

REASONED OPINION

Modification of the existing MRLs for thiamethoxam in carrots¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6(2) of the Regulation (EC) No 396/2005, The Netherlands received an application from Syngenta Crop Protection BV to modify the existing MRL for thiamethoxam in carrots. In order to accommodate the intended GAP in The Netherlands, the applicant proposes to raise the existing MRL of 0.1 mg/kg to 0.3 mg/kg. The Netherlands as the Evaluating Member State (EMS) 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.

EFSA derives the following conclusions regarding the application based on the above mentioned evaluation report and the Draft Assessment Report prepared by Spain in the framework of the peer review.

In the peer review the metabolism of thiamethoxam was investigated in four crop groups following three different application modes. The peer review concluded that for the representative uses evaluated under the peer review thiamethoxam and its metabolite clothianidin (CGA 322704) are relevant residues. Therefore the risk assessment and enforcement residue definition was established as “sum of thiamethoxam and CGA 322704, expressed as thiamethoxam”. Regarding carrots, the most representative metabolism study from the peer review is the metabolism study in potatoes after the seed treatment. The study indicates that the parent is the major residue of concern in roots/tubers. EFSA concludes that metabolism of thiamethoxam in carrots would proceed in a similar pathway as in potatoes and therefore no additional metabolism studies in carrots are required. Adequate analytical methods are available to enforce the proposed MRL in carrots.

Submitted supervised field trials indicate that a higher MRL of 0.3 mg/kg would be necessary to accommodate the intended GAP in The Netherlands.

Residue occurrence in rotational crops was also investigated under the current application, since carrots can be grown in rotation with other crops and since the active substance and several of its metabolites show slow degradation in the soil. Considering the proposed application rates of thiamethoxam and the mode of application, EFSA concludes that significant residue levels in rotational crops are not expected, provided that thiamethoxam is applied according to the proposed GAP.

1 On request from the European Commission, Question No EFSA-Q-2009-00633, issued on 3 September 2009.

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

Carrots are not a common livestock feeding item, therefore nature and magnitude of thiamethoxam residues in livestock was not considered under the current MRL application.

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 Regulation (EC) No 396/2005 as well as the STMR value as derived for the intended use on carrots as input values. Acute intake assessment for carrots was performed with the HR value as derived from the supervised field trials.

No chronic intake concerns were identified for any European diets. Total calculated intake values ranged from 5.8 – 26.6% of the ADI. The contribution of carrots to the total dietary intake is insignificant amounting for a maximum of 0.41 % of the ADI for French infant diet. No acute intake concerns were identified with regard to carrots (2.3 % of the ARfD).

Consequently EFSA concludes that the intended use of thiamethoxam on carrots is acceptable with regard to consumer safety.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Thiamethoxam and CGA 322704, expressed as thiamethoxam			
Carrots	0.1	0.3	The MRL proposal is supported by data and no risk for consumers was identified for the proposed use.

KEY WORDS

Thiamethoxam, carrots, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, neonicotinoids insecticide, clothiadin (CGA 322704)

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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 Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta Crop Protection BV³ to modify the existing MRL for the active substance thiamethoxam in carrots. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00633 and the following subject:

Thiamethoxam - Application to modify the existing MRL for thiamethoxam + n-(2-chloro-thiazol-5-ylmethyl)-n'-methyl-n''-nitro-guanidine (cga 322704) expressed as thiamethoxam in carrots from 0.1 mg/kg to 0.3 mg/kg.

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

TERMS OF REFERENCE

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

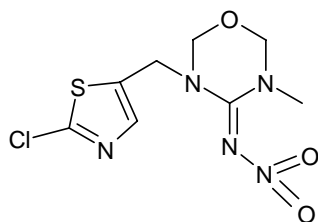
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 29 August 2009.

³ Syngenta Crop Protection BV, Jacon Obrechtlaan 3a, 4600 AM (PO Box 512), Bergen op Zoom, The Netherlands

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Thiamethoxam is the ISO common name for (E,Z)-3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene-N-nitroamine (IUPAC):



Molecular mass: 291.7

Thiamethoxam is a systemic insecticide belonging to the chemical class of neonicotinoids. It is used in agriculture as a foliar treatment against sucking insects and chewing pests. Thiamethoxam also shows very good activity against soil insects and early season sucking pests as well as some leaf feeding insect pests after seed and soil treatments.

