

REASONED OPINION OF EFSA

Modification of the existing MRLs for tebuconazole in swedes ad turnips¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00463)

Issued on 18 June 2009

SUMMARY

In order to authorize the use of tebuconazole on swedes and turnips, the Belgian authorities compiled on their own initiative an application to modify the existing MRLs for these crops. In order to accommodate the new use of tebuconazole on swedes and turnips it is proposed to raise the existing MRLs, which are set at the LOQ of 0.05 mg/kg, to 0.2 mg/kg. Belgium as the Evaluating Member State (EMS) 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 10 March 2009.

EFSA derives the following conclusions regarding the application, based on the above mentioned Evaluation Report and the Draft Assessment Report prepared by Denmark in the framework of Directive 91/414/EEC.

Metabolism of tebuconazole in primary plants was investigated in the framework of the peer review of Directive 91/414/EEC in three crop categories: 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. Triazole derivative metabolites are not only tebuconazole specific and are common metabolites of several substances belonging to the triazole chemical class. Since the EU methodology on how to consider 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 separate risk assessment has to be performed for TDMs as soon as a general approach on triazole compounds and their triazole derivative metabolites is defined. The MRL application for swedes and turnips does not require additional metabolism studies and conclusions of the peer review on metabolism of tebuconazole in plants apply also for these crops.

Adequate analytical methods are available to enforce the residue definition. Submitted supervised residue field trials indicate that an MRL of 0.3 mg/kg would be required for

¹ For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for tebuconazole in swedes ad turnips. *EFSA Scientific Report* (2009) 318, 1-30

swedes and turnips. Processing studies on swedes and turnips have not been submitted and are not considered necessary, since the contribution of these crops to the total dietary intake is very low.

The occurrence of tebuconazole residues in rotational crops was also investigated. In the peer review it was concluded that the identified metabolites in rotational crops are in accordance with the metabolic pathway observed in primary crops. However, the situation in rotational crops regarding TDMs should be reconsidered taking into account all active substances which produce these common metabolites as soon as the methodology for this type of assessment is available. With regard to the current application, EFSA concludes that significant residue levels of tebuconazole are not expected in rotational crops provided that tebuconazole is applied according to the proposed GAP.

The livestock dietary burden was calculated considering the existing and proposed MRLs for tebuconazole. The impact of swedes and turnips to the total livestock dietary burden is insignificant. Consequently, the need for modification of the existing MRLs for commodities of animal origin was not further investigated in the current application. Nevertheless, a full risk assessment of tebuconazole will be performed by EFSA in the framework of Article 12 (1) of the Regulation (EC) No 396/2005. 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 for tebuconazole as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of tebuconazole on swedes and turnips. 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 swedes and turnips, using the HR values as derived for the intended use of tebuconazole on these crops.

No chronic consumer intake concerns were identified for any of the European diets. Total calculated intake values ranged from 7 - 44% of the ADI. The contribution of swedes and turnips to the total dietary intake is insignificant, being below 0.1% of ADI. No acute intake concerns were identified for swedes and turnips (28% and 26% of the ARfD, respectively).

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 since at the moment the EU approach for the risk assessment of triazole metabolites is still under development.

EFSA concludes that the intended uses of tebuconazole on turnips and swedes are 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
Enforcement residue definition: Tebuconazole			

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Swedes, turnips	0.05*	0.3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses

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

Key words: Tebuconazole, swedes turnips, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, triazole fungicide, triazole derivative metabolites: triazole alanine, triazole acetic acid, 1,2,4-triazole and triazole lactic acid

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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 where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

Belgium, hereafter referred to as the Evaluating Member State (EMS), compiled an application to modify the existing MRLs for tebuconazole in swedes and turnips. This application was notified to the European Commission and EFSA and subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 10 March 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00463 and the following subject:

Tebuconazole - Application to modify the existing MRLs for tebuconazole in swedes from 0.05 mg/kg to 0.2 mg/kg and in turnips from 0.05 mg/kg to 0.2 mg/kg.

