5.4 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. It was also evaluated in 2010 and 2013 for additional maximum residue levels. At the Forty-fifth Session of the CCPR (2013), chlorantraniliprole was listed for consideration of further additional maximum residue levels by the 2014 JMPR.

The Meeting received information on registered use patterns, supervised residue trials and fate of residues in processing. Product labels were available from Australia, Canada, India, the Republic of South Africa and the United States of America.

The residue definition for compliance with MRL and for dietary intake for plant and animal commodities is chlorantraniliprole. The residue is considered fat soluble.

Methods of analysis

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

Stability of pesticide residues in stored analytical samples

Samples from the submitted studies were stored for periods less than the period of stability demonstrated in studies provided to the 2008 Meeting. Since the storage stability data from the 2008 JMPR cover a diverse range of crops and demonstrated stability of chlorantraniliprole for up to 2 years, it is considered that these data should be sufficient to cover the storage stability of all commodities in this submission.

The Meeting noted that concurrent storage stability data provided with the green onion residue trials also demonstrated stability of chlorantraniliprole residues over 24 months (the period for which the samples were stored) in fresh and dried green onions.

Results of supervised residue trials on crops

The Meeting received supervised trial data for application of chlorantraniliprole on oranges, mandarins, green onions (fresh and dried), chickpeas, mung beans and soya beans, barley, grain sorghum, wheat and peanuts.

Citrus fruits

Residue trials were conducted in citrus fruits in the Republic of South Africa (RSA) in 2010 according to the critical GAP in the RSA (up to 2 applications at 3.5 g ai/100L, and a 7 day PHI).

Four trials were conducted in oranges and four trials in mandarins. In one orange trial the rate of the second application was not known, so data from this trial were not considered for estimation of a maximum residue level and STMR.

The Meeting noted that the RSA GAP is for the citrus fruit group and that a group maximum residue level of 0.5 mg/kg for chlorantraniliprole in citrus fruits was estimated at the 2010 JMPR Meeting based on 2009 South African trials in oranges (4) and mandarins/ tangelos (4). An STMR of 0.07 mg/kg was estimated.

The new citrus data were combined with the 2009 data to give a larger data set on which to base an estimation of the maximum residue level and STMR.

The ranked order of residues in oranges (whole fruit) from supervised trials in the RSA in 2009 and 2010 according to GAP was: ***0.14***, 0.15, ***0.15***, 0.22, 0.22, ***0.24*** and 0.27 mg/kg (*new data in **bold italics***).

The ranked order of residues in mandarins and tangelos (whole fruit) from supervised trials in the RSA in 2009 and 2010 according to GAP was: ***0.11***, 0.14, ***0.15***, 0.18, ***0.22***, 0.25, ***0.30*** and 0.35 mg/kg (*new data in **bold italics***).

The Meeting noted that the RSA GAP is for the citrus group and considered a group maximum residue level. To consider a group maximum residue level, residues across individual crops should not differ by more than 5×median. The Meeting noted that the median of the oranges and mandarins/ tangelos differed by less than 5-fold (only a 1.1-fold difference).

In deciding whether to combine the datasets for oranges and mandarins/ tangelos for use in the statistical calculator or to only utilise the data from the commodity with the highest residues, the Meeting recognised the similarity of the datasets (Mann-Whitney U-Test). Therefore the Meeting decided to combine the data from oranges and mandarins/ tangelos in order to estimate a maximum residue level for citrus fruit.

The ranked order of residues in oranges and mandarins/ tangelos (whole fruit) from supervised trials in the RSA in 2009 and 2010 according to GAP was: 0.11, 0.14 (2), 0.15 (3), 0.18, 0.22 (3), 0.24, 0.25, 0.27, 0.30 and 0.35 mg/kg.

The ranked order of residues in oranges and mandarins/ tangelos (edible portion - flesh) from supervised trials in the RSA in 2009 and 2010 according to GAP was: 0.02, 0.04, 0.05 (4), 0.06 (3), 0.07 (2), 0.08 (2), 0.09 and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for residues of chlorantraniliprole in citrus fruits, together with an STMR of 0.06 mg/kg (based on the edible portion data). The Meeting estimated a median residue for whole citrus fruit of 0.22 mg/kg for use in processing calculations.

