5.9 CYFLUTHRIN/BETA-CYFLUTHRIN (157)

RESIDUE AND ANALYTICAL ASPECTS

Cyfluthrin and beta-cyfluthrin were evaluated for toxicology (JMPR 2006) and residues (JMPR 2007) under the periodic review programme, and maximum residue levels for cyfluthrin, arising from the use of either cyfluthrin or beta-cyfluthrin on a number of commodities, were recommended.

The definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities is: cyfluthrin (sum of isomers). The residue is fat-soluble.

The 2007 JMPR estimated short-term intakes for children that exceeded the ARfD for cyfluthrin and beta-cyfluthrin of 0.04 mg/kg bw for broccoli and head cabbage and noted that there was insufficient data to support an estimation of lower maximum residue levels based on alternative GAPs for these commodities.

At the Forty-first Session of the CCPR in 2009, the Committee agreed that if no data were available to support lower maximum residue level estimates for broccoli and head cabbage (based on alternative GAP), the draft MRLs would be considered for withdrawal at the 2010 session (ALINORM 09/32/24, para 106–107). While additional information on head cabbage was provided to the 2011 JMPR, this information was deemed insufficient to support an Alternative GAP evaluation and the Forty-second Session of the CCPR agreed to retain the draft MRL of 4 mg/kg on Cabbages, Head awaiting the evaluation of additional data by JMPR in 2012.

The Meeting received additional supervised trials data from Indonesia for beta-cyfluthrin on head cabbages and also received information from the manufacturer to support a new GAP in the USA for beta-cyfluthrin on soya beans.

Methods of residue analysis

Analytical methods for residues of cyfluthrin and beta-cyfluthrin in plant and animal matrices, including the methods used in the new soya bean studies, have been evaluated by the 2007 JMPR and generally involve extraction by homogenization with an organic solvent mixture (with varying proportions of polar and non-polar solvents) and liquid–liquid partition and column clean-up before GC-ECD or GC-MSD analysis. Validated LOQs ranged from 0.01 to 0.05 mg/kg. Validation data were provided for soya bean and its processed commodities, including procedural recoveries carried out during the residue trials and during the processing study.

The analytical method used in the supervised trials from Indonesia was based a multi-residue method with the modified clean-up method for chlorophyll and sulfuric compound co-extractants. The validation and procedural recovery rates support an LOQ of 0.01 mg/kg.

Results of supervised residue trials on crops

Cabbage, Head—beta-cyfluthrin

Based on US GAP and residue data for cyfluthrin, the 2007 JMPR estimated a maximum residue level of 4 mg/kg, an STMR of 0.25 mg/kg and an HR of 2.1 mg/kg for cyfluthrin in cabbage (head) but estimated that the short-term intake for children was 240% of the ARfD (0.04 mg/kg bw).

Critical GAP in Indonesia is 15 g ai/ha with a PHI of 7 days. In three trials with beta-cyfluthrin evaluated by the 2007 JMPR and in four more recent trials, all matching the GAP in Indonesia, residues were: < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.02 and 0.05 mg/kg (n=7).

The Meeting estimated a maximum residue level of 0.08 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.05 mg/kg for cyfluthrin on head cabbage to support the Alternative GAP in Indonesia and agreed to withdraw the previous maximum residue level recommendation of 4 mg/kg.

Soya bean—beta-cyfluthrin

Revised GAP in USA for beta-cyfluthrin on soya bean is a maximum of four applications/season of up to 25 g ai/ha, PHI 21 days.

In trials from USA, matching this GAP, residues in soya bean seed were: < 0.01 (12), 0.01 (3), 0.02, 0.02, 0.02 and 0.02 mg/kg (n=19)

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for cyfluthrin on soya bean (dry).

Animal feeds

Soya bean forage—beta-cyfluthrin

Revised GAP in USA for beta-cyfluthrin on soya bean is a maximum of four applications/season of up to 25 g ai/ha with a 15-day livestock withholding period for hay and forage.

