REASONED OPINION

Modification of the existing MRLs for thiacloprid in fresh herbs, herbal infusions (dried leaves) and tea[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Germany compiled an application to modify the existing MRLs for thiacloprid in fresh herbs and dried leaves of herbal infusions. In order to accommodate for new uses of thiacloprid in Germany, it is proposed to raise the existing MRLs in herbs from 3 mg/kg to 5 mg/kg and in herbal infusions (dried leaves) from 0.05 mg/kg (set at the LOQ) to 50 mg/kg. Germany 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 29 May 2009.

According to Article 6 of the Regulation (EC) No 396/2005, The United Kingdom received an application from Bayer CropScience to set an import tolerance for thiacloprid in tea (dried leaves and stalk, fermented or otherwise of *Camellia sinensis*) from India at the level of 10 mg/kg. The RMS United Kingdom 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 29 May 2009.

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

Metabolism of thiacloprid in plants is sufficiently elucidated in three crop categories and a general residue definition for risk assessment and monitoring was proposed by the peer review as parent thiacloprid. EFSA concludes that the results of the metabolism of thiacloprid in different crop groups can be extrapolated also to leafy vegetables. Therefore no additional metabolism studies are necessary.

A sufficiently validated multi-residue method with the LOQ of 0.01 mg/kg is available to control the compliance of the proposed MRLs in fresh herbs and dried leaves of herbal infusions. No specific analytical enforcement methods have been reported for tea. Since this matrix is considered as difficult to analyse, method validation data should be provided by the applicant to demonstrate that the analytical methods which are reported for herbs and herbal infusions are applicable also for the determination of thiacloprid residues in tea.

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1 On request from the European Commission], Question No EFSA-Q-2009-00702 and EFSA-Q-2009-00703, issued on 8 October 2009.

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The submitted residue trials performed in India and based on the India GAP were considered sufficient to derive the import tolerance of 10 mg/kg for tea. The submitted supervised residue field trials on herbs indicate that current MRLs for herbs and dried leaves of herbal infusions do not accommodate the intended GAP in Germany and higher MRLs would be required.

The occurrence of thiacloprid or its metabolites in rotational crops was also investigated. EFSA concluded that significant residues in rotational crops are not expected provided that thiacloprid is applied according to the proposed GAP for herbs and herbal infusions. Residues in commodities of animal origin were not assessed in the framework of this application considering that crops under consideration are not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and III of Regulation (EC) No 396/2005 as well as the STMR values for tea and herbal infusions (dried leaves) as derived from the supervised field trials. For some crops STMR values were available to refine the intake calculations. The acute intake assessment was performed only with regard to the crops under consideration. For herbs the HR value and for herbal infusions and tea the STMR values as derived for the intended were applied as an input values in the intake calculations.

Chronic intake assessment did not identify consumer intake concerns for any of the European diets. Total calculated intake values ranged from 15 – 78 % of the ADI. The contribution of fresh herbs to the total dietary intake accounts for a maximum of 3.33 % of the ADI for WHO Cluster diet D and 2.74 % of the ADI for tea for IE adult diet. No consumption data are available on dried leaves for herbal infusions therefore the contribution of these crops to the total dietary intake could not be estimated accurately. However, assuming a similar consumption for herbal infusions as for the tea, the contribution of herbal infusions to the total dietary intake would account for 18% of the ADI.

No acute intake concerns were identified for the crops under consideration. The short-term exposure of consumers to thiacloprid residues from tea accounts for a maximum of 6.4% of the ARfD. The highest consumer exposure to thiacloprid residues from fresh herbs is expected from consumption of celery leaves – 49.7% of the ARfD. The data on the consumption of dried leaves for herbal infusions have not been reported by the MS to EFSA, but the EMS Germany has national consumption data for dried peppermint consumed as tealike product. The national estimated short-term intake calculation was conducted for German children (large portion consumption 5 g per day, mean body weight of children 16.5 kg and age 2 to 5 years) using the available STMR value (13.6 mg/kg) as an input value. Acute risk assessment results in a NESTI of 14% of the ARfD for dried peppermint. It is thereby concluded that the consumption of dried leaves as herbal infusions will not result in acute consumer intake concerns.

Consequently EFSA concludes that proposed MRLs for tea, herbs and dried leaves for herbal infusions are safe with regard to consumer exposure. It is noted that a validated analytical method for the enforcement of the proposed MRL for thiacloprid in tea should be provided.

MRL recommendations are compiled in the table below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Thiacloprid			
Herbs	3.0	5.0	The MRL proposals are supported by data and no risk for consumers was identified for the proposed use. The MRL proposals are based on the NEU use only.
Herbal infusions (dried leaves)	0.05*	50.00	

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Tea (dried leaves and stalk, fermented or otherwise of *Camellia sinensis*)	0.05*	10.00	No risk for consumers was identified for the requested import tolerance. A validated analytical enforcement method should be provided.

