European Food Safety Authority

EFSA Scientific Report (2009) 230, 1-25

REASONED OPINION OF EFSA

Modification of the existing MRL for tetraconazole in apricots[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-740)

Issued on 22 January 2009

SUMMARY

Spain received an application from ISAGRO S.P.A. to modify the existing MRL for tetraconazole in apricots. Spain as an Evaluating Member State (EMS) drafted an Evaluation Report which was forwarded to the European Commission and to EFSA.

The current EC MRL for tetraconazole in apricots is set at the limit of quantification (0.02 mg/kg) and the applicant proposed the raising of the MRL to 0.1 mg/kg as an extrapolation from peaches to support the intended GAP in Spain.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the EFSA conclusion prepared in the framework of the peer review:

The toxicological profile of the active substance was investigated under the peer review and data were sufficient to conclude on an ADI value of 0.04 mg/kg bw/d and an ARfD value of 0.05 mg/kg bw/day.

The metabolism of tetraconazole has been assessed in the framework of the peer review in wheat, sugar beet and grapes. In grapes the main terminal residue is parent tetraconazole. In cereal grain and beet leaves the metabolism studies identified formation of triazole derivative metabolites (triazole alanine, triazole acetic acid and triazole hydroxypropionic acid) in much higher amounts than tetraconazole. Based on the studies a residue definition including tetraconazole and triazole derivative metabolites (triazole alanine, triazole acetic acid) has been provisionally established. A final residue definition for risk assessment in plant commodities is pending the clarification on the toxicological properties of metabolite triazole hydroxypropionic acid. The residue definition for monitoring has been provisionally proposed as tetraconazole only. Pending finalisation of the risk assessment on triazole compounds and the triazole derivative metabolites these metabolites may also need to be monitored in the future if included in the residue definition.

Pending the toxicological evaluation of the triazole metabolites and considering that the metabolism studies did not identify triazole derivative metabolites in fruits, it is proposed in

[1] For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit on the modification of the existing MRL for tetraconazole in apricots. *EFSA Scientific Report* (2009) 230, 1-25.

the framework of this application to define the relevant residue in apricots as tetraconazole based on the grape metabolism study.

In support of the intended GAP Spain submitted supervised field trials on peaches. From that an extrapolation to apricots is possible. To cover the intended GAP on apricots the MRL of 0.1 mg/kg is necessary.

Adequate analytical enforcement methods are available for the determination of tetraconazole residues in apricots.

The consumer intake calculations were performed using the EFSA PRIMo rev.2. The existing MRLs as established for in Annex III of the Regulation (EC) 396/2005 and the STMR value of 0.04 mg/kg for apricots as derived from the supervised field trials were used as input values. In addition, for several commodities STMR values as derived during the setting of temporary MRLs for tetraconazole are available and they were used as an input values in the chronic consumer intake calculations.

The chronic consumer intake assessment did not identify chronic intake concerns. The calculated theoretical maximum daily intake value ranged from 14.2 to 86.6 % of the ADI. The contribution of apricots in the dietary exposure is insignificant (below 0.4 % of the ADI).

The acute consumer intake assessment did not identify acute intake concerns since the IESTI is 5.6% of the ARfD.

It is concluded that the MRL proposal of 0.1 mg/kg for tetraconazole in apricots is acceptable with regard to consumer safety.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Apricots	0.02*	0.1	No consumer intake concerns are associated with the proposed MRL of 0.1 mg/kg for tetraconazole in apricots.

(*): Indicates that the MRL is set at the limit of analytical quantification.

Key words: Tetraconazole, apricots, MRL application, Regulation (EC) No 396/2005, triazole

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Chapter II of the regulation, dealing with the procedure to set new MRLs or to amend existing MRLs, entered into force on 2 September 2008.

According to Article 6(2) of Regulation (EC) 396/2005, Spain as an Evaluating Member State (EMS) received an application from ISAGRO S.P.A.[2] on the modification of the existing MRL for tetraconazole in apricots. On 6 October 2008, according to Article 9 of Regulation (EC) No 396/2005, the Evaluation Report prepared by the EMS on this subject was submitted to the European Commission and forwarded to EFSA.

After the receipt of the Evaluation Report, EFSA included the application in the EFSA Register of Questions with the number EFSA-Q-2008-740 with the following subject:

Tetraconazole – Application to modify the existing MRL for tetraconazole in apricots from 0.02 mg/kg to 0.1 mg/kg

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall assess MRL applications and the evaluation reports prepared by the responsible Member State and give a reasoned opinion on the risks to the consumer associated with the setting or modification of MRLs.

TERMS OF REFERENCE

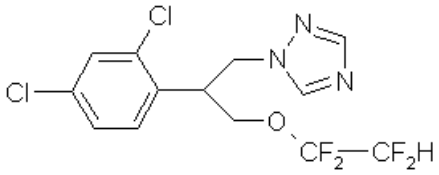
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State provide a reasoned opinion on the risks to the consumer and where relevant to the animals associated with the application. Particular attention shall be given to the requirements set out in that Article.

