REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for propiconazole in citrus fruits[1]

European Food Safety Authority[2,]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Spain, herewith referred to as the evaluating Member State (EMS), received an application from Makhteshim Agan España S.A. to modify the existing MRL for the active substance propiconazole in citrus fruits. In order to accommodate for the intended post-harvest use of propiconazole, the EMS proposed to raise the existing MRL in citrus fruit from the limit of quantification (0.05 mg/kg) to 5 mg/kg. According to EFSA the data are sufficient and according to the OECD methodology a MRL proposal of 6 mg/kg is derived for propiconazole in citrus fruits. The existing EU MRLs for propiconazole in food commodities of animal origin need to be modified for ruminant kidney, fat and meat reflecting the feed intake of citrus pomace. For ruminant liver and milk the existing MRLs do not have to be modified. Based on the risk assessment results, EFSA concludes that the intended use of propiconazole on citrus fruits and residues in ruminant meat, fat and kidney will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

KEY WORDS

Propiconazole, citrus fruits, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, chemical group, triazole fungicide.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005[3], Spain, herewith referred to as the evaluating Member State (EMS), received an application from Makhteshim Agan España S.A. to modify the existing MRL for the active substance propiconazole in citrus fruits. In order to accommodate for the intended post-harvest use of propiconazole, the EMS proposed to raise the existing MRL in citrus fruit from the limit of quantification (0.05 mg/kg) to 5 mg/kg. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 24 May 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared by the rapporteur Member State (RMS) Finland under Council Directive 91/414/EEC[4], the Commission Review Report on propiconazole as well as the previous reasoned opinions on propiconazole.

The toxicological profile of propiconazole was assessed under the peer review and the data were sufficient to conclude on an ADI value of 0.04 mg/kg bw per day and an ARfD value of 0.3 mg/kg bw.

The peer review concluded that the metabolism of propiconazole was sufficiently elucidated in primary crops and supported the residue definition for risk assessment and monitoring as parent compound. However, as propiconazole, similarly to other active substances belonging to the triazole class, when applied to plant is known to produce the degradation/metabolism products named triazole derivative metabolites (TDMs), EFSA is of the opinion that the residue definition may require to be revised pending the decision on the risk assessment methodology for all substances of the triazole chemical group. Nevertheless, as TDMs were mainly detected in the metabolism studies conducted on oilseeds and cereals with the triazole labelled propiconazole, the occurrence of TDMs in citrus fruits after post-harvest treatment is of a low relevance. Specific metabolism studies investigating the nature of propiconazole in post-harvest treatments are not available. Given the results of the available metabolism studies conducted with short PHI intervals where parent propiconazole was the main residue, a more extensive metabolism of propiconazole is unlikely in post-harvest treatment of citrus fruits. However, the need for an additional metabolism study with post-harvest application might be reconsidered in the framework of Article 12 of Regulation (EC) No 396/2005.

EFSA concludes that the submitted supervised residue trials are sufficient and according to the OECD methodology a MRL proposal of 6 mg/kg is derived for propiconazole in citrus fruits. For the supervised residue trials a minor deficiency was identified regarding the lack of storage stability data. Although studies are available to demonstrate that propiconazole residues are stable in high oil content matrices and dry matrices, the stability of residues should be also demonstrated for acidic matrices. Adequate analytical enforcement methods are available to control propiconazole residues in the crops under consideration.

A hydrolysis study simulating conditions of pasteurisation baking/brewing/boiling and sterilisation was not performed with propiconazole. The peer review did not derive specific risk assessment and enforcement residue definitions for processed commodities. Specific studies investigating the effect of processing on the magnitude of propiconazole residues in orange juice and marmalade were provided in the framework of the current application; a peeling factor was also derived. However, as the nature of propiconazole residues is not fully investigated and since the possible occurrence of TDMs in processed products should be reconsidered, EFSA does not recommend the derived processing factors for orange juice and marmalade to be included in Annex VI of Regulation (EC) No 396/2005. Further investigations, such as the performance of a hydrolysis study, are recommended.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.
[4] Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

Since the intended use refers to the post-harvest treatment of citrus fruits, the possible occurrence of propiconazole residues in rotational crops was not investigated.

Citrus pomace can be used as a livestock feed and thus a potential carry-over of residues into food of animal origin was assessed. The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for meat and dairy ruminants and is driven by the new intended use on citrus fruits. The metabolism in livestock has been sufficiently addressed in the framework of the peer review in lactating goats and laying hens. The peer review derived the risk assessment and enforcement residue definition as parent propiconazole. The calculated dietary burdens and the results of the livestock feeding studies were used to assess the occurrence of propiconazole residues in food commodities of animal origin. EFSA concluded that the existing EU MRLs for propiconazole need to be modified for ruminant kidney, fat and meat reflecting the feed intake of citrus pomace. For ruminant liver and milk the existing MRLs do not have to be modified.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For the calculation of the chronic exposure EFSA used the median residue value, multiplied by the peeling factor of 0.01, as derived from the residue trials on oranges and mandarins; this input value was used also for other citrus fruits. For ruminant meat, fat and kidney the median residue as derived from the feeding studies was used as an input value. For several commodities the median residue values were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to citrus fruits (considering the peeling factor) and ruminant meat, fat and kidney assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials and in livestock feeding studies (for animal commodities).

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

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 5.9% of the ADI (UK toddler diet). The contribution of residues in citrus fruits to the total consumer exposure was low, being the highest for oranges (0.16% of the ADI for DE child diet). The individual contribution of residues in ruminant meat, fat and kidney to the total consumer exposure was below 0.2% of the ADI, being the highest for bovine meat (0.18% of the ADI (ES child diet)).

No acute consumer risk was identified in relation to the propiconazole residues in citrus fruits and in ruminant meat, fat and kidney. The calculated maximum exposure in percentage of the ARfD was the highest for oranges, accounting for 1%. The calculated exposure to residues from animal commodities was the highest for bovine and sheep meet (0.2% of the ARfD).

EFSA concludes that the intended use of propiconazole on citrus fruits and residues in ruminant meat, fat and kidney will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. The risk assessment of TDMs could not be performed. However, TDMs in citrus fruits following post-harvest treatment is of a low relevance.

