

5.2 ACETAMIPRID (246)

RESIDUE AND ANALYTICAL ASPECTS

Acetamiprid was evaluated for the first time by the 2011 JMPR, where an ADI of 0–0.07 mg/kg bw and an ARfD of 0.1 mg/kg bw were established and maximum residue levels were recommended for a range of plant and animal commodities. The compound was re-evaluated by the 2012 JMPR.

At the Forty-sixth Session of the CCPR (2014), acetamiprid was listed for residue evaluation for additional maximum residue levels by the 2015 JMPR. The Meeting received information on supervised residue trials for asparagus, cucumber, mustard greens, sweet corn (corn-on-the-cob) and tomato including cherry tomatoes.

For both compliance with MRL and estimation of dietary intake, the residue is defined as acetamiprid for plant commodities, and the sum of acetamiprid and desmethyl-acetamiprid for animal commodities. The residue is not fat-soluble.

Methods of analysis

Acceptable analytical methods were developed and validated for determination of acetamiprid in asparagus, mustard greens and sweet corn. These methods were based on Method KP-216 which was considered suitable by 2011 JMPR. Other analytical methods used for sweet corn, cucumber and tomato were also fully validated. All methods used analysis by LC-MS/MS and the limits of quantification (LOQs) were 0.01 mg/kg in all matrices.

Stability of residues in stored analytical samples

In 2011, JMPR concluded that acetamiprid is stable for at least 12 months in apple, cabbage, cucumber and 16 months for lettuce.

The present Meeting received acetamiprid stability studies on asparagus, cucumber, mustard greens, sweet corn and tomato, showing that residues were stable under frozen condition for at least 426 days for asparagus, 304 days for cucumber and tomato, 382 days for mustard greens and 384–391 days for sweet corn samples (kernel plus cob with husk removed, forage and stover).

Based on the available storage stability information, the Meeting concluded that acetamiprid was stable for the period of actual storage days associated with the submitted residue trials.

Results of supervised trials on crops

Fruiting vegetables, Cucurbits

Cucumber

Supervised trials were conducted in China in 2013, matching the China GAP on cucumber (3 sprays applications at 0.090 kg ai/ha and a PHI of 2 days). Eight trials were conducted under field conditions. Another six trials were conducted under greenhouse conditions, two trials of which were not independent and another two trials were also not independent. Additionally, two decline studies on field-grown cucumber were conducted with one application at a rate of 0.090 kg ai/ha. The residues decreased with a half-life of 2.1 or 3.9 days.

From residue trials matching the China GAP on cucumber, acetamiprid residue values were as follows:

Field-grown cucumber (n=8): 0.011, 0.020, 0.024, 0.042, 0.059, 0.070, 0.12 and 0.13 mg/kg.

Greenhouse-grown cucumber (n=4): 0.027, 0.055, 0.072 and 0.089 mg/kg.

As the residue distributions of acetamiprid between field-grown and greenhouse-grown cucumber were similar, residue values were combined (n=12): 0.011, 0.020, 0.024, 0.027, 0.042, 0.055, 0.059, 0.070, 0.072, 0.089, 0.12 and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.057 mg/kg and an HR of 0.17 mg/kg (based on a highest single sample) for cucumber.

Further, the Meeting withdrew its previous recommendations for Fruiting vegetables, Cucurbits and estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.11 mg/kg for Fruiting vegetables, Cucurbits (except cucumber).

Fruiting vegetables, other than Cucurbits

Tomato

Supervised trials were conducted in China in 2013, matching the China GAP on tomato (2 sprays at 0.027 kg ai/ha and a PHI of 7 days). Eight trials on tomato were conducted under field conditions and an additional three trials on each of tomato and cherry tomato were conducted under greenhouse conditions. Additionally, two decline studies on field-grown tomato were conducted with one application at a rate of 0.041 kg ai/ha. The residues decreased with an average half-life of 11.6 days.

From residues trials matching the China GAP on tomato, acetamiprid residue values were as follows:

Field-grown tomato (n=8): < 0.01, 0.011, 0.011, 0.012, 0.020, 0.022, 0.022 and 0.025 mg/kg.

Greenhouse-grown tomato (n=3): < 0.01, 0.015 and 0.027 mg/kg.

Greenhouse-grown cherry tomato (n=3): 0.018, 0.021 and 0.050 mg/kg.

The 2011 JMPR recommended a maximum residue level of 0.2 mg/kg, an STMR of 0.04 mg/kg and an HR of 0.14 mg/kg for Fruiting vegetables, other than Cucurbits, based on residues in tomato (outdoor), sweet pepper and chili pepper conducted according to the US GAP (four foliar applications at 0.084 kg ai/ha and a PHI of 7 days). Since the authorization in the US represents the critical GAP, this Meeting confirmed its previous recommendations for Fruiting vegetables, other than Cucurbits (except sweet corn & mushrooms).

Sweet corn

Seven trials were conducted in the USA in 2009, matching a critical US GAP (two foliar sprays at 0.11 kg ai/ha with a 14-day retreatment interval and a PHI of 7 days). Residue concentrations in sweet corn (kernel plus cob with husk removed) from the USA trials were all < 0.01 mg/kg (n=7).

The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for sweet corn (corn-on-the-cob).

Leafy vegetables (including Brassica leafy vegetables)

Mustard greens

Eight trials on mustard greens were conducted in the USA in 2009, matching the US GAP (four foliar sprays at 0.11 kg ai/ha with a 7-day retreatment interval and a PHI of 3 days).

