European Food Safety Authority

EFSA Scientific Report (2009) 261, 1-24

REASONED OPINION OF EFSA

Modification of the existing MRLs for prothioconazole in head cabbage and Brussels sprouts[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00217)

Issued on 08 April 2009

SUMMARY

According to Article 6(1) of Regulation (EC) No 396/2005, The Netherlands received an application from the company Bayer CropScience to modify the existing MRLs for prothioconazole in Brussels sprouts and head cabbage. In order to accommodate for a new use of prothioconazole in these crops, the applicant proposes to raise the existing MRLs, which are currently set at the analytical limit of quantification, to 0.1 mg/kg. The subsequent evaluation report drafted by The Netherlands was forwarded to EFSA on 14 January 2009 according to Article 9 of the Regulation. Based on the evaluation report and the EFSA conclusion on the peer review of prothioconazole, EFSA derives the following conclusions regarding the application.

Metabolism of prothioconazole was investigated by seed treatment in wheat and by foliar treatment in wheat, peanut and sugar beet (roots and tops). Three different crop groups are covered by the available studies and residue definitions applicable to all plant commodities can be derived. For enforcement purposes, the residue is defined as prothioconazole-desthio. An analytical method for enforcement of this residue definition in the crops under evaluation is also available. The relevant residue for risk assessment however is defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio.

In support of the proposed GAPs for prothioconazole in Brussels sprouts and head cabbage, a sufficient number of supervised residues trials is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs. It is noted that residue levels according to the residue definition for risk assessment are not reported in the available residues trials, which is usually considered as essential for deriving a conversion factor between enforcement and risk assessment. An approximate conversion factor was therefore derived from the available metabolism studies. As the consumer exposure to prothioconazole residues is low in comparison with the toxicological

[1] For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for prothioconazole in head cabbage and Brussels sprouts. *EFSA Scientific Report* (2009) 261, 1-24

reference values, the use of the approximate conversion factor is considered acceptable in this particular case.

The effect of industrial and household processing was not investigated because head cabbage and Brussels sprouts only contribute in a minor amount to the exposure of consumers to prothioconazole residues (less than 10% of the ADI).

Occurrence of prothioconazole residues in rotational crops was investigated and it was concluded that the residue pattern in rotational crops is similar to that observed in primary crops. Provided that prothioconazole is applied according to the supported GAPs, no residue of any metabolite above 0.01 mg/kg is expected in rotational crops and no plant back restriction needs to be proposed.

The livestock dietary burden for livestock was calculated considering both the existing and the new proposed MRLs for prothioconazole-desthio. Occurrence of residues in foods of animal origin was however not further investigated in the framework of this application as the dietary burden was mainly driven by the existing uses of prothioconazole in cereals.

Chronic and acute intake calculations considering the new proposed MRLs were performed with revision 2 of the EFSA PRIMo. For the chronic intake calculations, all the existing MRLs for the active substance were considered as well. As no intake concerns were identified for all available European diets, the proposed uses are not expected to pose any risk to the European consumer. The recommendations resulting from the assessment are summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: *prothioconazole-desthio*			
Head cabbage	0.02*	0.1	MRL proposals are fully supported by data and no risk to consumers was identified.
Brussels sprouts	0.02*	0.1	

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

Key words: prothioconazole, head cabbage, Brussels sprouts, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, triazole fungicides, prothioconazole-desthio

TABLE OF CONTENTS

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 a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The Netherlands, hereafter referred to as the Evaluating Member State (EMS), received an application from the company Bayer CropScience[2] to modify the existing MRLs for the active substance prothioconazole in head cabbage and Brussels sprouts. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 14 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00217 and the following subject:

Prothioconazole - Application to modify the existing MRL for prothioconazole-desthio in head cabbage from 0.02 mg/kg to 0.1 mg/kg and in Brussels sprouts from 0.02* mg/kg to 0.1 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.

