5.31 THIAMETHOXAM (245)

see also CLOTHIANIDIN (238)

RESIDUE AND ANALYTICAL ASPECTS

Thiamethoxam is a neonicotinoid compound with broad-spectrum insecticidal properties. The compound was evaluated by the JMPR in 2010 (T, R), 2011 (R) and 2012 (R).The 2010 Meeting established an ADI for Thiamethoxam of 0–0.08 mg/kg bw and an ARfD of 1 mg/kg bw. It was listed by the Forty-fifth Session of CCPR (2013) for the evaluation of 2014 JMPR for additional MRLs.

The residue definition for enforcement for thiamethoxam in plant and animal commodities is thiamethoxam. The residue for dietary risk assessment for plant and animal commodities (except poultry) is thiamethoxam and clothianidin (considered separately). The residue definition for risk assessment dietary intake for poultry is the sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam and clothianidin (clothianidin to be considered separately from thiamethoxam). In the current appraisal CGA322704 is referred to as clothianidin.

At the 2014 JMPR Meeting residue data were submitted to support maximum residue level recommendations for use of thiamethoxam on several crops. Residue trials were conducted to support use avocado, mango, beans, mint and hops. In addition, trials were submitted by Republic of Korea to support the use on persimmon. Summaries of the trials have been provided to support the recommendations for thiamethoxam and clothianidin on the respective crops.

Methods of analysis

The Meeting received additional validation data for the analytical method REM 179.06 (evaluated by the 2010 Meeting) of thiamethoxam and clothianidin.

Most of the methods used in the supervised residue trials had previously been evaluated (2010 JMPR) and determined parent compound thiamethoxam and the metabolite clothianidin. Samples were extracted with methanol:water. The final residue could then be determined by HPLC-MS/MS. The Meeting considers validation of the method sufficient for the respective crops with an LOQ of 0.01 mg/kg for parent and its metabolite, respectively. The analytical methods not previously evaluated, but used in the trials for the current evaluation (LC-MS/MS Method 954/2010 and Method HPLC/DAD) were sufficiently validated.

Stability of pesticide residues in stored analytical samples

At the 2010 JMPR, thiamethoxam and clothianidin were shown to be stable for 1–2 years when stored frozen at < -18 °C or lower for a large range of commodities. The stability in the crops under evaluation in 2014 was sufficiently demonstrated in the respective residue trials.

Results of supervised residue trials on crops

The Meeting received supervised trials data for persimmon, avocado, mango, beans, mint (herbs) and hops.

Pome fruits

Residue data in support of the use of thiamethoxam and clothianidin on pome fruit (apples and pears) were previously evaluated by the 2010 JMPR. In 2010 insufficient data were submitted for the use of clothianidin on persimmons to lead to a maximum residue level recommendation (not yet categorized under pome fruit at that time). No data were previously submitted to support the use of thiamethoxam on persimmons.

The critical GAP for thiamethoxam on persimmon in Republic of Korea is for 3 foliar applications at 0.005 kg ai/hL (interval of 10 days) and a PHI of 7 days, until "leaves are dripping". The Meeting received two independent trials that were performed according to the Korean critical GAP using an application rate of 0.005 kg ai/hL.

As the GAPs for pome fruit and persimmon are different, a specific maximum residue level for persimmon would need to be estimated. However, the Meeting agreed that the dataset was insufficient for the estimation of a maximum residue level for persimmon.

The Meeting confirmed the maximum residue level, STMR and HR for thiamethoxam and clothianidin in pome fruit as recommended by the 2010 JMPR Meeting.

Assorted tropical and sub-tropical fruits – inedible peel

Supervised trials were available for avocado and mango. The use of thiamethoxam and/or clothianidin on avocados had not been previously evaluated by the JMPR. The use of thiamethoxam on mango was been evaluated by the 2010 JMPR, but there were insufficient data to support a maximum residue level recommendation. The Meeting had not previously received residue data supporting the use of clothianidin on mangoes.

Avocado

The critical GAP for use on avocado's in the USA is for 3 foliar directed applications at 0.070 kg ai/ha (minimum interval of 7 days) and no PHI.

Five field trials involving the use of thiamethoxam (3 foliar applications at approximately 70 g ai/ha, with a 6–7 day interval and PHI of 3 days) on avocados were performed in the USA (3) and in Mexico (2) in 2006 (4) and 2007 (1). Thiamethoxam residues on whole fruit (RAC) were not reported. Using a conversion factor to correct from flesh and peel to whole fruit (0.8× residue level), calculated residue levels in whole fruit were: < 0.01, 0.03, 0.06, 0.10, and 0.24 mg/kg (n=5). Converted clothianidin residues in RAC were: < 0.01, < 0.01, < 0.01, 0.016, and 0.016 mg/kg (n=5).

