REASONED OPINION

Modification of the existing MRLs for thiacloprid in table olives, olives for oil production, poppy seeds and various root vegetables[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, the Czech Republic received an application from Bayer s.r.o. to modify the existing MRL for thiacloprid in poppy seeds. In order to accommodate for the intended use of thiacloprid in the Czech Republic, it is proposed to raise the existing MRL in poppy seed from 0.02 mg/kg (set at the limit of quantification) to 0.3 mg/kg. The Czech Republic drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 May 2009.

According to Article 6 of the Regulation (EC) No 396/2005, Greece received an application from Bayer CropScience to modify the existing MRLs for thiacloprid in table olives and olives for oil production. In order to accommodate for the intended use of thiacloprid in the Southern Europe, it is proposed to raise the existing MRLs in table olives and olives for oil production from 0.02 mg/kg (set at the limit of quantification) to 4 mg/kg. Greece drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 31 July 2009.

According to Article 6 of the Regulation (EC) No 396/2005, the United Kingdom received an application from Horticultural Development Company to modify the existing MRLs for thiacloprid in various root crops: carrots, beetroot, horseradish, parsnips, parsley root and salsify. In order to accommodate for intended uses of thiacloprid in the United Kingdom, it is proposed to raise the existing MRLs for these crops from 0.02 mg/kg (set at the limit of quantification) to 0.05 mg/kg. The United Kingdom drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 3 September 2009.

Considering that all three applications refer to the modification of existing MRLs for thiacloprid, EFSA decided to address all MRL applications in one reasoned opinion.

EFSA derived the following conclusions based on the submitted evaluation reports prepared by Greece, the Czech Republic and the United Kingdom as well as the Draft Assessment Report (DAR) prepared by the United Kingdom under Directive 91/414/EEC.

1 On request from the European Commission, Question No EFSA-Q-2009-00741, EFSA-Q-2009-00632, EFSA-Q-2009-00791 issued on 2 December 2009.

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The toxicological profile of thiacloprid was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.01 mg/kg bw/d and an ARfD value of 0.03 mg/kg bw.

Metabolism of thiacloprid in plants was investigated in three crop categories and a general residue definition for risk assessment and monitoring was proposed by the peer review as parent thiacloprid. EFSA, however, is of the opinion that 6-chloronicotinic acid residues might occur in oilseeds in amounts requiring consideration in the consumer risk assessment. It should be noted that 6-chloronicotinic acid and its precursor 6-chloropicolyl alcohol are metabolites containing 6-chlorpyridinyl moiety, which is characteristic not only for thiacloprid but also for imidacloprid and acetamiprid. EFSA is of the opinion that the occurrence of 6-chloronicotinic acid in oilseeds has to be further investigated in the framework of Article 12 (2) of Regulation (EC) No 396/2005. Sufficiently validated analytical enforcement methods are available to control the compliance of the proposed MRLs for the current residue definition in all crops under consideration.

Submitted supervised residue field trials indicate that MRLs of 4 mg/kg for table olives and olives for oil production, 0.3 mg/kg for poppy seeds and 0.05 mg/kg for carrots, beetroot, horseradish, parsnips, parsley root and salsify would be necessary to accommodate the intended uses of thiacloprid.

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

Effects of processing on the nature of thiacloprid were studied in the peer review in hydrolysis study and results indicate that thiacloprid is stable under hydrolytic conditions and no formation of toxicologically relevant metabolites occurs. No processing studies for table olives have been submitted but are recommended taking into account the contribution of table olives to the acute consumer exposure. Processing studies with olives investigating the magnitude of thiacloprid residues in refined oil are available and the following processing factor was derived and is recommended for the inclusion in Annex VI of Regulation (EC) No 396/2005:

- Olives, refined oil: 0.02

No studies have been submitted to assess the magnitude of thiacloprid residues during the processing of carrots, beetroot, horseradish, parsley root, parsnips, salsify and poppy seeds. Such studies, however, are not necessary considering the low individual contribution of these crops to the total dietary intake

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and III of Regulation (EC) No 396/2005 as well as STMR values derived from the supervised residue field trials on olives, poppy seeds, carrots, beetroot, horseradish, parsley root, parsnips and salsify. In addition, for spring onions, leek, lamb`s lettuce, celery, fennel and tea EFSA used the values as obtained in the previously issued EFSA reasoned opinions on the modification of the existing MRLs for thiacloprid.

Acute intake assessment was performed only with regard to the crops under consideration. The relevant HR values for olives, poppy seeds, carrots, beetroot, horseradish, parsley root, parsnips and salsify as derived for the intended GAPs were used as input values in the acute intake calculations.

No long term intake concerns were identified for any of the European diets. The total calculated dietary intake ranged from 15 to 77.5% of the ADI. The contribution of table olives and olives for oil production to the total consumer exposure to thiacloprid residues accounted for a maximum of 0.41% and 0.2% of the ADI, respectively (WHO Cluster diet B). From roots crops under consideration, the highest consumer exposure was identified for carrots (0.27% of the ADI, FR Infant diet), for all other

crops being below 0.01% of the ADI. The contribution of thiacloprid residues in poppy seeds was insignificant accounting for a maximum of 0.023% of the ADI for WHO Regional European diet.