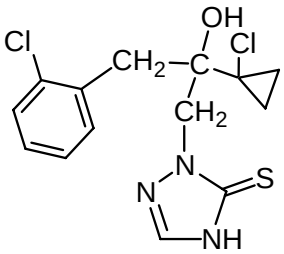
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

[2] Bayer CropScience, Energieweg 1, 3641 RT Mijndrecht, The Netherlands

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Prothioconazole is the ISO common name for (*RS*)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione (IUPAC).



Prothioconazole belongs to the class of fungicides which are commonly referred to as the triazoles. This class of fungicides includes compounds such as epoxiconazole and flusilazole. It is a systemic fungicide with protective, curative and eradicative activity. Its mode of action is steroid demethylation (ergosterol biosynthesis).

Prothioconazole was evaluated in the framework of Directive 91/414/EEC as a new active substance with The United Kingdom being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar applications on cereals and oilseed rape resulting in a decision on inclusion of the active substance in Annex I to the Directive. This decision was published by Directive 2008/44/EC and entered into force on 01 August 2008.

In the European Community, temporary MRLs are currently established for prothioconazole (Appendix B). These temporary MRLs have been derived from the MRLs that have been set at national level before Regulation (EC) 396/2005 entered into force. The MRLs for head cabbage and Brussels sprouts are established at the level of 0.02 mg/kg, which is equivalent to the analytical limit of quantification (LOQ). There are no Codex MRLs for prothioconazole.

The Netherlands now intend to authorize the use of prothioconazole on head cabbage and Brussels sprouts requiring a modification of the existing MRLs. A detailed overview of the GAP is available in Appendix A. It concerns 3 foliar outdoor applications with an application rate of 0.192 kg a.s./ha and a PHI of 21 days.

ASSESSMENT

1. Methods of analysis

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

An analytical method was evaluated in the framework of the peer review (EFSA, 2007). The analytical method reported is based on the GC-MS principle and analyses for prothioconazole-desthio. The method has been validated for commodities with high water content (tomatoes), high acid content (oranges), high oil content (canola seed) as well as dry commodities (cereal grain) with a LOQ of 0.02 mg/kg. In cereal forage and cereal straw the analytical method was validated with a LOQ of 0.05 mg/kg.

The commodities evaluated in the framework of this application are covered by the available data as they belong to the group of commodities with high water content.

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 prothioconazole residues (see section 3.2).

2. Mammalian toxicology

The toxicological properties of prothioconazole and its metabolite prothioconazole-desthio have been evaluated under the peer review of the active substance (EFSA, 2007). Reference values were derived and are now summarized in Table 2-1.

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

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Prothioconazole					
ADI	EFSA	2007	0.05	rat oncogenicity study	100
ARfD	EFSA	2007	0.2	rat oncogenicity study	100
Prothioconazole-desthio					
ADI	EFSA	2007	0.01	developmental rat study	100
ARfD	EFSA	2007	0.01	developmental rat study	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

During the peer review of prothioconazole, plant metabolism was investigated in wheat and peanut after foliar treatment and in wheat after seed treatment (EFSA, 2007). The main component of the residue identified in these studies was prothioconazole-desthio, a metabolite of prothioconazole that was shown to be even more toxic than the parent compound. As the parent compound was only present in minor amounts it was decided to define prothioconazole-desthio as the relevant residue for enforcement. Besides prothioconazole-desthio many other metabolites, which are structurally closely related to this compound, were identified. Their individual levels are generally low, but their total amount suggests that they may have a significant contribution to the toxicological burden the consumer is exposed to. Assuming that all these metabolites have a toxicological profile similar to prothioconazole-desthio, all the metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety were included in the risk assessment. As cleavage of the triazole moiety was also observed in the wheat metabolism study, these conclusions were considered provisional pending a combined risk assessment for the triazole compounds originating from the use of the different triazole fungicides.