According to Article 11 of that Regulation (EC) No 396/2005, the reasoned opinion shall be provided as soon as possible and at the latest within three months from the data of receipt of the application. In this case the deadline for submission of the reasoned opinion is 6 January 2009.

[2] ISAGRO S.P.A., Via Caldera 21, 20153, Milan, Italy

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Tetraconazole is the ISO common name of (RS)-2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propyl-1,1,2,2-tetrafluoroethyl ether.



Tetraconazole belongs to the class of conazole fungicides alternatively classified as N-substituted triazole fungicides. It is a systemic fungicide with protectant, curative and eradicant properties. Tetraconazole belongs to the Sterol Biosynthesis Inhibitors (SBI) group; it acts by inhibiting the metabolic pathway leading to fungal sterol production by blocking the lanosterol demethylation reaction.

Tetraconazole is used in agriculture, viticulture, horticulture, home gardening to control a range of fungal diseases.

On apricots it is used to control *Monilinia fructigena* and *Cladosporium carpophilum*.

The peer review of tetraconazole under Directive 91/414/EEC is not yet completed, but the EFSA conclusion is finalised and has been forwarded to the European Commission.

In the European Community currently temporary MRLs for tetraconazole are set in Annex III of Regulation (EC) 396/2005. These temporary MRLs have been derived from MRLs that have been set at national level before Regulation (EC) 396/2005 entered into force. The current EC MRLs are summarized in Appendix C. The MRL for apricots is set at the LOQ of 0.02 mg/kg.

No Codex MRLs are set for tetraconazole.

The GAP for which an authorisation is requested in Spain refers to an outdoor application of tetraconazole on apricots. The emulsifiable concentrate is applied as a spray four times per year. The minimum PHI is 14 days. The growth stage and the interval of applications are not specified.

The intended GAP is given in Appendix A.

ASSESSMENT

1. Methods of analysis

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

The analytical methods for the determination of tetraconazole in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Italy, 2005).

Sufficient validation data were submitted for the DFG method S19. The method is based on organic solvent extraction followed by GPC clean up and GC-MS analysis.

The validation data demonstrated that the limit of determination achievable with the method is 0.01 mg/kg for:

-dry commodities (wheat grain)

-high water content commodities (sugar beet)

and 0.02 mg/kg for:

- wheat (straw)

- high acid content commodities (grapes)

- high water content commodities (apples and tomatoes).

Aside from the methods provided by the applicant in the framework of the peer review, laboratories responsible for the official control of MRLs have developed their own methods or have included the active substance in the established multi-methods. In the database developed by the Community Reference Laboratories (CRL) for Residues of Pesticides (www.crl-pesticides.eu), in total 485 validation datasets (status January 2009) have been submitted regarding methods routinely used to determine tetraconazole residues in different matrices. Most of the validation data refer to the QuEChERS method.

For commodities with high water content, which apricots belong to, the validation data are available for cucumbers, apples, tomatoes, peppers, lettuce, pear, spinach, nectarines, cauliflower etc.

In the Table 1-1 the validation data for high water content commodities are summarised.

Table 1-1. **Validation data for high water content matrices**[3]

Chr	Matrix Type	Level min	Level max	Rec Median	Rec Mean	CV [%]	# of rec	% Rec (70-120%)	# of Labs
GC	Water containing	0,01	1	**101**	102	8,7	56	**98**	4
LC	Water containing	0,01	0,25	**95**	91	19,9	213	**85**	8

From the available data it is concluded that for the determination of tetraconazole in apricots adequate analytical methods are available.

[3] Source: Website of Community Reference Laboratories (CRL) for Pesticide Residues www.crl-pesticides.eu. January, 2009

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

No analytical method is required for food of animal origin since apricots are not used as a livestock feed.

2. Mammalian toxicology

Toxicological reference values for tetraconazole were derived in the framework of the peer review of Directive 91/414/EEC and are summarised in the Table 2-1 (Italy, 2005).

Table 2-1. **Overview of the toxicological reference values**

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	EFSA	2008	0.004	2 yr rat	100
ARfD	EFSA	2008	0.05	developmental study	100

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 studies of tetraconazole in plants are reported in the DAR (Italy, 2005) for the following crops:

- wheat (foliar spray, 1x 148 g a.s./ha)
- sugar beet (foliar spray, 3x100 g a.s./ha)
- grapes (foliar spray, 4x 22 - 26 mg a.s./L)

The studies cover three crop categories- dry commodities, root and tuber vegetables and fruit and fruiting vegetables.

Tetraconazole was radiolabelled in the triazole and phenyl ring. The main primary steps of metabolism of tetraconazole in these crops include hydroxylation of the phenyl ring, hydrolysis of the tetrafluoroethylether group as well as cleavage of the phenyl-triazole ring system. Several metabolites were found in a conjugated from. In wheat straw, sugar beet and grapes, tetraconazole represented the major compound of terminal residue at harvest while metabolites were present in amount one order of magnitude lower (1-10% TRR).