Thiamethoxam was peer reviewed under Directive 91/414/EEC as a new active substance with Spain being the designated Rapporteur Member State. The active substance was included in Annex I to this Directive by Commission Directive 2007/6/EC, which entered into force on 1 February 2007. When thiamethoxam was peer reviewed, EFSA was not involved; therefore no EFSA conclusion is available for the active substance. The representative uses evaluated under the peer review involve foliar application of thiamethoxam on a wide range of crops as well as seed treatment of wheat, barley, maize, oilseed, sugar beet, peas, cotton and potatoes.

The EU MRLs for thiamethoxam are established in Annex III of Regulation (EC) No 396/2005 (Appendix C). The current MRL for carrots is set at 0.1 mg/kg. Thiamethoxam has not been evaluated by the JMPR, but it is included in the tentative schedule of substances to be evaluated by the JMPR in the time period of 2010-2016 (WHO/FAO, 2009).

It should be noted, that clothianidin (CGA 322704)⁴, a pant metabolism product of thiamethoxam, is also the active substance of various registered plant protection products. For clothianidin separate EU MRLs are established in Regulation (EC) No 396/2005.

The GAP for which an authorization is requested in The Netherlands refers to a seed application of the active substance once at an application rate 0.03 – 0.12 kg a.s./ha (assuming 500.000- 2.000.000 seeds /ha). The details of the GAP are outlined in Appendix A.

⁴ CGA 322704: N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N''-nitro-guanidine

ASSESSMENT

1. Methods of analysis

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

Analytical enforcement methods for determination of thiamethoxam residues in commodities of plant origin were evaluated under the peer review of 91/414/EEC (Spain, 2001). Following methods are sufficiently validated for enforcement purposes:

- 1) for the determination of parent thiamethoxam in dry commodities and commodities with high water content: method REM 179.01 (HPLC-UV), validated at the LOQ of 0.02 mg/kg for edible and 0.05 mg/kg for non-edible commodities;
- 2) for the determination of parent thiamethoxam and CGA 322704 in dry crops, high water content crops, high fat content crops and high acid content crops: method REM 173-03 (HPLC-UV or MS/MS). Validated LOQ 0.02 mg/kg.

Consequently EFSA concludes that adequate enforcement analytical methods are available for the determination of thiamethoxam residues in carrots.

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

Carrots are not normally used as a livestock feed therefore analytical methods for the determination of thiamethoxam residues in food of animal origin are not of relevance.

2. Mammalian toxicology

The toxicological reference values for thiamethoxam were derived in the peer review under Directive 91/414/EEC and are compiled in Table 2-1 (European Commission, 2006).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Thiamethoxam					
ADI	COM	2006	0.026 mg/kg bw/d	18 month mice	100
ARfD	COM	2006	0.5 mg/kg bw	Rabbit developmental	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 the uptake and metabolism of thiamethoxam was studied in various crops following different application modes (Spain, 2001):

- Cereals: maize corn (seed treatment (0.461 - 0.488 kg a.s./100 kg seeds), soil treatment (0.488 kg a.s./ha)); rice (soil application 0.3 kg a.s./ha, foliar application 0.025 kg a.s./ha)
- Fruits and fruiting vegetables: pears (2 x 0.15 kg a.s./ha and 2 x 1.5 kg a.s./ha), cucumbers (0.5 – 2 kg a.s./ha)
- Leafy vegetables: lettuce (foliar application 3 x 0.051 - 0.054 kg a.s./ha), tobacco (furrow application 0.2 kg a.s./ha; foliar application 2.03 kg a.s./ha)
- Root and tuber vegetables: potatoes (seed application 1 x 0.0075 kg a.s./100 kg tubers; 1 x 0.0375 kg a.s./100 kg tubers)

Metabolism studies were performed both with ¹⁴C-thiazol- and ¹⁴C-oxadiazin thiamethoxam.