The metabolism studies evaluated in the framework of the peer review do not cover the crops supported in the framework of this application. An additional metabolism study with phenyl-labelled prothioconazole in sugar beets was therefore submitted by the applicant and evaluated by the EMS. In this study sugar beet plants received 4 foliar treatments at a rate of 0.228 kg a.s./ha. The metabolic pattern was found to be similar to the previous metabolism studies with prothioconazole-desthio representing 28% and 58% of the TRR in the leaves and roots, respectively. In addition, 38% of the TRR in the sugar beet leaves was related to several compounds containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety. The remaining radioactive residue in sugar beet leaves (33% of the TRR) and sugar beet roots (32% of the TRR) was attributed to a large range of minor unidentified compounds. Although the fate of the triazole moiety was not investigated in this study, occurrence of 1,2,4-triazole and its conjugates can be expected based on the metabolic pattern already elucidated for other triazole compounds.

Considering the additional metabolism study, metabolic patterns in three different crop groups were demonstrated to be similar. It is therefore concluded that the residue definitions derived in the peer review can be extended to all plant commodities. An analytical method for enforcement of prothioconazole-desthio in head cabbage and Brussels sprouts is also available (see section 1.1). As for the peer review, these residue definitions should be considered provisional pending a combined risk assessment for the triazole compounds originating from the use of the different triazole fungicides.

3.1.1.2. Magnitude of residues

The EMS reported 8 residues trials complying with the intended GAP for head cabbage as well as 8 trials complying with the intended GAP for Brussels sprouts. The results of these

trials are summarized in Table 3-1. It is noted that residue levels according to the residue definition for risk assessment are not reported in these trials, which is usually considered as essential for deriving a conversion factor between enforcement and risk assessment. However, based on the available metabolism study for sugar beets, where approximately half of the identified compounds in the beet leaves consisted of prothioconazole-desthio, an approximate factor of 2 is estimated by the EMS for conversion between the residue definitions for enforcement and risk assessment in leafy vegetables. As the consumer exposure to prothioconazole residues is low in comparison with the toxicological reference values, the use of the approximate conversion factor is considered acceptable in this particular case.

Storage stability of prothioconazole-desthio was demonstrated for a period of 24 months at -18 °C in commodities with high water content (spinach, sugar beet and tomatoes), high oil content (canola seeds) as well as dry commodities (dried peas, canola straw and canola pods). As all the residues trial samples for head cabbage and Brussels sprouts, belonging to the commodities with high water content, were stored for less than 12 months at -18 °C, degradation of residues during storage of the trial samples is not expected.

Also the validation data of the analytical methods used in the residues trials are reported by the EMS. Although the validation criteria are not all met, in particular with regard to the number of samples analyzed for recovery, it can be concluded that the method used for head cabbage and Brussels sprouts is reliable.

It is concluded that the available residues trials data are sufficient to derive MRL proposals and risk assessment values for the two commodities under evaluation (see also Table 3-1).

3.1.1.3. Effect of industrial processing and/or household preparation

Exposure of consumers to prothioconazole residues through the consumption of head cabbage and Brussels sprouts represents less then 10% of the ADI. Further investigation of residues in processed commodities is therefore not required.

3.1.2. Rotational crops

Occurrence of prothioconazole residues in rotational crops was investigated under the peer review of the active substance (EFSA, 2007). It was concluded that the residue pattern in rotational crops is similar to that observed in primary crops and provided that prothioconazole is applied according to the representative uses, no residue of any metabolite above 0.01 mg/kg is expected in rotational crops. Therefore no plant back restrictions were proposed.

Considering that the conditions of use supported in the framework of this application are similar, the conclusions of the peer review should also apply in the framework of this application.

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)	Approx. CF	Comments
			Enforcement	Risk assessment					
Residue definition for enforcement: *prothioconazole-desthio* Residue definition for risk assessment: *sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio*									
Head cabbage	NEU (NL)	Outdoor	4 x <0.01; 2 x 0.01; 0.02; 0.06	Not available	0.01	0.06	0.1	2.0	As no data are available for risk assessment, the conversion factor was derived from the available metabolism studies. R_{max} = 0.073 R_{ber} = 0.025
Brussels sprouts	NEU (NL)	Outdoor	3 x 0.02; 2 x 0.03; 2 x 0.04; 0.07	Not available	0.03	0.07	0.1	2.0	As no data are available for risk assessment, the conversion factor was derived from the available metabolism studies. R_{max} = 0.087 R_{ber} = 0.080

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

3.2. Nature and magnitude of residues in livestock

As head cabbage is commonly used as a feed item, the dietary burden for the different types of livestock was calculated using the EFSA livestock dietary burden calculator.