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

KEY WORDS

Thiacloprid, herbs, herbal infusion (dried leaves), tea, import tolerance, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, cyanamide insecticide

TABLE OF CONTENTS

Summary 1
Table of contents 4
Background 5
Terms of reference 5
The active substance and its use pattern 6
Assessment 7
1. Methods of analysis 7
1.1. Methods for enforcement of residues in food of plant origin 7
1.2. Methods for enforcement of residues in food of animal origin 7
2. Mammalian toxicology 7
3. Residues 8
3.1. Nature and magnitude of residues in plant 8
3.1.1. Primary crops 8
3.1.2. Rotational crops 11
3.2. Nature and magnitude of residues in livestock 12
4. Consumer risk assessment 12
Conclusions and recommendations 14
References 15
Appendix A – Good Agricultural Practices (GAPs) 16
Appendix B – Pesticide Residues Intake Model (PRIMo) 17
Appendix C – Existing EC MRLs 19
Abbreviations 22

BACKGROUND

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

Germany, hereafter referred to as the evaluating Member State for herbs and herbal infusions, compiled an application to modify the existing MRLs for the active substance thiacloprid in herbal infusions and herbs.

The United Kingdom, hereafter referred to as the evaluating Member State for tea, received an application from Bayer CropScience[3] to modify the existing MRL for the active substance thiacloprid in tea.

Both applications were notified to the European Commission and EFSA and subsequently evaluated in accordance with Article 8 of the Regulation. After completion, evaluation reports of Germany and The United Kingdom were submitted to the European Commission who forwarded the applications, the evaluation reports and the supporting dossiers to EFSA on 8 July 2009. Both applications were included in the EFSA Register of Question with the reference number EFSA-Q-2009-00702 and EFSA-Q-2009-00703 with the following subjects:

Thiacloprid - Application to modify the existing MRL in tea.

Thiacloprid - Application to modify the existing MRLs in herbal infusions and herbs.

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

TERMS OF REFERENCE

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

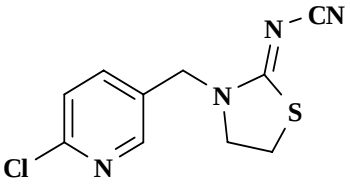
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 8 October 2009.

3 Bayer CropScience, Alfred Nobel Strasse 50, 40789, Monheim, Germany

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Thiacloprid is the ISO common name for (Z)-N-{3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-yliden}cyanamide (IUPAC).



Thiacloprid is a non-systemic insecticide. It acts as an agonist of the nicotinic acetylcholine receptors in the central nervous system. Thiacloprid is acutely toxic to insects by stomach and contact routes. The active substance is used by foliar applications against sucking and biting insects in pome fruit, stone fruit, small berries, cotton, vegetables, sugar beet, potatoes, rice and ornamentals. Pests controlled include aphids, whitefly, beetles (e.g. *Leptinotarsa decemlineata, Anthonomus pomorum, Lissorhoptrus oryzophilus*) and Lepidoptera such as leaf miners and *Cydia pomonella*.

Thiacloprid has been peer reviewed under Directive 91/414/EEC and is included in Annex I to this Directive by the Commission Directive 2004/99/EC for use as an insecticide only. The representative uses assessed under the peer review of Directive 91/414/EEC include the field and glasshouse uses of thiacloprid on pome fruit, fruiting vegetables, cucurbits (inedible peel) and ornamentals. Thiacloprid was not peer reviewed by EFSA therefore no EFSA conclusion is available.

MRLs for thiacloprid were set at EU level for the first time with Directive 2007/11/EC. The MRLs established under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC have been transferred to Annex II of Regulation (EC) No 396/2005. In Annex III, temporary MRLs have been established for crops that were not covered by the previous Community legislation. The existing MRLs for thiacloprid are summarized in Appendix C to this reasoned opinion. For leek, spring onions, lamb`s lettuce, celery and fennel the MRL proposals were recently assessed by EFSA (EFSA, 2009a, 2009b), but the recommendations made by EFSA are still awaiting the decision of the SCoFCAH.

Codex Alimentarius has established CXLs for thiacloprid in a wide range of commodities but there are no CXLs set for the crops under consideration.

The RMS United Kingdom reported the GAP for tea as authorized in India and which requires the setting of import tolerance. The India GAP concerns three applications of thiacloprid on tea plants at an application rate of 0.03 kg a.s./ha with the PHI of 7 days (Appendix A).

