5.5 CHLORANTRANILIPROLE (230)

The insecticide chlorantraniliprole was evaluated by the JMPR 2008 (T, R) and 2010 (R). The ADI for chlorantraniliprole is 0–2 mg/kg bw and an ARfD was considered unnecessary. The compound was listed by the Forty-fourth Session of the CCPR (2012) for the evaluation by the 2013 JMPR of residue data for avocadoes, pomegranates, strawberries and other berries, soya bean, radish, carrots, globe artichokes, wheat, rape seed, sunflower seed, coffee and hops.

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

Results from supervised residue trials on crops

Berries and other small fruits

Currently, there is a Codex MRL of 1 mg/kg for chlorantraniliprole in Berries and other small fruits, which replaced the previous MRL of 1 mg/kg in grapes.

In the USA, GAP for chlorantraniliprole in strawberry is for up to 4×0.05 –0.07 kg ai/ha (7 days interval; total 0.225 kg ai/ha/season). Eight trials conducted in the USA in 2011 at 2×0.11 kg ai/ha (7 days interval) gave residues at 1 day PHI of 0.18, 0.21, 0.22, 0.23, 0.24 (2), 0.40 and 0.68 mg/kg. Eight indoor trials were conducted in southern Europe, where there is no approved use.

Residues of chlorantraniliprole in grapes from 17 trials in Canada and the USA evaluated by the 2008 JMPR complying with GAP of the USA ($3 \times 0.07-0.11$ kg ai/ha and 14 days PHI) were 0.02, 0.04 (3), 0.08, 0.09 (2), 0.11, 0.12, 0.18, 0.20, 0.26, 0.32, 0.34, 0.46, 0.48 and 0.52 mg/kg.

In the USA and Canada, GAP in bushberries (include cranberry and blueberry) is $3 \times 0.07 - 0.11$ kg ai/ha and 1 day PHI, total 0.

225 kg ai/ha/season). Seventeen trials were conducted in Canada and USA in cranberry and blueberry using 2 applications of the maximum GAP rate, with residues at 1 day PHI of 0.11, 0.12 (2), 0.13 (2), 0.16, 0.18 (2), 0.21 (2), 0.23, 0.24, 0.29, 0.32, 0.46, 0.75 and 0.84 mg/kg.

Data evaluated by the 2010 JMPR on residues of chlorantraniliprole in caneberries (raspberries and blackberries) from eight trials in Canada and the USA complying with GAP of the USA were: 0.05, 0.09 (2), 0.24, 0.44, 0.48 (2) and 0.51 mg/kg

The Meeting confirms its previous recommendation of a maximum residue level of 1 mg/kg for chlorantraniliprole in berries and other small fruits.

Avocado

The GAP of chlorantraniliprole in avocado in New Zealand is 2×0.09 kg ai/ha (21 days interval) and a 14 day PHI. Two trials conducted in the country according to GAP gave residues in fruit of 0.03 and 0.08 mg/kg. Six other trials conducted at higher or lower GAP gave residues ranging from 0.07 to 0.31 mg/kg at 14 days DAT.

As only two trials were conducted according to GAP, the Meeting could not recommend a maximum residue level for chlorantraniliprole in avocado.

Pomegranate

The GAP of chlorantraniliprole in pomegranate in USA is 3×0.07 –0.11 kg ai/ha (7 days interval; max. 0.2 kg ai/ha/season) and a 1 day PHI. Five trials conducted in the country according to GAP gave residues of 0.09, 0.10 (2) and 0.12 (2) mg/kg.

The Meeting recommended a maximum residue level of 0.4 mg/kg and a STMR of 0.10 mg/kg for chlorantraniliprole in pomegranate.

Radish tops

Currently, there is a Codex MRL of 20 mg/kg for chlorantraniliprole in leafy vegetables.

In the USA, chlorantraniliprole is registered in root and tuber vegetables at a maximum rate of 4×0.07 kg ai/ha (3 day interval; max of 0.22 kg ai/ha/season) and a 1 day PHI. In six trials conducted in radish at 2×0.11 kg ai/ha gave residues in radish tops at a 1 day PHI of 3.9, 7.7, 10, 11, 19 and 22 mg/kg.

The Meeting recommended a maximum residue level of 40 mg/kg and a STMR of 10.5 mg/kg for chlorantraniliprole in radish leaves (including radish tops).

The Meeting agreed to withdraw its previous recommendation of 20 mg/kg for leafy vegetables for 20 mg/kg in leafy vegetables, except radish leaves.

Legume vegetables

In Italy, chlorantraniliprole is registered in beans at up to 2×0.04 kg ai/ha with a 3 day PHI. In five trials conducted in France, Italy and Spain in 2008/2009, according to this GAP, residues in fresh bean pods with seeds were 0.15 0.16, 0.40 (2) and 0.41 mg/kg. Five residue trials conducted in southern Europe according to the Italian GAP and submitted to the 2010 JMPR gave residues in fresh pods with seeds of 0.08, 0.09, 0.12, 0.16 and 0.25 mg/kg.

Trials conducted in southern Europe according to GAP (n=9) gave residues in bean pods with seeds of 0.08 (2), 0.12, 0.15, 0.16 (2), 0.40 (2) and 0.41 mg/kg.

In USA, the rate for legume vegetables is up to 4×0.07 kg ai/ha (max. of 0.225 kg ai/ha/season) and a 1 day PHI. In nine trials conducted in the USA and Canada (2008) at 2×0.11 kg ai/ha, residues in bean pods with seeds were: < 0.01, 0.10, 0.12 (3), 0.14 (2), 0.16 and 0.41 mg/kg.

In Australia, GAP for legume vegetable is 3×0.02 kg ai/ha and a 1 day PHI. In two trials conducted according to GAP, residues in bean pods with seeds were 0.08 (2) mg/kg.

Based on the European trials, the Meeting recommended a maximum residue level of 0.8 mg/kg and a STMR of 0.16 mg/kg for chlorantraniliprole in beans, except broad bean and soya bean (green pods and immature seeds).

In four trials conducted in peas in the USA and Canada according to GAP, residues in pea pods with seeds were 0.45, 0.48, 0.61 and 0.64 mg/kg.

In three trials conducted in Australia according to the Australian GAP for legume vegetables $(3 \times 0.02 \text{ kg ai/ha}, 1 \text{ day PHI})$, residues in pea pods with seeds were 0.04, 0.06 and 0.47 mg/kg.

Based on the US and Canadian trials, and with the support of the Australian trials, the Meeting recommended a maximum residue level of 2 mg/kg and a STMR of 0.545 mg/kg for chlorantraniliprole in Peas (pods and succulent = immature seeds).

In six trials conducted in the USA and Canada, according to GAP, residues in pea seed were 0.01, 0.02 (2) and 0.03 (3) mg/kg. In two trials conducted in Australia according to GAP, residues in pea seed were < 0.01 (2) mg/kg.

Based on trials conducted in Canada and the USA, and with the support of the Australian trials, the Meeting recommends a maximum residue level of 0.05 mg/kg and a STMR of 0.025 mg/kg for chlorantraniliprole in peas, shelled.

Soya bean, dry

The GAP chlorantraniliprole in soya bean in Brazil is 2×0.01 kg ai/ha, and a PHI of 21 days. Four trials conducted in 2010 according to GAP gave residues of < 0.01 mg/kg (4).

Four trials submitted to the 2010 JMPR used a furrow application (0.1 kg ai/ha) followed by two applications at the GAP rate gave residues at 21 days PHI of 0.10, 0.11 (2) and 0.12 mg/kg.

As only four trials according to GAP were submitted, the Meeting could not recommend a maximum residue level for chlorantraniliprole in soya beans.

Root and tuber vegetables

The current Codex MRL for chlorantraniliprole in Root and tuber vegetables is 0.02 mg/kg, following the recommendation made by the 2008 JMPR based on rotation crop data (0.01 mg/kg on radish root) and foliar trials on potatoes (< 0.01 mg/kg, n=27).

In the USA, chlorantraniliprole is registered in Root and tuber vegetables at a maximum rate of 4×0.07 kg ai/ha (3 days interval; max of 0.22 kg ai/ha/season) and a 1 day PHI. Six trials conducted in radish at 2×0.11 kg ai/ha gave residues at a 1 day PHI of 0.03, 0.04, 0.05, 0.06, 0.08 and 0.26 mg/kg in the radish root. The Meeting agreed that the contribution from previous use on the rotation regime would not significantly impact the final residues.

The Meeting estimates a maximum residue level of 0.5 mg/kg and a STMR of 0.055 mg/kg for chlorantraniliprole in radish.

Chlorantraniliprole is registered to be used in Italy in carrots at up to 2×0.04 kg ai/ha (7–10 days interval) and 21 days PHI. Nine trials conducted in southern Europe in 2009/2010 according to this GAP gave residues of < 0.004 (3), 0.004, 0.005 (2), 0.025, 0.03, and 0.036 mg/kg. Eight trials conducted in northern Europe at the same rate gave residues of < 0.004 (5) 0.01, 0.021, and 0.027 mg/kg. Residues in Europe can be combined as < 0.004 (8), 0.004, 0.005 (2) 0.01, 0.021, 0.025, 0.027, 0.03 and 0.036 mg/kg.

Considering the contribution from rotation crops (0.01 mg/kg), the Meeting estimated a maximum residue level of 0.08 mg/kg and a STMR of 0.02 mg/kg for chlorantraniliprole in carrots.

The Meeting agreed to replace its previous recommendation of 0.02 mg/kg for chlorantraniliprole in Root and tuber vegetables for 0.02 mg/kg in Root and tuber vegetables, except carrot and radish.

Globe artichoke

Chlorantraniliprole is registered for use in Italy in globe artichoke at 2×0.03 kg ai/ha (14 days interval) and a 3 day PHI. Four trials conducted in southern Europe at this GAP gave residues of 0.06, 0.07, 0.08 and 0.16 mg/kg.

The product is registered in the USA at 4×0.05 –0.11 kg ai/ha (4 days interval; max of 0.22 kg ai/ha/season) and a 3 day PHI. Four trials conducted with 2 applications of the GAP rate gave residues of 0.47, 0.53, 0.59 and 0.69 mg/kg.

Based on the US trials, the Meeting recommended a maximum residue level of 2 mg/kg and a STMR of 0.56 for chlorantraniliprole in globe artichoke.

Rice

Chlorantraniliprole is registered to be used in Brazil in rice as a foliar treatment at 1×0.03 kg ai/ha and a 15 day PHI. In eight trials conducted in the country according to GAP, residues were < 0.01, 0.02, 0.03, 0.10, 0.13 (2) and 0.16 (2) mg/kg.

In the USA, the product is registered as seed treatment at 0.06 mg ai/seed (0.09 kg ai/ha). Sixteen trials conducted at 0.10 mg ai/seed (0.56 kg ai/ha) gave residues ranging from 0.01 to 0.09 mg/kg. Three trials conducted within GAP gave residues in the grain of 0.01 (2) and 0.02 mg/kg.

Based on the Brazilian foliar trials conducted according to GAP, the Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.115 mg/kg for chlorantraniliprole in rice grain.

Two processing studies were submitted to the Meeting. In each, two different procedures were used to produce polished rice, with processing factors of 0.07 (2), 0.15 and 0.16, median of 0.11. This PF was applied to the residue data on rice grain to derive data on polish rice.

The Meeting estimates a maximum residue level of 0.04 mg/kg and a STMR of 0.013 mg/kg for chlorantraniliprole in polished rice.

Cereals, except rice

Currently, the Codex MRL for chlorantraniliprole in cereals is 0.02 mg/kg, following the recommendation made by the 2008 JMPR based on rotation crop data.

In the USA, three trials were conducted in barley, three in sorghum and five trials were conducted in wheat using 2×0.11 kg ai/ha. Residues in samples harvested at 1 DAT ranged from 0.19 to 2.2 mg/kg. As the compound is not registered for use in these crops in the USA, no estimations were made.

The Meeting replaced its previous recommendation of 0.02 mg/kg for cereals for 0.02 mg/kg in cereals, except rice.

Rape and sunflower seeds

Chlorantraniliprole is registered in Canada for oilseeds, except cotton, at 3×0.025 –0.07 kg ai/ha (max of 0.2 kg ai/ha/season) and a 1 day PHI. Twelve trials were conducted in the USA and Canada in rape seed (canola) and sunflower according to this GAP.

Six trials conducted in rape seed (canola) gave residues at of 0.14, 0.23, 0.25, 0.34, 0.83 and 1.0 mg/kg.

Six trials conducted in sunflower gave residues at of 0.03, 0.12, 0.16, 0.21, 0.79 and 0.82 mg/kg.

The Meeting estimates a maximum residue level of 2 mg/kg for chlorantraniliprole in rape seed and sunflower seed.

The Meeting estimates a STMR of 0.295 mg/kg for chlorantraniliprole in rape seed and of 0.185 mg/kg for sunflower seed.

Coffee

Chlorantraniliprole is registered in Brazil for use on coffee at 2×0.03 kg ai/ha with a 21 day PHI. Eight trials were conducted in Brazil matching this GAP, giving residues of < 0.01, 0.01 (3), 0.02 (3) and 0.03 mg/kg.

The Meeting recommended a maximum residue level of 0.05 mg/kg and a STMR of 0.015 mg/kg for chlorantraniliprole in coffee.

Hops

Chlorantraniliprole is registered in the USA for use in hops at 4×0.072 kg ai/ha (max. of 0.22 kg ai/ha/season) with a 0 day PHI. Four trials conducted at GAP (2×0.1 kg ai/ha) gave residues in dried cones of 7.6, 8.9, 13 and 19 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg and a STMR of 10.9 mg/kg for chlorantraniliprole in hops, dry.

Animal feeds

Three Australian trials conducted according to GAP gave residues at a 1 day PHI in bean and pea foliage of 0.31, 0.78 and 2.2 and mg/kg. In two pea trials, residues in empty pods were 0.05 and 0.20 mg/kg.

Five trials conducted in southern Europe in beans according to Italian GAP gave residues at a 3 day PHI in bean plants without pods of 2.4, 4.3, 4.5, 6.6 and 6.8, mg/kg.

The US label has no additional information covering the grazing of legume vegetables. Nineteen trials conducted in Canada and USA according to US GAP (4×0.07 kg ai/ha; max. of 0.225 kg ai/ha/season gave residues at a 1 day PHI in bean or pea plants with pods of 0.01, 1.7, 2.8, 3.0, 3.4, 3.8, 3.8, 4.3, 4.4, 4.5, 4.8, 4.9, 4.9, 5.2, 5.3, 5.5, 6.0, 6.2 and 6.4 mg/kg.

Based on Canadian and US data, the Meeting estimated a median residue of 4.4 mg/kg and a highest residue of 6.4 mg/kg for chlorantraniliprole in bean forage (green) and pea vines (green).

In ten trials conducted in wheat, sorghum and barley in the USA, residues were determined in forage, hay and straw. However, as these are not registered uses for chlorantraniliprole in USA, the data was not considered further.

Sixteen trials conducted in rice after seed treatment at a higher than GAP rate in USA, residues in straw ranged from 0.05 to 0.24 mg/kg.

Fate of residues during processing

At the present Meeting, a STMR of 0.115 mg/kg was estimated for rice grain. Two studies were conducted in rice.

The best Pf estimated for rice bran (n=4) was 1.7, leading to an estimated STMR-P of 0.196 mg/kg.

The best Pf estimated for rice hull (n=4) was 3.3. For animal dietary burden purposes, a median of 0.368 mg/kg was calculated for rice hull.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of chlorantraniliprole in farm animals on the basis of the OECD Animal Feed data published in the 2009 FAO Manual, the STMR, STMR-Ps or highest residue levels estimated at the present and previous JMPR Meetings (2008 and 2010). Dietary burden calculations are provided in Annex 6.

Livestock dietary burden for chlorantraniliprole, ppm of dry matter diet

	US-Canada		EU		Australia		Japan	
Commodity	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	7.6	3.4	19.9	10.7	31.7 ^a	15.7 ^c	3.5	1.5
Dairy cattle	13.4	6.0	22.4 ^b	10.1	26.8	13.1 ^d	15.8	6.7
Poultry - broiler	0.06	0.06	0.06	0.032	0.11	0.11	1.06	0.55
Poultry - layer	0.06	0.06	4.42 ^e	2.51 ^f	0.11	0.11	0.05	0.05

^a Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimated for mammalian tissues

^b Highest maximum dairy cattle dietary burden suitable for maximum residue level estimated for mammalian milk

^c Highest mean beef or dairy cattle dietary burden suitable for STMR estimated for mammalian tissues.

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

^e Highest maximum poultry dietary burden suitable for maximum residue level estimated for poultry tissues and eggs.

^f Highest mean poultry dietary burden suitable for STMR estimated for poultry tissues and eggs.

Animal commodity maximum residue level

The dietary burden estimated by the present Meeting for cattle is similar to that estimated by the 2010 JMPR and would not impact the previous recommendations for chlorantraniliprole in edible offal (mammalian), meat (from mammals other than marine mammals) and milk fats.

The calculated maximum poultry dietary burden suitable for maximum residue level estimated for poultry tissues and eggs was 4.4 ppm, about 2.4 times higher than the previous estimation. The calculated dietary burden for STMR estimation is 0.007 ppm.

In a metabolism study evaluated by the 2008 JMPR, poultry laying hens were dosed with [\frac{14}{C}]chlorantraniliprole for 14 days at 10 ppm in the diet. Residues found in eggs, muscle, liver and skin/fat and the residues expected in poultry commodities based on the calculated animal burden are shown in the table below. The levels which the estimations were based are in bold.

	Feed level, ppm, for	Residue,	Residue, mg/kg				
	Tissues and eggs residues	Eggs	Muscle	Liver	Fat		
Highest residue level,	hens						
Feeding study	10	0.308	0.0008	0.0196	0.009		
Calculated burden	4.42	0.135	0.0004	0.008	0.004		
STMR, hens							
Feeding study	10	0.282	0.0008	0.0196	0.009		
Calculated burden	2.5	0.07	0.0002	0.005	0.002		

The Meeting confirms its previous maximum residue level recommendation of 0.01* mg/kg for chlorantraniliprole in poultry meat (fat) and poultry edible offal, and estimated a STMR of 0 for poultry meat (fat) and 0.005 for poultry edible offal.

The Meeting estimated a maximum residue level of 0.2 mg/kg and a STMR of 0.07 for chlorantraniliprole in eggs.

The meeting withdraws its previous recommendation of 0.1 mg/kg for chlorantraniliprole in eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for chlorantraniliprole is 0–2 mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorantraniliprole was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current and previous JMPR. The results are shown in Annex 3. The IEDI was 0% of the maximum ADI. 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 for chlorantraniliprole was unnecessary. The Meeting therefore concluded that the short-term intake of chlorantraniliprole is unlikely to present a public health concern.