In order to cover the full toxicological charge of the residue, the dietary burden calculations should be based on the residue definition for risk assessment. For head cabbage, the STMR and the HR values, multiplied by the conversion factor for risk assessment are therefore used as input values for the median and maximum dietary burden calculation, respectively. STMR values, HR values and a conversion factor for risk assessment in cereal straw were derived in the framework of the peer review (EFSA, 2007) and therefore included in this calculation. It is noted that such values were also derived for wheat grain, barley grain and oilseed rape but these data are not in line with the existing MRLs in cereal grains and oilseeds. Therefore, the existing MRLs, multiplied by the conversion factor for risk assessment, were used instead. For oilseeds an additional default processing factor of 2 was included in order to account for the possible accumulation of residues in the press cake. A summary of the input values is available in Table 3-2.

To highlight the contribution of the proposed use on cabbage to the livestock dietary burden, a first calculation was performed for all feeding items, including cabbage (Table 3-3), while a second calculation was performed without considering the cabbage (Table 3-4). From these calculations it can be seen that the trigger value of 0.1 mg/kg DM is exceeded for each relevant livestock species, regardless whether cabbage is included in the calculation or not. Additionally, it can be concluded that the dietary burden is mainly driven by the existing uses of prothioconazole in cereals and that the proposed use of cabage will only contribute in a minor amount to the dietary burden. The occurrence of residues in products of animal origin is therefore not further investigated and existing MRLs for prothioconazole-desthio in commodities of animal origin are expected to cover the uses evaluated in the framework of this application. It is also noted that MRLs for prothioconazole in animal commodities will soon be reviewd in the framework of Article 12 of Regulation (EC) No 396/2005.

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**
Residue definition for risk assessment: *sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio*				
Cabbage	0.02	STMR * 2	0.12	HR * 2
Cereal grains	0.6	MRL * 2	0.6	MRL * 2
Cereal straw	1.26	STMR * 3 (EFSA, 2007)	3.3	HR * 3 (EFSA, 2007)
Oilseed cake	0.2	MRL * 2 * 2	0.2	MRL * 2 * 2

Table 3-3. **Results of the dietary burden calculation (including cabbage)**

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Dietary burden triggered?
Residue definition for risk assessment: *sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio*				
Dairy ruminants	0.049387	0.023860	Rye straw	Yes
Meat ruminants	0.099568	0.046346	Rye straw	Yes
Poultry	0.035020	0.032764	Barley grain	Yes
Pigs	0.027934	0.024186	Barley grain	Yes

Table 3-4. **Results of the dietary burden calculation (without cabbage)**

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Dietary burden triggered?
Residue definition for risk assessment: *sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio*				
Dairy ruminants	0.040592	0.023340	Rye straw	Yes
Meat ruminants	0.097176	0.046346	Rye straw	Yes
Poultry	0.032313	0.032313	Barley grain	Yes
Pigs	0.024186	0.024186	Barley grain	Yes

4. Consumer risk assessment

Chronic and acute intake calculations were performed for head cabbage and Brussels sprouts using the STMR values, the HR values and the conversion factors for risk assessment reported under section 3.1.1.2. For the chronic intake calculations, EFSA is also required to consider other crops with authorized uses. As detailed information on STMR values for these commodities is not available, the existing MRLs were used as input values (Appendix B). In order to accommodate the residue definition for risk assessment, MRLs higher than the LOQ were multiplied by the conversion factors derived in the framework of the peer review (EFSA, 2007). An overview of the input values that were inserted in revision 2 of the EFSA PRIMo is available in Table 4-1.

The detailed results of the intake calculations are reported in Appendix C to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 42 % of the ADI with the contribution of Brussels sprouts and head cabbage being below 0.2 % of the ADI. The acute intakes for these two crops represented in all cases less than 64% of the ARfD. Consequently, the supported uses are not expected to pose any risk to the European consumer.