The GAP for which an authorization is requested in Germany, refers to two applications of thiacloprid on peppermint and lemon balm at an application rate of 0.12 kg a.s./ha with the PHI of 7 days (Appendix A). It is proposed to establish a group tolerance for fresh herbs and herbal infusions (dried leaves).

EFSA bases its assessment on the evaluation report submitted by Germany and The United Kingdom (2009) and the draft assessment report prepared under Directive 91/414/EEC (United Kingdom, 2000).

ASSESSMENT

1. Methods of analysis

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

The analytical methods for the determination of thiacloprid in foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (The United Kingdom, 2000). For the determination of thiacloprid in high water content matrices and dry matrices, the HLPC-UV method with the LOQ of 0.02 mg/kg was sufficiently validated. No specific analytical methods for the determination of thiacloprid residues in tea, herbal infusions and herbs are available.

Germany as the EMS for herbs and herbal infusions in the evaluation report refers to a multi-residue method QuEChERS. In the database developed by the Community Reference Laboratories of Pesticides (CRL, 2009), this method is validated for the determination of thiacloprid residues in dry matrices, matrices with high water-, acid-, fat- and sugar content at the LOQ of 0.01 mg/kg. Considering that fresh herbs are matrix with high water content and assuming that dried leaves of herbs will have similar matrix properties, this method is expected to be applicable for these commodities. In addition, Germany refers to a single residue analytical method using LC-MS/MS detection for the quantification of thiacloprid residues in dry matrices and matrices with high water content at the LOQ of 0.01 mg/kg.

It is therefore concluded that sufficiently validated methods are available to enforce the proposed MRLs for thiacloprid in fresh herbs and dried leaves of herbal infusions at the LOQ of 0.01 mg/kg.

No specific analytical enforcement methods have been reported for tea. Since this matrix is considered as difficult to analyse, method validation data should be provided by the applicant to demonstrate that the above mentioned analytical methods is also applicable for the determination of thiacloprid residues in tea.

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

Since crops under consideration are not used as livestock feeding items, the availability of analytical enforcement methods for the determination of thiacloprid residues in commodities of animal origin was not investigated under the current application.

2. Mammalian toxicology

The toxicological reference values for thiacloprid were derived in the peer review under Directive 91/414/EEC and are compiled in Table 2-1 (European Commission, 2004).

Table 2-1. Overview of the toxicological reference values

	Source	**Year**	**Value**	**Study relied upon**	**Safety factor**
Thiacloprid					
ADI	COM	2004	0.01 mg/kg bw/d	2 yr rat	100
ARfD	COM	2004	0.03 mg/kg bw	Rat, acute neurotoxicity	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Under the peer review of Directive 91/414/EEC, metabolism studies were submitted for the following crop categories (The United Kingdom, 2000):

- fruits and fruiting vegetables: apples - 2 x 0.027 kg a.s./hL and tomatoes - 2 x 0.026 kg a.s./hL
- oilseeds and pulses: cotton seed - 3 x 0.019 kg a.s./hL
- cereals: wheat -2 x 0.05 kg a.s./ha

The metabolism in plant commodities was investigated with ^{14}C methylene labelled thiacloprid. In fruits and fruiting vegetables, the main component of the TRR was parent thiacloprid. From the metabolism studies in apple, it was apparent that no translocation from leaves to fruits occurs. Moreover, the study in tomatoes demonstrated that translocation does not occur from soil to fruit via roots. In the cotton seed parent thiacloprid was identified in small amounts (0.6 % TRR), while metabolite 6-chloronicotinic acid amounted for up to 46% of the TRR. This was concluded to be the result of partitioning and selective transport effect and also in cotton seeds parent was concluded to be the main component. In wheat grain and straw at harvest the parent thiacloprid accounted for 81% and 83% of the TRR respectively. Individual metabolites did not represent more than 6%.

Metabolism was sufficiently elucidated in three crop categories to propose a general residue definition for risk assessment and monitoring as parent thiacloprid. EFSA concludes that the results of metabolism of thiacloprid in different crop groups can be extrapolated also to leafy vegetables. Therefore no additional metabolism studies are necessary.

3.1.1.2. Magnitude of residues

For fresh herbs and herbal infusions, the EMS Germany reported six supervised residue field trials which were in accordance with the intended GAP. Three trials were performed on lemon balm and three trials were performed on peppermint. One peppermint trial was designed as a residue decline study where samples were analyzed at the day of application, 3 and 7 days after the last application.

The residues were not measured in fresh herbs. Instead, fresh herbs were dried and then analysed to derive the residue data in dried leaves for herbal infusions. The applicant proposed to recalculate the residues in unprocessed commodities (fresh herbs) by applying a factor of 0.1, assuming that the water content in dried leaves is 10 times lower than in fresh leaves. No data are available whether the drying leads to a loss if thiacloprid residues. However, considering the low volatility of the active substance, such losses are not likely to occur.