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

Summary table

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Propiconazole				
0110010	Grapefruit	0.05*	6	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended post-harvest use. The storage stability of propiconazole residues in high acid content matrices has to be confirmed.
0110020	Oranges			
0110030	Lemons			
0110040	Limes			
0110050	Mandarins			
1012010 1013010 1014010	Meat of bovine, sheep, goat	0.01*	0.05*	The MRL proposals are sufficiently supported by data and no risk for consumers was identified.
1012020 1013020 1014020	Fat of bovine, sheep, goat	0.01*	0.05*	
1012040 1013040 1014040	Kidney of bovine, sheep, goat	0.01*	0.05*	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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BACKGROUND

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

Spain, hereafter referred to as the evaluating Member State (EMS), received an application from Makhteshim Agan Espana S.A.[5] to modify the existing MRL for the active substance propiconazole in citrus fruits. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 24 May 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00606 and the following subject:

Propiconazole - Application to modify the existing MRLs in citrus fruits.

Spain proposed to raise the existing MRL of propiconazole in citrus fruits from the limit of quantification (0.05 mg/kg) to 5 mg/kg.

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

TERMS OF REFERENCE

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

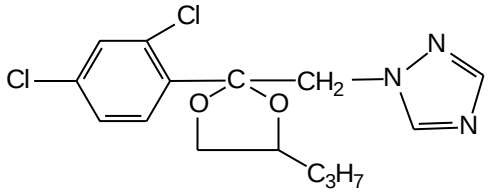
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests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

In this particular case the calculated deadline for providing the reasoned opinion is 24 August 2012.

[5] Makhteshim Agan Espana S.A., Aragonesas Agro,S.A., Paseo de Recoletos 16, 3a planta, 28001, Madrid, Spain

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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



Molecular weight: 342.2

Propiconazole is a systemic fungicide belonging to the chemical class of triazoles. It is a mixture of cis-trans isomers, 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, effectively preventing further infection and/or invasion of host tissues. The active substance is used against several fungal pathogens in a number of agricultural crops.

Propiconazole is an active substance for which Finland was designated as a rapporteur Member State (RMS). It has been peer reviewed under Council Directive 91/414/EEC and included in Annex I to this directive by the Commission Directive 2003/70/EC[6] for use as fungicide only. The representative uses assessed under the peer review of Council Directive 91/414/EEC include foliar applications to cereals, sugar beets, stone fruits and grass turf. Propiconazole was not peer reviewed by EFSA and thus no EFSA conclusion is 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 and wine grapes, apples, stone fruit (EFSA, 2010) and rice (EFSA, 2011) which were legally implemented in Regulations (EU) No 524/2011[7] and 270/2012[8], respectively. All existing EU MRLs, which are established for the parent compound only, are summarized in Appendix C of this reasoned opinion. The existing EU MRLs for propiconazole in citrus fruits are set at the LOQ of 0.05 mg/kg. Codex Alimentarius Commission (CAC) has established MRLs for propiconazole in a wide range of crops, but no CXLs are set for citrus fruits.

The details of the intended GAPs for post-harvest treatment of citrus fruits with propiconazole are given in Appendix A. According to the EMS, the GAP which involves drench treatment is considered as a critical GAP for which the raising of the existing MRL for propiconazole is required (Spain, 2012).

[6] Commission Directive 2003/70/EC of 17 July 2003. OJ L 184, 23.7.2003, p. 9-12.
[7] Regulation (EU) 524/2011 of 26 May 2011, OJ L 142, 28.5.2011, p. 1–56.
[8] Regulation (EU) 270/2012 of 26 March 2012, OJ L 89, 27.3.2012, p. 5-63.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Spain, 2012), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Finland, 1998, 2002), the Commission Review Report on propiconazole (EC, 2003), the JMPR Evaluation report (FAO, 2007) as well as the previous reasoned opinions on propiconazole (EFSA, 2010, 2011a). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of propiconazole residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (Finland, 1998) and have been also discussed in detail in the previously issued EFSA reasoned opinion (EFSA, 2010).

Adequate analytical multi-residue methods, based on HPLC-MS/MS principle, are available for the determination of propiconazole residues in high acid content matrices at a validated LOQ of 0.01 mg/kg (EFSA, 2010).

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

Analytical methods for the determination of propiconazole residues in food of animal origin were assessed during the peer review under Directive 91/414/EEC (Finland, 1998) and have been also discussed in detail in the previously issued EFSA reasoned opinion (EFSA, 2010).

The enforcement method is based on HPLC-MS/MS with the validated LOQ of 0.01 mg/kg for milk, tissues, organs and eggs. The GC-MS for the determination of propiconazole as 2,4-dichlorobenzoic acid (2.4-DCBA)[10] moiety was validated at LOQ of 0.01 mg/kg in milk and 0.05 mg/kg in tissues, organs and eggs (EFSA, 2010).

EFSA concludes that sufficiently validated analytical methods are available to control propiconazole residues with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs.

2. Mammalian toxicology

The toxicological profile of the propiconazole was assessed in the framework of the peer review under Directive 91/414/EEC (EC, 2003). The data were sufficient to derive toxicological reference values for propiconazole which are compiled in Table 2-1.

Metabolism studies in both mammalians and plants have shown that active substances belonging to the chemical class of triazoles are degraded/metabolized to common metabolites known as triazole derivative metabolites (TDMs), the major ones being the metabolites 1,2,4-triazole[11], triazole alanine[12], triazole lactic acid[13] and triazole acetic acid[14]. In 2007 the toxicological profile of TMDs was discussed by the experts in the EFSA Pesticide Risk Assessment Peer Review (PRAPeR Expert Meeting 14). The proposed toxicological reference values for the TDMs were finally published in the

[9] Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.
[10] 2,4-dichlorobenzoic acid. See Appendix D.
[11] 1H-[1,2,4]triazole. See Appendix D.
[12] 2–amino-3-[1,2,4]triazol-1-yl-propionic acid. See Appendix D.
[13] [1,2,4]triazol-1-yl-lactic acid. See Appendix D.
[14] [1,2,4]triazol-1-yl-acetic acid. See Appendix D.

EFSA conclusion on difenoconazole, another active substance belonging to the triazole class (EFSA, 2011b).