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

TERMS OF REFERENCE

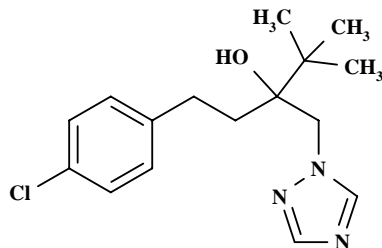
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

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 opinion was 10 June 2009.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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



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 C¹⁴-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 B). 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.

The current MRLs for swedes and turnips are set at the LOQ of 0.05 mg/kg. The existing tebuconazole MRLs for commodities of animal origin are set at 0.1 mg/kg, except for milk, honey, amphibians and snails where the MRLs at the LOQ of 0.05 mg/kg apply. Codex Alimentarius has established CXLs in a wide range of commodities, but no CXLs are set for swedes and turnips. The Codex MRLs for tebuconazole were considered when the temporary EC MRLs under Regulation (EC) No 396/2005 were established.

The GAP for which an authorization in Belgium is requested refers to an outdoor application of tebuconazole 1-2 times at an application rate of 0.200 kg a.s./ha. The minimum PHI is 21 day. The details of the GAP can be found 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 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 water content, EFSA concludes that there is adequate analytical method available to enforce the proposed MRLs for swedes and turnips.

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

The availability of analytical methods for enforcement of residues in food of animal origin was not investigated as the uses supported in the framework of this application are not expected to affect the dietary burden of livestock to tebuconazole residues.

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
Residue definition for risk assessment: 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/mg 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)
- fruits and fruiting vegetables: grapes (1 x 0.28 kg a.s./ha)

The metabolism was investigated using radio-labelled tebuconazole either in ¹⁴C-triazole or ¹⁴C-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 consider 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.

EFSA concludes that metabolism of tebuconazole in crops under consideration is sufficiently addressed and no additional metabolism studies are required; however, the conclusions of the peer review on metabolism of tebuconazole in plants apply also for these crops.

3.1.1.2. Magnitude of residues

In support of the proposed GAP, Belgium reported eight supervised residue field trials on carrots. An extrapolation to swedes and turnips is envisaged. Trials data are summarized in Table 3-1.

The trials were performed according to a more critical GAP in comparison to the proposed GAP in the terms of number of applications (three instead of two). In two trials the residue levels within a trial were higher at longer PHIs (day 28 and day 49). Therefore these higher values were used for deriving the MRL proposal. All residue trials were designed as decline studies showing a low decline rate between day 0 of the PHI and day 49 of the PHI. The number of applications might have an influence on the final residue concentrations in the crop, in particular if the interval between the applications is small. However, EFSA considers the trials data acceptable, but notes that the trials might slightly overestimate the expected residues on swedes and turnips.

Extrapolation from carrots to swedes and turnips is possible and the MRL proposal of 0.3 mg/kg is derived.

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 water content for a period of 30 months.

According to the evaluation of the EMS, the supervised field trials data can be considered valid both with regard to storage stability and analytical methods.

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					
Residue definition for enforcement and risk assessment: tebuconazole									
Swedes, turnips	NEU	Outdoor	0.09 ^e ; 0.101 ^f ; 0.108; 0.112; 0.126; 0.179; 0.189; 0.219	0.09 ^e ; 0.101 ^f ; 0.108; 0.112; 0.126; 0.179; 0.189; 0.219	0.119	0.219	0.3	1.0	Residue trails were performed on carrots but can be extrapolated to crops under consideration. R _{ber} =0.37 mg/kg R _{max} =0.29 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.

^e- Indicates that the residue value was taken at longer PHI of 28 days.

^f- Indicates that the residue value was taken at longer PHI of 49 days.

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 hydrolysis study in the framework of the peer review representing three processing conditions: sterilisation (100° C at pH 5 for 60 min.), pasteurisation (120° C at pH 6 for 20 min.) and baking, brewing and boiling (90° 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.

Several studies on the effects of processing on the magnitude of tebuconazole residues in barley and grapes were performed in the framework of the peer review and respective processing factors were obtained.

Under the current application no processing studies have been submitted and they are not considered necessary since the contribution of swedes and turnips to the total dietary intake is insignificant.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Swedes and turnips can be grown in rotation. According to the soil degradation studies performed in the framework of the peer review, the DT₉₀ value of tebuconazole based on the field and laboratory studies exceeds 100 days (Denmark, 2007). In this case further consideration has to be given to the behaviour of tebuconazole in rotational crops.

