

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for thiacloprid in spinach and similar leaves¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance thiacloprid in spinach and similar leaves crop group. In order to accommodate the intended indoor and outdoor uses of thiacloprid in Belgium, the EMS proposed to raise the existing MRLs for thiacloprid in spinach and similar leaves group or only in spinach and beet leaves to 0.15 mg/kg. Belgium drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA, the submitted residue trials data on lettuce are not sufficient to support the residue data extrapolation to the whole group of spinach and similar leaves. Alternatively, the EMS proposed to extrapolate four outdoor residue trials data on open leaf lettuce to spinach and beet leaves only. Although this extrapolation is not explicitly mentioned in the European guidance document, EFSA is of the opinion that the proposal is acceptable, considering the morphological similarities between spinach/beet leaves and open leaf varieties of lettuce and taking into account that spinach and beet leaves are minor crops. Thus, a MRL proposal of 0.15 mg/kg is derived. Based on the risk assessment results EFSA concludes that the intended use of thiacloprid on spinach and beet leaves will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

© European Food Safety Authority, 2013

KEY WORDS

Thiacloprid, spinach and similar, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, neonicotinoid insecticide

¹ On request from the European Commission, Question No EFSA-Q-2013-00314, approved on 24 September 2013.

² Correspondence: pesticides.mrl@efsa.europa.eu

Suggested citation: European Food Safety Authority, 2013. Reasoned opinion on the modification of the existing MRLs for thiacloprid in spinach and similar leaves. EFSA Journal 2013;11(9):3382, 26 pp. doi:10.2903/j.efsa.2013.3382

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance thiacloprid in spinach and similar leaves crop group. In order to accommodate the intended indoor and outdoor uses of thiacloprid in Belgium, the EMS proposed to raise the existing MRLs for thiacloprid in spinach and similar leaves group or only in spinach and beet leaves to 0.15 mg/kg. Belgium drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 2 July 2013.

The toxicological profile of thiacloprid was assessed under the peer review and the data were sufficient to conclude on an ADI value of 0.01 mg/kg bw per day and an ARfD of 0.03 mg/kg bw.

The metabolism of thiacloprid in plants was investigated in three crop groups and the residue definition for risk assessment and enforcement was established as parent thiacloprid. These residue definitions are applicable also to the crops under consideration.

EFSA concludes that the submitted supervised residue trials data on lettuce are not sufficient to support the residue data extrapolation to the whole group of spinach and similar leaves. Alternatively, the EMS proposed to extrapolate four outdoor residue trials data on open leaf lettuce to spinach and beet leaves only. Although this extrapolation is not explicitly mentioned in the European guidance document, EFSA is of the opinion that the proposal is acceptable, considering the morphological similarities between spinach/beet leaves and open leaf varieties of lettuce and taking into account that spinach and beet leaves are minor crops. Thus, a MRL proposal of 0.15 mg/kg is derived. Adequate analytical enforcement methods are available to control the residues of thiacloprid in spinach and beet leaves.

The effect of processing on the nature of thiacloprid was investigated in the framework of the peer review. Thiacloprid was stable under typical processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable. Specific processing studies with spinach or beet leaves have not been submitted in the framework of the current application. Given the low individual contribution of residues in these crops to the total consumer exposure, such studies are not explicitly required.

The metabolism of thiacloprid in rotational crops proceeds in a similar pathway as in primary crops and thus the same residue definitions are applicable. The results of the rotational crop metabolism study indicate that significant thiacloprid residues are unlikely to occur in rotational/succeeding crops, provided that thiacloprid on spinach and beet leaves is used according to the intended GAP.

Spinach and beet leaves are not fed to livestock and therefore the nature and magnitude of thiacloprid residues in livestock was not assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). To calculate the chronic exposure from residues in spinach and beet leaves, EFSA used the median residue value as derived from the residue trials on lettuce. For several other crops the risk assessment values were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to spinach and beet leaves.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 77% of the ADI (DE child diet). The contribution of residues in spinach and beet leaves to the total consumer exposure accounted for a maximum of 0.25% (FR toddler diet) and 0.03% (ES child diet) of the ADI, respectively.

No acute consumer risk was identified in relation to the intended use of thiacloprid on spinach and beet leaves. The calculated maximum exposure was 4.5% ARfD for spinach and 3.5% ARfD for beet leaves.

EFSA concludes that the intended use of thiacloprid on spinach and beet leaves will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Thiacloprid (F)				
0252010	Spinach	0.02*	0.15	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the outdoor use.
0252030	Beet leaves	0.02*	0.15	

(a): According to Annex I of Regulation (EC) No 396/2005.

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

(F): Fat-soluble.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	4
Background	5
Terms of reference.....	5
The active substance and its use pattern.....	6
Assessment	7
1. Method 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
Appendices	18
Appendix A. Good Agricultural Practice (GAPs)	18
Appendix B. Pesticide Residue Intake Model (PRIMo).....	19
Appendix C. Existing EU maximum residue levels (MRLs)	21
Appendix D. List of metabolites and related structural formula.....	24
Abbreviations	25

BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to set or to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Belgium⁶, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for thiacloprid in spinach and similar leaves. This application was notified to the European Commission and EFSA and was subsequently evaluated in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 2 April 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00314 and the following subject:

Thiacloprid - Application to modify the existing MRLs in spinach and similar (leaves).