In trials from USA, matching this GAP, residues in soya bean forage (fresh weight) were: 0.1, 0.13, 0.25, 0.29, 0.29, 0.32, 0.33, 0.34, 0.34, 0.38, 0.42, 0.42, 0.43, 0.47, 0.5, 0.66, 0.7, 0.8, 0.8 and 1.0 mg/kg (n=20).

The Meeting estimated a median residue of 0.4 mg/kg and a highest residue of 1.0 mg/kg for cyfluthrin on soya bean forage (fresh weight).

Soya bean hay—beta-cyfluthrin

Revised GAP in USA for beta-cyfluthrin on soya bean is a maximum of four applications/season of up to 25°g°ai/ha, PHI 21 days and with a 15-day livestock withholding period for hay and forage.

In trials from USA, matching this GAP, residues in soya bean hay (fresh weight) were: 0.3, 0.49, 0.73, 0.74, 0.83, 0.88, 0.95, 1.1, 1.1, 1.1, 1.2, 1.2, 1.2, 1.4, 1.5, 1.5, 1.5, 1.7 and 2.2 mg/kg (n=20).

The Meeting estimated a maximum residue level of 4 mg/kg for soya bean hay (after correcting for 85% dry matter) and estimated a median residue of 1.15 mg/kg (fresh weight) and a highest residue of 2.2 mg/kg (fresh weight).

Fate of residues during processing

The 2007 JMPR reviewed the results of processing studies and estimated processing factors and STMR-Ps for cyfluthrin in a range of commodities and a new beta-cyfluthrin processing study on soya beans was provided to the Meeting. The only processed commodity of relevance to the commodities considered at the Meeting is soya bean aspirated grain fraction. The Meeting estimated a processing factor of 2218 for cyfluthrin in soya bean aspirated grain fraction and based on the STMR of 0.01 mg/kg established for soya bean (dry) the Meeting estimated an STMR-P of 22 mg/kg.

Residues in animal commodities

Livestock dietary burdens

The Meeting estimated the dietary burden of cyfluthrin in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops) and using information on cyfluthrin residues in animal feedstuffs reported by the 2007 JMPR.

Dietary burden calculations for beef and dairy cattle, calculated using the animal diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report) are summarized below.

	Animal dietary burden, cyfluthrin, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	1.35	1.35	0.16	0.11	2.43[a]	1.22[c]	0.002	0.002
Dairy cattle	0.69	0.39	0.21	0.16	1.55[b]	0.88[d]	0.001	0.001
Poultry – broiler	0.011	0.011	0.017[e]	0.017[f]	0.005	0.005	–	–
Poultry – layer	0.011	0.011	0.39[f]	0.22[g]	0.005	0.005	–	–

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

[g] Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

[h] Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

Livestock feeding studies

The 2007 JMPR reviewed feeding studies with cyfluthrin on lactating dairy cows and laying hens and the conclusions from these residue transfer studies were used to estimate residue levels of fluopyram and its metabolites in milk, eggs and livestock tissues, based on the above dietary burdens. The maximum and mean residues identified by the 2007 JMPR in milk, fat and muscle following 28 daily doses of cyfluthrin corresponding to 4.5 ppm in the diet and in liver and kidney from animals in the 40 ppm dose group (where samples were subjected to strong extraction required to release the majority of cyfluthrin residues) were used to estimate transfer of residues to livestock tissues and milk.

Animal commodity maximum residue levels

Cattle

Maximum and mean residues expected in milk and tissues were obtained by using the residue transfer factors estimated by the 2007 JMPR.

For maximum residue estimation, the high residues of cyfluthrin were calculated by extrapolating the maximum dietary burden (2.43 ppm) from the 4.5 ppm feeding level (40 ppm for liver and kidney) in the dairy cow feeding study and using the highest tissue concentrations of cyfluthrin from individual animals within those feeding groups.