In mature corn in both studies after seed treatment the major part of the TRR was in maize fodder (0.238 - 0.346 mg/kg) with comparatively low levels in maize grain (0.015 - 0.023 mg/kg). Studies indicate high translocation from seeds to aerial plant parts. In oxadiazin study the main component of the TRR in grain was parent thiamethoxam (15.1% TRR (0.002 mg/kg)) and metabolite CGA 322704 (9.6% TRR). In maize fodder the relevant residues were NOA 407475⁵ (8.5% (0.02 mg/kg)) and NOA 421275⁶ (10.1% (0.024 mg/kg)). Non-extractable residues in thiazol study either after seed or soil treatment in mature crops were higher (grain >61% TRR, fodder >42 %TRR) than in oxadiazin study (grain >24% TRR, fodder >30% TRR).

In rice grain from soil application neither the parent compound nor any metabolite was found above 10 % TRR or 0.05 mg/kg. In rice grain from foliar application parent thiamethoxam and CGA 322704 accounted for 12 % and 10 % of TRR but did not exceed 0.05 mg/kg. Therefore, parent thiamethoxam is considered relevant residue for rice grain.

In pears the majority of the TRR in oxadiazin and thiazol studies was found in organic fraction (65.8 - 75.7% TRR) and the major part of the TRR consisted of parent thiamethoxam (28 - 29.3 % TRR), CGA 322704 (19.1 - 24.3% TRR). The aqueous fractions consisted of large amount of sugars and coextractants. For pear fruit parent thiamethoxam and CGA 322704 (together account for 47 % TRR (0.33 mg/kg)) are considered relevant residues. A considerable amount of the residue was associated with aqueous fractions and sugars (7 - 17 % TRR (0.03 - 0.12 mg/kg) and non-extractable residue (7 - 9 % TRR (0.035 - 0.065 mg/kg).

In cucumbers, extractable radioactivity was high in studies with both radiolabels (75.2 - 94.06% TRR or 0.026-0.029 mg/kg). Parent thiamethoxam and NOA 407475 exceeded 10 % of the TRR for cucumber fruits, but the absolute amounts found were all well below 0.05 mg/kg and therefore parent compound was considered relevant residue. The appearance of some glucoside conjugate metabolites

⁵ NOA 407475: 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylideneamine

⁶ NOA 421275: N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-guanidine

suggest that part of the non-identified and the non extractable residue will not be completely metabolised thiamethoxam but sugar and starch conjugates of thiamethoxam moieties. The amount of non-extractable residue in the thiazol study (0.012 mg/kg) was higher than the non-extractable residue in the oxadiazin study (0.002 mg/kg) indicating the possible bounding of the chlorothiazol moiety. The need to assess the toxicity and bioavailability of these moieties was indicated since the amount of total identified residue was very low (< 41 %).

In lettuce, in both studies with various pre-harvest intervals, the major part of the TRR was parent thiamethoxam. The second major fraction was metabolite NOA 405217, but it did not exceed 7.9% TRR or 0.05 mg/kg (oxadiazin study, 14 day PHI). In lettuce, parent thiamethoxam is considered the major residue.

In tobacco, in both studies parent thiamethoxam was the major residue accounting for up to 14.4 – 15.3% TRR (0.2 - 0.28 mg/kg). Several other metabolites exceeding 10% of the TRR or 0.05 mg/kg were identified: NOA 407475 (0.24 mg/kg), CGA 353968⁷ (0.08 mg/kg), N-glucoside of CGA 353968 (0.24 mg/kg) and NOA 421275 (0.11 mg/kg) and NOA 408445⁸ (0.12 mg/kg) indicating a more intensive metabolism in crop leaves with a high number of produced metabolites. These metabolites together with parent thiamethoxam are considered relevant residue in tobacco.

In mature potato tubers in oxadiazin and thiazol studies extractable residues accounted for 75.3 - 84.5% TRR (or 0.17 mg/kg and 0.11 mg/kg), respectively. Parent thiamethoxam was the major unchanged metabolite, but occurred in relatively low levels - 10.3 % TRR or 0.01 mg/kg (oxadiazin study) and 13.1% TRR or 0.029 mg/kg (thiazol study). Metabolite CGA 322704 accounted for 6.0% TRR or 0.008 mg/kg (oxadiazin study) and 6.2 % TRR or 0.014 mg/kg (thiazol study). All other metabolites were below 0.01 mg/kg. Parent thiamethoxam is the residue of concern in potatoes after seed treatment.

