5.6 CHLORANTRANILIPROLE (230)

TOXICOLOGY

Chlorantraniliprole is the ISO approved common name for 3-bromo-*N*-[4-chloro-2-methyl-6-(methylcarbamoyl)phenyl]-1-(3-chloropyridin-2-yl)-1*H*-pyrazole-5-carboxamide). Chlorantraniliprole (CAS No. 500008-45-7) is an insecticide that operates by a highly specific biochemical mode of action. It binds and activates ryanodine receptors, resulting in depletion of intracellular calcium stores and leading to muscle paralysis and death. Comparative studies have demonstrated that differential selectivity of chlorantraniliprole for insect receptors is more than 350-fold that for mammalian receptors.

Chlorantraniliprole is being evaluated for the first time by the present Meeting at the request of CCPR. The present JMPR review was based on a global assessment of the substance, which was performed in 2007 by 10 countries under the auspices of the Organization for Economic Co-operation and Development (OECD).

All critical studies complied with GLP.

Biochemical aspects

After oral administration, the extent of absorption of chlorantraniliprole is dependent on the dose administered. At a single dose of 10 mg/kg bw, absorption was about 73–85%, with 18–30% being excreted in the urine and 49–53% being excreted in the bile within 48 h. At a single dose of 200 mg/kg bw, absorption was about 14%, with 4% and 5–7% of the dose excreted in the urine and bile, respectively, within 48 h. Excretion in expired air was insignificant. Plasma half-lives were 38–43 h in males and 78–82 h in females. After multiple doses (10 mg/kg bw per day for 14 days) with chlorantraniliprole, peak plasma concentrations in males and females were about two and seven times higher than after a single dose at 10 mg/kg bw, respectively. Distribution in tissues was extensive, with 0.8% and 3% remaining in the tissues of males and females, respectively, 168 h after a single dose at 10 mg/kg bw.

Chlorantraniliprole is extensively metabolized through tolyl methyl and *N*-methyl carbon hydroxylation, followed by *N*-demethylation, nitrogen-to-carbon cyclization with loss of a water molecule resulting in the formation of the pyrimidone ring, oxidation of alcohols to carboxylic acids, amide-bridge cleavage, amine hydrolysis, and *O*-glucuronidation. The potential for hydroxylation of the tolyl methyl and *N*-methyl carbon groups was greater in males than in females. After a single dose at 200 mg/kg bw, excretion of the parent compound in the urine and faeces (78.9–85.5%) was 12 to16-fold that at 10 mg/kg bw (4.9–7.3%). The profile of metabolites after a single dose at 200 mg/kg bw or after repeated doses at 10 mg/kg bw per day was similar to the profile after a single dose at 10 mg/kg bw.

Toxicological data

The acute toxicity of chlorantraniliprole is low (oral and dermal LD_{50}, > 5000 mg/kg bw; inhalation LC_{50}, > 5.1 mg/L). Apart from ocular and nasal discharge observed in a study in which chlorantraniliprole was administered by inhalation, no clinical signs of toxicity were observed in studies of acute toxicity. Chlorantraniliprole is not irritating to the skin and eyes, and is not a skin sensitizer (Magnussen & Kligman test in guinea-pigs; local lymph node assay in mice).

Chlorantraniliprole shows low toxicity after repeated doses. Occasionally, reductions in body-weight gain were observed in studies with repeated doses. However, these reductions often did not occur on consecutive weeks but were seen sporadically, were not dose-related and were not

consistently found in different studies at similar or higher doses. Therefore, the incidental changes in body-weight gain were not considered to be a compound-related effect.

In short-term studies with chlorantraniliprole administered orally (gavage or diet), no adverse effects were observed at any dose tested, i.e., up to 7000 ppm, equal to 1443 mg/kg bw per day, in feeding studies in mice, up to 20 000 ppm, equal to 1188 mg/kg bw per day, in a feeding study in rats, and up to 40 000 ppm, equal to 1164 mg/kg bw per day, in a 1-year feeding study in dogs.

In an 18-month feeding study in mice, the NOAEL was 1200 ppm, equal to 158 mg/kg bw per day, on the basis of presence of eosinophilic foci in the liver, accompanied by hepatocellular hypertrophy and increased liver weight at 7000 ppm, equal to 935 mg/kg bw per day, in males only. No information on the chemical-specific mechanism of action was available to evaluate the relevance of liver foci to exposure of humans. However, the Meeting noted that this is a possible species- and sex-specific response that is of questionable toxicological significance and relevance, and thus the NOAEL of 158 mg/kg bw per day on the basis of these end-points is likely to be conservative.

In a 2-year feeding study in rats, the NOAEL was 20 000 ppm, equal to 805 mg/kg bw per day, the highest dose tested.

No treatment-related changes in the incidence of tumours were observed.

The Meeting concluded that chlorantraniliprole is not carcinogenic in rodents.

Chlorantraniliprole was tested for genotoxicity in adequate range of studies of genotoxicity in vitro and in vivo. No evidence for genotoxicity was observed in any test. The Meeting concluded that chlorantraniliprole is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that chlorantraniliprole is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity with chlorantraniliprole in rats, the NOAEL for parental, offspring and reproductive toxicity was 20 000 ppm, equal to 1199 mg/kg bw per day, the highest dose tested.

In a study of developmental toxicity in rats, the NOAEL for maternal and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested. In a study of developmental toxicity in rabbits, the NOAEL for maternal and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a study of acute neurotoxicity in rats given chlorantraniliprole orally by gavage, the NOAEL was 2000 mg/kg bw per day, i.e., the highest dose tested. In a 90-day dietary study of neurotoxicity in rats, the NOAEL was 20 000 ppm, equal to 1313 mg/kg bw per day, the highest dose tested.

In a dietary study of immunotoxicity in mice, the NOAEL was 7000 ppm, equal to 1144 mg/kg bw per day, the highest dose tested. In a dietary study of immunotoxicity in rats, the NOAEL was 20 000 ppm, equal to 1494 mg/kg bw per day, the highest dose tested.