The Meeting agreed that the dataset for avocados matching the USA critical GAP could be used to support a maximum residue level recommendation for avocados, and estimated a maximum residue level of 0.5 mg/kg for thiamethoxam and a maximum residue level of 0.03 mg/kg for clothianidin on avocado.

The residue data for estimating the STMR and HR (flesh+peel) were: < 0.01, 0.04, 0.08, 0.12, and 0.30 mg/kg (n=5), resulting in an STMR and HR of 0.08 mg/kg and 0.30 mg/kg, respectively for thiamethoxam.

Clothianidin residues (flesh+peel) were: < 0.01, < 0.01, < 0.01, 0.02, and 0.02 mg/kg (n=5), resulting in STMR and HR estimates of 0.01 and 0.02 mg/kg, respectively.

Mango

Field trials involving the use of thiamethoxam on mango were performed in South Africa. Eight trials in 2003–2005 were evaluated by the JMPR in 2010. Trials performed 2011–2012 were submitted to the 2014 Meeting.

The critical GAP for use of thiamethoxam on mangoes in the South Africa is a single soil application at 1.44 g ai/tree poured from a jug with a PHI of 130 days. Seven residue trials (three in 2003/2005 and four in 2011/2012) matched the South African GAP, using a single soil application at a rate of 1.44 g ai/tree and a PHI of 130 days. Thiamethoxam residues (whole fruit) were: 0.01, 0.02, 0.02, 0.02, 0.036#, 0.08#, and 0.088# mg/kg. Clothianidin residues were: < 0.01, 0.01, 0.01, < 0.02#, < 0.02#, < 0.02# and 0.02 mg/kg. The values identified with # are residue data of flesh and peel corrected for stone using a default conversion factor of 0.8, because the weights of the different fractions of the fruit were not reported in the 2010 evaluation.

The Meeting agreed that the dataset for mangoes matching the South African critical GAP could be used to support a maximum residue level recommendation for mangoes, and estimated a maximum residue level of 0.2 mg/kg for thiamethoxam on mango. For clothianidin the Meeting estimated a maximum residue level of 0.04 mg/kg.

For the STMR and HR estimates the residue data excluding the stone are used. Thiamethoxam residues (flesh+peel) were: 0.01, 0.03, 0.03, 0.03, 0.04, 0.10, and 0.11 mg/kg, resulting in a STMR and HR of 0.03 and 0.11 mg/kg, respectively for thiamethoxam. Clothianidin residues (flesh and peel) were: 0.01, < 0.02, 0.02, 0.02, 0.02, 0.02, and 0.02 mg/kg. The Meeting estimated STMR and HR values of 0.02 and 0.02, respectively for clothianidin.

Legume vegetables

The Meeting received data on the use of thiamethoxam on fresh beans. A Portuguese label for use of thiamethoxam on fresh beans was submitted to the Meeting. The label included indoor use (foliar application and drip irrigation) and outdoor use (foliar application).

Indoor use: No data were submitted to support the indoor use (neither the foliar, nor the drip irrigation uses).

Outdoor use: The use of thiamethoxam on beans and peas had been evaluated by the 2010 Meeting. In 2010 the data reviewed covered seed treatment use; therefore the datasets could not be combined. According to the 2010 evaluation there was no GAP for clothianidin on legume vegetables. The critical GAP for outdoor use of thiamethoxam is a double foliar application of 100 g ai/ha, with an interval of 7 days and a PHI of 3 days.

Eight field trials involving fresh beans (with pods) were conducted in 2003 and 2004 in Spain. The critical GAP for outdoor use was supported with seven trials using two foliar applications of 93–113 g ai/ha (total rate of 200 g ai/ha within ±25% range), 6–8 day interval and 3 day PHI. Thiamethoxam residues were: 0.03, 0.08, 0.08, 0.08, 0.09, 0.16, and 0.18 mg/kg.

The Meeting agreed that the dataset for fresh beans matching the Portuguese critical GAP for outdoor use could be used to support a maximum residue level recommendation for fresh beans, and estimated a maximum residue level of 0.3 mg/kg for thiamethoxam in fresh beans.

The Meeting estimated STMR and HR values of 0.08 and 0.18 mg/kg, respectively for thiamethoxam in fresh beans.

The same trials were used for clothianidin. The residues were: 0.04, 0.04, 0.06, 0.07, 0.08, 0.09, and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for clothianidin and STMR and HR values of 0.07 mg/kg and 0.10 mg/kg, respectively for clothianidin in fresh beans.