No acute intake concerns were identified with regard to the proposed MRLs for crops under consideration. The highest acute consumer exposure to thiacloprid residues was identified from table olives, accounting for 27% of the ARfD. The exposure from olives intended for oil production was insignificant (0.04% of the ARfD). From root crops the highest acute consumer exposure was identified for carrots (8.5% of the ARfD), followed by beetroot (5.8% of the ARfD), salsify (5.2% of the ARfD) and parsnips (4.8% of the ARfD). The contribution of poppy seeds to the acute consumer exposure to thiacloprid residues accounted for 0.5% of the ARfD.

Consequently, EFSA concludes that intended uses of thiacloprid on olives, carrots, horseradish, beetroot, parsnips, parsley root, salsify and poppy seeds are acceptable as they will not result in an exceedance of toxicological reference values. EFSA derived the following recommendations:

Code number (according to Regulation (EC) No 396/2005)	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Thiacloprid				
0161030	Table olives	0.02*	4	MRL proposals are sufficiently supported by data and no risk for consumers was identified for intended uses.
0402010	Olives for oil production	0.02*	4	
0401030	Poppy seed	0.05*	0.3	
0213010	Beetroot	0.02*	0.05	
0213020	Carrots	0.02*		
0213040	Horseradish	0.02*		
0213060	Parsnips	0.02*		
0213070	Parsley root	0.02*		
0213090	Salsify	0.02*		

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

KEY WORDS

Thiacloprid, table olives, olives for oil production, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, cyanamide insecticide

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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.

The Czech Republic, hereafter referred to as the evaluating Member State (EMS) for poppy seeds, received an application from Bayer s.r.o. on behalf of Bayer CropScience AG[3] to modify the existing MRL for the active substance thiacloprid in poppy seeds.

Greece, hereafter referred to as the evaluating Member State (EMS) for olives, received an application from the company Bayer CropScience[4] to modify the existing MRLs for the active substance thiacloprid in table olives and olives for oil production.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS) for root crops, received an application from the Horticultural Development Company[5] to modify the existing MRL for the active substance thiacloprid in various root crops.

The above mentioned applications were 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 Czech Republic was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00632 and the following subject:

*Thiacloprid - Application to modify the existing MRL for thiacloprid in poppy seeds from 0.05*mg/kg to 0.3 mg/kg.*

On 1 July 2009 some data requirements were identified for the MRL application on poppy seeds, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 23 September.

After completion, the evaluation report of the EMS Greece was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 31 July. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00741 and the following subject:

Thiacloprid - Application to modify the existing MRLs in table olives and olives for oil production.

After completion, the evaluation report of the EMS United Kingdom was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 3 September 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00791 and the following subject:

Thiacloprid - Application to modify the existing MRLs in various root crops.

For the reasons of efficiency EFSA combined all submitted applications and then proceeded with the assessment as required by Article 10 of the Regulation.

3 Bayer s.r.o., Litvinovska 609/3, 19021, Praha, the Czech Republic
4 Bayer CropScience, Rue Jean Marie Leclair 16, 69009, Lyon, France
5 Horticultural Development Company, c/o Stockbridge Technology Centre, YO8 3TZ, Selby, The United Kingdom

TERMS OF REFERENCE

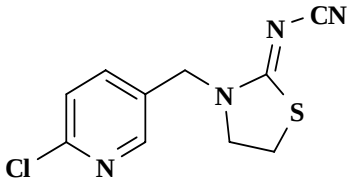
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

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 these particular cases the calculated deadlines for providing the reasoned opinion is 30 October 2009 for the MRL application on olives, 21 November 2009 for the MRL application on poppy seeds and 3 December 2009 for the MRL application on various root crops.

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).



Molecular weight: 252.7

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

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

MRLs for thiacloprid were set at EU level for the first time with Directive 2007/11/EC. The MRLs established under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC have been transferred to Annex II of Regulation (EC) No 396/2005. In Annex III, temporary MRLs have been established for crops that were not covered by the previous Community legislation. The existing MRLs for thiacloprid are summarized in Appendix C to this reasoned opinion. MRL proposals for lamb`s lettuce, celery, fennel, tea, fresh herbs and herbal infusions were recently assessed by EFSA (EFSA, 2009b, 2009c), but the recommendations made by EFSA are still awaiting the decision of the SCoFCAH. The existing EC MRLs for all the crops under consideration are set at the LOQ (0.02 mg/kg for table olives, olives for oil production, carrots, beetroot, horseradish, parsley root, parsnips and salsify and 0.05 mg/kg for poppy seed).

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

The submitted GAPs according to which the modification of the existing MRLs is requested are summarized in Appendix A.

EFSA bases its assessment on the evaluation reports submitted by Greece (2009), the Czech Republic (2009) and the United Kingdom (2009), the Draft Assessment Report (DAR) prepared under Directive 91/414/EEC (the United Kingdom, 2000) and the JMPR Evaluation report (WHO/FAO, 2006). The assessment is performed according to the currently valid EU guidance documents for consumer risk assessment (European Commission, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2008).