EMS proposed to raise the existing MRLs of thiacloprid in spinach and similar leaves group or only in spinach and beet leaves from the limit of quantification (LOQ) of 0.02 mg/kg to 0.15 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with 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.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) 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 deadline for providing the reasoned opinion is 2 July 2013.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

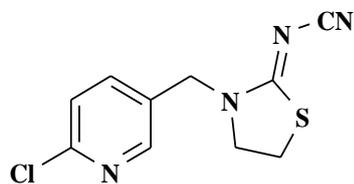
⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

⁶ FPS Health, Food chain Safety and Environment, DG4, Place Victor Horta, 40 box 10, Eurostation II, local 7D115, 1060, Brussels

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Thiacloprid is the ISO common name for (Z)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide (IUPAC).



Thiacloprid belongs to the group of neonicotinoid insecticides. It is a non-systemic active substance which acts as an agonist of the nicotinic acetylcholine receptors (nAChR) in the central nervous system leading to a disruption of the nerve signal transmission. The active substance is used by foliar applications against sucking and biting insects in several crops such as pome fruit, stone fruit, berries, cotton, oilseeds, 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 was evaluated in the framework of Directive 91/414/EEC with the United Kingdom being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were field and indoor uses on pome fruits, peaches, tomatoes, peppers, cucurbits and ornamentals. Following the peer review a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2004/99/EC⁷. According to Regulation (EU) No 540/2011⁸, thiacloprid is considered to be approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as insecticide only. As EFSA was not yet involved in the peer review of thiacloprid, an EFSA conclusion is not available.

The EU MRLs for thiacloprid are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for leek, spring onions, lamb's lettuce, celery, fennel, fresh herbs, herbal infusions, tea, olives, carrots, horseradish, beetroot, parsnips, parsley root, salsify, poppy seeds, strawberries, figs, radish, cotton seeds and peas with pods (EFSA, 2009a, 2009b, 2009c, 2009d, 2010a, 2010b, 2010c, 2010d) which have been taken over in the MRL legislation. The existing EU MRL for thiacloprid in spinach and similar leaves is currently established at the LOQ of 0.02 mg/kg. Codex Alimentarius Commission has established CXLs for thiacloprid in various crops, except spinach.

The MRL review of thiacloprid according to Article 12 of Regulation (EC) No 396/2005 is currently ongoing and the final reasoned opinion is expected beginning of 2014.

The details of the intended GAP for the use of thiacloprid in Belgium are given in Appendix A.

⁷ Commission Directive 2004/99/EC of 01 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances. OJ L 309, 6.10.2004, p. 6-8.

⁸ Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Belgium, 2013), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (United Kingdom, 2000), the Commission Review Report on thiacloprid (EC, 2004) and the conclusions from previous EFSA reasoned opinions on thiacloprid (EFSA, 2009a, 2009b, 2009c, 2009d, 2010a, 2010b, 2010c, 2010d). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

The applicability of the available analytical enforcement methods for the determination of thiacloprid in plant matrices in routine monitoring was investigated in the framework of the peer review (United Kingdom, 2000) as well as in the previous EFSA reasoned opinions (EFSA, 2010d).

An HPLC-UV method is sufficiently validated at the LOQ of 0.02 mg/kg for the determination of thiacloprid in high water content matrices and in dry matrices (United Kingdom, 2000). Also the multi-residue QuEChERS method (HPLC-MS/MS) is validated for the determination of thiacloprid residues in matrices with high water-, high acid content and in dry matrices at the LOQ of 0.01 mg/kg (EURL, 2013).

EFSA concludes that sufficiently validated analytical methods are available to control residues of thiacloprid in spinach and similar leaves.

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

Analytical methods for the determination of thiacloprid residues in food of animal origin were not assessed in the current application since spinach and similar leaves are not fed to livestock.

2. Mammalian toxicology

The toxicological assessment of thiacloprid was peer reviewed under Directive 91/414/EEC and toxicological reference values (Table 2-1) were established by the European Commission (2004).

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Thiacloprid					
ADI	EC	2004	0.01 mg/kg bw per day	2 years rat	100
ARfD	EC	2004	0.03 mg/kg bw	Acute neurotoxicity study in rats	100

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

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 the metabolism of thiacloprid was investigated for foliar and soil applications on fruits and fruiting vegetables (apple, tomato) and on pulses and oilseeds (cotton) (United Kingdom, 2000). An additional metabolism study for foliar application on cereals (wheat) was evaluated by the RMS after Annex I inclusion and by the JMPR (FAO, 2006). In all studies, thiacloprid was radio-labelled on methylene position. The details of these studies are reported in the previously issued EFSA reasoned opinion (EFSA, 2010d).

In fruits and fruiting vegetables, the main component of the TRR was parent thiacloprid. From the metabolism studies in apple it was apparent that residue translocation from leaves to fruits does not occur. Moreover, the study in tomatoes demonstrated that translocation does not occur from soil to fruit via roots. In wheat grain and straw at harvest the parent thiacloprid accounted for 81% and 83% of the total radioactivity, respectively. Individual metabolites did not represent more than 6%. In the cotton seed parent thiacloprid was identified in small amounts (0.6% TRR), while metabolite 6-chloronicotinic acid¹⁰ amounted for up to 46% of the TRR.

The metabolic pathway involves hydroxylation of the thiazolidine ring and oxidative cleavage of the methylene bridge. Further conjugation with sugars, phosphate/sulphate and endogenous plant components can also occur. The main resulting metabolite, 6-chloronicotinic acid, was found in high levels in cotton seed only.

