

5.37 TRIFLOXYSTROBIN (213)

RESIDUE AND ANALYTICAL ASPECTS

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0–0.04 mg/kg bw, decided that an ARfD is unnecessary and concluded that the residue definition for plant commodities for compliance with MRL values was trifloxystrobin. For animal commodities for compliance with MRL values as well as for dietary risk assessment for both plant and animal commodities, the residue definition was the sum of trifloxystrobin and (*E,E*)-methoxyimino- $\{2-[1-(3\text{-trifluoromethyl-phenyl})\text{ ethylidene-aminooxymethyl}]\text{-phenyl}\}$ acetic acid = CGA321113) (expressed as trifloxystrobin equivalents). The residue is fat soluble.

Trifloxystrobin was scheduled at the 48th session of the CCPR for the evaluation of additional MRLs for head cabbage, cauliflower, broccoli, spinach, cotton and ginseng by the 2017 JMPR.

Methods of analysis

The method used for the analysis of head cabbage, cauliflower, broccoli, spinach and cotton samples was method 200177 which was evaluated by the 2004 and 2015 JMPR. The Meeting received summarized information on an analytical method for trifloxystrobin and CGA321113 residues in ginseng. Mean recoveries were within the range 70–120% for all commodities investigated and supported LOQs of 0.03 mg/kg (2014 trials) to 0.06 mg/kg (2013 trials) for ginseng and 0.07 mg/kg for ginseng processed commodities. The method is suitable for the analysis of residues in ginseng and ginseng processed commodities.

Stability of residues in stored analytical samples

The stability of residues in samples on frozen storage was evaluated by the 2004 JMPR for a range of commodities. Residues of trifloxystrobin and CGA321113 were stable under freezer storage conditions for at least 24 months in the case of grapefruit, cucumber, potato and wheat commodities (grain, straw and whole plant) or 18 months for apple (fruit, wet pomace), peanut (nutmeat, oil) and grape juice. The stability data covered commodities that are representative of high water content (apple, cucumber, grape juice), high acid content (grapefruit), high oil content (peanut) and high protein/starch content (potato, wheat) and can be extrapolated to the commodities considered at the current Meeting. Samples in the trials considered by the current Meeting were stored frozen for periods less than the period of stability demonstrated in studies supplied to the 2004 JMPR and are therefore considered unlikely to have been adversely affected by storage.

Results of supervised residue trials on crops

The Meeting received information on supervised field trials on brassicas (broccoli, cauliflower and cabbage), spinach, cotton and ginseng.

The sum of trifloxystrobin and CGA321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA321113 as trifloxystrobin. As CGA321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA321113 were below the LOQ, their sum was calculated as in the examples provided by the 2004 JMPR and copied below.

Trifloxystrobin (mg/kg)	CGA321113 (mg/kg)	Total (expressed as trifloxystrobin) (mg/kg)
< 0.02	< 0.02	< 0.02
< 0.02	0.03	0.05
0.10	< 0.02	0.10
0.92	0.16	1.1

Brassicas

The critical GAP in the USA for brassica, head and stem vegetables is for two to three applications at a maximum rate of 139 g ai/ha, at 7-14 day intervals and a PHI of 0 days with a maximum seasonal rate of 281 g ai/ha/yr.

Three trials in broccoli (trifloxystrobin: 0.44, 0.67, 0.68 mg/kg) three trials in cauliflower (< 0.01, 0.01, 0.32 mg/kg) and six trials in head cabbage (with wrapper leaves) (0.03, 0.11, 0.37, 0.47, 0.48, 0.58 mg/kg) matched cGAP in the USA.

Corresponding total residues were:

Broccoli (0.46, 0.67, 0.70 mg/kg)

Cauliflower (< 0.01, 0.01, 0.36 mg/kg)

Head cabbage (without wrapper leaves) (< 0.01, < 0.01, 0.01, 0.01, 0.01, 0.03 mg/kg)

The number of trials on broccoli and cauliflower are too few to estimate a maximum residue level for these crops. The Meeting explored the possibility of estimating a group maximum residue level for subgroup 010A, flowerhead brassicas based on the combined dataset however, the residue data for broccoli and cauliflower were from two different populations and could not be combined. The Meeting concluded there is insufficient data to estimate a new maximum residue levels for both broccoli and cauliflower.

For cabbages, utilising the residues from trials (n=6) approximating cGAP (139±25% g ai/ha) in the USA, the Meeting recommended a maximum residue level of 1.5 mg/kg, and an STMR of 0.01 mg/kg for head cabbage to replace the previous recommendation of 0.5 mg/kg.