Acetamiprid residues in mustard greens were (8): 0.30, 1.2, 1.6, 1.7, 2.2, 2.4, 2.7 and 9.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg, an STMR of 2.0 mg/kg and an HR of 10 mg/kg (based on highest single sample) for mustard greens. However, this would result in an exceedance of the ARfD and an alternative GAP for mustard greens was not identified.

*Stalk and stem vegetables**Asparagus*

Eight trials on asparagus were conducted in the USA in 2008 and 2009, matching the US GAP (two sprays at 0.11 kg ai/ha with a 10-day retreatment interval and a PHI of 1 day).

Acetamiprid residues in asparagus were (n=8): 0.12, 0.16, 0.21, 0.26 (3), 0.29 and 0.41 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.26 mg/kg and an HR of 0.43 mg/kg (based on highest single sample) for asparagus.

Primary feed commodities*Sweet corn forage and stover*

The trial conditions are described under the food commodity. For feed commodity, sweet corn forage and stover samples were harvested in the seven USA trials. In one trial, the PHI in sampling of stover did not match the US GAP.

Acetamiprid residues in sweet corn forage were (n=7): 0.41, 0.76, 1.4, 1.4, 2.4, 4.7 and 9.1 mg/kg.

Acetamiprid residues in sweet corn stover were (n=6): 0.21, 2.6, 2.8, 2.8, 8.4 and 20 mg/kg.

The Meeting estimated a median residue of 1.4 mg/kg and highest residue of 9.1 mg/kg for sweet corn forage.

The Meeting estimated a maximum residue level of 40 mg/kg, median residue level of 2.8 mg/kg and highest residue of 20 mg/kg on a dry weight basis for sweet corn stover.

Residues in animal commodities*Livestock dietary burden*

Dietary burden calculations considered by the current Meeting for beef cattle and dairy cattle, incorporating sweet corn, are presented in Annex 6. Dietary burdens for poultry were not calculated as sweet corn (forage, stover and cannery waste) is not a relevant feed item.

The dietary burdens for beef cattle and dairy cattle were estimated using OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

Summary of cattle dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	1.1	0.29	0.83	0.28	18 ^a	2.7 ^b
Dairy cattle	9.5 ^c	1.6	0.84	0.29	9.0	1.7 ^d

^a Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat and edible offal

^b Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat and edible offal

^c Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk

^d Highest mean dairy cattle dietary burden suitable for STMR estimates for milk

Animal commodity maximum residue levels

Livestock feeding studies involving administration of acetamiprid to dairy cows were reported in the 2011 JMPR Report.

Estimated maximum and mean dietary burdens were 18 ppm and 2.7 ppm for beef cattle and 9.5 ppm and 1.7 ppm for dairy cattle, respectively. The calculation to estimate total residues (acetamiprid plus desmethyl-acetamiprid) for maximum residue levels, STMR and HR values are shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study ^a	5.77	0.063					
	17.4	0.209	17.4	0.289	0.64	0.86	0.153
Dietary burden and residue estimate	9.5	0.11	18	0.30	0.67	0.89	0.16
STMR beef or dairy cattle							
Feeding study ^b	5.77	0.063	5.77	0.048	0.15	0.24	0.037
	1.7	0.019	2.7	0.022	0.070	0.11	0.017
Dietary burden and residue estimate							

^a Highest residues for tissues and mean residue for milk

^b Mean residues for tissues and milk

For beef and dairy cattle, the Meeting estimated HR values for acetamiprid (total residue) of 0.30 mg/kg in muscle, 0.89 mg/kg in edible offal (based on kidney) and 0.16 mg/kg in fat. STMR values were estimated at levels of 0.019 mg/kg for milk, 0.022 mg/kg for muscle, 0.11 mg/kg in edible offal (based on kidney) and 0.017 mg/kg for fat.

The Meeting also estimated the following maximum residue levels to replace its previous recommendations: 0.2 mg/kg for milk, 0.5 mg/kg for meat (from mammals other than marine mammals), 0.3 mg/kg for mammalian fats (except milk fats) and 1.0 mg/kg for edible offal (mammalian).

The previous recommendations for poultry tissues and eggs are maintained.

RECOMMENDATIONS

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

Definition of the residue for plant commodities (for compliance with MRL and estimation of dietary intake): *acetamiprid*.

Definition of the residue for animal commodities (for compliance with MRL and estimation of dietary intake): *sum of acetamiprid and desmethyl-acetamiprid, expressed as acetamiprid*.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The 2011 JMPR established an ADI of 0–0.07 mg/kg bw for acetamiprid. The International Estimated Daily Intakes (IEDIs) for acetamiprid were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the current and previous Meeting. The results are shown in Annex 3 in the 2015 JMPR Report.

The calculated IEDIs represented 0–4% of the maximum ADI. The Meeting concluded that the long-term intake of residues of acetamiprid from used that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2011 JMPR established an ARfD of 0.1 mg/kg bw. The International Estimated Short Term Intakes (IESTIs) for acetamiprid was calculated for the food commodities using HR/ STMR estimated by the current Meeting. The results are shown in Annex 4 in the 2015 JMPR Report.

For mustard greens, the IESTI represented 490% and 200% of the ARfD for children and general population, respectively. No alternative GAP was available. On the basis of information provided to the JMPR, the Meeting concluded that the short-term intake of acetamiprid from consumption of mustard greens may present a public health concern.

Estimates of intake for the other commodities considered by the 2015 JMPR were within 0-10% ARfD. The Meeting concluded that the short-term intake of acetamiprid for these other commodities may not present a public health concern when acetamiprid is used in ways that were considered by the Meeting.