Only in cereal grain triazole derivative metabolites triazole alanine (50.1% TRR) and triazole acetic acid (24.9% TRR) were present in significantly higher amounts than tetraconazole (6.3% TRR). In addition, the metabolite triazolyl hydroxyl propionic acid was found in sugar beet leaves (7.1 % TRR). This metabolite had not been identified in metabolism studies with other triazole compounds assessed in the peer review.

In grapes only small amounts of metabolites were produced in the metabolism study, and only two of them were tentatively identified.

Based on the studies a residue definition including tetraconazole and triazole derivative metabolites (triazole alanine, triazole acetic acid) has been provisionally established. A final residue definition for plant commodities for risk assessment is pending the clarification on the toxicological properties of metabolite triazole hydroxypropionic acid.

The residue definition for monitoring is provisionally proposed as tetraconazole only. Pending finalisation of the risk assessment on triazole compounds and the triazole derivative metabolites these metabolites may also need to be monitored in future (EFSA, 2008).

The current residue definition in Regulation (EC) No 306/2005 is parent tetraconazole only.

As apricots belong to the fruit category, it can be considered that the metabolic pattern in apricots is comparable with the metabolic pattern in grapes and no additional metabolism studies are needed.

Pending the toxicological evaluation of the triazole metabolites and considering that the metabolism studies did not identify triazole derivative metabolites in fruits, it is proposed in the framework of this application to define the relevant residue in apricots as tetraconazole based on the grape metabolism study.

3.1.1.2. Magnitude of residues

Storage stability and analytical methods

Storage stability studies submitted in the framework of the per review demonstrate that tetraconazole residue are stable under deep freeze conditions in dry commodities (cereal grain and straw), high water content commodities (apple, sugar beet root) and high acid content commodities (grapes) for three years (Italy, 2005).

According to the evaluation of the EMS, supervised field trial samples were stored under the storage temperature of -20 C° and the storage period did not exceed the demonstrated storage period of tetraconazole residues in high water content commodities.

Analytical methods used in the analysis of field trial samples were validated at the LOQ of 0.01 and 0.02 mg/kg and acceptable recovery rates were achieved. According to the evaluation of the EMS it is concluded that analytical methods used in the analysis of supervised field trial samples were sufficiently validated (Spain, 2008).

Residue trials

The applicant submitted twelve supervised field trials on peaches corresponding to the intended GAP in Spain (Spain, 2008). Supervised field trials residue data are summarized in Table 3-1. More details regarding residue trials can be found in Appendix B.

All residue trials were performed on peaches in Italy and Spain. Submitted residue decline studies demonstrate that the highest residue levels are on the day 3 and 7 after the last application followed by decrease in residue levels with longer PHI.

The residue levels from all trials at the intended GAP of 14 days were in the range of 0.02-0.09 mg/kg. Submitted trials are sufficient to allow extrapolation from peaches to apricots.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Peaches	SEU	Outdoor	3x 0.02; 2x 0.03; 0.04; 0.05; 2x 0.06; 2x 0.07; 0.09	3x 0.02; 2x 0.03; 0.04; 0.05; 2x 0.06; 2x 0.07; 0.09	0.04	0.09	0.1	1.0	R_{ber}= 0.11 mg/kg R_{max}=0.12 mg/kg

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(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 residues trial.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

As demonstrated in the studies submitted in the framework of the peer review, tetraconazole was shown to be stable under standard hydrolytic conditions in buffer solutions simulating pasteurization, boiling, baking, brewing, and sterilization (Italy, 2005).

Since the applicant has not provided studies on the effects of processing on the nature and magnitude of residues of tetraconazole in apricots, no specific processing factors can be derived.

3.1.2. Rotational crops

Rotational crops are not relevant for the current application since apricots are perennial crops and are not grown in rotation.

3.2. Nature and magnitude of residues in livestock

Since apricots are not consumed by livestock and its by-products are not used as feedingstuff, nature and magnitude studies of residues in livestock are not of relevance regarding the current application.

4. Consumer risk assessment

The consumer intake calculations were performed using the EFSA PRIMo rev.2. The existing MRLs as established for in Annex III of the Regulation (EC) 396/2005 and the STMR value of 0.04 mg/kg for apricots were used as input values. In addition, several STMR values as derived during the setting of temporary MRLs are available and they were used as an input values in the chronic consumer intake calculations.

The input values used in the consumer risk assessment are summarized in the Table 4-1.