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**
Residue definition for risk assessment: *sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio*				
Head cabbage	0.02	STMR * 2	0.12	HR * 2
Brussels sprouts	0.06	STMR * 2	0.14	HR * 2
Leek	0.1	MRL * 2	n.c.	-
Oilseeds	0.1	MRL * 2	n.c.	-
Barley	0.6	MRL * 2	n.c.	-
Oats	0.1	MRL * 2	n.c.	-
Rye	0.2	MRL * 2	n.c.	-
Wheat	0.2	MRL * 2	n.c.	-
Other plant commodities	0.02*	LOQ	n.c.	-
Meat	0.5	MRL * 10	n.c.	-
Fat	0.2	MRL * 4	n.c.	-
Liver (bovine and swine)	0.4	MRL * 2	n.c.	-
Liver (others)	0.1	MRL * 2	n.c.	-
Kidney	0.1	MRL * 2	n.c.	-
Eggs	0.05	MRL	n.c.	-
Other animal commodities	0.01*	LOQ	n.c.	-

n.c. not considered in the framework of this application

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(1) of Regulation (EC) No 396/2005, The Netherlands received an application from the company Bayer CropScience to modify the existing MRLs for prothioconazole in Brussels sprouts and head cabbage. In order to accommodate for a new use of prothioconazole in these crops, the applicant proposes to raise the existing MRLs, which are currently set at the analytical limit of quantification, to 0.1 mg/kg. The subsequent evaluation report drafted by The Netherlands was forwarded to EFSA on 14 January 2009 according to Article 9 of the Regulation. Based on the evaluation report and the EFSA conclusion on the peer review of prothioconazole, EFSA derives the following conclusions regarding the application.

Metabolism of prothioconazole was investigated by seed treatment in wheat and by foliar treatment in wheat, peanut and sugar beet (roots and tops). Three different crop groups are covered by the available studies and residue definitions applicable to all plant commodities can be derived. For enforcement purposes, the residue is defined as prothioconazole-desthio. An analytical method for enforcement of this residue definition in the crops under evaluation is also available. The relevant residue for risk assessment however is defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio.

In support of the proposed GAPs for prothioconazole in Brussels sprouts and head cabbage, a sufficient number of supervised residues trials is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs. It is noted that residue levels according to the residue definition for risk assessment are not reported in the available residues trials, which is usually considered as essential for deriving a conversion factor between enforcement and risk assessment. An approximate conversion factor was therefore derived from the available metabolism studies. As the consumer exposure to prothioconazole residues is low in comparison with the toxicological reference values, the use of the approximate conversion factor is considered acceptable in this particular case.

The effect of industrial and household processing was not investigated because head cabbage and Brussels sprouts only contribute in a minor amount to the exposure of consumers to prothioconazole residues (less than 10% of the ADI).

Occurrence of prothioconazole residues in rotational crops was investigated and it was concluded that the residue pattern in rotational crops is similar to that observed in primary crops. Provided that prothioconazole is applied according to the supported GAPs, no residue of any metabolite above 0.01 mg/kg is expected in rotational crops and no plant back restriction needs to be proposed.

The livestock dietary burden for livestock was calculated considering both the existing and the new proposed MRLs for prothioconazole-desthio. Occurrence of residues in foods of animal origin was however not further investigated in the framework of this application as the dietary burden was mainly driven by the existing uses of prothioconazole in cereals.

Chronic and acute intake calculations considering the new proposed MRLs were performed with revision 2 of the EFSA PRIMo. For the chronic intake calculations, all the existing MRLs for the active substance were considered as well. As no intake concerns were identified for all available European diets, the proposed uses are not expected to pose any risk to the

European consumer. The recommendations resulting from the assessment are summarized in the table below.

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

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: *prothioconazole-desthio*			
Head cabbage	0.02*	0.1	MRL proposals are fully supported by data and no risk to consumers was identified.
Brussels sprouts	0.02*	0.1	

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

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the proposal for MRLs of prothioconazole on head cabbage and Brussels sprouts prepared by the Evaluating Member State The Netherlands under Regulation (EC) No 396/2005. Forwarded to EFSA on 14 January 2009.
2. Summary of additional residue studies for prothioconazole prepared by the Evaluating Member State The Netherlands under Regulation (EC) No 396/2005. Forwarded to EFSA on 14 January 2009.