An overview of the 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 day	Rat, chronic toxicity study	100
ARfD	EC	2003	0.3 mg/kg bw	Rat, developmental study	100
Metabolites: 1,2,4-triazole and triazole acetic acid					
ADI	EFSA	2011	0.02 mg/kg bw per day	Rat, multigenerational study	1000
ARfD	EFSA	2011	0.06 mg/kg bw	Rat, developmental study	500
Metabolite: triazole alanine					
ADI	EFSA	2011	0.1 mg/kg bw per day	Rat, developmental study	1000
ARfD	EFSA	2011	0.1 mg/kg bw	Rat, developmental study	1000

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of propiconazole was investigated for foliar application on cereals (winter and spring wheat, rice), on fruits and fruiting vegetables (grapevines, tomatoes), on pulses and oilseeds (peanuts) in the framework of the peer review of Council Directive 91/414/EEC (Finland, 1998, 2002) and on leafy vegetables (celery) and root vegetables (carrots) by the JMPR (FAO, 2007), using ^{14}C-triazole and ^{14}C-phenyl labelled propiconazole and ^{14}C-triazole labeled 1,2,4 triazole. The information on study designs as well as discussion of results has been reported detail in the previously issued EFSA reasoned opinion (EFSA, 2010).

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

- Hydroxylation and oxidative decarboxylation of butyl side-chain leading eventually to deketalization. The various hydroxylated metabolites are conjugated with sugars.
- Hydrolysis of the dioxolane ring to form the ketone followed by reduction to the alkanol[15];
- Cleavage of the phenyl-triazole bridge to form free triazole which is further conjugated with endogenous serine to form triazole alanine and triazole acetic acid. A significant formation of TDMs was observed only in the metabolism studies with cereals and oilseeds.

The degradation of propiconazole was extensive. At harvest, the unchanged parent compound was present in all edible parts of the tested crops with the exception of winter wheat grains. Several non-polar metabolites were present and in most of the studies at amounts below 10% of the TRR. These metabolites were also observed in animal metabolism and were considered as not toxicologically

[15] 1-(2,4-dichlorophenyl)-2-(1,2,4)triazol-1-yl-ethanol. See Appendix D.

relevant. TDMs were detected in significant amounts in the metabolism studies conducted with the triazole labelling on oilseeds and cereals.

The peer review concluded that the metabolism of propiconazole was sufficiently elucidated in primary crops and supported the residue definition for risk assessment and monitoring as parent compound propiconazole (Finland, 1998, 2002). EFSA emphasizes that the above assessment did not take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment is performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available. The existing enforcement residue definition established in Regulation (EC) No 396/2005 is set as parent propiconazole only.

Specific metabolism studies investigating the nature of propiconazole in post-harvest treatments are not available. Given the results of the available metabolism studies conducted with short PHI intervals where parent propiconazole was the main residue, a more extensive metabolism of propiconazole is unlikely in post-harvest treatment of citrus fruits. However, the need for an additional metabolism study with post-harvest application might be reconsidered in the framework of Article 12 of Regulation (EC) No 396/2005.

Citrus fruits, for which MRL modifications are requested, do not belong to the pulses/oilseed and cereal groups, thus the occurrence of TDMs might be of minor relevance. EFSA concludes that for the post-harvest treatment of citrus fruit the residue definitions agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

The applicant submitted in total 8 GAP compliant residue trials on oranges (4 trials) and mandarins (4 trials). Trials were performed in Spain. The post-harvest treatment was performed by drenching of fruits for 20-30 seconds in a solution containing 60 g a.s./hL. Samples of fruits were analysed on the day of the treatment and 7, 14, 21 and 28 days after the treatment. The highest residue observed within a trial was used for deriving risk assessment values and the MRL proposal. In 1 trial the highest residue was observed on the day of a treatment, in 4 trials the highest residue was 14 DAT, and in 3 trials the highest residue was in a sample taken 28 DAT.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 3-1.

In the framework of the peer review the 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). In the addendum of the DAR a storage stability study was performed on a number of crops, although study details have not been reported. Results showed that residues of propiconazole determined as 2,4-dichlorobenzoic acid (DCBA) are stable in peaches, bananas, corn meal, wheat grain, peanut hay, peanut hulls, peanut nutmeat, celery and corn oil for a minimum of 36 months and in carrots for a minimum of 10 months of freezer storage (Finland, 2002).

The residue trial samples of oranges and mandarins prior to analysis were stored deep frozen for a period not exceeding 118 days (*ca*. 4 months). EFSA notes that storage stability studies have not been performed with high acid content commodities. However, taking into account that propiconazole is stable in high oil content matrices for at least 6 months, it is unlikely that significant degradation of propiconazole had occurred in citrus fruits for the 4 month storage interval. However, the need for adequate study investigating the storage stability of propiconazole in high acid content matrices will be considered in the framework of Article 12 of Regulation (EC) No 396/2005.

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

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Propiconazole)	**Risk assessment** (Propiconazole)					
Oranges, *mandarines* → grapefruit, limes, lemons	EU	Indoor	1.46[h]; 1.6[f]; 1.63[g]; 1.74[g]; *1.31[h]; 1.65[h]; 1.73[g]; 2.31[g]*	1.46[h]; 1.6[f]; 1.63[g]; 1.74[g]; *1.31[h]; 1.65[h]; 1.73[g]; 2.31[g]*	1.64	2.31	6.0	1.0	R_{ber}= 3.48 R_{max}= 2.61 MRL_{OECD} = 5.13/6.0

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).
(f) : Post treatment interval of 0 days.
(g): Post treatment interval of 14 days.
(h): Post treatment interval of 28 days

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, in the framework of the MRL application, two studies were assessed which investigated the stability of propiconazole in aqueous solutions at pH values ranging from 1 to 13 at elevated temperature of 70°C (EFSA, 2011). The incubation period was 28 days. No significant hydrolysis was observed under these conditions. In a subsequent study, the hydrolytic behaviour of propiconazole was tested at pH values 4, 5, 7 and 9 at a temperature of 50°C. Also under these conditions no significant degradation was found. Although these studies were not performed in accordance with the EU guidelines (EC, 1997d), they give some indications that the active substance is stable at least at temperatures up to 70°C. However, further studies performed in line with the EU guidelines are required to confirm the results of these two studies. Based on the preliminary information, it is assumed that for processed commodities the same enforcement residue definition is applicable as for unprocessed commodities, i.e. parent propiconazole.