Table 4-1. **Input values for the consumer risk assessment**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Apricots	0.04	STMR (Spain, 2008)	0.09	HR (Spain, 2008)
Apples	0.07	STMR (Spain, 2007)	Acute intake assessment was performed only with regard to the current MRL proposal for apricots.	
Peaches	0.04	STMR (Spain, 2007)		
Tomatoes	0.03	STMR (Spain, 2007)		
Cucurbits (edible peel)	0.045	STMR (Spain, 2007)		
Melons	0.016	STMR (Spain, 2007)		
Sugar beet (root)	0.01	STMR (Belgium, 2007)		
Chicory (root)	0.01	STMR (Belgium, 2007)		
Swine, bovine, sheep meat	0.02	STMR (Belgium, 2007)		
Swine, bovine, sheep, goat fat	0.21	STMR (Belgium, 2007)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine, bovine, sheep, goat liver	0.51	STMR (Belgium, 2007)		
Swine, bovine kidney	0.06	STMR (Belgium, 2007)		
Milk and cream	0.02	STMR (Belgium, 2007)		

The summary of the intake calculation can be found in Appendix D.

The chronic consumer intake assessment did not identify chronic intake concerns. The calculated theoretical maximum daily intake value ranged from 14.2 to 86.6 % of the ADI. The contribution of apricots in the dietary exposure is insignificant being below 0.4 % of the ADI.

The acute consumer intake assessment did not identify acute intake concerns since the IESTI is 5.6% of the ARfD.

It is concluded that the MRL proposal of 0.1 mg/kg for tetraconazole in apricots is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

Spain received an application from ISAGRO S.P.A. to modify the existing MRL for tetraconazole in apricots. Spain as an Evaluating Member State (EMS) drafted an Evaluation Report which was forwarded to the European Commission and to EFSA.

The current EC MRL for tetraconazole in apricots is set at the limit of quantification (0.02 mg/kg) and the applicant proposed the raising of the MRL to 0.1 mg/kg as an extrapolation from peaches to support the intended GAP in Spain.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the EFSA conclusion prepared in the framework of the peer review:

The toxicological profile of the active substance was investigated under the peer review and data were sufficient to conclude on an ADI value of 0.04 mg/kg bw/d and an ARfD value of 0.05 mg/kg bw/day.

The metabolism of tetraconazole has been assessed in the framework of the peer review in wheat, sugar beet and grapes. In grapes the main terminal residue is parent tetraconazole. In cereal grain and beet leaves the metabolism studies identified formation of triazole derivative metabolites (triazole alanine, triazole acetic acid and triazole hydroxypropionic acid) in much higher amounts than tetraconazole. Based on the studies a residue definition including tetraconazole and triazole derivative metabolites (triazole alanine, triazole acetic acid) has been provisionally established. A final residue definition for risk assessment in plant commodities is pending the clarification on the toxicological properties of metabolite triazole hydroxypropionic acid. The residue definition for monitoring has been provisionally proposed as tetraconazole only. Pending finalisation of the risk assessment on triazole compounds and the triazole derivative metabolites these metabolites may also need to be monitored in the future if included in the residue definition.

Pending the toxicological evaluation of the triazole metabolites and considering that the metabolism studies did not identify triazole derivative metabolites in fruits, it is proposed in the framework of this application to define the relevant residue in apricots as tetraconazole based on the grape metabolism study.

In support of the intended GAP Spain submitted supervised field trials on peaches. From that an extrapolation to apricots is possible. To cover the intended GAP on apricots the MRL of 0.1 mg/kg is necessary.

Adequate analytical enforcement methods are available for the determination of tetraconazole residues in apricots.

The consumer intake calculations were performed using the EFSA PRIMo rev.2. The existing MRLs as established for in Annex III of the Regulation (EC) 396/2005 and the STMR value of 0.04 mg/kg for apricots as derived from the supervised field trials were used as input values. In addition, for several commodities STMR values as derived during the setting of temporary MRLs for tetraconazole are available and they were used as an input values in the chronic consumer intake calculations.

The chronic consumer intake assessment did not identify chronic intake concerns. The calculated theoretical maximum daily intake value ranged from 14.2 to 86.6 % of the ADI. The contribution of apricots in the dietary exposure is insignificant (below 0.4 % of the ADI).

The acute consumer intake assessment did not identify acute intake concerns since the IESTI is 5.6% of the ARfD.

It is concluded that the MRL proposal of 0.1 mg/kg for tetraconazole in apricots is acceptable with regard to consumer safety.

Table 5-1. **Overview of the proposed EC MRLs**

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Apricots	0.02*	0.1	No consumer intake concerns are associated with the proposed MRL of 0.1 mg/kg for tetraconazole in apricots.

(*): Indicates that the MRL is set at the limit of analytical quantification.

REFERENCES

EFSA, 2008. Conclusion regarding the peer review of the pesticide risk assessment of active substance tetraconazole. *EFSA Scientific Report (2008) 152, 1-86.*

Italy, 2005. Draft assessment report on tetraconazole prepeared in the framweork of Directive 91/414/EEC.

Spain, 2008. Evaluation report: MRL of tetraconazole on apricots, prepared by Subdirección General de Gestión de Riesgos AlimentariosAgencia Española de Seguridad Alimentaria y Nutrición in the framework of the Regulation (EC) No 396/2005, May 2008.

Belgium, 2007. MRL proposal for chicory (root), sugar beet (root), swine, bovine, sheep meat, fat, liver, goat fat and liver, swine and bovine kidney, milk and cream. Doc.20070503. 1-4.

