5.5 CHLORANTRANILIPROLE (230)

RESIDUE AND ANALYTICAL ASPECTS

Chlorantraniliprole was first evaluated for residues and toxicological aspects by the 2008 JMPR. The 2008 JMPR established an ADI for chlorantraniliprole of 0–2 mg/kg bw and concluded that an ARfD was unnecessary. The residue definition for compliance with MRL and for dietary intake for plant and animal commodities is chlorantraniliprole. The residue is considered fat soluble. It was last evaluated in 2014 for additional maximum residue levels. At the 47th Session of the CCPR (2015), chlorantraniliprole was listed for consideration of further additional maximum residue levels by the 2016 JMPR.

The Meeting received information on registered use patterns, supervised residue trials on spring onions, cereals (barley, sorghum, wheat) and peanuts that were previously submitted to the 2014 JMPR as well as a residue transfer study in laying hens. Product labels were available from Canada and the United States of America.

Methods of analysis

Residue trial samples in crops were analysed using LC-MS/MS methods based on those previously evaluated by the JMPR in 2008.

An analytical method was provided reported for the analysis of chlorantraniliprole and selected metabolites (IN-K9T00, IN-HXH44, IN-GAZ70, IN-EQW78) in poultry tissues and eggs. The basic approach employs homogenisation and extraction with acetonitrile:hexane. Clean-up of tissue extracts is by SPE (hydrophilic lipophilic balanced polymer and strong anion exchange in sequence). Residues are determined by LC-MS/MS. The analytical method for chlorantraniliprole and selected metabolites was validated with LOQs of 0.01 mg/kg for each analyte.

Stability of pesticide residues in stored analytical samples

As reported by the 2014 JMPR, samples were stored frozen for periods less than the period of stability demonstrated in studies provided to the 2008 Meeting and were satisfactory.

Results of supervised residue trials on crops

Supervised residue trial data for were available for chlorantraniliprole on spring onions, cereals (barley, sorghum, wheat) and peanuts. The trials were evaluated by the 2014 JMPR.

Bulb vegetables-green onion

The critical GAP for bulb vegetables (Crop group 3-07) in the USA is for applications at a maximum rate of 110 g ai/ha, with a maximum of 225 g ai/ha/season, at intervals of 7 days and a PHI of 1 day. None of the trials from Canada and the USA approximated critical GAP in the USA as the spray interval employed was too short at 3 days.

The critical GAP for bulb vegetables, green onions (US crop subgroup 3-07B) in Canada is for applications at a maximum rate of 75 g ai/ha, with a maximum of 225 g ai/ha/season, at intervals of 5 days and a PHI of 1 day. None of the trials from Canada and the USA approximated critical GAP in Canada. The data were not suitable for application of proportionality as the number of sprays, spray intervals and application rates deviated from critical GAP.

Cereals

Chlorantraniliprole is approved for use on cereals in Canada and the USA. Critical GAP in the USA for cereals (except corn and rice) is applications at up to 110 g ai/ha, maximum seasonal application 225 g ai/ha, at intervals of 7 days with a PHI of 1 day. In trials approximating critical GAP in the USA residues in cereal grain were:

Barley (n = 3): 1.9, 1.9 and 2.0 mg/kg

Sorghum (n = 3): 0.79, 1.2 and 1.5 mg/kg

Wheat (n = 5): 0.18, 0.19, 0.23, 0.25 and 0.41 mg/kg.

The Meeting considered the number of trials in the individual cereal crops insufficient to estimate maximum residue level for barley, sorghum and wheat and decided to consider whether it would be possible to estimate a group maximum residue level for cereal grains (except corn and rice). In considering whether a group maximum residue level is possible the Meeting noted the median residues differed by more than a factor of 5; as a result it would not be appropriate to combine the trials on the individual crops to make a larger dataset, the number of trials remained insufficient to estimate a maximum residue level.

Peanuts

The critical GAP in the USA is applications at 110 g ai/ha, a maximum of 224 g ai/ha/year, with a 5 day retreatment interval and a PHI of 1 day. In five trials conducted in peanuts in the USA in which two applications of chlorantraniliprole were made at 111–115 g ai/ha (total application rate of 224–228 g ai/ha) with a 5– 6 day retreatment interval and a PHI of 1 day residues were: < 0.01, < 0.01, < 0.01, 0.012, 0.034 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg and STMR of 0.01 mg/kg for chlorantraniliprole in peanuts.

Animal feeds

Cereals

Chlorantraniliprole is approved for use on cereals in Canada and the USA. Critical GAP in the USA for cereals (except corn and rice) is application at a maximum of 110 g ai/ha, maximum seasonal application 225 g ai/ha, at intervals of 7 days with a PHI of 1 day (no PHI for forage or hay). In trials approximating critical GAP in the USA residues in cereal forage were:

Sorghum forage (n = 3): 2.7, 3.4, 4.1 mg/kg.

Wheat forage (n = 4): 4.3, 4.3, 4.4, 4.6 mg/kg.

The Meeting noted that residues in sorghum and wheat forage are similar and agreed to use them in mutual support to estimate a median and highest residue for cereal forage (except maize and rice) of 4.3 and 4.6 mg/kg (as received basis) respectively.

In trials approximating critical GAP in the USA residues in cereal fodder were:

Barley hay (n = 3): 5.5, 9.2, 11 mg/kg;

Wheat hay (n = 4): 8.6, 9.5, 11, 11 mg/kg; for hay, and

Barley straw (n = 3): 3.6, 12, 14 mg/kg;

Sorghum stover (n = 3): 3.4, 4.1, 5.9 mg/kg;

Wheat straw (n = 4): 0.19, 4.5, 6.4, 15 mg/kg; for straw and stover.