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 the database developed by the Community Reference Laboratory (CRL) for Residues of Pesticides (www.crl-pesticides.eu), the QuEChERS (Anastasiades et al, 2003) multi-residue method is validated at the LOQ of 0.01 mg/kg for the determination of thiacloprid residues in dry matrices, matrices with high water-, acid-, fat- and sugar content. For plant matrices with high oil content, an analytical method with HLPC-MS/MS detection is reported by the EMS Czech Republic as sufficiently validated at the LOQ of 0.02 mg/kg.

It is therefore concluded that sufficiently validated analytical methods are available to enforce the proposed MRLs in table olives, olives for oil production, poppy seeds, carrots, beetroot, horseradish, parsley root, parsnips and salsify according to the existing residue definition which comprises parent thiacloprid only.

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

The availability of analytical enforcement methods for the determination of thiacloprid residues in foodstuffs of animal origin was not investigated for the current application since no MRLs for commodities of animal origin are proposed.

2. Mammalian toxicology

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

Table 2-1. Overview of the toxicological reference values

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

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

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

- fruits and fruiting vegetables: spray application on apples (2 x 0.027 kg a.s./hL) and tomatoes (2 x 0.026 kg a.s./hL)
- oilseeds and pulses: spray application on cotton seed (0.375 kg a.s./ha)
- cereals: spray application on wheat (2 x 0.05 kg a.s./ha)

The metabolism in plant commodities was investigated with ^{14}C-methylene labelled thiacloprid. In fruits and fruiting vegetables, the main component of the TRR was parent thiacloprid accounting for more than 80% of the TRR. From the metabolism studies in apple, it was apparent that no translocation from leaves to fruits occurs. In apples parent thiacloprid accounted for 82.4% TRR in the surface wash. Moreover, a supplementary study with tomatoes demonstrated that translocation does not occur from soil to fruit via roots.

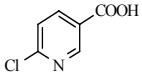
In cotton leaves, the TRR accounted for 30.4 mg eq./kg with parent thiacloprid being the major component of the TRR (83.9%; 25.46 mg/kg). The TRR in cotton seed at harvest accounted for 1.12 mg eq./kg. In the cotton seed parent thiacloprid was identified in small amounts (0.6% TRR; 0.01 mg/kg), while metabolite 6-chloronicotinic acid (M03)[6] was the main residue amounting for up to 46% of the TRR (0.51 mg/kg). The major portion of the unidentified radioactive residues were characterised as compounds containing the 6-chloronicotinic acid (41.35% TRR (0.46 mg/kg)). Therefore, the total residue based on or identical with 6-chloronicotinic acid (including the parent compound) equalled to 87.7% (0.98 mg/kg) (WHO/FAO, 2006). According to the toxicity studies, 6-chloronicotinic acid was also identified in rat metabolism, indicating that its toxicity would be covered by the toxicological studies with the parent compound.

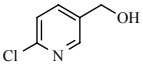
In wheat grain and straw at harvest the parent thiacloprid accounted for 81% and 83% of the TRR respectively. Individual metabolites did not represent more than 6% of the TRR.

In each crop tested, except cotton seeds, unchanged thiacloprid was found to be relevant residue on the surface of the crop and amounted for more than 80% of the TRR. The main metabolic reactions were explained as follows:

- hydroxylation of the parent compound at the thiazolidine ring;

- oxidative cleavage at the methylene bridge leading to the partially and fully oxidised products 6-chloropicolyl alcohol (M36)[7], 6-chloronicotinic acid;

[6] M03: 6-chloro-3-pyridinecarboxylic acid 

[7] M36: 6-chloro-3-pyridinemethanol 

- conjugation of these two aglycones with sugars, phosphate/sulphate and endogenous plant components.

The peer review concluded that metabolism of thiacloprid was sufficiently elucidated in three crop categories to propose a general residue definition for risk assessment and monitoring as parent thiacloprid.

EFSA, however, is of the opinion that 6-chloronicotinic acid (M03) residues might occur in oilseeds in amounts requiring consideration in the consumer risk assessment. It is noted that 6-chloronicotinic acid and its precursor 6-chloropicolyl alcohol (M36) are metabolites containing the 6-chlorpyridinyl moiety, which is characteristic not only for thiacloprid but also for imidacloprid and acetamiprid. EFSA agrees with the residue definition of the peer review, but is of the opinion that the occurrence of 6-chloronicotinic acid in oilseeds has to be further addressed under the review of existing MRLs for thiacloprid according to Article 12 (2) of Regulation (EC) No 396/2005.

3.1.1.2. Magnitude of residues

1. Poppy seed

The applicant submitted eight residue trials on rapeseed. Trials were performed in France, Germany, and Sweden in 2001 and 2002. The extrapolation of residue data to poppy seed is proposed. The residue values in the trials ranged from <0.02 mg/kg to 0.16 mg/kg.

2. Table olives and olives for oil production

The applicant in support of the intended GAP (a full cover application of thiacloprid) submitted eight residue trials on olives. Residue trials were performed in Spain, Greece, Portugal and Italy covering two seasons in 2003 and 2004 with an application rate slightly exceeding the intended one (0.144 kg a.s/ha instead of 0.125 kg a.s./ha). Residue trials were designed as residue decline studies. One trial was disregarded by EFSA since trial samples from different PHIs may have been mixed up. Residue values from all trials were in the range from 0.2 to 2.4 mg/kg.