In the peer review it was concluded that even though metabolic route seems to be very similar among different plants, the composition of the final residue is very dependent on the plant, the part of the plant analysed (leaves, grain, fruit) and the PHI, and therefore a general residue definition for all plant commodities could not be proposed. It was concluded that “*sum of thiamethoxam and metabolite CGA 322704 expressed as thiamethoxam*” should be established as the risk assessment and enforcement residue definition for plants covered by the representative uses considered in the peer review. The toxicological properties of two metabolites, CGA 322704 and NOA 407475 were also investigated and both metabolites were found to be of low acute oral toxicity to rats. In the peer review it was also noted that for many of the crops residues are much higher in non-edible parts (leaves, forage and foliage) and that a number of metabolites appear there at relevant levels therefore these residues may have to be taken into account to assess animal intake.

The most representative metabolism study for carrots is the metabolism study in potatoes after seed treatment. The study indicates that the parent is the major residue of concern in roots/tubers. Therefore EFSA considers that metabolism in carrots is sufficiently elucidated and no additional metabolism studies are necessary.

It should be noted, that metabolite CGA 322704 or *clothianidin* is not only the metabolism product of thiamethoxam, but also the active substance of several registered plant protection products. For clothianidin separate EU MRLs are established in Regulation (EC) No 396/2005. In the framework of the MRL review, the RMS Spain proposed to change the existing enforcement residue definition for thiamethoxam to thiamethoxam only, meaning that clothianidin residues that occur from the use of thiamethoxam would be covered by clothianidin MRLs. However, the impact of the proposal to the existing MRLs will be considered in the framework of the MRL review according to Article 12(2) of Regulation (EC) No 396/2005.

⁷ CGA 353968: N-(chloro-thiazol-5-ylmethyl)-N'-methyl urea

⁸ NOA 408445: [(2-chloro-thiazole-5-carbonyl)-amino]-acetic acid

3.1.1.2. Magnitude of residues

In support of the proposed GAP the applicant submitted eight supervised residue field trials on carrots. Trials were performed over two seasons in the Northern Europe. The samples were analyzed both for thiamethoxam and clothianidin (metabolite CGA 322704) separately. Only in two samples the residue levels for both compounds exceeded the LOQ of 0.02 mg/kg. The highest observed residue levels of metabolite CGA 322704 in those two samples were 0.03 mg/kg, being approximately four times less than parent thiamethoxam. The conversion factor of 1.17 was derived from the molecular weight. The adjustment was not applied for expressing the results as parent thiamethoxam since that would not have a significant impact on the overall residue values.

Summary of residue trials data are available in Table 3-1.

The storage stability of thiamethoxam and its metabolite CGA 322704 was evaluated under the peer review of Directive 91/414/EEC. Studies demonstrate that both compounds are stable for at least 24 months when stored deep frozen in commodities with high water and high oil content and in dry commodities (Spain, 2001). Supervised field trial samples prior analyses were stored deep frozen for a maximum of 285 days, thereby not exceeding the demonstrated storage stability period of the active substance and its metabolite.

For the analyses of the supervised residue field trials samples the method REM 179.06 (LC-MS/MS) was used. Method was sufficiently validated for the determination of thiamethoxam and CGA 322704 at the LOQ of 0.02 mg/kg (for each compound).

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

Commodity	Region ^(a)	Outdoor /Indoor	Individual trial results (mg/kg)		STM ^R (mg/kg) _(b)	HR (mg/kg) _(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (sum of thiamethoxam and CGA 322704, expressed as thiamethoxam)	Risk assessment (sum of thiamethoxam and CGA 322704, expressed as thiamethoxam)					
Carrots	NEU	Outdoor	6 x <0.04 ^a ; 0.15 ^b ; 0.18 ^b	6 x <0.04 ^a ; 0.15 ^b ; 0.18 ^b	0.04	0.18	0.3	1.0	R _{ber} = 0.25 mg/kg R _{max} =0.26 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.