The applicant has also investigated the magnitude of propiconazole residues in orange after processing of fruits into juice and marmalade. Oranges were treated according to the intended GAP and samples from the residue trials were taken for processing. Harvested fruit were washed prior to the processing. Residues of propiconazole were determined in pasteurized juice; marmalade was sterilised for 10 minutes. Results show reduction of residues in both processed commodities.

In all trials at two post-treatment intervals (7 and 28 days) the pulp and peel were analysed separately to determine a peeling factor. Residues in the whole fruit were within a range of 1.31 to 2.31 mg/kg, whereas residues in the pulp were significantly lower (below 0.01 mg/kg to 0.027 mg/kg), indicating no significant translocation of residue from peel to pulp. The median peeling factor for samples taken 7 DAT is 0.012 and the median peeling factor for samples taken 28 DAT is 0.009.

The derived processing factors and a peeling factor are compiled in Table 3-2.

Table 3-2: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: Propiconazole				
Oranges, pasteurized juice	4	0.013	1.0	
Oranges, marmalade	4	0.48	1.0	
Oranges, peeled	4	0.01	1.0	The median peeling factor for samples taken 7 DAT is 0.012 and the median peeling factor for samples taken 28 DAT is 0.009.

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

Since the nature of propiconazole residues is not fully investigated and since the possible occurrence of TDMs in processed products has to be reconsidered, EFSA does not recommend inclusion of the derived processing factors for juice and marmalade in Annex VI of Regulation (EC) No 396/2005. The peeling factor is applicable for the exposure assessment purposes.

3.1.2. Rotational crops

Since the proposed use of propiconazole refers to a post-harvest treatment, possible occurrence of propiconazole residues in rotational/succeeding crops was not further investigated.

3.2. Nature and magnitude of residues in livestock

Since citrus fruit pomace can be fed to livestock, the nature and magnitude of propiconazole residues in livestock was assessed in the framework of this application.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the latest FAO recommendations (FAO, 2009) considering the livestock intake from citrus fruit pomace and from all other feed products for which the existing EU MRL is set above the LOQ (apples, peanuts, oats and barley).

The dietary burden calculated in a previous EFSA reasoned opinion is now updated with the mean residue value for citrus fruits as observed in the submitted residue trials (Table 3-1) and expressed as citrus pomace by applying a default processing factor of 2.5. For other feed commodities the input values were as reported in the previous EFSA reasoned opinion (EFSA, 2010).

The input values for the dietary burden calculation are summarised in Table 3-3.

Table 3-3: 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				
Citrus pomace	4.1	Median residue*PF (Table 3-1)	4.1	Median residue*PF (Table 3-1)
Apple pomace (wet)	0.0925	Median residue *PF (EFSA, 2010)	0.0925	Median residue *PF (EFSA, 2010)
Barley and oat, grain	0.03	Median residue (EFSA, 2010)	0.03	Median residue (EFSA, 2010)
Barley and oat, straw	0.28	Median residue (EFSA, 2010)	1.03	Highest residue (EFSA, 2010)
Peanuts	0.07	Median residue (EFSA, 2010)	0.07	Median residue (EFSA, 2010)
Peanut meal	0.14	Median residue (EFSA, 2010)	0.14	Median residue (EFSA, 2010)

In order to estimate the contribution of propiconazole residues in citrus fruits to the total livestock dietary exposure, EFSA performed two dietary burden calculations: in scenario 1 citrus fruit pomace was excluded from the calculation (Table 3-4), while in scenario 2 citrus fruit pomace was included in the dietary burden calculation (Table 3-5).

The results of the dietary burden calculation are summarised in the following tables:

Table 3-4: Results of the dietary burden calculation **(excluding citrus pomace)**

	Maximum dietary burden (mg/kg bw per day)	**Median dietary burden** (mg/kg bw per day)	**Highest contributing commodity**[(a)]	**Max dietary burden** (mg/kg DM)	**Trigger exceeded** (Y/N)
Risk assessment residue definition: Propiconazole					
Dairy ruminants	0.012	0.006	Barley straw	0.34	Y
Meat ruminants	0.032	0.014	Barley straw	0.75	Y
Poultry	0.003	0.003	Barley grain	0.04	N
Pigs	0.002	0.002	Peanut meal	0.06	N

(a): Calculated for the maximum dietary burden

Table 3-5: Results of the dietary burden calculation **(including citrus pomace)**

	Maximum dietary burden (mg/kg bw per day)	**Median dietary burden** (mg/kg bw per day)	**Highest contributing commodity**[(a)]	**Max dietary burden** (mg/kg DM)	**Trigger exceeded** (Y/N)
Risk assessment residue definition: Propiconazole					
Dairy ruminants	0.076	0.069	Orange pomace	2.11	Y
Meat ruminants	0.256	0.237	Orange pomace	5.96	Y
Poultry	0.003	0.003	Barley grain	0.04	N
Pigs	0.002	0.002	Peanut meal	0.06	N

(a): Calculated for the maximum dietary burden

The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for meat and dairy ruminants and the dietary burden is driven by the new intended use on citrus fruits. Consequently, the carry-over of propiconazole residues into food commodities of animal origin has to be further investigated.

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 the 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 3-6.

Table 3-6: Summary of available metabolism studies in livestock

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Comments**
				Rate (mg/kg bw per day)	**Duration (days)**	**Commodity**	**Time**	
Lactating ruminants	Goat	^{14}C-triazole	1	0.13	10	Milk	Twice daily	Study I
						Urine and faeces	Daily	
						Tissues	At sacrifice	

Group	Species	Label position	No of animal	Application details		Sample details		Comments
				Rate (mg/kg bw per day)	Duration (days)	Commodity	Time	
		^{14}C-phenyl	2	3.08-3.11	4	Milk	Daily	Study II
						Urine and faeces	Daily	
						Tissues	At sacrifice	
		^{14}C-triazole	2	1.12 – 1.15	7	Milk	Twice daily	Study III
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying hen	Hens	^{14}C-phenyl ^{14}C-triazole	2(a)	2.98 – 3.16	16	Eggs	Daily	Study I
						Excreta	Daily	
						Tissues	At sacrifice	
		^{14}C-phenyl	4	5.35 – 6.58	8	Eggs	Daily	Study II
						Excreta	Daily	
						Tissues	At sacrifice	

(a): One animal per label.