The applicant in support of the intended GAP (bait application of thiacloprid) submitted eight residue trials on olives performed over two seasons in 2002 and 2003 in Italy, Greece and Spain. Applications were made approximately to 10% of each individual tree and included 2% of protein in the application solution as a bait. One residue trial was disregarded since according to the EU Guidance document (European Commission, 1997) the application rate exceeded the intended application rate for more than 25% (36%). Nevertheless, residue data indicate that a bait application is less critical resulting in significantly lower residue situation in the crop. Residue values from all trials were in the range from 0.07 to 0.42 mg/kg.

Residue data following a full cover application of thiacloprid on olives were used to derive the MRL proposal and risk assessment values.

3. Various root crops: carrots, beetroot, horseradish, parsley root, parsnips, salsify

The applicant submitted eight supervised residue trials on carrots performed in the United Kingdom, Germany, France and the Netherlands in 2006 and 2007. The extrapolation to beetroot, horseradish, parsley root, parsnips and salsify is proposed. Residue values from all trials were in the range of <0.01 mg/kg to 0.04 mg/kg.

Results of residue trials data are summarized in Table 3-1. The number of submitted residue trials is sufficient to support the proposed extrapolations (European Commission, 2008). Submitted supervised residue field trials indicate that MRLs of 4 mg/kg for table olives and olives for oil production, 0.3

mg/kg for poppy seeds and 0.05 mg/kg for carrots, beetroot, horseradish, parsnips, parsley root and salsify would be necessary to accommodate intended uses of thiacloprid.

The storage stability of thiacloprid in treated crops was evaluated under the peer review of Directive 91/414/EEC (the United Kingdom, 2000). Studies demonstrated storage stability of thiacloprid in commodities with high water content for up to 18 months when stored below -18°C. According to the JMPR Evaluation of thiacloprid, the storage stability of thiacloprid is demonstrated in dry commodities, commodities with high oil, high water and high acid content for 24 months when samples are stored deep frozen (WHO/FAO, 2006). Rape seed samples and carrot samples prior analyses were stored deep frozen for a maximum of 8 and 5 months, respectively. According to the EMS Greece, olives samples prior analyses also were stored for a period not exceeding the demonstrated storage stability period of thiacloprid. Consequently it is concluded that residue data are considered valid with regard to storage stability.

According to the EMSs, analytical methods used to analyse the residue trial samples have been sufficiently validated and are fit for purpose.

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

Commodity	Region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement (Thiacloprid)	Risk assessment (Thiacloprid)					
Olives *(GAP1 with a full cover application)*	SEU	Outdoor	0.2; 0.37; 0.42; 0.51; 0.99; 1.4; 2.4	0.2; 0.37; 0.42; 0.51; 0.99; 1.4; 2.4	**0.51**	**2.4**	**4**	1.0	Residue trials data indicate that a full cover application of thiacloprid on olives results in a more critical residue situation and therefore these data were used for deriving the MRL proposal and risk assessment values (indicated in bold). $R_{ber\ GAP1}$=2.8 mg/kg $R_{maxGAP1}$=3.55 mg/kg $R_{berGAP2}$=0.72 mg/kg $R_{maxGAP2}$=0.71 mg/kg
Olives *(GAP2 with a bait application)*	SEU	Outdoor	0.07; 0.14; 0.19; 0.23; 0.34; 0.42	0.07; 0.14; 0.19; 0.23; 0.34; 0.42	0.21	0.42	1	1.0	
Rape seed ⟶ Poppy seeds	NEU	Outdoor	<0.02; 3 x 0.05; 2 x 0.07; 0.08; 0.16	<0.02; 3 x 0.05; 2 x 0.07; 0.08; 0.16	0.06	0.16	**0.3**	1.0	Residue trials were performed on rape seed but residues data can be extrapolated to poppy seed (European Commission, 2008). R_{ber}=0.16 mg/kg R_{max}=0.20 mg/kg
Carrots ⟶ Beetroot, horseradish, parsley root, parsnips, salsify	NEU	Outdoor	6 x <0.01; 0.01; 0.04	6 x <0.01; 0.01; 0.04	0.01	0.04	**0.05**	1.0	Residue trials were performed on carrots but residue data can be extrapolated to beetroot, horseradish, parsley root, parsnips, salsify (European Commission, 2008). R_{ber}=0.02 mg/kg R_{max}=0.048 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.

3.1.1.3. Effect of industrial processing and/or household preparation

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

No studies have been submitted to assess the magnitude of thiacloprid residues during the processing of carrots, beetroot, horseradish, parsley root, parsnips, salsify and poppy seeds. Such studies, however, are not necessary considering the low individual contribution of these crops to the total dietary intake.

The applicant submitted four studies investigating effects of processing on the magnitude of thiacloprid residues in various processed products of olives: wet press cake (wet pomace), crude oil, pre-clarified crude oil, neutralized crude oil and refined oil. Olives were harvested after three spray applications of thiacloprid (0.144 kg a.s./ha, 14 day PHI) to olive trees in Greece, Spain and Italy. Results indicate that the concentration of residues occurs only in wet pomace (median processing factor 1.37). In all other fractions of processed olives thiacloprid residues decrease, resulting in residues ≤0.01 mg/kg in refined oil.

