European Food Safety Authority

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REASONED OPINION OF EFSA

Modification of the existing MRLs for thiacloprid in leek and spring onions[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00221)

Issued on 26 March 2009

SUMMARY

Germany received an application from Landwirtschaftskammer Nordrhein-Westfalen, Pflanzenschutzdienst to modify the existing MRLs for thiacloprid in leek and spring onions. Germany as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

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

The metabolism of thiacloprid in primary crops is elucidated in several crop categories (fruit and fruiting vegetables, cereals and pulses and oilseeds) and a general residue definition has been derived for all commodities of plant origin as thiacloprid (parent only). Consequently, the MRL application for leek and spring onions does not require additional metabolism studies.

Submitted supervised residues field trials indicate that the current MRL of 0.02 mg/kg for leek and spring onions does not accommodate the intended GAP in Germany and a higher MRL of 0.1 mg/kg would be necessary. Adequate analytical methods are available to enforce the MRL in leek and spring onions.

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.

Residues in commodities of animal origin were not assessed in the framework of this application considering that leek and spring onions are not usually fed to livestock.

The consumer risk assessment was performed with the EFSA PRIMo-rev. 2, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 as well as the HR

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and STMR values derived for the intended use on leek and spring onions. The chronic dietary intake calculations did not identify consumer intake concerns for any of European diets. The intake values ranged from 14 to 77% of the ADI. Acute risk assessment did not identify consumer intake concerns regarding leek and spring onions.

EFSA concludes that the intended use of thiacloprid on leek and spring onions is acceptable with regard to consumer safety.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Leek, spring onions	0.02*	0.1	The MRL proposal is fully supported by data and no risk for consumers was identified for the intended uses.

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

Key words: Thiacloprid, leek, spring onions, MRL application, Regulation (EC) No 396/2005, consumer risk assessment

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

Germany, hereafter referred to as the Evaluating Member State (EMS), received an application from the Landwirtschaftskammer Nordrhein-Westfalen, Pflanzenschutzdienst[2] to modify the existing MRL for thiacloprid in leek and spring onions. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 14 January 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00221 and the following subject:

Thiacloprid - Application to modify the existing MRL for thiacloprid in leek from 0.02 mg/kg to 0.1 mg/kg and in spring onions from 0.02 mg/kg to 0.1 mg/kg

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

TERMS OF REFERENCE

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

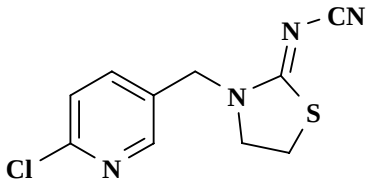
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

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

[2] Landwirtschaftskammer Nordrhein-Westfalen, Pflanzenschutzdienst, Siebengebirgsstrasse 200, 53229, Bonn, 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 acute 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 the 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.

In the European Community the MRLs for thiacloprid are established in Annexes II and IIIB of the Regulation (EC) No 396/2005 and are summarized in Appendix B. The current MRLs for spring onions and leeks are set at the LOQ of 0.02 mg/kg. Codex Alimentarius has established CXLs for thiacloprid in a wide range of commodities but there is no CXLs set for spring onions and leek.

The GAP for which an authorisation is requested in Germany refers to an outdoor use of thiacloprid on leek and Welsh onions (spring onions). For both crops the SC formulation should be applied three times at an application rate of 0.096 kg a.s./ha. The minimum waiting period for spring onions is 7 days and for leek 14 days. The details of the GAPs can be found in Appendix A.

ASSESSMENT

1. Methods of analysis

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

The analytical methods for the determination of 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. In addition, the EMS refers to the QuEChERS multi residue method with the LOQ of 0.01 mg/kg for the commodities with high water content, high acid content and dry commodities.

It is concluded that adequate analytical methods are available for the enforcement of the proposed MRL for leek and spring onions with the LOQ of 0.02 mg/kg.

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

Commodities under consideration are not used as a livestock feedingstuff. Therefore analytical methods for determination of thiacloprid in the food of animal origin are not of relevance for the setting of the MRLs in leek and spring onions.

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 3-1 (European Commission, 2004).

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

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Thiacloprid					
ADI	COM	2004	0.01	2 yr rat	100
ARfD	COM	2004	0.03	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))

According to the RMS United Kingdom, an additional metabolism study on wheat (2 x 0.05 kg a.s./ha) was evaluated therefore covering the third crop category which was necessary to conclude on the metabolic pattern of thiacloprid in all primary plant commodities.

The metabolism in plant commodities was investigated with ^{14}C methylene labelled thiacloprid. In fruits and fruiting vegetables, the main TRR was parent thiacloprid. From the metabolism studies in apple, it was apparent that no translocation from leaves to fruits occurs. Moreover, translocation does not occur also from soil to fruit via roots, as identified in study with tomatoes. In the cotton seed parent thiacloprid was identified in small amounts (0.6 % TRR), but metabolite 6-chloronicotinic acid amounted for up to 46% of the TRR which was concluded to be the result of partitioning and selective transport effects. 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%.