For the import tolerance request for tea, the applicant submitted eight supervised residue field trials on tea plants from Northern and Southern parts of India. The tea shoots were harvested on 0, 7 and 14 day after the last application. One portion of the harvested tea shoots (7 day PHI) was used to manufacture black tea. The other portion of harvested shoots was processed (drying) to green tea. All these substrates were analyzed for thiacloprid residues. EFSA used residue data on green tea and black tea to derive MRL proposal and risk assessment values. The residues in black tea were slightly higher resulting in higher STMR and HR values but in the same MRL proposal as would be derived from residues data in green tea.

Residue trials data are summarized in table 3-1.

Data on the supervised field trials are considered sufficient to propose MRLs for thiacloprid in tea, fresh herbs and herbal infusions (dried leaves).

The storage stability of thiacloprid in treated crops has been evaluated under the peer review of Directive 91/414/EEC (The United Kingdom, 2000). Studies demonstrated storage stability of thiacloprid in commodities with high water content for up to 18 months when stored below -18°C. According to the JMPR Evaluation of thiacloprid, the storage stability of thiacloprid is demonstrated in dry commodities, commodities with high oil, high water and high acid content for 24 months when samples are stored deep frozen (WHO/FAO, 2006) Samples of tea leaves were stored 0-20 days prior analyses. The storage of fresh herbs prior drying and the storage of dried leaves prior analysis did not exceed 7 days. It can be concluded that residue data are valid with regard to storage stability.

According to the EMS, analytical methods used to analyse samples of dried leaves (for herbal infusions) and tea are sufficiently validated and fit for purpose.

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 (Thiacloprid)	Risk assessment (Thiacloprid)					
Peppermint, lemon balm → Whole group of herbal infusions (dried leaves)	NEU	Outdoor	4.0; 5.4; 12.0; 15.2; 22.9; 26.3	4.0; 5.4; 12.0; 15.2; 22.9; 26.3	13.6	26.3	50.0	1.0	The residue trials were performed on lemon balm and peppermint. Crops were dried before analyses. R_{ber}=47.5 mg/kg R_{max}=47.88 mg/kg
Peppermint, lemon balm → Whole group of fresh herbs	NEU	Outdoor	-	-	-	2.6	5.00	1.0	No residue data are available for fresh herbs since residue trial samples were analyzed after drying. Risk assessment values and the MRL proposal was derived by applying a factor 0.1, assuming that the water content in dried leaves is 10 times lower than in fresh leaves.
Green tea	Import (India)	Outdoor	0.47; 1.36; 1.45; 1.81; 1.89; 2.55; 2.76; 7.1	0.47; 1.36; 1.45; 1.81; 1.89; 2.55; 2.76; 7.1	1.85	7.1	10.00	1.0	Residue trials indicate higher residue levels in black tea. These data were used for deriving the risk assessment values (indicated in bold). $R_{ber\ green\ tea}$=5.42 mg/kg $R_{max\ green\ tea}$=8.86 mg/kg $R_{ber\ black\ tea}$=5.55 mg/kg $R_{max\ black\ tea}$=9.99 mg/kg
Black tea	Import (India)	Outdoor	0.47; 1.31; 1.61; 1.85; 2.3; 2.35; 2.92; 8.04	0.47; 1.31; 1.61; 1.85; 2.3; 2.35; 2.92; 8.04	**2.08**	**8.04**	**10.00**	**1.0**	

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

3.1.1.3. Effect of industrial processing and/or household preparation

In the peer review the effects of processing on the nature of thiacloprid was studied in the aqueous solutions of thiacloprid under three test conditions: pH 4 (90°C 20 minutes), pH 5 (100°C 60 minutes) and pH 6 (120°C 100 minutes) (The United kingdom, 2000). It was concluded that thiacloprid is stable under representative processing conditions and no formation of toxicologically relevant metabolites occurs.

With regard to tea, the applicant provided data on the residue levels in green tea, black tea (section 3.1.1.2.). Green tea was produced form harvested shoots which where withered and sun dried. The processing of black tea involves fermentation.

In addition, studies are available for the magnitude of thiacloprid residues in tea infusion. Tea infusion was prepared from the black tea as 2% solution in water and analyzed for residues. From these data a provisional processing factor of 1 was obtained.