The Meeting withdrew its previous recommendation of 0.5 mg/kg for chlorantraniliprole in citrus fruits.

Bulb vegetables – green onion

The GAP for bulb vegetables in the USA is for up to 4 applications at a maximum rate of 73 g ai/ha, or a maximum of 224 g ai/ha, with a 7 day retreatment interval and a PHI of 1 day.

Residue trials were conducted in green onions in the USA (3) and Canada (2) in which two applications of chlorantraniliprole were made at 110–118 g ai/ha (223–228 g ai/ha per crop) with a 3 day retreatment interval and a PHI of 1 day.

The Meeting did not estimate a maximum residue level as the trials did not comply with the GAP.

Pulses

Chickpeas

The critical GAP in India is 2 applications at 25 g ai/ha and an 11-day PHI.

Four residue trials were conducted in chickpea (Bengal gram) in India in which two foliar applications of chlorantraniliprole were made at 25 or 50 g ai/ha. The PHI was 11–23 days.

Only one trial matches the Indian GAP. The observed residues were < 0.03 mg/kg.

The Meeting determined that a single trial was insufficient for estimation of a maximum residue level.

Three residue trials were conducted in chickpeas in Australia according to the GAP in Australia (2 applications at 24.5 g ai/ha, 7 day retreatment interval and a 14 day PHI).

The residues from supervised trials in Australia according to GAP, in ranked order, were: < 0.01, 0.015 and 0.025 mg/kg.

The Meeting decided that the number of trials available was not adequate to estimate a maximum residue level for chickpeas (dry).

Mung beans

Residue trials were conducted in mung beans in Australia according to the critical GAP in Australia (2 applications at 24.5 g ai/ha, 7 day retreatment interval and a 14 day PHI).

The residues from supervised trials in Australia according to GAP, in ranked order, were: 0.092, 0.17 and 0.26 mg/kg.

The Meeting concluded that the number of trials available was not adequate to estimate a maximum residue level for mung beans (dry).

Soya beans

The GAP for soya beans in Australia is 2 applications at 24.5 g ai/ha, 7-day retreatment interval, and a 14 day PHI.

Residue trials were conducted in soya beans in Australia.

The residues from supervised trials in Australia according to GAP, in ranked order, were: < 0.01 (3) and 0.029 mg/kg.

Residue trials conducted in soya beans in Japan, considered by the 2010 JMPR, showed that residues in dry soya beans were < 0.01 (2) mg/kg after 3 applications at 25 g ai/ha at 7 day intervals and with a 14 day PHI. These trials match the Australian GAP, with the exception of three rather than two applications being made. However, the Meeting noted that the additional application had no effect on the residues in the Japanese trials, which were below the LOQ.

The Australian and Japanese soya bean data were combined and the ranked order of residues from supervised trials in Australia and Japan according to Australian GAP were: < 0.01 (5) and 0.029 mg/kg.

The Meeting estimated a maximum residue level and an STMR value of 0.05 and 0.01 mg/kg respectively for chlorantraniliprole in soya beans.

Cereals

The Codex MRL for chlorantraniliprole in cereal grains is 0.02 mg/kg following the recommendation of the 2008 JMPR based on rotational crop data. An STMR of 0.01 mg/kg was estimated.

A study conducted on cereals in the USA in 2009–2010 (three trials in barley and sorghum and five in wheat) was submitted to the 2013 JMPR. As the compound was not registered in the USA for these crops, no estimations of maximum residue levels or STMRs were made. The study has been resubmitted, with relevant registered label use patterns in the USA and Canada for cereal grains except corn and wild rice, and is evaluated here against the critical Canadian GAP.

The GAP for cereals in Canada is 3 × 75 g ai/ha applications, with a 7-day retreatment interval and a 1-day PHI.

However, the submitted cereal trials were conducted with 2 × 111–117 g ai/ha applications (RTI 7 days, PHI 1 day). The Meeting therefore did not estimate maximum residue levels for cereal grains as the trials were not conducted in accordance with the GAP.