Spain, 2007. MRL proposal for apples, tomatoes, melons, cucurbits (edible peel), peaches. Doc. 270407,1-21.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and / or situation	F or G	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
Apricot	F	Sphaeroteca pannosa	ME EC	125 g/L 100 g/L	Spray		4	0.0025-0.005		<0,050	14	

APPENDIX B – SUMMARY OF FIELD RESIDUE TRIALS

CROP country, year	Application				Portion analyzed	Residues, mg/kg after PHI days									Reference
	Formulation (type and content of a.s., in g/l)	N°	kg a.s./ha	kg a.s./hl		0	4	7	14	21	28	34	41	58	Trial code
Italy, 1989	EC, 100	4	0.040	0.004	Peach	0.41	--	0.19	0.07	--	--	--	--	0.03	TEPES8901
Italy, 1989	EC, 100	4	0.040	0.004	Peach	0.26	--	0.16	0.09	--	--	--	--	--	TEPES8902
Italy, 1992	EC, 100	4	0.07	0.005	Peach	--	--	0.067	0.035	--	--	--	0.026	--	TEPES9201
		5	0.07		Peach	0.094	--	--	0.056	--	0.034	0.026	--	--	
	EW, 125	5	0.07		Peach	0.117	--	--	0.060	--	0.039	0.028	--	--	
Italy, 1992	EC, 100	4	2x0.03 2x0.04	0.005	Peach	0.088	--	0.086	0.046	0.038	0.021	--	--	--	TEPES9202
		5	2x0.03 3x0.04		Peach	0.084	0.064	0.040 0.036	0.033	--	--	--	--	--	
	EW, 125	5	2x0.03 3x0.04		Peach	0.103	0.064	0.058 0.032	0.027	--	--	--	--	--	
Italy, 2003	EC, 100	4	0.040	0.004	Peach	0.1777	0.1949	0.0731 0.0686	0.0648						TEPES0301
Italy, 2003	EC, 100	4	0.040		Peach	0.2312	0.1615	0.0973 0.0858	0.0239						TEPES0302
Spain, 2003	EC, 100	4	0.040		Peach	0.1845	0.1536	0.0965 0.0740	0.0212						TEPES0303
Spain, 2003	EC, 100	4	0.040		Peach	0.2178	0.1988	0.0711 0.0688	0.0234						TEPES0304

APPENDIX C - CURRENT EC MRLS AS IN REGULATION 396/2005

Groups and examples of individual products to which the MRLs apply	Tetraconazole
1. FRUIT FRESH OR FROZEN; NUTS	
(i) Citrus fruit	0,02*
Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
Lemons (Citron, lemon)	0,02*
Limes	0,02*
Mandarins (Clementine, tangerine and other hybrids)	0,02*
Others	0,02*
(ii) Tree nuts (shelled or unshelled)	0,02*
Almonds	0,02*
Brazil nuts	0,02*
Cashew nuts	0,02*
Chestnuts	0,02*
Coconuts	0,02*
Hazelnuts (Filbert)	0,02*
Macadamia	0,02*
Pecans	0,02*
Pine nuts	0,02*
Pistachios	0,02*
Walnuts	0,02*
Others	0,02*
(iii) Pome fruit	0,3*
Apples (Crab apple)	0.3*
Pears (Oriental pear)	0,3*
Quinces	0,3*
Medlar	0,3*
Loquat	0,3*
Others	0,3*
(iv) Stone fruit	
Apricots	0.02*
Cherries (sweet cherries, sour cherries)	0,02*
Peaches (Nectarines and similar hybrids)	0.1
Plums (Damson, greengage, mirabelle)	0,05
Others	0,02*
(v) Berries & small fruit	
(a) Table and wine grapes	0,5
Table grapes	0,5
Wine grapes	0,5
(b) Strawberries	0,2
(c) Cane fruit	0,2
Blackberries	0,2
Dewberries (Loganberries, Boysenberries, and cloudberries)	0,2
Raspberries (Wineberries)	0,2
Others	0,2
(d) Other small fruit & berries	0,2
Blueberries (Bilberries cowberries (red bilberries))	0,2
Cranberries	0,2
Currants (red, black and white)	0,2
Gooseberries (Including hybrids with other ribes species)	0,2
Rose hips	0,2
Mulberries (arbutus berry)	0,2
Azarole (mediteranean medlar)	0,2
Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,2
Others	0,2
(vi) Miscellaneous fruit	0,02*
(a) Edible peel	0,02*
Dates	0,02*
Figs	0,02*
Table olives	0,02*
Kumquats (Marumi kumquats, nagami kumquats)	0,02*