To date, chlorantraniliprole has only been produced on a pilot scale. In the limited number of workers involved with the synthesis of this compound to date, no illnesses have been attributed to exposure associated with the handling, testing, or manufacturing of chlorantraniliprole.

The rat metabolite 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-3,8-dimethyl-4(3*H*)-quinazolinone (IN-EQW78) was also a significant metabolite in soil, water, and sediment. The substances 2,6-dichloro-4-methyl-11*H*-pyrido[2,1-*b*]quinazolin-11-one (IN-ECD73) and 3-bromo-*N*-methyl-1*H*-pyrazole-5-carboxamide (IN-F6L99) were metabolites only observed at low concentrations in soil and as degradates in studies of high-temperature food processing. In studies of acute toxicity, these three chlorantraniliprole metabolites had LD_{50}s of > 2000 mg/kg bw. These metabolites gave negative results in a test for reverse mutation.

The Meeting concluded that the existing database on chlorantraniliprole is sufficient to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI for chlorantraniliprole of 0–2 mg/kg bw on the basis of eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight in mice in an 18-month feeding study for which the NOAEL was 158 mg/kg bw per day, and using a safety factor of 100. There was no available information on the chemical-specific mechanism of action with which to evaluate the relevance of the liver foci to exposure of humans. The Meeting noted, however, that this is a possible species- and sex-specific response that is of questionable toxicological significance and relevance, and thus the NOAEL of 158 mg/kg bw per day (and consequently the ADI) identified on the basis of these end-points is likely to be conservative.

The Meeting concluded that it was not necessary to establish an ARfD for chlorantraniliprole in view of its low acute toxicity, the absence of developmental toxicity, and the absence of any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant for risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month study of toxicity and carcinogenicity[a]	Toxicity	1200 ppm, equal to 158 mg/kg bw per day	7000 ppm, equal to 935 mg/kg bw per day
		Carcinogenicity	7000 ppm, equal to 935 mg/kg bw per day[c]	—[c]
Rat	2-year study of toxicity and carcinogenicity[a]	Toxicity	20 000 ppm, equal to 805 mg/kg bw per day	—[c]
		Carcinogenicity	20 000 ppm, equal to 805 mg/kg bw per day[c]	—[c]
	Two-generation study of reproductive toxicity[a]	Parental	20 000 ppm, equal to 1199 mg/kg bw per day	—[c]
		Offspring toxicity	20 000 ppm, equal to 1199 mg/kg bw per day	—[c]
		Reproductive toxicity	20 000 ppm, equal to 1199 mg/kg bw per day	—[c]
	Developmental toxicity[b]	Maternal toxicity	1000 mg/kg bw per day	—[c]
		Foetotoxicity	1000 mg/kg bw per day	—[c]
	Acute neurotoxicity[b]	Neurotoxicity	2000 mg/kg bw per day	—[c]
	90-day neurotoxicity[a]	Neurotoxicity	20 000 ppm, equal to 1313 mg/kg bw per day	—[c]
Rabbit	Developmental toxicity[b]	Maternal toxicity	1000 mg/kg bw per day	—[c]
		Foetotoxicity	1000 mg/kg bw per day	—[c]
Dog	1-year study[a]	Toxicity	40 000 ppm, equal to 1164 mg/kg bw per day	—[c]

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

0–2 mg/kg bw

Estimate of acute reference dose

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposures

Critical end-points for setting guidance values for exposure to chlorantraniliprole

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of absorption	Rapid, incomplete and dose-dependent oral absorption (73–85% at 10 mg/kg bw; 14% at 200 mg/kg bw).
Distribution	Extensive (rats)
Potential for accumulation	Low in males, moderate in females (rats)
Rate and extent of excretion	Plasma half-lives: males, 38–43 h; females, 78–82 h
	At 10 mg/kg bw: 18–30% in urine, 49–53% in bile, within 48 h.
	At 200 mg/kg bw: 4% in the urine, 5–7% in bile, within 48 h.
Metabolism in animals	Extensive, through tolyl methyl and *N*-methyl carbon hydroxylation, followed by *N*-demethylation, nitrogen-to-carbon cyclization, formation of a pyrimidone ring, oxidation of alcohols to carboxylic acids, amide-bridge cleavage, amine hydrolysis, and *O*-glucuronidation.
Toxicologically significant compounds (animals, plants and environment)	Chlorantraniliprole
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.1 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Dermal sensitization	Not sensitizing (Magnussen & Kligman test in guinea-pigs; local lymph node assay in mice)
Short-term studies of toxicity	
Target/critical effect	None
Lowest relevant oral NOAEL	1443 mg/kg bw per day (mice), 1188 mg/kg bw per day (rats), 1164 mg/kg bw per day (dogs); highest doses tested
Lowest relevant dermal NOAEL	1000 mg/kg bw per day. i.e., highest dose tested (rat)

Lowest relevant inhalatory NOAEC	No data available
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver: eosinophilic foci, hepatocellular hypertrophy, increased liver weight (mice)
Lowest relevant NOAEL	1200 ppm, equal to 158 mg/kg bw per day (mice)
Carcinogenicity	Not carcinogenic (mice, rats)
Genotoxicity	
	Not genotoxic in vitro or in vivo
Reproductive toxicity	
Reproduction target/critical effect	No reproductive effects (rats)
Lowest relevant reproductive NOAEL	20 000 ppm, equal to 1199 mg/kg bw per day, i.e., highest dose tested (rats)
Developmental target	No developmental effects (rats, rabbits)
Lowest relevant developmental NOAEL	1000 mg/kg bw per day i.e., highest dose tested (rats, rabbits)
Neurotoxicity/delayed neurotoxicity	
Neurotoxicity	No neurotoxic effects
Lowest relevant oral NOAEL	2000 mg/kg bw, i.e., highest dose tested (acute toxicity in rats treated by gavage)
	1313 mg/kg bw per day i.e., highest dose tested (90-day dietary study in rats)
Other toxicological studies	
Immunotoxicity	Not immunotoxic
Lowest relevant oral NOAEL	7000 ppm, equal to 1144 mg/kg bw per day, i.e., highest dose tested (28-day study in mice)
	20 000 ppm, equal to 1494 mg/kg bw per day i.e., highest dose tested (28-day study in rats)
Medical data	
	No adverse effects observed in workers involved with the synthesis of this compound

Summary

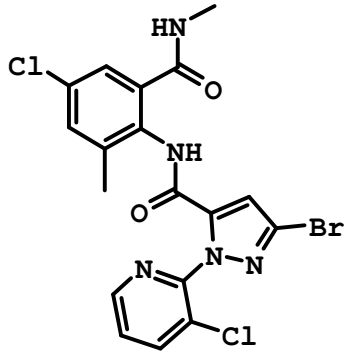
	Value	*Study*	*Safety factor*
ADI	0–2 mg/kg bw	Mouse, 18-month study	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

Chlorantraniliprole was considered for the first time by the present Meeting. The Meeting received information on chlorantraniliprole metabolism and environmental fate, methods of residue analysis, freezer storage stability, national registered use patterns, supervised residue trials, farm animal feeding studies and fate of residues in processing.

The 2008 JMPR established an ADI and ARfD for chlorantraniliprole of 0-2 mg/kg bw/day and not required respectively.

Chlorantraniliprole is 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide.



The following abbreviations are used for the metabolites discussed below:

IN-DBC80	3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxylic acid
IN-EQW78	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-3, 8-dimethyl-4(3*H*)-quinazolinone
IN-ECD73	2,6-dichloro-4-methyl-11*H*-pyrido[2,1-b]quinazolin-11-one
IN-F9N04	*N*-[2-(Aminocarbonyl)-4-chloro-6-methylphenyl]-3-bromo-1-(3-chloro-2-pyridinyl)1*H*-pyrazole-5-carboxamide
IN-F6L99	5-Bromo-*N*-methyl-1*H*-pyrazole-3-carboxamide
IN-GAZ70	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-methyl-4(3*H*)-quinazolinone
IN-H2H20	3-Bromo-*N*-[4-chloro-2-[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide
IN-HXH44	3-Bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide
IN-L8F56	2-Amino-5-chloro-3-[(methylamino)carbonyl]benzoic acid
IN-LEM10	2-[5-Bromo-2-(3-chloro-pyridin-2-yl)-2*H* pyrazol-3-yl]-6-chloro-3,4-dihydro-3-methyl-4-oxo-8-quinazolinecarboxylic acid
IN-K9T00	3-Bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[[(hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-

	pyrazole-5-carboxamide
IN-K3X21	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-(hydroxymethyl)-3-methyl-4(3*H*)-quinazolinone
IN-K7H29	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-(hydroxymethyl)-4(3*H*)-quinazolinone
IN-KAA24	2-[[[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]carbonyl]amino]-5-chloro-3-[(methylamino)carbonyl]benzoic acid

Animal metabolism

Radiolabelled chlorantraniliprole (separately [^{14}C]labelled at the benzamide-carbonyl and pyrazole-carbonyl positions) was used in the metabolism and environmental studies. The metabolism of laboratory animals was qualitatively the same as for farm animals though some species related differences were noted. The proposed major route of chlorantraniliprole metabolism in livestock is via (i) hydroxylation of the N-methyl group (to IN-H2H20) or hydroxylation of the tolyl methyl group (to IN-HXH44); (ii) cyclization with loss of water to a quinazolinone derivative (IN-EQW78); and (iii) N-demethylation via IN-H2H20 to IN-F9N04.

Lactating goats were orally dosed with a 1:1 mixture of [benzamide carbonyl-^{14}C] and [pyrazole carbonyl-^{14}C]chlorantraniliprole at 0.36 mg/kg bw for 7 consecutive days equivalent to 10 ppm in the feed.

The majority of the administered dose was recovered in excreta (79% in faeces, 11% in urine) with an additional 3.9% recovered from the cage wash. Radioactivity retained in tissues, bile or secreted in milk accounted for approximately 1.3% of the administered dose. Overall 95% of administered radioactivity was accounted for.

Radiocarbon content in various tissues were highest in liver (0.64 mg/kg) followed by kidney (0.076 mg/kg), fat (0.07 mg/kg) and muscle (0.016 mg/kg) while in milk residues were 0.067 mg/kg for a composite sample from 1 through 7 days of the study. Chlorantraniliprole was the major component of the extracted radioactivity identified in kidney (19%), muscle (41%), and fat (35–75%) samples and was also present in liver (4%) where IN-L8F56 was the major component (7.5%). In milk chlorantraniliprole (24% TRR), IN-K9T00 (26% TRR) and IN-HXH44 (27% TRR) were the major components identified.

Laying hens were orally dosed with a 1:1 mixture of [benzamide carbonyl-^{14}C] and [pyrazole carbonyl-^{14}C]chlorantraniliprole at 0.8 mg/kg bw/day for 14 days. The majority of the administered radioactivity was excreted (98% over the 14 day dosing period), with 5% recovered from cage wash and approximately 3% in eggs (white and yolks). In tissues, the highest concentrations of radioactivity were in liver (0.52 mg/kg), followed by fat (0.052 mg/kg) and muscle (0.022 mg/kg). Chlorantraniliprole (25–30%) and IN-GAZ70 (29–37%) were the major components of the radioactivity in eggs with a large number of metabolites individually present at < 10% TRR, principally IN-K7H29, IN-H2H20, IN-EQW78 and IN-F9N04. In liver and muscle, no single component (unchanged parent compound or metabolite) was present at levels > 10% TRR with chlorantraniliprole present at only 2.2–3.7% TRR. Chlorantraniliprole formed the major component of the residue in skin with fat at 18% TRR. No other metabolite exceeded 9% TRR in skin and fat.

Plant metabolism

The Meeting received information on the fate of [^{14}C]chlorantraniliprole after foliar application to apple, tomato, lettuce and cotton and as a soil drench to rice.

Metabolism studies in apples, tomato, lettuce and cotton demonstrated that following foliar application, chlorantraniliprole was not metabolized to any great extent. With up to three consecutive foliar applications of chlorantraniliprole to apples (3×100 g ai/ha), tomatoes (3×100 g ai/ha) and lettuce (3×100 g ai/ha), and following a single application to cotton (1×150 g ai/ha), parent compound was the major component of the radioactive residues at 85%, 92%, 89% and 57% of the TRR respectively for apples, tomatoes, lettuce and cotton seed. When applied as a soil drench to rice crops (1×300 g ai/ha), the metabolism was complex due to uptake of degradates in water through the roots. Parent compound was the major component of the TRR in grain at harvest (51% TRR). For straw, numerous metabolites were identified in addition to parent compound. IN-GAZ70 (0.049 mg/kg) and IN-EQW78 (0.039 mg/kg) were two major metabolites in the rice straw but were present at less than 7% of the TRR. Minor metabolites (< 0.035 mg/kg) identified in rice straw included IN-KAA24, IN HXH40, IN H2H20, IN-HXH44, and IN-F6L99.

Environmental fate

Hydrolysis in water is pH dependent. Chlorantraniliprole is considered stable at pH 4 and 7 but is hydrolysed at pH 9 with a half-life of < 10 days. At pH 9, chlorantraniliprole undergoes cyclization followed by irreversible dehydration to form IN-EQW78. Abiotic hydrolysis is unlikely to contribute significantly to the degradation of chlorantraniliprole residues in aquatic systems unless the pH is high.

The aerobic degradation of chlorantraniliprole in soil is primarily by abiotic cyclization followed by dehydration to form IN-EQW78, with subsequent demethylation forming IN-GAZ70. Alternative pathways include abiotic rearrangement followed by cleavage to form IN-F6L99 and IN-ECD73. Ultimately mineralisation to $^{14}CO_2$ occurs. The half-life for degradation of chlorantraniliprole in soil is estimated to be >100 days and sometimes > 1000 days. The degradation is sometimes limited by sequestration (or aging) of the compound in soil. The sequestration of chlorantraniliprole in soil makes the compound more difficult to extract and protects the compound from degradation, while limiting mobility. Chlorantraniliprole is considered to be persistent.

The log Kow of chlorantraniliprole (log Kow 2.86, pH 7) and the results of the rice metabolism study suggests chlorantraniliprole may be translocated in plants. In confined and field rotational crop studies, residues of chlorantraniliprole were found in leafy vegetables, root vegetables and cereal grain. Residues of chlorantraniliprole and metabolites were also detected in forage and fodder. It is concluded that rotational crops may contain significant residues of chlorantraniliprole.

Methods of Analysis

Several different analytical methods have been reported for the analysis of chlorantraniliprole and selected metabolites/degradates in plant material (IN-EQW78, IN-ECD73, IN-F6L99) and animal commodities (IN-K9T00, IN-HXH44, IN-GAZ70, IN-EQW78). The basic approach employs extraction by homogenisation with acetonitrile:water, and column clean-up using SPE (hydrophilic-lipophilic balanced polymer and strong anion exchange in sequence). Residues are determined by gas chromatography with an electron capture detector or liquid chromatography with mass spectra detection.

The analytical methods for chlorantraniliprole and selected metabolites have been extensively validated with numerous recoveries on a wide range of substrates with LOQs of 0.01 mg/kg for each analyte.

German official multi-residue method (DFG-S19) with LC-MS/MS detection was validated for chlorantraniliprole in plant and chlorantraniliprole, IN-K9T00, IN-HXH44, IN-GAZ70 and IN-EQW78 in animal commodities. LOQs were 0.01 mg/kg for each analyte.

Stability of pesticide residues in stored analytical samples

Freezer storage stability was tested for a range of representative substrates. Residues of chlorantraniliprole were stable in fortified sample crops and their processed products for the duration of the studies. Chlorantraniliprole was stable in homogenized samples stored frozen for at least 24 months for apple, grape, tomato, lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay and cotton seed. Chlorantraniliprole and metabolites (IN-EQW78, IN-ECDW73 and IN-F6L99) were stable for at least 12 months, the period of frozen storage studied for the processed commodities tomato ketchup, raisin, cotton seed meal, cotton seed oil, and apple juice. Residues of chlorantraniliprole and the metabolites IN-K9T00, IN-HXH44, IN-GAZ70 and IN-EQW78 were stable in bovine liver, kidney, muscle, fat and milk stored frozen for at least 12 months.

Residue definition

The residue following use of chlorantraniliprole on crops following foliar application is predominantly chlorantraniliprole. Similarly, chlorantraniliprole is the major component of the residue in rotational crops.

In the lactating goat metabolism study, chlorantraniliprole is the major component of the residue in edible tissues while in milk IN-HXH44 and IN-K9T00, and in eggs from the laying hen study IN-GAZ70, were present at slightly higher levels than chlorantraniliprole. Residues of chlorantraniliprole and metabolites decline rapidly on removal of exposure sources. None of the metabolites were identified by the 2008 JMPR as being of toxicological concern. Chlorantraniliprole and metabolites are considered to have low toxicity. At low doses the metabolites IN-HXH44 and IN-K9T00 are detected in milk in the absence of parent compound in the lactating dairy cow feeding study.

The Meeting recommended that the residue definition for plant and animal commodities, for compliance with MRLs and for estimation of dietary intake should be chlorantraniliprole.

The log Kow of chlorantraniliprole (log Kow 2.86, pH 7) suggests that chlorantraniliprole might be borderline fat soluble. The ratio of chlorantraniliprole residues in muscle and fat observed in the livestock metabolism and feeding studies (lactating goat: 1:3.7–1:7.8; lactating cow 1:4.7, laying hen 1:12) and ratio of residues in whole milk to cream (1:5.4) support the conclusion that chlorantraniliprole is fat soluble.

The Meeting recommended that chlorantraniliprole be described as fat-soluble

Proposed definition of the residue (for compliance with MRL and for estimation of dietary intake): *chlorantraniliprole*.

The residue is fat-soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of chlorantraniliprole on numerous crops: apples, pears, apricots, peaches, nectarines, plums, cherries, grapes, strawberries, Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower and Chinese cabbage), peppers, tomatoes, lettuce, spinach, mustard greens, celery, potatoes, cotton, almonds and pecans.

Residue trial data was made available from Argentina, Australia, New Zealand, Canada, member states of the European Union and the USA. As information on GAP of Australia, New Zealand and members states of the European Union were not supplied, trials from these countries were not considered in estimating maximum residue levels, however, the results are summarized in the 2008 JMPR Monograph.

Apples and pears

Data were available from supervised trials on apples in several countries including Argentina, Canada and the USA for which GAP information was available.

In Argentina chlorantraniliprole is permitted to be used on apples with a maximum of two foliar sprays at a spray concentration of 4 g ai/hL and a PHI of 14 days. Three trials complied with the GAP of Argentina with residues of < 0.06, 0.12 and 0.19 mg/kg.

The GAPs of Canada and the USA are similar and the GAP of the USA was used to evaluate trials on pome fruit from the two countries (USA GAP: 111 g ai/ha, PHI 14 days with a maximum seasonal application of 224 g ai/ha).

Residues of chlorantraniliprole in apples from 16 trials in Canada and the USA complying with GAP of the USA were: 0.010, 0.012, 0.022, 0.030, 0.038, 0.045, 0.056, 0.061, 0.072, 0.073, 0.078, 0.088, 0.088 and 0.093, 0.11 and 0.23 mg/kg.

Nine of eleven trials on pears from Canada and the USA complying with GAP of the USA had residues of chlorantraniliprole of: 0.016, 0.026, 0.033, 0.059, 0.070, 0.085, 0.10, 0.12 and 0.13 mg/kg.

The Meeting noted that the use patterns for apple and pears in the USA were the same and that the residues populations for each crop could be used to support the other. The Meeting decided to combine the data for apples and pears to increase the database for the purposes of estimating a maximum residue level, STMR and HR and to make a recommendation for pome fruit.

Residues in rank order (n = 25), median underlined, were: 0.010, 0.012, 0.016, 0.022, 0.026, 0.030, 0.033, 0.038, 0.045, 0.056, 0.059, 0.061, 0.070, 0.072, 0.073, 0.078, 0.085, 0.088, 0.088, 0.093, 0.10, 0.11, 0.12, 0.13 and 0.23 mg/kg.

The Meeting estimated maximum residue level and STMR values for chlorantraniliprole in pome fruit of 0.4 and 0.07 mg/kg respectively.

Stone fruit

Data were available from supervised trials on stone fruit in Argentina, Australia, member states of the European Union, Canada and the USA. GAP information was only available for Argentina, Canada and the USA.

In Argentina chlorantraniliprole is permitted to be used on peaches with a maximum of two foliar sprays at a spray concentration of 5 g ai/hL and a PHI of 7 days. No trials complied with GAP of Argentina.

The GAPs of Canada and the USA are similar and the GAP of the USA was used to evaluate trials on stone fruit from the two countries (USA GAP: 111 g ai/ha, PHI 10 days with a maximum seasonal application of 224 g ai/ha). The USA GAP advises against the use of adjuvants when spraying cherries. As GAP of Canada does not advise against the use of adjuvants for cherries, where trials were conducted at the same location with and without adjuvants, the value from the trial plot with the highest residue was selected for estimating maximum residue levels. As there were no restrictions for other stone fruit, data were also selected from the plot at a trial location with the highest residue that complied with GAP.

Residues of chlorantraniliprole in cherries from eight trials in Canada and the USA complying with GAP of the USA were: 0.056, 0.11, 0.18, 0.19, 0.21, 0.26, 0.45 and 0.57 mg/kg.

Residues of chlorantraniliprole in peaches from 17 trials in Canada and the USA complying with GAP of the USA were: 0.072, 0.090, 0.092, 0.10, 0.10, 0.11, 0.12, 0.12, 0.13, 0.13, 0.14, 0.14, 0.16, 0.18, 0.25, 0.26 and 0.31 mg/kg.

Eleven trials on plums from Canada and the USA complied with GAP of the USA with residues of: < 0.01 (4), 0.011, 0.015, 0.026, 0.029, 0.066, 0.067 and 0.076 mg/kg. The STMR for plums is 0.015 mg/kg.

The use pattern in the USA is for stone fruit and the residues populations for each crop could be used to support a crop group recommendation. The Meeting decided to use the data on the crop with the highest residues, cherries, in estimating a maximum residue level and STMR for stone fruit.

The Meeting estimated maximum residue level and, STMR values for chlorantraniliprole in stone fruit of 1 and 0.20 mg/kg respectively.

Grapes

Data were available from supervised trials on grapes in Australia, member states of the European Union, Canada and the USA. GAP information was only available for Canada and the USA.

The GAPs of Canada and the USA are similar. The GAP of Canada was used to evaluate trials on grapes from the two countries (Canada GAP: 111 g ai/ha, PHI 14 days with a maximum seasonal application of 224 g ai/ha) as GAP of Canada does not advise against the use of adjuvants for grapes. The Meeting noted that the residue populations corresponding to treatments with and without adjuvants were from similar populations and where they were from the same location should be treated as replicates with the value from the trial plot with the highest residue selected for estimating maximum residue levels.

Residues of chlorantraniliprole in grapes from 17 trials in Canada and the USA, complying with GAP of the USA, were (in rank order, median underlined): 0.015, 0.042, 0.044, 0.044, 0.083, 0.091, 0.093, 0.11, 0.119, 0.18, 0.20, 0.26, 0.32, 0.34, 0.46, 0.48 and 0.52 mg/kg.

The Meeting estimated maximum residue level and STMR values for chlorantraniliprole in grapes of 1 and 0.119 mg/kg respectively.

Brassica vegetables

Chlorantraniliprole is registered in the USA for use on Brassica vegetables at 73 g ai/ha, PHI of 3 days and a maximum application per season of 224 g ai/ha. Trials were available from Canada and the USA in which crops were treated twice at three day intervals at 112 g ai/ha with harvest 3 days after the last spray. The trials did not comply with GAP of Canada and the USA and could not be used to estimate a maximum residue level.

Fruiting vegetables, Cucurbits

Trials on cucurbits were reported from Canada and the USA (USA GAP: 100 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues on cucumbers in seven trials from the USA matching GAP in rank order were: < 0.01, 0.011, 0.012, 0.015, 0.017, 0.076 and 0.076 mg/kg.

Residues on melons (cantaloupe, muskmelon) in seven trials from the USA matching GAP in rank order were: 0.010, 0.027, 0.052, 0.065, 0.081, 0.090 and 0.10 mg/kg. Data on residues in the edible portion for melons in trials complying with USA GAP were not available.

Chlorantraniliprole residues on summer squash (including zucchini) in six trials from the USA matching GAP, in rank order were: 0.017, 0.023, 0.040, 0.054, 0.076 and 0.081 mg/kg.

The use-pattern in the USA is for fruiting vegetables, cucurbits and the Meeting decided to use the data on the crop with the highest residues (melons) to estimate a maximum residue level for the group.

The Meeting estimated a maximum residue level and an STMR value for chlorantraniliprole in fruiting vegetables, cucurbits of 0.3 and 0.065 mg/kg respectively.

Fruiting vegetables, other than Cucurbits

Trials on tomatoes were reported from Canada and the USA (USA GAP: 110 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in twenty trials from the USA matching GAP in rank order (median underlined) were: 0.018, 0.032, 0.032, 0.040, 0.040, 0.044, 0.051, 0.059, 0.061, 0.070, 0.071, 0.082, 0.092, 0.095, 0.10, 0.11, 0.14, 0.14, 0.14 and 0.18 mg/kg.

Trials on peppers were reported from the USA (GAP: 110 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in eleven trials on peppers (Bell) from the USA matching GAP in rank order (median underlined) were: 0.013, 0.019, 0.022, 0.024, 0.069, 0.090, 0.11, 0.11, 0.13, 0.14 and 0.18 mg/kg.

Chlorantraniliprole residues in chilli peppers in nine trials from the USA matching GAP in rank order were (median underlined): 0.019, 0.035, 0.059, 0.063, 0.066, 0.069, 0.13, 0.21 and 0.41 mg/kg.

The Meeting decided that the trials in tomatoes, sweet and chilli peppers could be used to support a crop group maximum residue level for fruiting vegetables, other than Cucurbits except mushrooms and sweet corn. The Meeting decided to use the data on the crop with the highest residues (chilli peppers) to estimate a maximum residue level for the group.

The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in fruiting vegetables other than cucurbits (except mushrooms and sweet corn) of 0.6 and 0.066 mg/kg respectively.

Leafy vegetables

Trials on lettuce, spinach and mustard greens were reported from Canada and the USA (GAP: 110 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in fourteen trials on lettuce from Canada and the USA matching GAP in rank order were: < 0.01, 0.012, 0.43, 0.55, 1.3, 2.2, 2.4, 3.2, 3.9, 3.9, 4.0, 4.5, 5.3 and 6.2 mg/kg.

Chlorantraniliprole residues in seven trials on spinach from Canada and the USA matching GAP in rank order were: 3.4, 5.6, 6.8, 7.3, 7.4, 8.6 and 8.9 mg/kg.

Mustard greens are classified as a brassica vegetable in the US crop classification system and as a leafy vegetable according to the Codex classification. In considering trials on mustard greens and as explained for Brassica vegetables, the Meeting considered the trials did not comply with GAP of the USA.

The Meeting noted that the registered use of chlorantraniliprole in the USA is for leafy vegetables and decided to recommend a group MRL. The Meeting decided to use the data on the crop with the highest residues (spinach) to estimate a maximum residue level for the group. The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in leafy vegetables of 20 and 7.3 mg/kg respectively.

Celery

Chlorantraniliprole residues in seven trials on celery from Canada and the USA matching GAP (same as for leafy vegetables) in rank order were (median underlined): 0.99, 1.4, 2.1, 2.1, 2.6, 3.6 and

3.6 mg/kg. The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in celery of 7 and 2.1 mg/kg respectively.

Potatoes

Trials on potatoes were reported from Canada and the USA (US GAP: 49–74 g ai/ha, PHI of 14 days and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in twenty-seven trials from the USA matching GAP in rank order were (median underlined): < 0.01 (27) mg/kg.

Uptake of persistent residues from soil may also give rise to residues in potatoes tubers. Maximum residue levels and the potential for residues in succeeding and/or rotational crops are discussed under rotational crops below.

Tree nuts

Trials were available from the USA on residues of chlorantraniliprole in almonds and pecans but were unable to be evaluated as no relevant GAP existed at the time of evaluation.

Cotton seed

Trials on cotton were reported from the USA (GAP: 110 g ai/ha, PHI of 21 days and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in thirteen trials from the USA matching GAP in rank order were (median underlined): < 0.01, 0.016, 0.022, 0.029, 0.031, 0.047, 0.049, 0.054, 0.081, 0.082, 0.083, 0.13 and 0.25 mg/kg.

The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in cotton seed of 0.3 and 0.049 mg/kg respectively.

Animal feedstuffs

Cotton gin-trash

Chlorantraniliprole field trials on cotton were made available to the Meeting from the USA (GAP: 110 g ai/ha, PHI of 21 days and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues on cotton gin-trash were 1.1, 2.4, 3.3, 4.1, 6.4, 12 and 13 mg/kg (fresh weight basis). The Meeting estimated an STMR value for chlorantraniliprole in cotton gin-trash of 4.1 mg/kg.

Almond hulls

The trial data could not be evaluated as no GAP was available.

Rotational crops

Residues of chlorantraniliprole are persistent in soil and may be taken up by following crops. In the USA the total seasonal application rate for crops is 220 g ai/ha. Studies of residues in rotational crops were made available to the meeting where in confined rotational crop studies soil was treated at 300–900 g ai/ha and in field studies bare soil and preceding crops were treated at 200–600 g ai/ha and 220 g ai/ha respectively.

Residues in leafy vegetables were < 0.01 (5) and 0.010 mg/kg in lettuce, < 0.01 (2) and 0.010 mg/kg in spinach and < 0.01 (4) mg/kg in Swiss chard. The levels in leafy vegetables from

rotational crops are adequately covered by the recommendation for leafy vegetables of 20 mg/kg. Similarly residues of chlorantraniliprole in leaves/tops of turnips were < 0.01 (3) mg/kg, in beets < 0.01 (3), 0.015 and 0.034 mg/kg and in radish tops < 0.01, 0.010, 0.030, 0.068, 0.070 and 0.16 mg/kg and are also covered by the recommendation for leafy vegetables.

Residues in root and tuber vegetables grown as follow-crops were < 0.01 (3) mg/kg for turnip roots, < 0.01 (5) mg/kg for beet roots and < 0.01 (5) and 0.010 mg/kg for radish roots. Residues were observed at levels between the LOD and LOQ of the analytical method. Trials on root vegetables for foliar application according to GAP only supported a maximum residue level recommendation for potatoes of 0.01 mg/kg; no data on residues in potatoes grown as follow crops or on the combined effect of potatoes grown in soils containing residues (follow crops) and foliar application were made available to the Meeting. Residues in other root vegetables at harvest after planting as follow-crops were: < 0.01 (13) and 0.010 mg/kg.

Noting the residue data on follow-crops, the Meeting decided to recommend a maximum residue level for root and tuber vegetables of 0.02 mg/kg and an STMR of 0.01 mg/kg. The estimated maximum residue level for residues taken up from soil would accommodate residues arising from foliar application to potatoes.

Residues in follow-crop cereal grains were < 0.01 (3) mg/kg for oats and < 0.01 (8) mg/kg. As residues were observed in grain at levels above the LOD but below the LOQ of the analytical method, the Meeting decided to combine the data on follow-crop cereal grains and recommend maximum residue level and STMR values of 0.02 and 0.01 mg/kg respectively for cereal grain.

Corresponding residues in cereal forage (oat and wheat) were: < 0.01, 0.013, 0.016, 0.020, 0.022, 0.022, 0.031, 0.039, 0.043, 0.052 and 0.083 mg/kg. The Meeting decided to combine the data on forage of follow-crop cereals and recommend STMR and highest residue values of 0.022 and 0.083 mg/kg respectively for forage of cereals.

Residues in cereal hay (oat and wheat) were: < 0.01, 0.015, 0.017, 0.031, 0.043, 0.045, 0.051, 0.058, 0.10, 0.14 and 0.15 mg/kg. The estimated STMR and highest residue values for hay of cereals are 0.045 (or 0.051 mg/kg on a dry weight basis) and 0.15 mg/kg (or 0.17 mg/kg on a dry weight basis) respectively.

Residues in cereal straw (oat and wheat) were: < 0.01, 0.011, 0.014, 0.018, 0.030, 0.032, 0.039, 0.061, 0.078, 0.082 and 0.12 mg/kg. The estimated STMR and highest residue values for straw of cereals are 0.032 (or 0.036 mg/kg on a dry weight basis) and 0.12 mg/kg (or 0.136 mg/kg on a dry weight basis) respectively.

Residues in hay were higher than straw and the Meeting decided to use the hay data on follow-crop cereals and recommend a maximum residue level, STMR and highest residue for straw and hay of cereals of 0.3, 0.051 and 0.17 mg/kg respectively.

Two trials on residues in pulses (soya bean) with residues in seed of < 0.01 (2) mg/kg were available. Residues in forage were 0.027 and 0.041 mg/kg while residues in hay were 0.037 and 0.055 mg/kg. The Meeting considered two trials on pulses grown as rotational crops to be inadequate for the purposes of estimating maximum residue levels, STMRs and highest residues.

No trials on residues in follow-crops were available brassica vegetables, stalk and stem vegetables, legume vegetables, bulb vegetables, pulses, oilseeds, grass/pasture and legume animal feeds.

Fate of residues during processing

The fate of chlorantraniliprole residues has been examined in apples, grapes, plum and cotton processing studies. Processing of tomatoes into purée and paste showed a slight increase of chlorantraniliprole residues in the processed commodities when compared to the RAC. Whilst there was a decrease in residues found in the corresponding juice and ketchup. Apples and grapes showed a

decrease in residues found in the juice, but an increase in pomace, raisins and apple peel. There was a concentration into the hulls of cottonseed. Estimated processing factors and STMR-Ps are summarised below.

Summary of processing factors for chlorantraniliprole residues.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	PF (Mean, median or best estimate)	RAC-STMR (mg/kg)	STMR-P(mg/kg)
Apple	Pomace, dry	9.3 11 12 13	11.5	0.07	0.805
	Juice	< 0.06 < 0.09 < 0.19 < 0.19	< 0.14		< 0.0098
	Purée	0.09 0.09 < 0.19 < 0.19	0.09		< 0.0063
	Sauce	< 0.09 < 0.19 < 0.19 0.27	0.27		0.0189
	Preserves, canned	< 0.06 < 0.09 < 0.19 < 0.19	< 0.14		< 0.0098
Plum	Prune	1.9	1.9	0.015	0.0285
Grape	Pomace dry	6.1 12	9	0.119	1.07
	Juice	0.43 0.46 1.0 1.7	0.73		0.0869
	Raisin	2.7 2.9 4.0 7.1	3.45		0.411
	White wine	< 0.15 < 0.29	< 0.22		0.0262
	Red wine	0.76 1.6	1.18		0.140
Tomato	Canned tomatoes	< 0.2 0.23 0.33 0.65	0.28	0.066	0.0197
	Juice	0.57 0.78 0.89 1.1	0.835		0.0589
	Ketchup	0.72 0.74 1.2 1.6	0.98		0.0691
	Purée	1.2 1.4 1.5 1.7	1.45		0.102
	Paste	0.61 1.1 2.0 2.4	1.55		0.109
	Pomace, wet	1.2 1.4	1.3		0.0916
Cotton	Hulls	2.1	2.1	0.049	0.103
	Meal	0.75	0.75		0.0368
	Oil, refined	0.25	0.25		0.0122

Chlorantraniliprole concentrated in prunes, fruit pomace (apple, grape and tomato), raisins, cotton seed meal and hulls. As the estimated residues for the processed commodities raisins, cotton seed hulls and meal in the table above, are below the maximum residue levels proposed for the raw agricultural commodities the Meeting decided it was not necessary to make recommendations for maximum residue levels for these processed commodities.

The Meeting decided to estimate a maximum residue for chilli pepper (dried) of 5 mg/kg following application of a default dehydration factor of 7 to the estimated maximum residue level of 0.6 mg/kg for chilli pepper (7×0.6 = 4.2 mg/kg).

Farm animal dietary burden

The Meeting estimated the dietary burden of chlorantraniliprole in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed as dry weight.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the animal diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

		Animal dietary burden, chlorantraniliprole, ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	0.45	0.18	0.67[a]
	mean	0.35	0.11	0.48[c]
Dairy cattle	max	0.25	0.15	0.63[b]
	mean	0.09	0.074	0.47[d]
Poultry - broiler	max	0.012	0.007	0.007
	mean	0.012	0.007	0.007
Poultry - layer	max	0.011	0.057[e]	0.007
	mean	0.011	0.020[f]	0.007

[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 and eggs.

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

The chlorantraniliprole dietary burdens for animal commodity MRL and STMR estimation (residue levels in animal feeds expressed on dry weight) are: beef cattle 0.67 and 0.48 ppm, dairy cattle 0.63 and 0.47 ppm and poultry 0.057 and 0.020 ppm.

Farm animal feeding studies

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were dosed with chlorantraniliprole for 28 days at the equivalent of 1, 3, 10 and 50 ppm in the diet. Average residues of chlorantraniliprole in milk for the 3 ppm dose group were < 0.01 (3) mg/kg. Chlorantraniliprole residues in liver and fat were higher than in other tissues. Average residues for tissues for the 3 ppm dosing level (3 animals per dose group) were all < 0.01 mg/kg for liver, fat, kidney and muscle.

The Meeting also received information on the residue levels arising in tissues and eggs when laying hens were dosed with [^{14}C]chlorantraniliprole for 14 days at the equivalent of 10 ppm in the diet. Residues in eggs were 0.308 mg/kg. Of tissues, residues of chlorantraniliprole were highest in liver at 0.0193 mg/kg, followed by skin and fat at 0.0093 mg/kg and muscle 0.0008 mg/kg at 23 h after the last dose.

Animal commodity maximum residue levels

The maximum dietary burden for beef and dairy cattle is 0.67 and 0.63 ppm respectively, so the levels of residues in tissues can be obtained from the 1 ppm feeding level. Maximum residues expected in tissues are: fat, muscle, liver and kidney are 0.0067 mg/kg (0.01×0.67/1) and the mean residue for milk 0.0063 mg/kg. At the 3 ppm dose level, average residues of chlorantraniliprole were 0.015 mg/kg in cream and < 0.01 mg/kg in whole milk (0.025 and 0.005 mg/kg respectively for cream and whole milk for the 10 ppm dose level at day 14). Expected residues in cream are 5× the residues in whole milk or 5×0.0063 = 0.0315 mg/kg. The fat content of cream is 40–60% and the Meeting estimated the mean residue for milk fat to be 2×0.0315 = 0.063 mg/kg.

The Meeting estimated maximum residue levels for meat (from mammals other than marine mammals) 0.01* mg/kg (fat); edible offal (mammalian) 0.01* mg/kg; milks 0.01* mg/kg and 0.01* mg/kg for milk fat.

As no residues are expected at the maximum dietary burden, estimated STMRs are 0 mg/kg for meat (from mammals other than marine mammals), fat (from mammals other than marine mammals), edible offal mammalian, milk and 0.047 mg/kg for milk fat.

The maximum dietary burden for poultry is 0.057 ppm. Maximum residues expected at 23 h after last feeding are: muscle, skin/fat, liver and eggs are 0.0000016, 0.000019, 0.000039 and 0.000616 mg/kg.

The maximum residue levels for poultry meat 0.01* mg/kg (fat); poultry offal 0.01* and eggs 0.01* mg/kg.

The mean dietary burden for poultry is 0.02 ppm. No residues are expected in poultry tissues and eggs of birds at the mean dietary burden. STMRs for poultry meat, skin/fat, edible offal and eggs are all 0 mg/kg.

FURTHER WORK OR INFORMATION

Desirable

Information on residues in follow crops, especially for brassica vegetables, stalk and stem vegetables, legume vegetables, bulb vegetables, pulses, oilseeds, grass/pasture and legume animal feeds.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of chlorantraniliprole has resulted in recommendations for MRLs and STMRs for raw and processed commodities. Consumption data were available for 19 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3.

The International Estimated Daily Intakes for the 13 GEMS/Food regional diets, based on estimated STMRs were 0% (0–0.3%) of the maximum ADI of 2 mg/kg bw (Annex 3). 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 is unnecessary. The Meeting therefore concluded that the short-term intake of chlorantraniliprole residues is unlikely to present a public health concern.