Lactating goats

Goats were dosed with 0.13 – 1.15 mg/kg bw per day of ^{14}C-triazole labelled propiconazole and 3.1 mg/kg bw per day of ^{14}C-phenyl labelled propiconazole. Studies demonstrate that most of the administered radioactivity was eliminated in urine (up to 69% TRR) and faeces (up to 39% TRR). Tissues and milk exhibited low levels of ^{14}C-residues.

Study I. Low accumulation of radioactivity was observed in milk (0.18%), or tissues (0.04%). Radioactivity in milk reached plateau on the 6th day of dosing at an average level of 0.015 mg eq./kg. The TRR in tissues was <0.02 mg eq./kg, except for kidney (0.029 mg eq./kg) and liver (0.096 mg eq./kg). Main metabolites in milk were 1,2,4-triazole (39% TRR) and CGA-91304[16](13-16% TRR).

Study II. The average amount of the radioactivity was the highest in liver (3.83 mg eq./kg) and kidney (2.53 mg eq./kg), with lower levels present in muscle and fat (0.08 mg/eq./kg). The radioactivity in milk increased during the 4 day dosing period and on the last day accounted for 0.22 mg eq./kg. Parent propiconazole at levels exceeding 10% TRR was identified only in liver and fat (12.4% and 19.9%, respectively). Metabolites CGA-118244[17] and alkanol CGA-91305[18] accounted for 18.6% and 14.1% in liver, 8.8% and 17.3% in kidney, 15.7% and 35.5% in muscle, 33.4% and 30.7% in fat and 23.8% and 24.4% in milk, respectively.

Study III. The highest average amount of the radioactivity was found in liver (0.645 mg eq./kg) and kidney (0.282 mg eq./kg), while fat and muscle contained the lowest levels of TRR (0.088 and 0.022 mg eq./kg, respectively). In milk the average plateau concentration (0.125-0.149 mg eq./kg) was reached on day 4th of dosing. The main residues (above 10% TRR) were propiconazole in fat (17.9% TRR), alkanol CGA-91305 in liver (16.1%), kidney (16.6%) and fat (16.4%) and 1,2,4-triazole in kidney (22.6%), muscle (58.6%), fat (17.2%) and milk (65.8%).

[16] CGA-91304: ketone. See Appendix D.
[17] CGA 118244: β-hydroxy alcohol. See Appendix D
[18] CGA-91305: alkanol. See Appendix D

Laying hens

Hens were dosed with 3.16 mg/kg bw/d of ^{14}C-triazole labelled propiconazole and 2.98 – 6.58 mg/kg bw per day of ^{14}C-phenyl labelled propiconazole. Studies demonstrate that most of the administered radioactivity (>94% TRR) was eliminated in excreta. Tissues, eggs and milk exhibited low levels of ^{14}C-residues. In hens, highest levels of radioactivity were found in liver and kidney (4.2 and 3.9 mg eq/kg, respectively; high dose). In eggs, no plateau was reached (1.2 and 1.7 mg eq./kg with the low and high doses, respectively). Propiconazole is only found in significant amounts in hen skin/fat (40% TRR) and eggs (12% TRR in yolk, 28% TRR in white). 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) and β-hydroxy alcohol CGA-118244 (52% TRR in egg white).

The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. The metabolites containing the dichlorophenyl-moiety were also found in rodents. Thus, they are considered not to be of greater toxicity than the parent propiconazole. The peer review concluded that the enforcement and risk assessment residue definition in livestock should be set as parent propiconazole. However, since significant amounts of other propiconazole metabolites containing 2,4-dichlorobenzoic acid moiety were identified in animal matrices, EFSA recommends that the residue definition for risk assessment is reconsidered in the framework of Article 12 of Regulation (EC) NO 396/2005.

Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.2). Although the log $P_{o/w}$ of propiconazole is higher than 3, the feeding studies did not give an indication that an accumulation in fat would occur.

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 per day). Three groups of laying hens, each consisting of fifteen 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 per day). The samples were analyzed for parent propiconazole and for total residues containing the 2,4-DCBA moiety and results were reported separately. Results of livestock feeding studies are summarized in Table 3-7. In milk a plateau level was reached after 14 days of exposure.

For deriving the risk assessment values and the MRL proposals, EFSA considered the residue data reported for parent propiconazole only, since currently the existing risk assessment and enforcement residue definitions are set as parent propiconazole. In case the risk assessment residue definition will be modified under Article 12 of Regulation (EC) NO 396/2005, the risk assessment values would have to be recalculated.

The MRLs were derived according to the FAO recommendations (FAO, 2009) and are summarized in Table 3-7.

For poultry and pigs the dietary burden was not triggered (Table 3-5) and thus the magnitude of residues in food commodities of poultry and pig was not further investigated.

According to the feeding studies, residues above the LOQ of 0.05 mg/kg are not expected in ruminant kidney, fat, and muscle; in milk residues are not expected above the LOQ of 0.01 mg/kg, considering the calculated dietary burdens (Table 3-5). The existing MRLs for ruminant meat, fat and kidney are set at the default LOQ of 0.01 mg/kg. Thus, a revision of the LOQ MRLs should be considered for these commodities taking into account the LOQ of the feeding study. In liver, residues above the LOQ

are expected and a MRL proposal of 0.1 mg/kg was derived. However, according to Regulation (EC) No 396/2005, the existing MRL in liver is already established at 0.1 mg/kg and in milk at the LOQ of 0.01 mg/kg. Thus, no modification of the existing MRLs for propiconazole is proposed for ruminant liver and milk.

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. The storage conditions of the samples from the livestock feeding studies are not available. Considering that storage stability in eggs, fat and muscle was only demonstrated for 5 to 9.5 months, this information would be desirable in order to confirm the validity of the reported livestock feeding studies. Degradation of residues during storage of other tissues samples is not expected.