Fresh herbs

The Meeting received data on the use of thiamethoxam on mints. No uses of thiamethoxam or clothianidin on fresh herbs (mints) have previously been evaluated by the JMPR.

Mints

Field trials involving the use of thiamethoxam on mint were performed in the USA in 1999.

The critical GAP for mint in the USA is 3 foliar applications of 0.070 kg ai/ha (minimum interval 14 days, maximum total rate of 0.21 kg ai/ha per season) and PHI of 7 days. Five trials matched this GAP (3×0.072–0.074 kg/ai/ha, interval 13–15 days, PHI 6–7 days), although slightly higher applications rates were used (< 25% difference). Thiamethoxam residues were: 0.24, 0.28, 0.34, 0.36, and 0.86 mg/kg.

The Meeting agreed that the dataset on mints matching the USA GAP could be used to support a maximum residue level recommendation for mints and estimated a maximum residue level of 1.5 mg/kg for thiamethoxam on mint and STMR and HR values of 0.34 and 0.86 mg/kg, respectively for thiamethoxam.

The same trials were used to derive the residue levels for clothianidin. Residues were: 0.06, 0.07, 0.11, 0.11, and 0.12 mg/kg.

The Meeting agreed that the dataset on mints could be used to support a maximum residue level for mints and estimated a maximum residue level of 0.3 mg/kg for clothianidin and STMR and HR values of 0.11 mg/kg and 0.12 mg/kg, respectively for clothianidin.

Dried herbs

The Meeting received data on the use of thiamethoxam on hops. The use of thiamethoxam on hops was evaluated by the 2010 Meeting. No maximum residue level was recommend due to the limited dataset (n=3). The JMPR has not evaluated any uses for clothianidin on dried herbs.

Hops

Field trials involving hops were performed in the USA in 2002 (three evaluated by JMPR 2010) and 2011 (one submitted in 2014).

The critical GAP for hops in the USA is a single soil surface treatment (band application with incorporation) at a rate of 0.14 kg ai/ha and a PHI of 65 days. The trials performed in the USA matched this GAP (1×0.13–0.14 and PHI 62–66 days).

Thiamethoxam residues in hops (dried cones) were: < 0.025, 0.027, 0.029, and 0.055 mg/kg. The Meeting agreed that the dataset for hops matching the USA GAP could be used to support a maximum residue level recommendation for hop, and estimated a maximum residue level of 0.09 mg/kg for thiamethoxam on dried hops. The Meeting estimated STMR and HR values of 0.028 and 0.055 mg/kg, respectively for thiamethoxam.

Clothianidin residues were: < 0.025, 0.025, 0.027, and 0.028 mg/kg. The Meeting estimated a maximum residue level of 0.07 mg/kg for clothianidin on hops. The Meeting estimated STMR and HR values of 0.026 and 0.028 mg/kg, respectively for clothianidin, respectively.

Legume animal feeds

The Meeting received data on the outdoor use of thiamethoxam on fresh beans. The use of thiamethoxam on beans and peas has been evaluated by the 2010 Meeting, but only covered seed treatment uses and provided residue data for thiamethoxam and clothianidin in pea vines and pea hay/fodder (dry), but not for bean forage. No residue data for clothianidin in legume animal feeds was available.

Bean forage

The Portuguese outdoor GAP for use of thiamethoxam on beans is a foliar application 2×100 g ai/ha, with a PHI of 3 days and a minimum interval of 7 days.

Outdoor use

Eight field trials involving fresh beans (with pods) were conducted in 2003 and 2004 in Spain. The application rates were two foliar treatments of 69–113 g ai/ha with an interval of 6–8 days and a PHI of 3 days, matching the Portuguese GAP. Residues in bean forage were determined in four field trials. Thiamethoxam residues in bean forage (rest of plants harvested at BBCH < 80) were: 0.56,

0.82, 0.93, and 1.4 mg/kg. Clothianidin residues in bean forage were: 0.06, 0.07, 0.08, and 0.11 mg/kg.

The Meeting agreed that the dataset for fresh bean forage matching the outdoor Portuguese GAP could be used to estimate median residues of 0.87 and 0.075 mg/kg for thiamethoxam and clothianidin, respectively. The respective highest residues are 1.4 and 0.11 mg/kg.

Fate of residues during processing

Processing studies were undertaken for mango and mint. Processing factors based on the residue for parent and metabolite clothianidin are listed in the table below. Using the $STMR_{RAC}$ obtained from the thiamethoxam use, the Meeting estimated STMR-Ps for processed commodities to be used in dietary intake calculations.