Spinach

In the USA the critical GAP for leafy greens is for two applications at a maximum rate of 139 g ai/ha, at an interval of 14 days with a PHI of 0 days.

Six trials in spinach approximated critical GAP (139±25% g ai/ha) with trifloxystrobin residues (n=6): 4.8, 5.3, 7.6, 7.6, 9.5 and 10 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg for spinach.

Corresponding total residues were: 4.8, 5.4, 7.6, 7.6, 9.6 and 10 mg/kg. The Meeting estimated an STMR of 7.6 mg/kg for spinach.

Cotton seed

The critical GAP for cotton is for 3 applications at a maximum rate of 137 g ai/ha, at 14 day intervals and a PHI of 30 days.

In eleven trials approximating critical GAP (137±25% g ai/ha) residues of trifloxystrobin were (n=11): < 0.01, < 0.01, < 0.01, 0.02, 0.03, 0.03, 0.08, 0.10, 0.11, 0.20 and 0.26 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for cottonseed.

Residues of CGA311123 were all < 0.01 mg/kg and did not contribute to the total residue. The Meeting estimated an STMR of 0.03 mg/kg.

Ginseng

The critical GAP for ginseng in the Republic of Korea is for 3 applications at a maximum rate of 3.35 g ai/hL, at 10 day intervals and a PHI of 21 days.

In six trials from the Republic of Korea approximating critical GAP (3.35±25% g ai/hL) residues were (n=6): < 0.03 < 0.03 < 0.03, < 0.06, < 0.06, < 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.03* mg/kg and STMR of 0.03 mg/kg for ginseng.

Animal feedstuffs*Cotton gin by-products*

The critical GAP for cotton is for 3 applications at a maximum rate of 137 g ai/ha, at 14 day intervals and a PHI of 30 days. In three trials approximating critical GAP residues of trifloxystrobin were (n=3): 0.24, 0.71, 0.93 mg/kg. The Meeting estimated a median residue for cotton gin by-products of 0.71 mg/kg and a highest residue of 0.93 mg/kg.

Fate of residues in processing

No residues were detected in fresh ginseng or in ginseng processed products. Residues in processed ginseng products will be covered by the maximum residue level recommended for fresh ginseng.

Trifloxystrobin did not concentrate in any of the other processed commodities considered by the current meeting.

Summary of trifloxystrobin processing factors

Commodity	Processing fraction	PF _{tri}	PF _{tot} (best estimate)	STMR _{RAC tot}	STMR-P = STMR _{RAC tot} × PF _{tot}
Broccoli	Washed broccoli	0.78	0.80		
	Cooked broccoli	0.88	0.84		
Spinach	Washed spinach	1.0	1.0		
	Cooked spinach	0.36	0.36		
Cotton seed	Meal	< 0.003 < 0.06	< 0.003 < 0.05 (0.003)	0.03	0.00009
	Hulls	0.05 0.11	0.05 0.17 (0.11)		0.0033
	Crude oil	0.04 < 0.06	0.04 < 0.05 (0.04)		0.0012
	Refined oil	0.02 < 0.06	0.02 < 0.05 (0.02)		0.0006

PF_{tri} = processing factor for trifloxystrobin

PF_{tot} = processing factor for the sum of trifloxystrobin and CGA321113

Residues in animal commodities*Estimation of livestock dietary burdens*

The only commodity used as a livestock feed and for which the JMPR has made recommendations are cabbage with wrapper leaves and cotton gin by-products (gin trash). The additional contribution to the dietary burden using the estimated median and highest residue levels is less than 10% of the total. Based on the minor change in livestock dietary burden, the Meeting did not recalculate residues in animal commodities or revise its recommendations for maximum residue levels.

RECOMMENDATIONS

On the basis of the data obtained from supervised residue trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

Residue in plant commodities

for compliance with MRLs: *trifloxystrobin*

for estimation of dietary exposure: *sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.*

Residue in animal commodities

For compliance with MRLs and estimation of dietary exposure:

sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 17 GEMS/Food cluster diets using STMRS and STMR-Ps estimated by the JMPR in 2004, 2015 and current meeting. The results are shown in Annex 3.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–7% of the maximum ADI. The Meeting concluded that the long-term dietary exposure to residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The 2004 JMPR decided that an ARfD for trifloxystrobin was unnecessary. The Meeting therefore concluded that the short-term dietary exposure to residues of trifloxystrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.