Metabolism was sufficiently elucidated in three crop categories to propose a general residue definition for risk assessment and monitoring as parent thiacloprid. This conclusion, however, has to be confirmed in the framework of the MRL review according to Article 12 of Regulation (EC) No 396/2005. Thiacloprid is also set as enforcement residue definition by the JMPR and in the Regulation (EC) No 396/2005.

EFSA concludes that the results of metabolism of thiacloprid in different crop groups can be extrapolated to leafy vegetables. Therefore no additional metabolism studies are necessary.

3.1.1.2. Magnitude of residues

In support of the NEU outdoor use on spinach and similar leaf crops, the EMS submitted four GAP compliant residue trials on an open leaf variety lettuce. All trials have been performed in Belgium in 2011. Residues of thiacloprid ranged from 0.02 to 0.06 mg/kg.

In support of the indoor use in total sixteen residue trials on lettuce were submitted. Trials were performed in various European countries in 2002 and 2005. Eight of the submitted residue trials were overdosed (performed with two applications instead of one); moreover, in four of these trials samples were analysed only at the PHI of 7 days and no information was provided on the residue situation in a crop at the intended PHI of 14 days. EFSA disregarded these trials as incompliant with the GAP. The remaining four overdosed trials were all decline trials and indicated that second application has an impact on the residue levels in the crop. Thus, EFSA disregarded these trials, too. Finally, eight GAP compliant residue trials were available. Only one of these trials was performed with an open leaf lettuce variety, remaining trials being performed with head forming lettuce variety. Residues of thiacloprid ranged from <0.05 to 1.2 mg/kg.

¹⁰ 6-chloronicotinic acid: See Appendix D

The EMS proposes to extrapolate residue data from lettuce to the whole group of spinach and similar leaves. According to the EU guidance document (EC, 2011) such an extrapolation is possible, provided that at least eight residue trials on lettuce have been submitted with a minimum of four trials on an open leaf lettuce variety. Thus, for the NEU outdoor use on the whole group of spinach and similar, additional four residue trials would be required while for the indoor use on the whole group of spinach and similar, additional three GAP compliant residue trials on an open leaf lettuce variety would be required. EFSA therefore concludes that, considering the data requirements defined in the EU guidance document, the available data set is not sufficient to support the indoor and outdoor use on spinach and similar leaves group.

The EMS, being aware of these data gaps, as an alternative option proposes to extrapolate residue data from four outdoor trials on open leaf lettuce to spinach and beet leaves only. Given that these are minor crops and a group tolerance is not intended and the fact that open leaf varieties of lettuce are morphologically similar to spinach and beet leaves, this proposal can be accepted, although this extrapolation is not explicitly mentioned in the EU guidance document. Thus, a MRL proposal of 0.15 mg/kg is derived, based on the NEU outdoor use.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The potential degradation of thiacloprid residues during storage was assessed in the framework of the peer review where storage stability of thiacloprid was demonstrated for a period of 18 months at -18°C in commodities with high water content (apple, tomato and melon) (United Kingdom, 2000). The supervised residue trial samples from the NEU outdoor use were stored within this period of time (9.5 months) and therefore it is concluded that the residue data are considered valid with regard to storage stability. Information on the storage period of indoor residue trial samples prior to analysis was not provided.

According to the EMS, the analytical method used to analyse the supervised residue outdoor trial samples has been sufficiently validated and was proven to be fit for the purpose (Belgium, 2013). Information on the validation of the analytical methods used to analyse indoor residue trial samples was not provided.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Thiacloprid)	Risk assessment (Thiacloprid)					
Lettuce (open leaf lettuce variety) → spinach, beet leaves	NEU	Outdoor	0.021; 0.033; 0.036; 0.06	0.021; 0.033; 0.036; 0.06	0.035	0.06	0.15	1.0	$R_{ber} = 0.11$ $R_{max} = 0.12$ $MRL_{OECD} = 0.11/0.15$
Lettuce → spinach and similar leaves (spinach, purslane, beet leaves)	EU	Indoor	<0.05; 2 x 0.05; 0.08; 0.13; 0.58; 0.62; 1.2 ^f	<0.05; 2 x 0.05; 0.08; 0.13; 0.58; 0.62; 1.2 ^f	The submitted residue data are not sufficient to extrapolate to the whole group of spinach and similar leaves. Additional three GAP compliant residue trials on an open leaf lettuce variety are required (EC, 2011).				

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).

(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 residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber} , R_{max} ; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): A trial performed with an open leaf lettuce variety.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of thiacloprid was investigated in the framework of the peer review in standard hydrolysis studies. From these studies, it was concluded that pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues (United Kingdom, 2000). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

Specific studies to assess the magnitude of thiacloprid residues during the processing of spinach or beet leaves have not been submitted in the framework of the current application. Given the low individual contribution of residues in these crops to the total consumer exposure, such studies are not explicitly required.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Spinach and beet leaves can be grown in a crop rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, DT₉₀ value of thiacloprid is expected to be lower than the trigger value of 100 days (EC, 2004). However, soil metabolites of thiacloprid were more persistent in soil. In particular, the metabolites M02¹¹ with DT₉₀ values ranging from 106 to 1047 days (NEU), M30¹² with a highest DT₉₀ of 262 days and M34¹³ with a highest DT₉₀ of 175 days. Due to the persistence of thiacloprid metabolites in soil, and according to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature of residues

The metabolism of thiacloprid in rotational crops was investigated in the framework of the peer review under Directive 91/414/EEC (United Kingdom, 2000). The details of metabolism studies are reported in the previously issued EFSA reasoned opinion (EFSA, 2010d).

