REASONED OPINION

Modification of the existing MRLs for tebuconazole in mandarins and passion fruit[1]

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Spain received an application from Makhteshim Agan España S.A. to modify the existing MRL for tebuconazole in mandarins. In order to accommodate for a new use of tebuconazole in Spain, it is proposed to raise the existing MRL in mandarins from 0.05 mg/kg (the limit of quantification) to 3 mg/kg. Spain drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 20 July 2009.

According to Article 6 of the Regulation (EC) No 396/2005, the United Kingdom received an application from COLEACP/PIP to set an import tolerance for tebuconazole in passion fruit from Kenya at the level of 1 mg/kg. According to Article 6 (4) of the Regulation, the import tolerance requests should be submitted to the rapporteur Member State which in the case of tebuconazole is Denmark. The United Kingdom and Denmark agreed that the United Kingdom will draft an evaluation report for the requested import tolerance. The respective evaluation report according to Article 8 of Regulation (EC) No 396/2005 was submitted to the European Commission and forwarded to EFSA on 20 July 2009.

Considering that both applications refer to the modification of the existing MRLs for tebuconazole, EFSA decided to address both MRL applications in one reasoned opinion. EFSA derived the following conclusions based on the submitted evaluation reports prepared by Spain and The United Kingdom as well as the EFSA conclusion on the peer review of tebuconazole, the Draft Assessment Report (DAR) prepared by Denmark under Directive 91/414/EEC and the JMPR Evaluation 2008.

Metabolism of tebuconazole in primary plants is sufficiently elucidated in cereals, pulses and oilseeds, fruits and fruiting vegetables. Apart from wheat grains and peanut kernels, in all other plant parts investigated, unchanged tebuconazole was identified as the main compound. In wheat grains and peanut kernels due to extensive metabolism of tebuconazole significant amounts of triazole derivative metabolites (TDMs) were identified which are common metabolites of several substances of the triazole chemical class and which require a separate risk assessment. Pending the common approach on how to consider TDMs in the risk assessment, the peer review proposed parent tebuconazole as provisional residue definition for monitoring and risk assessment for plant products. The intended use on mandarins concerns post harvest application of tebuconazole and for this use currently no

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metabolism studies are available. Nevertheless, EFSA considers that post harvest use will not result in a more complex residue situation and that metabolism study on grapes is sufficient to describe the nature of tebuconazole in mandarins following the post harvest use. It is therefore concluded that metabolism of tebuconazole in crops under consideration is sufficiently addressed and parent tebuconazole is the major residue of concern. Adequate analytical methods are available to control the compliance of the proposed MRLs in mandarins and passion fruit.

Supervised residue field trials indicate that the existing MRLs of 0.05 mg/kg for mandarins and passion fruit are insufficient to accommodate the relevant GAPs and higher MRLs of 3mg/kg and 1 mg/kg would be required for mandarins and passion fruit respectively.

Hydrolysis study demonstrates that under conditions simulating sterilization, pasteurization and baking/boiling, tebuconazole does not undergo degradation. From the submitted processing study with oranges, the following processing factor is recommended for the inclusion in Annex VI of Regulation (EC) No 396/2005:

- Citrus fruit, juice: 0.02 *(post harvest treatment)*

The occurrence of tebuconazole residues in rotational or succeeding crops was not investigated as the crop rotation is not relevant for the submitted MRL applications.

The occurrence of tebuconazole residues in commodities of animal origin was also investigated since mandarin pomace can be fed to livestock. Considering the existing uses of tebuconazole in Europe on crops that can be used as a livestock feed, a significant exposure of livestock to tebuconazole residues was identified. Livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter for all types of livestock. However, considering the available data, EFSA came to the conclusion that there is no need to amend the existing MRLs for animal commodities since livestock feeding studies indicate that the potential livestock exposure through consumption of treated feed items will not result in tebuconazole residues above the LOQ in commodities of animal origin. In the peer review the provisional risk assessment and enforcement residue definition for the commodities of animal origin was set as the sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole, but was not enforced in the Regulation (EC) No 396/2005. Provided that there exists analytical method able to analyse all compounds included in the residue definition, EFSA recommends amending the existing residue definition (which is set as parent tebuconazole) to the residue definition which was proposed in the peer review. The proposed amendment will not have an impact on consumer risk assessment and will not result in a need to amend the levels of the existing MRLs. It should be noted that the contribution of the TDMs to the livestock dietary exposure was not assessed since comprehensive data on their occurrence in feed commodities are not available as well as no common EU approach has yet been developed on how to consider triazole metabolites in the risk assessment.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR values (multiplied by the peeling factor) derived for the intended use of tebuconazole on passion fruit and mandarins. For several other crops the STMR values were available to refine the intake calculations. Acute intake assessment was performed only with regard to passion fruit and mandarins, using the highest residue expected in the edible part of the crop.

No long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values ranged from 6.9 – 44.3 % of the ADI. The contribution of mandarins and passion fruit to the overall consumer exposure to tebuconazole residues accounts for 0.45 % of the ADI (NL child diet) and 0.2% of the ADI (DE child diet) respectively. No short term intake concerns were identified with regard to mandarins (45.4% of the ARfD) and passion fruit (0.3% of the ARfD).

It should be noted that the contribution of TDM residues in primary crops, rotational crops and products of animal origin resulting from the use of tebuconazole has not been taken into account in the consumer risk assessment awaiting the development of a global EU approach on the risk assessment of these metabolites.

EFSA concludes that the intended use of tebuconazole on mandarins and the requested import tolerance of passion fruit will not result in consumer intake concerns.

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: *Tebuconazole*			
Mandarins	0.05*	3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended use on mandarins and for the requested import tolerance on passion fruit.
Passion fruit	0.05*	1	
Existing enforcement residue definition for commodities of animal origin: *Tebuconazole* Recommended enforcement residue definition for commodities of animal origin (provided that sufficiently validated analytical enforcement method is available to analyse all compounds included in the residue definition): *The sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole.*.			

