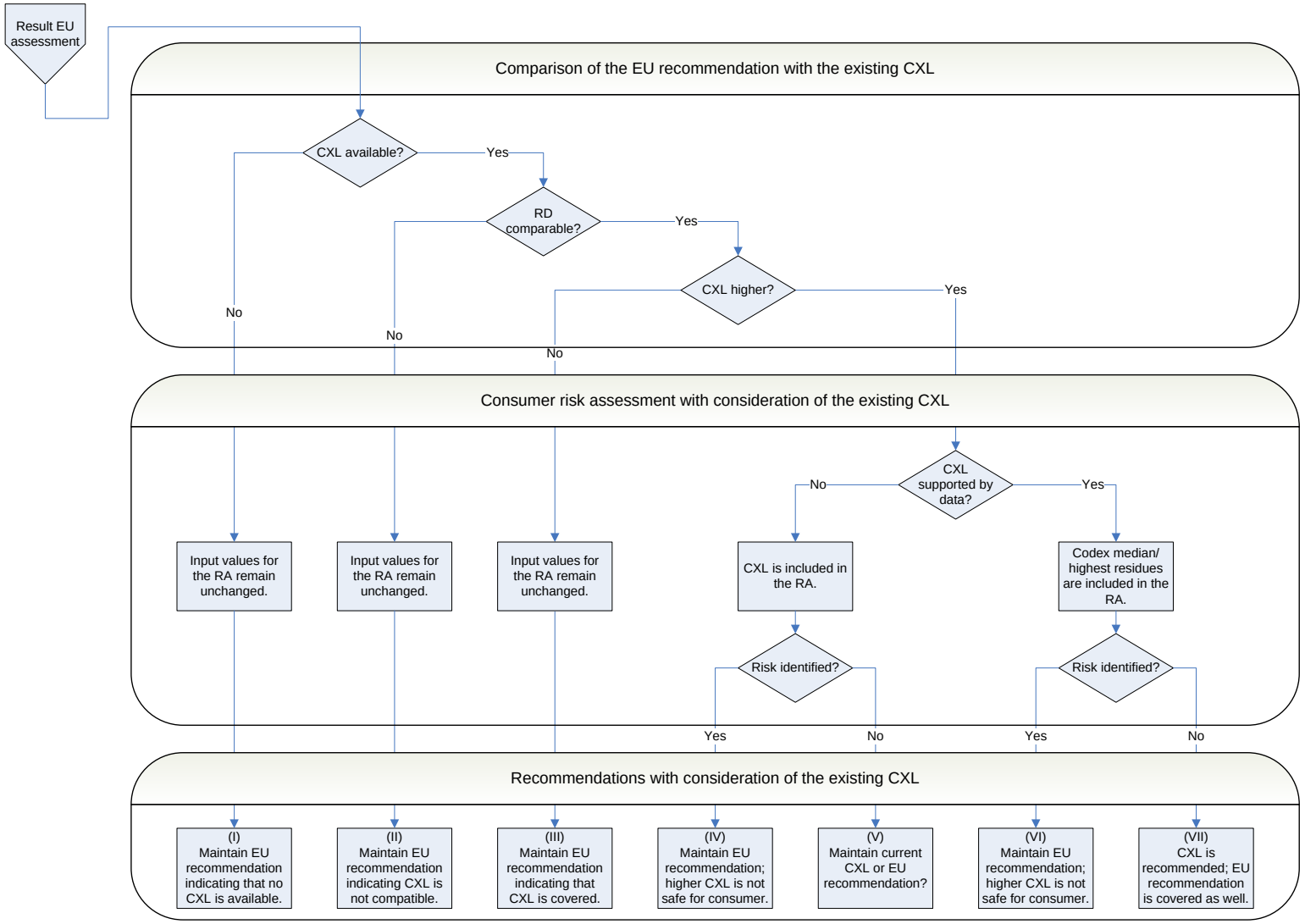
n.a.: not applicable

n.c.: not considered

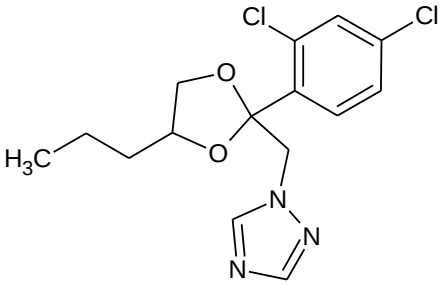
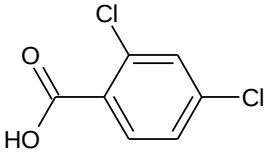
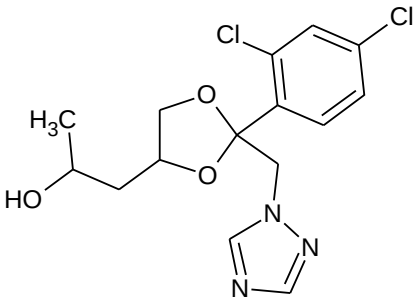
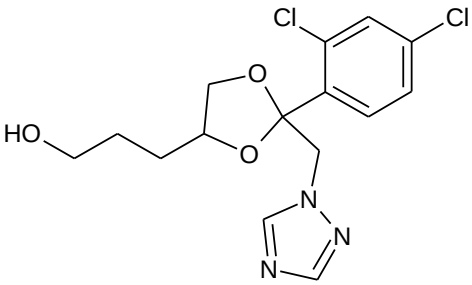
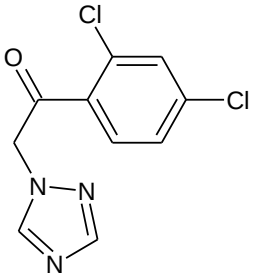
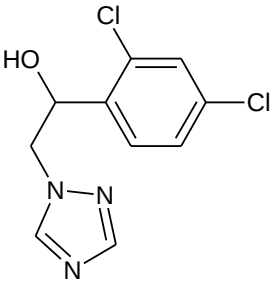
n.k.: not known

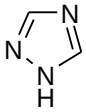
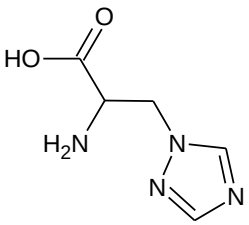
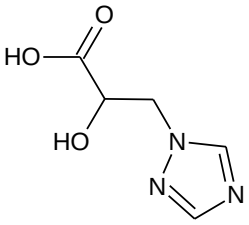
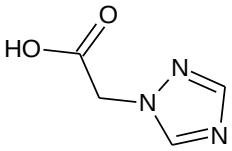
APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
Propiconazole (CGA 64250)	(2*RS*,4*RS*;2*RS*,4*SR*)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole	
2,4-DCBA (CGA 177291)	2,4-dichlorobenzoic acid	
β-hydroxy alcohol (CGA 118244)	1-[[2-(2,4-dichlorophenyl)-4-(2-hydroxypropyl)-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole	
γ-hydroxy alcohol (CGA 118245)	3-[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]propan-1-ol	
Ketone (CGA 91304)	1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)ethanone	
Alkanol (CGA 91305)	(1RS)-1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)ethanol	

1,2,4-triazole (CGA 71019)	1H-1,2,4-triazole	
Triazole alanine (CGA 131013)	3-(1H-1,2,4-triazol-1-yl)-DL-alanine	
Triazole lactic acid (CGA 205369)	(2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propanoic acid	
Triazole acetic acid (CGA 142856)	1H-1,2,4-triazol-1-ylacetic acid	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry
ha	hectare

HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient n-octanol/water
PROFile	(EFSA) Pesticide Residue Overview File
PRIMo	(EFSA) Pesticide Residues Intake Model
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
RA	risk assessment
RAC	raw agricultural commodity
RMS	rapporteur Member State
RSD	relative standard deviation
SEU	Southern European Union
TDM	triazole derivative metabolite
TRR	total radioactive residue
WHO	World Health Organization