In all rotational crops thiacloprid was never detected (below the LOQ) and the residues of individual metabolites were generally low, less than 0.1 mg/kg, with the exception of metabolites M02, M30, M34 and M37¹⁴ in wheat hay and straw. However these metabolites were considered of no toxicological concern and the peer review concluded that the residue definition established in primary crops is also applicable to rotational crops (United Kingdom, 2000).

3.1.2.3. Magnitude of residues

The rotational crop metabolism study was performed with an application rate of 0.42 kg a.s./ha, which is significantly higher (3.5N) than the intended seasonal application rate on spinach and beet leaves. The results demonstrate that at all plant back intervals the final residues in the samples of lettuce, turnips and wheat declined successively with each sampling date. At harvest, thiacloprid residues were not detectable (below LOQ) in any sample grown on soil which was treated 30, 170 and 354 days before the crops were planted. Therefore no significant thiacloprid residues are expected in rotational/succeeding crops planted after spinach and beet leaves, provided that thiacloprid is applied on these crops according to the intended GAP.

¹¹ M02: 3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene}urea. See Appendix D.

¹² M30: Sodium 2-[[[(aminocarbonyl)amino]-carbonyl][(6-chloro-3-pyridinyl)-methyl]amino]ethanesulfonate. See Appendix D.

¹³ M34: Sodium 2-[(aminocarbonyl][(6-chloro-3-pyridinyl)methyl]amino]ethane-sulfonate; see AppendixD.

¹⁴ M37: See Appendix D.

3.2. Nature and magnitude of residues in livestock

Spinach and beet leaves are not fed to livestock and therefore the nature and magnitude of thiacloprid residues in livestock was not assessed in the framework of this application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹⁵ (EFSA, 2007).

For the calculation of chronic exposure from residues in spinach and beet leaves, EFSA used the median residue value as derived from the residue trials on lettuce (see Table 3-1). For several other crops the risk assessment values were available from the previously issued EFSA reasoned opinions to refine the exposure calculation (EFSA, 2009a, 2009b, 2009c, 2009d, 2010a, 2010b, 2010c, 2010d). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIA of Regulation (EC) No 396/2005 were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to spinach and beet leaves, assuming the consumption of a large portion of these food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Thiacloprid				
Spinach, beet leaves	0.035	Median residue (lettuce) (Table 3-1)	0.06	Highest residue (lettuce) (Table 3-1)
Peas (with pod)	0.04	Median residue (EFSA, 2010d)	Acute exposure assessment was performed only for the crops under consideration.	
Cotton seed	0.02	Median residue (EFSA, 2010c)		
Figs	0.094	Median residue (EFSA, 2010b)		
Strawberries	0.265	Median residue (EFSA, 2010a)		

¹⁵ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Table olives	0.51	Median residue EFSA, 2009d)		
Olives for oil production	0.01	Median residue (EFSA, 2009d)		
Carrots, beetroot, horseradish, parsley root, parsnips, salsify	0.01	Median residue (EFSA, 2009d)		
Poppy seed	0.06	Median residue (EFSA, 2009d)		
Rape seed	0.06	Median residue (EFSA, 2009d)		
Herbal infusions (dried leaves)	13.6	Median residue (EFSA, 2009c)		
Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	2.08	Median residue (EFSA, 2009c)		
Lamb`'s lettuce	2.63	Median residue (EFSA, 2009b)		
Celery	0.21	Median residue (EFSA, 2009b)		
Fennel	0.21	Median residue (EFSA, 2009b)		
Spring onions	0.02	Median residue (EFSA, 2009a)		
Leek	0.01	Median residue (EFSA, 2009a)		
Other commodities of plant and animal origin	MRL	See Appendix C		

The estimated exposure was then compared with the toxicological reference values derived for thiacloprid (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 77% of the ADI (DE child diet). The contribution of residues in spinach and beet leaves to the total consumer exposure accounted for a maximum of 0.25% (FR toddler diet) and 0.03% (ES child diet) of the ADI, respectively.

No acute consumer risk was identified in relation to the intended use of thiacloprid on spinach and beet leaves. The calculated maximum exposure was 4.5% ARfD for spinach and 3.5% ARfD for beet leaves.

EFSA concludes that the intended use of thiacloprid on spinach and beet leaves will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of thiacloprid was assessed under the peer review and the data were sufficient to conclude on an ADI value of 0.01 mg/kg bw per day and an ARfD of 0.03 mg/kg bw.

The metabolism of thiacloprid in plants was investigated in three crop groups and the residue definition for risk assessment and enforcement was established as parent thiacloprid. These residue definitions are applicable also to the crops under consideration.

EFSA concludes that the submitted supervised residue trials data on lettuce are not sufficient to support the residue data extrapolation to the whole group of spinach and similar leaves. Alternatively, the EMS proposed to extrapolate four outdoor residue trials data on open leaf lettuce to spinach and beet leaves only. Although this extrapolation is not explicitly mentioned in the European guidance document, EFSA is of the opinion that the proposal is acceptable, considering the morphological similarities between spinach/beet leaves and open leaf varieties of lettuce and taking into account that spinach and beet leaves are minor crops. Thus, a MRL proposal of 0.15 mg/kg is derived. Adequate analytical enforcement methods are available to control the residues of thiacloprid in spinach and beet leaves.