3.1.2.2. Nature of residues

The nature of tebuconazole residues in rotational crops was investigated using ¹⁴C-labelled tebuconazole in either triazole or the phenyl ring. These studies were used also for assessing the magnitude of tebuconazole in rotational crops.

In the first study tebuconazole (¹⁴C-triazole label) was applied once at an application rate of 0.5 kg a.s./ha on wheat used as a primary crop and then at the same application rate of 0.5 kg a.s./ha applied on the soil after the harvest of wheat. Kale, red beets and spring wheat were sown 30, 136 and 273 DAT. Parent tebuconazole was found at the levels of 0.05 mg/kg or 15% TRR only in kale (DAT 29). TDMs, mainly triazole alanine, triazole lactic acid and triazole acetic acid, were detected in all rotational crops in all DAT (except in wheat forage at 29 and 273 DAT) at significant levels, indicating that TDMs are relevant metabolites in succeeding crops. Triazole alanine was the major compound found in wheat grain (71 %TRR, 25.1 mg/kg at 122 DAT), beet roots (58% TRR, 0.11 mg/kg at 29 DAT) and kale (85.5 %TRR, 1.71 mg/kg at 273 DAT). Triazole lactic acid was observed for up to 52% TRR in wheat straw and beet tops and triazole acetic acid was observed for up to 51% TRR in wheat forage.

In the second study (¹⁴C-phenyl label) tebuconazole was applied at the total application rate of 0.56 kg a.s./ha on a bare soil and 30, 136 and 273 DAT kale, red beets and spring wheat were sown. Unchanged tebuconazole was found in higher amounts in beet roots and kale amounting for up to 35% (0.017 mg/kg) and 45% (0.048 mg/kg) of the TRR respectively. Tebuconazole was identified in lower amounts also in wheat straw (10.6% TRR, 0.058 mg/kg at 30 DAT) and in beet tops (13.1 % TRR, 0.005 mg/kg at 30 DAT).

In the peer review it was concluded that the identified metabolites in rotational crops are in accordance with the metabolic pathway observed in primary crops. However, the situation in rotational crops regarding TDMs should be reconsidered taking into account all active substances which produce these common metabolites as soon as the methodology for this type of assessment is available.

3.1.2.3. Magnitude of residues

The magnitude of tebuconazole residues in rotational crops was evaluated in the framework of the peer review in three confined rotational crop studies (two of them are discussed in section 3.1.2.2.) and four field rotational crop studies (Denmark, 2007).

In the third confined rotational crop study tebuconazole (¹⁴C-phenyl label) was applied on a bare soil at a rate of 2.5 kg a.s./ha and 32 and 152 DAT wheat was sown. Tebuconazole amounted for less than 0.01 mg/kg in grain at both planting intervals and ≤ 2.27 mg/kg in straw, forage and chaff. In addition, ten other metabolites were identified in straw, forage and chaff, out of which hydroxy-tebuconazole-glucoside was detected in wheat straw at levels of 1.05 mg/kg (32 DAT) and 0.58 mg/kg (152 DAT). Hydroxy-tebuconazole-3-acetoxy-glucoside was detected in wheat straw at levels of 0.596 mg/kg (32 DAT) and 0.68 mg/kg (152 DAT).

Four field rotational crop studies were performed by applying unlabelled tebuconazole at a total application rate of 0.5 kg a.s./ha on a bare soil. Wheat was sown as rotational crop. In wheat grain, straw and forage the residues of tebuconazole were below 0.05 mg/kg.

Considering the application rates proposed in the framework of this application and taking into account that a part of the applied substance is intercepted by the treated crops, it is concluded that significant levels of tebuconazole are not expected in rotational crops provided that tebuconazole is applied according to the proposed GAP. Nevertheless, the studies on the nature and magnitude of tebuconazole residues in rotational crops indicate that triazole derivative metabolites will be of concern in rotational crops and this situation will be reconsidered as soon as a global approach on TDMs will be defined.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden

According to the EU Guidance document on livestock feeding studies Appendix G (Document 7031/VI/95 rev.4) turnips and swedes are potential feed items for chicken, dairy ruminants, meat ruminants and pigs (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 could be potential livestock feed items and for which the EC MRLs for tebuconazole are currently set above the LOQ of 0.05 mg/kg. For swedes and turnips the input values were obtained from the supervised residues field trials (Table 3-1). For head cabbage, dry beans, lupines and apples the STMR and HR values were obtained from the reports of the EU Member States 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 assessment of temporary EU MRLs for tebuconazole. For

potatoes and rape seed the existing MRLs were used as an input values. The input values are summarized in Table 3-2.