Table 3-2. Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition Thiacloprid				
Olives, refined oil	4	< 0.02	1.0	The residues in refined oil were in the range of <0.01 to 0.01 mg/kg while the residues in raw olives ranged form 0.2 to 1.4 mg/kg.

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

Although the contribution of table olives in the chronic intake calculation is low, specific processing studies would be desirable, since the acute consumer exposure is significant.

The derived processing factor for refine oil is recommended to be included in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration except olives can be grown in a crop rotation therefore the possible occurrence of thiacloprid residues in rotational and/or succeeding crops have to be considered.

According to the soil degradation studies performed in the framework of the peer review, the DT_{90} value of thiacloprid based on the field and laboratory studies is less than 100 days (the United

Kingdom, 2000). Thiacloprid metabolites are more persistent in the soil. The DT_{90lab} value of metabolite M02[8] 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[9] and M34[10] is 262 and 175 days respectively, meaning that rotational crop studies are required.

3.1.2.2. Nature of residues

In the peer review the metabolism of thiacloprid in rotational crops was studied in lettuce, wheat and turnips (the United Kingdom, 2000). The ^{14}C methylene labelled thiacloprid was applied to bare soil at an application rate of 0.424 kg a.s./ha (2N seasonal application rate on root crops and 3N seasonal application rate on poppy seeds). 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[11] - were detected in rotational crops but the absolute concentrations were low (below 0.1 mg/kg for each of them with exception of wheat straw). During the peer review it was decided not to include these metabolites in the residue definition since they were considered of no toxicological concern. Peer review concluded that metabolism of thiacloprid in rotational crops proceeds in a similar pathway than in primary crops and the same residue definition is applicable.

3.1.2.3. Magnitude of residues

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

EFSA concludes that residues of thiacloprid will not be present in rotational and/or succeeding crops provided that the active substance is applied according to the intended GAP.

3.2. Nature and magnitude of residues in livestock

None of the crops under consideration is a livestock feeding item according to the EU Guidance document on livestock feeding studies (European Commission, 1996) and therefore the nature and magnitude of thiacloprid residues in livestock was not investigated for the current application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model) (EFSA, 2007). For the chronic intake assessment EFSA used the existing MRLs as

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

established in Annexes II and III of Regulation (EC) No 396/2005 as well as the STMR values derived from the supervised field trials on olives, poppy seeds, carrots, beetroot, horseradish, parsley root, parsnips and salsify (see Table 3-1). In addition, for spring onions, leek, lamb`s lettuce, celery, fennel and tea EFSA used the values as obtained in the previously issued EFSA reasoned opinions on the modification of the existing MRLs for thiacloprid (EFSA, 2009a, 2009b, 2009c).

The acute intake assessment was performed only with regard to the crops under consideration. The relevant HR values for olives, poppy seeds, carrots, beetroot, horseradish, parsley root, parsnips and salsify (see Table 3-1) as derived for the intended GAPs were used as input values in the acute intake calculations.

Input values are summarized in Table 4-1.

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Thiacloprid				
Table olives	0.51[a]	STMR	2.4[a]	HR
Olives for oil production	0.01 (0.51[a] *0.02)	STMR*PF[b]	0.01 (0.51[a] *0.02)	STMR*PF[b]
Carrots, beetroot, horseradish, parsley root, parsnips and salsify	0.01	STMR	0.04	HR
Poppy seeds	0.06	STMR	0.16	HR
Tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*)	2.08	STMR (EFSA, 2009c)	Acute risk assessment was performed only with regard to crops under consideration.	
Spring onions	0.02	STMR (EFSA, 2009a)		
Leek	0.01	STMR (EFSA, 2009a)		
Lamb`s lettuce	2.63	STMR (EFSA, 2009b)		
Celery, fennel	0.21	STMR (EFSA, 2009b)		
Other commodities	MRL	Appendix C		

[a] values based on the GAP with a full cover application of thiacloprid (see Table 3-1).
[b]- processing factor as derived for refined oil (see section 3.1.1.3.)

Summary of intake calculations is available in Appendix B.

No long term intake concerns were identified for any of the European diets. The total calculated dietary intake ranged from 15 to 77.5% of the ADI. The contribution of table olives and olives for oil production to the total consumer exposure to thiacloprid residues accounted for a maximum of 0.41% and 0.2% of the ADI, respectively (WHO Cluster diet B). From the roots crops under consideration, the highest consumer exposure was identified for carrots (0.27% of the ADI, FR infant diet), for all other crops being below 0.01% of the ADI. The contribution of thiacloprid residues in poppy seeds was insignificant accounting for a maximum of 0.023% of the ADI for WHO Regional European diet.