Groups and examples of individual products to which the MRLs apply	Tetraconazole
Carambola (Bilimbi)	0,02*
Persimmon	0,02*
Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,02*
Others	0,02*
(b) Inedible peel, small	0,02*
Kiwi	0,02*
Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
Passion fruit	0,02*
Prickly pear (cactus fruit)	0,02*
Star apple	0,02*
American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
Others	0,02*
(c) Inedible peel, large	0,02*
Avocados	0,02*
Bananas (Dwarf banana, plantain, apple banana)	0,02*
Mangoes	0,02*
Papaya	0,02*
Pomegranate	0,02*
Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
Guava	0,02*
Pineapples	0,02*
Bread fruit (Jackfruit)	0,02*
Durian	0,02*
Soursop (guanabana)	0,02*
Others	0,02*
2. VEGETABLES FRESH OR FROZEN	
(i) Root and tuber vegetables	0,02*
(a) Potatoes	0,02*
(b) Tropical root and tuber vegetables	0,02*
Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
Sweet potatoes	0,02*
Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
Arrowroot	0,02*
Others	0,02*
(c) Other root and tuber vegetables except sugar beet	0,02*
Beetroot	0,02*
Carrots	0,02*
Celeriac	0,02*
Horseradish	0,02*
Jerusalem artichokes	0,02*
Parsnips	0,02*
Parsley root	0,02*
Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
Swedes	0,02*
Turnips	0,02*
Others	0,02*
(ii) Bulb vegetables	0,02*
Garlic	0,02*
Onions (Silverskin onions)	0,02*
Shallots	0,02*
Spring onions (Welsh onion and similar varieties)	0,02*
Others	0,02*
(iii) Fruiting vegetables	
(a) Solanacea	
Tomatoes (Cherry tomatoes,)	0.1
Peppers (Chilli peppers)	0,1
Aubergines (egg plants) (Pepino)	0,02*
Okra, lady s fingers	0,02*
Others	0,02*
(b) Cucurbits - edible peel	0.2
Cucumbers	0.2

Groups and examples of individual products to which the MRLs apply	Tetraconazole
Gherkins	0.2
Courgettes (Summer squash, marrow (patisson))	0.2
Others	0.2
(c) Cucurbits-inedible peel	0,05
Melons (Kiwano)	0.05
Pumpkins (Winter squash)	0,05
Watermelons	0,05
Others	0,05
(d) Sweet corn	0,02*
(e) Other fruiting vegetables	0,02*
(iv) Brassica vegetables	0,02*
(a) Flowering brassica	0,02*
Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
Cauliflower	0,02*
Others	0,02*
(b) Head brassica	0,02*
Brussels sprouts	0,02*
Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
Others	0,02*
(c) Leafy brassica	0,02*
Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
Kale (Borecole (curly kale), collards)	0,02*
Others ( )	0,02*
(d) Kohlrabi	0,02*
(v) Leaf vegetables & fresh herbs	0,02*
(a) Lettuce and other salad plants including Brassicacea	0,02*
Lamb´s lettuce (Italian cornsalad)	0,02*
Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,02*
Cress	0,02*
Land cress	0,02*
Rocket, Rucola (Wild rocket)	0,02*
Red mustard	0,02*
Leaves and sprouts of Brassica spp (Mizuna)	0,02*
Others	0,02*
(b) Spinach & similar (leaves)	0,02*
Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
Purslane (Winter purslane (miner s lettuce), garden purslane, common purslane, sorrel, glassworth)	0,02*
Beet leaves (chard) (Leaves of beetroot)	0,02*
Others	0,02*
(c) Vine leaves (grape leaves)	0,02*
(d) Water cress	0,02*
(e) Witloof	0,02*
(f) Herbs	0,02*
Chervil	0,02*
Chives	0,02*
Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,02*
Parsley	0,02*
Sage (Winter savory, summer savory,)	0,02*
Rosemary	0,02*
Thyme (marjoram, oregano)	0,02*
Basil (Balm leaves, mint, peppermint)	0,02*
Bay leaves (laurel)	0,02*
Tarragon (Hyssop)	0,02*
Others	0,02*
(vi) Legume vegetables (fresh)	0,02*

Groups and examples of individual products to which the MRLs apply	Tetraconazole
Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
Peas (with pods) (Mangetout (sugar peas))	0,02*
Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
Lentils	0,02*
Others	0,02*
(vii) Stem vegetables (fresh)	
Asparagus	0,02*
Cardoons	0,02*
Celery	0,05
Fennel	0,02*
Globe artichokes	0,2
Leek	0,02*
Rhubarb	0,02*
Bamboo shoots	0,02*
Palm hearts	0,02*
Others	0,02*
(viii) Fungi	0,02*
Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
Wild (Chanterelle, Truffle, Morel ,)	0,02*
Others	0,02*
(ix). Sea weeds	0,02*
3. PULSES, DRY	0,02*
Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
Lentils	0,02*
Peas (Chickpeas, field peas, chickling vetch)	0,02*
Lupins	0,02*
Others	0,02*
4. OILSEEDS AND OILFRUITS	0,02*
(i) Oilseeds	0,02*
Linseed	0,02*
Peanuts	0,02*
Poppy seed	0,02*
Sesame seed	0,02*
Sunflower seed	0,02*
Rape seed (Bird rapeseed, turnip rape)	0,02*
Soya bean	0,02*
Mustard seed	0,02*
Cotton seed	0,02*
Pumpkin seeds	0,02*
Safflower	0,02*
Borage	0,02*
Gold of pleasure	0,02*
Hempseed	0,02*
Castor bean	0,02*
Others	0,02*
(ii) Oilfruits	0,02*
Olives for oil production	0,02*
Palm nuts (palmoil kernels)	0,02*
Palmfruit	0,02*
Kapok	0,02*
Others	0,02*
5. CEREALS	
Barley	0,1
Buckwheat	0,05
Maize	0,05
Millet (Foxtail millet, teff)	0,05
Oats	0,1
Rice	0,05
Rye	0,05
Sorghum	0,05
Wheat (Spelt Triticale)	0,1
Others	0,05
6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*

