REASONED OPINION

EFSA Journal

APPROVED: 02 July 2015 PUBLISHED: 17 July 2015

doi:10.2903/j.efsa.2015.4191

Modification of the existing maximum residue level for thiacloprid in Jerusalem artichokes

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Belgium, compiled an application to modify the existing maximum residue level (MRL) for the active substance thiacloprid in Jerusalem artichokes. In order to accommodate for the intended use of thiacloprid Belgium proposed to raise the value of the existing MRL from the limit of quantification (LOQ) of 0.02 mg/kg to 0.05 mg/kg. Belgium drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. EFSA concludes to derive a MRL proposal of 0.05 mg/kg on Jerusalem artichokes by extrapolation of data from carrots. Adequate analytical enforcement methods are available to monitor the residues of thiacloprid on the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of thiacloprid on Jerusalem artichokes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

Keywords: thiacloprid, Jerusalem artichokes, MRL application, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2015-00282

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Suggested citation: EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue level (MRL) for thiacloprid in Jerusalem artichokes. EFSA Journal 2015;13(7):4191, 18 pp. doi:10.2903/j.efsa.2015.4191

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Belgium, compiled an application to modify the existing maximum residue level (MRL) for the active substance thiacloprid in Jerusalem artichokes. In order to accommodate for the intended use of thiacloprid, Belgium proposed to raise the value of the existing MRL from the LOQ of 0.02 mg/kg to 0.05 mg/kg. Belgium drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 8 May 2015.

EFSA bases its assessment on the evaluation report, the draft assessment report (DAR) prepared under Council Directive 91/414/EEC, the Commission review report on thiacloprid, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluation report as well as the conclusions from previous EFSA opinions on thiacloprid.

The toxicological profile of thiacloprid was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day and an acute reference dose (ARfD) of 0.03 mg/kg bw.

The metabolism of thiacloprid in primary crops was investigated in the fruit (apple, tomato), the pulses/oilseeds (cotton) and the cereals (wheat) crop groups following foliar applications and in tomato after soil treatment. From these studies, the review of the existing MRL under Article 12 of Regulation (EC) No 396/2005 confirmed the residue definitions for enforcement and for risk assessment as thiacloprid, which are applicable to the crop under consideration.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.05 mg/kg on Jerusalem artichokes by extrapolation of data from carrots. Adequate analytical enforcement methods are available to monitor the residues of thiacloprid on the commodity under consideration at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of thiacloprid residues in processed commodities are not required due to the low contribution of residues in Jerusalem artichokes to total consumer exposure.

Based on the available information on the nature and magnitude of residues in rotational crops, EFSA concludes that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used on Jerusalem artichokes according to the proposed good agricultural practice (GAP).

Residues of thiacloprid in commodities of animal origin were not assessed, since the crop under consideration in this MRL application is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the Article 12 MRL review a comprehensive dietary exposure assessment was performed. EFSA updated the long-term consumer exposure assessment with the median residue level (STMR) derived for Jerusalem artichokes from the residue trials on carrots. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term or acute consumer intake concerns were identified. The highest calculated chronic intake accounted for 33 % of the ADI (German child), the highest acute exposure for Jerusalem artichokes being less than 1 % of the ARfD.

EFSA concludes that the proposed use of thiacloprid on Jerusalem artichokes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Thiacloprid				
0213050	Jerusalem artichokes	0.02*	0.05	Extrapolation from carrots.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,[2] repealed by Regulation (EC) No 1107/2009,[3] shall submit to a Member State, when appropriate, an application to modify a MRL.

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRL for thiacloprid in Jerusalem artichokes. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission and to EFSA on 8 May 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00282 and the following subject:

Thiacloprid - Modification of existing MRLs in Jerusalem artichoke.

Belgium proposed to raise the existing MRL of thiacloprid in Jerusalem artichokes from the limit of quantification (LOQ) of 0.02 mg/kg to 0.05 mg/kg.

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

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

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months, if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Thiacloprid is the ISO common name for (*Z*)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide (IUPAC). The chemical structure of the active substance is reported in Appendix C. Thiacloprid has been approved for use as an insecticide.

Thiacloprid was evaluated in the framework of Council Directive 91/414/EEC with the United Kingdom designated as the rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2004/99/EC[4] which entered into force on 1 January 2005 for use as an insecticide. In accordance with Commission Implementing Regulation (EU) No 540/2011[5] thiacloprid is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses supporting the Annex I inclusion included the uses on various pome fruits, stone fruits, fruiting vegetables, cucurbits and ornamentals. Thiacloprid was not peer reviewed by EFSA, therefore an EFSA conclusion is not available.

[1] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.
[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
[4] Commission Directive 2004/99/EC of 1 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances. OJ L 309, 06.10.2004, p.6–8.
[5] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1–186.