The Meeting agreed to utilise the data for straw and stover to estimate a maximum residue level for fodder of cereals (except maize and rice) and decided to combine the data for straw and stover. The combined dataset is:

0.19, 3.4, 3.6, 4.1, 4.5, 5.9, 6.4, 12, 14, 15 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg (dry weight basis), median residue of 5.2 mg/kg (as received) and highest residue of 15 mg/kg (as received) for chlorantraniliprole in fodder of cereals (except corn and rice).

Residues in animal commodities

Farm animal feeding studies

The Meeting received information on the residue levels in tissues and eggs of laying hens dosed with chlorantraniliprole at the equivalent of 4.8, 18.8 and 51.9 ppm in the feed for 28 consecutive days.

Mean and highest residues of chlorantraniliprole (parent compound) in eggs were 0.132 and 0.147 mg/kg for the 4.8 ppm group, 0.296 and 0.512 mg/kg for the 18.8 ppm group, 0.447 and 0.680 mg/kg for the 51.9 ppm group.

Mean and highest residues of chlorantraniliprole (parent compound) in liver were 0.038 and 0.054 mg/kg for the 4.8 ppm group, 0.092 and 0.122 mg/kg for the 18.8 ppm group, 0.147 and 0.178 for the 51.9 ppm group.

Mean and highest residues of chlorantraniliprole (parent compound) in muscle were 0.011 and 0.016 mg/kg for the 4.8 ppm group, 0.027 and 0.036 mg/kg for the 18.8 ppm group, 0.049 and 0.054 for the 51.9 ppm group.

Mean and highest residues of chlorantraniliprole (parent compound) in skin and fat were 0.042 and 0.066 mg/kg for the 4.8 ppm group, 0.096 and 0.141 for the 18.8 ppm group, 0.168 and 0.212 for the 51.9 ppm group.

Estimation of livestock dietary burdens

The Meeting recalculated the livestock dietary burden based on the uses considered by the current Meeting and by the 2008, 2010, 2013 and 2014 Meetings on the basis of diets listed in the 2016 edition of the FAO Manual Appendix IX (OECD Feedstuff Table). The maximum dietary burdens are 36 ppm for beef cattle and 30 ppm for dairy cattle, while the mean dietary burdens are 18 ppm for beef cattle and 17 ppm for dairy cattle. These values have changed only marginally from those calculated by the 2013 Meeting (beef cattle maximum/mean of 31.7/15.7 ppm, and dairy cattle maximum/mean of 26.8/13.1 ppm). The Meeting confirmed its previous recommendations for maximum residue levels and STMR values for meat from mammals other than marine mammals, milks and edible offal (mammalian).

The maximum and mean dietary burdens for poultry were unchanged from those previously calculated. The current Meeting noted previous maximum residue level estimates for poultry commodities were based on a laying hen metabolism study and decided to estimate residues in poultry commodities using the newly available laying hen residue transfer study.

Summary of poultry dietary burden (ppm dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	Max	mean	max	Mean	max	Mean
Broilers	0.064	0.064	0.073	0.051	0.118	0.118	1.454	0.869
Layers	0.064	0.064	4.8[A]	3.6[B]	0.118	0.118	0.053	0.053

[A] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs

[B] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

Animal commodity maximum residue levels

The calculation used to estimate highest total residues for use in estimating maximum residue levels, STMR and HR values is shown below.

	Feed level (ppm) for egg residues	Residues (mg/kg) in eggs	Feed level (ppm) for tissue residues	Residues (mg/kg)		
				Muscle	Liver	Skin and Fat
MRL						
Feeding study [A]	4.8	0.162	4.8	0.016	0.054	0.066
Dietary burden and high residue estimates	4.8	0.162	4.8	0.016	0.054	0.066
STMR						
Feeding study [B]	4.8	0.132	4.8	0.011	0.038	0.042
Dietary burden and median residue estimates	3.6	0.099	3.6	0.008	0.028	0.031

[A] highest residues for tissues and eggs

[B] mean residues for tissues and eggs

The Meeting confirmed its previous recommendations for maximum residue level of 0.2 mg/kg and recommended an STMR of 0.099 mg/kg for eggs.

The meeting estimated maximum residue levels of 0.02 mg/kg for poultry meat, 0.07 mg/kg for poultry edible offal and 0.08 mg/kg for poultry fats to replace its previous recommendations of 0.01*and 0.01* and 0.01* mg/kg respectively. The Meeting also estimated the following STMR values: poultry muscle 0.008 mg/kg; poultry fat 0.031 mg/kg; poultry edible offal 0.028 mg/kg and eggs 0.099 mg/kg.

RECOMMENDATIONS FURTHER WORK OR INFORMATION

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 and IESTI assessment.

Definition of the residue (for compliance with MRL and for dietary risk assessment) for plant and animal commodities: *chlorantraniliprole.*

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The 2008 JMPR established an Acceptable Daily Intake (ADI) of 0–2 mg/kg bw for chlorantraniliprole.

The evaluation of chlorantraniliprole resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed

food commodities, dietary intakes were calculated for the 17 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDIs in the seventeen Cluster Diets, based on the estimated STMRs were 0–1% of the maximum ADI (2 mg/kg bw). The Meeting concluded that the long-term dietary exposure to residues of chlorantraniliprole from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The 2008 JMPR decided that an ARfD for chlorantraniliprole was unnecessary. The Meeting therefore concluded that the short-term dietary exposure to residues of chlorantraniliprole resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.