No acute intake concerns were identified with regard to the proposed MRLs for crops under consideration. The highest acute consumer exposure to thiacloprid residues was identified from table

olives, accounting for 27% of the ARfD. The exposure from olives intended for oil production was insignificant (0.04% of the ARfD). From the root crops the highest acute consumer exposure was identified for carrots (8.5% of the ARfD), followed by beetroot (5.8% of the ARfD), salsify (5.2% of the ARfD) and parsnips (4.8% of the ARfD). The contribution of poppy seeds to the acute consumer exposure to thiacloprid residues accounted for 0.5% of the ARfD.

Consequently, EFSA concludes that the intended uses of thiacloprid on olives, carrots, horseradish, beetroot, parsnips, parsley root, salsify and poppy seeds are acceptable as they will not result in an exceedance of toxicological reference values.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of thiacloprid was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.01 mg/kg bw/d and an ARfD value of 0.03 mg/kg bw.

Metabolism of thiacloprid in plants was investigated in three crop categories and a general residue definition for risk assessment and monitoring was proposed by the peer review as parent thiacloprid. EFSA, however, is of the opinion that 6-chloronicotinic acid residues might occur in oilseeds in amounts requiring consideration in the consumer risk assessment. It should be noted that 6-chloronicotinic acid and its precursor 6-chloropicolyl alcohol are metabolites containing 6-chlorpyridinyl moiety, which is characteristic not only for thiacloprid but also for imidacloprid and acetamiprid. EFSA is of the opinion that the occurrence of 6-chloronicotinic acid in oilseeds has to be further investigated in the framework of Article 12 (2) of Regulation (EC) No 396/2005. Sufficiently validated analytical enforcement methods are available to control the compliance of the proposed MRLs for the current residue definition in all crops under consideration.

Submitted supervised residue field trials indicate that MRLs of 4 mg/kg for table olives and olives for oil production, 0.3 mg/kg for poppy seeds and 0.05 mg/kg for carrots, beetroot, horseradish, parsnips, parsley root and salsify would be necessary to accommodate the intended uses of thiacloprid.

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

Effects of processing on the nature of thiacloprid were studied in the peer review in hydrolysis study and results indicate that thiacloprid is stable under hydrolytic conditions and no formation of toxicologically relevant metabolites occurs. No processing studies for table olives have been submitted but are recommended taking into account the contribution of table olives to the acute consumer exposure. Processing studies with olives investigating the magnitude of thiacloprid residues in refined oil are available and the following processing factor was derived and is recommended for the inclusion in Annex VI of Regulation (EC) No 396/2005:

- Olives, refined oil: 0.02

No studies have been submitted to assess the magnitude of thiacloprid residues during the processing of carrots, beetroot, horseradish, parsley root, parsnips, salsify and poppy seeds. Such studies, however, are not necessary considering the low individual contribution of these crops to the total dietary intake

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and III of Regulation (EC) No 396/2005 as well as STMR values derived from the supervised residue field trials on olives, poppy seeds, carrots, beetroot, horseradish, parsley root, parsnips and salsify. In addition, for spring onions, leek, lamb`s lettuce, celery, fennel and tea EFSA used the values as obtained in the previously issued EFSA reasoned opinions on the modification of the existing MRLs for thiacloprid.

Acute intake assessment was performed only with regard to the crops under consideration. The relevant HR values for olives, poppy seeds, carrots, beetroot, horseradish, parsley root, parsnips and salsify as derived for the intended GAPs were used as input values in the acute intake calculations.

No long term intake concerns were identified for any of the European diets. The total calculated dietary intake ranged from 15 to 77.5% of the ADI. The contribution of table olives and olives for oil production to the total consumer exposure to thiacloprid residues accounted for a maximum of 0.41% and 0.2% of the ADI, respectively (WHO Cluster diet B). From roots crops under consideration, the highest consumer exposure was identified for carrots (0.27% of the ADI, FR Infant diet), for all other crops being below 0.01% of the ADI. The contribution of thiacloprid residues in poppy seeds was insignificant accounting for a maximum of 0.023% of the ADI for WHO Regional European diet.

No acute intake concerns were identified with regard to the proposed MRLs for crops under consideration. The highest acute consumer exposure to thiacloprid residues was identified from table olives, accounting for 27% of the ARfD. The exposure from olives intended for oil production was insignificant (0.04% of the ARfD). From root crops the highest acute consumer exposure was identified for carrots (8.5% of the ARfD), followed by beetroot (5.8% of the ARfD), salsify (5.2% of the ARfD) and parsnips (4.8% of the ARfD). The contribution of poppy seeds to the acute consumer exposure to thiacloprid residues accounted for 0.5% of the ARfD.

Consequently, EFSA concludes that intended uses of thiacloprid on olives, carrots, horseradish, beetroot, parsnips, parsley root, salsify and poppy seeds are acceptable as they will not result in an exceedance of toxicological reference values.