Table 3-7: 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 day)	Max. (mg/kg bw per day)	Dose Level (mg/kg bw/d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: propiconazole **Risk assessment residue definition:** propiconazole												
Ruminant meat	0.237	0.256	0.59	3	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.05*	1.0
			2.95	3	<0.05	<0.05	<0.05	<0.05				
			6.10	3	<0.05	<0.05	<0.05	<0.05				
Ruminant fat	0.237	0.256	0.59	3	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.05*	1.0
			2.95	3	<0.05	<0.05	<0.05	<0.05				
			6.10	3	0.06	0.08	0.06	0.08				
Ruminant liver	0.237	0.256	0.59	3	0.08	0.14	0.08	0.14	0.03	0.06	0.1	1.0
			2.95	3	0.22	0.34	0.22	0.34				
			6.10	3	0.42	0.66	0.42	0.66				
Ruminant kidney	0.237	0.256	0.59	3	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.05*	1.0
			2.95	3	<0.05	<0.05	<0.05	<0.05				
			6.10	3	<0.05	<0.05	<0.05	<0.05				
Milk	0.07	0.08	0.59	12	<0.01[(d)]	n.a.	<0.01[(d)]	n.a.	<0.01	<0.01	0.01*	1.0
			2.95	12	<0.01[(d)]	n.a.	<0.01[(d)]	n.a.				
			6.10	12	<0.01[(d)]	n.a.	<0.01[(d)]	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 (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.
(F): MRL is expressed as mg/kg of fat contained in the whole product.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population [19] (EFSA, 2007b).

For the calculation of the chronic exposure, EFSA used the median residue value, multiplied by the peeling factor of 0.01, as derived from the residue trials on oranges and mandarins (see Tables 3-1 and 3-2); this input value was used also for other citrus fruits. For ruminant meat, fat and kidney the median residue (LOQ) as derived from the feeding studies (Table 3-7) was used as an input value. For several commodities the median residue values as reported in previously issued EFSA reasoned opinions were available to refine the exposure calculation (EFSA, 2010, 2011). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

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

The acute exposure assessment was performed only with regard to citrus fruits and ruminant meat, fat and kidney assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials and in livestock feeding studies (for animal commodities). The peeling factor of 0.01 was applied to account for residues in citrus fruit pulp. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007b).

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Propiconazole				
Oranges, mandarins, limes, lemons, grapefruit	0.016	Median residue (1.64)*peeling factor (0.01) (Tables 3-1, 3-2)	0.02	Highest residue (2.31)* peeling factor (0.01) (Tables 3-1, 3-2)
Fat, muscle, kidney of bovine, sheep and goat	0.05	Median residue (LOQ) (Table 3-7)	0.05	Highest residue (LOQ) (Table 3-7)
Apples	0.04	Median residue (EFSA, 2010)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Table grapes and wine grapes	0.04	Median residue (EFSA, 2010)		
Apricots, peaches	0.02	Median residue (EFSA, 2010)		

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rice	0.26	Median residue (EFSA, 2011)		
Other commodities of plant and animal origin	MRL	See Appendix C		

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

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 5.9% of the ADI (UK toddler diet). The contribution of residues in citrus fruits to the total consumer exposure was low, being the highest for oranges (0.16% of the ADI for DE child diet). The individual contribution of residues in ruminant meat, fat and kidney to the total consumer exposure was below 0.2% of the ADI, being the highest for bovine meat (0.18% of the ADI (ES child diet)).

No acute consumer risk was identified in relation to the propiconazole residues in citrus fruits and in ruminant meat, fat and kidney. The calculated maximum exposure in percentage of the ARfD was the highest for oranges, accounting for 1%. The calculated exposure to residues from animal commodities was the highest for bovine and sheep meet (0.2% of the ARfD).

EFSA concludes that the intended use of propiconazole on citrus fruits will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. The risk assessment for TDMs is postponed. However, TDMs in citrus (following post-harvest treatment) is of low relevance.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of propiconazole was assessed under the peer review and the data were sufficient to conclude on an ADI value of 0.04 mg/kg bw per day and an ARfD value of 0.3 mg/kg bw.

The peer review concluded that the metabolism of propiconazole was sufficiently elucidated in primary crops and supported the residue definition for risk assessment and monitoring as parent compound. However, as propiconazole, similarly to other active substances belonging to the triazole class, when applied to plant is known to produce the degradation/metabolism products named triazole derivative metabolites (TDMs), EFSA is of the opinion that the residue definition may require to be revised pending the decision on the risk assessment methodology for all substances of the triazole chemical group. Nevertheless, as TDMs were mainly detected in the metabolism studies conducted on oilseeds and cereals with the triazole labelled propiconazole, the occurrence of TDMs in citrus fruits after post-harvest treatment is of a low relevance. Specific metabolism studies investigating the nature of propiconazole in post-harvest treatments are not available. Given the results of the available metabolism studies conducted with short PHI intervals where parent propiconazole was the main residue, a more extensive metabolism of propiconazole is unlikely in post-harvest treatment of citrus fruits. However, the need for an additional metabolism study with post-harvest application might be reconsidered in the framework of Article 12 of Regulation (EC) No 396/2005.

EFSA concludes that the submitted supervised residue trials are sufficient and according to the OECD methodology a MRL proposal of 6 mg/kg is derived for propiconazole in citrus fruits. For the supervised residue trials a minor deficiency was identified regarding the lack of storage stability data. Although studies are available to demonstrate that propiconazole residues are stable in high oil content matrices and dry matrices, the stability of residues should be also demonstrated for acidic matrices. Adequate analytical enforcement methods are available to control propiconazole residues in the crops under consideration.

A hydrolysis study simulating conditions of pasteurisation baking/brewing/boiling and sterilisation was not performed with propiconazole. The peer review did not derive specific risk assessment and enforcement residue definitions for processed commodities. Specific studies investigating the effect of processing on the magnitude of propiconazole residues in orange juice and marmalade were provided in the framework of the current application; a peeling factor was also derived. However, as the nature of propiconazole residues is not fully investigated and since the possible occurrence of TDMs in processed products should be reconsidered, EFSA does not recommend the derived processing factors for orange juice and marmalade to be included in Annex VI of Regulation (EC) No 396/2005. Further investigations, such as the performance of a hydrolysis study, are recommended.