Table 3-2. 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				
Swedes, turnips	0.119	STMR	0.219	HR
Apples pomace	0.795 (0.24*3.3)	STMR (Spain, 2007) *PF (WHO/ FAO, 2008)	0.795 (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	0.055	STMR (Denmark, 2007)	0.055	STMR (Denmark, 2007)
Barley straw	5.8	STMR (Denmark, 2007)	13.0	HR (Denmark, 2007)
Dry beans	0.05	STMR(Germany, 2007)	0.12	HR (Germany, 2007)
Dry lupines	0.06	STMR (Germany, 2007)	0.12	HR (Germany, 2007)
Potatoes	0.2	MRL	0.2	MRL
Rape seed	0.3	MRL	0.3	MRL

In order to estimate the contribution of swedes and turnips to the total livestock dietary burden EFSA first performed dietary burden calculations for all commodities excluding swedes and turnips (Table 3-3.) and compared them to the second dietary burden calculation, which was performed including swedes and turnips (Table 3-4.).

Table 3-3. Results of the dietary burden calculation (excluding swedes and turnips)

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Residue intake (mg/kg DM)	Dietary burden triggered?
Dairy ruminants	0.17729	0.09186	Barley straw	4.88	Yes
Meat ruminants	0.39249	0.20022	Barley straw	9.16	Yes
Poultry	0.03441	0.02832	Potatoes	0.54	Yes
Pigs	0.05893	0.04736	Potatoes	1.47	Yes

Table 3-4. Results of the dietary burden calculation (including swedes and turnips)

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Residue intake (mg/kg DM)	Dietary burden triggered?
Dairy ruminants	0.18664	0.09186	Barley straw	5.13	Yes
Meat ruminants	0.39799	0.20022	Barley straw	9.28	Yes

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Residue intake (mg/kg DM)	Dietary burden triggered?
Poultry	0.04523	0.02832	Potatoes	0.72	Yes
Pigs	0.07949	0.04736	Potatoes	1.98	Yes

The calculated dietary burdens in both cases exceed the trigger value of 0.1 mg/kg DM for all relevant livestock species, but are mainly driven by tebuconazole residues in barley straw and potatoes. As the supported use of tebuconazole on swedes and turnips does not significantly affect the livestock dietary burden, the need for the modification of the existing MRLs for animal commodities was not further investigated in the framework of this application. The current MRLs for animal commodities are supposed to reflect the residues in feed (excluding swedes and turnips) and the additional dietary burden related to swedes and turnips would not significantly change the MRLs values. Nevertheless, a full risk assessment of tebuconazole MRLs will be performed by EFSA in the framework of Article 12 (1) of 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 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.

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 derived for the intended use of tebuconazole on swedes and turnips. For several 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 swedes and turnips, using the HR values as derived for the intended use of tebuconazole on these crops.

Input values for risk assessment are summarized in 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
Risk assessment residue definition: Tebuconazole				
Swedes, turnips	0.119	STMR	0.219	HR
Apples, pears	0.24	STMR (Spain, 2007)	Acute intake assessment was performed only with regard to swedes and turnips	
Table and wine grapes	0.45	STMR (Spain, 2007)		
Other small fruits and berries	0.38	STMR (Germany, 2007)		
Carrots, celeriac, parsnips and parsley root	0.12	STMR (Germany, 2007)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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)	0.485	STMR (Germany, 2007)		
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 consumer intake calculations can be found in Appendix C.

No chronic consumer intake concerns were identified for any of the European diets. Total calculated intake values ranged from 7 - 44% of the ADI. The contribution of swedes and turnips to the total dietary intake is insignificant: 0.1% of the ADI for swedes (IE Adult diet) and 0.11% of the ADI for turnips (FR toddler diet).