The EU MRLs for thiacloprid are currently established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs for thiacloprid. The proposals from these reasoned opinions have been considered in the preparation of EU legislation. The MRL changes are summarised in Table 1.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure[(a)]	Considered by Regulation	Remarks
Art. 10 (EFSA, 2009a)	(EC) 1050/2009	leek and spring onions EFSA-Q-2009-00221
Art. 10 (EFSA, 2009b)	(EC) No 459/2010	lamb's lettuce, celery, fennel EFSA-Q-2009-00461
Art. 10 (EFSA, 2009c)	(EC) No 750/2010	fresh herbs, herbal infusions (dried leaves), tea EFSA-Q-2009-00702-00703
Art. 10 (EFSA, 2009d)	(EC) No 750/2010	olives, poppy seeds and various root crops EFSA-Q-2009-00632-00741-00791
Art. 10 (EFSA, 2010a)	(EC) No 765/2010	strawberries EFSA-Q-2009-00872
Art. 10 (EFSA, 2010b)	(EC) No 508/2011	figs and various crops EFSA-Q-2010-00692-00693
Art. 10 (EFSA, 2010c)	(EC) No 508/2011	cotton seed EFSA-Q-2010-00905
Art. 10 (EFSA, 2010d)	(EC) No 813/2011	peas with pods EFSA-Q-2010-01053
Art. 10 (EFSA, 2013)	(EC) No 364/2014	spinach and similar leaves EFSA-Q-2013-00314

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005

EFSA has recently issued a reasoned opinion for thiacloprid which reviewed all uses authorised at EU level and Codex maximum residue limits (CXLs) according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014). Modifications of the existing MRLs were proposed for several crops, which have been voted by the Standing Committee on Plants, Animals, Food and Feed (SCPAFF) at the meeting held on February 2015, but not yet implemented in the EU legislation. It is noted that no EU use was reported for thiacloprid on Jerusalem artichokes in the framework of the Article 12 MRL review. Codex Alimentarius has established CXLs for a wide range of commodities, but no CXL has been set for Jerusalem artichokes.

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

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Belgium, 2015), the DAR prepared under Council Directive 91/414/EEC (United Kingdom, 2000), the Commission review report on thiacloprid (European Commission, 2004), the JMPR evaluation report (FAO, 2006) as well as the conclusions from previous EFSA reasoned opinions on thiacloprid (EFSA 2009a, b, c, d, 2010a, b, c, d, 2013, 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by

Commission Regulation (EU) No 546/2011[6] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of thiacloprid in plant commodities were assessed in the framework of the peer review and the Article 12 MRL review (United Kingdom, 2000; EFSA, 2014). EFSA concluded that adequate analytical methods are available to monitor residues of thiacloprid in high water content commodities, to which group Jerusalem artichoke belongs, with a LOQ of 0.01 mg/kg (EFSA, 2014).

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

Analytical methods for the determination of thiacloprid residues in food of animal origin are not assessed in the current application, since Jerusalem artichokes are not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance thiacloprid was assessed in the framework of the peer review under Council Directive 91/414/EEC (European Commission, 2004). The data were sufficient to derive the toxicological reference values compiled in Table 2.

Table 2: Overview of the toxicological reference values

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

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of thiacloprid in primary crops was evaluated in the framework of the peer review under Council Directive 91/414/EEC and the Article 12 MRL review (United Kingdom, 2000; EFSA, 2014). The details of the metabolism studies are reported in a previous EFSA reasoned opinion (EFSA, 2014). An overview of the metabolism study designs is presented in Table 3.

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

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[a] (DALA)	Comments
Fruit	Apple	Foliar (2× 270 g/ha)[b]	Fruit: 14	
		Foliar, above and below fruit (2× 270 g/ha)	Fruit: 14	Translocation study
	Tomato	Foliar (2× 260 g/ha) [b]	Fruit, 3, 14	
		Soil (2× 130 g/ha) [b]	Fruit, 3, 14	
Cereals	Wheat	Foliar (2× 50 g/ha)	Grain, straw: 120	
Pulses/Oilseeds	Cotton	Foliar (3× 190 g/ha)[b]	Leaves, gin trash, seeds: 120	

(a): DALA, days after last application.
(b): Dose rate expressed as g a.s./ha equivalent assuming an application rate of 10 hL/ha (EFSA, 2014).

The review of the existing MRLs for thiacloprid confirmed the residue definition for enforcement and for risk assessment as parent thiacloprid. The current residue definition set in Regulation (EC) No 396/2005 is identical. However, EFSA proposed to classify the residue as not fat-soluble (EFSA, 2014).

For the use on Jerusalem artichokes, EFSA concludes that the metabolism of thiacloprid is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the MRL review are applicable.