Since the intended use refers to the post-harvest treatment of citrus fruits, the possible occurrence of propiconazole residues in rotational crops was not investigated.

Citrus pomace can be used as a livestock feed and thus a potential carry-over of residues into food of animal origin was assessed. The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for meat and dairy ruminants and is driven by the new intended use on citrus fruits. The metabolism in livestock has been sufficiently addressed in the framework of the peer review in lactating goats and laying hens. The peer review derived the risk assessment and enforcement residue definition as parent propiconazole. The calculated dietary burdens and the results of the livestock feeding studies were used to assess the occurrence of propiconazole residues in food commodities of animal origin. EFSA concluded that the existing EU MRLs for propiconazole need to be modified for ruminant kidney, fat and meat reflecting the feed intake of citrus pomace. For ruminant liver and milk the existing MRLs do not have to be modified.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For the calculation of the chronic exposure EFSA used the median residue value, multiplied by the peeling factor of 0.01, as derived from the residue trials on oranges and mandarins; this input value was used also for other citrus fruits. For ruminant meat, fat and kidney the median residue as derived from the feeding studies was used as an input value. For several commodities the median residue values were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to citrus fruits (considering the peeling factor) and ruminant meat, fat and kidney assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials and in livestock feeding studies (for animal commodities).

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

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 5.9% of the ADI (UK toddler diet). The contribution of residues in citrus fruits to the total consumer exposure was low, being the highest for oranges (0.16% of the ADI for DE child diet). The individual contribution of residues in ruminant meat, fat and kidney to the total consumer exposure was below 0.2% of the ADI, being the highest for bovine meat (0.18% of the ADI (ES child diet)).

No acute consumer risk was identified in relation to the propiconazole residues in citrus fruits and in ruminant meat, fat and kidney. The calculated maximum exposure in percentage of the ARfD was the highest for oranges, accounting for 1%. The calculated exposure to residues from animal commodities was the highest for bovine and sheep meet (0.2% of the ARfD).

EFSA concludes that the intended use of propiconazole on citrus fruits and residues in ruminant meat, fat and kidney will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition : Propiconazole				
0110010	Grapefruit	0.05*	6	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended post-harvest use. The storage stability of propiconazole residues in high acid content matrices has to be confirmed.
0110020	Oranges			
0110030	Lemons			
0110040	Limes			
0110050	Mandarins			
1012010 1013010 1014010	Meat of bovine, sheep, goat	0.01*	0.05*	The MRL proposals are sufficiently supported by data and no risk for consumers was identified.
1012020 1013020 1014020	Fat of bovine, sheep, goat	0.01*	0.05*	
1012040 1013040 1014040	Kidney of bovine, sheep, goat	0.01*	0.05*	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled ©	Formulation type (d – f)	Formulation conc. Of a.s. (i)	Application method kind (f – h)	Application growth stage & season (j)	Application number min max (k)	Application interval min max	Application rate per treatment kg as/hL max	Application rate per treatment water L/t min max	Application rate per treatment kg a.s./ha min max	PHI (days) (l)	Remarks (m)
Citrus	SPAIN	I	*Penicillium sp, Geotrichum candidum spp*	EC	100 g/L	Drencher	-	1	-	0.06	7 L water/t of fruit	4.2 g a.s./t of fruit	n.a	**Critical GAP.** Maintaining the treatment for 30 seconds using about 40 tons of fruit per 1.000 litres of broth 0.6% product
Citrus	SPAIN	I	*Penicillium sp, Geotrichum candidum spp*	EC	100 g/L	Overhead spray	-	1	-	0.09 – 0.12	1.5 L water/t of fruit	1.35 – 1.8 g a.s./t of fruit	n.a.	0.9 – 1.2% product

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

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Propiconazole			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		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**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 6
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)
5.9	UK Toddler	2.9	Sugar beet (root)	0.5	Milk and cream,	0.5	Wheat	
5.6	WHO Cluster diet B	1.1	Wheat	0.4	Tomatoes	0.3	Rice	
5.2	NL child	0.7	Potatoes	0.7	Milk and cream,	0.6	Apples	
4.9	UK Infant	1.3	Sugar beet (root)	1.0	Milk and cream,	0.4	Rice	
4.8	IE adult	0.6	Barley	0.4	Sweet potatoes	0.3	Maize	
4.7	DE child	1.2	Apples	0.5	Wheat	0.4	Bananas	
4.4	FR toddler	1.0	Milk and cream,	0.6	Potatoes	0.3	Wheat	
3.7	WHO cluster diet E	0.5	Wheat	0.5	Potatoes	0.4	Barley	
3.5	DK child	0.7	Wheat	0.6	Rye	0.3	Milk and cream,	
3.3	WHO cluster diet D	0.8	Wheat	0.5	Potatoes	0.4	Rice	
3.1	WHO Cluster diet F	0.5	Wheat	0.4	Potatoes	0.3	Barley	
3.0	ES child	0.6	Wheat	0.3	Rice	0.3	Milk and cream,	
3.0	SE general population 90th percentile	0.5	Potatoes	0.5	Bananas	0.4	Wheat	
3.0	PT General population	0.7	Potatoes	0.5	Rice	0.5	Wheat	
2.9	FR infant	0.6	Milk and cream,	0.5	Potatoes	0.3	Carrots	
2.8	WHO regional European diet	0.5	Potatoes	0.4	Wheat	0.2	Barley	
2.3	NL general	0.3	Potatoes	0.3	Wheat	0.2	Barley	
2.1	IT kids/toddler	0.8	Wheat	0.2	Other cereal	0.2	Tomatoes	
2.0	UK vegetarian	0.5	Sugar beet (root)	0.3	Wheat	0.2	Rice	
2.0	ES adult	0.3	Wheat	0.2	Barley	0.2	Rice	
1.9	FR all population	0.4	Wheat	0.4	Wine grapes	0.1	Potatoes	
1.8	UK Adult	0.5	Sugar beet (root)	0.2	Rice	0.2	Wheat	
1.6	LT adult	0.4	Potatoes	0.2	Apples	0.1	Rice	
1.5	IT adult	0.5	Wheat	0.1	Tomatoes	0.1	Rice	
1.5	DK adult	0.3	Wheat	0.2	Potatoes	0.1	Wine grapes	
1.2	PL general population	0.4	Potatoes	0.2	Apples	0.1	Tomatoes	
1.1	FI adult	0.2	Potatoes	0.1	Milk and cream,	0.1	Wheat	