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

KEY WORDS

Tebuconazole, mandarins, passion fruit, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, triazole fungicide, triazole derivative metabolites

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that when a Member State considers that the modification of an MRL is necessary, Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation. In addition, Article 6 of that regulation lays down that any party having a legitimate commercial interest may submit to the rapporteur Member State designated pursuant to Directive 91/414/EEC an application to set an import tolerance in accordance with the provisions of Article 7 of that regulation.

Spain, hereafter referred to as the evaluating Member State for mandarins, received an application from Makhteshim Agan España S.A.[3] to modify the existing MRLs for the active substance tebuconazole in mandarins.

The United Kingdom received an application from COLEACP/PIP[4] to set an import tolerance for tebuconazole in passion fruit from Kenya. According to Article 6 (4) of the Regulation, the import tolerance requests should be submitted to the rapporteur Member State which in the case of tebuconazole is Denmark. The United Kingdom and Denmark agreed that the United Kingdom will draft an evaluation report for the requested import tolerance.

Both applications were notified to the European Commission and EFSA and subsequently evaluated in accordance with Article 8 of the Regulation. After completion, evaluation reports of Spain and The United Kingdom were submitted to the European Commission who forwarded the applications, the evaluation reports and the supporting dossiers to EFSA on 20 July 2009. Both applications were included in the EFSA Register of Question with the reference number EFSA-Q-2009-00725 and EFSA-Q-2009-00728 with the following subjects:

Tebuconazole - Application to modify the existing MRL for in mandarins.

Tebuconazole - Application to modify the existing MRL in passion fruit.

EFSA then proceeded with the assessment of the both applications as required by Article 10 of the Regulation.

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 associated with the application.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months 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 opinions is 20 October 2009.

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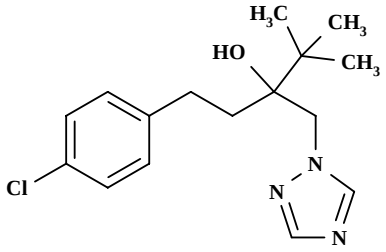
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Tebuconazole is the ISO common name for (*RS*)-1-p-chlorophenyl-4,4-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-pentan-3-ol (IUPAC) with the following chemical structure:



MW: 307.8 g/mol

Tebuconazole is a systemic fungicide belonging to the chemical class of triazole fungicides. Its mode of action has been shown to inhibit the demethylation at the C^{14}-position in the fungal sterol biosynthesis. Tebuconazole controls fungal diseases when applied as foliar application and as seed treatment on various crops.

Tebuconazole was assessed under Directive 91/414/EEC in stage three with Denmark being the designated Rapporteur Member State. The peer review of tebuconazole was finalized and an EFSA conclusion was issued on 25 September 2008. Tebuconazole was included in Annex I to Directive 91/414/EEC by Commission Directive 2008/125/EC for the uses as a fungicide. The representative uses evaluated in the framework of the peer review refers to a foliar application on grapes, cereals and as a seed treatment of barley.

In the European Community currently temporary MRLs are established for tebuconazole in the Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). These temporary MRLs have been derived from the MRLs that have been set at national level before Regulation (EC) No 396/2005 legally applied. The residue definition for tebuconazole in the Regulation (EC) No 396/2005 is set as parent tebuconazole. Recently the MRL proposal for tebuconazole in swedes and turnips have been assessed by EFSA (EFSA, 2009) and recommendations of EFSA were considered in the SCoFCAH on 15-16 October 2009.

The current MRL for tebuconazole in mandarins and passion fruit is set at the LOQ of 0.05 mg/kg. Codex Alimentarius has established CXLs in a wide range of commodities, but no CXLs are set for mandarins and passion fruit.

The GAP for which an authorization is requested in Spain refers to a post-harvest application of tebuconazole (drench) on mandarins once at a rate of 0.645 kg a.s./hL. The Kenya GAP on passion fruit refers to a maximum of three applications at a rate of 0.2 kg a.s./ha. The minimum PHI is 3 days. The details of GAPs are summarized 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 tebuconazole residues in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Denmark, 2007). For the determination of tebuconazole residues in dry commodities and commodities with high acid and high water content the multi residue method DFG S19 is sufficiently validated at the LOQ of 0.02 mg/kg.

Since crops under consideration are commodities with high acid content, EFSA concludes that there are adequate analytical methods available to enforce the proposed MRLs for mandarins and passion fruit.

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

The analytical methods for the determination of tebuconazole residues in the foodstuffs of animal origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Denmark, 2007). A multi residue method DFG S19 (GC-MS) is sufficiently validated for the determination of parent tebuconazole in animal tissues, milk and eggs with the LOQ of 0.02 mg/kg.

For the determination of tebuconazole and hydroxy-tebuconazole in animal tissues and eggs, a method using GC-NP detection is validated at the LOQ of 0.05 mg/kg (for each compound). In milk an LOQ of 0.01 mg/kg can be achieved. It is not specified whether the method is also able to analyse tebuconazole conjugates as relevant for the enforcement residue definition in the commodities of animal origin.

2. Mammalian toxicology

Toxicological reference values for tebuconazole have been derived in the framework of the peer review (EFSA, 2008) and are summarized in Table 2-1.