3.1.1.2. Magnitude of residues

Specific residue trials on Jerusalem artichokes have not been submitted. The EMS proposed to extrapolate the MRL of 0.05 mg/kg derived from the NEU residue trials on carrots conducted according to the intended GAP and already assessed in the framework of the Article 12 MRL review (EFSA, 2014). The number of residue trials is sufficient to support the proposed extrapolation, which is foreseen in the EU guidance (European Commission, 2011).

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposal are summarised in Table 4.

Residues of thiacloprid were found to be stable at ≤ 18 °C for up to 18 months in matrices with high water content (EFSA, 2014). The supervised residue trial samples were already assessed by EFSA and considered as valid with regards to storage stability and the analytical determination of residues (EFSA, 2014).

EFSA concludes that the data support the following MRL proposal:

– 0.05 mg/kg Jerusalem artichokes in NEU (extrapolation from trials on carrots)

Table 4: Overview of the available residues trials data

Crop (GAPs)	**Region/ Indoor**[a]	**Residue levels observed in the supervised residue trials**[b] (mg/kg)	**Recommendations/comments**[c]	**MRL proposal** (mg/kg)	**HR**[d] (mg/kg)	**STMR**[e] (mg/kg)
Carrots (2 × 120 g/ha, PHI 7 days)	NEU	8× <0.01; 2× 0.01; 3× 0.02; 0.04	Trials on carrots previously assessed (EFSA, 2004). **Extrapolation to Jerusalem artichokes**. MRL_{OECD}: 0.05/0.05	0.05	0.04	0.01

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order.
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).
(d): HR: Highest residue level according to the residue definition for risk assessment.
(e): STMR: Median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

Based on the available information on the nature of thiacloprid residues, EFSA concluded that the compound is hydrolytically stable under the representative processing conditions and for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2014).

Specific studies to assess the magnitude of residues of thiacloprid during the processing of Jerusalem artichokes were not provided in the framework of the current MRL application (Belgium, 2015). However, they are considered unnecessary due to the low contribution of residues in this crop to the total consumer exposure.

3.1.2. Rotational crops

Jerusalem artichoke can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed (European Commission, 1997c).

The nature and magnitude of thiacloprid residues in rotational crops was investigated during the peer review (United Kingdom, 2000) in lettuce, wheat and turnips sown into soil treated at 424 g a.s./ha (1.75N the intended application rate on Jerusalem artichokes). The Article 12 MRL review confirmed that the residue definition as parent compound established in primary crops also applies to rotational crops and that residues resulting from the soil uptake are not expected to exceed 0.01 mg/kg, provided that the thiacloprid is applied on plants in compliance to the authorised uses (EFSA, 2014).

Since the intended use of thiacloprid on Jerusalem artichokes is not more critical that the existing uses assessed in the framework of the Article 12 MRL review, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is applied on the crop under consideration according to the proposed GAP.

3.2. Nature and magnitude of residues in livestock

As Jerusalem artichokes are not normally fed to livestock, the nature and magnitude of thiacloprid residues in livestock is not assessed in the framework of this application (European Commission, 1996).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for thiacloprid according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level and the acceptable CXLs (EFSA, 2014). EFSA updated the long-term consumer exposure assessment with the STMR derived for Jerusalem artichokes from the residue trials on carrots (see Table 4). The food commodities, for which no uses were reported in the framework of the Article 12 MRL review, were excluded from the exposure calculation, assuming that there is no use of thiacloprid on these crops.

The acute exposure assessment was performed only with regard to the commodity under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys and that this item contained residues at the HR as observed in supervised field trials (see Table 4). A variability factor accounting for the inhomogeneous distribution on the individual item consumed was included in the calculation (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 5.

Table 5: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition: Thiacloprid				
Jerusalem artichokes	0.01	STMR (carrot, NEU)	0.04	HR (carrot, NEU)
Other plant and animal origin commodities	See Table 4-3 of the Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thiacloprid according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014).		Acute risk assessment undertaken only with regard to the crop under consideration	

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

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, a long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The total intake calculated accounted for 33 % of the ADI (German child), with the contribution of the residues in Jerusalem artichokes to the total exposure accounting for a maximum of 0.01 %.

An acute consumer risk was not identified in relation to the MRL proposal for Jerusalem artichokes, as the highest acute exposure calculated was 0.8 % of the ARfD (British adult vegetarian).