The data on the effects of processing on the magnitude of thiacloprid residues in fresh herbs, tea and dried leaves for herbal infusions were not submitted but are not relevant, taking into account the low contribution of these crops to the total dietary intake.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Occurrence of thiacloprid residues in rotational crop is not of relevance for the requested import tolerance on tea. Fresh herbs can be grown in crop rotation and in this case residues in rotational crops should be considered. According to the soil degradation studies performed in the framework of the peer review, the DT_{90} value of thiacloprid based on the field and laboratory studies is less than 100 days. Thiacloprid metabolites are more persistent in the soil. The DT_{90lab} value of metabolite M02[4] is 262 days and the DT_{90f} value amounts 1047 days (NEU) and 357 days (SEU). The possible accumulation of M02 in the Northern European soils is not excluded. The highest DT_{90lab} for soil metabolites M30[5] and M34[6] is 262 and 175 days respectively, meaning that rotational crop studies are required.

3.1.2.2. Nature of residues

In the peer review the metabolism of thiacloprid in rotational crops was studied in lettuce, wheat and turnips (The United Kingdom, 2000). The ^{14}C methylene labelled thiacloprid was applied to bare soil at an application rate of 0.424 kg a.s./ha (2N seasonal application rate on herbs). The crops were grown in three rotations, planted 30 DAT, 170 DAT and 354 DAT. Parent thiacloprid was not identified in levels >0.01 mg/kg in any rotational crop. In general, four metabolites - M02, M30, M34 and M37[7] - were detected in rotational crops but the absolute concentrations were low (below 0.1 mg/kg for each of them with exception of wheat straw). During the peer review it was decided not to include these metabolites in the residue definition since they were considered of no toxicological concern. Peer review concluded that metabolism of thiacloprid in rotational crops proceeds in a similar pathway than in primary crops and the same residue definition is applicable.

[4] M02: Z)-[3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]urea)
[5] M30: 2[1-(6-chloropyridine-3-ylmethyl)-3-carbamoyl-ureido]-ethane sulfonic acid sodium salt
[6] M34: 2-{(aminocarbonyl)[6-chloro-3-pyridinyl)methyl]amino}ethane sulfonic acid, sodium salt
[7] M37: {3-[(6-chloro-3-pyridinyl)methyl]-4-hydroxy-2-thiazolidinylidene}urea

3.1.2.3. Magnitude of residues

According to the studies as reported in section 3.1.2.2., in lettuce planted 30 DAT thiacloprid metabolites M37 an M02 were 0.043 mg/kg and 0.02 mg/kg, respectively. In lettuce planted 170 DAT only M02 was still present at 0.019 mg/kg. In turnip bulbs no parent or metabolites were identified at levels >0.01 mg/kg. In turnip tops the distribution of residues was slightly different, indicating that in a crop planted 30 DAT all four metabolites were present at levels >0.01 mg/kg but not higher than 0.074 mg/kg or 42.3% TRR (metabolite M02). In turnips planted 170 DAT and 354 DAT the metabolites in leaves did not exceed 0.02 mg/kg (M37). Concerning wheat, the highest metabolite levels have been observed in wheat straw from wheat planted 30 DAT and 170 DAT respectively: M30 (0.52 and 0.8 mg/kg), M37 (0.18 and 0.41 mg/kg), M02 (0.23 and 0.47 mg/kg) and M34 (0.15 and 0.50 mg/kg). In wheat grain the highest levels of metabolites were observed in crops sown 170 DAT, but the levels did not exceed 0.04 mg/kg (M34).

Since the intended seasonal application rate of thiacloprid on herbs is more than two times lower than the one investigated in the rotational crop studies, EFSA concludes that significant residues of thiacloprid will not be present in rotational or succeeding crops provided that the active substance is applied according to the intended GAP.

3.2. Nature and magnitude of residues in livestock

Crops under consideration are not used as a livestock feed therefore the nature and magnitude of thiacloprid residues in livestock was not addressed under the current application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic intake assessment EFSA used the existing MRLs as established in Annex II and III of Regulation (EC) No 396/2005 as well as the STMR values for tea and dried leaves for herbal infusions as derived from the supervised field trials. For fresh herbs the MRL value was used as an intake value. In addition, for spring onions, leek, lamb`s lettuce, celery and fennel EFSA used the values as obtained in the previously issued EFSA reasoned opinion on the modification of the existing MRLs for thiacloprid (EFSA, 2009a, 2009b).

The acute intake assessment was performed only with regard to the crops under consideration. For herbs the HR value and for herbal infusions and tea the STMR values as derived for the intended were applied as an input values in the intake calculations.

Input values 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
Thiacloprid				
Herbs	5.00	MRL	2.6	HR
Herbal infusions (dried leaves)	13.6	STMR	13.6	STMR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*)	2.08	STMR (black tea)	2.08	STMR (black tea)
Spring onions	0.02	STMR (EFSA, 2009a)	Acute risk assessment was performed only with regard to crops under consideration.	
Leek	0.01	STMR (EFSA, 2009a)		
Lamb`s letttuce	2.63	STMR (EFSA, 2009b)		
Celery, fennel	0.21	STMR (EFSA, 2009b)		
Other commodities	MRL	Appendix C		

Summary of intake calculations is available in Appendix B.