Commodity	PFs	PF (median or best estimate)	STMR-P = $STMR_{pulp+peel}$ x PF (mg/kg)	HR-P = $HR_{pulp+peel}$ x PF (mg/kg)	PFs	PF (median or best estimate)	STMR-P = $STMR_{RAC}$ x PF (mg/kg)	HR-P = HR_{RAC} x PF (mg/kg)
	Parent thiamethoxam ($STMR_{pulp+peel}$ = 0.03 mg/kg $HR_{pulp+peel}$ = 0.11 mg/kg)				clothianidin ($STMR_{pulp+peel}$ = 0.02 mg/kg, $HR_{pulp+peel}$= 0.02 mg/kg)			
Mango, dried flesh	4.0, 6.7, 7.3, 5.0	5.9	0.18	0.65	5.7, 8.4, 7.00, 4.00	6.3	0.13	0.13
Mint, oil	< 0.02, < 0.03	< 0.02	n.a.	n.a.	< 0.22, < 0.19	< 0.20	n.a.	n.a.

Residues in animal commodities

The Meeting estimated the dietary burden of thiamethoxam residues (thiamethoxam only, for CGA322704 see clothianidin appraisal 2014) on the basis of the livestock diets listed in the FAO manual Appendix IX (OECD feedstuff table) using the OECD_Feed_Calculator_V1_4. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values from feed is suitable for estimating STMR values for animal commodities.

The Meeting recalculated the livestock dietary burden based on the uses presented by the 2010 JMPR and including the residue values for fresh bean forage from the 2014 JMPR Meeting. The maximum dietary burden for cattle for MRL (tissues) setting changed slightly from 5.2 to 6.1 ppm, and the mean dietary burden for cattle changed only marginally from 2.1 to 2.4 ppm. For residue level estimations in milk the dietary burden raised from 5.2 to 6.1 ppm (maximum) and from 1.6 to 2.4 ppm (mean). The new maximum dietary burden of thiamethoxam for poultry of 1.64 ppm is only marginally higher than the maximum dietary burden of 1.59 ppm as calculated by the Meeting in 2010, rounded both 1.6 ppm. The new mean dietary burden for poultry of 0.59 ppm is not changed since the evaluation in 2010.

The Meeting agreed that no new mean and maximum residue level estimations are needed and confirmed its previous recommendations.

Residue data for clothianidin used for the dietary burden calculation were derived from the 2010 JMPR appraisal for clothianidin, where the data from thiamethoxam and clothianidin use were combined and included the residue data on bean forage from the 2014 JMPR Meeting. For the dietary burden calculations and recommendations for animal commodities see appraisal clothianidin 2014.

RECOMMENDATIONS

Thiamethoxam

On the basis of the data from supervised residue trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

The 2011 Meeting recommended the following residue definition for thiamethoxam:

Definition of the residue for animal and plant commodities (for compliance with the MRL): *thiamethoxam*.

Definition of the residue for plants and animals (except poultry), (for estimation of dietary intake): *thiamethoxam and clothianidin* (considered separately).

Definition of the residue for poultry (for estimation of dietary intake): *sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam and clothianidin* (clothianidin to be considered separately from thiamethoxam).

The residue is not fat-soluble.

Note that thiamethoxam metabolite CGA322704 (N-(2-chlorothiazol-5-ylmethyl)-N'-methyl-N''-nitroguanidine) will appear as clothianidin in the analytical method and residues of CGA322704 occurring in food are included in the clothianidin MRLs.

Metabolite CGA 265307: N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine.

Metabolite MU3: amino-([(2-chlorothiazol-5-ylmethyl)-amino]-methylene)-hydrazide.

The recommendations for clothianidin resulting from thiamethoxam use are listed in the clothianidin appraisal 2014.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of thiamethoxam, based on the STMRs estimated for 112 commodities, for the 17 cluster diets were in the range of 1–3% of the maximum ADI (0.08 mg/kg bw) (Annex 3 to the 2014 Report). The Meeting concluded that the long-term intake of residues of thiamethoxam resulting from its uses that have been considered by the 2010, 2011 2012 and the present Meeting is unlikely to present a public health concern.

For the International Estimated Daily Intakes (IEDI) for clothianidin resulting from thiamethoxam and clothianidin use see appraisal clothianidin 2014.

Short-term intake

The International Estimated Short Term Intake (IESTI) for thiamethoxam was calculated for food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4 to the 2014 Report.

The IESTI represented 0–1% of the ARfD (1.0 mg/kg bw). The Meeting concluded that the short-term intake of residues of thiamethoxam, when used in ways that have been considered by the present Meeting, is unlikely to present a public health concern.