The effect of processing on the nature of thiacloprid was investigated in the framework of the peer review. Thiacloprid was stable under typical processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable. Specific processing studies with spinach or beet leaves have not been submitted in the framework of the current application. Given the low individual contribution of residues in these crops to the total consumer exposure, such studies are not explicitly required.

The metabolism of thiacloprid in rotational crops proceeds in a similar pathway as in primary crops and thus the same residue definitions are applicable. The results of the rotational crop metabolism study indicate that significant thiacloprid residues are unlikely to occur in rotational/succeeding crops, provided that thiacloprid on spinach and beet leaves is used according to the intended GAP.

Spinach and beet leaves are not fed to livestock and therefore the nature and magnitude of thiacloprid residues in livestock was not assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). To calculate the chronic exposure from residues in spinach and beet leaves, EFSA used the median residue value as derived from the residue trials on lettuce. For several other crops the risk assessment values were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to spinach and beet leaves.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake accounted for up to 77% of the ADI (DE child diet). The contribution of residues in spinach and beet leaves to the total consumer exposure accounted for a maximum of 0.25% (FR toddler diet) and 0.03% (ES child diet) of the ADI, respectively.

No acute consumer risk was identified in relation to the intended use of thiacloprid on spinach and beet leaves. The calculated maximum exposure was 4.5% ARfD for spinach and 3.5% ARfD for beet leaves.

EFSA concludes that the intended use of thiacloprid on spinach and beet leaves will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Thiacloprid (F)				
0252010	Spinach	0.02*	0.15	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the outdoor use.
0252030	Beet leaves	0.02*	0.15	

(a): According to Annex I of Regulation (EC) No 396/2005.

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

(F): Fat-soluble

REFERENCES

Belgium, 2013. Evaluation report on the modification of MRLs for thiacloprid in spinach and similar leaves prepared by the evaluating Member State EMS under Article 8 of Regulation (EC) No 396/2005, 20 March 2013, 17 pp.

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.

EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4.

EC (European Commission), 2004. Review Report for the active substance thiacloprid. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 June 2004 in view of the inclusion of thiacloprid in Annex I of Directive 91/414/EEC. SANCO/4347/2000-Final, 13 May 2004, 63 pp.

EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

- EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.
- EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.
- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs.
- EFSA (European Food Safety Authority), 2009a. Reasoned opinion on the modification of the existing MRLs for thiacloprid in leek and spring onions prepared by the Pesticides Unit (PRAPeR). EFSA Scientific Report (2009) 256, 1-25.
- EFSA (European Food Safety Authority), 2009b. Reasoned opinion on the modification of the existing MRLs for thiacloprid in lamb's lettuce, celery and fennel prepared by the Pesticides Unit (PRAPeR). EFSA Scientific Report (2009) 307, 1-26.
- EFSA (European Food Safety Authority), 2009c. Reasoned opinion on the modification of the existing MRLs for thiacloprid in fresh herbs, herbal infusions (dried leaves) and tea prepared by the Pesticides Unit (PRAPeR) on the request from the European Commission. EFSA Journal 2009; 7(10):1346, 1-23.
- EFSA (European Food Safety Authority), 2009d. Reasoned opinion on the modification of the existing MRLs for thiacloprid in table olives, olives for oil production, poppy seeds and various root vegetables prepared by the Pesticides Unit (PRAPeR) on the request from the European Commission. EFSA Journal 2009;7(12):1410, 1-28.
- EFSA (European Food Safety Authority), 2010a. Reasoned opinion on the modification of the existing MRL for thiacloprid in strawberries prepared by the Pesticides Unit (PRAPeR) on the request from the European Commission. EFSA Journal 2010;8(1):1498, 23 pp.
- EFSA (European Food Safety Authority), 2010b. Reasoned opinion on the modification of the existing MRL for thiacloprid in figs and various crops prepared by the Pesticides Unit (PRAPeR) on the request from the European Commission. EFSA Journal 2010;8(7):1668, 25 pp.
- EFSA (European Food Safety Authority), 2010c. Reasoned opinion on the modification of the existing MRL for thiacloprid in cotton seed prepared by the Pesticides Unit (PRAPeR). EFSA Journal 2010;8(8):1713, 25 pp.
- EFSA (European Food Safety Authority), 2010d. Reasoned opinion on the modification of the existing MRL for thiacloprid in peas (with pods) prepared by the Pesticides Unit (PRAPeR). EFSA Journal 2010;8(12):1939, 27 pp.
- EURL (European Union Reference Laboratories for Pesticide Residues), 2013. Data pool on method validation for pesticide residues. Status on 25 June 2013. Available online: www.eurl-pesticides-datapool.eu
- FAO (Food and Agriculture Organisation of the United Nations), 2006. Thiacloprid. In: Pesticide residues in food – 2006. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 189/2.
- FAO (Food and Agriculture Organisation of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.
- Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany.
- OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues.

United Kingdom, 2000. Draft Assessment Report on the active thiacloprid prepared by the rapporteur Member State in the framework of Directive 91/414/EEC. November 2000.

APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Spinach and baby spinach/ Spinach and similar leaves	BELGIUM	F/G	Aphids	WG	480 g/L	spray		1			0.12	14	

Remarks: (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)

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

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

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. Pesticide Residue Intake Model (PRIMO)

		Thiacloprid				Prepare workbook for refined calculations		
Status of the active substance:		Included		Code no.				
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:		EC		Source of ARfD:		EC		
Year of evaluation:		2004		Year of evaluation:		2004		
Chronic risk assessment								
Chronic risk assessment - refined calculations		TMDI (range) in % of ADI minimum - maximum						
		15 77						
		No of diets exceeding ADI: ---						
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
77.1	DE child	36.2	Apples	4.8	Tomatoes	4.3	Milk and cream,	
71.8	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	
59.3	IE adult	12.4	Barley	3.5	Blackberries	2.7	Tea (dried leaves and stalks,	
49.2	FR toddler	11.9	Milk and cream,	11.0	Beans (with pods)	7.9	Apples	
40.6	DK child	7.0	Apples	5.5	Wheat	4.9	Cucumbers	
40.5	WHO regional European diet	7.5	Lettuce	5.5	Tomatoes	3.3	Barley	
40.5	WHO cluster diet E	8.1	Barley	3.9	Wheat	2.8	Beans (with pods)	
37.6	ES child	8.3	Lettuce	4.9	Tomatoes	4.4	Wheat	
37.3	WHO cluster diet D	6.5	Wheat	5.1	Tomatoes	3.3	Herbs	
35.9	ES adult	10.7	Lettuce	4.9	Barley	3.9	Tomatoes	
35.9	UK Toddler	6.2	Milk and cream,	5.1	Apples	4.6	Sugar beet (root)	
35.2	UK Infant	11.6	Milk and cream,	4.7	Apples	2.6	Wheat	
34.4	IT kids/toddler	7.1	Tomatoes	6.6	Wheat	5.8	Lettuce	
34.3	WHO Cluster diet F	6.0	Barley	6.0	Lettuce	3.6	Wheat	
33.5	FR infant	8.4	Beans (with pods)	7.7	Milk and cream,	7.5	Apples	
33.3	IT adult	7.5	Lettuce	5.8	Tomatoes	4.1	Wheat	
30.7	SE general population 90th percentile	3.8	Tomatoes	3.7	Milk and cream,	3.2	Wheat	
30.2	NL general	3.7	Barley	3.5	Apples	2.5	Beans (with pods)	
21.7	FR all population	3.8	Other lettuce and other salad	3.3	Wheat	2.2	Tomatoes	
21.2	PT General population	4.5	Tomatoes	3.9	Wheat	3.2	Apples	
19.8	LT adult	5.6	Apples	3.1	Tomatoes	1.3	Lettuce	
19.4	UK vegetarian	3.1	Tomatoes	2.8	Lettuce	2.0	Wheat	
16.9	PL general population	6.1	Apples	4.4	Tomatoes	0.8	Pears	
15.3	DK adult	2.4	Apples	2.1	Tomatoes	2.0	Wheat	
15.0	FI adult	2.1	Tomatoes	1.7	Milk and cream,	1.6	Lettuce	
14.9	UK Adult	2.3	Lettuce	2.2	Tomatoes	1.7	Wheat	
Conclusion:								
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Thiacloprid is unlikely to present a public health concern.								

Acute risk assessment /children						Acute risk assessment / adults / general population						
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 variability factor of 3.												
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	4.5	Spinach	0.06 / -	4.5	Spinach	0.06 / -	1.8	Spinach	0.06 / -	1.8	Spinach	0.06 / -
3.5	Beet leaves (chard)	0.06 / -	2.7	Beet leaves	0.06 / -	1.5	Beet leaves (chard)	0.06 / -	1.3	Beet leaves (chard)	0.06 / -	
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:			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)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
<p>*) 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.</p> <p>**) pTMRL: provisional temporary MRL</p> <p>***) pTMRL: provisional temporary MRL for unprocessed commodity</p>												
<p>Conclusion:</p> <p>For Thiacloprid IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.</p> <p>No exceedance of the ARfD/ADI was identified for any unprocessed commodity.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>												

Appendix C. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 17/09/2013 13:20))