In general, it was concluded that metabolism of thiacloprid is similar in all plant commodities and a general residue definition for risk assessment and monitoring could be proposed as thiacloprid (parent only).

3.1.1.2. Magnitude of residues

The applicant in support of the proposed GAPs submitted nine supervised residues field trials on leek and six trials on spring onions. The extrapolation from spring onions to Welsh onions is possible. The supervised residues field trials data are summarized in Table 3-1. From the supervised residues field trials data an MRL proposal of 0.1 mg/kg can be supported for both commodities.

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 apple, tomato and melon peel for up to 18 months when stored below -18°C. According to the evaluation of the EMS, the supervised residues field trials data are considered valid both with regards to analytical methods and storage stability.

Table 3-1. **Overview of the available residues trials data**

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Thiacloprid									
Spring onions (Welsh onions)	NEU	Outdoor	2 x <0.01; 2 x 0.02; 0.05; 0.06	2 x <0.01; 2 x 0.02; 0.05; 0.06	0.02	0.06	0.1	1.0	R_{ber}= 0.105 mg/kg R_{max}=0.108 mg/kg
Leek	NEU	Outdoor	3 x <0.01; 3 x 0.01; 2 x 0.03; 0.07	3 x <0.01; 3 x 0.01; 2 x 0.03; 0.07	0.01	0.07	0.1	1.0	R_{ber}=0.060 mg/kg R_{max}=0.083 mg/kg

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

3.1.1.3. Effect of industrial processing and/or household preparation

In the peer review a study on 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.

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

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Leek and spring onions both can be grown in rotation. 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. More persistent in soil are thiacloprid metabolites. The DT_{90lab} value of metabolite M02[3] 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[4] and M34[5] is 262 and 175 days respectively.

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. 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[6] - were detected in rotational crops at levels >0.01 mg/kg. The highest amounts of them were identified in wheat straw, exceeding 0.1 mg/kg. However, during the peer review it was decided not to include these metabolites in the residue definition since they were considered of no toxicological concern. In addition, the studies on the magnitude of residues in rotational crops (see section 3.1.2.3.) demonstrate that for the intended use of thiacloprid on leeks and spring onions no significant residues (exceeding 0.01 mg/kg) will be expected in rotational crops.

3.1.2.3. Magnitude of residues

In lettuce, planted 30 DAT the 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

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

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).

Considering that application rates proposed in the framework of this application is significantly lower and that a part of the applied substance is intercepted by the treated crop, it is concluded that significant residue levels in rotational crops are not expected provided that thiacloprid is applied according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

Since crops under consideration are not fed to livestock, studies on nature and magnitude of residues in livestock are not of relevance regarding the current MRL proposal.

4. Consumer risk assessment

The consumer risk assessment is performed with the EFSA PRIMo-rev. 2 (Pesticide Residue Intake Model), using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 as well as the HR and STMR values derived for the intended use on leek and spring onions. 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				
Spring onions	0.02	STMR	0.06	HR
Leek	0.01	STMR	0.07	HR

The summary of intake calculations can be found in Appendix C.

No chronic consumer intake concerns were identified for any of European diets. The intake values were in the range of 14 – 77% of the ADI. The contribution of leek and spring onions to the total dietary intake is insignificant being 0.07% of the ADI for leeks and less than 0.01 % of the ADI for spring onions. Acute risk assessment did not identify consumer intake concerns regarding leek and spring onions.

EFSA concludes that the intended use of thiacloprid on leek and spring onions is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

Germany received an application from Landwirtschaftskammer Nordrhein-Westfalen, Pflanzenschutzdienst to modify the existing MRLs for thiacloprid in leek and spring onions. Germany as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

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

The metabolism of thiacloprid in primary crops is elucidated in several crop categories (fruit and fruiting vegetables, cereals and pulses and oilseeds) and a general residue definition has been derived for all commodities of plant origin as thiacloprid (parent only). Consequently, the MRL application for leek and spring onions does not require additional metabolism studies.

Submitted supervised residues field trials indicate that the current MRL of 0.02 mg/kg for leek and spring onions does not accommodate the intended GAP in Germany and a higher MRL of 0.1 mg/kg would be necessary. Adequate analytical methods are available to enforce the MRL in leek and spring onions.

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.

Residues in commodities of animal origin were not assessed in the framework of this application considering that leek and spring onions are not usually fed to livestock.

The consumer risk assessment was performed with the EFSA PRIMo-rev. 2, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 as well as the HR and STMR values derived for the intended use on leek and spring onions. The chronic dietary intake calculations did not identify consumer intake concerns for any of European diets. The intake values ranged from 14 to 77% of the ADI. Acute risk assessment did not identify consumer intake concerns regarding leek and spring onions.

EFSA concludes that the intended use of thiacloprid on leek and spring onions is acceptable with regard to consumer safety.