No acute intake concerns were identified for swedes and turnips (28% and 26% of the ARfD, respectively).

Nevertheless 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 uses of tebuconazole on turnips and swedes are acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

In order to authorize the use of tebuconazole on swedes and turnips, the Belgian authorities compiled on their own initiative an application to modify the existing MRLs for these crops. In order to accommodate the new use of tebuconazole on swedes and turnips it is proposed to raise the existing MRLs, which are set at the LOQ of 0.05 mg/kg, to 0.2 mg/kg. Belgium as the Evaluating Member State (EMS) 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 10 March 2009.

EFSA derives the following conclusions regarding the application, based on the above mentioned Evaluation Report and the Draft Assessment Report prepared by Denmark in the framework of Directive 91/414/EEC.

Metabolism of tebuconazole in primary plants was investigated in the framework of the peer review of Directive 91/414/EEC in three crop categories: 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. Triazole derivative metabolites are not only tebuconazole specific and are common metabolites of several substances belonging to the triazole chemical class. Since the EU methodology on how to consider 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 separate risk assessment has to be performed for TDMs as soon as a general approach on triazole compounds and their triazole derivative metabolites is defined. The MRL application for swedes and turnips does not require additional metabolism studies and conclusions of the peer review on metabolism of tebuconazole in plants apply also for these crops.

Adequate analytical methods are available to enforce the residue definition. Submitted supervised residue field trials indicate that an MRL of 0.3 mg/kg would be required for swedes and turnips. Processing studies on swedes and turnips have not been submitted and are not considered necessary, since the contribution of these crops to the total dietary intake is very low.

The occurrence of tebuconazole residues in rotational crops was also investigated. In the peer review it was concluded that the identified metabolites in rotational crops are in accordance with the metabolic pathway observed in primary crops. However, the situation in rotational crops regarding TDMs should be reconsidered taking into account all active substances which produce these common metabolites as soon as the methodology for this type of assessment is available. With regard to the current application, EFSA concludes that significant residue levels of tebuconazole are not expected in rotational crops provided that tebuconazole is applied according to the proposed GAP.

The livestock dietary burden was calculated considering the existing and proposed MRLs for tebuconazole. The impact of swedes and turnips to the total livestock dietary burden is insignificant. Consequently, the need for modification of the existing MRLs for commodities of animal origin was not further investigated in the current application. Nevertheless, a full risk assessment of tebuconazole will be performed by EFSA in the framework of Article 12 (1) of the Regulation (EC) No 396/2005. 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 for tebuconazole as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of tebuconazole on swedes and turnips. 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 swedes and turnips, using the HR values as derived for the intended use of tebuconazole on these crops.

No chronic consumer intake concerns were identified for any of the European diets. Total calculated intake values ranged from 7 - 44% of the ADI. The contribution of swedes and turnips to the total dietary intake is insignificant, being below 0.1% of ADI. No acute intake concerns were identified for swedes and turnips (28% and 26% of the ARfD, respectively).

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 since at the moment the EU approach for the risk assessment of triazole metabolites is still under development.

EFSA concludes that the intended uses of tebuconazole on turnips and swedes are 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
Enforcement residue definition: Tebuconazole			
Swedes, turnips	0.05*	0.3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses

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

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for tebuconazole in turnips and swedes prepared by Belgium under Regulation (EC) No 396/2005. Submitted to EFSA on 10 March 2009.

REFERENCES

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No. min max (k)	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	
Turnip and swedes	Belgium (NEU)	F	Leaf blight, black spot, powdery mildew	WG	50% (+ 25% trifloxystrobin)			1-2	21 days			0.2	21

(a) In case of group of crops the Codex classification should be used

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi

(d) Suspension concentrate (= flowable concentrate) (SC)

(e) Use CIPAC/FAO Codes where appropriate

(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

(i) g/kg or g/l

(j) Growth stage at last treatment

(k) PHI = Pre-harvest interval

(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

APPENDIX B – EXISTING EC MRLs

Codenumber	Groups and examples of individual products to which the MRLs apply	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