^a: Amount of CGA 322704: <0.02 mg/kg (LOQ) for each individual trial result

^b: Amount of CGA 322704: 0.03 mg/kg

3.1.1.3. Effect of industrial processing and/or household preparation

Effects of processing on the nature of thiamethoxam residues were investigated under the peer review of Directive 91/414/EEC in hydrolysis studies simulating relevant processing steps (Spain, 2001). ¹⁴C-thiazol-thiamethoxam was incubated in aqueous solution at 90°C (pH 4, 20 min.), 100°C (pH 5, 60 min.) and 120°C (pH 6, 20 min.). Results indicate that thiamethoxam is stable under pasteurization and boiling conditions and no degradation products are formed. Only in the process of sterilization a marginal unknown radioactive fraction of 1.7 % was found. An identification of this fraction was not considered necessary since for the proposed MRLs under the peer review, the actual amounts of this component would be far below 0.01 mg/kg. Taking into account the residue levels in raw carrots, it is not expected that the levels of this unknown fraction would be of relevance.

No studies on the effects of the processing on the magnitude of thiamethoxam have been submitted in support of the MRL application for carrots, but are not considered necessary taking into account the insignificant contribution of thiamethoxam residues to the total dietary intake.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Carrots can be grown in rotation. According to the soil degradation studies performed in the framework of the peer review, the DT₉₀ values of thiamethoxam based on the field and laboratory studies are 270 (max) days and 459 days, respectively (Spain, 2001). In addition, several thiamethoxam metabolites - CGA 322704, NOA 407475, and CGA 355190⁹ - demonstrate slow degradation in the soil, exceeding the trigger value of 100 days.

In this case possible occurrence of thiamethoxam residues in rotational crops should be investigated.

3.1.2.2. Nature of residues

Nature of thiamethoxam in rotational crops was studied in a confined study by applying ¹⁴C-thiazol- and ¹⁴C-oxadiazin thiamethoxam on a bare soil at an application rate of 0.207 kg a.s./ha and 0.200 g a.s./ha, respectively (Spain, 2001). The plant back intervals and rotational crops were as follows: 29 days (lettuce, radish, spring wheat), 104 days (spring wheat), 119 days (lettuce, radish), 180 days (winter wheat) and 362 days (lettuce, radish, spring wheat).

In the peer review it was concluded that the metabolic pattern observed in rotational crop studies is the same as in the metabolism studies with primary plants. The uptake of radiolabelled substance in succeeding crops clearly indicates the systemic behaviour of thiamethoxam, however, the concentration of determined metabolites is low. Again accumulation of thiamethoxam related metabolites is observed in cereal leaves. The residue that may be found in edible parts of succeeding crops is the same residue that arises from direct application to the crop. The same residue definition as for primary plants applies also to rotational crops.

3.1.2.3. Magnitude of residues

Available confined rotational crop studies (see section 3.1.2.2) were used to estimate the magnitude of residues in succeeding crops following the application of thiamethoxam. After all plant back periods in both studies (¹⁴C-thiazol- and ¹⁴C-oxadiazin studies) no residue above 0.01 mg/kg were found in radish roots. In lettuce, residue levels ranged from 0.034 - 0.035 mg/kg (29 DAT) to 0.013 - 0.012

⁹ CGA 355190: 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-one

mg/kg (119 DAT). No residues above 0.01 mg/kg were found in lettuce and summer wheat grain for the plant back period of 362 days. The residues in wheat straw were the highest from all crops or crop parts analyzed, amounting for up to 0.753 mg/kg (29 DAT, thiazole study), 0.233 mg/kg (119 DAT oxadiazine study) and 0.082 mg/kg (362 DAT, thiazole study).

Considering the maximum proposed application rate of thiamethoxam on carrot (0.12 kg a.s/ha) and the mode of application (seed treatment), EFSA concludes that significant residue levels in rotational crops are not expected, provided that thiamethoxam is applied according to the proposed GAP.

3.2. Nature and magnitude of residues in livestock

Carrots are not a common livestock feeding item, therefore nature and magnitude of thiamethoxam residues in livestock was not considered under the current MRL application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic intake assessment EFSA used the existing MRLs as established in Annex III Regulation (EC) No 396/2005 as well as the STMR value derived for the intended use of thiamethoxam on carrots.

The acute intake assessment was performed only for carrots using the HR value derived for the intended use as an input value in the intake calculation.

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: sum of thiamethoxam and CGA 322704, expressed as thiamethoxam				
Carrots	0.04	STMR	0.18	HR
Other commodities	MRL	See Appendix C	Acute risk assessment is not relevant.	