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

	Source	Year	Value	Study relied upon	Safety factor
Tebuconazole					
ADI	EFSA	2008	0.03 mg/kg bw/d	1 yr dog study (supported by developmental mouse study; safety factor 300)	100
ARfD	EFSA	2008	0.03 mg/kg bw	Developmental mouse study	300

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of tebuconazole was investigated in the framework of the peer review of Directive 91/414/EEC (Denmark, 2007) in the following primary crops:

- cereals: wheat - seed treatment (0.011 kg a.s./100 kg seed); wheat - foliar application (1 x 0.5 kg a.s./ha)
- pulses and oilseeds: peanuts (1 x 0.25 - 0.593 kg a.s./ha), foliar application
- fruits and fruiting vegetables: grapes (1 x 0.28 kg a.s./ha), foliar application

The metabolism was investigated using radio-labelled tebuconazole either in ^{14}C-triazole or ^{14}C-phenyl ring. Apart from wheat grains and peanut kernels, in all other plant parts investigated unchanged tebuconazole was identified as the main compound of the TRR. No bond cleavage of the molecule was observed. In contrast, in wheat grains and peanut kernels tebuconazole was extensively metabolised and the major compounds identified at harvest were the triazole derivative metabolites (TDMs): triazole alanine (80% TRR in wheat grain, 54% TRR in peanut kernels), triazole acetic acid (13% TRR in wheat grain) and 1,2,4-triazole and triazole lactic acid (peanut kernels, 10.5% and 9.9% TRR, respectively). Triazole derivative metabolites are not only tebuconazole specific and are common metabolites of several substances belonging to the triazole chemical class. Since the EU approach on how to assess these metabolites in the risk assessment is still under development, it was decided in the peer review to set parent tebuconazole as provisional risk assessment and enforcement residue definition for all plant commodities. It was concluded that a separate risk assessment has to be performed for TDMs once a general approach on triazole compounds and their triazole derivative metabolites is available.

In grapes following the foliar application of tebuconazole, most of the radioactivity was recovered in the surface rinses and the only compound identified in the samples collected 0 to 28 days after application was unchanged tebuconazole accounting for 92% to 99% of the TRR. It can therefore be concluded that in fruit and fruiting vegetables parent tebuconazole is the main residue of concern.

The intended use of tebuconazole on mandarins concerns a post harvest application of the active substance and for which currently no metabolism studies are available. Nevertheless, EFSA considers that post harvest use will not result in a more complex residue profile and that the metabolism study on grapes is sufficient to describe the nature of tebuconazole in mandarins following the post harvest use. Therefore EFSA concludes that metabolism of tebuconazole in mandarins and passion fruit is sufficiently addressed and that no additional metabolism studies are necessary. Parent tebuconazole is the major residue expected in these crops.

3.1.1.2. Magnitude of residues

In support of the proposed GAP for tebuconazole on mandarins, the applicant submitted four supervised residue trials. Mandarins are considered as a major crop according to the EU Guidance document 7525/VI/95 rev.8 and at least eight residue trials would be requested (European Commission, 2008). However, the post harvest application of the active substance is expected to have a higher level of homogeneous distribution of residues in the fruit and a lower number of trials could be sufficient. Residue levels in mandarins are within a range of 1.09 -1.75 mg/kg. EFSA considered the submitted residue trials as representative for the residue situation in the crop. Mandarin samples

were analysed for the residues in peel and in the pulp. Afterwards the values were recalculated for the total residue in fruit. Residue data indicate that tebuconazole residues are mainly located in the peel (from 3.6 – 6.2 mg/kg) while in the pulp the total residue levels are significantly lower (< LOD - 0.26 mg/kg).

For the import tolerance request on passion fruits, the applicant submitted five supervised residue field trials from Kenya. Residue trials were performed over two seasons (2006 and 2007). Passion fruit samples were analysed for the residue distribution between the peel and the pulp. Residue data indicate that residues in the pulp are approximately 20 times lower than in the peel.

Residue trials data are summarized in Table 3-1.

Storage stability of tebuconazole was investigated in the framework of the peer review in various commodities of plant origin (Denmark, 2007). Tebuconazole residues are demonstrated to be stable in matrices with high acid content for a period of 30 months. Passion fruit samples were stored deep frozen for up to 6 months thus not exceeding the demonstrated storage stability period of tebuconazole. According to the EMS Spain, mandarin samples were stored deep frozen not exceeding the demonstrated storage stability period of tebuconazole.

Mandarin samples were analyzed with a multi-residue method where detection of residues is done by HLPC-MS/MS. Validation data demonstrate that the method is suitable for the analyses of tebuconazole residues at the LOQ of 0.02 mg/kg. The achievable limit of detection (LOD) is 0.006 mg/kg. Passion fruit samples were analyzed with QuEChERS method where detection of residues was done by HLPC-MS/MS. The method is considered sufficiently validated at the LOQ of 0.01 mg/kg.

Supervised residue trials indicate that the existing MRLs of 0.05* mg/kg for mandarins and passion fruit are insufficient to accommodate the proposed GAPs and higher MRLs of 3mg/kg and 1 mg/kg would be required for mandarins and passion fruit respectively.

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 (Tebuconazole)	Risk assessment (Tebuconazole)					
Mandarins	Spain	Post harvest	1.09; 1.209; 1.378; 1.75	1.09; 1.209; 1.378; 1.75	1.29	1.75	3	1.0	Rber=3.31 mg/kg Rmax=2.84 mg/kg
Passion fruit	Kenya	Outdoor	0.11; 0.17; 0.29; 0.44; 0.59	0.11; 0.17; 0.29; 0.44; 0.59	0.29	0.59	1	1.0	Rber=1.03 mg/kg Rmax=1.15 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.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of tebuconazole residues has been investigated in the framework of the peer review in hydrolysis study simulating sterilisation (100º C at pH 5 for 60 min.), pasteurisation (120º C at pH 6 for 20 min.) and baking, brewing and boiling (90º C at pH 4 for 20 min.) (Denmark, 2007). These studies demonstrate that parent tebuconazole is stable under hydrolysis conditions. Formation of toxicologically relevant degradation products was not observed.

No specific processing studies on the magnitude of tebuconazole residues in mandarins and passion fruits have been submitted by the applicants. However, from the supervised residue trials data the following "peeling" factors were derived: 0.14 for mandarins and 0.09 for passion fruit.