The STMR values for the tissues were calculated by extrapolating the STMR dietary burden (1.22 ppm from the same feeding levels (4.5 ppm for muscle and fat, 40 ppm for liver and kidney) and using the mean tissue concentrations of cyfluthrin from those feeding groups.

For milk MRL estimation, the high residues in the milk were calculated by extrapolating the maximum dietary burden for dairy cattle (1.55 ppm) from the feeding level (4.5 ppm) in the dairy cow feeding study and using the mean milk concentrations of cyfluthrin from this feeding group.

The STMR value for milk was calculated by extrapolating the mean dietary burden for dairy cows (0.88 ppm) from the 4.5 ppm feeding level and using the mean milk concentrations of cyfluthrin from this feeding group.

	Feed level (mg/kg) for milk residues	Residues (mg/kg) in milk	Feed level (mg/kg) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	4.5	0.02	4.5 40	< 0.01	 0.14[c]	 0.18c	0.3
Dietary burden and residue estimate	1.55[b]	0.007	2.43[a]	< 0.01	0.009	0.011	0.16
STMR beef or dairy cattle							
Feeding study [b]	4.5	0.02	4.5 40	< 0.01	 0.14[c]	 0.18[c]	0.25
Dietary burden and residue estimate	0.88[d]	0.004	1.22[c]	< 0.01	0.004	0.005	0.067

[a] Highest residues for tissues and mean residues for milk

[b] Mean residues for tissues and for milk

[c] Residue values for kidney and liver were obtained from the dosing level equivalent to 40 ppm in the feed as only these samples were subject to reanalysis using a stronger extraction process

Residues of cyfluthrin expected in cattle milk and tissues for use in estimating maximum residue levels are: 0.16 mg/kg (fat), < 0.01 mg/kg (muscle), 0.009 mg/kg (liver) and 0.011 mg/kg (kidney) and the mean residue for milk is 0.007 mg/kg.

The Meeting estimated maximum residue levels of 0.2 mg/kg (fat) for cyfluthrin in meat (from mammals other than marine mammals), 0.02 mg/kg for edible offal (mammalian) and 0.01 mg/kg for milks.

Estimated HRs for cyfluthrin are 0.16 mg/kg for mammalian fat, 0.01 mg/kg for mammalian muscle, 0.01 mg/kg for edible offal and STMRs are 0.07 mg/kg for mammalian fat, 0.01 mg/kg for mammalian muscle, 0.005 mg/kg for edible offal and 0.004 mg/kg for milks.

The Meeting also agreed to withdraw the previous recommended maximum residue levels of 1 mg/kg (fat) for meat (from mammals other than marine mammals), 0.05 mg/kg for liver of cattle, goats, pigs and sheep, 0.05 mg/kg for kidney of cattle, goats, pigs and sheep and 0.04 mg/kg for milks.

Poultry

The highest maximum and the mean dietary burdens for poultry are 0.39 ppm and 0.22 ppm respectively. No residues above the LOQ of the analytical method used were observed in the feeding study for laying hens at the lowest dose level equivalent to 2 ppm in the diet (about five times higher than the maximum burden in poultry). Maximum residues expected in muscle, fat, liver, kidney and eggs are all < 0.01 mg/kg.

The Meeting confirmed the 2007 JMPR recommended maximum residue levels for poultry meat of 0.01* mg/kg (fat); poultry offal 0.01* and eggs 0.01* mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for cyfluthrin was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of cyfluthrin for the 13 GEMS/Food regional diets, based on estimated STMRs were 0–2% of the maximum ADI of 0.04 mg/kg bw (Annex 3). The

Meeting concluded that the long-term intake of residues of cyfluthrin from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for cyfluthrin was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available (Annex 4).

For cyfluthrin the IESTI varied from 0–6% of the ARfD (0.04 mg/kg bw) and the Meeting concluded that the short-term intake of residues of cyfluthrin from uses considered by the Meeting is unlikely to present a public health concern.