Summary of consumer intake calculations can be found in Appendix B.

No chronic intake concerns were identified for any European diets. Total calculated intake values ranged from 5.8 – 26.6% of the ADI. The contribution of carrots to the total dietary intake is insignificant amounting for a maximum of 0.41 % of the ADI for French infant diet. No acute intake concerns were identified with regard to carrots (2.3 % of the ARfD).

Consequently EFSA concludes that the intended use of thiamethoxam on carrots is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

EFSA derives the following conclusions regarding the application based on the evaluation report prepared by the EMS The Netherlands and the Draft Assessment Report prepared by Spain in the framework of the peer review.

In the peer review the metabolism of thiamethoxam was investigated in four crop groups following three different application modes. The peer review concluded that for the representative uses evaluated under the peer review thiamethoxam and its metabolite clothianidin (CGA 322704) are relevant residues. Therefore the risk assessment and enforcement residue definition was established as “sum of thiamethoxam and CGA 322704, expressed as thiamethoxam”. Regarding carrots, the most representative metabolism study from the peer review is the metabolism study in potatoes after the seed treatment. The study indicates that the parent is the major residue of concern in roots/tubers. EFSA concludes that metabolism of thiamethoxam in carrots would proceed in a similar pathway as in potatoes and therefore no additional metabolism studies in carrots are required. Adequate analytical methods are available to enforce the proposed MRL in carrots.

Submitted supervised field trials indicate that a higher MRL of 0.3 mg/kg would be necessary to accommodate the intended GAP in The Netherlands.

Residue occurrence in rotational crops was also investigated under the current application, since carrots can be grown in rotation with other crops and since the active substance and several of its metabolites show slow degradation in the soil. Considering the proposed application rates of thiamethoxam and the mode of application, EFSA concludes that significant residue levels in rotational crops are not expected, provided that thiamethoxam is applied according to the proposed GAP.

Carrots are not a common livestock feeding item, therefore nature and magnitude of thiamethoxam residues in livestock was not considered under the current MRL application.

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 Regulation (EC) No 396/2005 as well as the STMR value as derived for the intended use on carrots as input values. Acute intake assessment for carrots was performed with the HR value as derived from the supervised field trials.

No chronic intake concerns were identified for any European diets. Total calculated intake values ranged from 5.8 – 26.6% of the ADI. The contribution of carrots to the total dietary intake is insignificant amounting for a maximum of 0.41 % of the ADI for French infant diet. No acute intake concerns were identified with regard to carrots (2.3 % of the ARfD).

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RECOMMENDATIONS

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Thiamethoxam and CGA 322704, expressed as thiamethoxam			

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Carrots	0.1	0.3	The MRL proposal is supported by data and no risk for consumers was identified for the proposed use.

DOCUMENTATION PROVIDED TO EFSA

REFERENCES

- The Netherlands, 2009. Evaluation report on the modification of the MRL for thiamethoxam in carrots prepared by the evaluating Member State The Netherlands under Article 8 of Regulation (EC) No 396/2005, 14 February 2009.
- Spain, 2001. Draft Assessment Report (DAR) on the active substance thiamethoxam prepared by the Rapporteur Member State Spain in the framework of Directive 91/414/EEC, March 2001.
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- WHO/FAO, 2009. Report of the Joint Meeting of the FAO/WHO Food Standards Programme Codex Alimentarius Commission and Report of the 41st Session of the Codex Committee on Pesticide Residues. ALINORM 09/32/24.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and / or situation (a)	Country and/or region	Product name	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment				PHI (days) (l)	Remarks: (m)			
					Type (d - f)	Conc. of as (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg as/ha min max						
Carrot	NL	Cruiser 70 WS	F	<i>Psila rosae</i>	WS	70	Seed treatment	seed BBCH 0 feb-aug	1	1	6 g/unit	6 g/unit	n.a	n.a	0.03*	0.12 *	n.a.	* based on 500.000-2.000.000 seeds/ha; unit = 100.000 seeds

- Remarks:**
- (a) For crops, Codex (or other, e.g. EU) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), 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 RESIDUES INTAKE MODEL (PRIMO)

Thiamethoxam			
Status of the active substance:	Included	Code no.	159
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.026	ARfD (mg/kg bw):	0.5
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2006	Year of evaluation:	2006