In addition, the applicant submitted processing studies on oranges. Oranges after post-harvest treatment with tebuconazole were processed into marmalade and juice. Studies indicate no concentration of tebuconazole residues in the matrices of processed commodities.

Table 3-2. **Overview of the available processing studies**

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition Tebuconazole				
Oranges, juice	4	0.02	1	Processing factor is derived for the post harvest treatment of citrus fruits.
Oranges, marmalade	4	0.17	1	No data are available on the sugar, water, fruit content in the marmalade.

(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 production of marmalade is not a standardized process, EFSA is not in the favour of recommending the derived processing factor for marmalade for the inclusion in Annex VI of Regulation (EC) No 396/2005.

The derived processing factor of 0.02 for citrus fruit juice is recommended for the inclusion in Annex VI of Regulation (EC) No. 396/2005.

3.1.2. Rotational crops

For passion fruit and mandarins the crop rotation is not relevant and was therefore not investigated in the framework of MRL applications.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

According to the Appendix G of the EU Guidance document on livestock feeding studies, mandarin pomace is a potential feed item for dairy and meat ruminants (European Commission, 1996). The dietary burden for different types of livestock was calculated using the EFSA livestock dietary burden calculator, taking into account the crops which are potential livestock feed items and for which the EC

MRLs for tebuconazole are currently set above the LOQ of 0.05 mg/kg (i.e. apples, cabbage, potatoes, turnips, swedes, beans, lupines, rape seed, soya bean, wheat, rye, maize, barley and oats).

For head cabbage, dry beans, lupines and apples the STMR and HR values were obtained from the reports of the EU Member States as prepared in the framework of the risk assessment of temporary MRLs for tebuconazole in 2007. The processing factor for apples to wet pomace was derived by the JMPR evaluation of tebuconazole in 2008 (WHO/FAO, 2008). The same value was obtained by Spain and was reported in the framework of the assessment of temporary EC MRLs for tebuconazole. For barley grain and straw, the input values were as derived in the framework of the peer review. For potatoes, rape seed, soya bean, maize, rye and wheat the MRLs were used as no information is available regarding STMRs.

The input values are summarized 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: Tebuconazole				
Mandarin pomace (dry pomace)	2.99 (1.29*2.3[a])	STMR*PF	2.99 (1.29*2.3[a])	STMR*PF
Apple pomace (wet pomace)	0.8 (0.24*3.3)	STMR (Spain, 2007) *PF (WHO/ FAO, 2008)	0.8 (0.24*3.3)	STMR (Spain, 2007) *PF (WHO/FAO, 2008)
Head cabbage	0.29	STMR (Belgium, 2007)	0.56	HR (Belgium, 2007)
Barley grain	0.38	STMR (EFSA, 2008)	0.38	STMR (EFSA, 2008)
Oat grain	0.38	STMR (EFSA, 2008)	0.38	STMR (EFSA, 2008)
Wheat, rye, maize grain	0.2	MRL	0.2	MRL
Barley straw	5.8	STMR (Denmark, 2007)	13.0	HR (Denmark, 2007)
Swedes, turnips	0.12	STMR (EFSA, 2009)	0.22	HR (EFSA, 2009)
Dry beans	0.05	STMR(Germany, 2007)	0.12	HR (Germany, 2007)
Dry lupines	0.06	STMR (Germany, 2007)	0.12	HR (Germany, 2007)
Rape seed	0.3	MRL	0.3	MRL
Soya bean	0.1	MRL	0.1	MRL

[a] – indicative processing factor (obtained from one processing study reported in the evaluation report)

To estimate the contribution of mandarin pomace to the livestock exposure to tebuconazole residues, EFSA carried out two dietary burden calculations, excluding (Table 3-4) and including (Table 3-5) citrus pomace from the dietary burden. The results from the dietary burden calculation are summarized in the tables below.

Table 3-4. Results of the dietary burden calculation excluding mandarin pomace

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: Tebuconazole					
Dairy ruminants	0.1873	0.0924	Barley straw	5.15	Yes
Meat ruminants	0.3981	0.2007	Barley straw	9.29	Yes
Poultry	0.0611	0.0440	Barley grain	0.97	Yes
Pigs	0.0812	0.0489	Potatoes	2.03	Yes

Table 3-5. Results of the dietary burden calculation including mandarin pomace

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: Tebuconazole					
Dairy ruminants	0.1873	0.1173	Barley straw	5.15	Yes
Meat ruminants	0.5099	0.3231	Mandarin pomace	11.9	Yes
Poultry	0.0611	0.0440	Barley grain	0.97	Yes
Pigs	0.0812	0.0489	Potatoes	2.03	Yes

From the comparison of two scenarios it is evident that citrus pomace is a major contributor in meat ruminant diet which increases the dietary burden by approximately 30%. Since dietary burden for all types of livestock exceeds the trigger value of 0.1 mg/kg DM, the setting of MRLs in commodities of animal origin has to be considered. Currently the EC MRLs for commodities of animal are set at 0.1 mg/kg for meat, liver, kidney, fat and edible offal of all types of livestock as well as for eggs and at the LOQ of 0.05 mg/kg for milk (Appendix C). For the representative uses considered in the peer review, EFSA concluded that the MRLs for commodities of animal origin have to bet set at the LOQs according to the residue definition proposed in the peer review (see 3.2.2.). The LOQ for tebuconazole and hydroxy-tebuconazole (relevant residues in commodities of animal origin) is 0.05 mg/kg giving a combined LOQ of 0.1 mg/kg which was enforced in the Regulation (EC) No 396/2005.

It should be noted, that the possible contribution of TDMs present in animal feed has not been considered in the livestock dietary burden calculation since no comprehensive data on TDM residues in feed are available as well as no common EU approach has yet been developed on how to consider triazole metabolites in the risk assessment.