Groups and examples of individual products to which the MRLs apply	Tetraconazole
(ii) Coffee beans	0,02*
(iii) Herbal infusions (dried)	0,02*
(a) Flowers	0,02*
Camomille flowers	0,02*
Hybiscus flowers	0,02*
Rose petals	0,02*
Jasmine flowers	0,02*
Lime (linden)	0,02*
Others	0,02*
(b) Leaves	0,02*
Strawberry leaves	0,02*
Rooibos leaves	0,02*
Maté	0,02*
Others	0,02*
(c) Roots	0,02*
Valerian root	0,02*
Ginseng root	0,02*
Others	0,02*
(d) Other herbal infusions	0,02*
(iv) Cocoa (fermented beans)	0,02*
(v) Carob (st johns bread)	0,02*
7. HOPS (dried) , including hop pellets and unconcentrated powder	0,02*
8. SPICES	0,02*
(i) Seeds	0,02*
Anise	0,02*
Black caraway	0,02*
Celery seed (Lovage seed)	0,02*
Coriander seed	0,02*
Cumin seed	0,02*
Dill seed	0,02*
Fennel seed	0,02*
Fenugreek	0,02*
Nutmeg	0,02*
Others	0,02*
(ii) Fruits and berries	0,02*
Allspice	0,02*
Anise pepper (Japan pepper)	0,02*
Caraway	0,02*
Cardamom	0,02*
Juniper berries	0,02*
Pepper, black and white (Long pepper, pink pepper)	0,02*
Vanilla pods	0,02*
Tamarind	0,02*
Others	0,02*
(iii) Bark	0,02*
Cinnamon (Cassia)	0,02*
Others	0,02*
(iv) Roots or rhizome	0,02*
Liquorice	0,02*
Ginger	0,02*
Turmeric (Curcuma)	0,02*
Horse-radish	0,02*
Others	0,02*
(v) Buds	0,02*
Cloves	0,02*
Capers	0,02*
Others	0,02*
(vi) Flower stigma	0,02*
Saffron	0,02*
Others	0,02*
(vii) Aril	0,02*
Mace	0,02*
Others	0,02*
9. SUGAR PLANTS	
Sugar beet (root)	0.05
Sugar cane	0,02*
Chicory roots	0.05
Others	0,02*
10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
(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	

Groups and examples of individual products to which the MRLs apply	Tetraconazole
(a) Swine	0,05
Meat	0.05
Fat free of lean meat	0.5
Liver	1
Kidney	0.2
Edible offal	0,05
Others	0,05
(b) Bovine	
Meat	0.05
Fat	0.5
Liver	1
Kidney	0.2
Edible offal	0,5
Others	0,05
(c) Sheep	
Meat	0.05
Fat	0.5
Liver	1
Kidney	0,5
Edible offal	0,5
Others	0,5
(d) Goat	
Meat	0,5
Fat	0.5
Liver	1
Kidney	0,5
Edible offal	0,5
Others	0,5
(e) Horses, asses, mules or hinnies	
Meat	0,5
Fat	0,5
Liver	1
Kidney	0,5
Edible offal	0,5
Others	0,5
(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,02*
Meat	0,02*
Fat	0,02*
Liver	1
Kidney	0,05
Edible offal	0,02*
Others	0,02*
(g) Other farm animals (Rabbit, Kangaroo)	0,5
Meat	0,5
Fat	0,5
Liver	0,5
Kidney	0,5
Edible offal	0,5
Others	0,5
(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0.05
Cattle	0.05
Sheep	0.05
Goat	0.05
Horse	0.05
Others	0.05
(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	0,02*
Chicken	0,02*
Duck	0,02*
Goose	0,02*
Quail	0,02*
Others	0,02*
(iv) Honey (Royal jelly, pollen)	0,02
(v) Amphibians and reptiles (Frog legs, crocodiles)	0,02
(vi) Snails	0,02
(vii) Other terrestrial animal products	0,5

APPENDIX D – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Tetraconazole

Status of the active substance:	**pending**	Code no.	**158**
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.004**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

For chronic RA input values - STMR - apples-0.07; peaches-0.04; apricots-0.04; tomatoes-0.03; cucurbits(edible peel)-0.045; melons-0.016; sugar beet (root)-0.01; chicory roots-0.025; swine, bovine:meat-0.02, fat-0.21, liver-0.51, kidney-0.06;sheep meat-0.02,fat-0.21, liver-0.51; goat fat-0.21, liver-0.51; milk and cream-0.02 mg/kg; For acute RA - HR for apricots 0.09mg/kg

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
14	87
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)
86.6	NL child	14.7	Milk and cream,	14.7	Milk and milk products: Cattle	11.9	Wheat	
83.9	DE child	21.1	Apples	15.9	Table grapes	10.3	Wheat	
83.2	WHO Cluster diet B	22.4	Wine grapes	21.3	Wheat	4.3	Table grapes	
69.4	FR all population	50.0	Wine grapes	8.2	Wheat	1.4	Table grapes	
64.8	IE adult	15.6	Wine grapes	5.7	Wheat	5.0	Pears	
57.4	PT General population	31.1	Wine grapes	9.8	Wheat	3.5	Table grapes	
54.6	WHO cluster diet E	20.1	Wine grapes	9.9	Wheat	2.0	Barley	
50.7	FR toddler	19.8	Milk and cream,	6.6	Wheat	4.6	Apples	
50.1	DK child	13.8	Wheat	6.3	Milk and cream,	5.5	Rye	
46.2	FR infant	12.9	Milk and cream,	12.9	Milk and cream,	4.4	Apples	
45.4	UK Infant	19.4	Milk and cream,	6.6	Wheat	2.7	Apples	
44.1	ES child	11.1	Wheat	6.3	Milk and cream,	6.2	Milk and milk products: Cattle	
43.5	UK Toddler	10.3	Milk and cream,	9.8	Wheat	5.7	Sugar beet (root)	
42.8	WHO cluster diet D	16.3	Wheat	4.5	Wine grapes	2.5	Milk and cream,	
38.0	WHO Cluster diet F	9.0	Wheat	7.5	Wine grapes	2.0	Milk and cream,	
36.1	NL general	7.9	Wine grapes	5.2	Wheat	3.3	Milk and cream,	
35.7	SE general population 90th percentile	8.0	Wheat	6.2	Milk and cream,	6.2	Milk and cream,	
35.6	DK adult	17.4	Wine grapes	5.0	Wheat	2.7	Milk and cream,	
35.0	WHO regional European diet	7.4	Wheat	2.9	Wine grapes	2.4	Milk and cream,	
31.0	ES adult	5.9	Wheat	5.2	Wine grapes	2.5	Milk and cream,	
29.2	IT kids/toddler	16.6	Wheat	2.6	Pears	1.9	Other cereal	
26.1	UK Adult	13.5	Wine grapes	4.2	Wheat	1.5	Milk and cream,	
25.4	UK vegetarian	10.2	Wine grapes	5.1	Wheat	1.6	Milk and cream,	
20.7	IT adult	10.3	Wheat	1.8	Pears	1.6	Table grapes	
20.5	LT adult	3.3	Apples	2.6	Wheat	2.0	Milk and cream,	
16.2	FI adult	3.8	Wine grapes	2.8	Milk and cream,	2.5	Wheat	
14.2	PL general population	4.0	Table grapes	3.6	Apples	2.1	Pears	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Tetraconazole 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)
65.5	Table grapes	0.5 / -	65.5	Table grapes	0.5 / -	31.7	Table grapes	0.5 / -	31.7	Table grapes	0.5 / -
58.8	Apples	0.3 / -	43.3	Apples	0.3 / -	23.7	Wine grapes	0.5 / -	23.7	Wine grapes	0.5 / -
54.6	Pears	0.3 / -	39.3	Pears	0.3 / -	13.5	Apples	0.3 / -	11.2	Apples	0.3 / -
23.4	Cucumbers	0.2 / -	23.4	Cucumbers	0.2 / -	12.9	Pears	0.3 / -	9.9	Pears	0.3 / -
18.6	Courgettes	0.2 / -	16.1	Bovine: Liver	1 / -	10.8	Courgettes	0.2 / -	8.1	Courgettes	0.2 / -
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)		
32.9	Grape juice	0.5 / -			3.9	Apple juice	0.3 / -		
30.6	Apple juice	0.3 / -			3.9	Wine	0.5 / -		
10.5	Pear juice	0.3 / -			0.9	Bread/pizza	0.1 / -		
6.4	Elderberry juice	0.2 / -			0.7	Quince jelly	0.3 / -		
4.8	Raspberries juice	0.2 / -			0.4	Raisins	0.5 / -		

*) 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 Tetraconazole 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.

GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
DAT	Days After Treatment
EC	European Community
EC	Emulsifiable Concentrate
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
HR	Highest Residue
ILV	Independent Laboratory Validation
IESTI	International Estimated Short Term Intake
ISO	International Standardization Organization
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	Limit of Detection
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit.
PHI	Pre Harvest Interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	Supervised Trials Median Residue
TRR	Total Radioactive Residue
TMDI	Theoretical Maximum Daily Intake