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum 6 - 27						
		No of diets exceeding ADI:		---				
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
26.6	WHO Cluster diet B	6.9	Lettuce	3.4	Wine grapes	2.4	Tomatoes	
26.3	DE child	9.3	Apples	2.9	Oranges	2.4	Table grapes	
25.9	NL child	4.9	Apples	3.9	Scarole (broad-leaf endive)	2.4	Oranges	
18.2	FR all population	7.7	Wine grapes	3.7	Other lettuce and other salad plants	1.8	Lettuce	
17.2	IE adult	2.4	Wine grapes	1.6	Lettuce	0.9	Potatoes	
17.0	ES adult	10.3	Lettuce	1.0	Oranges	0.8	Wine grapes	
16.9	ES child	8.0	Lettuce	1.7	Oranges	1.0	Milk and cream,	
16.6	WHO regional European diet	7.2	Lettuce	1.5	Potatoes	0.8	Tomatoes	
16.3	IT adult	7.3	Lettuce	3.0	Other lettuce and other salad plants	0.9	Tomatoes	
14.9	FR toddler	3.0	Milk and cream,	2.0	Apples	1.9	Potatoes	
14.8	WHO cluster diet E	3.1	Wine grapes	1.8	Lettuce	1.5	Potatoes	
14.6	IT kids/toddler	5.6	Lettuce	2.1	Other lettuce and other salad plants	1.3	Wheat	
14.6	UK Toddler	4.4	Sugar beet (root)	1.6	Milk and cream,	1.5	Oranges	
14.0	WHO Cluster diet F	5.8	Lettuce	1.3	Potatoes	1.1	Wine grapes	
13.8	DK child	2.7	Lettuce	1.9	Cucumbers	1.8	Apples	
13.1	NL general	2.3	Lettuce	2.2	Scarole (broad-leaf endive)	1.2	Wine grapes	
12.6	PT General population	4.8	Wine grapes	2.1	Potatoes	0.8	Apples	
12.0	UK Infant	3.0	Milk and cream,	1.9	Sugar beet (root)	1.3	Potatoes	
9.8	WHO cluster diet D	1.6	Potatoes	1.3	Wheat	0.8	Tomatoes	
9.7	UK vegetarian	2.7	Lettuce	1.6	Wine grapes	0.7	Sugar beet (root)	
9.7	FR infant	2.0	Milk and cream,	1.9	Apples	1.6	Potatoes	
9.6	SE general population 90th percentile	1.6	Potatoes	1.0	Milk and cream,	0.8	Apples	
8.6	UK Adult	2.3	Lettuce	2.1	Wine grapes	0.8	Sugar beet (root)	
7.0	DK adult	2.7	Wine grapes	0.6	Apples	0.6	Potatoes	
6.5	LT adult	1.4	Apples	1.2	Potatoes	1.2	Lettuce	
6.2	PL general population	1.6	Apples	1.3	Potatoes	0.7	Tomatoes	
5.8	FI adult	1.5	Lettuce	0.7	Oranges	0.6	Wine grapes	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations
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The acute risk assessment is based on the ARfD.

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

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

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

Threshold MRL is the calculated residue level which would 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)
	2.3	Carrots	0.18 / -	1.6	Carrots	0.18 / -	0.4	Carrots	0.18 / -	0.3	Carrots	0.18 / -
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)
	3.3	Grape juice	0.5 / -	0.4	Orange juice	0.2 / -
2.6	Carrot, juice	0.3 / -	0.4	Wine	0.5 / -	
2.0	Apple juice	0.2 / -	0.3	Apple juice	0.2 / -	
2.0	Orange juice	0.2 / -	0.1	Peach preserved with	0.3 / -	
1.1	Peach juice	0.3 / -	0.1	Tomato (preserved-	0.2 / -	

*) 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 Thiamethoxam IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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