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

Conclusions and recommendations

The information submitted was sufficient to propose the MRL in the table below:

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Thiacloprid				
0213050	Jerusalem artichokes	0.02*	0.05	Extrapolation from carrots.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CXL	Codex maximum residue limit (Codex MRL)
DALA	days after last application
DAR	draft assessment report
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
HR	highest residue
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers, nowadays DG SANTE
SC	suspension concentrate
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly Standing Committee on the Food Chain and Animal Health (SCFCAH))
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization

Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation[a]	MS or NEU/SEU or Country	F G or I [b]	Pest or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (days) [l]	Remarks [m]
				type [d-f]	conc. a.s.[i]	Method kind[f-h]	Growth stage & season[j]	Number min-max [k]	Interval min-max	g/hL min-max	Water L/ha min-max	g/ha min-max		
Jerusalem artichokes	Belgium	F	Aphids	SC	480 g/L	spraying		1-2				120	7	

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil-born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), water soluble granule (WG)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) all abbreviations must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated
(i) g/kg or µg/L
(j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix B – Pesticide Residue Intake Model (PRIMo)

Thiachloprid			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.03**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum	maximum
	4	33
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)
33.0	DE child	12.1	Apples	5.9	Herbal infusions (dried)	4.3	Milk and milk products: Cattle	1.3
29.1	WHO Cluster diet B	9.8	Olives for oil production	4.5	Tomatoes	2.1	Wheat	1.9
25.5	NL child	8.8	Milk and milk products: Cattle	6.3	Apples	1.2	Wheat	1.8
16.3	FR infant	7.7	Milk and milk products: Cattle	2.5	Apples	1.3	Strawberries	1.3
15.5	IE adult	2.5	Tea (dried leaves and stalks,	0.8	Milk and milk products: Cattle	0.8	Apples	1.6
15.3	ES child	3.7	Milk and milk products: Cattle	3.7	Olives for oil production	1.4	Tomatoes	0.6
12.0	UK Toddler	4.6	Sugar beet (root)	1.7	Apples	1.0	Wheat	5.7
11.8	SE general population 90th percentile	3.7	Milk and milk products: Cattle	1.1	Tomatoes	1.1	Apples	1.3
11.7	WHO regional European diet	1.6	Tomatoes	1.4	Milk and milk products: Cattle	0.8	Potatoes	1.2
11.4	WHO cluster diet E	1.0	Wheat	0.9	Milk and milk products: Cattle	0.9	Olives for oil production	1.6
11.3	FR toddler	2.6	Apples	1.7	Strawberries	1.3	Beans (with pods)	1.5
11.3	WHO cluster diet D	1.6	Wheat	1.5	Tomatoes	1.4	Milk and milk products: Cattle	1.4
10.9	DK child	2.3	Apples	2.3	Cucumbers	1.4	Wheat	1.6
9.9	ES adult	2.2	Olives for oil production	1.5	Milk and milk products: Cattle	1.1	Tomatoes	0.4
9.0	UK Infant	2.0	Sugar beet (root)	1.6	Apples	1.1	Tea (dried leaves and stalks,	3.2
8.6	PT General population	1.3	Olives for oil production	1.3	Tomatoes	1.1	Potatoes	1.9
8.4	WHO Cluster diet F	1.2	Milk and milk products: Cattle	1.0	Tomatoes	0.9	Wheat	1.2
8.0	NL general	2.0	Milk and milk products: Cattle	1.2	Apples	0.6	Tomatoes	1.0
8.0	IT kids/toddler	2.1	Tomatoes	1.7	Wheat	0.9	Apples	0.3
7.2	FR all population	1.0	Olives for oil production	0.8	Wheat	0.8	Milk and milk products: Cattle	1.2
6.9	IT adult	1.7	Tomatoes	1.0	Wheat	0.8	Apples	0.2
6.9	LT adult	1.9	Apples	1.2	Milk and milk products: Cattle	0.9	Tomatoes	1.0
5.9	UK vegetarian	0.9	Tea (dried leaves and stalks,	0.9	Tomatoes	0.8	Sugar beet (root)	1.4
5.6	PL general population	2.0	Apples	1.3	Tomatoes	0.7	Potatoes	0.9
4.9	UK Adult	1.0	Tea (dried leaves and stalks,	0.8	Sugar beet (root)	0.6	Tomatoes	1.4
4.5	DK adult	0.8	Apples	0.6	Tomatoes	0.5	Wheat	0.8
3.6	FI adult	0.6	Tomatoes	0.4	Apples	0.4	Cucumbers	0.5

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Thiachloprid 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)
							0.8	Jerusalem artichokes	0.04 / -	0.6	Jerusalem artichokes	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:**		**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)			
	239.8	Raspberries juice	6 / 2.5				6.6	Apple juice	0.3 / -			
	53.4	Elderberry juice	1 / -				3.3	Peach preserved with syrup	0.5 / -			
	51.0	Apple juice	0.3 / -				3.2	Tomato (preserved-	0.5 / -			
	33.7	Cuurant juice	1 / -				2.7	Quince jelly	0.7 / -			
	29.8	Peach juice	0.5 / -				1.5	Bread/pizza	0.1 / -			
*) 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.												

Appendix C – Used compound code

Code/Trivial name	Chemical name	Structural formula
Thiacloprid	(*Z*)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide