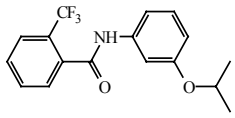
FLUTOLANIL

First draft prepared by Denis Hamilton, Animal and Plant Health Service, Department of Primary Industries, Australia

IDENTITY

ISO common name:	flutolanil
Synonyms:	Moncut, Monarch, NNF-136
Chemical name:	α,α,α-trifluoro-3'-isopropoxy-*o*-toluanilide
IUPAC:	
Chemical Abstracts:	*N*-[3-(1-methylethoxy)phenyl]-2-(trifluoromethyl)benzamide
CAS number:	66332-96-5
CIPAC number:	524
Molecular formula:	$C_{17}H_{16}F_3NO_2$
Molecular mass:	323.3
Structural formula:	

PHYSICAL AND CHEMICAL PROPERTIES

Pure active ingredient

Appearance:	powder
Odour:	slightly chemical
Melting point:	104.7-106.8°C
Relative density:	1.321±0.002 at 20°C
Vapour pressure:	4.1×10^{-7} Pa at 20°C. 1.0×10^{-6} Pa at 25°C
Henry's law constant:	
Solubility in water, 20°C	8.0 mg/l in natural pH range
Solubility in organic solvents, g/l at 20°C:	acetone: 606 g/l acetonitrile: 334 g/l dichloromethane: 378 g/l ethyl acetate: 365 g/l *n*-hexane: 0.395 g/l methanol: 322 g/l *n*-octanol: 42.3 g/l toluene: 35.4 g/l
Octanol/water partition coefficient:	log P_{ow} : 3.17
Hydrolysis (sterile solution):	stable under acidic, neutral and basic conditions

Photolysis in water:	Half-life at 25°C in pH 7 buffer: 150 and 270-300 days with and without photosensitiser

Technical material

Appearance:	solid
Colour	pale yellow-grey
Odour	slightly chemical

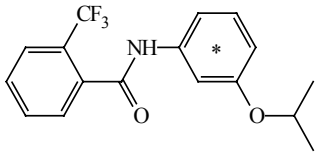
FORMULATIONS

Flutolanil is available in the following formulations:

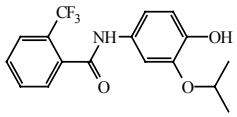
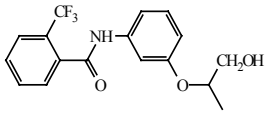
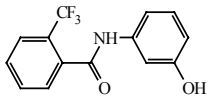
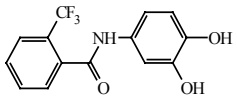
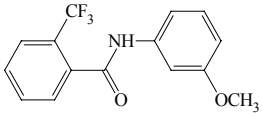
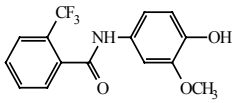
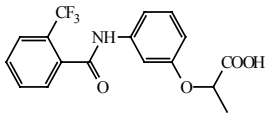
Dustable powder, 15 g/kg
Dustable powder, 20 g/kg
Emulsifiable concentrate, 150 g/l
Granule, 210 g/kg
Granule, 70 g/kg
Suspension concentrate, 200 g/l
Wettable granules, 650 g/kg
Wettable powder, 250 g/kg
Wettable powder, 500 g/kg
Wettable powder, 700 g/kg

METABOLISM AND ENVIRONMENTAL FATE

Flutolanil labelled with ^{14}C in the aniline ring was used in the metabolism studies.



Metabolites are given various abbreviations and code numbers in the studies. These are shown below.

 M-2 (HFT)	 M-3 (HIP)	 M-4 (DIP)	 M-5 (HDP)
 M-6 (MDP)	 M-7 (HMD)	 M-11	

Animal metabolism

The Meeting received reports on studies on rats, lactating goats and laying hens.

Rats. After the oral administration of [^{14}C]flutolanil approximately 57% of the dose was excreted as 3'-hydroxy-2-trifluoromethylbenzanilide (DIP M-4) or its conjugates (Aizawa and Okada, 1982).

Other identified metabolites were 4'-hydroxy-3'-isopropoxy-2-trifluoromethylbenzanilide (HFT M-2) and 4'-hydroxy-3'-methoxy-2-trifluoromethylbenzanilide (HMD M-7).

Goats. ^{14}C residues were measured in the tissues, milk and excreta of two lactating dairy goats weighing 51.5 and 62.5 kg dosed once daily for 4 consecutive days by gelatin capsule containing 0.61 mg/kg of [^{14}C]flutolanil, equivalent to 31-38 ppm in the diet (Hawkins *et al.*, 1991). The goats were milked twice daily and produced approximately 2.1 (goat 1) and 2.3 (goat 2) l/day. The goats were slaughtered 6 (goat 1) and 24 h (goat 2) after the final dose and samples of loin and foreleg muscle, subcutaneous and omental fat, liver, kidney were analysed. The average total recovery of ^{14}C was 102.8%.

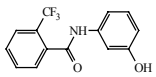
Excretion was fairly slow with 27 and 40% of the administered ^{14}C in the first dose being excreted by both goats in the urine and faeces in the first 24 h. 52% of the administered ^{14}C was recovered in the excreta, milk and cage wash from goat 1 at slaughter 6 h after the final dose and 65% 24 h after the last dose from goat 2. Extracts of the excreta were used for identifying metabolites. The main metabolites in the urine were the sulfate and glucuronide conjugates of M-4 and the glucuronide conjugates of M-7 and M-2.

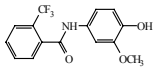
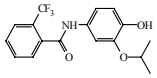
Most of the ^{14}C residue was in the liver, kidney and milk with a very little in the muscle and fat (Table 1). Extracts of liver, kidney and milk were examined by TLC both before and after treatment with glucuronidase and sulfatase to hydrolyse conjugates. Conjugates of M-4 accounted for most of the residue in the milk. In goat 1 (higher residue) most of the residue in the kidneys was accounted for by three identified metabolites present as conjugates. In the liver only 27% of the ^{14}C was identified. 70-80% of the unidentified components in liver and kidney were sulfate or glucuronide conjugates.

Table 1. Distribution of ^{14}C in the tissues and milk of lactating goats after daily oral dosing for 4 consecutive days at a rate of 0.61 mg/kg bw/day of [^{14}C]flutolanil (Hawkins *et al.*, 1991).

Sample	^{14}C as flutolanil, mg/kg or mg/l	
	Goat 1	Goat 2
Liver	0.30	0.11
Kidneys	0.37	0.087
Muscle	0.004	<0.004
Fat	0.043	<0.013
Bile	21	6.7
Milk day 1, evening	0.021	0.023
Milk day 2, morning	0.018	0.024
Milk day 2, evening	0.037	0.027
Milk day 3, morning	0.02	0.032
Milk day 3, evening	0.032	0.039
Milk day 4, morning	0.025	0.026
Milk day 4, evening	0.034	0.04
Milk day 5, morning		0.028

Table 2. Identified metabolites in the milk, liver and kidneys of goats dosed with [^{14}C]flutolanil for 4 consecutive days (Hawkins *et al.*, 1991).

Metabolite	^{14}C as % of total ^{14}C in the extract					
	Milk day 4 evening		Liver		Kidney	
	Goat 1	Goat 2	Goat 1	Goat 2	Goat 1	Goat 2
M-4 conjugates 	83	86	24	14	35	22

Metabolite	^{14}C as % of total ^{14}C in the extract					
	Milk day 4 evening		Liver		Kidney	
	Goat 1	Goat 2	Goat 1	Goat 2	Goat 1	Goat 2
M-7 conjugates 			3.5	-	6.4	6.2
M-2 conjugates 					23	5.2

Laying hens. ^{14}C residues were measured in the tissues, eggs and excreta from four groups of 5 hens weighing 1.5-2.3 kg which had been dosed once a day for 4 consecutive days by gelatin capsule with 0.035 (groups 1 and 2) and 1.0 (groups 3 and 4) mg/kg bw of [^{14}C]flutolanil, theoretically equivalent (assuming feed dry weight consumption is 7% of body weight) to 0.5 and 14 ppm in the diet (Hawkins *et al.*, 1989). Eggs were collected daily, excreta at 24-hour intervals and the hens were killed 6 (groups 1 and 3) and 24 hours (groups 2 and 4) after the last dose for skin/fat, liver, kidneys, breast and thigh muscle samples.

Excretion was rapid with 73 and 88% of the ^{14}C in the first low dose group and 90-106% in the first high-dose was excreted in the first 24 hours. At the completion of the experiment 86-89% of the low dose and 83-100% of the high dose had been excreted within 24 hours. The highest levels in the tissues were in the kidneys and liver (Table 3). Very little residue appeared in the muscle, skin and fat, or eggs. Liver and kidney extracts were investigated in the same way as for goats. Metabolite M-4 was identified by TLC in the kidney extracts as a sulfate or glucuronide conjugate accounting for 46% and 48% of the ^{14}C in the extract for the two doses. The presence of metabolite M-4 as conjugates was also indicated in the liver extracts, but the ^{14}C levels were too low for quantitative assessment.

Table 3. Distribution of ^{14}C in the tissues and eggs of laying hens after oral dosing daily for 4 consecutive days with [^{14}C]flutolanil (Hawkins *et al.*, 1989). Values for the tissues are the means for the groups of 5.

Sample	Radiolabel as flutolanil, mg/kg			
	Dose 0.035 mg kg/bw/day		Dose 1 mg/kg bw/day	
	Group 1 (6 h)	Group 2 (24 h)	Group 3 (6 h)	Group 4 (24 h)
Kidneys	0.009	0.001	0.065	0.010
Liver	0.012	0.008	0.135	0.070
Muscle	<0.001	<0.001	<0.005	<0.005
Skin and fat	0.003	<0.002	0.016	<0.014
Eggs day 1	<0.0007 (7)		<0.0044 (8)	
Eggs day 2	<0.0007 (7)		<0.0044 (6), 0.0044 (1)	
Eggs day 3	<0.0007 (6)		<0.0044 (4), 0.0054 (4)	
Eggs day 4	<0.0007 (3), 0.009 (3)		<0.0044 (2), 0.0068 (2)	

Flutolanil itself is not a component of the residue in animal tissues, milk and eggs. The main identified residue component was metabolite M-4 present as conjugates. The residue is evidently fat-soluble.

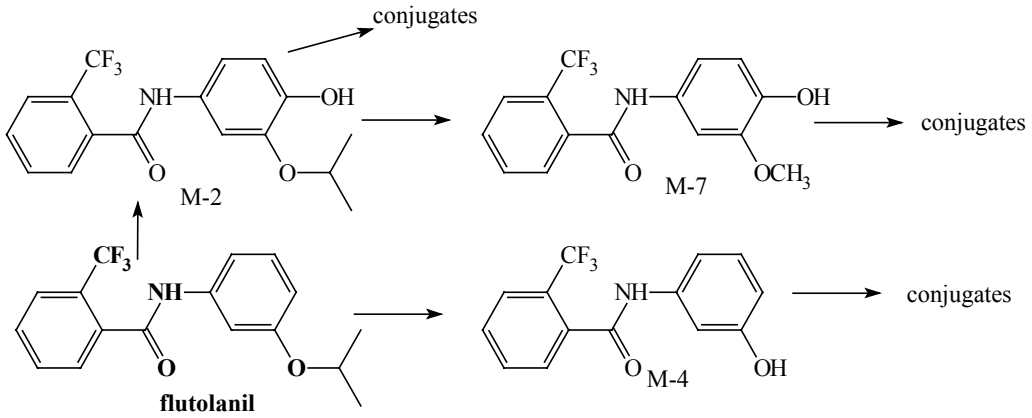


Figure 1. Flutolanil metabolism in animals.

Plant metabolism

Trials on rice, potatoes and peanuts were reported to the present Meeting. Flutolanil was a major part of the identified residue in rice and potatoes. In peanuts, levels of metabolites M-3 and M-4 exceeded those of flutolanil. Residues of flutolanil and its metabolites are readily translocated from treated foliage to other parts of the plant.

Rice. Plants were treated twice with [^{14}C]flutolanil formulated as a WP at the equivalent of 0.56 kg ai/ha 92 and 106 days after planting (Smith *et al.*, 1994). Immature plants were sampled just before the second treatment, and the rice harvested at maturity approximately 30 days after the second treatment. Samples consisted of foliage above and below the water-line and of the seed-head (at maturity including husk and grain).

Most of the residue was extracted as flutolanil with a small percentage of metabolite M-4 (Table 4). The unidentified material was examined to determine the nature of the conjugated residue. As levels in the grain were too low the work was concentrated on the husk and mature foliage from below the water line. Substrates were hydrolysed and partitioned at various pH levels, which released small amounts of flutolanil and metabolite M-4. The remaining small polar and bound ^{14}C residues were not further characterized.

Table 4. Disposition and nature of the residues when [^{14}C]flutolanil formulated as a WP was applied to rice plants at the equivalent of 0.56 kg ai/ha (Smith *et al.*, 1994).

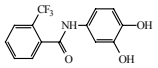
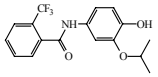
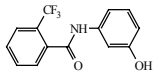
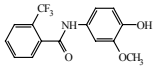
Sample	^{14}C, mg/kg as flutolanil		% of total ^{14}C		
	Total	Extractable	Flutolanil	M-4	Unidentified
Immature foliage below water	0.79	0.83	82	2.1	16
Immature foliage above water	6.1	5.4	94	2.5	3
Immature seed head	0.37	0.40	93	0.9	6
Mature foliage below water	12	10.5	81	0.2	19
Mature foliage above water	20.6	21.6	93	0	7
Husk	7.2	7.4	78	5.3	16
Grain	0.32	0.29	64	2.3	34

Potatoes. Flutolanil may be used directly on seed tubers or as an in-furrow treatment at sowing. A study by Lewis (1999) included four treatments with [^{14}C]flutolanil: (A1) 120 mg ai/kg applied to the surface of the seed potato with harvest of new tubers at maturity 131 days later; (A2) 360 mg ai/kg

similarly applied and harvested, an exaggerated treatment to assist with identifications; (A3) 360 ai/kg similarly applied with harvest of new tubers 52 days later; (B) an SC formulation applied to the row at sowing at 4.5 kg ai/ha with harvest at maturity 132 days later. Acetonitrile solutions of flutolanil were used for the direct treatments. A control group of potatoes was maintained close to the test containers to detect transfer of ^{14}C between plants in different containers via evolved CO_2. No ^{14}C was detected in the controls.

The peel and flesh from treatment A1 were separated and extracted separately. ^{14}C levels in the tubers were 0.014 mg/kg as flutolonil, with 0.008 mg/kg in the flesh and 0.044 mg/kg in the peel. The peel and flesh were combined for subsequent work-up and analysis. Extracts of foliage and tubers were analysed by TLC and HPLC. Water-soluble ^{14}C residues were acid- and base-hydrolysed to release conjugates, which were further examined. The levels of ^{14}C were mostly below 0.1 mg/kg, which made identification difficult. Flutolanil was the main identified component in the tubers. The results are summarized in Table 5.

Table 5. Nature of the residue in potato plants and tubers treated at sowing with [^{14}C]flutolanil (Lewis, 1999).

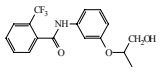
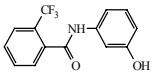
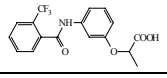
Component of the residue	Treatment A3		Treatment A1	Treatment B
	Foliage, immature	Tuber, immature	Tuber, mature	Tuber, mature
Total ^{14}C, mg/kg as flutolanil	0.295	0.029	0.014	0.12
Flutolanil, % of total ^{14}C	4	57	21	35
M-5, free, % of total ^{14}C 		2		
M-2, conjugated, % of total ^{14}C 	36		8	
M-4, free, % of total ^{14}C 		2		
M-4, conjugated, % of total ^{14}C	7		12	13
M-7, free, % of total ^{14}C 	6			

Peanuts. Flutolanil may be used as a banded spray at 2.2 kg ai/ha. Plants, 64 days after sowing, were treated at 2.2 kg ai/ha with [^{14}C]flutolanil formulated as a WP (Smith Downey *et al.*, 1993). The mature crop was harvested 84 days later and separated into vines, shells and nuts for analysis and identification of the residue (Table 6).

The main identified components were flutolanil and M-4, free or conjugated; traces of metabolites M-3 and M-11 were also identified. Compounds A and B were substantial components and were subjected to further efforts at identification. 10 µg samples of each were isolated and taken through the analytical method containing the trifluoromethylbenzoyl ring (alkaline hydrolysis to trifluorobenzoic acid and methylation for GC-MS analysis). A and B were both fully accounted for (112% and 103%), demonstrating that they still contained both rings of the flutolanil molecule. The EIMS of metabolite A suggested that it was a conjugate of M-4, but no parent ion was discernible. Metabolite B was shown to be related to A, but again no parent ion was seen. Metabolites A and B have not been fully identified, but are likely to be stable conjugates of M-4, and they are determined by the standard residue method.

A substantial part of the residue in the nuts themselves was unidentifiable. Approximately 27% was fibre-bound and much of the remainder (50% of the total) included many minor components each less than 5% of the total. Characterization was unsuccessful.

Table 6. Nature of the residues in peanuts after foliar treatment with [^{14}C]flutolanil 84 days before harvest (Smith Downey *et al.*, 1993).

Component of the residue	Vines	Shells	Nuts
Total ^{14}C as flutolanil	12 mg/kg	3.0 mg/kg	0.39 mg/kg
	Residue expressed as % of total ^{14}C		
Extractable ^{14}C	90	57	73
Flutolanil, free	17	3.4	1.0
Flutolanil, conjugated	1.4	7.8	
M-3, conjugated 			3.3
M-4, free 	3.0	11.7	
M-4, conjugated	10.6	5.0	10.2
M-11, conjugated 	1.0		2.0
Metabolite A	17	5.5	3.3
Metabolite B	20	2.2	0.9
Metabolite C			2.7

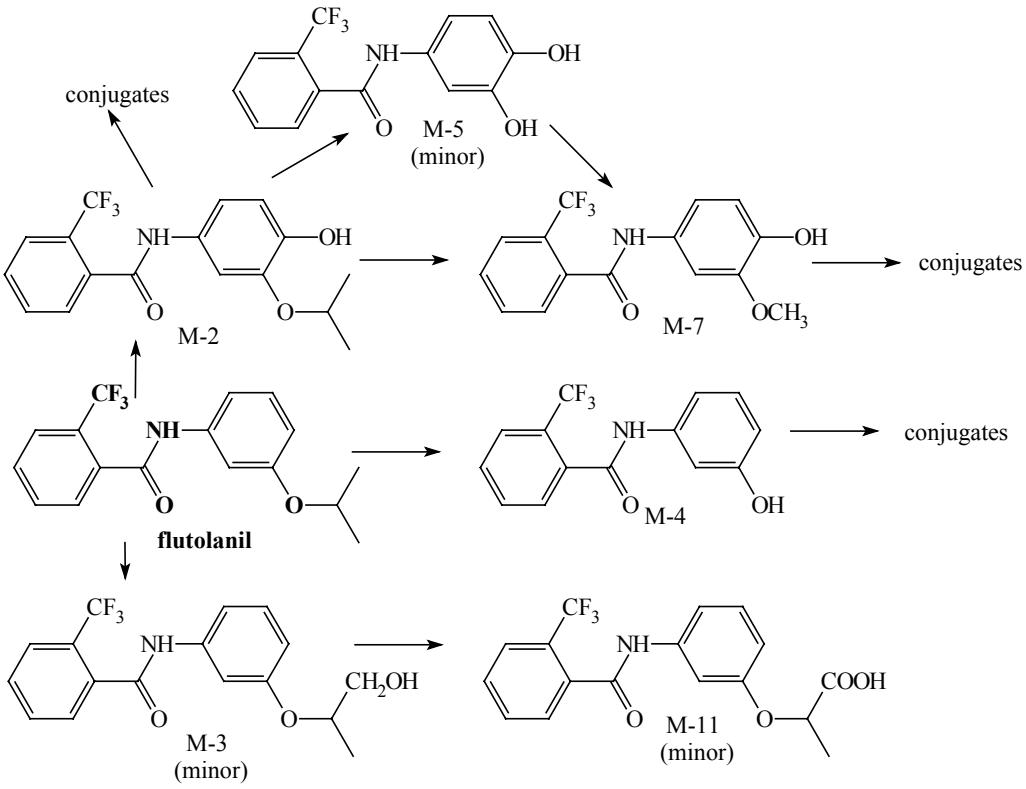


Figure 2. Flutolanil metabolism in plants.

Environmental fate in soil

The Meeting received information on photolysis aerobic degradation in normal and flooded soils (rice paddy) and adsorption-desorption experiments.

Soil photolysis. Carpenter (1991) exposed [^{14}C]flutolanil on an air-dry sandy loam soil (56% sand, 26% silt, 18% clay, 1.6% organic matter, pH 6.8) to a xenon-arc lamp to simulate sunlight for 30 days at 25°C with a 12 h light/12 h dark cycle. The soil depth was approximately 1-2 mm and the [^{14}C]flutolanil dose was 88 µg/g or 22.4 µg/cm^2. Samples were removed after controlled periods of exposure (0, 1, 3, 7, 15, 21 and 30 days) for analysis. The recovery of ^{14}C was in the range 98-119% from irradiated samples and 111-121% from the dark controls. There was no detectable loss of flutolanil throughout the 30 days.

Aerobic degradation. Morgenroth (1993) incubated [^{14}C]flutolanil at a field rate of 9 kg ai/ha (equivalent to 6 mg ai/kg dry soil in the top 10 cm) in a Speyer 2.2 loamy sand (82% sand, 13% silt, 5.1% clay, 2.3% organic carbon, pH 6.0), a Breda sandy loam (74% sand, 14% silt, 12% clay, 2.4% organic carbon, pH 7.1), a Westmaas loam (34% sand, 48% silt, 19% clay, 1.0% organic carbon, pH 7.2) and a St Maartensbrug sand (95% sand, 2.0% silt, 3.5% clay, 0.6% organic carbon, pH 7.4) under aerobic conditions in the dark at 20°C and 100% field capacity moisture for 105 days. Recoveries of ^{14}C, including volatiles, were in the range of 93.6-101.6%. The results are summarized in Table 7.

The half-lives of flutolanil in the soils were 119 days (Speyer 2.2), approximately 380 days (Breda), approximately 150 days (Westmaas) and approximately 400 days (St Maartensbrug). Mineralization was quite slow with 2.9% to 9.9% of the dose released as CO_2 over the 105 days from the four soils. Volatiles other than CO_2 were negligible. After 105 days the unextractable ^{14}C was 24, 14, 28 and 9.4% of the dose respectively.

Table 7. Aerobic degradation of [^{14}C]flutolanil at 6 mg ai/kg on dry soil for 105 days (Morgenroth, 1993).

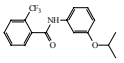
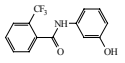
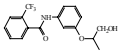
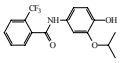
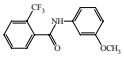
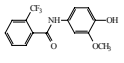
Soil, compound	% of ^{14}C dose						
	Day 0	Day 7	Day 14	Day 28	Day 56	Day 78	Day 105
Speyer 2.2 loamy sand							
Flutolanil	99	94	90	81	70	59	55
CO_2		0.2	1.3	3	4	8.5	9.9
Breda sandy loam							
Flutolanil	99	99	99	94	90	89	82
CO_2		0.2	0.2	0.5	2.4	1.7	2.9
Westmaas loam							
Flutolanil	99	94	93	86	77	70	60
CO_2		0.2	0.4	1	3.3	4.2	5.9
St Maartensbrug sand							
Flutolanil	100	98	95	88	89	87	82
CO_2		0.5	0.4	1.3	2.1	2.9	3.4

Aizawa (1982) studied the fate of [^{14}C]flutolanil under aerobic flooded and upland conditions and identified degradation products on three soils, Tochigi volcanic ash clay loam (53% sand, 25% silt, 22% clay, 16% organic matter, pH 5.4), Saitama alluvial loam (52% sand, 36% silt, 14% clay, 4.9% organic matter, pH 4.8) and Okayama alluvial sandy loam (60% sand, 33% silt, 6.9% clay, 3.1% organic matter, pH 5.3). The soils were pre-conditioned and then treated with [^{14}C]flutolanil at 1.75 mg/kg and maintained at 30°C in the dark under aerobic conditions either flooded to a depth of 0.5 cm or at 60% maximum water capacity. Volatiles including CO_2 were collected. ^{14}C recoveries were in the range 95.3-100.7%.

The levels of flutolanil in the water phase 10 days after treatment were 0.02 and 0.04 mg/l in the three systems, but decreased with time, probably as more flutolanil became adsorbed or bound to the soil. After the incubation period, the systems were extracted and analysed for residual flutolanil and degradation products (Table 8).

Flutolanil constituted the main part of the residue. The main product was DIP (M-4) but it never exceeded 2-3% of the dose. The estimated half-lives in the Tochigi, Saitama and Okayama soils were 160, 300 and 210 days for aerobic flooded and 190, 320 and 300 days for upland conditions respectively, based on the first 90 days.

Table 8. Levels of flutolanil and degradation products in soils treated with [^{14}C]flutolanil at 1.75 mg/kg and maintained at 30°C in the dark under aerobic conditions either flooded or at 60% maximum water capacity (Aizawa, 1982).

	% of applied ^{14}C						
	Flutolanil	DIP (M-4)	HIP (M-3)	HFT (M-2)	MDP (M-6)	HMD (M-7)	CO_2
							
Tochigi soil, aerobic, flooded							
0 days	99						
10	92	0.5	0.2				0.1
30	85	0.6	0.1	0.1			0.1
90	67	0.4	0.1	0.1			3.8
180	57	0.7	0.1	0.1			7.7
Tochigi soil, upland							
0 days	99						
10	94	1.5	0.1	<0.1		<0.1	0.3
30	85	1.7	<0.1	<0.1	0.1	0.3	1.9
90	75	2.2	<0.1	<0.1	0.1	0.1	4.2
180	67	1.5	<0.1		0.1		5.9
Saitama soil, aerobic, flooded							
0 days	98						
10	94	0.7	0.2				<0.1
30	92	1.0	0.1	0.1			0.1
90	81	0.7	<0.1	0.2			1.2
180	70	0.7	0.1	<0.1			2.9
Saitama soil, upland							
0 days	98						
10	94	1.0	0.1	<0.1			0.1
30	91	1.1		0.1	0.1		0.4
90	85	1.5	0.1	0.2	<0.1	0.1	0.2
180	81	1.2	0.1	<0.1	0.2	0.9	0.4
Okayama soil, aerobic, flooded							
0 days	99						
10	93	0.5	0.1	<0.1			0.1
30	88	1.7	0.2	0.3			0.4
90	75	1.3	<0.1	0.4			1.8
180	67	1.6		0.5			3.2
Okayama soil, upland							
0 days	98						
10	96	1.5	<0.1	0.1			0.1
30	90	2.1	<0.1	0.1	<0.1	0.1	0.3
90	81	2.8		0.1	0.2	0.3	2.2
180	79	2.1		0.1	0.4	0.1	3.9

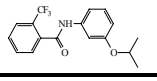
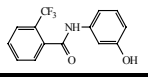
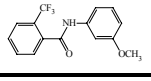
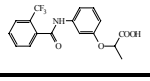
Swanson (1996) incubated [^{14}C]flutolanil at 1.1 mg/kg in a sandy loam soil under aerobic conditions in the dark at 25°C for 365 days and collected volatiles. Samples were analysed at

intervals. ^{14}C recoveries were in the range 96.7% to 101.8%. The sandy loam soil was characterized as 64% sand, 25% silt, 10% clay, 5.6% organic matter and pH 7.4.

The results are summarized in Table 9. Residues associated with the humin fraction had reached 27% of the applied radiolabel by day 365, and approximately 29% had been evolved as CO_2. M-4, M-6 and M-11 always remained as minor parts of the residue, never individually exceeding 5% of the applied ^{14}C or 10% of the flutolanil residue at the time.

The rate of degradation was calculated using a biphasic model, which produced a half-life of 106 days, with estimated half-lives of 21 days for unbound flutolanil and 290 days for sorbed flutolanil.

Table 9. Aerobic incubation of [^{14}C]flutolanil at 1.1 mg/kg in a sandy loam soil in the dark at 25°C (Swanson, 1996).

Incubation, days	Concentrations as % of applied ^{14}C.					
	Flutolanil	M-4	M-6	M-11	CO_2	Unextractable
						
0	98	0	0	0		0.1
14	83	2.2	0.5	0.5	2.2	5.2
30	71	2.0	2.9	1.0	5.2	9.3
63	61	1.3	2.9	1.9	9.6	14
77	56	1.5	3.2	3.2	11	13
92	54	1.3	2.7	2.9	11	15
116	52	0.4	3.2	1.0		
148	41	1.2	3.7	2.5	19	20
212	42	0.4	3.2	1.0		
274	34	0.2	3.0	0.6	23	24
365	27	0.5	2.2	0.9	29	27

Adsorption-desorption. Daly (1997) measured the adsorption and desorption of [^{14}C]flutolanil on a sand, a clay, a Mississippi sediment, a clay loam and a sandy loam soil. Flutolanil was stable in soil over the times required for equilibration. Adsorption measurements were made on 0.01 M $CaCl_2$ solutions of flutolanil (initial concentrations 0.5, 1.0, 2.0 and 4.8 mg/l) in equilibrium with the soils at 25°C in the dark (24 h for the clay loam and sandy loam and 63 hours for the sand, clay and sediment, Table 10). Desorption measurements were made after 20 h shaking at 25°C. Radiolabel ^{14}C recoveries ranged from 91% to 99%.

The K_d values indicate that flutolanil is strongly adsorbed to four of the soils. The exception is the sand with a low organic carbon content. The K_{oc} values fall into the 500-2000 range, classifying the compound as having low mobility.

Table 10. Soil properties, and the adsorption and desorption of flutolanil in 5 soils (Daly, 1997).

Soil	Soil properties						Adsorption		Desorption	
	% sand	% silt	% clay	% organic carbon	pH	CEC, meq/100 g	K_d	K_{oc}	K_d	K_{oc}
Sand	93	3.0	4.0	0.1	6.5	3.8	1.34	1340	6.4	6420
Clay soil	8.0	34	58	1.2	6.7	26	10.6	880	14.4	1200
Mississippi sediment	28	38	34	1.95	7.5	21	10.3	530	14.3	733
Clay loam	26	46	28	2.45	7.8	25	16.0	650	22.6	922
Sandy loam	76	16	8.0	3.1	6.1	11	35.5	1150	48.9	1580

Williams and Berghaus (1992) measured the adsorption and desorption of [^{14}C]flutolanil on five soils (Table 11). Adsorption measurements were made on 0.01 M $CaCl_2$ solutions of flutolanil (initial concentrations 0.5, 1.0, 2.0 and 4.8 mg/l) with equilibrium achieved by shaking for 48 h at 25°C in the dark. Desorption measurements were also made after 48 h shaking at 25°C. ^{14}C recoveries ranged from 94% to 102%. The K_{oc} values again classify flutolanil as having low mobility.

Table 11. Soil properties and adsorption and desorption of flutolanil on 5 soils (Williams and Berghaus, 1992).

Soil	Soil properties						Adsorption		Desorption	
	% sand	% silt	% clay	% organic carbon	pH	CEC, meq/100 g	K_d	K_{oc}	K_d	K_{oc}
Sand	98	2	0	0.17	8.0	11.5	1.0	570	2.8	1600
Loam	50	40	10	0.47	8.0	23.8	2.8	590	3.9	830
Clay loam	28	34	38	2.85	7.4	30.5	13.0	460	18.8	660
Clay loam	22	44	34	0.64	6.2	24.0	4.0	630	5.7	890
Loamy sand	83	13	4	1.57	4.8	6.2	15.8	1005	20.8	1330

Flutolanil on soil is stable to photolysis, and reasonably stable to aerobic and anaerobic degradation, when it remains a major part of the residue. It is classified as having low mobility in soil.

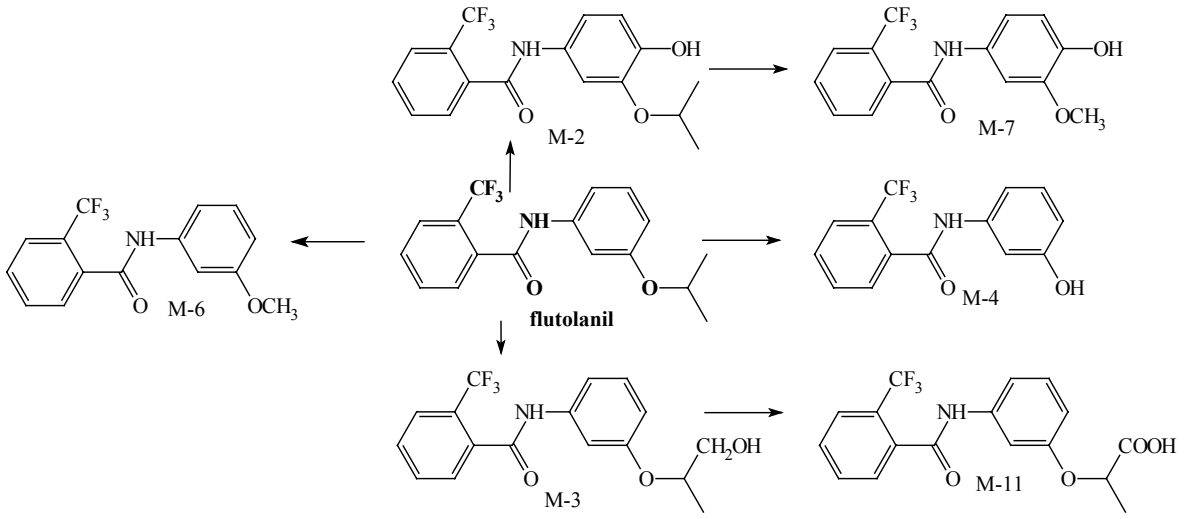


Figure 3. Flutolanil degradation in soil.

Environmental fate in water-sediment systems

The Meeting received information on the fate of flutolanil during hydrolysis in sterile aqueous buffer solutions, photolysis in aqueous solution, and incubation in aerobic and anaerobic water-sediment systems.

Daly and Ediger (1987) measured the hydrolysis of [^{14}C]flutolanil in sterile buffers of pH 5, 7 (two buffers, one based on TRIS (tris(hydroxymethyl)aminomethane) and the other on HEPES (*N*-2-hydroxyethylpiperazine-*N*-2-ethanesulfonic acid) and 9 stored at 25°C in the dark for 30 days. Nominal test concentrations were 4.5 mg/l, with measured values of 3.91, 3.66, 3.75 and 2.97 mg/l.

Samples were taken for ^{14}C and TLC analysis on days 0, 7, 14, 22 and 30. The mean radiolabel recovery was in the range 94-107%. Hydrolysis of flutolanil was insufficient to be observed.

Carpenter and Fennessey (1991) subjected [^{14}C]flutolanil in solution to photolysis for 30 days at 25°C with a xenon lamp with a similar spectral range to sunlight but at about half the intensity, so 24 h of irradiation was taken as equivalent to 12 h of sunlight. [^{14}C]flutolanil was dissolved in an aqueous pH 7 buffer at 3.88 mg/l for the unsensitised and at 3.93 mg/l in pH 7 buffer containing 1% acetone for the sensitised experiment. The photolysis tubes were filled as completely as possible to minimise interactions with air. ^{14}C recovery in the sensitised experiment was 93-100% and in the unsensitised experiment 99-102%. No degradation was observed in the dark controls.

Very little ^{14}C was released as volatiles. The loss of flutolanil is shown in Table 12. The estimated half-life of flutolanil during unsensitised photolysis was approximately 270-290 days, and when sensitised photolysis was rapid in the first three days and then much slower (long term half-life approximately 150 days). Solutions were analysed by TLC and both sensitised and unsensitised photolyses produced polar material that remained at the origin in the TLC systems being used.

Table 12. Degradation of [^{14}C]flutolanil in solution during photolysis with a xenon lamp (Carpenter and Fennessey, 1991).

Sample day	flutolanil as % initial conc	
	Unsensitised	Sensitised
0.00	100	100
1.00	97	92
2.96	98	68
6.95	97	67
13.9	98	67
21.0	94	62
30.0	92	61

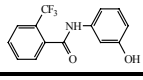
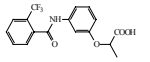
Bashir (1991) investigated polar material produced in the acetone-sensitised photolysis of [^{14}C]flutolanil in the above experiment. Flutolanil and 3 zones of polar material on the TLC plate accounted for most of the radiolabel. The polar zones were further purified and examined by radio-LC-MS. The spectra suggested artefacts formed by reaction of flutolanil with acetone and the TRIS buffer, which would not occur in the natural environment and so were not investigated further.

Wyss-Benz (1993) incubated [^{14}C]flutolanil in two aerobic water-sediment systems: pond water-sediment (85% sand, 11% silt, 4.3% clay, 0.15% organic carbon, pH 7.2), and ditch water-sediment (23% sand, 51% silt, 26% clay, 2.1% organic carbon, pH 6.7) in the dark at 20°C for 105 days. Dosing was equivalent to a field application rate of 20 kg ai/ha with a 1% drift rate to a ditch of 25 cm depth. Each system consisted of 530 ml of the water and 250 g or 200 g of wet sediment in one-l metabolism flasks: a sediment height of about 2 cm and a water column of about 6 cm. A dose of 46.3 µg [^{14}C]flutolanil was applied to each system. ^{14}C recoveries were in the range 93-102%.

Over the 105 days the radiolabel generally continued to partition from the water to the sediment phase (Table 13). Mineralisation was slow, with only 5.2% and 3.7% occurring by the conclusion of the experiments. Flutolanil itself was reasonably persistent with estimated half-lives of 90 days and 240 days in the pond and ditch systems respectively. The unextractable radiolabel reached 26% and 15% of the dose by 105 days and was found mainly bound to the humin fractions of the sediments. Small amounts of M-4 and M-11 were identified (Table 13). An unidentified product accounted for 3.6 and 2.7% of the doses in the two systems.

Flutolanil was reasonably persistent in the aerobic water-sediment systems. It disappeared by degradation to organic compounds and CO_2 and by degradation and binding to the sediment. At all times flutolanil was a major part of the residue.

Table 13. Distribution of ^{14}C and % representing flutolanil and its degradation products in aerobic water-sediment systems treated with [^{14}C]flutolanil (Wyss-Benz, 1993). Reported values are means of duplicate runs.

Days	Radiolabel as % of dose						
	Water phase	Sediment phase	Flutolanil	CO_2	Unextractable	M-4 	M-11 
Pond							
0	95	5.9	98		1.3	<0.1	
0.25	97	2.8	97	<0.1	0.8		
1	92	3.6	92	<0.1	1.0		
2	80	18	96	<0.1	0.8		
7	74	25	95	<0.1	2.7	<0.1	
14	60	38	88	0.2	5.2		
30	54	43	83	0.6	7.3	2.8	1.8
62	45	47	56	2.7	20	6.8	5.5
105	38	51	45	5.2	26	5.6	8.3
Ditch							
0	98	4.3	101		0.9		
0.25	98	3.2	98	<0.1	0.7		
1	94	2.2	91	<0.1	0.6		
2	72	25	94	<0.1	1.0		
7	38	61	91	0.2	5.2		
14	31	66	90	0.4	3.8		
30	18	79	85	1.2	7.5	0.7	0.8
62	16	81	78	2.6	12.6	2.8	0.9
105	14	78	72	3.7	15	2.4	1.8

Daly (1991) incubated [^{14}C]flutolanil anaerobically in a water-sediment system in the dark at 25°C for 12 months at a nominal dose rate of 5 mg per kg of sediment (initial measured dose 4.2 mg/kg), corresponding to an application rate of 1.1 kg ai/ha in the top 25 mm of sediment. Samples of sediment and water were taken at intervals for analysis. The sediment was a Mississippi clay untreated by pesticides (20% sand, 34% silt, 46% clay, 1.8% organic matter, pH 6.1) and microbiologically active. 100-109% of the ^{14}C was accounted for. A second experiment with a higher dose (50 mg/kg sediment) was set up to facilitate the identification of products. The recovery of ^{14}C in the high-dose experiment was 95-103%.

Flutolanil was degraded slowly and remained the main component of the residue (Table 14). Evolved volatiles, including CO_2, accounted for 0.38% of the dose after 12 months. The residue continually became more associated with the sediment and less with the water. In the higher dose experiment up to 1% of the dose was characterized as M-4 and up to 0.16% as M-5.

Table 14. Distribution of radiolabel and % present as flutolanil in anaerobic water-sediment systems treated with [^{14}C]flutolanil (Daly, 1991).

Time	Radiolabel as % of dose							
	5 mg/kg dose				50 mg/kg dose			
	Water phase	Sediment		% of initial residue as flutolanil	Water phase	Sediment		% of initial residue as flutolanil
		extractable	unextractable			extractable	un-extractable	
0 days	51	49	0.3	94				
14 days	14	83	3.3	81				
1 month	16	93	3.6	94				
2 months	14	84	4.4	95				
3 months	8.6	84	8.0	82	14	87	3.1	92
4 months	7.8	92	4.8	85				
6 months	7.3	89	5.5	93	9.2	79	7.5	80
9 months	6.2	96	7.7	94	9.6	85	8.1	83
12 months	0.3	100	8.1	97	8.7	86	6.0	90

Flutolanil was stable to hydrolysis and photolysis in buffered aqueous solutions and reasonably stable in aerobic and anaerobic water-sediment systems.

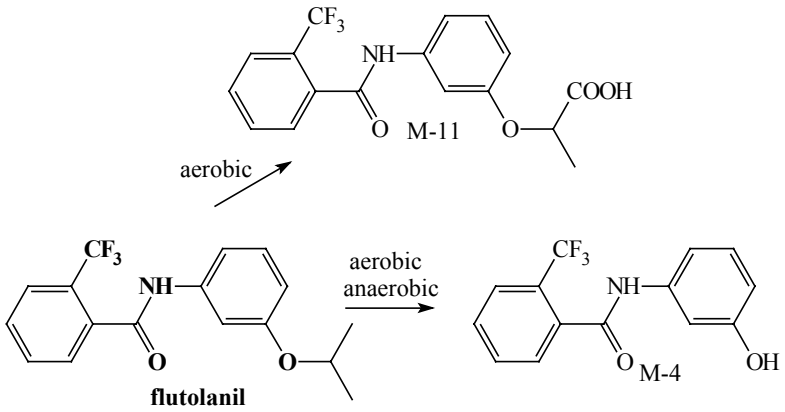


Figure 4. Degradation of flutolanil in water-sediment systems.

RESIDUE ANALYSIS

Analytical methods

The Meeting received descriptions, with validation data, of analytical methods for flutolanil and its metabolites. Methods used in the Japanese trials on rice measured intact flutolanil and M-4 separately. A common moiety method was used in the USA for crops, animal tissues, eggs and milk which converts flutolanil and its metabolites to methyl trifluoromethylbenzoate for measurement by GLC.

In a GLC method described by Goto (1981) to determine residues of flutolanil in apples, brown rice and rice straw, samples are finely milled and extracted with acetone in a homogeniser for several minutes, then the mixture is shaken for 15 minutes, filtered and evaporated. The residue is taken up in acetone, water and a solution of ammonium chloride in phosphoric acid, to be filtered again through Celite. Saturated sodium chloride is then added to the filtrate which is extracted with

hexane, the hexane is evaporated, and the residue dissolved in benzene with clean-up on a silica gel column, eluted with ethyl acetate in benzene. The eluate is evaporated and the residue dissolved in a small volume of acetone for GLC with an NPD. Recoveries from this method and subsequent modifications are summarized in Table 15. The method used by Kaneuchi (1991) was similar, but details of solvents, clean-up columns etc. were different.

Goto (1983) described some variations including an extra procedure for the determination of metabolite M-4. After the hexane extraction of the solution treated with saturated sodium chloride, the solution is extracted with dichloromethane to recover M-4, which is evaporated and the residues methylated with methyl iodide and sodium hydride in DMSO and benzene. Standard M-4 is methylated in the same way. Dilute HCl and hexane are added to the reaction tube, which is shaken vigorously and the hexane layer analysed by GLC (Table 15).

Table 15. Analytical recoveries of flutolanil and metabolite M-4 from various spiked substrates using methods described by Goto (1981, 1983) and modifications.

Crop	Analyte	Spike conc, mg/kg	No.	Mean recovery, %	Recovery range, %	Ref
Apple	flutolanil	0.1	2		92, 93	Goto, 1981
Brown rice	flutolanil	0.2	2		90 97	Goto, 1981
Brown rice	flutolanil	0.1	2		96 96	Goto, 1983
Brown rice	flutolanil	0.1	2		97 100	Goto, 1984
Brown rice	flutolanil	0.1	2		95 100	Goto, 1985
Brown rice	flutolanil	0.1	2		89 87	Goto, 1988
Brown rice	flutolanil	0.2	4	91	89-92	Hirano and Kaneuchi, 1994
Brown rice	flutolanil	0.4	4	92	90-93	Ishibashi et al. 1995
Brown rice	flutolanil	0.2	4	86	84-89	Kaneuchi, 1991
Brown rice	flutolanil	0.2	3	94	91-97	Kaneuchi, 1992
Brown rice	flutolanil	0.4	2		76 75	Komatsu and Yabusaki, 1991
Brown rice	flutolanil	0.4	4	99	95-102	Komatsu and Yabusaki, 1996
Brown rice	flutolanil	0.4	2		98 96	Matano and Odanaka, 1994
Brown rice	M-4	0.1	2		78 78	Goto, 1983
Brown rice	M-4	0.1	2		85 93	Goto, 1984
Brown rice	M-4	0.1	2		98 95	Goto, 1985
Rice straw	flutolanil	0.4	2		90 90	Goto, 1981
Rice straw	flutolanil	0.2	2		108 98	Goto, 1983
Rice straw	M-4	0.4	2		74 75	Goto, 1983

Wiens (1998) validated the common moiety method for residues of flutolanil and its metabolites convertible to 2-trifluoromethylbenzoic acid. The details of the extraction and base hydrolysis depend on the substrate while the methylation and GLC are largely independent of the substrate.

Rice and whole peanuts are extracted with acetone. Peanut kernels are extracted with acetone+acetonitrile+water, animal fat with acetonitrile+hexane, and the extracts concentrated for base hydrolysis. This is in Teflon culture tubes with screw caps, and requires heating with 50% w/w NaOH at 200°C for 3-4 hours. The cooled reaction mixture is transferred to a separating funnel with water, acetone and sulfuric acid, where the residue is partitioned from the aqueous layer (pH 1) into dichloromethane, then methylated with a mixture of methyl iodide and tetrabutylammonium hydroxide for GC-MSD analysis. Whole milk, eggs and animal tissues other than fat are hydrolysed directly.

Wiens described difficulties experienced during the testing of the method. The vigorous hydrolysis was a critical step and very poor recoveries were easily obtained. The high temperature

tended to distort the reaction tubes resulting in leakage around the cap. The tube holder had to be exactly the right size. Too much fat in a sample would also reduce recoveries, while for fat-free samples an olive oil keeper was needed. Yield in the methylation step was poor for some samples, possibly influenced by the amount of reagent and whether it was fresh or aged. The recoveries shown in Table 16 are final values achieved after considerable testing and adjustment.

Bowman (1992) validated the common moiety method for flutolanil residues in rice grain and bran. Samples are Soxhlet-extracted with acetone, and the solvent evaporated to leave a residue for hexane-acetonitrile partition clean-up. The residue is then hydrolysed with 50% NaOH at 200°C in a tightly sealed teflon tube for 3 hours. After cooling and acidification the resulting 2-trifluoromethylbenzoic acid is extracted into toluene, and the extract cleaned up on a diol cartridge, evaporated to a small volume, methylated with diazomethane and further cleaned up on a NH_2 cartridge for analysis by GC-MS. The free acid is fairly volatile and the methyl ester quite volatile; both are easily lost during evaporation. The method was tested at fortifications of 2 and 10 mg/kg. Recoveries of flutolanil and M-4 are summarized in Table 16.

Table 16. Analytical recoveries of flutolanil and metabolites from various spiked substrates by the common moiety method.

Sample	Analyte	Spike conc, mg/kg	No.	Mean recovery, %	Recovery range, %	Ref
Beef fat	flutolanil	0.05, 0.50	4	76	75-79	Wiens, 1998
Beef fat	M-2	0.05, 0.50	8	74	65-80	Wiens, 1998
Beef fat	M-4	0.05, 0.50	8	69	58-75	Wiens, 1998
Beef fat	M-7	0.05, 0.50	4	73	68-81	Wiens, 1998
Beef muscle	flutolanil	0.05, 0.25	4	85	77-93	Wiens, 1998
Beef muscle	M-2	0.05, 0.25	4	88	85-90	Wiens, 1998
Beef muscle	M-4	0.05, 0.25	4	91	90-92	Wiens, 1998
Beef muscle	M-7	0.05, 0.25	4	93	88-101	Wiens, 1998
Egg	flutolanil	0.05, 0.25	4	83	80-86	Wiens, 1998
Egg	M-2	0.05, 0.25	4	83	81-88	Wiens, 1998
Egg	M-4	0.05, 0.25	4	75	72-78	Wiens, 1998
Egg	M-7	0.05, 0.25	4	90	77-100	Wiens, 1998
Milk	flutolanil	0.05, 0.25	4	87	73-112	Wiens, 1998
Milk	M-2	0.05, 0.25	4	79	74-89	Wiens, 1998
Milk	M-4	0.05, 0.25	4	87	74-101	Wiens, 1998
Milk	M-7	0.05, 0.25	4	91	85-101	Wiens, 1998
Peanut hay	flutolanil	7.5, 50	4	79	73-83	Wiens, 1998
Peanut hay	M-3	7.5, 50	12	74	57-114	Wiens, 1998
Peanut hay	M-4	7.5, 50	4	106	86-115	Wiens, 1998
Peanut kernel	flutolanil	0.40, 1.2	4	79	76-83	Wiens, 1998
Peanut kernel	M-3	0.40, 1.2	16	73	62-90	Wiens, 1998
Peanut kernel	M-4	0.40, 1.2	12	65	58-79	Wiens, 1998
Rice grain	flutolanil	0.20, 2.0	4	73	69-77	Wiens, 1998
Rice grain	M-4	0.20, 2.0	12	58	39-99	Wiens, 1998
Rice bran	flutolanil	2.0, 10	4	87	82-92	Bowman, 1992
Rice bran	M-4	2.0, 10	4	86	81-88	Bowman, 1992
Rice grain	flutolanil	2.0, 10	4	83	73-89	Bowman, 1992
Rice grain	M-4	2.0, 10	4	74	68-83	Bowman, 1992

Stability of residues in stored analytical samples

The Meeting received information on the stability of flutolanil and its metabolites in rice commodities during freezer storage of analytical samples.

Finely ground rice grain and straw were fortified separately with flutolanil and metabolite M-4 (desisopropyl-flutolanil) at 1 mg/kg (grain) and 20 mg/kg (straw) and stored in 20 g aliquots in glass

jars in a freezer at -20°C for 31 months (Neal, 1993). Flutolanil and M-4 were Soxhlet-extracted with acetone, the extract evaporated, and the residue taken up in acetonitrile and washed with hexane to remove oils. The extract was evaporated to dryness and hydrolysed with NaOH at 200°C for 3 hours, converting the residues to 2-trifluoromethylbenzoic acid which was methylated with diazomethane for GC-MS determination.

Flutolanil and M-4 residues were stable in frozen rice decreasing by about 30% after 700-900 days. In rice straw flutolanil decreased by approximately 30% in 15 months, and M-4 did not decrease during the 31 months. It should be noted that these results refer to the stability of the trifluoromethylbenzoic acid moiety, not necessarily the intact flutolanil or M-4.

Table 17. Freezer storage data for rice grain and straw samples treated with flutolanil and metabolite M-4 and stored for 31 months in the dark at a nominal -20°C (Neal, 1993).

Storage, days	Stored, mg/kg	Procedural recovery %	Storage, days	Stored, mg/kg	Procedural recovery %
Flutolanil - grain			Flutolanil - straw		
126	1.08 0.87 1.17	121	129	24.6 24.2 19.9	94 113
391	0.94 0.98 0.98	91 94	437	15.8 17.4 16.7	79 81
699	0.68 0.79 0.72	67 79	702	15.2 13.3 14.8	71 73
931	0.61 0.79 0.72	79 71	953	13.3 12.4[1]	67 68
Estimated time for 30% decrease: 22 months			Estimated time for 30% decrease: 15 months		
M-4 - grain			M-4 - straw		
126	1.07 1.08 1.11	119 121	129	16.3 25.6 20.6	126 108
399	0.79 0.77 0.83	80 87	447	16.2 17.2 16.0	86 88
699	0.59 0.70 0.61	73 80	702	13.8 13.7 14.6	76 77
931	0.76 0.76 0.72	70 85	953	16.3 16.1 17.6	88 93
Estimated time for 30% decrease: 23 months			Estimated time for 30% decrease: >31 months		

[1] values not accepted because average procedural recovery <70%

The stability of flutolanil in brown rice during storage was tested during the supervised residue trials in Japan. Ground samples from the control plot were spiked with flutolanil when the samples arrived at the laboratory, then analysed at the same time as the treated samples, giving a measure of the storage stability of the residues (Table 18).

Table 18. Freezer storage stability of flutolanil in spiked brown rice samples analysed by the method described by Goto (1981) with subsequent variations.

Spike conc, mg/kg	Temp	Date spiked	Date analysed	Interval, days	% residue remaining	Ref
0.1	-10°C	6-Oct-86	17-Aug-87	315	102 96	Goto, 1988
2.0	-20°C	26-Nov-90	28-Jan-91	63	99 98	Komatsu and Yabusaki, 1991
2.0	-20°C	14-Dec-90	28-Jan-91	45	102 96	Komatsu and Yabusaki, 1991
0.2	-20°C	1-Nov-91	14-Feb-92	105	90 93	Kaneuchi, 1992
0.2	-20°C	1-Oct-93	10-Feb-94	132	96 91	Hirano and Kaneuchi, 1994
0.4	-20°C	6-Oct-93	13-Apr-94	189	94 93	Matano and Odanaka, 1994
0.4	-20°C	20-Oct-93	13-Apr-94	175	90 90	Matano and Odanaka, 1994
0.4	-20°C	26-Oct-93	13-Apr-94	169	99 93	Matano and Odanaka, 1994
0.4	-20°C	25-Nov-93	13-Apr-94	139	94 93	Matano and Odanaka, 1994
0.2	-20°C	3-Dec-93	10-Feb-94	69	97 100	Hirano and Kaneuchi, 1994
1.0	-20°C	26-Sep-95	10-Apr-96	197	93 90	Komatsu and Yabusaki, 1996
1.0	-20°C	7-Dec-95	10-Apr-96	125	91 89	Komatsu and Yabusaki, 1996

Definition of the residue

Flutolanil itself was not identified as a component of the residue in tissues, milk or eggs. The main identified component in the milk, liver and kidneys of dosed dairy cows was metabolite M-4 present as sulfate and glucuronide conjugates. Levels in muscle and fat were very low and the residue should not be classed as fat-soluble. In laying hens the main identified residue in kidneys and liver was metabolite M-4 as conjugates, and levels in muscle, skin and fat, and eggs were very low.

Flutolanil itself was the main identified residue in treated rice and potatoes.

Two analytical methods for flutolanil residues are available: the first measures intact flutolanil and M-4 separately; the second is a common moiety method for flutolanil and metabolites convertible to 2-trifluoromethylbenzoic acid which uses a very vigorous hydrolysis step (50% NaOH at 200ºC for 3-4 hours) and it is difficult to obtain good recoveries although this method better covers those situations in which flutolanil itself is not a major part of the residue, as in animal commodities.

The Meeting preferred an analytical method for enforcement purposes that measures intact flutolanil and decided that the parent compound only would be a suitable definition of the residue in crops for enforcement purposes. Because flutolanil is a major part of the residue in rice it is also a suitable definition for risk assessment.

In animal commodities flutolanil is not present and the common moiety method is necessary to measure levels of the identified residue. The Meeting decided that the residue measured by the common moiety method would be suitable for enforcement and risk assessment for animal commodities.

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 classed as fat-soluble.

USE PATTERN

Flutolanil is a systemic fungicide with protective and curative action. It is registered for the control of sheath blight (Rhizoctonia solani) in rice and Southern stem rot (white mould) and the limb/pod rot complex in peanuts, as well as for disease control on potatoes, wheat, Japanese butterbur, lettuce, Welsh onion, pear, cucumber, tomato, egg plant, sweet peppers, sugar beet, honeywort, spinach and ginger.

Information on registered uses was reported to the Meeting (Table 19).

Table 19. Registered uses of flutolanil on rice.

Country	%, Form	Application				PHI, days
		Method	Rate, kg ai/ha	Spray conc., kg ai/hl	No.[1]	
China	20 WP		0.33			30
Colombia	20 SC [2]		0.3			
Dominica	50 WP				-	-

Country	%, Form	Application				PHI, days
		Method	Rate, kg ai/ha	Spray conc., kg ai/hl	No.[1]	
Indonesia	25 WP				-	-
Japan	1.5 D [2]	dust	0.45-0.6		3	14
Japan	15 EC [2]	spray		0.010-0.015	3	14
Japan	2 D [2]	dust	0.6-0.8		3	14
Japan	20 SC [2]	aerial or ground	0.17-0.20	0.013-0.020 hv	3	14
Japan	21 G [2]	granules	2.1		3	45
Japan	22 Oil sol.		1.5-2.2		3	54
Japan	25 WP [2]	spray		0.025	3	14
Japan	50 WP			0.020-0.025	3	14
Japan	65 WG [2]	aerial	0.33-0.39	1.0-4.3	3	14
Japan	7 G [2]	apply onto submerged surfaces	2.1-2.8		3	45
Korea	15 EC [2]		0.18-0.24		5	7
Korea	20 SC				-	-
Korea	25 WP				-	-
Malaysia	15 EC [2]			0.03-0.038		14
Malaysia	50 WP [2]			0.03-0.04		14
Panama	20 SC				-	-
Sri Lanka	50 WP				-	-
Taiwan	15 EC				-	-
Taiwan	20 SC				-	-
Taiwan	50 WP [2]			0.020-0.025	3	14
Thailand	25 WP				-	-
Uruguay	50 WP [2]		0.3-0.4		-	14
USA	50 WP[2]	aerial 47-94 l/ha	0.39-0.78		(1.6)	30
USA	70 WP [2]	aerial 47-94 l/ha	0.39-0.55		(1.1)	30
Venezuela	20 SC				-	-

[1] Figures in parentheses maximum kg ai/ha/season
[2] label provided

RESIDUES RESULTING FROM SUPERVISED TRIALS

The Meeting received information on supervised field trials on rice (Tables 21-24).

Table 21	Rice in Japan
Table 22	Rice in the USA
Table 23	Rice straw in Japan
Table 24	Rice straw in the USA

Recent trials were generally well documented with full laboratory and field reports. Information on older trials was supplied in a more summarized form. Laboratory reports included method validation showing batch recoveries with spiking at levels similar to those occurring in samples from the supervised trials. Dates of analyses and/or duration of sample storage were also provided. Although trials included control plots, no control data are recorded in the Tables except when residues in control samples exceeded the LOQ. Results are recorded unadjusted for recoveries.

When residues were not detected they are shown as below the LOQ (e.g. <0.05 mg/kg). Residues, application rates and spray concentrations have generally been rounded to two significant figures or, for residues near the LOQ, to one significant figure. Residue values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels, and are double underlined.

Conditions of the supervised residue trials are summarized in Table 20. Unreplicated plots were used in most trials. In some trials plots were sprayed on different days so that when all plots

were harvested on the same day samples with different PHIs would be available. Most field reports provided data on the sprayer used, plot size, sample size and sampling date.

Periods of freezer storage between sampling and analysis were recorded for all trials. In US rice trials in 1988 analytical samples were stored for approximately 900 days. Freezer storage data were available for 931 days, which showed that the residues may have decreased by approximately 30% during storage. The results were considered acceptable. In all other trials storage periods for analytical samples was less than 15 months.

Residue data in the Japanese trials were produced by an analytical method that measured intact flutolanil, while the data in the US trials were produced by the common moiety method.

Table 20. Sprayers, plot sizes and field sample sizes in the supervised trials on rice.

Country	Year	Sprayer	Plot size	Sample size	Trial design
Japan	1981	knapsack, hanging type sprayer	38, 50 m^2	2 kg	4 plots for 4 PHIs
Japan	1982	power sprayer with gun nozzle, aircraft	0.2, 5.0 ha	1-4 kg	unreplicated plot
Japan	1983		30 m^2	4-5 kg	unreplicated plot
Japan	1984	hanging type sprayer, helicopter	16 m^2 , 6.0 ha	4 kg	unreplicated plot
Japan	1986	knapsack	50 m^2	2 kg	unreplicated plot
Japan	1990	helicopter	0.5 ha		unreplicated plot
Japan	1990	knapsack, shoulder spray	20, 50 m^2	2, 8 kg	unreplicated plots, 4 plots for 4 PHIs
Japan	1991	helicopter	0.5, 0.9 ha		unreplicated plot
Japan	1993	backpack power, duster	8-30 m^2	2 kg	unreplicated plots, 4 plots for 4 PHIs, and duplicate plots
Japan	1994	duster, power applicator	100, 500 m^2	2, 4 kg	unreplicated plot
Japan	1995	knapsack power sprayer	38, 2000 m^2	2 kg	unreplicated plot
USA	1988	fixed wing aircraft	0.02-0.03 ha	1 kg	unreplicated plot
USA	1990	fixed wing aircraft	0.40-0.85 ha	3-7 kg	unreplicated plot
USA	1991	fixed wing aircraft		450 kg	unreplicated plot
USA	1992	backpack CO_2 sprayer		1.5-5 kg	unreplicated plot

Table 21. Flutolanil and metabolite M-4 residues in brown rice resulting from supervised trials in Japan.

Location, year (variety)	Application					PHI	Residues, mg/kg		Ref
	Form	kg ai/ha	kg ai/hl	water, l/ha	no.	days	flutolanil	M-4	
Kumamoto, 1980 (Nankai No. 71)	WP	0.75	0.05	1500	3 [1]	14 21 30 45	0.11 0.15 0.25 0.054		NNC-R-No. 2
Wakayama, 1980 (Nihonbare)	WP	0.75	0.05	1500	3 [1]	17 24 33 48	0.070 0.097 0.21 0.056 c 0.006		NNC-R-No. 2
Fukushima, 1982 (Akihikari)	WP	0.40	0.025	1600	1	62	<0.005	<0.005	NNC-R-No. 7

Location, year (variety)	Application					PHI days	Residues, mg/kg		Ref
	Form	kg ai/ha	kg ai/hl	water, l/ha	no.		flutolanil	M-4	
Fukushima, 1982 (Akihikari)	WP	0.40	5.0	8.0	a 1	62	0.011	<0.005	NNC-R-No. 7
Mie, 1982 (Ozora)	WP	0.40	0.025	1600	1	40	0.051	<0.005	NNC-R-No. 7
Mie, 1982 (Ozora)	WP	0.40	5.0	8.0	a 1	40	0.006	<0.005	NNC-R-No. 7
Ishikawa, 1983 (Koshijiwase)	GR	2.8			3 [1]	30 44 58	0.042 0.034 0.028	0.013 0.012 0.012	NNC-R-No. 14
Kochi, 1983 (Koganenishiki)	GR	2.8			3 [1]	30 45 60	0.044 0.040 0.050 c <0.005	0.009 0.017 0.012 c 0.005	NNC-R-No. 14
Akita, 1984 (Sasanishiki)	SC	0.33	11.0	3.0	a 1	43	0.13	0.021 c 0.005	NNC-R-No. 9
Akita, 1984 (Sasanishiki)	SC	0.33	0.025	1300	1	43	0.17	0.024 c 0.005	NNC-R-No. 9
Iwate, 1984 (Akihikari)	SC	0.33	11.0	3.0	a 1	41	0.049	0.032 c 0.005	NNC-R-No. 9
Iwate, 1984 (Akihikari)	SC	0.33	0.025	1300	1	41	0.17	0.022 c 0.005	NNC-R-No. 9
Ibaraki, 1986 (Koshihikari)	DP	0.6			3 [1]	14 20 30 45	<0.005 0.032 0.033 0.005		NNC-R-No. 18
Kumamoto, 1986 (Nihonbare)	DP	0.6			3 [1]	14 21 30 45	0.006 0.063 0.045 0.020		NNC-R-No. 18
Nagano, 1990 (Yaekogane)	SC	0.20	2.5	8.0	a 3	16	0.31		NNC-R-No. 21
Shizuoka, 1990 (Akitakomachi)	SC	0.20	2.5	8.0	a 3	14	0.12 c 0.006		NNC-R-No. 21
Hiroshima, 1990 (Chuseishinsenbon)	EC	0.23	0.015	1500	3 [1]	14 28 42 56	0.10 0.28 0.08 <0.01		NNC-R-No. 25
Shiga, 1990 (Nihonbare)	EC	0.23	0.015	1500	3 [1]	14 28 42 56	0.04 0.04 0.02 <0.01		NNC-R-No. 25
Nagano, 1991 (Yaekogane)	SC	0.32	4.0	8.0	a 3	14	0.035		NNC-R-No. 24

Location, year (variety)	Application					PHI days	Residues, mg/kg		Ref
	Form	kg ai/ha	kg ai/hl	water, l/ha	no.		flutolanil	M-4	
Shizuoka, 1991 (Kumuhikari)	SC	0.32	4.0	8.0	a 3	15	0.040		NNC-R-No. 24
Ibaraki, 1993 (Koshihikari)	SC	0.17	0.067	250	3	14	0.20		NNC-R-No. 27
Ibaraki, 1993 (Koshihikari)	SC	0.36	0.14	250	3	14	0.31		NNC-R-No. 27
Ishikawa, 1993 (Koshihikari)	SC	0.36	0.14	250	3	14	0.09		NNC-R-No. 27
Ishikawa, 1993 (Koshihikari)	SC	0.17	0.067	250	3	14	0.17		NNC-R-No. 27
Aichi, 1993 (Tsukinohikari)	DP	0.80			3 [1]	14 21 28 35	0.03 0.01 0.02 0.01		NNC-R-No. 28
Chiba, 1993 (Hatsuboshi)	DP	0.80			3 [1]	14 21 28 36	0.20 0.08 0.06 <0.01		NNC-R-No. 28
Hyogo, 1993 (Nihonbare)	DP	0.80			3 [1]	14 21 28 35	0.06 0.08 0.06 0.06		NNC-R-No. 28
Nagano, 1993 (Akibare)	DP	0.80			3 [1]	14 21 28 38	0.18 0.10 0.07 0.04		NNC-R-No. 28
Fukui, 1994 (Hanaechizen)	GR +bags	1× 2.8 +2× 2.0			3	42	0.06 c 0.01		NNC-R-No. 34
Wakayama, 1994 (Hinohikari)	GR +bags	1× 0.2.8 +2× 2.0			3	45	0.03		NNC-R-No. 34
Ishikawa, 1995 (Ishikawashu No. 30)	oil	2.2	pouring from the levee into the water surface of the field		3	50	0.01		NNC-R-No. 39
Aichi, 1995 (Koshihikari)	oil	2.2	pouring from the levee into the water surface of the field		3	43	0.04		NNC-R-No. 39

[1] Treatment schedules adjusted so that all plots were harvested on the same day to give different PHIs.
c: sample from control plot
a: aerial application

Table 22. Flutolanil residues in rice (common moiety method) resulting from supervised trials in the USA.

Location, year (variety)	Application					PHI days	Commodity	Residues, mg/kg	Ref
	Form	kg ai/ha	kg ai/hl	water, l/ha	no.				
TX, 1988 (Gulfmont)	50 WP	0.56		94	a 2	42	whole grain hulled	0.06 <0.05[1]	R642.02.88 TLS-01
LA, 1988 (Gulfmont)	50 WP	0.56		94	a 2	48	whole grain hulled	<0.05 <0.05[1]	R642.02.88 TLS-03
AR, 1988 (Y 7817 RiceTec)	50 WP	0.56		140 +120	a 2	46	whole grain hulled	0.20 0.06[1]	R642.02.88 JDL-01
CA, 1988 (Pearl Medium Grade)	50 WP	0.56		94	a 2	58	hulled	0.07[1]	R642.02.88 JCA-01
AZ, 1990 (Katy)	50 WP	0.56		94	a 2	30	whole whole	0.22 c 0.018[2]	R642.01.90 JDL-01
CA, 1990 (M201)	50 WP	0.56		94	a 2	29	whole	6.2	R642.01.90 DRC-01
LA, 1990 (Lemont)	50 WP	0.56		94	a 2	30	whole	1.1	R642.01.90 TLS-01
LA, 1992 (Lemont)	70 WG	0.58		160	2	30	grain	0.25	AU-92R-01 TLS-01
LA, 1992 (Lemont)	70 WG	0.58		160	2	29	grain	1.7	AU-92R-01 TLS-02
MS, 1992 (Lemont)	70 WG	0.62		66 +72	2	30	grain	0.99	AU-92R-01 TLS-03
AR, 1992 (New Bonnet)	70 WG	0.58		62 +69	2	31	grain	1.7	AU-92R-01 JDL-01
AR, 1992 (New Bonnet)	70 WG	0.58		93	2	30	grain	0.62	AU-92R-01 JDL-02
TX, 1992 (Gulfront)	70 WG	0.62		120	2	30	grain	1.3	AU-92R-01 JDL-03
TX, 1992 (Gulfront)	70 WG	0.57		120	2	30	grain	1.4	AU-92R-01 JDL-04

[1] Samples stored in freezer for approximately 900 days
[2] R642.01.90 JDL-01 report states that treated and control samples appear to have been inadvertently switched in the field.
a: aerial application

Table 23. Flutolanil and M-4 residues in rice straw resulting from supervised trials in Japan.

Location, year (variety)	Application					PHI days	Residues, mg/kg		Ref
	Form	kg ai/ha	kg ai/hl	water, l/ha	no.		flutolanil	M-4	
Kumamoto, 1980 (Nankai No. 71)	WP	0.75	0.05	1500	3 [1]	14 21 30 45	4.8 3.3 2.2 0.50 c 0.06		NNC-R-No. 2
Wakayama, 1980 (Nihonbare)	WP	0.75	0.05	1500	3 [1]	17 24 33 48	8.4 7.4 0.96 0.33		NNC-R-No. 2
Mie, 1982 (Ozora)	WP	0.40	0.025	1600	1	40	0.92	0.17	NNC-R-No. 7
Mie, 1982 (Ozora)	WP	0.40	5.0	8.0	a 1	40	0.44	0.02	NNC-R-No. 7
Fukushima, 1982 (Akihikari)	WP	0.40	0.025	1600	1	62	1.0 c 0.78	0.06 c 0.02	NNC-R-No. 7
Fukushima, 1982 (Akihikari)	WP	0.40	5.0	8.0	a 1	62	3.2 c 0.78	0.16 c 0.02	NNC-R-No. 7

[1] Treatment schedules adjusted so that all plots were harvested on the same day to give different PHIs.
c: sample from control plot
a: aerial application

Table 24. Flutolanil residues in rice straw (common moiety method) resulting from supervised trials in the USA.

Location, year (variety)	Application					PHI days	Residues, mg/kg	Ref
	Form	kg ai/ha	kg ai/hl	water, l/ha	no.			
AZ, 1990 (Katy)	50 WP	0.56		94	a 2	30	1.3 c 0.18 [1]	R642.01.90 JDL-01
CA, 1990 (M201)	50 WP	0.56		94	a 2	29	6.4	R642.01.90 DRC-1
LA, 1990 (Lemont)	50 WP	0.56		94	a 2	30	3.8 4.4	R642.01.90 TLS-01
LA, 1992 (Lemont)	70 WG	0.58		160	2	30	1.0	AU-92R-01 TLS-01
LA, 1992 (Lemont)	70 WG	0.58		160	2	29	5.7	AU-92R-01 TLS-02
MS, 1992 (Lemont)	70 WG	0.62		66 +72	2	30	7.4	AU-92R-01 TLS-03
AR, 1992 (New Bonnet)	70 WG	0.58		62 +69	2	31	0.95	AU-92R-01 JDL-01
AR, 1992 (New Bonnet)	70 WG	0.58		93	2	30	3.6	AU-92R-01 JDL-02
TX, 1992 (Gulfront)	70 WG	0.62		120	2	30	3.8	AU-92R-01 JDL-03
TX, 1992 (Gulfront)	70 WG	0.57		120	2	30	3.1	AU-92R-01 JDL-04

[1] R642.01.90 JDL-01 report states that treated and control samples appear to have been inadvertently switched in the field.
a: aerial application

Table 25. Residue interpretation Table for flutolanil residues in rice. The commodity in the Japanese trials is brown rice and in the US trials whole rice.

Country	Use pattern				Trial	flutolanil, mg/kg
	kg ai/ha	kg ai/hl	no.	PHI days[1]		
Japan GAP	2.1-2.8 GR		3	45		
Japan	2.8 GR		3	60 (45)	NNC-R-No. 14	0.050
Japan	2.8 GR		3	44	NNC-R-No. 14	0.034
Japan	2.8 GR + 2× 2.0 bags		3	42	NNC-R-No. 34	0.06
Japan	2.8 GR + 2× 2.0 bags		3	45	NNC-R-No. 34	0.03
Japan GAP	0.45-0.6 DP		3	14		
Japan	0.6 DP		3	30 (14)	NNC-R-No. 18	0.033
Japan	0.6 DP		3	21 (14)	NNC-R-No. 18	0.063
Japan	0.8 DP		3	14	NNC-R-No. 28	0.03
Japan	0.8 DP		3	14	NNC-R-No. 28	0.20
Japan	0.8 DP		3	21 (14)	NNC-R-No. 28	0.08
Japan	0.8 DP		3	14	NNC-R-No. 28	0.18
Japan GAP	0.17-0.20 SC		3	14		
Japan	0.20 SC	2.5	a 3	16	NNC-R-No. 21	0.31
Japan	0.20 SC	2.5	a 3	14	NNC-R-No. 21	0.12
Japan	0.23 EC	0.015	3	28 (14)	NNC-R-No. 25	0.28
Japan	0.23 EC	0.015	3	14	NNC-R-No. 25	0.04

Country	Use pattern				Trial	flutolanil, mg/kg
	kg ai/ha	kg ai/hl	no.	PHI days[1]		
Japan	0.17 SC	0.067	3	14	NNC-R-No. 27	0.20
Japan	0.17 SC	0.067	3	14	NNC-R-No. 27	0.17
Japan GAP	1.5-2.2 oil		3	54		
Japan	2.2 oil		3	50	NNC-R-No. 39	0.01
Japan	2.2 oil		3	43	NNC-R-No. 39	0.04
US GAP	0.39-0.78 WP		a	30		
USA	0.56 WP		a 2	30	R642.01.90 JDL-01	0.22
USA	0.56 WP		a 2	29	R642.01.90 DRC-01	6.2
USA	0.56 WP		a 2	30	R642.01.90 TLS-01	1.1
USA	0.58 WG		2	30	AU-92R-01 TLS-01	0.25
USA	0.58 WG		2	29	AU-92R-01 TLS-02	1.7
USA	0.62 WG		2	30	AU-92R-01 TLS-03	0.99
USA	0.58 WG		2	31	AU-92R-01 JDL-01	1.7
USA	0.58 WG		2	30	AU-92R-01 JDL-02	0.62
USA	0.62 WG		2	30	AU-92R-01 JDL-03	1.3
USA	0.57 WG		2	30	AU-92R-01 JDL-04	1.4

[1] Where PHIs in parentheses are shown, results were available at the PHIs in parentheses, but the residue levels were higher at the longer intervals.
a: aerial application.

Farm animal feeding studies

A trial on lactating dairy cows and one on laying hens, which provided information on likely residues in animal tissues, milk and eggs from residues in the diet, were reported to the Meeting.

Cows. Groups of 3 lactating Holstein cows each weighing 400-600 kg were dosed twice daily by gelatin capsule with flutolanil at 1.6, 4.7 and 16 mg/kg bw/day, equivalent to 39, 116, and 388 ppm in the dry-weight diet, for 28 consecutive days (Campbell, 1994a). Milk was collected each day for analysis. On day 29 two cows from each group were slaughtered within 24 hours of the last dose, and loin, leg and flank muscle, perirenal, omental and somatic fat, liver and kidney samples were analysed. The remaining animal in each group was put on a residue-free diet for a further 7 days before slaughter. Animals consumed approximately 20 kg dry-weight feed each per day.

The tissues and milk were analysed by the method that includes flutolanil and metabolites with the 2-trifluoromethylbenzoic acid moiety, and recoveries determined in milk (flutolanil, M-2, M-4, M-7), cream (flutolanil, M-2, M-7), skimmed milk (flutolanil, M-2, M-4), muscle (M-2), liver (M-4), kidney (M-7) and fat (flutolanil).

Residues did not exceed the LOQ (0.05 mg/kg) in milk or skimmed milk at the 1.6 and 4.7 mg/kg bw/day doses, but were detected in cream on one occasion at the middle dose. At the highest dose residues were found in the milk, cream and skimmed milk (Table 26), but not consistently in the 3 cows within each group.

Residues did not appear in the muscle even at the highest dose. The residues in the kidneys and fat at all dose levels fell below the LOQ (0.05 mg/kg) after 7 days of a residue-free diet. The residues in fat at the medium and high doses were in inverse order to the dosing levels, and were highest and most persistent in the liver after the 7 days on a residue-free diet the levels were still some 40-70% of the levels after the final doses.

Table 26. Flutolanil residues (common moiety method) in the milk and cream of lactating Holstein cows dosed with flutolanil for 28 consecutive days, and then with 1 animal per group on a residue-free diet for 7 days, adjusted for a recovery of 76.3% (Campbell, 1994a).

Day	Flutolanil residues, mg/kg (common moiety method)		
	Dose 1.6 mg/kg bw	Dose 4.7 mg/kg bw	Dose 16 mg/kg bw
Milk			
7			<0.05 0.1 0.06
14			<0.05 0.11 <0.05
21			<0.05 0.08 <0.05
27		<0.05 (3)	0.05 <0.05 0.05
28	<0.05 (3)	<0.05 (3)	<0.05 0.08 <0.05
35	<0.05	<0.05	<0.05
Cream			
7			0.06 0.11 0.08
14			<0.05 0.09 0.08
21			0.07 0.08 0.05
24		<0.05 (2) 0.06	0.07 0.1 0.08
28	<0.05 (3)	<0.05 (3)	0.05 0.1 0.07
35	<0.05	<0.05	<0.05
Skimmed milk			
7			0.05 0.1 0.05
14			<0.05 0.08 0.05
21			0.05 0.08 0.14
24		<0.05 (3)	<0.05 (3)
28	<0.05 (3)	<0.05 (3)	<0.05 0.07 <0.05
35	<0.05	<0.05	<0.05

Table 27. Flutolanil residues (common moiety method) in the tissues of lactating Holstein cows dosed with flutolanil for 28 consecutive days, and then with 1 animal per group on a residue-free diet for 7 days (Campbell, 1994a). The results are adjusted for a recovery of 88.3%.

Sample	Flutolanil residues, mg/kg (common moiety method)		
	Dose 1.6 mg/kg bw	Dose 4.7 mg/kg bw	Dose 16 mg/kg bw
Muscle, day 29	<0.05 (2)	<0.05 (2)	<0.05 (2)
Muscle, day 36	<0.05	<0.05	<0.05
Liver, day 29	2.0 1.4	3.0 1.7	7.8 7.1
Liver, day 36	0.86	2.0	2.9
Kidney, day 29	0.05 0.79	1.1 0.72	3.0 2.4
Kidney, day 36	<0.05	<0.05	<0.05
Fat, day 29	0.06 <0.05	0.26 0.16	0.11 0.05
Fat, day 36	<0.05	<0.05	<0.05

Poultry. Groups of 20 laying hens were dosed once daily by gelatin capsule with flutolanil at 0.039, 0.12 and 0.39 mg/kg bw/day, equivalent to 0.78, 2.4 and 7.8 ppm in the dry-weight diet for 28 consecutive days (Campbell, 1994b). Eggs were collected twice daily. On day 29 four hens from each group were slaughtered within 24 hours of the last dose. Breast and thigh muscle, liver, fat and skin were collected for analysis. The remaining hens in each group was placed on a residue-free diet for a further 7 or 14 days before slaughter. The results are shown in Table 28 and Table 29.

Eggs and tissues were analysed by the method that includes flutolanil and metabolites with the 2-trifluoromethylbenzoic acid moiety. The method was validated for eggs (flutolanil, M-2, M-4, M-7), muscle (flutolanil, M-7), liver (M-2), fat (M-7) and skin (M-1).

Residues were not detected (LOQ 0.05 mg/kg) in the eggs of the hens treated at any dose level.

Table 28. Flutolanil residues (common moiety method) in the eggs, whites and yolks of laying hens dosed with flutolanil for 28 consecutive days, and of eggs from hens on a residue-free diet for 7 or 14 days thereafter (Campbell, 1994b).

day	Flutolanil residues, mg/kg (common moiety method)		
	Dose 0.039 mg/kg bw	Dose 0.12 mg/kg bw	Dose 0.39 mg/kg bw
Eggs			
14	<0.05 (4)	<0.05 (4)	<0.05 (4)
28	<0.05 (4)	<0.05 (4)	<0.05 (4)
35	<0.05 (2)	<0.05 (2)	<0.05 (2)
42	<0.05	<0.05	<0.05
Whites			
14	<0.05	<0.05	<0.05
28	<0.05	<0.05	<0.05
Yolks			
14	<0.05	<0.05	<0.05
28	<0.05	<0.05	<0.05

Flutolanil residues were not detected (<0.05 mg/kg) in the muscle, fat or skin even at the highest dose. They were found in the liver at the highest dose only, but disappeared (<0.05 mg/kg) after 7 days of a residue-free diet.

Table 29. Flutolanil residues (common moiety method) in the tissues of laying hens dosed with flutolanil for 28 consecutive days, and then on a residue-free diet for 7 days (Campbell, 1994b).

Sample	Flutolanil residues, mg/kg (common moiety method)		
	Dose 0.039 mg/kg bw	Dose 0.12 mg/kg bw	Dose 0.39 mg/kg bw
Breast muscle, day 29	<0.05 (3)	<0.05 (3)	<0.05 (3)
Breast muscle, day 36	<0.05	<0.05	<0.05
Thigh muscle, day 29	<0.05 (3)	<0.05 (3)	<0.05 (3)
Thigh muscle, day 36	<0.05	<0.05	<0.05
Liver, day 29	<0.05 (3)	<0.05 (3)	0.08, 0.10, 0.20
Liver, day 36	<0.05	<0.05	<0.05
Fat, day 29	<0.05 (3)	<0.05 (3)	<0.05 (3)
Fat, day 36	<0.05	<0.05	<0.05
Skin, day 29	<0.05 (3)	<0.05 (3)	<0.05 (3)
Skin, day 36	<0.05	<0.05	<0.05

FATE OF RESIDUES IN STORAGE AND PROCESSING

The Meeting received information on flutolanil residues in milled fractions of rice.

Brady (1992b) treated rice twice with flutolanil and, 31 days after the second treatment, harvested approximately 450 kg for processing (Table 30). In one process the rice was milled to hulls, brown and polished rice, and bran, and in a second was converted to grain dust fractions.

Residues decreased in the brown rice and were below the LOQ (0.05 mg/kg) in the polished rice, as measured by the common moiety method.

Table 30. Flutolanil residues (common moiety method) in rice and its processed fractions in supervised trials in the USA.

Location, year (variety)	Application				PHI days	Sample	Residues, mg/kg	Ref
	Form	kg ai/ha	water, l/ha	no.				
LA, 1991 (Lemont)	50 WP	0.56	94	a 2	31	raw whole grain - field raw whole grain - processor hulls brown bran polished grain dust top of 2030 µm grain dust top of 1190 µm grain dust top of 841 µm grain dust top of 420 µm grain dust through 420 µm cleaned	0.33 0.30 0.32 0.31 1.1 0.10 0.45 <0.05 0.37 0.53 0.96 0.82 1.4 0.27	Brady, 1992b (AU-91R-04 TLS-01) [1]

[1] There was no report or flow diagram.

Table 31. Calculated processing factors for conversion of raw whole grain rice to processed fractions.

Sample	Processing factor
Rice hulls	3.5
Brown rice	0.32
Rice bran	1.4
Polished rice	<0.16
Cleaned rice	0.86

RESIDUES IN FOOD IN COMMERCE OR AT CONSUMPTION

Monitoring data

No monitoring data were available.

NATIONAL MAXIMUM RESIDUE LIMITS

The following national MRLs were reported to the Meeting.

Country	MRL, mg/kg	Commodity
Japan	2	hulled rice

Country	MRL, mg/kg	Commodity
USA	2	rice grain
	3	rice bran
	7	rice hulls
	8	rice straw

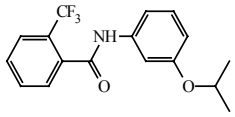
Definition of the residue

Japan: flutolanil
USA: flutolanil and its metabolites converted to 2-trifluoromethylbenzoic acid.

APPRAISAL

Residue and analytical aspects of flutolanil were considered for the first time by the present Meeting.

Flutolanil is a systemic fungicide with protective and curative action. It has registered uses for control of sheath blight (Rhizoctonia solani) in rice and Southern stem rot (white mould) and the limb/pod rot complex in peanuts. Flutolanil also has registered uses for disease control on potatoes, wheat, Japanese butterbur, lettuce, Welsh onion, pear, cucumber, tomato, egg plant, sweet peppers, sugar beet, honeywort, spinach and ginger.



The Meeting received information on flutolanil metabolism and environmental fate, methods of residue analysis, freezer storage stability, national registered use patterns, supervised residue trials, farm animal feeding studies, fate of residues in processing and national MRLs.

Animal metabolism

The Meeting received animal metabolism studies for rats, lactating goats and laying hens. Flutolanil ^{14}C labelled in the aniline ring was used in all the metabolism studies.

After the oral administration of [^{14}C]flutolanil to rats, approximately 57% of the dose was excreted as 3'-hydroxy-2-trifluoromethylbenzanilide (metabolite M-4) or its conjugates. Other identified metabolites were 4'-hydroxy-3'-isopropoxy-2-trifluoromethylbenzanilide (metabolite M-2) and 4'-hydroxy-3'-methoxy-2-trifluoromethylbenzanilide (metabolite M-7).

When lactating goats were dosed with [^{14}C]flutolanil the ^{14}C residue appeared mainly in the liver, kidney and milk with very little in muscle and fat. The main component of the residue was metabolite M-4 with small amounts of M-7 and M-2. Flutolanil was not a component of the residue. Radiolabel reached a plateau in milk by approximately day 2-3.

Radiolabel was rapidly excreted (73 and 88% in 24 hours) after administration of [^{14}C]flutolanil to laying hens. Very little radiolabel appeared in the muscle, skin and fat or eggs. Metabolite M-4 present as sulphate or glucuronide conjugates was the major identified part of the residue.

Flutolanil itself is not an identified component of the residue in animal tissues, milk and eggs. Residue levels in the fat tissue were too low for identification and it is theoretically possible that

parent flutolanil is present at low levels in the fat. The main identified residue component is metabolite M-4 present as conjugates. The residue does not behave as a fat-soluble residue.

Plant metabolism

The Meeting received plant metabolism studies for rice, potatoes and peanuts.

Flutolanil parent was the major part (64%) of the residue in rice grain harvested at maturity 30 days after a second foliar treatment with [^{14}C]flutolanil. Metabolite M-4 was a minor part of the residue (2.3%). Flutolanil and M-4 were translocated to all parts of the plant.

Flutolanil may be used on potatoes in two ways: directly on the seed potato tubers or as an in-furrow treatment at sowing. When [^{14}C]flutolanil was used in these ways and tubers were harvested 4.3 months later flutolanil parent constituted 21% and 35% of the ^{14}C in the tubers. Conjugated M-4 was found at 12% and 13% of the ^{14}C and conjugated metabolite M-2 constituted 8% of the residue in the first treatment but was not identified in the second. This study demonstrates that flutolanil is quite persistent in the crop.

When [^{14}C]flutolanil was applied to a peanut crop as a banded spray and the mature crop was harvested 84 days later the main identified components of the residue in the nuts were: free flutolanil (1%), conjugated M-4 (10%), conjugated metabolite M-3 (3.3%) and conjugated metabolite M-11 (2.0%). M-3 is 3'-(2-hydroxy-1-methylethoxy)-2-trifluoromethylbenzanilide. M-11 is 2-[3-(α,α,α-trifluoro-*o*-toluoylamino)phenoxy]propionic acid. Free flutolanil constituted 17% of the residue in peanut foliage with M-4 and M-11 also identified. Other metabolites were not fully characterised, but were shown to contain the trifluoromethylbenzoate group measured by the common moiety analytical method.

The major metabolites in plants and animals are the same (M-4, M-2 and M-7). Additional minor metabolites identified in crop tissues are present at only low percentages of the radiolabel. They are essentially oxidation and hydroxylation products of flutolanil.

In the edible part of peanuts two metabolites (M-3 and M-11) not seen to any extent in rats or goats were found at low levels. Both these compounds are closely related to parent structurally (oxidation of an isopropyl group to an alcohol or acid). There are also some unidentified metabolites at similar levels. It is unlikely that there will be any toxicological effects at the levels of exposure resulting from these residues (probably <0.0002 mg/kg bw/day - <1% of the proposed ADI for flutolanil).

Environmental fate in soil

Flutolanil was stable to soil surface photolysis.

When incubated in soils under aerobic conditions at 20°C the disappearance half-lives for [^{14}C]flutolanil ranged from 119-400 days for the soils tested.

Under aerobic flooded and upland conditions the calculated half-lives (0-90 days data) in 3 soils at 30°C were 160-320 days with disappearance rates marginally higher in each case under the flooded conditions. The longer term disappearance rates were much slower, with only 2.5-15% of the residue lost from day 90 to day 180. Flutolanil was always the major part of the residue. Identified metabolites did not exceed 3% of the dose.

Under aerobic conditions at 25°C in a sandy loam soil the estimated half-life for unbound flutolanil was 21 days and 290 days for sorbed flutolanil. Metabolites M-4, M-6 and M-11 were minor parts of the residue and never individually exceeded 5% of the dose.

Flutolanil is strongly adsorbed to most soils and is classified as low mobility through soil.

Environmental fate in water-sediment systems

In a 30-days study at 25°C in the dark at pH 5, 7 and 9 in sterile solutions, the hydrolysis of [^{14}C]flutolanil was insufficient to be observed.

Flutolanil was slowly degraded in non-sensitised solution photolysis with only 8% loss in 30 days. In sensitised photolysis (1% acetone) 32% was lost in the first 3 days and then another 7% by day 30.

When [^{14}C]flutolanil was incubated at 20°C in an aerobic water-sediment system the flutolanil continued over the 105 days of the experiment to partition from the water to the sediment. Mineralisation was slow at 3.7% and 5.2% of the dose in 105 days. Small amounts of M-4 and M-11 were produced but flutolanil remained as the majority of the residue.

In an anaerobic water-sediment system at 25°C for 12 months [^{14}C]flutolanil degraded very slowly with negligible mineralisation. The residue continued to partition from the aqueous phase to the sediment and at the end of 12 months only 0.3% of the dose was present in the aqueous phase.

Analytical methods

The Meeting received descriptions and validation data for analytical methods for flutolanil and its metabolites. Methods used in the Japanese trials on rice measured the intact flutolanil and metabolite M-4 separately. A common moiety method was used in the USA. It converts flutolanil and metabolites to methyl trifluoromethylbenzoate for measurement by GC. The method applies to crops, animal tissues, eggs and milk.

In the first method flutolanil is extracted from crops with acetone, cleaned up and the residue is measured by GLC-NPFID. In a modification, metabolite M-4 (a phenol) was extracted from an acid solution, methylated and subjected to a separate GLC measurement. Various modifications of these procedures were used in the Japanese rice trials. Procedural recoveries were generally in the 75-100% range for test concentrations of 0.1, 0.2 and 0.4 mg/kg. The stated LOQ was 0.005 mg/kg, but no recovery data were available at this level.

The common moiety analytical method for residues of flutolanil and metabolites convertible to 2-trifluoromethylbenzoic acid was used in the US trials on rice. The details of the extraction and base hydrolysis sections of the method depend on the substrate while the latter portions of the method, i.e. methylation and GC analysis are largely independent of the substrate. Rice and peanuts are extracted with acetone. Animal fat is extracted with acetonitrile+hexane. The extracts are concentrated ready for base hydrolysis. Whole milk, eggs and animal tissues other than fat are hydrolysed directly. The base hydrolysis requires heating with 50% w/w NaOH at 200°C for 3-4 hours. After solvent partition cleanup, the residue is then methylated with a methyl iodide/tetrabutyl ammonium hydroxide mixture ready for GC-MSD analysis. Poor recoveries easily occur, but satisfactory recoveries (>70%) may be obtained with experience and attention to critical parts of the method. LOQ = 0.05 mg/kg.

Stability of pesticide residues in stored analytical samples

The Meeting received freezer storage stability data for flutolanil and metabolite M-4 for rice grain and rice straw. Samples were stored for 31 months in the dark at a nominal -20°C.

Flutolanil and M-4 residues were stable in freezer storage in rice with a loss of about 30% of the residue after 700-900 days. Flutolanil residues in rice straw declined by approximately 30% in 15 months. Metabolite M-4 residues in rice straw did not decline during the 31 months of the test.

The stability of flutolanil residues in brown rice during storage of analytical samples was tested during the supervised residue trials on rice in Japan. Flutolanil residues were spiked into ground samples from the control plot when the samples arrived at the laboratory. The fortified samples were then analysed at the same time as treated samples, giving a measure of the storage stability of the residues. Residues were stable for the tested intervals (45-315 days).

Residue definition

Flutolanil itself was not identified as a component of the residue in tissues, milk and eggs of farm animals. The main identified component of the residue in milk, liver and kidney of dosed dairy cows was metabolite M-4 present as sulphate and glucuronide conjugates. Levels of residue in muscle and fat were very low. The residue should not be classed as fat-soluble. In laying hens dosed with flutolanil the main identified residue in kidney and liver was metabolite M-4 as conjugates. Residue levels in muscle, skin and fat and eggs were very low.

Flutolanil itself was the major part of the identified residue in treated rice and potatoes.

Two analytical methods for flutolanil residues are available: the first measures intact flutolanil and metabolite M-4 separately; the second is a common moiety method for flutolanil and metabolites convertible to 2-trifluoromethylbenzoic acid. The common moiety method uses a very vigorous hydrolysis step (50% NaOH at 200ºC for 3-4 hours) and poor recoveries are easily obtained. However, the common moiety method will better cover those situations where flutolanil itself is not part of the residue, as in animal commodities.

The Meeting preferred an analytical method for enforcement purposes that measures intact flutolanil and decided that flutolanil parent only would be suitable as a residue definition for crops for enforcement purposes. Because flutolanil is a major part of the residue in rice it is also a suitable residue definition for risk assessment.

In animal commodities parent flutolanil is not present and the common moiety method is necessary to measure levels of the identified residue. The Meeting decided that the residue measured by the common moiety method would be suitable for enforcement and risk assessment for animal commodities.

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

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

The residue is not classed as fat-soluble.

Results of supervised trials

Rice. In Japan, flutolanil may be used in a number of ways on rice. The results of supervised residue trials on rice with these different treatments were provided to the Meeting.

Rice paddies may be treated with granules by application to submerged surfaces at 2.1-2.8 kg ai/ha with harvest permitted 45 days later. In a trial matching these conditions the residue in brown

rice at 60 days was higher than at 45 days and was taken for evaluation: 0.050 mg/kg. In a second trial the residue at day 44 was 0.034 mg/kg. In two further trials the second and third applications were of soluble bag formulations at 2.0 kg ai/ha with harvest 42 and 45 days later and were accepted as equivalent to GAP. Residues in brown rice were 0.06 and 0.03 mg/kg. In summary, the residues from the 4 trials were: 0.03, 0.034, 0.05 and 0.06 mg/kg.

Flutolanil may also be used in Japan by application of a soluble oil to the water surface at 1.5-2.2 kg ai/ha with harvest 54 days later. Residues in brown rice following this method of use were 0.01 and 0.04 mg/kg.

In Japan rice may be treated directly with a flutolanil dust at 0.6 kg ai/ha with harvest 14 days later. In 6 trials where application rates were 0.6-0.8 kg ai/ha and the PHI was 14 days (in some cases residues were higher at 21 and 30 days) the residues in brown rice were: 0.03, 0.033, 0.063, 0.08, 0.18 and 0.20 mg/kg.

Flutolanil SC may be sprayed on rice in Japan at 0.17-0.20 kg ai/ha with a PHI of 14 days. In 6 trials matching these conditions (rates 0.17-0.23 kg ai/ha), with one trial where residues after 28 days were higher than at 14 days and in 2 trials with an EC formulation, flutolanil residues in brown rice were: 0.04, 0.12, 0.17, 0.20, 0.28 and 0.31 mg/kg.

The Japanese trial residues on brown rice from indirect treatment (treatment of the water or submerged surfaces) are: 0.01, 0.03, 0.04, 0.046, 0.06 and 0.062 mg/kg, and from direct treatment (treatment of the rice plants) are: 0.03, 0.04, 0.033, 0.063, 0.08, 0.12, 0.17, 0.18 0.20, 0.20, 0.28 and 0.31 mg/kg. The residues from the indirect and direct treatments appear to be from different populations and should not be combined.

In USA flutolanil may be applied on rice as a WP at 0.39-0.78 kg ai/ha and the rice may be harvested 30 days later. In 10 US trials where the application rate was 0.56-0.62 kg ai/ha of a WP or WG formulation the residue levels in rank order, median underlined, for whole rice were: 0.22, 0.25, 0.62, 0.99, <u>1.1</u>, <u>1.3</u>, 1.4, 1.7, 1.7 and 6.2 mg/kg. The residues in the US trials were measured by the common moiety method but are considered essentially equivalent to residues of flutolanil only because flutolanil is the major component of the residue in rice.

The processing factor for whole rice → brown rice is 0.32. When this factor is applied to the US residue data the calculated residue levels for brown rice become (rank order, median underlined): 0.070, 0.080, 0.20, 0.32, <u>0.35</u>, <u>0.42</u>, 0.45, 0.54, 0.54 and 1.98 mg/kg.

The Japanese trial data on brown rice from direct treatment and the US data on brown rice appear to be from different populations and should not be combined. The Meeting used the US data for the rice evaluation.

The Meeting estimated a maximum residue level and an STMR value of 2 and 0.39 mg/kg, respectively for flutolanil residues in husked rice.

<u>Rice straw</u>. Rice straw was collected from the US trials described previously. Flutolanil residue levels in the rice straw, in rank order, median underlined, were: 0.95, 1.0, 1.3, 3.1, <u>3.6</u>, <u>3.8</u>, 4.4, 5.7, 6.4 and 7.4 mg/kg.

The Meeting estimated a maximum residue level and an STMR value of 10 and 3.7 mg/kg, respectively for flutolanil residues in rice straw and fodder, dry.

Processing

In a processing study, rice was treated according to US GAP and a portion of approximately 450 kg was milled and polished. Calculated processing factors from the residue in the raw whole grain were: rice hulls 3.5, brown rice 0.32, rice bran 1.4 and polished rice <0.16. Flutolanil residues in the polished rice were below LOQ (0.05 mg/kg) so the processing factor is a 'less than' value.

The Meeting used the processing factors and the estimated STMR and maximum residue level for brown rice to estimate STMRs and maximum residue levels for the other processed commodities

Farm animal dietary burden

The Meeting estimated the farm animal dietary burden for flutolanil based on the residues resulting from its use on rice.

Maximum farm animal dietary burden estimation

						Choose diets, %			Residue contribution, mg/kg		
Commodity	group	residue mg/kg	basis	% dry matter	residue, on dry wt mg/kg	*Beef cattle*	*Dairy cattle*	*Poultry*	Beef cattle	Dairy cattle	Poultry
Rice grain	GC	2	MRL	88	2.3	*40*	*40*	*60*	0.91	0.91	1.36
Rice straw	AS	10	MRL	90	11.1	*10*	*10*		1.11	1.11	
Rice hulls	CM	4.3	STMR-P	90	4.8	*10*	*10*	*15*	0.48	0.48	0.72
Rice bran	CM	1.7	STMR-P	90	1.9						
					TOTAL	*60*	*60*	*75*			
						Maximum dietary burden			2.50	2.50	2.08

STMR farm animal dietary burden estimation

						Choose diets, %			Residue contribution, mg/kg		
Commodity	group	residue mg/kg	basis	% dry matter	residue, on dry wt mg/kg	*Beef cattle*	*Dairy cattle*	*Poultry*	Beef cattle	Dairy cattle	Poultry
Rice grain	GC	0.39	STMR	88	0.44	*40*	*40*	*60*	0.18	0.18	0.27
Rice straw	AS	3.7	STMR	90	4.1	*10*	*10*		0.41	0.41	
Rice hulls	CM	4.3	STMR-P	90	4.8	*10*	*10*	*15*	0.48	0.48	0.72
Rice bran	CM	1.7	STMR-P	90	1.9						
					TOTAL	*60*	*60*	*75*			
						STMR dietary burden			**1.07**	**1.07**	**0.98**

The flutolanil dietary burdens for animal commodity MRL and STMR estimation (residue levels in animal feeds expressed on dry weight) are: beef cattle 2.5 and 1.07 mg/kg, dairy cattle 2.5 and 1.07 mg/kg and poultry 2.08 and 0.98 mg/kg.

Farm animal feeding studies

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were dosed with flutolanil for 28 consecutive days at the equivalent of 39, 116 and 388 ppm in the diet. Residues in milk and tissues were measured by the common moiety method with a LOQ of 0.05 mg/kg.

Residues did not exceed the LOQ in milk at the two lower feeding levels and did not exceed the LOQ in muscle at any feeding level.

At the lowest feeding level of 39 ppm, residues of 2.0 and 1.4 mg/kg flutolanil moiety appeared in liver and 0.05 and 0.79 mg/kg in kidney with corresponding higher residues at the higher feeding levels.

Residues in eggs and tissues were measured by the common moiety method when laying hens were dosed with flutolanil for 28 consecutive days at the equivalent of 0.78, 2.4 and 7.8 ppm (dry-weight) in the diet and slaughtered on day 29.

Residues did not exceed the LOQ (0.05 mg/kg) in eggs, muscle, fat or skin at any feeding level.

Residues in the liver were not detected (LOQ 0.05 mg/kg) at the lowest and middle feeding groups and were present at 0.08, 0.10 and 0.20 mg/kg in the liver from the highest feeding group.

Animal commodity maximum residue levels

The Meeting agreed to apply the results of the dietary burden calculations and the dairy cow feeding study to mammalian food-producing farm animals generally.

Dietary burdens were the same for beef and dairy cattle: maximum 2.5 mg/kg, STMR 1.07 mg/kg.

At a feeding level of 39 ppm, residues in milk were below LOQ. At the second feeding level, 116 ppm, residues in milk and cream were below LOQ except for one sample of cream where the residue was 0.06 mg/kg. The dietary burdens for dairy cattle were far below these feeding levels and effectively nil residues should occur in milk. The Meeting estimated a maximum residue level and an STMR value for flutolanil residues in milks of 0.05* mg/kg and 0 mg/kg, respectively.

No residues exceeded LOQ in muscle at any feeding level. Again effectively nil residues should occur in muscle. The Meeting estimated a maximum residue level and an STMR value for flutolanil residues in mammalian meat of 0.05* mg/kg and 0 mg/kg, respectively.

The lowest feeding level (39 ppm) did produce measurable levels of flutolanil moiety residues in liver (2.0 and 1.4 mg/kg) and kidney (0.05 and 0.79 mg/kg). Estimated residues were calculated by multiplying the residues found in the feeding trials by the dietary burdens and dividing by the feeding level (39 ppm). The results are shown in the following table.

Feeding level [ppm] (*interpolated*)		Flutolanil moiety residues, mg/kg								
	Actual	Milk Mean	Fat high	mean	Muscle high	mean	Liver high	mean	Kidney high	mean
MRL beef	*(2.5)*		*(0.004)*		*(<0.003)*		*(0.13)*		*(0.051)*	
	[39]		0.06		<0.05		2.0		0.79	
MRL dairy	*(2.5)*	*(<0.003)*								
	[39]	<0.05								
STMR beef	*(1.07)*			*(0.001)*		*(<0.001)*		*(0.047)*		*(0.012)*
	[39]			0.05		<0.05		1.7		0.42
STMR dairy	*(1.07)*	*(<0.001)*								
	[39]	<0.05								

The Meeting estimated a maximum residue level and an STMR value for flutolanil residues in liver of cattle, goats, pigs and sheep of 0.2 mg/kg and 0.047 mg/kg, respectively.

The Meeting estimated a maximum residue level and an STMR value for flutolanil residues in kidney of cattle, goats, pigs and sheep of 0.1 mg/kg and 0.012 mg/kg, respectively.

The Meeting agreed to apply the results of the dietary burden calculations and the laying hen feeding study to poultry. Dietary burdens were: maximum 2.08 mg/kg and STMR 0.98 mg/kg.

At feeding levels of 0.78 and 2.4 ppm, residues in eggs, muscle, liver, fat and skin were all below LOQ (0.05 mg/kg). The maximum dietary burden (2.08 mg/kg) was less than the second feeding level. Therefore the Meeting estimated a maximum residue levels of 0.05* mg/kg for eggs, poultry meat and poultry edible offal.

At the highest feeding level of 7.8 ppm residues in eggs, muscle, fat and skin were all below LOQ (0.05 mg/kg), suggesting that the residues in eggs, muscle, fat and skin were substantially below the LOQ at the STMR dietary burden (0.98 mg/kg). The Meeting estimated STMR values of 0 for eggs and poultry meat. Residues of 0.08, 0.10 and 0.20 mg/kg appeared in liver at a feeding level of 7.8 ppm, suggesting that residues in liver cannot be considered as "effectively zero." The Meeting estimated an STMR value of 0.05 mg/kg for poultry edible offal.

RECOMMENDATIONS

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

Definition of the residue for 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.

CCN	Commodity Name	MRL, mg/kg	STMR or STMR-P mg/kg
PE 0112	Eggs	0.05*	0
MO 0098	Kidney of cattle, goats, pigs and sheep	0.1	0.012
MO 0099	Liver of cattle, goats, pigs and sheep	0.2	0.047
MM 0095	Meat (from mammals other than marine mammals)	0.05*	0
ML 0106	Milks	0.05*	0
PO 0111	Poultry, Edible offal of	0.05*	0.05
PM 0110	Poultry meat	0.05*	0
CM 1206	Rice bran, unprocessed	10	1.7

CCN	Commodity Name	MRL, mg/kg	STMR or STMR-P mg/kg
AS 0649	Rice straw and fodder, dry	10	3.7
CM 0649	Rice, husked	2	0.39
CM 1205	Rice, polished	1	0.195

* at or about the LOQ

DIETARY RISK ASSESSMENT

Chronic intake

The International Estimated Daily Intakes of flutolanil, based on the STMRs estimated for 9 commodities, for the five GEMS/Food regional diets were in the range of 0 to 1% of the ADI (Annex 3). The Meeting concluded that the long-term intake of residues of flutolanil resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

The Meeting decided that an acute RfD is unnecessary and concluded that the short-term intake of flutolanil residues is unlikely to present a public health concern.

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