Chronic intake assessment did not identify consumer intake concerns for any of European diets. The total calculated intake values ranged from 15 – 78 % of the ADI. The contribution of fresh herbs to the total dietary intake accounts for a maximum of 3.33 % of the ADI for a WHO Cluster diet D and for tea 2.74 % of the ADI for IE adult diet. No consumption data are available on dried leaves for herbal infusions therefore the contribution of these crops to the total dietary intake could not be estimated accurately. However, assuming a similar consumption for herbal infusions as for the tea, the contribution of herbal infusions to the total dietary intake would account for 18% of the ADI (IE adult diet).

No acute intake concerns were identified for the crops under consideration. The short-term exposure of consumers to thiacloprid residues from tea accounts for a maximum of 6.4% of the ARfD. The highest consumer exposure to thiacloprid residues from fresh herbs is expected from consumption of celery leaves – 49.7% of the ARfD[8]. The data on the consumption of dried leaves for herbal infusions have not been reported by the MS to EFSA, but the EMS Germany has national consumption data for dried peppermint consumed as tealike product. The national estimated short-term intake calculation was conducted for German children (large portion consumption 5 g per day, mean body weight of children 16.5 kg and age 2 to 5 years) using the available STMR value (13.6 mg/kg) as an input value. Acute risk assessment results in a NESTI of 14% of the ARfD for dried peppermint. It is thereby concluded that the consumption of dried leaves as herbal infusions will not result in acute consumer intake concerns.

Consequently EFSA concludes that proposed MRLs for tea, herbs and dried leaves for herbal infusions are safe with regard to consumer exposure.

[8] It is noted that the safety margin to the toxicological reference value is narrow when the exposure is calculated with the proposed MRL (95.6% of the ADI).

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Metabolism of thiacloprid in plants is sufficiently elucidated in three crop categories and a general residue definition for risk assessment and monitoring was proposed by the peer review as parent thiacloprid. EFSA concludes that the results of the metabolism of thiacloprid in different crop groups can be extrapolated also to leafy vegetables. Therefore no additional metabolism studies are necessary.

A sufficiently validated multi-residue method with the LOQ of 0.01 mg/kg is available to control the compliance of the proposed MRLs in fresh herbs and dried leaves of herbal infusions. No specific analytical enforcement methods have been reported for tea. Since this matrix is considered as difficult to analyse, method validation data should be provided by the applicant to demonstrate that the analytical methods which are reported for herbs and herbal infusions are applicable also for the determination of thiacloprid residues in tea.

The submitted residue trials performed in India and based on the India GAP were considered sufficient to derive the import tolerance of 10 mg/kg for tea. The submitted supervised residue field trials on herbs indicate that current MRLs for herbs and dried leaves of herbal infusions do not accommodate the intended GAP in Germany and higher MRLs would be required.

The occurrence of thiacloprid or its metabolites in rotational crops was also investigated. EFSA concluded that significant residue levels in rotational crops are not expected provided that thiacloprid is applied according to the proposed GAP for herbs and herbal infusions. Residues in commodities of animal origin were not assessed in the framework of this application considering that crops under consideration are not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and III of Regulation (EC) No 396/2005 as well as the STMR values for tea and herbal infusions (dried leaves) as derived from the supervised field trials. For some crops STMR values were available to refine the intake calculations. The acute intake assessment was performed only with regard to the crops under consideration. For herbs the HR value and for herbal infusions and tea the STMR values as derived for the intended were applied as an input values in the intake calculations.

Chronic intake assessment did not identify consumer intake concerns for any of the European diets. Total calculated intake values ranged from 15 – 78 % of the ADI. The contribution of fresh herbs to the total dietary intake accounts for a maximum of 3.33 % of the ADI for WHO Cluster diet D and 2.74 % of the ADI for tea for IE adult diet. No consumption data are available on dried leaves for herbal infusions therefore the contribution of these crops to the total dietary intake could not be estimated accurately. However, assuming a similar consumption for herbal infusions as for the tea, the contribution of herbal infusions to the total dietary intake would account for 18% of the ADI.

No acute intake concerns were identified for the crops under consideration. The short-term exposure of consumers to thiacloprid residues from tea accounts for a maximum of 6.4% of the ARfD. The highest consumer exposure to thiacloprid residues from fresh herbs is expected from consumption of celery leaves – 49.7% of the ARfD. The data on the consumption of dried leaves for herbal infusions have not been reported by the MS to EFSA, but the EMS Germany has national consumption data for dried peppermint consumed as tealike product. The national estimated short-term intake calculation was conducted for German children (large portion consumption 5 g per day, mean body weight of children 16.5 kg and age 2 to 5 years) using the available STMR value (13.6 mg/kg) as an input value. Acute risk assessment results in a NESTI of 14% of the ARfD for dried peppermint. It is thereby

concluded that the consumption of dried leaves as herbal infusions will not result in acute consumer intake concerns.