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

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Leek, spring onions	0.02*	0.1	The MRL proposal is fully supported by data and no risk for consumers was identified for the intended uses.

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

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for thiacloprid in leek and spring onions under Regulation (EC) No 396/2005. Prepared by Germany.

REFERENCES

The United Kingdom, 2000. Draft Assessment Report on thiacloprid under Directive 91/414/EEC. November 2000.

European Commission, 2004. Review report for the active substance thiacloprid. May, 2004.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and / or situation (a)	F, G or I (b)	Pest or group of pests Controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d – f)	Conc. of a.i. (i)	method, kind (f - h)	growth stage (j)	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
Welsh onion	F	Aphids, Thrips	SC	480 g/l	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible	3 ; 3	0.016 - 0.024	400 - 600	0.096	7	
Leek	F	Aphids, Thrips	SC	480 g/l	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible	3 ; 3	0.016 - 0.024	400 - 600	0.096	14	
Leek	F	Leek moth	SC	480 g/l	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible	3 ; 3	0.016 - 0.024	400 - 600	0.096	14	

(a) In case of group of crops the Codex classification should be used
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi
(d) Suspension concentrate (= flowable concentrate) (SC)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding,grazing)/minimal intervals between applications

APPENDIX B – EXISTING EC MRLS

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	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
	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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
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
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
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
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02*
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
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

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
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	

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Thiacloprid

Status of the active substance:	**Inlcuded**	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**

For acute RA- HR values for leek - 0.07 mg/kg and for spring onion -0.06 mg/kg; For chronic RA - STMR values for leek -0.01 mg/kg and 0.02 mg/kg for spring onions.

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum	maximum
	14	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	pTMRLs at LOQ (in % of ADI)
77.00	DE child	36.2	Apples	4.8	Tomatoes	4.3	Milk and cream,	
71.5	NL child	19.0	Apples	8.8	Milk and cream,	5.0	Beans (with pods)	
68.8	WHO Cluster diet B	15.4	Tomatoes	8.5	Wheat	7.2	Lettuce	
55.4	IE adult	12.4	Barley	3.5	Blackberries	2.5	Apples	
50.6	FR toddler	11.9	Milk and cream,	11.0	Beans (with pods)	7.9	Apples	
42.6	DK child	7.0	Apples	5.5	Wheat	4.9	Cucumbers	
40.2	WHO cluster diet E	8.1	Barley	3.9	Wheat	2.8	Beans (with pods)	
39.2	WHO regional European diet	7.5	Lettuce	5.5	Tomatoes	3.3	Barley	
37.4	ES child	8.3	Lettuce	4.9	Tomatoes	4.4	Wheat	
35.9	UK Toddler	6.2	Milk and cream,	5.1	Apples	4.6	Sugar beet (root)	
35.8	ES adult	10.7	Lettuce	4.9	Barley	3.9	Tomatoes	
35.2	WHO cluster diet D	6.5	Wheat	5.1	Tomatoes	2.2	Barley	
34.8	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	UK Infant	11.6	Milk and cream,	4.7	Apples	2.6	Wheat	
33.9	IT kids/toddler	7.1	Tomatoes	6.6	Wheat	5.8	Lettuce	
32.6	IT adult	7.5	Lettuce	5.8	Tomatoes	4.1	Wheat	
30.4	SE general population 90th percentile	3.8	Tomatoes	3.7	Milk and cream,	3.2	Wheat	
29.8	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 plants	3.3	Wheat	2.2	Tomatoes	
20.9	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	
18.4	UK vegetarian	3.1	Tomatoes	2.8	Lettuce	2.0	Wheat	
16.7	PL general population	6.1	Apples	4.4	Tomatoes	0.8	Pears	
15.7	DK adult	2.4	Apples	2.1	Tomatoes	2.0	Wheat	
15.2	FI adult	2.1	Tomatoes	1.7	Milk and cream,	1.6	Lettuce	
14.0	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)
13.75	Leek	0.07 / -	9.8	Leek	0.07 / -	4.5	Leek	0.07 / -	3.4	Leek	0.07 / -
0.9	Spring onions	0.06 / -	0.9	Spring onions	0.06 / -	0.2	Spring onions	0.06 / -	0.2	Spring onions	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:		**1**			**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)		
119.9	Raspberries juice	3 / 2.5			6.6	Apple juice	0.3 / -		
53.4	Elderberry juice	1 / -			3.2	Tomato (preserved-fresh)	0.5 / -		
51.0	Apple juice	0.3 / -			2.0	Peach preserved with	0.3 / -		
33.7	Cuurant juice	1 / -			1.5	Bread/pizza	0.1 / -		
29.1	Tomato juice	0.5 / -			1.1	Quince jelly	0.3 / -		

*) 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, the ARfD/ADI was exceeded in one or several cases.

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT_{90lab}	period required for 90 percent dissipation (from laboratory studies)
DT_{90f}	period required for 90 percent dissipation (from field studies)
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
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level

LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PHI	pre harvest interval
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