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)
1.0	Oranges	0.0231 / -	0.7	Oranges	0.0231 / -	0.2	Oranges	0.0231 / -	0.2	Oranges	0.0231 / -
0.7	Grapefruit	0.0231 / -	0.7	Grapefruit	0.0231 / -	0.2	Grapefruit	0.0231 / -	0.1	Grapefruit	0.0231 / -
0.4	Mandarins	0.0231 / -	0.3	Mandarins	0.0231 / -	0.1	Mandarins	0.0231 / -	0.1	Bovine: Meat	0.05 / -
0.3	Lemons	0.0231 / -	0.2	Bovine: Meat	0.05 / -	0.1	Bovine: Meat	0.05 / -	0.1	Mandarins	0.0231 / -
0.2	Bovine: Meat	0.05 / -	0.2	Lemons	0.0231 / -	0.1	Sheep: Meat	0.05 / -	0.1	Sheep: Meat	0.05 / -
0.2	Sheep: Meat	0.05 / -	0.2	Sheep: Meat	0.05 / -	0.1	Lemons	0.0231 / -	0.0	Lemons	0.0231 / -
0.2	Limes	0.0231 / -	0.1	Limes	0.0231 / -	0.0	Limes	0.0231 / -	0.0	Limes	0.0231 / -
0.1	Bovine: Kidney	0.05 / -	0.1	Bovine: Kidney	0.05 / -	0.0	Bovine: Kidney	0.05 / -	0.0	Bovine: Kidney	0.05 / -
0.0	Bovine: Fat	0.05 / -	0.0	Bovine: Fat	0.05 / -	0.0	Goat: Meat	0.05 / -	0.0	Goat: Meat	0.05 / -
0.0	Other citrus fruit	0.0231 / -	0.0	Other citrus fruit	0.0231 / -	0.0	Bovine: Fat	0.05 / -	0.0	Bovine: Fat	0.05 / -

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)
1.3	Orange juice	0.078 / -	0.3	Orange juice	0.078 / -

*) 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.

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides – Web Version – EU MRLs (File created on 28/11/2012 15:46)

Code number	Groups and examples of individual products to which the MRLs apply	Propiconazole
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	
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, 30rench30ra)	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	© 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 (30rench30ranean 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	© 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	© 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	© Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Propiconazole
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	© 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,	0,05*
	sorrel, glassworth)	
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	© 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 (31rench 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	© 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*
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*

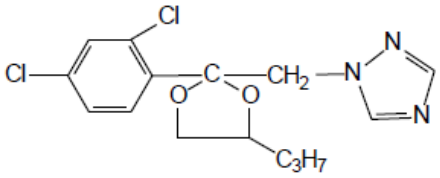
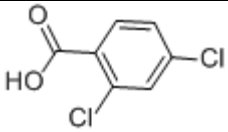
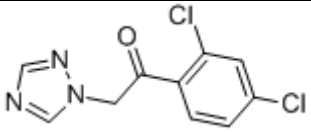
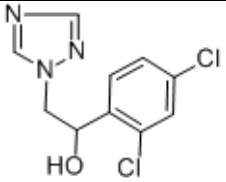
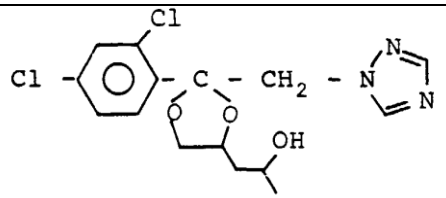
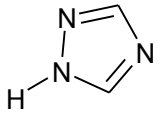
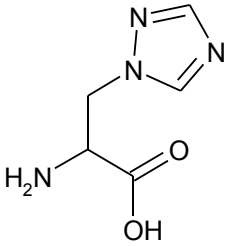
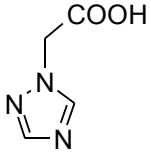
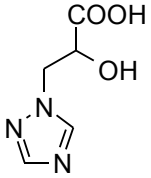
Code number	Groups and examples of individual products to which the MRLs apply	Propiconazole
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	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*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Propiconazole
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	0,01*
1012020	Fat	0,01*
1012030	Liver	0,1
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	© Sheep	
1013010	Meat	0,01*
1013020	Fat	0,01*
1013030	Liver	0,1
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Propiconazole
1014000	(d) Goat	
1014010	Meat	0,01*
1014020	Fat	0,01*
1014030	Liver	0,1
1014040	Kidney	0,01*
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*
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	
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 lower limit of analytical determination

D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structure
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 (CAS number 50-84-0)	
Ketone (CGA-91304)	1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)ethanone (CAS number 58905-16-1)	
Alkanol (CGA-91305)	1-(2,4-dichlorophenyl)-2-(1,2,4)triazol-1-yl-ethanol (CAS number 58905-18-3)	
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	
Triazole derivative metabolites		
1,2,4-triazole	1*H*-1,2,4-triazole (free triazole) (CAS number 288-88-0)	
Triazole alanine	(RS)-2-amino-3-(1*H*-1,2,4 triazol-1-yl)propanoic acid or 3-(1*H*-1,2,4-triazol-1-yl)-D,L-alanine (CAS number 86362-20-1)	
Triazole acetic acid	1*H*-1,2,4-triazol-1-ylacetic acid (CAS number 28711-29-7)	
Triazole lactic acid or Triazole hydroxy propionic acid	(R,S)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid	

ABBREVIATIONS

ADI	acceptable daily intake
ArfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DAT	days after treatment
DE	Germany
DM	dry matter
EC	European Community
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ES	Spain
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level

MS	Member States
MS/MS	tandem mass spectrometry
MSD	mass spectrometry detector
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
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
RD	residue definition
RMS	rapporteur Member State
TDM	triazole derivative metabolites
TRR	total radioactive residues
UK	The United Kingdom
WHO	World Health Organisation