REFERENCES

EFSA, 2007. Conclusion of EFSA prepared by the Pesticides Unit (PRAPeR) on the peer review of the pesticide risk assessment of the active substance prothioconazole. *EFSA Scientific Report* (2007) 106, 1-98.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

INTENDED USE PATTERN, NORTHERN EUROPE, BCS														
Crop and/or situation	Member State or Country	F, G or I	Pests or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
				type	conc of a.s.	method kind	growth stage	number (range)	interval (days)	a.s. (kg/hL)	water (L/ha)	a.s. (kg/ha)		
Cabbage (red, savoy, pointer and white, Brussel Sprouts)	Netherlands	F	Mycosphaerella brassicicola	SC	480 g/l	Spray treatment	August-November BBCH 15-49	3	14	0.096	200	0.192	21	

F = Field; G = Glasshouse, I = Indoors

APPENDIX B – LIST OF EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 24/02/2009 14:09)		
Code number	**Groups and examples of individual products to which the MRLs apply (a)**	**Prothioconazole (Prothioconazole-desthio) (R)**
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,02*
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,02*
130010	Apples (Crab apple)	0,02*
130020	Pears (Oriental pear)	0,02*
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
140000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage, mirabelle)	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	0,02*
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*
153030	Raspberries (Wineberries)	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	0,02*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*
154020	Cranberries	0,02*
154030	Currants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids with other ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediteranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Blimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*

163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	0,02*
210000	(i) Root and tuber vegetables	0,02*
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	0,02*
231000	(a) Solanacea	0,02*
231010	Tomatoes (Cherry tomatoes,)	0,02*
231020	Peppers (Chili peppers)	0,02*
231030	Aubergines (egg plants) (Pepino)	0,02*
231040	Okra, lady s fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,02*
232010	Cucumbers	0,02*
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	0,02*
233010	Melons (Kiwano)	0,02*
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,02*
233990	Others	0,02*
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	0,02*
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	0,02*
243990	Others ( )	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	0,02*
251000	(a) Lettuce and other salad plants including Brassicacea	0,02*
251010	Lamb´s lettuce (Italian cornsalad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*

252020	Purslane (Winter purslane (miner s lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory,)	0,02*
256060	Rosemary	0,02*
256070	Thyme (marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,05
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel,)	0,02*
280990	Others	0,02*
290000	(ix). Sea weeds	0,02*
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,05
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)	0,05
401070	Soya bean	0,05
401080	Mustard seed	0,05
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	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	
500010	Barley	0,3
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,05
500060	Rice	0,02*
500070	Rye	0,1
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0,1
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*

610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomile flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (stjohns bread)	0,02*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (Curcuma)	0,02*
840040	Horse-radish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*
860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	0,05
1011020	Fat free of lean meat	0,05
1011030	Liver	0,2
1011040	Kidney	0,05
1011050	Edible offal	0,05
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0,05
1012020	Fat	0,05
1012030	Liver	0,2
1012040	Kidney	0,05
1012050	Edible offal	0,05
1012990	Others	0,05
1013000	(c) Sheep	
1013010	Meat	0,05
1013020	Fat	0,05
1013030	Liver	0,05
1013040	Kidney	0,05
1013050	Edible offal	0,05
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0,05
1014020	Fat	0,05

1014030	Liver	0,05
1014040	Kidney	0,05
1014050	Edible offal	0,05
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,05
1015020	Fat	0,05
1015030	Liver	0,05
1015040	Kidney	0,05
1015050	Edible offal	0,05
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	0,05
1016020	Fat	0,05
1016030	Liver	0,05
1016040	Kidney	0,05
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	0,05
1017020	Fat	0,05
1017030	Liver	0,05
1017040	Kidney	0,05
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(i) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,01*
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
1030000	(ii) 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	0,05
1030010	Chicken	0,05
1030020	Duck	0,05
1030030	Goose	0,05
1030040	Quail	0,05
1030990	Others	0,05
1040000	(iv) Honey (Royaljelly, pollen)	0,01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products	0,01*

Pesticide residues and maximum residue levels (mg/kg)
(*) Indicates lower limit of analytical determination

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Prothioconazole

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
2	42
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)
42.0	WHO Cluster diet B	17.1	Wheat	4.9	Poultry: Meat	4.1	Bovine: Meat	6.0
37.7	NL child	9.5	Wheat	7.8	Swine: Meat	6.0	Bovine: Meat	8.4
34.7	ES child	8.9	Wheat	7.1	Bovine: Meat	6.4	Poultry: Meat	3.9
32.1	WHO cluster diet E	7.9	Wheat	5.1	Poultry: Meat	4.9	Barley	3.4
29.9	WHO Cluster diet F	7.2	Wheat	5.8	Swine: Meat	4.5	Bovine: Meat	2.7
29.9	WHO regional European diet	6.3	Swine: Meat	5.9	Wheat	5.3	Bovine: Meat	3.2
28.4	IE adult	7.4	Barley	4.6	Wheat	2.0	Bovine: Meat	5.6
27.3	FR toddler	6.7	Bovine: Meat	5.2	Wheat	4.2	Poultry: Meat	8.1
26.3	WHO cluster diet D	13.0	Wheat	3.0	Bovine: Meat	2.0	Poultry: Meat	3.1
25.4	DE child	8.2	Wheat	3.0	Poultry: Meat	2.4	Apples	7.6
25.0	DK child	11.0	Wheat	8.8	Rye	1.3	Milk and cream,	3.8
22.3	ES adult	4.7	Wheat	3.7	Bovine: Meat	3.6	Swine: Meat	2.3
20.3	NL general	4.6	Swine: Meat	4.1	Wheat	3.5	Bovine: Meat	2.9
18.0	UK Toddler	7.8	Wheat	4.6	Sugar beet (root)	2.1	Milk and cream,	9.4
16.7	FR all population	6.6	Wheat	3.0	Poultry: Meat	2.5	Bovine: Meat	2.3
15.4	UK Infant	5.2	Wheat	3.9	Milk and cream,	2.0	Sugar beet (root)	8.7
15.4	IT kids/toddler	13.3	Wheat	0.3	Other cereal	0.3	Tomatoes	1.9
15.0	LT adult	4.8	Swine: Meat	2.2	Rye	2.1	Wheat	2.0
14.2	FR infant	2.9	Bovine: Meat	2.8	Poultry: Meat	2.6	Milk and cream,	5.7
12.1	PT General population	7.8	Wheat	1.1	Potatoes	0.5	Wine grapes	3.2
11.9	SE general population 90th percentile	6.4	Wheat	1.2	Milk and cream,	0.8	Potatoes	4.4
10.6	DK adult	4.0	Wheat	2.8	Bovine: Meat	1.4	Rye	1.9
10.0	IT adult	8.3	Wheat	0.2	Tomatoes	0.2	Apples	1.6
7.4	UK vegetarian	4.1	Wheat	0.8	Sugar beet (root)	0.3	Milk and cream,	2.7
6.2	UK Adult	3.4	Wheat	0.8	Sugar beet (root)	0.3	Milk and cream,	2.4
5.4	FI adult	2.0	Wheat	1.4	Rye	0.6	Milk and cream,	1.7
2.0	PL general population	0.7	Potatoes	0.4	Apples	0.2	Tomatoes	1.9

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Prothioconazole 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)
63.2	Head cabbage	0.12 / -	37.9	Head cabbage	0.12 / -	38.1	Head cabbage	0.12 / -	22.9	Head cabbage	0.12 / -
12.3	Brussels sprouts	0.14 / -	12.3	Brussels sprouts	0.14 / -	7.1	Brussels sprouts	0.14 / -	7.1	Brussels sprouts	0.14 / -
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)			

*) 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 Prothioconazole 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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DM	dry matter
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
GC-MS	gas chromatography with detection by mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SC	suspension concentrate
STMR	supervised trials median residue
TRR	total radioactive residue