FLUTOLANIL (205)

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EXPLANATION

Flutolanil is a systemic fungicide with protective and curative actions. It was evaluated by JMPR in 2002 for the first time for toxicologically and for residues. The 2002 JMPR allocated an ADI of 0–0.09 mg/kg bw, and ARfD unnecessary. It also determined that the definition of residues should be flutolanil for plant commodities (for compliance with MRLs and for estimation of dietary intake) and flutolanil and transformation products, (containing the 2-trifluoromethylbenzoic acid moiety), expressed as flutolanil, for animal commodities (for compliance with MRLs and for estimation of dietary intake). It recommended a maximum residue level for rice, husked; rice, polished; rice bran, unprocessed; rice straw and fodder, dry; tissues of cattle goats, pigs, sheep and poultry; milks; and eggs.

The current Meeting received information on analytical methods, storage stability, use patterns and supervised trials to support estimation of maximum residue levels for broccoli, cabbage and mustard greens.

RESIDUE ANALYSIS

Analytical methods

The Meeting received information on the analytical method used for the determination of flutolanil which is based on the method XAM-65, LC-MS method, and which was originally developed for analysis of flutolanil and its metabolite M-4 in cotton seed and corn grain. It has been modified for the determination of flutolanil and its metabolite M-4 in Brassica vegetables (Corley, 2009a, b and c).

Flutolanil was extracted from broccoli or mustard green samples with acetone. Samples were partitioned twice with ethyl acetate:dichloromethane (1:9). The top layers were dried down and reconstituted in acetone. Following clean-up on a Florisil column, eluates were dried down and reconstituted in mobile phase. Flutolanil in cabbage samples was extracted with methanol:water (1:1, v/v). The analysis was carried out using LC-MS/MS (electro-spray ionization mode; molecular ion of 324 ($m+H^+$) m/z and product ion of 282 m/z).

The modified XAM-65 method was validated for the determination of residues of flutolanil in broccoli, cabbage and mustard greens at three different fortification levels, 0.05, 0.5 and 5 mg/kg. Recoveries were 96–110%, 97–106% and 83–110% for broccoli, cabbage and mustard greens, respectively. These were all within the acceptable range of 70–110%, with the relative standard deviation below 10% (Table 1).

Table 1 Recovery results obtained for the determination of flutolanil by the modified method XAM65

Matrix	Fortification level (mg/kg)	N	Recoveries (%)				Mean (%)	RSD (%)
Broccoli	0.05	3	109,	110,	97		105	6.9
	0.5	3	103,	101,	96		100	3.6
	5	3	97,	103,	108		103	5.4
Cabbage	0.05	3	105,	102,	103		103	1.5
	0.5	3	102,	104,	106		104	1.9
	5	3	98,	100,	97		98	1.6
Mustard greens	0.05	4	98,	88,	88,	83	89	7.0
	0.5	4	94,	99,	101,	109,	101	6.2
	5	3	92,	103,	100,	110	101	7.4

The calculated limit of detection (LOD), limit of quantification (LOQ) and lowest level of method validation (LLMV) are shown in Table 2.

Table 2 LOD, LOQ and LLMV of the modified method XAM65 for flutolanil in the matrices relevant to the current review

Matrix	LOD (mg/kg)	LOQ (mg/kg)	LLMV (mg/kg)
Broccoli	0.01	0.03	0.05
Cabbage	0.005	0.015	0.05
Mustard greens	0.008	0.02	0.05

Stability of pesticide residues in stored analytical samples

Storage stability studies were conducted on broccoli in conjunction with supervised trials. Flutolanil in the frozen condition was stable up to 569 days at -22–-4 °C (102–114% remaining) in broccoli, 297 days at -29–-10 °C (95–101% remaining) in cabbage and 519 days at -22–-4 °C (107–114% remaining) in mustard greens. The concurrent recovery spike extracted and analysed along with the storage stability samples showed 95% and 111% recoveries for flutolanil. In the supervised residue trial studies, samples were stored frozen for periods shorter than the respective period tested for the storage stability studies. The storage stability data indicate that the compound was stable under the conditions that the samples were held between sampling and analyses (Corley, 2009a, b and c).

Table 3 Stability of flutolanil in frozen Brassica vegetables

Matrix	Fortification level (mg/kg)	Storage (days)	% Remaining		Concurrent recovery (%) [a]
			Actual	Average	
Broccoli	0.5	569 (-22– -4 °C)	114, 102, 104	107 ± 6	111 (at 0.05 mg/kg) 103 (at 5 mg/kg)
Cabbage	0.5	297 (-29– -10 °C)	101, 97, 95	98 ± 5	111 at 0.5 mg/kg
Mustard greens	0.5	519 (-22–-4°C)	114, 107, 112	111 ± 4	98 (at 0.05 mg/kg) 95 (at 5 mg/kg)

[a] Analyses conducted on the same day

USE PATTERNS

The authorized uses relevant to the supervised trials data submitted to the current Meeting are summarized in Table 4.

Table 4 Registered uses of flutolanil in the USA relevant to the residue evaluation by the current Meeting

Crop	Form g ai/L	Application					PHI days
		Method	Rate kg ai/ha	Water L/ha	Timing	No.	
Brassica leafy vegetables (Head and stem Brassica) (Brassica leafy greens) (Turnip greens)	WP 700	In-furrow or Directed spray	0.863	> 28	At planting	1	–
		Soil drench			At planting	1	45
		Banded application directed at plant bases		281–468	Immediately after transplanting	1	

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting considered residue data from supervised field trials conducted in the USA on broccoli, cabbage and mustard greens with flutolanil WP formulation (700 g ai/kg nominal concentration).

Application rates and residue concentrations were reported as flutolanil. Residue concentrations are recorded unadjusted for recoveries or for residue values in control samples. Where multiple samples were taken from a single plot, individual results are reported, and the calculated average concentration (in parentheses) is used for estimation of maximum residue levels. Where trials were conducted in the same location, with the same or similar varieties, same or similar formulations,

and the same equipment, and at the same or similar timing, they are not regarded as independent and only one result from these trials was chosen for the estimation of a maximum residue level.

Residues from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels and they are underlined.

Crop Group	Commodity	Table No.
Brassica vegetables	Broccoli	Table 5
	Cabbage	Table 6
	Mustard greens	Table 7

Brassica vegetables

Broccoli

A total of eleven field trials were conducted across the USA. Each field trial site consisted of one untreated control plot and one treated plot. Common cultural practices were followed to maintain the broccoli crop. Additional maintenance pesticides and fertilizers were used at all of the sites (except CA66) to produce a commercial quality crop. No adjuvants were used in any of the trials. At all the trials, a single ground application directed in a narrow band at the base of the transplants or over the seed furrow was made at the time of seeding or immediately after transplanting. All applications were made using appropriate equipment, and the carrier volume was sufficient to provide adequate dispersal of the test substance. At the NJ34 trial, the treated area was calculated using the narrow band into which the test substance was sprayed instead of using the entire row width. This resulted in an under-application of the test substance by 45% at the NJ34 trial. At all the trials, the untreated samples were harvested before or simultaneously with the treated samples by different people. Samples were harvested using techniques simulating commercial practices. The commercially mature broccoli heads (including stems and jacket leaves) were harvested 56–106 days after the application.

The samples were analysed using the modified XAM-65 method for both Flutolanil (parent) and its metabolite M-4. No detectable residues of flutolanil or M-4 above the lowest level of method validation (0.05 mg/kg) were found in any of the untreated samples. An apparent flutolanil residue of approximately 0.02 mg/kg was found in the untreated control sample from the OH*11 trial. Also, apparent flutolanil residues of approximately 0.01 mg/kg and 0.009 mg/kg (at or below the calculated LOD) were found in the treated samples from the same trial. All other apparent peaks occurring at or around the retention times for flutolanil and M-4 were below the calculated limit of detection for both compounds and well below the lowest calibration standard.

Table 5 Residues of flutolanil in broccoli from supervised trials conducted in the USA in 2006 (Corley, 2009a; PR No. 09263)

Broccoli Year, *Location* (variety)	Application				DAT	Portion analysed	Residues (mg/kg)		Trial ID
	Method	Timing	Rate kg ai/ha	No			Flutolanil [b]	M-4	
2006 Salinas, CA (Patron)	Directed at transplant base	Transplants	848	1	68	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	CA*62
2006 Salinas, CA [a] (Marathon)	Directed at transplant base	Transplants (4–5 leaf stage)	841	1	68	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	CA*63
2006 Salinas, CA [a] (Everest)	Directed at transplant base	Transplants	841	1	76	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	CA*64

Broccoli Year, *Location* (variety)	Application				DAT	Portion analysed	Residues (mg/kg)		Trial ID
	Method	Timing	Rate kg ai/ha	No			Flutolanil [b]	M-4	
2006 Holtville, CA (Triathalon)	Directed at transplant base	Transplant	869	1	98	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	CA65
2006 Irvine, CA (Packman F1)	Directed at transplant base	Seedling	819	1	64	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	CA66
2006 Salisbury, MD (De Cicco)	Directed in narrow band over transplant	Transplant (2 leaf stage)	844	1	62	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	MD11
2006 Bridgeton, NJ (Packman)	Directed at transplant base	Transplant	461	1	54	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	NJ34
2006 Las Cruces, NM (Packman)	Directed at transplant base	Seedling	866	1	83	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	NM07
2006 Willard, OH (Packman)	Directed at transplant base	Transplants	845	1	56	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	OH*11
2006 Aurora, OR (General)	Directed at open seed furrow	Seed (at planting)	864	1	78	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	OR18
2006 Weslaco, TX (Heritage)	Directed at open seed furrow	Seed (at planting)	854	1	106	Flower heads	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	TX25

DAT: days after treatment

[a] Same location.

[b] Average residue concentration in parentheses

Cabbage

A total of nine field trials were conducted across the USA. Each field trial site consisted of one untreated control plot and one treated plot. Common cultural practices were followed to maintain the cabbage crop. Additional maintenance pesticides and fertilizers were used at all of the sites to produce a commercial quality crop. No adjuvants were used in any of the trials. At all the trials, a single ground application directed in a narrow band at the base of the plant or over the seed furrow was made at the time of transplanting or seeding. All applications were made using appropriate equipment, and the carrier volume was sufficient to provide adequate dispersal of the test substance. At all the trials, the untreated samples were harvested before the treated samples. Samples were harvested using techniques simulating commercial practices. The commercially mature cabbage heads were harvested 62–138 days after the application.

The samples were analysed using the modified XAM-65 method for both flutolanil and its metabolite M-4. No detectable residues of flutolanil or M-4 above the lowest level of method validation (0.05 mg/kg) were found in any of the untreated control samples.

Table 6 Residues of flutolanil in cabbage from supervised trials conducted in the USA in 2005 (Corley, 2009b; PR No. 08840)

Cabbage Year *Location* (variety)	Application				DAT	Portion analysed	Residues (mg/kg)		Trial ID
	Method	Timing	Rate kg ai/ha	No			Flutolanil [a]	M-4	

Cabbage Year *Location* (variety)	Application				DAT	Portion analysed	Residues (mg/kg)		Trial ID
	Method	Timing	Rate kg ai/ha	No			Flutolanil [a]	M-4	
2005 Salinas, CA. (Charmant)	Directed at plant base	3–4 leaf stage	842	1	78	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	CA*106
2005 Brighton, CO. (Blue Lagoon)	Directed at plant base	Vegetative	828	1	81	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	CO14
2005 Citra, FL (Bravo)	Directed at plant base	Transplant	853	1	83	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	FL41
2005 Tifton, GA (Primax)	Directed over seed furrow	Seed	853	1	97	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	GA*12
2005 North Rose, NY. (Blue Thunder)	Directed at plant base	3–4 leaf stage	857	1	84	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	NY13
2005 Freeville, NY. (Amtrak)	Directed at plant base	4 leaf stage	807	1	92	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	NY14
2005 Charleston, SC. (Fortuna)	Directed at plant base	Seedling	883	1	85	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	SC*03
2005 Weslaco, TX (Blue Vantage)	Directed over seed furrow	Seed	846	1	138	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	TX*26
2005 Arlington, WI (Blue Vantage)	Directed at plant base	Transplant	862	1	62	Heads (with wrapper leaves)	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	WI19

DAT: days after treatment

[a] Average residue concentration in parentheses

Leafy vegetables

Mustard greens

A total of ten field trials were conducted across the USA. Each field trial site consisted of one untreated control plot and one treated plot. Common cultural practices were followed to maintain the greens (mustard) crop. Additional maintenance pesticides and fertilizers were used at all of the sites to produce a commercial quality crop. No adjuvants were used in any of the trials. At all the trials, a single ground application directed in a narrow band over the seed furrow was made at the time of seeding. All applications were made using appropriate equipment, and the carrier volume was sufficient to provide adequate dispersal of the test substance. At the NC11 & NJ16 trials, the treated area was calculated using the narrow band into which the test substance was sprayed instead of using the entire row width as specified by the protocol. This resulted in an under-application of the test substance by 34% and 74% at the NC11 & NJ16 trials respectively. At all the trials, the untreated samples were harvested before the treated samples. Samples were harvested using techniques simulating some commercial practices. The commercially mature mustard greens mustard were harvested 31–63 days after the application.

The samples were analysed using the modified XAM-65 method. The samples were analysed for both Flutolanil (parent) and its metabolite M-4. The two treated samples from the CA67 trial showed residues of 0.06 and 0.05 mg/kg of flutolanil. Residues of flutolanil and/or M-4 ranging from approximately 0.01 to 0.03 mg/kg were detected in treated samples from some of the trials. However, these residues were well below the LLMV and around or below the calculated LOQ making the

numbers unquantifiable. No detectable residues of flutolanil or M-4 above the lowest level of method validation (0.05 mg/kg) were found in any of the untreated control samples.

Table 7 Residues of flutolanil in mustard greens from supervised trials conducted in the USA in 2006 (Corley, 2009c; PR No. 08760)

Mustard greens Year, *Location* (variety)	Application				DAT	Portion analysed	Residues (mg/kg)		Trial ID
	Method	Timing	Rate kg ai/ha	No			Flutolanil [a]	M-4	
2006 Holtville, CA (Mizuna)	Directed at open seed furrow	Seed (at planting)	868	1	48	Plants	0.05 0.06 (0.055)	< 0.05 < 0.05	CA67
2006 Citra, FL (Florida Broadleaf)	Directed at open seed furrow	Seed (at planting)	879	1	37	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	FL25
2006 Clinton, NC (Southern Giant Curled)	Directed over Seed Furrow	Seed (at planting)	557	1	42	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	NC11
2006 Bridgeton, NJ (Southern Curled)	Directed over Seed Furrow	Seed (at planting)	219	1	41	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	NJ16
2006 Las Cruces, NM (Southern Giant Curled)	Directed at open seed furrow	Seed (at planting)	862	1	54	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	NM08
2006 Willard, OH (Savanna)	Directed over Seed Furrow	Seed (at planting)	843	1	31	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	OH*23
2006 Charleston, SC (Florida Broadleaf Mustard)	Directed over Seed Furrow	Seed (at planting)	859	1	54	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	SC*08
2006 Jackson, TN (Florida Broadleaf)	Directed at open seed furrow	Seed (at planting)	848	1	63	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	TN11
2006 Weslaco, TX (Florida Broadleaf)	Directed at open seed furrow	Seed (at planting)	848	1	46	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	TX*27
2006 Arlington, WI (Florida Broadleaf)	Directed at open seed furrow	Seed (at planting)	845	1	49	Plants	< 0.05 < 0.05 (< 0.05)	< 0.05 < 0.05	WI16

DAT: days after treatment

[a] Average residue concentration in parentheses

APPRAISAL

Flutolanil was evaluated by JMPR in 2002 for the first time toxicologically and for residues. The 2002 JMPR allocated an ADI of 0–0.09 mg/kg bw and ARfD unnecessary. It also determined that the definition of residues should be flutolanil for plant commodities (for compliance with MRLs and for estimation of dietary intake) and flutolanil and transformation products containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil for animal commodities (for compliance with MRLs and for estimation of dietary intake) and recommended a maximum residue level for rice, husked; rice, polished; rice bran, unprocessed; rice straw and fodder, dry; tissues of cattle goats, pigs, sheep and poultry; milks; and eggs.

The current Meeting received information on analytical methods, storage stability, use patterns and supervised trials to support estimation of maximum residue levels for broccoli, cabbage and mustard greens.

Methods of analysis

The Meeting received information on the analytical method used for the determination of flutolanil. Flutolanil in broccoli or mustard green was extracted with acetone and flutolanil in cabbage was extracted with methanol:water (1:1, v/v). Acetone extract or methanol extract was partitioned with ethyl acetate:dichloromethane (1:9) and the top layer was dried down and reconstituted in acetone. Following clean up on a Florisil column, eluates were dried down, reconstituted in mobile phase. The analysis is carried out using LC-MS/MS (electro-spray ionization mode; molecular ion of 324 ($m+H^+$) m/z and product ion of 282 m/z).

This method was found to be suitable for the determination of residues of flutolanil in broccoli, cabbage and mustard greens with recoveries of 83–110%, 97–106% and 83–110%, respectively, for these matrices at fortification levels 0.05–5 mg/kg.

The LOQ was 0.05 mg/kg for broccoli, cabbage and mustard green.

Stability of pesticide residues in stored analytical samples

Storage stability studies were conducted on broccoli in conjunction with supervised trials.

Flutolanil in the frozen condition was stable up to 569 days at -22 to -4 °C (102–114% remaining) in broccoli, 297 days at -29 – -10°C (95-101% remaining) in cabbage and 519 days at -22 to -4 °C (107–114% remaining) in mustard green.

In the supervised residue trial studies, samples were stored frozen for periods shorter than the respective periods tested for the storage stability studies.

Results of supervised residue trials on crops

The Meeting considered residue data from supervised field trials conducted in the USA on broccoli, cabbage and mustard green with a flutolanil WP formulation (700 g ai/kg nominal concentration).

Brassica vegetables

The approved use of flutolanil in the USA on the crop group Brassica leafy vegetables (including Brassica vegetables) consists of one application at a rate of 0.863 kg ai/ha either as an in-furrow or directed spray (minimum of 28 L/ha) or as soil drench at planting (PHI of 45 days), or, when transplanted, as a banded application directed at plant bases immediately after transplanting (281–468 L/ha).

According to the review of information on environmental fate by the 2002 JMPR, flutolanil is strongly adsorbed to most soils and is classified as low mobility through soil.

Broccoli

A total of eleven field trials were conducted across the USA. At all the trials, a single ground application directed in a narrow band at the base of the transplants or over the seed furrow was made at the time of seeding or immediately after transplanting. The commercially mature broccoli heads (including stems, and jacket leaves) were harvested 56–106 days after the application.

Residues of flutolanil in broccoli from trials in accordance with US GAP were all < 0.05 mg/kg (9). The Meeting estimated a maximum residue level of 0.05 * mg/kg. As flutolanil is applied at the time of planting or immediately after transplanting and flutolanil is unlikely to be taken up from soil by crops, the Meeting estimated an STMR of 0 mg/kg.

Cabbages, Head

A total of nine field trials were conducted across the USA. At all the trials, a single ground application directed in a narrow band at the base of the plant or over the seed furrow was made at the time of transplanting or seeding. The commercially mature cabbage heads were harvested 62–138 days after the application.

Residues of flutolanil in head cabbages from trials in matching US GAP were all < 0.05 mg/kg (9). The Meeting estimated a maximum residue level of 0.05* mg/kg. Applying the same rational as for broccoli on soil uptake, the Meeting estimated an STMR of 0 mg/kg. The Meeting also estimated a highest residue of 0 mg/kg for the purpose of calculating livestock dietary burdens.

Leafy vegetables

Mustard greens

A total of ten field trials were conducted across the USA. At all the trials, a single ground application directed in a narrow band over the seed furrow was made at the time of seeding. The commercially mature mustard greens mustard were harvested 31–63 days after the application.

Residues of flutolanil in mustard greens from trials matching US GAP were < 0.05 (7) and 0.055 mg/kg. The Meeting estimated a maximum residue level of 0.07 mg/kg. The Meeting estimated an STMR of 0.05 mg/kg.

Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead Brassicas; and Brassica leafy vegetables

The GAP in the USA covers the crop group Brassica leafy vegetables, including head and stem Brassica, Brassica leafy vegetables and turnip greens. As this GAP involves one application at planting or immediately after transplanting, residues in commodities in this group harvested at their maturity are expected to be very low, as was observed in the trials on broccoli, cabbage and mustard greens.

Consequently, the Meeting decided to extend the recommendations for maximum residue levels of 0.05* mg/kg and STMRs of 0 mg/kg for broccoli and head cabbage to the group Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead Brassicas (VB 0040); and the recommended maximum residue level of 0.07 mg/kg and STMRs of 0.05 mg/kg for mustard greens to Brassica leafy vegetables (VL 0054).

Residues in animal commodities

Estimation of dietary burdens

The Meeting noted that in addition to rice grain, rice bran, rice hulls and rice straw from which dietary burdens were calculated by the 2002 JMPR, cabbages can also be fed to beef and dairy cattle and laying hens. Although both the STMR and highest residue of head cabbages were estimated to be 0 mg/kg and therefore not impacting on animal dietary burden, as the OECD Animal Feeding Table had been revised since the last evaluation, the maximum and mean dietary burdens were re-calculated using the highest residue and STMR/median residue of the above-mentioned commodities on a basis of the updated OECD Animal Feeding Table. The summary of calculated dietary burdens is shown in the following table.

Summary of livestock dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	Mean	max	Mean	max	mean	Max	mean
Beef cattle	0.372	0.372	0.822	0.411	5.83[a]	3.37[b]	4.90	2.64
Dairy cattle	0.372	0.372	0.789	0.584	2.78[c]	1.96[d]	2.24	1.22
Broiler	0.278	0.278	0.189	0.189	0.599	0.599	0.094	0.094
Layer	0.278	0.278	0.094	0.094	0.599[e]	0.599[f]	0.378	0.378

[a] Suitable for estimating maximum residue levels for meat, fat and edible offal of cattle.

[b] Suitable for estimating STMRs for meat, fat and edible offal of cattle.

[c] Suitable for estimating maximum residue level for milk of cattle.

[d] Suitable for estimating STMR for milk of cattle.

[e] Suitable for estimating maximum residue levels for meat, fat, edible offal of poultry.

[f] Suitable for estimating STMRs for meat, fat, edible offal of poultry.

Residues in milk and mammalian tissues

The 2002 JMPR reviewed a cattle feeding study conducted at levels equivalent to 39, 116 and 388 ppm in the feed.

The maximum and mean dietary burdens in cattle were 2.78 and 1.96 ppm of dry matter diet respectively for estimating a maximum residue level and STMR for milk; and 5.83 and 3.37 ppm respectively for estimating maximum residue levels and STMRs for tissues. The maximum residue levels, STMRs and highest residues for relevant commodities of animal origin were estimated using the residue levels in tissues and milk at 39 ppm feeding group.

	Feed level (ppm) for milk residues	Flutolanil* (mg/kg) in milk	Feed level (ppm) for tissue residues	Flutolanil * (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	39	< 0.05	39	< 0.05	2.0	0.79	0.06
Dietary burden and highest residue	2.78	< 0.004	5.83	< 0.007	0.299	0.118	0.009
STMR beef or dairy cattle							
Feeding study [b]	39	< 0.05	39	< 0.05	1.7	0.42	0.05
Dietary burden and mean residue	1.96	< 0.003	3.37	< 0.004	0.147	0.036	0.004

[a] highest residues for tissues and mean residue for milk

[b] mean residues for tissues and mean residue for milk

* From the common moiety method

The Meeting estimated STMRs of 0.147 and 0.036 mg/kg for liver and kidney respectively. As the residues in meat were < 0.05 mg/kg in any of feeding groups, the Meeting confirmed the existing STMR for meat at 0 mg/kg. Since the calculated STMR for milk was less than one tenth of the LOQ, the Meeting decided to use the existing STMR of 0 mg/kg.

The Meeting confirmed the previous maximum residue level recommendations of 0.05* and 0.05* mg/kg for milks and meat (from mammals other than marine mammals), and estimated a maximum reside level of 0.5 mg/kg for edible offal (mammalian) and withdrew the previous recommendations for liver and kidney.

Residues in eggs and poultry tissues

The 2002 JMPR reviewed a chicken feeding study conducted at levels equivalent to 0.78, 2.4 and 7.8 ppm in the feed. The maximum of calculated poultry dietary burden was 0.60 ppm.

At the lowest feeding level in the feeding study, residues from the common moiety method were all < 0.05 mg/kg in the eggs and all tissues tested. As a result the Meeting confirmed the existing maximum residue levels for eggs, poultry meat and poultry, edible offal of 0.05 * mg/kg.

At all feeding levels, residues did not exceed the LOQ of 0.05 mg/kg in eggs, muscle, fat or skin. The Meeting therefore confirmed the previously estimated STMRs of 0 mg/kg for these commodities.

Residues in the liver were below 0.05 mg/kg in the lowest and middle feeding groups but were detected at 0.08, 0.10 and 0.20 mg/kg in the highest feeding group. The Meeting, therefore also confirmed the STMR of 0.05 mg/kg for poultry, edible offal of.

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 and IESTI assessment.

Definition of the residue for plant commodities (for compliance with MRLs and for estimation of dietary intake): flutolanil.

Definition of the residue for animal commodities (for compliance with MRLs and for estimation of dietary intake): flutolanil and transformation products containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil.

The residue is not fat-soluble.

Commodity		Recommended MRL, mg/kg		STMR/STMR-P mg/kg
CCN	Name	New	Previous	
VL 0054	Brassica leafy vegetables	0.07	-	0.05
VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.05*	-	0
MO 0105	Edible offal (mammalian)	0.5	-	Liver, 0.147 Kidney, 0.036
MO 0098	Kidney of cattle, goats, pigs and sheep	W	0.1	
MO 0099	Liver of cattle, goats, pigs and sheep	W	0.2	

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of flutolanil were calculated for the 13 GEMS/Food cluster diets using STMRs estimated by the 2002 and current Meetings (Annex 3). The ADI is 0–0.09 mg/kg bw and the calculated IEDIs were 0–1% of the maximum ADI. The Meeting concluded that the long-term intake of residues of flutolanil resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The 2002 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of flutolanil is unlikely to present a public health concern.

REFERENCES

Code.	Author	Year	Title, Institute, Report reference
09263	Corley, J	2009a	Flutolanil: Magnitude of the Residue on Broccoli
08840	Corley, J	2009b	Flutolanil: Magnitude of the Residue on Cabbage
08760	Corley, J	2009c	Flutolanil: Magnitude of the Residue on Greens (Mustard)