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

APPENDIX C – EXISTING EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,2
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,2
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,2
110030	Lemons (Citron, lemon)	0,2
110040	Limes	0,2
110050	Mandarins (Clementine, tangerine and other hybrids)	0,2
110990	Others	0,2
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	(Filbert)	
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,2
130020	Pears (Oriental pear)	0,2
130030	Quinces	0,1
130040	Medlar	0,1
130050	Loquat	0,1
130990	Others	0,1
140000	(iv) Stone fruit	0,3
140010	Apricots	0,3
140020	Cherries (sweet cherries, sour cherries)	0,5
140030	Peaches (Nectarines and similar hybrids)	0,3
140040	Plums (Damson, greengage, mirabelle)	0,3
140990	Others	0,3
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,5
151010	Table grapes	0,5
151020	Wine grapes	0,5
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	(Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	and other treeberries)	
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	
162010	Kiwi	0,2
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	(cactus fruit)	
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,5
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,1
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	0,1
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	(Scorzenera, Spanish salsify (Spanish oysterplant))	
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,1
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,2
231020	Peppers (Chilli peppers)	0,5
231030	Aubergines (egg plants) (Pepino)	0,2
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	0,3
232020	Gherkins	0,2
232030	Courgettes (Summer squash, marrow	0,3

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	(patisson))	
232990	Others	0,1
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,2
233020	Pumpkins (Winter squash)	0,1
233030	Watermelons	0,2
233990	Others	0,1
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,2
241000	(a) Flowering brassica	0,2
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,2
241020	Cauliflower	0,2
241990	Others	0,2
242000	(b) Head brassica	0,2
242010	Brussels sprouts	0,2
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,2
242990	Others	0,2
243000	(c) Leafy brassica	0,2
243010	Chinese cabbage (Indian (Chinese)	0,2

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	
243020	Kale (Borecole (curly kale), collards)	0,2
243990	Others	0,2
244000	(d) Kohlrabi	0,2
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	5
251010	Lamb's lettuce (Italian cornsalad)	5
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	5
251040	Cress	5
251050	Land cress	5
251060	Rocket,	5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	Rucola (Wild rocket)	
251070	Red mustard	5
251080	Leaves and sprouts of Brassica spp (Mizuna)	5
251990	Others	5
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	leaves, lovage, angelica, sweet cicely and other Apiacea)	
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,2
260040	Peas (without	0,2

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	Pods) (Garden pea, green pea, chickpea)	
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel .)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	beans, cowpeas)	
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,2
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	0,05*
401000	(i) Oilseeds	0,05*
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)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
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	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,1
631000	(a) Flowers	0,1
631010	Camomille flowers	0,1
631020	Hybiscus flowers	0,1
631030	Rose petals	0,1
631040	Jasmine flowers	0,1

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
631050	Lime (linden)	0,1
631990	Others	0,1
632000	(b) Leaves	0,1
632010	Strawberry leaves	0,1
632020	Rooibos leaves	0,1
632030	Maté	0,1
632990	Others	0,1
633000	(c) Roots	0,1
633010	Valerian root	0,1
633020	Ginseng root	0,1
633990	Others	0,1
639000	(d) Other herbal infusions	0,1
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,1
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	and berries	
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	0,05*
900010	Sugar beet	0,05*

Code number	Groups and samples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	(root)	
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,01*
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	0,01*
1011000	(a) Swine	0,01*
1011010	Meat	0,01*
1011020	Fat free of lean meat	0,01*
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*
1011990	Others	0,01*

Code number	Groups and samples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
1012000	(b) Bovine	0,01*
1012010	Meat	0,01*
1012020	Fat	0,01*
1012030	Liver	0,01*
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	0,01*
1013010	Meat	0,01*
1013020	Fat	0,01*
1013030	Liver	0,01*
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	0,01*
1014010	Meat	0,01*
1014020	Fat	0,01*
1014030	Liver	0,01*
1014040	Kidney	0,01*
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Meat	0,01*
1015020	Fat	0,01*
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea	0,01*

Code number	Groups and samples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	fowl-, ostrich, pigeon	
1016010	Meat	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017010	Meat	0,01*
1017020	Fat	0,01*
1017030	Liver	0,01*
1017040	Kidney	0,01*
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	0,02
1020010	Cattle	0,02
1020020	Sheep	0,02
1020030	Goat	0,02
1020040	Horse	0,02
1020990	Others	0,02
1030000	(iii) Birds'	0,01*

Code number	Groups and samples of individual products to which the MRLs apply (a)	Thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam)
	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	
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)	0,01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry

LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	rappporteur Member State
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WHO	World Health Organisation
WS	Water dispersible powder for slurry treatment