Consequently EFSA concludes that proposed MRLs for tea, herbs and dried leaves for herbal infusions are safe with regard to consumer exposure. It is noted that a validated analytical method for the enforcement of the proposed MRL of thiacloprid in tea should be provided.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Thiacloprid			
Herbs	3.0	5.0	The MRL proposals are supported by data and no risk for consumers was identified for the proposed uses. The MRL proposals are based on the NEU use only.
Herbal infusions (dried leaves)	0.05*	50.00	
Tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*)	0.05*	10.00	No risk for consumers was identified for the requested import tolerance. A validated analytical enforcement method should be provided.

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

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	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)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	kg as/L min max	water L/ha min max	kg as/ha min max		
Herbs (balm leaves, mint)	Germany	F	Sucking insects	SC	480 g/l	spray	From BBCH 12	2	0.012-0.06	200-1000	0.12	7	
Tea	India	F		240SC		spray		3	0.125		0.03	7	Interval between application 7 days

(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 – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Thiacloprid			
Status of the active substance:	**included**	Code no.	**#N/A**
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.03**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	15 78
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)
78.2	DE child	36.2	Apples	4.8	Tomatoes	4.3	Milk and cream,	
72.3	NL child	19.0	Apples	8.8	Milk and cream,	5.0	Beans (with pods)	
71.0	WHO Cluster diet B	15.4	Tomatoes	8.5	Wheat	7.2	Lettuce	
59.4	IE adult	12.4	Barley	3.5	Blackberries	2.7	Tea (dried leaves and stalks,	
50.6	FR toddler	11.9	Milk and cream,	11.0	Beans (with pods)	7.9	Apples	
42.0	WHO cluster diet E	8.1	Barley	3.9	Wheat	2.8	Beans (with pods)	
40.9	DK child	7.0	Apples	5.5	Wheat	4.9	Cucumbers	
40.8	WHO regional European diet	7.5	Lettuce	5.5	Tomatoes	3.3	Barley	
37.6	ES child	8.3	Lettuce	4.9	Tomatoes	4.4	Wheat	
37.4	WHO cluster diet D	6.5	Wheat	5.1	Tomatoes	3.3	Herbs	
36.4	UK Toddler	6.2	Milk and cream,	5.1	Apples	4.6	Sugar beet (root)	
35.9	ES adult	10.7	Lettuce	4.9	Barley	3.9	Tomatoes	
35.9	UK Infant	11.6	Milk and cream,	4.7	Apples	2.6	Wheat	
35.1	WHO Cluster diet F	6.0	Barley	6.0	Lettuce	3.6	Wheat	
34.7	FR infant	8.4	Beans (with pods)	7.7	Milk and cream,	7.5	Apples	
34.6	IT kids/toddler	7.1	Tomatoes	6.6	Wheat	5.8	Lettuce	
33.3	IT adult	7.5	Lettuce	5.8	Tomatoes	4.1	Wheat	
30.9	SE general population 90th percentile	3.8	Tomatoes	3.7	Milk and cream,	3.2	Wheat	
30.4	NL general	3.7	Barley	3.5	Apples	2.5	Beans (with pods)	
21.9	FR all population	3.8	Other lettuce and other salad plants	3.3	Wheat	2.2	Tomatoes	
21.0	PT General population	4.5	Tomatoes	3.9	Wheat	3.2	Apples	
19.9	LT adult	5.6	Apples	3.1	Tomatoes	1.3	Lettuce	
19.6	UK vegetarian	3.1	Tomatoes	2.8	Lettuce	2.0	Wheat	
17.0	PL general population	6.1	Apples	4.4	Tomatoes	0.8	Pears	
15.4	DK adult	2.4	Apples	2.1	Tomatoes	2.0	Wheat	
15.1	FI adult	2.1	Tomatoes	1.7	Milk and cream,	1.6	Lettuce	
15.0	UK Adult	2.3	Lettuce	2.2	Tomatoes	1.7	Wheat	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Thiacloprid 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)
49.7	Celery leaves	2.6 / -	49.7	Celery leaves	2.6 / -	10.4	Parsley	2.6 / -	10.4	Parsley	2.6 / -
11.2	Chervil	2.6 / -	11.2	Chervil	2.6 / -	2.1	Tea	2.08 / -	2.1	Tea	2.08 / -
6.6	Parsley	2.6 / -	6.6	Parsley	2.6 / -	1.4	Herbs	2.6 / -	1.4	Herbs	2.6 / -
6.4	Tea	2.08 / -	6.4	Tea	2.08 / -	1.1	Celery leaves	2.6 / -	1.1	Celery leaves	2.6 / -
6.0	Basil	2.6 / -	6.0	Basil	2.6 / -	0.5	Chives	2.6 / -	0.5	Chives	2.6 / -
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 Thiacloprid IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX C – EXISTING EC MRLS

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
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	0,3
130010	Apples (Crab apple)	0,3
130020	Pears (Oriental pear)	0,3
130030	Quinces	0,3
130040	Medlar	0,3
130050	Loquat	0,3
130990	Others	0,3
140000	(iv) Stone fruit	
140010	Apricots	0,3
140020	Cherries (sweet cherries, sour cherries)	0,3
140030	Peaches (Nectarines and similar hybrids)	0,3
140040	Plums (Damson, greengage, mirabelle)	0,1
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,5
153000	(c) Cane fruit	
153010	Blackberries	3
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	1
153030	Raspberries (Wineberries)	3
153990	Others	1
154000	(d) Other small fruit & berries	1
154010	Blueberries (Bilberries cowberries (red bilberries))	1
154020	Cranberries	1
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other ribes species)	1
154050	Rose hips	1
154060	Mulberries (arbutus berry)	1
154070	Azarole (mediteranean medlar)	1
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	1
154990	Others	1
160000	(vi) Miscellaneous fruit	
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 (Bilimbi)	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	
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,5
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	
210000	(i) Root and tuber vegetables	
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	
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,1
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* (0.1)[a]
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,5
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	0,5
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,3
232010	Cucumbers	0,3
232020	Gherkins	0,3
232030	Courgettes (Summer squash, marrow (patisson))	0,3
232990	Others	0,3
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,2
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,2
233990	Others	0,02*
234000	(d) Sweet corn	0,1

239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1
241020	Cauliflower	0,1
241990	Others	0,1
242000	(b) Head brassica	
242010	Brussels sprouts	0,05
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,2
242990	Others	0,02*
243000	(c) Leafy brassica	1
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)	1
243990	Others	1
244000	(d) Kohlrabi	0,05
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	2 (5.0)[a]
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	2
251040	Cress	2
251050	Land cress	2
251060	Rocket, Rucola (Wild rocket)	3
251070	Red mustard	2
251080	Leaves and sprouts of Brassica spp (Mizuna)	2
251990	Others	2
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, glassworth)	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	3
256010	Chervil	3
256020	Chives	3
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	3
256040	Parsley	3
256050	Sage (Winter savory, summer savory,)	3
256060	Rosemary	3
256070	Thyme (marjoram, oregano)	3
256080	Basil (Balm leaves, mint, peppermint)	3
256090	Bay leaves (laurel)	3
256100	Tarragon (Hyssop)	3
256990	Others	3
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1
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)	0,2
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,3 (0.5)[a]
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02* (0.1)[a]
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	
300000	3. PULSES, DRY	0,1
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1
300020	Lentils	0,1
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1
300040	Lupins	0,1
300990	Others	0,1
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,3
401070	Soya bean	0,05*
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	
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	1
500020	Buckwheat	0,05
500030	Maize	0,05
500040	Millet (Foxtail millet, teff)	0,05
500050	Oats	1
500060	Rice	0,05
500070	Rye	0,05
500080	Sorghum	0,05
500090	Wheat (Spelt Triticale)	0,1
500990	Others	0,05
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
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	0,1*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*

810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
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	0,3
1011040	Kidney	0,3
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0,05
1012020	Fat	0,05
1012030	Liver	0,3
1012040	Kidney	0,3
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	
1013010	Meat	0,05
1013020	Fat	0,05
1013030	Liver	0,3
1013040	Kidney	0,3
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0,05
1014020	Fat	0,05
1014030	Liver	0,3
1014040	Kidney	0,3
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,05
1015020	Fat	0,05
1015030	Liver	0,3
1015040	Kidney	0,3
1015050	Edible offal	0,01*
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	0,3
1016040	Kidney	0,3
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	0,3
1017040	Kidney	0,3
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,03
1020010	Cattle	0,03
1020020	Sheep	0,03
1020030	Goat	0,03
1020040	Horse	0,03
1020990	Others	0,03
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen)	0,2
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	
Code number	Groups and examples of individual products to which the MRLs apply (a)	

[a] Residue value as proposed by EFSA in its reasoned opinions but not considered at SCoFCAH by 20 September 2009

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CS	capsule suspension
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
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient

L	litre
LC	liquid chromatography
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NESTI	National Estimated Short Term Intake
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WHO	World Health Organisation