3.2.2. Nature of residues

The metabolism of tebuconazole in livestock was investigated in lactating goats with [phenyl-UL-14C]-tebuconazole and [triazolyl-3,5-^{14}C]-tebuconazole and in laying hens with [phenyl-UL-14C]-tebuconazole (Denmark, 2007).

In goat metabolism studies, tebuconazole parent compound was generally observed in low proportions (<15%) in milk and all tissues, the main metabolites being the conjugates of tebuconazole and of hydroxy-tebuconazole, both accounting for more than 50% of the TRR. In the laying hen studies the parent tebuconazole was observed in higher amounts accounting for more than 35% of the TRR in

muscle, fat and egg. Tebuconazole was more extensively metabolised in kidney and liver where hydroxy-tebuconazole, tebuconazole-carboxylic acid[5] and hydroxy-tebuconazole-sulphate[6] were found in higher proportions (up to 19%, 24% and 67% respectively). The metabolite 1,2,4-triazole was found in low proportion in hen muscle (11% TRR) and eggs (14% TRR) but these proportions have to be reconsidered on the basis of animals fed with parent tebuconazole only.

The main metabolic pathway consists of hydroxylation of tebuconazole to hydroxyl-tebuconazole and further oxidation to tebuconazole carboxylic acid followed by conjugation. The metabolic pathway in goat, hen and rat was considered as being similar since generally the same metabolic steps were involved and the same metabolites were found (EFSA, 2007).

In the peer review it was concluded that a provisional risk assessment and enforcement residue definition (pending the outcome of the global risk assessment of TDMs) for the commodities of animal origin should be set as the sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole.

In this regard EFSA recommends amending the existing residue definition in Regulation (EC) No 396/2005 (which is set as parent tebuconazole) to the residue definition which was proposed in the peer review. This is not expected to have an impact on the consumer risk assessment as well as it will not result in a need to amend the levels of the existing MRLs, since, according to EFSA understanding, they are already set according to the residue definition proposed in the peer review.

3.2.3. Magnitude of residues

The magnitude of tebuconazole residues in livestock was investigated in the feeding studies with lactating cattle and laying hen (Denmark, 2007). Two feeding studies with lactating cows have been reported in the DAR. In the first study four groups of dairy cows were fed daily with capsules containing tebuconazole at levels equivalent to 0, 25 (2N of the calculated dietary intake of dry feed), 75 and 250 mg/kg dry feed. In the second study four groups of dairy cows were fed daily with capsules containing tebuconazole at levels of 0, 30 (2.5N the calculated dietary intake of dry feed), 90 and 300 mg/kg in dry feed for 28 consecutive days. Laying hens were fed daily with doses of tebuconazole at levels 0, 2, 6 and 20 mg/kg in dry feed.

In milk, at all dose levels below 100 mg/kg dry feed and all sampling times the content of tebuconazole was less than 0.05 mg/kg. Detectable amounts of hydroxy-tebuconazole were found in milk only at the highest dose levels of 250 mg/kg and 300 mg/kg. No detectable amounts were found in fat or muscle at any dose level. From the second feeding study, tebuconazole was not detected in kidney at all while hydroxy-tebuconazole was found in amounts of 0.7 - 0.9 mg/kg at the 90 mg/kg dose level and 1.2 – 2.5 mg/kg at the highest dose level of 300 mg/kg. In liver from the same study no residues were found at the lowest dose level while both substances were detected at the two highest dose levels in increasing amounts. In the liver from the first feeding study, detectable amounts of both tebuconazole and hydroxy-tebuconazole were found at all dose levels. At the dose level of 25 mg/kg, tebuconazole and hydroxy-tebuconazole residues accounted for a maximum of 0.07 mg/kg and 0.1 mg/kg, respectively.

In laying hen, no residues were detected at the dose level of 6 mg/kg therefore the samples from the 2 mg/kg dose group were not analysed. Only in liver from the highest dose group a residue above the LOQ was found.

[5] tebuconazole-carboxylic acid: 5-(4-chlorophenyl)-3-hydroxy-2,2-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentanoic acid
[6] hydroxy-tebuconazole-sulphate: sodium 5-(4-chlorophenyl)-3-hydroxy-2,2-dimethyl-3-(1h-1,2,4-triazol-1-ylmethyl)pentyl sulfate

The storage stability of tebuconazole in animal matrices was assessed in the framework of the peer review of Directive 91/414/EEC (Denmark, 2007).In the cattle liver, kidney, muscle, fat and milk tebuconazole residues are stable for 23 weeks when deep frozen. The same storage stability conditions have been assessed and considered sufficient for poultry liver, muscle, fat and egg.

With regard to the current MRL application EFSA concludes that there is no need to amend the levels of the existing MRLs for animal commodities since livestock feeding studies indicate that the potential livestock exposure through consumption of treated feed items will not result in tebuconazole residues above the LOQ in commodities of animal origin.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residues Intake Model). For the chronic intake assessment EFSA used the existing MRLs for tebuconazole as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR values (multiplied by the peeling factor) derived for the intended use of tebuconazole on passion fruit and mandarins. For swedes and turnips the STMR values were as derived in previously issued EFSA reasoned opinion on the modification of the existing MRLs for tebuconazole (EFSA, 2009). For various plant commodities EFSA looked for available STMR values which were reported from several EU MS in the framework of the risk assessment of temporary MRLs for tebuconazole.

Acute intake assessment was performed only with regard to passion fruit and mandarins, using the highest residue expected in the edible part of the crop (see 3.1.1.3.) as derived for the intended use of tebuconazole on these crops.

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**
Risk assessment residue definition: Tebuconazole				
Passion fruit	0.03	STMR*PF (peeling factor of 0.09)	0.05	HR*PF (peeling factor of 0.09)
Mandarins	0.18	STMR*PF (peeling factor of 0.14)	0.25	HR*PF (peeling factor of 0.14)
Swedes, turnips	0.12	STMR (EFSA, 2009)	Acute intake assessment was performed only with regard to mandarins and passion fruit.	
Apples, pears	0.24	STMR (Spain, 2007)		
Table and wine grapes	0.53	STMR (Germany, 2007)		
Other small fruits and berries	0.38	STMR (Germany, 2007)		
Carrots, celeriac, parsnips and parsley root	0.12	STMR (Germany, 2007)		
Tomatoes	0.18	STMR (Spain, 2007)		
Peppers	0.2	STMR (Spain, 2007)		
Head cabbage	0.29	STMR (Belgium, 2007)		
Beans (with pods), peas (with pods)	0.49	STMR (Germany, 2007)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Leek	0.21	STMR (Germany, 2007)		
Beans (dry)	0.05	STMR (Germany, 2007)		
Lupines	0.06	STMR (Germany, 2007)		
Barley, oats	0.055	STMR (Denmark, 2007)		
Apple, pear juice	0.01	STMR*PF (0.03) (Spain, 2007)		
Grape juice	0.03	STMR(Spain, 2007)*PF (0.063) Germany, 2007)		
Elderberry juice	0.38	STMR (Germany, 2007)		

The summary of intake calculation can be found in Appendix B.

No long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values ranged from 6.9 – 44.3 % of the ADI. The contribution of mandarins and passion fruit to the total consumer exposure to tebuconazole residues accounts for 0.45 % of the ADI (NL child diet) and 0.2% of the ADI (DE child diet) respectively.

No short term intake concerns were identified with regard to mandarins (45.4% of the ARfD) and passion fruit (0.3% of the ARfD).

It should be noted that the contribution of TDM residues in primary crops, rotational crops and products of animal origin resulting from the use of tebuconazole has not been taken into account in the consumer risk assessment awaiting the development of a global EU approach on the risk assessment of these metabolites which are common for several substances of the triazole chemical class.

EFSA concludes that the intended use of tebuconazole on mandarins and the requested import tolerance of passion fruit will not result in consumer intake concerns.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Metabolism of tebuconazole in primary plants is sufficiently elucidated in cereals, pulses and oilseeds, fruits and fruiting vegetables. Apart from wheat grains and peanut kernels, in all other plant parts investigated, unchanged tebuconazole was identified as the main compound. In wheat grains and peanut kernels due to extensive metabolism of tebuconazole significant amounts of triazole derivative metabolites (TDMs) were identified which are common metabolites of several substances of the triazole chemical class and which require a separate risk assessment. Pending the common approach on how to consider TDMs in the risk assessment, the peer review proposed parent tebuconazole as provisional residue definition for monitoring and risk assessment for plant products. The intended use on mandarins concerns post harvest application of tebuconazole and for this use currently no metabolism studies are available. Nevertheless, EFSA considers that post harvest use will not result in a more complex residue situation and that metabolism study on grapes is sufficient to describe the nature of tebuconazole in mandarins following the post harvest use. It is therefore concluded that metabolism of tebuconazole in crops under consideration is sufficiently addressed and parent tebuconazole is the major residue of concern. Adequate analytical methods are available to control the compliance of the proposed MRLs in mandarins and passion fruit.

Supervised residue field trials indicate that the existing MRLs of 0.05 mg/kg for mandarins and passion fruit are insufficient to accommodate the relevant GAPs and higher MRLs of 3mg/kg and 1 mg/kg would be required for mandarins and passion fruit, respectively.

Hydrolysis study demonstrates that under conditions simulating sterilization, pasteurization and baking/boiling, tebuconazole does not undergo degradation. From the submitted processing study with oranges, the following processing factor is recommended for the inclusion in Annex VI of Regulation (EC) No 396/2005:

- Citrus fruit, juice: 0.02 *(post harvest treatment)*

The occurrence of tebuconazole residues in rotational or succeeding crops was not investigated as the crop rotation is not relevant for the submitted MRL applications.

The occurrence of tebuconazole residues in commodities of animal origin was also investigated since mandarin pomace can be fed to livestock. Considering the existing uses of tebuconazole in Europe on crops that can be used as a livestock feed, a significant exposure of livestock to tebuconazole residues was identified. Livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter for all types of livestock. However, considering the available data, EFSA came to the conclusion that there is no need to amend the existing MRLs for animal commodities since livestock feeding studies indicate that the potential livestock exposure through consumption of treated feed items will not result in tebuconazole residues above the LOQ in commodities of animal origin. In the peer review the provisional risk assessment and enforcement residue definition for the commodities of animal origin was set as the sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole, but was not enforced in the Regulation (EC) No 396/2005. Provided that there exists analytical method able to analyse all compounds included in the residue definition, EFSA recommends amending the existing residue definition (which is set as parent tebuconazole) to the residue definition which was proposed in the peer review. The proposed amendment will not have an impact on the consumer risk assessment and will not result in a need to amend the levels of the existing MRLs. It should be noted that the contribution of the TDMs to the livestock dietary exposure was not assessed since comprehensive data on their occurrence in feed commodities are not available as well as no

common EU approach has yet been developed on how to consider triazole metabolites in the risk assessment.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR values (multiplied by the peeling factor) derived for the intended use of tebuconazole on passion fruit and mandarins. For several other crops the STMR values were available to refine the intake calculations. Acute intake assessment was performed only with regard to passion fruit and mandarins, using the highest residue expected in the edible part of the crop.

No long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values ranged from 6.9 – 44.3 % of the ADI. The contribution of mandarins and passion fruit to the overall consumer exposure to tebuconazole residues accounts for 0.45 % of the ADI (NL child diet) and 0.2% of the ADI (DE child diet) respectively. No short term intake concerns were identified with regard to mandarins (45.4% of the ARfD) and passion fruit (0.3% of the ARfD).

It should be noted that the contribution of TDM residues in primary crops, rotational crops and products of animal origin resulting from the use of tebuconazole has not been taken into account in the consumer risk assessment awaiting the development of a global EU approach on the risk assessment of these metabolites.

EFSA concludes that the intended use of tebuconazole on mandarins and the requested import tolerance of passion fruit will not result in consumer intake concerns.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Tebuconazole			
Mandarins	0.05*	3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended use on mandarins and for the requested import tolerance on passion fruit.
Passion fruit	0.05*	1	
Existing enforcement residue definition for commodities of animal origin: *Tebuconazole* Recommended enforcement residue definition for commodities of animal origin (provided that sufficiently validated analytical enforcement method is available to analyse all compounds included in the residue definition): *The sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole.*.			

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

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and / or situation (a)	Country and/or region	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d - f)	Conc. of as (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Passion fruit	Kenya	F	*Alternaria, Septoria, Cladosporium*	EW	250 g/L	Spray		1 - 3		1000	0.2	3	
Mandarin	Spain	F	*Penicillium sp, Botrytis spp, Alternaria spp, Rhizopus sp, Geotrichum candidum*	SC	430 g/L	Drench	Post harvest	1	0.645			Post harvest	Maintaining the treatment for 30 seconds using about 40 tons of fruit per 1,000L of broth

Remarks:

(a) For crops, Codex (or other, e.g. EU) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(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 (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), 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

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Tebuconazole			
Status of the active substance:	Inlcuded	Code no.	152
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	0.03
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
7	44
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)
44.3	DE child	9.7	Apples	7.2	Herbal infusions (dried)	6.0	Cherries	
34.5	NL child	5.1	Apples	4.9	Milk and cream,	3.9	Potatoes	
33.9	WHO Cluster diet B	5.7	Wheat	3.5	Rice	3.2	Wine grapes	
26.7	FR toddler	6.6	Milk and cream,	3.4	Potatoes	2.4	Rice	
25.0	IE adult	2.2	Wine grapes	1.9	Peaches	1.5	Maize	
24.1	UK Infant	6.5	Milk and cream,	4.2	Rice	2.2	Potatoes	
23.1	PT General population	5.2	Rice	4.4	Wine grapes	3.6	Potatoes	
22.5	UK Toddler	3.8	Rice	3.8	Sugar beet (root)	3.4	Milk and cream,	
21.3	WHO cluster diet E	2.8	Wine grapes	2.6	Wheat	2.6	Potatoes	
21.3	DK child	3.7	Wheat	2.9	Rye	2.7	Cucumbers	
21.2	WHO cluster diet D	4.3	Wheat	3.7	Rice	2.7	Potatoes	
18.6	SE general population 90th percentile	2.8	Potatoes	2.7	Rice	2.1	Wheat	
18.2	ES child	3.2	Rice	3.0	Wheat	2.1	Milk and cream,	
17.0	FR infant	4.3	Milk and cream,	2.8	Potatoes	2.0	Apples	
16.8	WHO regional European diet	2.7	Potatoes	2.0	Wheat	1.3	Rice	
16.1	FR all population	7.1	Wine grapes	2.2	Wheat	0.8	Rice	
14.7	WHO Cluster diet F	2.4	Wheat	2.3	Potatoes	1.4	Rice	
14.1	IT kids/toddler	4.4	Wheat	1.5	Cherries	1.3	Rice	
13.8	NL general	1.8	Potatoes	1.4	Wheat	1.1	Wine grapes	
12.1	ES adult	1.6	Rice	1.6	Wheat	1.1	Cherries	
11.5	UK vegetarian	2.5	Rice	1.4	Wine grapes	1.4	Wheat	
11.2	IT adult	2.8	Wheat	1.3	Peaches	1.2	Rice	
10.9	UK Adult	2.4	Rice	1.9	Wine grapes	1.1	Wheat	
10.6	DK adult	2.5	Wine grapes	1.3	Wheat	1.0	Potatoes	
10.5	LT adult	2.1	Potatoes	1.5	Apples	1.4	Rice	
9.1	PL general population	2.3	Potatoes	1.6	Apples	1.5	Cherries	
6.9	FI adult	0.9	Milk and cream,	0.8	Potatoes	0.7	Rice	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Tebuconazole 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)
45.4	Mandarins	0.245 / -	34.2	Mandarins	0.245 / -	11.0	Mandarins	0.245 / -	8.5	Mandarins	0.245 / -
0.3	Passion fruit	0.0531 / -	0.3	Passion fruit	0.0531 / -	0.3	Passion fruit	0.0531 / -	0.3	Passion fruit	0.0531 / -
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)			
71.5	Carrot, juice	0.5 / -				25.7	Wine	2 / -			
67.4	Cuurant juice	2 / -				6.7	Peach preserved with syrup	1 / -			
59.7	Peach juice	1 / -				6.4	Tomato (preserved-	1 / -			
58.1	Tomato juice	1 / -				2.9	Bread/pizza	0.2 / -			
48.3	Blueberries	2 / -				2.7	Raisins	2 / -			

*) 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 Tebuconazole IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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

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

APPENDIX C – EXISTING EC MRLS

Pesticides - Web Version - EU MRLs
(File created on 28/10/2009 10:16)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Tebuconazole
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)	1
130020	Pears (Oriental pear)	1
130030	Quinces	0,5
130040	Medlar	0,5
130050	Loquat	0,5
130990	Others	0,5
140000	(iv) Stone fruit	
140010	Apricots	1
140020	Cherries (sweet cherries, sour cherries)	5
140030	Peaches (Nectarines and similar hybrids)	1
140040	Plums (Damson, greengage, mirabelle)	0,5
140990	Others	0,5
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2
151010	Table grapes	2
151020	Wine grapes	2
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	1
153010	Blackberries	1
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	1
153030	Raspberries (Wineberries)	1
153990	Others	1
154000	(d) Other small fruit & berries	2
154010	Blueberries (Bilberries cowberries (red bilberries))	2
154020	Cranberries	2
154030	Currants (red, black and white)	2
154040	Gooseberries (Including hybrids with other ribes species)	2
154050	Rose hips	2
154060	Mulberries (arbutus berry)	2
154070	Azarole (mediteranean medlar)	2
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	2
154990	Others	2
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	
162010	Kiwi	0,5
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,1
163040	Papaya	2
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	
211000	(a) Potatoes	0,2
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	0,5
213030	Celeriac	0,5
213040	Horseradish	0,4
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,5
213070	Parsley root	0,5
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,4
213100	Swedes	0,05* (0.3)[7]
213110	Turnips	0,05* (0.3)[8]
213990	Others	0,05*
220000	(ii) Bulb vegetables	

[7] MRL proposal as recommended by EFSA and considered in SCoFCAH on 15-16 October 2009. Not legally implemented by 30 October 2009.
[8] See footnote for swedes.

220010	Garlic	0,1
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,5
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes)	1
231020	Peppers (Chilli peppers)	0,5
231030	Aubergines (egg plants) (Pepino)	0,5
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	0,5
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,2
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,2
233020	Pumpkins (Winter squash)	0,2
233030	Watermelons	0,2
233990	Others	0,05*
234000	(d) Sweet corn	0,2
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	1
241990	Others	0,05*
242000	(b) Head brassica	
242010	Brussels sprouts	0,5
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	1
242990	Others	0,5
243000	(c) Leafy brassica	
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	1
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	
256010	Chervil	0,05*
256020	Chives	0,5
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)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	2
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	2
260030	Peas (with pods) (Mangetout (sugar peas))	2
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	0,3
270040	Fennel	0,05*
270050	Globe artichokes	0,5
270060	Leek	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	
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,2
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,2
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,3
401070	Soya bean	0,1
401080	Mustard seed	0,2
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	2
500020	Buckwheat	0,2
500030	Maize	0,2

500040	Millet (Foxtail millet, teff)	0,2
500050	Oats	2
500060	Rice	2
500070	Rye	0,2
500080	Sorghum	0,2
500090	Wheat (Spelt Triticale)	0,2
500990	Others	0,2
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	50
631000	(a) Flowers	50
631010	Camomille flowers	50
631020	Hybiscus flowers	50
631030	Rose petals	50
631040	Jasmine flowers	50
631050	Lime (linden)	50
631990	Others	50
632000	(b) Leaves	50
632010	Strawberry leaves	50
632020	Rooibos leaves	50
632030	Maté	50
632990	Others	50
633000	(c) Roots	50
633010	Valerian root	50
633020	Ginseng root	50
633990	Others	50
639000	(d) Other herbal infusions	50
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	30
800000	8. SPICES	
810000	(i) Seeds	
810010	Anise	2
810020	Black caraway	2
810030	Celery seed (Lovage seed)	1
810040	Coriander seed	2
810050	Cumin seed	1
810060	Dill seed	1
810070	Fennel seed	2
810080	Fenugreek	1
810090	Nutmeg	1
810990	Others	1
820000	(ii) Fruits and berries	1
820010	Allspice	1
820020	Anise pepper (Japan pepper)	1
820030	Caraway	1
820040	Cardamom	1
820050	Juniper berries	1
820060	Pepper, black and white (Long pepper, pink pepper)	1
820070	Vanilla pods	1
820080	Tamarind	1
820990	Others	1
830000	(iii) Bark	1
830010	Cinnamon (Cassia)	1
830990	Others	1
840000	(iv) Roots or rhizome	1
840010	Liquorice	1
840020	Ginger	1
840030	Turmeric (Curcuma)	1
840040	Horseradish	1
840990	Others	1
850000	(v) Buds	1
850010	Cloves	1
850020	Capers	1
850990	Others	1
860000	(vi) Flower stigma	1
860010	Saffron	1
860990	Others	1
870000	(vii) Aril	1
870010	Mace	1
870990	Others	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*
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	0,1
1011000	(a) Swine	0,1
1011010	Meat	0,1
1011020	Fat free of lean meat	0,1
1011030	Liver	0,1
1011040	Kidney	0,1
1011050	Edible offal	0,1
1011990	Others	0,1
1012000	(b) Bovine	0,1
1012010	Meat	0,1
1012020	Fat	0,1
1012030	Liver	0,1
1012040	Kidney	0,1
1012050	Edible offal	0,1
1012990	Others	0,1
1013000	(c) Sheep	0,1
1013010	Meat	0,1
1013020	Fat	0,1
1013030	Liver	0,1
1013040	Kidney	0,1
1013050	Edible offal	0,1
1013990	Others	0,1
1014000	(d) Goat	0,1
1014010	Meat	0,1
1014020	Fat	0,1
1014030	Liver	0,1
1014040	Kidney	0,1
1014050	Edible offal	0,1
1014990	Others	0,1
1015000	(e) Horses, asses, mules or hinnies	0,1
1015010	Meat	0,1
1015020	Fat	0,1
1015030	Liver	0,1
1015040	Kidney	0,1
1015050	Edible offal	0,1
1015990	Others	0,1
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,1
1016010	Meat	0,1
1016020	Fat	0,1
1016030	Liver	0,1
1016040	Kidney	0,1
1016050	Edible offal	0,1
1016990	Others	0,1
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,1
1017010	Meat	0,1
1017020	Fat	0,1
1017030	Liver	0,1
1017040	Kidney	0,1
1017050	Edible offal	0,1
1017990	Others	0,1
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,1
1030010	Chicken	0,1
1030020	Duck	0,1
1030030	Goose	0,1
1030040	Quail	0,1
1030990	Others	0,1
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,1

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GR	granule
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organisation
WP	wettable powder