RECOMMENDATIONS

Code number	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition Thiacloprid				
0161030	Table olives	0.02*	4	MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.
0402010	Olives for oil production	0.02*	4	
0401030	Poppy seed	0.05*	0.3	
0213010	Beetroot	0.02*	0.05	
0213020	Carrots	0.02*		
0213040	Horseradish	0.02*		
0213060	Parsnips	0.02*		
0213070	Parsley root	0.02*		
0213090	Salsify	0.02*		

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

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks: (l)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	Interval between appl. (days)	No. min max	kg as/L min max	water L/ha min max	kg as/ha min max		
Olives	SEU	F	*Prays oleae, Bactrocera oleae, Euphyllura* spp.	OD	100	Full cover appl.	BBCH 55-71	14	1-3	0.01	1250	0.125	14	
	SEU	F	*Bactrocera oleae*	OD	100	Bait appl.	From June until Dec.	14	1-5	0.03	54	0.0162	14	
Poppy seeds	The Czech Republic	F	*Ceutorhynchus maculaalba, Dasineura papveris*	OD	240	Foliar spray	BBCH 51-61	-	2	0.024	300	0.072	30	Product label rate: max 0.3 L/ha
Carrots, parsnip, parsley root, salsify, red beet, horseradish	The United Kingdom	F		OD	240	Foliar spray	-	-	2	-	300	0.096	7	

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

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

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

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
15	78
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
77.5	DE child	36.2	Apples	4.8	Tomatoes	4.3	Milk and cream,	
70.0	NL child	19.0	Apples	8.8	Milk and cream,	5.0	Beans (with pods)	
69.1	WHO Cluster diet B	15.4	Tomatoes	8.5	Wheat	7.2	Lettuce	
58.0	IE adult	12.4	Barley	3.5	Blackberries	2.7	Tea (dried leaves and stalks,	
49.3	FR toddler	11.9	Milk and cream,	11.0	Beans (with pods)	7.9	Apples	
40.6	WHO cluster diet E	8.1	Barley	3.9	Wheat	2.8	Beans (with pods)	
40.4	DK child	7.0	Apples	5.5	Wheat	4.9	Cucumbers	
39.0	WHO regional European diet	7.5	Lettuce	5.5	Tomatoes	3.3	Barley	
36.6	WHO cluster diet D	6.5	Wheat	5.1	Tomatoes	3.3	Herbs	
36.2	UK Toddler	6.2	Milk and cream,	5.1	Apples	4.6	Sugar beet (root)	
35.4	UK Infant	11.6	Milk and cream,	4.7	Apples	2.6	Wheat	
35.3	ES child	8.3	Lettuce	4.9	Tomatoes	4.4	Wheat	
34.7	ES adult	10.7	Lettuce	4.9	Barley	3.9	Tomatoes	
34.6	IT kids/toddler	7.1	Tomatoes	6.6	Wheat	5.8	Lettuce	
34.0	FR infant	8.4	Beans (with pods)	7.7	Milk and cream,	7.5	Apples	
33.7	WHO Cluster diet F	6.0	Barley	6.0	Lettuce	3.6	Wheat	
33.4	IT adult	7.5	Lettuce	5.8	Tomatoes	4.1	Wheat	
31.0	SE general population 90th percentile	3.8	Tomatoes	3.7	Milk and cream,	3.2	Wheat	
29.2	NL general	3.7	Barley	3.5	Apples	2.5	Beans (with pods)	
21.3	FR all population	3.8	Other lettuce and other salad plants	3.3	Wheat	2.2	Tomatoes	
21.2	PT General population	4.5	Tomatoes	3.9	Wheat	3.2	Apples	
19.6	UK vegetarian	3.1	Tomatoes	2.8	Lettuce	2.0	Wheat	
19.0	LT adult	5.6	Apples	3.1	Tomatoes	1.3	Lettuce	
16.9	PL general population	6.1	Apples	4.4	Tomatoes	0.8	Pears	
15.1	FI adult	2.1	Tomatoes	1.7	Milk and cream,	1.6	Lettuce	
15.0	DK adult	2.4	Apples	2.1	Tomatoes	2.0	Wheat	
15.0	UK Adult	2.3	Lettuce	2.2	Tomatoes	1.7	Wheat	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Thiacloprid is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
26.97	Table olives	2.4 / -	27.0	Table olives	2.4 / -	10.7	Table olives	2.4 / -	10.7	Table olives	2.4 / -
8.45	Carrots	0.04 / -	6.0	Carrots	0.04 / -	1.9	Parsnips	0.04 / -	1.4	Beetroot	0.04 / -
5.84	Beetroot	0.04 / -	4.3	Beetroot	0.04 / -	1.8	Beetroot	0.04 / -	1.4	Parsnips	0.04 / -
5.24	Salsify	0.04 / -	3.7	Salsify	0.04 / -	1.6	Carrots	0.04 / -	1.3	Carrots	0.04 / -
4.82	Parsnips	0.04 / -	3.4	Parsnips	0.04 / -	1.4	Salsify	0.04 / -	1.0	Salsify	0.04 / -
0.53	Poppy seed	0.16 / -	0.5	Poppy seed	0.16 / -	0.2	Poppy seed	0.16 / -	0.2	Poppy seed	0.16 / -
0.27	Parsley root	0.04 / -	0.2	Parsley root	0.04 / -	0.1	Horseradish	0.04 / -	0.1	Horseradish	0.04 / -
0.04	Olives for oil production	0.0102 / -	0.0	Olives for oil production	0.0102 / -	0.1	Parsley root	0.04 / -	0.1	Parsley root	0.04 / -
0.02	Horseradish	0.04 / -	0.0	Horseradish	0.04 / -						
No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---								