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)	Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)	Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)	Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
100000	1. FRUIT FRESH OR FROZEN NUTS		140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,1	161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	0,02*	200000	2. VEGETABLES FRESH OR FROZEN	
110000	(i) Citrus fruit	0,02*	140990	Others	0,02*	161050	Carambola (Bilimbi)	0,02*	210000	(i) Root and tuber vegetables	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,02*	150000	(v) Berries & small fruit		161060	Persimmon	0,02*	211000	(a) Potatoes	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*	151000	(a) Table and wine grapes	0,02*	161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilian cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,02*	212000	(b) Tropical root and tuber vegetables	0,02*
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,02*	151010	Table grapes	0,02*	161990	Others	0,02*	212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,02*
110040	Limes	0,02*	151020	Wine grapes	0,02*	162000	(b) Inedible peel, small	0,02*	212020	Sweet potatoes	0,02*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,02*	152000	(b) Strawberries	1	162010	Kiwi	0,02*	212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,02*
110990	Others	0,02*	153000	(c) Cane fruit		162020	Lychee (Litchi) (Pulakan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0,02*	212040	Arrowroot	0,02*
120000	(ii) Tree nuts	0,02*	153010	Blackberries	3	162030	Passion fruit	0,02*	212990	Others	0,02*
120010	Almonds	0,02*	153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberries and other Rubus hybrids)	1	162040	Prickly pear (cactus fruit)	0,02*	213000	(c) Other root and tuber vegetables except sugar beet	
120020	Brazil nuts	0,02*	153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	3	162050	Star apple	0,02*	213010	Beetroot	0,05
120030	Cashew nuts	0,02*	153990	Others	1	162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammy sapote)	0,02*	213020	Carrots	0,05
120040	Chestnuts	0,02*	154000	(d) Other small fruit & berries	1	162990	Others	0,02*	213030	Celeriac	0,1
120050	Coconuts	0,02*	154010	Blueberries (Bilberries)	1	163000	(c) Inedible peel, large		213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,05
120060	Hazelnuts (Filbert)	0,02*	154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	1	163010	Avocados	0,02*	213050	Jerusalem artichokes (Crosne)	0,02*
120070	Macadamia	0,02*	154030	Cumants (red, black and white)	1	163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*	213060	Parsnips	0,05
120080	Pecans	0,02*	154040	Gooseberries (Including hybrids with other Ribes species)	1	163030	Mangoes	0,02*	213070	Parsley root	0,05
120090	Pine nuts	0,02*	154050	Rose hips	1	163040	Papaya	0,5	213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,02*
120100	Pistachios	0,02*	154060	Mulberries (Arbutus berry)	1	163050	Pomegranate	0,02*	213090	Salsify (Scorzonera, Spanish salsify/Spanish oysterplant, edible burdock)	0,05
120110	Walnuts	0,02*	154070	Azarole (mediterranean medlar) (Kiviberry (Actinidia arguta))	1	163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0,02*	213100	Swedes	0,02*
120990	Others	0,02*	154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sawallowthorn, hawthorn, serviceberries, and other treeberries)	1	163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0,02*	213110	Turnips	0,02*
130000	(iii) Pome fruit	0,3	154990	Others	1	163080	Pineapples	0,02*	213990	Others	0,02*
130010	Apples (Crab apple)	0,3	160000	(vi) Miscellaneous fruit		163090	Bread fruit (Jackfruit)	0,02*	220000	(ii) Bulb vegetables	
130020	Pears (Oriental pear)	0,3	161000	(a) Edible peel		163100	Durian	0,02*	220010	Garlic	0,02*
130030	Quinces	0,3	161010	Dates	0,02*	163110	Soursop (guanabana)	0,02*	220020	Onions (Other bulb onions, silverskin onions)	0,02*
130040	Medlar	0,3	161020	Figs	0,4	163990	Others	0,02*	220030	Shallots	0,02*
130050	Loquat	0,3	161030	Table olives	4				220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,1
130990	Others	0,3							220990	Others	0,02*
140000	(iv) Stone fruit								230000	(iii) Fruiting vegetables	
140010	Apricots	0,3							231000	(a) Solanacea	
140020	Cherries (Sweet cherries, sour cherries)	0,3							231010	Tomatoes (Cherry tomatoes,	0,5
140030	Peaches (Nectarines and similar hybrids)	0,3									

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
	Physalis spp., gojiberry, wolfberry (<i>Lycium barbarum</i> and <i>L. chinense</i>), tree tomato)	
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino, antioewa/white eggplant (<i>S. macrocarpon</i>))	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), lauki (<i>Lagenaria siceraria</i>), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,3
232990	Others	0,3
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,2
233020	Pumpkins (Winter squash, marrow (late variety))	0,02*
233030	Watermelons	0,2
233990	Others	0,02*
234000	(d) Sweet corn (Baby corn)	0,1
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,1
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	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 or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choi sum, Peking cabbage/pe-tsai)	1
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	1
243990	Others	1
244000	(d) Kohlrabi	0,05

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	
251010	Lamb's lettuce (Italian corn salad)	5
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, curly leaf endive, sugar loaf (<i>C. endivia</i> var. <i>crispum</i> /C. <i>intybus</i> var. <i>foliosum</i>), dandelion greens)	2
251040	Cress (Mung bean sprouts, alfalfa sprouts)	2
251050	Land cress	2
251060	Rocket, Rucola (Wild rocket (<i>Diplotaxis</i> spp.))	3
251070	Red mustard	2
251080	Leaves and sprouts of Brassica spp. including tumip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	2
251990	Others	2
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajar leaves, bitterblad/bitawiri)	0,02*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glasswort, agetti (<i>Salsola</i> soda))	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (<i>Acacia pennata</i>))	0,02*
254000	(d) Water cress (Moming glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (<i>Ipomea</i>	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
	aquatica), water clover, water mimosa)	
255000	(e) Witloof	0,02*
256000	(f) Herbs	5
256010	Chervil	5
256020	Chives	5
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cicely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (<i>Eryngium foetidum</i>))	5
256040	Parsley (leaves of root parsley)	5
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	5
256060	Rosemary	5
256070	Thyme (Marjoram, oregano)	5
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	5
256090	Bay leaves (laurel) (Lemon grass)	5
256100	Tarragon (Hyssop)	5
256990	Others	5
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	1
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0,2
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 (Borago officinalis stems)	0,02*
270030	Celery	0,5

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
270040	Fennel	0,5
270050	Globe artichokes (Banana flower)	0,02*
270060	Leek	0,1
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 fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0,02*
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	0,02*
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	0,3
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	0,15
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,05*
401110	Safflower	0,05*
401120	Borage (Purple viper's bugloss/Canary flower (<i>Echium plantagineum</i>), Com Gronwell (<i>Buglossoides arvensis</i>))	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
401990	Others	0,05*
402000	(ii) Oilfruits	
402010	Olives for oil production	4
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 (Amaranthus, quinoa)	0,05
500030	Maize	0,05
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,05
500050	Oats	1
500060	Rice (Indian/wild rice (Zizania aquatica))	0,05
500070	Rye	0,05
500080	Sorghum	0,05
500090	Wheat (Spelt, triticale)	0,1
500990	Others (Canary grass seeds (Phalaris canariensis))	0,05
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea	10
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	
631000	(a) Flowers	0,1
631010	Camomille flowers	0,1
631020	Hybiscus flowers	0,1
631030	Rose petals	0,1
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,1
631050	Lime (linden)	0,1
631990	Others	0,1
632000	b) Leaves	50
632010	Strawberry leaves	50
632020	Rooibos leaves (Ginkgo leaves)	50
632030	Maté	50
632990	Others	50
633000	(c) Roots	0,1
633010	Valerian root	0,1
633020	Ginseng root	0,1
633990	Others	0,1
639000	(d) Other herbal infusions	0,1
640000	(iv) Cocoabeans (fermented or dried)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried)	0,1
800000	8. SPICES	0,1

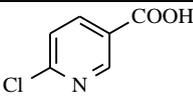
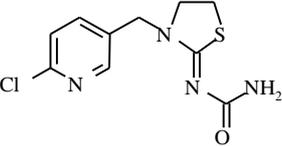
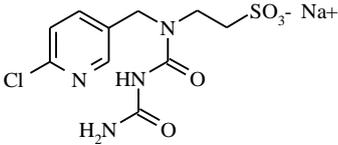
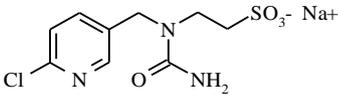
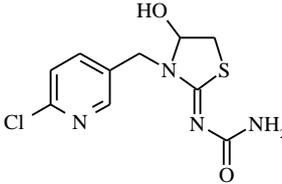
Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
810000	(i) Seeds	0,1
810010	Anise	0,1
810020	Black caraway	0,1
810030	Celery seed (Lovage seed)	0,1
810040	Coriander seed	0,1
810050	Cumin seed	0,1
810060	Dill seed	0,1
810070	Fennel seed	0,1
810080	Fenugreek	0,1
810090	Nutmeg	0,1
810990	Others	0,1
820000	(ii) Fruits and berries	0,1
820010	Allspice	0,1
820020	Sichuan pepper (Anise pepper, Japan pepper)	0,1
820030	Caraway	0,1
820040	Cardamom	0,1
820050	Juniper berries	0,1
820060	Pepper, black, green and white (Long pepper, pink pepper)	0,1
820070	Vanilla pods	0,1
820080	Tamarind	0,1
820990	Others	0,1
830000	(iii) Bark	0,1
830010	Cinnamon (Cassia)	0,1
830990	Others	0,1
840000	(iv) Roots or rhizome	0,1
840010	Liquorice	0,1
840020	Ginger	0,1
840030	Turmeric (Curcuma)	0,1
840040	Horseradish	0,1
840990	Others	0,1
850000	(v) Buds	0,1
850010	Cloves	0,1
850020	Capers	0,1
850990	Others	0,1
860000	(vi) Flower stigma	0,1
860010	Saffron	0,1
860990	Others	0,1
870000	(vii) Aril	0,1
870010	Mace	0,1
870990	Others	0,1
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-	

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
	TERRESTRIAL ANIMALS	
1010000	(j) Tissue	
1011000	(a) Swine	
1011010	Muscle	0,05
1011020	Fat	0,05
1011030	Liver	0,3
1011040	Kidney	0,3
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Muscle	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	Muscle	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	Muscle	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	Muscle	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	Muscle	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, deer)	

Code number	Groups and examples of individual products to which the MRLs apply	Thiacloprid (F)
1017010	Muscle	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	0,03
1020010	Cattle	0,03
1020020	Sheep	0,03
1020030	Goat	0,03
1020040	Horse	0,03
1020990	Others	0,03
1030000	(iii) Bird eggs	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, honey comb with honey (comb honey))	0,2
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products (Wild game)	0,01*

(*): Indicates lower limit of analytical determination
(F): Fat soluble

Appendix D. List of metabolites and related structural formula

Common name	Other name	Structure
6-chloronicotinic acid (M03)	6-chloro-3-pyridinecarboxylic acid	
(Z)-[3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]urea (M02)	{3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene}urea	
2-[1-(6-chloropyridine-3-ylmethyl)-3-carbamoylureido]ethane sulfonic acid sodium salt (M30)	Sodium 2-[[[(aminocarbonyl)amino]-carbonyl][(6-chloro-3-pyridinyl)-methyl]amino]ethanesulfonate	
Sodium 2-[(aminocarbonyl][(6-chloro-3-pyridinyl)methyl]amino]ethanesulfonate (M34)	2-[(aminocarbonyl][(6-chloro-3-pyridinyl)methyl]amino]ethanesulfonic acid, sodium salt	
{3-[(6-chloro-3-pyridinyl)methyl]-4-hydroxy-2-thiazolidinylidene}urea (M37)	//	

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DE	Germany
DT ₉₀	period required for 90 % dissipation
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
ES	Spain
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
FR	France
GAP	good agricultural practice
ha	hectare
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra-violet detector
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)

R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RMS	rappporteur Member State
SCFAH	Standing Committee on the Food Chain and Animal Health
WG	water dispersible granule