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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 cloudberrries)	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 shallowthorn), hawthorn, service berries, and other treeberries)	2
154990	Others	2
160000	(vi) Miscellaneous fruit	

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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*

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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 (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,4
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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	

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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*

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	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 cicely 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

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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	

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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*

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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*

Codenumber	Groups and examples of individual products to which the MRLs apply	Tebuconazole
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
* Indicated the limit of quantification of the analytical method		

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Tebuconazole			
Status of the active substance:	Included	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	pTMRs at LOQ (in % of ADI)
43.8	DE child	9.7	Apples	7.2	Herbal infusions (dried)	6.0	Cherries	
34.0	NL child	5.1	Apples	4.9	Milk and cream,	3.9	Potatoes	
33.2	WHO Cluster diet B	5.7	Wheat	3.5	Rice	2.7	Wine grapes	
26.6	FR toddler	6.6	Milk and cream,	3.4	Potatoes	2.4	Rice	
24.3	IE adult	1.9	Peaches	1.9	Wine grapes	1.5	Maize	
24.1	UK Infant	6.5	Milk and cream,	4.2	Rice	2.2	Potatoes	
22.3	PT General population	5.2	Rice	3.7	Wine grapes	3.6	Potatoes	
22.3	UK Toddler	3.8	Rice	3.8	Sugar beet (root)	3.4	Milk and cream,	
21.2	DK child	3.7	Wheat	2.9	Rye	2.7	Cucumbers	
21.0	WHO cluster diet D	4.3	Wheat	3.7	Rice	2.7	Potatoes	
20.8	WHO cluster diet E	2.6	Wheat	2.6	Potatoes	2.4	Wine grapes	
18.4	SE general population 90th percentile	2.8	Potatoes	2.7	Rice	2.1	Wheat	
18.1	ES child	3.2	Rice	3.0	Wheat	2.1	Milk and cream,	
16.9	FR infant	4.3	Milk and cream,	2.8	Potatoes	2.0	Apples	
16.6	WHO regional European diet	2.7	Potatoes	2.0	Wheat	1.3	Rice	
14.9	FR all population	6.0	Wine grapes	2.2	Wheat	0.8	Rice	
14.4	WHO Cluster diet F	2.4	Wheat	2.3	Potatoes	1.4	Rice	
14.0	IT kids/toddler	4.4	Wheat	1.5	Cherries	1.3	Rice	
13.4	NL general	1.8	Potatoes	1.4	Wheat	1.1	Milk and cream,	
11.9	ES adult	1.6	Rice	1.6	Wheat	1.1	Cherries	
11.3	UK vegetarian	2.5	Rice	1.4	Wheat	1.2	Wine grapes	
11.1	IT adult	2.8	Wheat	1.3	Peaches	1.2	Rice	
10.6	UK Adult	2.4	Rice	1.6	Wine grapes	1.1	Wheat	
10.5	LT adult	2.1	Potatoes	1.5	Apples	1.4	Rice	
10.1	DK adult	2.1	Wine grapes	1.3	Wheat	1.0	Potatoes	
9.0	PL general population	2.3	Potatoes	1.6	Apples	1.5	Cherries	
6.7	FI adult	0.9	Milk and cream,	0.8	Potatoes	0.7	Rice	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs 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
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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 variability factor of 3.

Threshold MRL is the calculated residue level which would lead 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)
	37.8	Swedes	0.219 / -	37.8	Swedes	0.219 / -	17.4	Swedes	0.219 / -	17.4	Swedes	0.219 / -
26.2	Turnips	0.219 / -	18.7	Turnips	0.219 / -	7.7	Turnips	0.219 / -	5.6	Turnips	0.219 / -	
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: ---		
	IESTI 1 ***)			IESTI 2 ***)		
	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	Courant juice	2 / -	21.9	Apple juice	1 / -	
59.7	Peach juice	1 / -	6.7	Peach preserved with	1 / -	
58.1	Tomato juice	1 / -	6.4	Tomato (preserved-	1 / -	
48.3	Blueberries	2 / -	2.9	Bread/pizza	0.2 / -	

*) 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.

GLOSSARY / 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
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
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
GS	growth stage
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States

NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TDMs	Triazole Derivative Metabolites
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organisation