Peanuts

The GAP in the USA is up to 4 applications at a rate of 73g ai/ha (or a maximum of 224 g ai/ha/year) with a 3 day retreatment interval and a PHI of 1 day.

Six residues trials were 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.

A maximum residue level and STMR were not estimated as the trials did not match the GAP.

Animal feeds

The Meeting received supervised trials data for chickpea, mung bean and soya bean forage, barley hay and straw, grain sorghum forage and stover and wheat forage, hay and straw.

Pulses forages

The GAP in Australia for chickpea, mung bean and soya bean is 2 × 24.5 g ai/ha applications with a 14-day grazing PHI.

Data for mung bean, chickpea and soya bean forage is available from the Australian trials, but does not match GAP as only one application was made, while in the chickpea trials, forage was not sampled at the correct PHI. The Meeting therefore did not estimate median and highest residues for pulse forages.

Cereals forages and fodders

Residue data for sorghum and wheat forage, barley and wheat hay, wheat straw and sorghum stover were received. The Meeting determined that the trials did not match the Canadian GAP, and maximum residue levels and median and highest residues were not estimated.

Fate of residues during processing

The Meeting received a processing study for wheat. STMR-P values were estimated for wheat grain processed commodities using the cereal grains STMR value of 0.01 mg/kg estimated by the 2008 Meeting based on rotational crop data (see table below).

A study for processing oranges into juice was considering by the 2010 Meeting (see table below).

Processing Factors for chlorantraniliprole from the processing of raw agricultural commodities (RACs)

RAC	Processed Commodity	Best Estimate Processing Factor	RAC MRL	RAC STMR	Processed Commodity STMR-P/median residue
Wheat	Aspirated Grain Fractions	33	0.02	0.01	0.34
	Bran	1.04			0.011
	Flour	0.38			0.004
	Middlings	0.28			0.003
	Shorts	0.7			0.007
	Germ	1.13			0.011
Oranges	Juice	0.17	0.7	0.22	0.037

Animal commodities

The Meeting recalculated the livestock dietary based on the uses considered by the current Meeting and by the 2008, 2010 and 2013 Meetings on the basis of diets listed in the FAO Manual Appendix IX (OECD Feedstuff Table).

The maximum dietary burdens are 36.1 ppm for beef cattle and 29.0 ppm for dairy cattle, while the mean dietary burdens are 17.4 ppm for beef cattle and 13.6 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 maximum and mean dietary burdens for poultry were unchanged from those previously calculated.

The Meeting confirmed its previous recommendations for maximum residue levels and STMR values for meat from mammals other than marine mammals, milks, edible offal (mammalian), poultry meat, poultry, edible offal of, and eggs.

The Meeting noted that maximum residue levels have not previously been estimated for mammalian fats and poultry fats.

The Meeting noted that the 2010 Meeting estimated a maximum residue level of 0.2 mg/kg for meat (from mammals other than marine mammals) of 0.2 mg/kg (fat), together with STMR values of 0.049 mg/kg in fat and 0.009 mg/kg in muscle. The dietary burden has not changed significantly since. The Meeting estimated a maximum residue level of 0.2 mg/kg for mammalian fats (except milk fats), together with an STMR of 0.049 mg/kg.

The Meeting noted that the 2013 Meeting estimated a maximum residue level of 0.01* mg/kg (fat) and an STMR of 0 for poultry meat. The dietary burden has not changed significantly. The Meeting estimated a maximum residue level of 0.01* mg/kg for poultry fats, together with an STMR of 0.

RECOMMENDATIONS

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

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

The residue is fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of chlorantraniliprole has resulted in recommendations for MRLs and STMRs for raw and processed commodities. The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on STMRs estimated by this Meeting and the 2008, 2010 and 2013 Meetings were in the range 0–1 % of the maximum ADI of 2 mg/kg bw (see Annex 3 to the 2014 Report).

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

Short-term intake

The 2008 JMPR decided that an ARfD was unnecessary and concluded that the short-term intake of residues of chlorantraniliprole is unlikely to present a public health concern.