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		*****)**				*****)**	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Thiacloprid IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX C – EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 27/11/2009 10:24)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,3
130010	Apples (Crab apple)	0,3
130020	Pears (Oriental pear)	0,3
130030	Quinces	0,3
130040	Medlar	0,3
130050	Loquat	0,3
130990	Others	0,3
140000	(iv) Stone fruit	
140010	Apricots	0,3
140020	Cherries (sweet cherries, sour cherries)	0,3
140030	Peaches (Nectarines and similar hybrids)	0,3
140040	Plums (Damson, greengage, mirabelle)	0,1
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,5
153000	(c) Cane fruit	
153010	Blackberries	3
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	1
153030	Raspberries (Wineberries)	3
153990	Others	1
154000	(d) Other small fruit & berries	1
154010	Blueberries (Bilberries cowberries (red bilberries))	1
154020	Cranberries	1
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other ribes species)	1
154050	Rose hips	1
154060	Mulberries (arbutus berry)	1
154070	Azarole (mediteranean medlar)	1
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	1
154990	Others	1
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,5
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
	vegetables	
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,1
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,1
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and	0,02*
	similar varieties)	
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,5
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	0,5
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,3
232010	Cucumbers	0,3
232020	Gherkins	0,3
232030	Courgettes (Summer squash, marrow (patisson))	0,3
232990	Others	0,3
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,2
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,2
233990	Others	0,02*
234000	(d) Sweet corn	0,1
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1
241020	Cauliflower	0,1
241990	Others	0,1
242000	(b) Head brassica	
242010	Brussels sprouts	0,05
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,2
242990	Others	0,02*
243000	(c) Leafy brassica	1
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	1
243020	Kale (Borecole (curly kale), collards)	1
243990	Others	1
244000	(d) Kohlrabi	0,05
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	2 (5)[12]
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	3
	(Wild rocket)	
251070	Red mustard	2
251080	Leaves and sprouts of Brassica spp (Mizuna)	2
251990	Others	2
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	3 (5)[13]
256010	Chervil	
256020	Chives	
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	
256040	Parsley	
256050	Sage (Winter savory,	

[12] MRL proposal as derived by EFSA (EFSA, 2009b) and considered in SCoFCAH on 15-16 October. Not legally enforced by 30 November 2009.

[13] MRL proposal as derived by EFSA (EFSA, 2009c) and considered in SCoFCAH on 15-16 October. Not legally enforced by 30 November 2009

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
	summer savory,)	
256060	Rosemary	
256070	Thyme (marjoram, oregano)	
256080	Basil (Balm leaves, mint, peppermint)	
256090	Bay leaves (laurel)	
256100	Tarragon (Hyssop)	
256990	Others	
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,2
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,3 (0.5)[14]
270040	Fennel	0,02* (0.5)[15]
270050	Globe artichokes	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 (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,1
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1
300020	Lentils	0,1
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1
300040	Lupins	0,1
300990	Others	0,1
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,3
401070	Soya bean	0,05*
401080	Mustard seed	0,2
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	1
500020	Buckwheat	0,05
500030	Maize	0,05
500040	Millet (Foxtail millet, teff)	0,05
500050	Oats	1
500060	Rice	0,05
500070	Rye	0,05
500080	Sorghum	0,05
500090	Wheat (Spelt Triticale)	0,1
500990	Others	0,05
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*(10)[16]
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*(50)[17]
632010	Strawberry leaves	
632020	Rooibos leaves	
632030	Maté	
632990	Others	
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*

[14] See footnote 12
[15] See footnote 12
[16] See footnote 13
[17] See footnote 13

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiacloprid (F)
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	0,05
1011020	Fat free of lean meat	0,05
1011030	Liver	0,3
1011040	Kidney	0,3
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0,05
1012020	Fat	0,05
1012030	Liver	0,3
1012040	Kidney	0,3
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	
1013010	Meat	0,05
1013020	Fat	0,05
1013030	Liver	0,3
1013040	Kidney	0,3
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0,05
1014020	Fat	0,05
1014030	Liver	0,3
1014040	Kidney	0,3
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,05
1015020	Fat	0,05
1015030	Liver	0,3
1015040	Kidney	0,3
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	0,05
1016020	Fat	0,05
1016030	Liver	0,3
1016040	Kidney	0,3
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	0,05
1017020	Fat	0,05
1017030	Liver	0,3
1017040	Kidney	0,3
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,03
1020010	Cattle	0,03
1020020	Sheep	0,03
1020030	Goat	0,03
1020040	Horse	0,03
1020990	Others	0,03
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen)	0,2
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	
*-indicates the lowest level of analytical quantification		

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CS	capsule suspension
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DP	dustable powder
DT_{90lab}	period required for 90 percent dissipation (laboratory studies)
DT_{90f}	period required for 90 percent dissipation (field studies)
dw	dry weight
EC	European Community
EC	emulsifiable concentrate
ECD	electron capture detection
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionization detection
GAP	good agricultural practice
GC	gas chromatography
GR	granule
GS	growth stage
ha	hectare

hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	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
OD	Oil dispersion
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SCoFCAH	Standing Committee on Food Chain and Animal Health
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation