FATE OF RESIDUES IN STORAGE AND PROCESSING

In processing

In hydrolysis experiments designed to simulate typical processing operations (Reischmann, 2000) [pyrrole-4-^{14}C]fludioxonil was incubated in aqueous buffer solutions at a concentration of 0.9 mg/l at 90°C (pH 4, 20 min.), 100°C (pH 5 60 min.) and 120°C (pH 6, 20 min.) (Table 121). Suitable aqueous buffer solutions were prepared at concentrations ≤ 0.01 M to keep the pH constant and to avoid any possible catalytic effects of the buffer.

Sterilised test solutions were heated and then allowed to cool before neutralisation. The total recovered radioactivity was measured for each test solution and the identity of the radioactive components checked by both HPLC and 2D-TLC against reference standards.

Table 121. Representative hydrolysis conditions.

Temperature (°C)	pH	Incubation time (min)	Process represented
90	4	20	Pasteurization
100	5	60	Baking, brewing, boiling
120	6	20	sterilisation

After incubation, the radioactivity in the neutralised buffer solutions represented unchanged fludioxonil (96.2–106.3% of the applied radioactivity), demonstrating that no significant hydrolytic degradation had taken place under the simulated processing conditions.

Processing studies on plums, strawberries, grapes, citrus, tomato, potato, and cotton seed were reported.

Residues are incurred in plums both as a result of foliar treatment and post-harvest applications. The latter treatments are applied to plums in the USA intended for supply directly to the retail trade, according to the manufacturer. Plums harvested after foliar treatments may be further processed however.

In a trial in Germany fludioxonil, formulated as WG 62.5, was applied to plum trees three times during the season as a foliar treatment (0.22 g ai/ha/application) at one test location. Fruit was harvested 14 days after the final treatment and residues measured in plums, washed plums, washing water, plum purée and prunes. A flow chart for processing is given in Figure 4. The results are shown in Table 122.

In two French and one Swiss trials (Maffezzoni, Report 9812203, 1999, Report 9812204, 1999; Salvi, Report 2012/00, 2002) fludioxonil, formulated as WG 62.5, was applied to plum trees as a foliar spray three times during the season at 0.15-0.16 kg ai/ha/application. The fruit were harvested 14 days after the final treatment. Residues were measured in the fresh plums and in the dried plums (prunes).

Figure 4. Flow chart for plum processing.

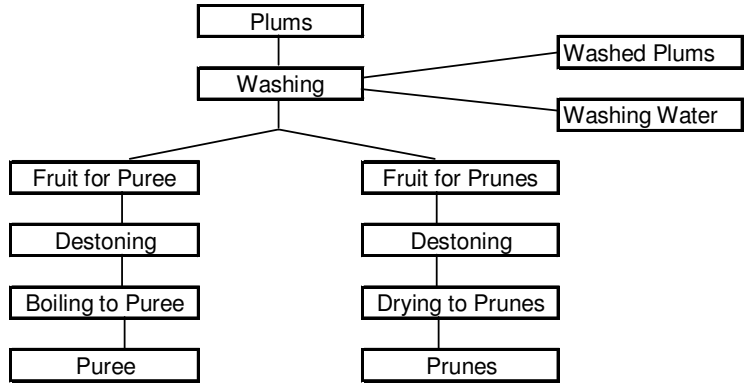


Table 122. Fludioxonil residues in plums and processed commodities from trials in France, Germany, and Switzerland.

Country Year (variety)	Application				Commodity	Fludioxonil mg/kg	Processing factor	Author Date Study No. Syn No.
	Form	kg ai/ha	water, l/ha	PHI days				
Germany 2000 (Hauszwetsche (Schäfer))	WG 62.5	0.225	1500	14	Plums Plums Washed plums Dried plums Plum jam Plum juice Plum pomace Plum preserves Plum purée	<0.02 control 0.06 0.05 0.16 0.04 0.006 0.13 0.03 0.07	 0.83 2.67 0.67 0.10 2.16 0.50 1.17	Smith, 2000 gr 90898 5205
France (South) 1998 (Plum d'Ente)	WG 62.5	0.15	1028-1047	14	Plums Dried plums	0.05* 0.09*	1.80	Maffezzoni 1999 9812203 4988
France (South) 1998 (Plum d'Ente)	WG 62.5	0.15	1000-1022	14	Plums Dried plums	0.03* 0.06*	2.00	Maffezzoni 1999 9812204 4989
Switzerland 2001 (Fellenberg)	WG 62.5	0.15	930	14	Plums Plum purée Prunes	0.036 0.016** 0.043**	 0.44 1.19	Salvi 2002 2012/00 5497
							Means: **n** Prunes 1.92 4 Jam 0.67 1 Juice 0.10	

Country Year (variety)	Application				Commodity	Fludioxonil mg/kg	Processing factor	Author Date Study No. Syn No.
	Form	kg ai/ha	water, l/ha	PHI days				
							1 Preserves 0.50 1 Purée 0.80 2	

* mean of two determinations
** mean of four determinations

In one trial in France and three in Germany (Pointurier, Report 011101, 2001; Beinhauer, Report GR02196, 1996, Report GR02296, 1996) fludioxonil formulated as WG 62.5 was applied to protected strawberries (France) or field-grown strawberries (Germany) three times during the season at 250 g ai/ha. The fruit were harvested 3 or 7 days (France) or 10 days (Germany) after the final treatment. Residues were measured in the washed strawberries, washing water, strawberry preserves, strawberry jam and juice. Results are shown in Table 123.

Table123. Fludioxonil residues in strawberries and processed commodities from trials in France and Germany.

Country Year (Variety)	Application				Commodity	Fludioxonil, mg/kg	Processing factor	Author Date Study No. Syn No
	Form	kg ai/ha	water, l/ha	PHI days				
France (North) 2001 (Chandler)	WG 62.5	0.250	400	3	Strawberries Washed berries Washing water Preserves Jam Juice	0.19 0.09 0.07 0.08, 0.08, 0.12, 0.13 (0.10*) 0.06, 0.05, 0.07, 0.06 (0.06*) 0.03, 0.03, 0.04, 0.03 (0.03*)	 0.47 0.53 0.32 0.16	Pointurier 2002 0011101 5337
Germany 1996 (Senga-Sengana)	WG 62.5	0.250	2000	10	Strawberries Washed berries Preserves Jam	0.14, 0.13** 0.12, 0.11** 0.11, 0.10** 0.07, 0.07**	 0.86 0.79 0.50	Beinhauer 1996 gr02196 0877
Germany 1996 (Korona)	WG 62.5	0.250	2000	10	Strawberries Washed berries Preserves Jam	0.39, 0.37** 0.17, 0.17** 0.21, 0.20** 0.08, 0.08**	 0.45 0.55 0.21	Walser 1996 2188/96 0878
							Means: Washed fruit 0.59 (n = 3) Preserves 0.62 (n = 3 Jam 0.34 (n = 1) Juice 0.16 (n = 1)	

* mean of four separately processed samples

** duplicate analyses, mean used to calculate processing factors

Three grape trials in Greece were used to obtain field-incurred residues for processing grapes into raisins (Kuhne, Report 02-2111, 2003, Report 02-2112, Report 02-2113, 2003). Fludioxonil was applied to grape vines as a foliar spray, formulated as WG 62.5, twice during the season at 0.250 kg ai/ha/application. Grapes harvested 7 days after the final treatment were sun-dried on the ground for 40 days. The crop was turned over twice during the drying period. Residues measured in grapes and raisins are shown in Table 124.

Table 124. Fludioxonil residues in grapes and raisins from trials in Greece.

Year (variety)	Application				PHI days	Commodity	Fludioxonil mg/kg,	Author Date Study No. Syn No
	Form	No	g/l	kg ai/ha				
2002 (Black Corinth)	WG 62.5	2	0.250	0.250	0 7 15 7 Processing factor	Berries Berries Berries Raisin --- 1.4	0.34 0.41, 0.22 (0.32) 0.38 0.50, 0.43 (0.46) --- 1.4	Kühne 2003 02-2111 5574
2002 (Sultana)	WG 62.5	2	0.250	0.250	0 7 14 7 Transfer factor	Berries Berries Berries Raisin 1.2	0.62 0.42, 0.39 (0.40) 0.35 0.51, 0.43 (0.47) 1.2	Kühne 2003 02-2112 5575
2002 (Sultana)	WG 62.5	2	0.250	0.250	0 7 14 7 Processing factor	Berries Berries Berries Raisin 1.2	0.59 0.37, 0.36 (0.36) 0.26 0.46, 0.44 (0.45) 1.2	Kühne 2003 02-2113 5576

In twelve trials in Chile, fludioxonil formulated as WG 62.5 was applied to grape vines as a foliar spray twice during the season at 0.193-0.517 kg ai/ha (Walser, Reports 2218/95, 1996, 2119/95, 1996, 2220/95, 1996, 2221/95, 1996, 2222/95, 1996, 2223/95, 1996, 2224/95, 1996, 2225/95, 1996, 2226/95, 1996, 2227/95, 1996, 2228/95, 1996, 2229/95, 1996). The fruit were harvested 7 or 21 days after the final treatment. Grapes were processed into raisins by one of two procedures. The first was a local practice of spreading the grapes (15 kg) on cardboard in the sun for about 20 days. The mixture was turned twice each day. The other was an industrial procedure. The grapes (16 kg) were washed with 1% aqueous sodium hydroxide at 80°C, followed by a cold water rinse, then treated with "sulfur gas" for 8 hours and subsequently dried in an oven at 65°C and 35% relative humidity for 35 hours. The final moisture content was about 14%. Finally, the raisins were air-dried for five days. In all cases, juice was produced in Switzerland by pressing grapes (10 kg) in a hydraulic press. Residues were measured in grapes, juice, and raisins by HPLC (REM 133). Residues and processing factors are summarized in Table 125.

Table 125. Fludioxonil residues in grapes, raisins and juice from trials in Chile.

Year (variety)	Application				PHI Days	Commodity	Residues, mg/kg	Processing factor, raisin	Processing factor, juice	Author Date Study No. Syn No
	Formu-lation	No.	g/l	kg ai/ha						
1995 (Thompson Seedless)	WG 62.5	2	0.16 - 0.17	0.196 - 0.253	7 29 230	Berries Raisins Juice	0.27, 0.22 (0.24) 0.14, 0.13 (0.14) 0.17, 0.16 (0.16)	0.58	0.67	Walser 1996 2218/95 0840
1995 (Thompson Seedless)	WG 62.5	2	0.17 - 0.20	0.195 - 0.249	7 29 230	Berries Raisins Juice	0.21, 0.16 (0.18) 0.17, 0.15 (0,16) 0.18, 0.17 (0.18)	0.89	1.0	Walser 1996 2219/95 0841
1995 (Thompson Seedless)	WG 62.5	2	0.17 - 0.20	0.196 - 0.252	21 43 244	Berries Raisins Juice	0.21, 0.16 (0.18) 0.13, 0.11 (0.12) 0.14, 0.14 (0.14)	0.67	0.78	Walser 1996 2220/95 0842
1995 (Thompson Seedless)	WG 62.5	2	0.17 - 0.20	0.193 - 0.248	21 43 244	Berries Raisins Juice	0.16, 0.13 (0.14) 0.10, 0.09 (0.10) 0.12, 0.12 (0.12)	0.71	0.86	Walser 1996 2221/95 0843
1995 (Thompson Seedless)	WG 62.5	2	0.32 - 0.36	0.394 - 0.495	7 29 230	Berries Raisins Juice	0.29, 0.27 (0.28) 0.30, 0.27 (0.28) 0.24, 0.23 (0.24)	1.0	0.86	Walser 1996 2222/95 0844
1995 (Thompson Seedless)	WG 62.5	2	0.30 - 0.32	0.394 - 0.517	21 43 244	Berries Raisins Juice	0.32, 0.36 (0.34) 0.41, 0.39 (0.40) 0.28, 0.26 (0.27)	1.2	0.79	Walser 1996 2223/95 0845
1995 (Thompson Seedless)	WG 62.5	2	0.20 - 0.25	0.196 - 0.247	7 18 181	Berries Raisins[1] Juice	0.25, 0.32 (0.28) 0.54, 0.43 (0.48) 0.29, 0.25 (0.27)	1.7	0.96	Walser 1996 2224/95 0846
1995 (Thompson Seedless)	WG 62.5	2	0.20 - 0.23	0.200 - 0.233	21 32 195	Berries Raisins[1] Juice	0.25, 0.23 (0.24) 0.31, 0.28 (0.30) 0.16, 0.16 (0.16)	1.2	0.67	Walser 1996 2225/95 0847
1995 (Thompson Seedless)	WG 62.5	2	0.20 - 0.25	0.198 - 0.249	7 18 181	Berries Raisins[1] Juice	0.30, 0.27 (0.28) 0.34, 0.29 (0.32) 0.28, 0.19 (0.24)	1.1	0.86	Walser 1996 2226/95 0848
1995 (Thompson Seedless)	WG 62.5	2	0.20 - 0.25	0.199 - 0.244	21 32 195	Berries Raisins[1] Juice	0.33, 0.27 (0.30) 0.36, 0.31 (0.34) 0.26, 0.17 (0.22)	1.1	0.73	Walser 1996 2227/95 0849
1995 (Thompson Seedless)	WG 62.5	2	0.40 - 0.49	0.396 - 0.494	7 18 181	Berries Raisins[1] Juice	0.76, 0.76 (0.76) 0.98, 0.86 (0.92) 0.80, 0.79 (0.80)	1.2	1.0	Walser 1996 2228/95 0850
1995 (Thompson Seedless)	WG 62.5	2	0.40 - 0.49	0.398 - 0.463	21 32 195	Berries Raisins[1] Juice	0.74, 0.43 (0.58) 0.64, 0.62 (0.63) 0.64, 0.56 (0.60)	1.1	1.0	Walser 1996 2229/95 0851
							Mean	1.1	0.92	
							Mean combined with Greek processing factors (Table 124)	1.1		

[1] Commercial process.

Fifteen grape trials in Germany, Italy, Spain, and Switzerland were used to obtain field-incurred residues for processing grapes into wine (Ipach, Reports gr 51295, 1997, gr 51195, 1997; gr 51095, 1997; Lefevre, Report gr 5094, 1996; Walser, Reports 205095, 1996, 2049/95, 1996, 2066/96,

1997, 2007/96, 1997, 2008/96, 1997; Kissling, Reports 2057/94, 1995, 2058/94, 1995, 2059/94, 1995, 2109/94, 1995, 2101/94, 1995; Maffezzoni, Reports OF 94143, 1995, OF 95123/KJ46, 1996, OF95122, 1996, OF 95123/TP14, 1996, OF 95123/BY87, 1996). Fludioxonil was applied to grape vines as a foliar spray, formulated as WG 62.5, twice during the season at between 0.25 and 0.30 kg ai/ha, i.e. within 25% of the application rate of 25 g ai/ha in the typical European GAP. The fruit were harvested for processing 21 to 50 days after the final treatment.

A typical wine-making procedure was described briefly in several of the reports. The grapes were crushed and stems removed. Approximately 50 mg of SO_2 1 l was added, equivalent to 100 mg 1 l of potassium disulfide, and the crush mixture was heated to 60°C, poured into a steel vat and cooled overnight. The following day Trenolin red (20 mg/100 l) was added to assist cell splitting, and the mixture was pressed. Typically, 40 kg of grapes yielded 28 l of must. The must was allowed to stand until solids settled. Sugar was added to the separated must liquid, which was transferred to 25 l glass balloon flasks, to which were added a yeast inoculaton (5 g/100 l). The young wine was separated from the yeast and sampled. To the remaining young wine was added 100 mg SO_2/l and 2g Bentonite. After additional maturation, the wine was filtered. The temperature in the wine cellar ranged from 8 to 15°C. The entire process occurred over 1–14 months (first or young wine, about 9-120 days), with processing initiated immediately after harvest. Samples were stored frozen before analysis.

Residues were measured in grapes, juice, must, pomace, young wine, and wine. The results and processing factors are shown in Table 126**.**

Table 126. F ludioxonil residues in grapes and wine from trials in Germany, Italy, Spain, France, and Switzerland.

Country Year (variety)	Application				PHI days	Sample	Fludioxonil mg/kg or mg/l	Transfer factor	Author Year Study No. Syngenta No
	Form	No.	g/l	kg ai/ha					
Germany 1995 (Dornfelder)	WG 62.5	2	0.38	0.30	0	Berries	1.15		Ipach 1999 gr 51295 0717
					13	Berries	0.50		
					28	Berries	0.36		
					36	Berries	*0.28*		
					38	Must	0.029; 0.029	0.10	
					41	Berries	0.24		
					157	Young wine	0.005; 0.005	0.018	
					435	Wine	0.008; 0.007	0.028	
Germany 1995 (Scheurebe)	WG 62.5	2	0.38	0.30	0	Berries	0.67		Ipach 1997 gr 51195 0718
					13	Berries	0.47		
					28	Berries	0.33		
					34	Berries	*0.17*		
					35	Must	0.076; 0.067 (0.072)	0.42	
					41	Berries	0.20		
					157	Young wine	0.008; 0.007	0.044	
					435	Wine	0.008; 0.007	0.044	

Country Year (variety)	Application				PHI days	Sample	Fludioxonil	Transfer factor	Author Year Study No. Syngenta No
	Form	No.	g/l	kg ai/ha			mg/kg or mg/l		
Germany 1995 (Müller-Thurgau)	WG 62.5	2	0.38	0.30	0	Berries	0.95		Ipach 1997 gr 51095
					13	Berries	0.53		
					28	Berries	0.34		
					34	Berries	*0.31*		0719
					35	Must	0.075; 0.075	0.24	
					41	Berries	0.24		
					157	Young wine	<0.005; <0.005	0.016	
					435	Wine	0.006; 0.006	0.019	
Germany gr 52694 1994 (Kerner)	WG 62.5	2	0.38	0.30	0B	Berries	0.16		Lefevre 1996 gr 5094 0813
					0	Berries	0.62		
					14	Berries	0.36		
					29	Berries	0.25		
					34	Berries	*0.17*		
					36	Must	0.054	0.32	
					43	Berries	0.16		
					147	Young wine	0.007	0.041	
					302	Wine	0.005	0.029	
Germany gr 52794 1994 (Dornfelder)	WG 62.5	2	0.38	0.30	0B	Berries	0.27		Lefevre 1996 gr 5094 0813
					0	Berries	0.68		
					14	Berries	0.32		
					29	Berries	0.2		
					34	Berries	*0.24*		
					36	Must	0.005	0.021	
					43	Berries	0.21		
					147	Young wine	0.016	0.067	
					302	Wine	<0.005	0.021	
Switzerland 1995 (Pinot Noir)	WG 62.5	2	0.38	0.30	0B	Berries	0.14		Walser 1996 2050/95 1093
					0	Berries	3.26		
					14	Berries	1.43		
					28	Berries	1.22		
					35	Berries	*1.64*		
					35	Juice	1.84	1.1	
					42	Berries	1.0		
					44	Wine, 1st fermentation	0.18	0.11	
					210	Wine, 2nd fermentation	0.089	0.054	
Switzerland 1995 (Chasselas)	WG 62.5	2	0.38	0.30	0B	Berries	0.07		Walser 1996 2049/95 1092
					0	Berries	1.49		
					14	Berries	1.19		
					28	Berries	0.79		
					35	Berries	*0.99*		
					35	Juice	0.27	0.27	
					42	Berries	0.41		
					44	Wine, 1st fermentation	0.31	0.31	
					210	Wine, 2nd fermentation	0.011	0.011	
Switzerland 1994 (Pinot Noir)	WG 62.5	2	0.38	0.30	0	Berries	5.2		Kissling 1995 2057/94 1136
					35	Berries	1.4		
					42	Berries	1.2		
					50	Berries	*1.6*		
					50	Juice	2.0	1.2	
					61	Wine, 1st fermentation	0.1	0.062	
					222	Wine, 2nd fermentation	0.054	0.034	

Country Year (variety)	Application				PHI days	Sample	Fludioxonil mg/kg or mg/l	Transfer factor	Author Year Study No. Syngenta No
	Form	No.	g/l	kg ai/ha					
Switzerland 1994 (Chasselas)	WG 62.5	2	0.38	0.30	0	Berries	3.8		Kissling 1995 2058/94 1137
					35	Berries	0.66		
					42	Berries	0.9		
					49	Berries	*0.6*		
					49	Juice	0.24	0.40	
					61	Wine, 1st fermentation	0.2	0.33	
					222	Wine, 2nd fermentation	0.022	0.037	
Switzerland 1994 (Chasselas)	WG 62.5	2	0.38	0.30	0	Berries	2.7		Kissling 1995 2059/94 1138
					36	Berries	1.3		
					43	Berries	1.1		
					49	Berries	*1.4*		
					49	Juice,	0.39	0.28	
					62	Wine, 1st fermentation	0.15	0.11	
					223	Wine, 2nd fermentation	0.012	0.0086	
Italy 1996 (Moscato)	WG 62.5	2	0.36	0.25	0B	Berries	0.1		Walser 1997 2066/96 0971
					0	Berries	0.88		
					14	Berries	0.27		
					21	Berries	0.31		
					28	Berries	*0.41*		
					29	Must, analysis1	0.186	0.45	
					29	Must, analysis2	0.245	0.60	
								avg 0.52	
					42	Young wine, analysis1	0.074	0.18	
					42	Young wine, analysis2	0.067	0.16	
								avg 0.17	
					220	Wine, analysis1	0.047	0.11	
					220	Wine, analysis2	0.045	0.11	
								avg 0.11	
Spain 1996 (Mazuelo)	WG 62.5	2	0.30 0.50	0.25	0B	Berries	<0.02		Walser 1997 2007/96 0928
					0	Berries	0.6		
					7	Berries	0.51		
					14	Berries	0.12		
					21	Berries	0.22		
					28	Berries	*0.31*		
					28	Must, specimen 1	0.245	0.79	
					28	Must, specimen 2	0.229	0.74	
								avg 0.76	
					45	Wine, specimen 1	0.071	0.23	
					45	Wine, specimen 2	0.066	0.22	
								avg 0.22	

Country Year (variety)	Application				PHI days	Sample	Fludioxonil mg/kg or mg/l	Transfer factor	Author Year Study No. Syngenta No
	Form	No.	g/l	kg ai/ha					
Italy 1994 (Trebbiano Romagnolo)	WG 62.5	2	0.25	0.25	0 7 14 21 21 	Berries Berries Berries Berries Must Young wine Wine	0.59 0.55 0.63 *0.43* 0.12 0.089 <0.005	 0.28 0.21 0.012	Kissling 1995 2109/94 0658
Spain 1994 (Macabeo)	WG 62.5	2	0.16	0.25	0 12 19 22 26 26 49	Berries Berries Berries Juice Berries Must Wine	1.28 0.77 *0.53* 0.59 0.56 0.55 0.12	 1.1 1.1 1.0 0.23	Kissling 1995 2101/94 1134
Spain 1996 (Macabeo)	WG 62.5	2	0.38 - 0.39	0.24 - 0.26	0B 0 7 14 21 28 28 28 71 71	Berries Berries Berries Berries Berries Berries Must, specimen 1 Must, specimen 2 Wine, specimen 1 Wine, specimen 2	0.1 1.62 1.32 0.76 0.41 *0.3* 0.640 0.685 0.070 0.072	 2.1 2.3 avg 2.2 0.23 0.24 avg 0.24	Walser 1997 2008/96 0962
France South 1994 (Cabernet Franc)	WG 62.5	1	2.0	0.30	70	Berries grape juice must wine	0.07 0.05 0.07 0.04	 0.71 1.0 0.57	Maffezzoni 1995 OF94143 0595
France South 1994 (Ugni Blanc)	WG 62.5	1	2.0	0.30	89	Berries Grape juice must wine	0.03 0.01 0.05 0.02	 0.33 1.7 0.67	Maffezzoni 1995 OF94143 0595
France 1994 (Tranpram- ilo)	WG 62.5	1	3.0	0.30	55	Berries Grape juice must wine	0.07 0.05 0.09 0.06	 0.71 1.3 0.86	Maffezzoni 1995 OF94143 0595
France 1994 (Pinot Noir)	WG 62.5	1	2.7	0.30	73	Berries Grape juice must wine	0.02 0.01 <0.01 <0.01	 0.59 0.50 0.50	Maffezzoni 1995 OF94143 0595
France, North 1996 (Gamay)	WG 62.5	1	1.5	0.30	70	Berries Wine	0.08 0.02	 0.25	Maffezzoni 1996 OF95123 0783
France, North 1995 (Gamay)	WG 62.5	1	1.5	0.30	70	Berries Wine	0.09 0.02	 0.22	Maffezzoni 1996 OF95122 0707

Country Year (variety)	Application				PHI days	Sample	Fludioxonil mg/kg or mg/l	Transfer factor	Author Year Study No. Syngenta No
	Form	No.	g/l	kg ai/ha					
France, South 1995 (Cabernet Franc)	WG 62.5	1	1.5	0.30	66	Berries Wine	0.11 0.03	0.27	Maffezzoni 1996 OF95123 0782
France, South 1995 (Carignan/ Monticola	WG 62.5	1	2.3	0.30	72	Berries Wine	0.05 0.01	0.20	Maffezzoni 1996 OF95123 0784
AVERAGE & RANGE							Wine (<100 day) Wine (>100 day)	**0.30±**0.22 0.012-0.86 **0.036±**0.028 0.0086-0.11	n = 17 n=11

0B: before final treatment
Must: pressed grape juice used for wine fermentation

Lemons treated with fludioxonil by a packing line spray with storage wax (Deco 202) at 930 g ai per 250,000 kg fruit were taken through a small batch processing operation simulating normal commercial processing (Thompson, Report 07947, 2003; see Table 64). The fruit were washed (brushwasher and spray) and surface-abraded for oil recovery (abrasion peeler and spray). The oil emulsion was treated with commercial pectinase, separated, and the oil fraction centrifuged for recovery, freeze/thawed, dried and filtered. The abraded fruit was juiced (Juice Tree juice extractor), the peels being collected and the juice finished by screening to remove peel and coarse pulp. A sample of juice was pasteurized at 93.3°C (200°F) for canning. The peel was shredded (Rietz grinder) and the solid fractions neutralised with lime, pressed and dried. Samples of unwashed fruit, juice, oil and dried pulp were frozen before analysis.

Residues are presented in Table 127.

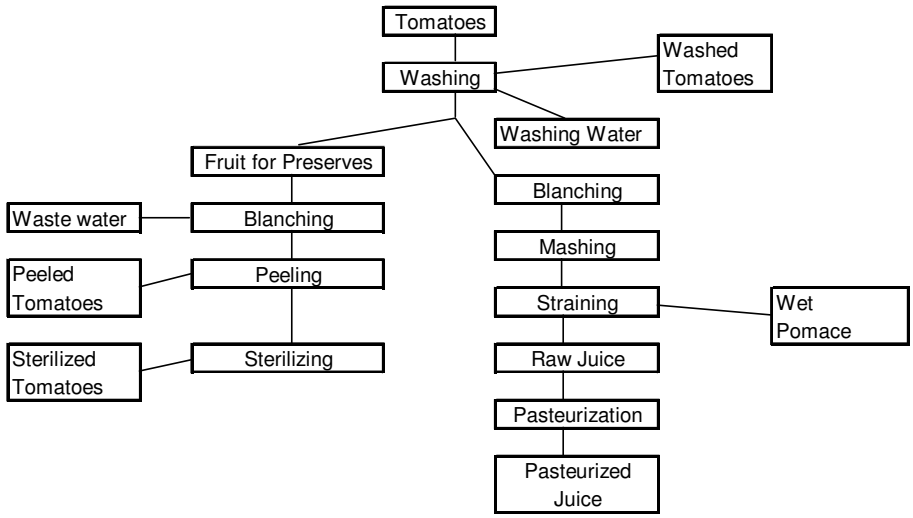
Table 127. Fludioxonil residues in lemons and processed commodities from a trial in California, USA.

Year (variety)	Form	Application rate (g as/liter)	No	PHI (days).	Commodity	Fludioxonil, mg/kg[4]	Processing factor	Author Date Study No. Syn No
Packing line spray with storage wax[1]								
2001 (Eureka)	50 WP	10.[1]	1	0	Unwashed fruit Juice Oil Pulp	0.65 <0.02 39.7 1.39	 0.031 61 2.1	Thompson 2003 IR4-07947

[1] 0.93 kg ai/250,000 kg fruit

A tomato trial in Switzerland was used to obtain field-incurred residues for processing (Tribolet, Report 2126/99, 2000). Fludioxonil formulated as WG 62.5 was applied to tomato plants as a foliar spray three times during the season at 0.250 kg/ha. The tomatoes were harvested 7 days after the final treatment. Two studies were carried out to produce juice, paste and preserves. Residues were measured in raw fruit, washed fruit, washing water, wet pomace, raw juice, pasteurised juice, raw paste, pasteurised paste, peeled fruit, washing water from peeling and preserves. Two follow-on processing studies were also carried out in which residues were measured in raw fruit, pasteurised juice, pasteurised paste and preserves. A flow diagram outlining the processing is given in Figure 5.

Figure 5. Flow chart for tomato processing.



The results from these processing studies are shown in Table 128.

Table 128. Fludioxonil residues in tomatoes and processed commodities from a trial in Switzerland.

Year (variety)	Application					PHI days .	Commodity	Fludioxonil mg/kg	Transfer factor	Author Date Study No. Syn No
	Form.	kg ai/ha	kg ai/hl	water l/ha	no.					
1999	WG	250	0.017	1500	3	B*	Tomato	<0.02		
(Petula)	62.5					7	Tomato	0.05	1.0	
							Washed fruit	0.020	0.40	
Study 1							Washing water	0.019		
							Wet pomace	0.182	3.6	
							Raw juice	0.010		
							Pasteurized juice	0.011	0.22	
							Raw paste	0.081		
							Pasteurized paste	0.078	1.6	
							Peeled tomatoes	<0.02	0.40	
							Washing water from peeling	0.010		
							Preserves	<0.01	0.20	

Year (variety)	Application Form.	kg ai/ha	kg ai/hl	water l/ha	no.	PHI days.	Commodity	Fludioxonil mg/kg	Transfer factor	Author Date Study No. Syn No
1999 (Petula) Study 2						7	Tomato	0.05	1.0	Tribolet 2000 2126/99 5345
							Washed fruit	0.15	3.0	
							Washing water	0.023		
							Wet pomace	0.149	3.0	
							Raw juice	0.015		
							Pasteurized juice	0.011	0.22	
							Raw paste	0.076		
							Pasteurized paste	0.054	1.1	
							Peeled tomatoes	<0.02	0.40	
							Washing water from peeling	0.011		
							Preserves	<0.01	0.20	
1999 (Petula) Follow-on Study 1						7	Tomato	0.05	1.0	Tribolet 2000 2126/99 5345
							Pasteurized juice	0.012	0.24	
							Pasteurized paste	0.076	1.5	
							Preserves	<0.01	0.20	
1999 (Petula) Follow-on Study 2						7	Tomato	0.05	1.0	Tribolet 2000 2126/99 5345
							Pasteurized juice	0.010	0.20	
							Pasteurized paste	0.059	1.2	
							Preserves	<0.01	0.20	
AVERAGE/RANGE										
							Peeled tomato		0.4	n=2
							Pasteurized juice		0.22 0.20-0.24	n=4
							Pasteurized paste		1.4 1.1-1.6	n=4
							Pomace (wet)		3.3 3.0-3.6	n=2

* before treatment

A processing study on potatoes was carried out in the USA in which seed pieces were treated with fludioxonil at target rates of 5, 15 and 25 g ai/100 kg and planted at 12 sites in 11 states (Selman, Report 426006, 1996). Samples from trials in California and Idaho (PHI 99 and 143 days respectively) were used to determine residues in processed commodities. The Idaho potatoes had no residues (<0.01 mg/kg), whereas one of two samples analysed from the California trial, conducted at a threefold rate, had a value of 0.019 mg/kg; the other was <0.01 mg/kg. See Table 101. See Table 129 for results of the processing study, and Table 130 the processing factors for the animal feed items culls and peel and trimmings.

Table 129. Fludioxonil residues in potatoes and processed fractions after application as a seed treatment in the USA.

Location Year (variety)	Application Form	No.	g ai/100 kg seed	Residues mg/kg PHI days	Commodity	Fludioxonil mg/kg	Author Date Study No. Syn No

Location Year (variety)	Application			Residues mg/kg			Author Date Study No. Syn No
	Form	No.	g ai/100 kg seed	PHI days	Commodity	Fludioxonil mg/kg	
CA 1992 (Red La Soda)	DP 0.5%	1	5	99	Tubers before processing Culls Wet peel and trimmings Potatoes peeled and rinsed Potato chips Potato granules	<0.01 <0.01 0.010 <0.01 <0.01 <0.01	Selman 1996 ABR-93027 0747
CA 1992 (Red La Soda)	DP 1.5%	1	15	99	Tubers before processing Culls Wet peel and trimmings Potatoes peeled and rinsed Potato chips Potato granules	<0.01 0.022 0.016 <0.01 <0.01 <0.01	Selman 1996 ABR-93027 0747
CA 1992 (Red La Soda)	DP 2.5%	1	25	99	Tubers before processing Culls Wet peel and trimmings Potatoes peeled and rinsed Potato chips Potato granules	<0.01 <0.01 0.031 <0.01 <0.01 <0.01	Selman 1996 ABR-93027 0747
ID 1992 (Russet Burbank)	DP 0.5%	1	5	143	Tubers before processing Culls Wet peel and trimmings Potatoes sliced and peeled Potato chips Potato granules	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	Selman 1996 ABR-93027 0747
ID 1992 (Russet Burbank)	DP 1.5%	1	15	143	Tubers before processing Culls Wet peel and trimmings Potatoes sliced and peeled Potato chips Potato granules	<0.01 <0.01 0.015 <0.01 <0.01 <0.01	Selman 1996 ABR-93027 0747
ID 1992 (Russet Burbank)	DP 2.5%	1	25	143	Tubers before processing Culls Wet peel and trimmings Potatoes sliced and peeled Potato chips Potato granules	<0.01 <0.01 0.017 <0.01 <0.01 <0.01	Selman 1996 ABR-93027 0747

* 2 samples combined for processing

Residues were below the limit of quantification (<0.01 mg/kg) in tubers before processing, but were quantified in potato culls from one trial in which potatoes were seed-treated at 15 g ai/100 kg seed and in wet peel and trimmings from two trials in which potatoes were treated at 5, 15 and 25 g ai/100 kg seed. In cases where residues were measurable in processed fractions, transfer values were calculated by taking residues in tubers before processing as equal to the LOQ (0.01 mg/kg).

Table 130. Processing factors for potato processed fractions.

Commodity	Seed treatment (g ai/100 kg seed)	Fludioxonil from CA trial (mg/kg)	Fludioxonil from ID trial (mg/kg)	Processing factor (CA trial)	Processing factor (ID trial)
Tubers before processing	5 (1X)	<0.01	<0.01		
Tubers before processing	15 (3X)	<0.01	<0.01		
Tubers before processing	25 (5X)	<0.01	<0.01		
Culls	5	<0.01	<0.01	nc	nc
Culls	15	0.022	<0.01	2.2	nc
Culls	25	<0.01	<0.01	nc	nc
Wet peel and trimmings	5	0.010	<0.01	1.0	nc
Wet peel and trimmings	15	0.016	0.015	1.6	1.5

Wet peel and trimmings	25	0.031	0.017	3.1	1.7
Mean wet peel and trimmings				1.8	
Culls				<2.2	

nc: not calculable

Residues in cereal grain (wheat, barley, maize, rye, etc) harvested after seed treatment with fludioxonil at rates of 2.3–10 g ai/100 g seed were below the LOQ (0.02 or 0.04 mg/kg depending on analytical method). Some processing data are included with the field trials summarized above. However, the residues in both the raw agricultural commodity and the processed commodity, e.g. flour, were below the limit of quantification (<0.02-<0.05) so processing factors could not be calculated. It is unlikely that exaggerated treatment rates on the seeds (up to tenfold) would have yielded quantifiable residues in the crops.

A similar situation exists with the seed treatment of oilseed crops. Six supervised trials were conducted in the USA to determine the residues in dehulled cotton seed, field trash and processing and ginning fractions at harvest following use of seed treated with fludioxonil (4 FS, 48% fludioxonil w/w) at target rates of 5 and 15 g ai/100 kg seed (Vincent, Report ABR-9711, 1998). However, residues were not quantifiable in either the seed or the processed products, so processing factors could not be calculated.

Table 131. Processing of cotton seed in the USA into refined oil, meal, and hulls.

Location Year (Variety)	Form	g ai/ 100 kg seed	Sample	PHI (days)	Fludioxonil mg/kg	Author Date Study No. Syn No
CA	FS 4	14.6	Undelinted seed Hulls Meal Refined oil	189 189 189 189	<0.05 <0.05 <0.05 <0.05	Vincent 1998 ABR-97111 59-96
MS	FS 4	8.33	Field trash Gin trash Undelinted seed	152 152 152	<0.05 <0.05 <0.05	Vincent 1998 ABR-97111 59-96
TX	FS 4	12.6	Gin trash Undelinted seed Hulls Meal Refined oil	165 165 165 165 165	<0.05 <0.05 <0.05 <0.05 <0.05	Vincent 1998 ABR-97111 59-96
TX	FS 4	4.89	Field trash Gin trash Undelinted seed	132 132 132	<0.05 <0.05 <0.05	Vincent 1998 ABR-97111 59-96
OK	FS 4	5.96	Field trash Gin trash Undelinted seed	174 174 174	<0.05 <0.05 <0.05	Vincent 1998 ABR-97111 59-96
NM	FS 4	4.44	Field trash Gin trash Undelinted seed	188 188 188	<0.05 <0.05 <0.05	Vincent 1998 ABR-97111 59-96
Greece 1991 (S80)	FS 100	10.0	Hulls Seeds, dehulled	175 175	<0.02, <0.02 <0.02, <0.02	Mair 1993 2119/91 0252
Greece 1991 (S80)	FS 100	20.0	Hulls Seeds, dehulled	175 175	<0.02, <0.02 <0.02, <0.02	Mair 1993 2120/91 0253
Greece 1997 (Eva)	ES 104	2.50	Hulls Seeds, dehulled	149 149	<0.05, <0.05 <0.02, <0.02	Kühne 1999 2309/97

Location Year (Variety)	Form	g ai/ 100 kg seed	Sample	PHI (days)	Fludioxonil mg/kg	Author Date Study No. Syn No
						1673
Greece 1997 (Eva)	ES 104	2.50	Hulls Seeds, dehulled	165 165	<0.05, <0.05 <0.02, <0.02	Kühne 1999 2310/97 1674
Greece 1997 (Eva)	ES 104	2.50	Hulls Seeds, dehulled	159 159	<0.05, <0.05 <0.02, <0.02	Kühne 1999 2311/97 1675

RESIDUES IN ANIMAL COMMODITIES

Farm animal feeding studies

A ruminant feeding study was reported. No study was available on poultry feeding.

A feeding study on cows was carried out at three dosing levels equivalent to 0.55 ppm (0.017-0.019 mg/kg bw) (1x), 1.62 ppm (0.052–0.060 mg/kg bw) (3x) and 5.5 ppm (0.173–0.200 mg/kg bw) (10x) fludioxonil in the diet together with a control Holstein cow (Boyette, Reports BIOL-94016, 1996, BIOL-94010, 1996). There were 3 cows in each of the treatment groups. After acclimatization, fludioxonil was administered daily to the cows in gelatine capsules for 28-30 consecutive days. Milk samples were collected before dosing on days 0, 1, 3, 7, 14, 21 and 26 and the cows were killed on days 28-30, all within 24 hours of the final dose. Omental fat, perirenal fat, round muscle, tenderloin muscle, liver and kidney were collected. Milk and tissue samples were analysed for residues of fludioxonil and metabolites via oxidation to CGA-192155, method AG-616 (See Residue Analysis section). The LOQ for fludioxonil was 0.01 mg/kg for milk and muscle and 0.05 mg/kg for all other tissues.

The results are shown in Tables 132 and 133. Residues of fludioxonil were found in milk samples taken at days 3, 7, 14 and 21 from cows fed at the highest dose rate (5.5 ppm in the diet), the maximum residue (0.019 mg/kg) being found in the sample taken from cow 4A at 14 days. The day 14 samples also gave the highest mean residue (0.010 mg/kg). Fludioxonil residues in milk samples taken from cows fed at the 1x and 3x dose rates were all below the limit of quantification (<0.01 mg/kg).

No residues of fludioxonil were found at or above the limit of quantification (0.01 mg/kg for muscle, 0.05 mg/kg for other tissues) in any of the tissues analysed.

Table 132. Residues of fludioxonil and metabolites (converted to CGA-192155) found in milk from ruminant feeding study.

Animal number	Dose level in diet	Residues (mg/kg) at dosing (day)						
		0 (pre-dosing)	1	3	7	14	21	26
2A	1x	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
2B	0.55 ppm	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
2C		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
3A	3x	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
3B	1.62 ppm	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
3C		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
4A	10x	<0.01	<0.01	<0.01	<0.01	**0.019**	**0.012**	<0.01
4B	5.5 ppm	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
4C		<0.01	<0.01	**0.016**	**0.011**	**0.010**	**0.014**	<0.01

Table 133: Residues of fludioxonil and metabolites (converted to CGA-192155) found in tissues from ruminant feeding study.

Animal number	Dose level in diet	Residues (mg/kg)					
		Round muscle	Tenderloin muscle	Liver	Kidney	Perirenal fat	Omental fat
2A	1x	na	na	na	na	na	na
2B	0.55 ppm	na	na	na	na	na	na
2C		na	na	na	na	na	na
3A	3x	na	na	na	na	na	na
3B	1.62 ppm	na	na	na	na	na	na
3C		na	na	na	na	na	na
4A	10x	<0.01	<0.01	<0.05	<0.05	<0.05	<0.05
4B	5.5 ppm	<0.01	<0.01	<0.05	<0.05	<0.05	<0.05
4C		<0.01	<0.01	<0.05	<0.05	<0.05	<0.05

na: not analysed

NATIONAL MAXIMUM RESIDUE LIMITS

The various national maximum residues limits (MRLs) are listed in Table134. The information was supplied by the manufacturer.

Table 134. National MRLs.[1]

	Country	MRL (mg/kg)	Commodity	Notes
FRUIT				
Stone fruits	Switzerland	0.5		
Stone fruits	USA	5		
Apple	USA	(5)		IR-4 proposed
Apricot	Austria	(0.5)		Draft publication
Apricot	Canada	2		
Apricot	France	0.5		
Apricot	Germany	0.5		IT, German conciliation procedure
Apricot	Italy	0.5		
Apricot	Japan	0.5		
Blackberry	Slovenia	1		
Blackberry	Switzerland	1		
Bushberry	USA	2		
Caneberry	USA	5		
Cherry	Austria	(0.5)		Draft publication
Cherry	France	0.3		
Cherry	Italy	0.5		
Cherry	Japan	0.5		
Citrus	USA	(10)		IR-4 proposed
Citrus, dried pulp	USA	(20)		IR-4 proposed
Elder	Austria	2		Draft publication
Grape	Australia	2		
Grape	Austria	2		
Grape	Belgium	2		
Grape	Bolivia	2		
Grape	Bolivia	0.2	Wine	

	Country	MRL (mg/kg)	Commodity	Notes
Grape	Canada	1		
Grape	Canada	1		
Grape	Croatia	0.02		
Grape	Cyprus	0.5	Wine	
Grape	Cyprus	0.2		
Grape	France	0.5		
Grape	France	0.2	Wine	
Grape	Germany	2		
Grape	Israel	1		
Grape	Italy	2		
Grape	Italy	0.5	Wine	
Grape	Japan	5		
Grape	Lebanon	3		
Grape	Luxembourg	0.5		
Grape	Luxembourg	0.2	Wine	
Grape	Netherlands	2		
Grape	Paraguay	0.5		
Grape	Paraguay	0.2	Wine	
Grape	Portugal	2		
Grape	Portugal	0.3	Wine	
Grape	Romania	0.02		
Grape	Serbia+Montenegro	0.02		
Grape	Slovenia	0.02		
Grape	South Africa	0.05		
Grape	South Africa	0.05	Wine	
Grape	Spain	1		
Grape	Spain	1	Fruit juice	
Grape	Spain	0.2	Wine	
Grape	Switzerland	3		
Grape	Switzerland	0.5	Wine	
Grape	Taiwan	0.5		
Grape	Turkey	0.5		
Grape	Turkey	0.2	Wine	
Grape	USA	1		
Grape	Uruguay	2		
Grape	Uruguay	0.2	Wine	
Grape	Yugoslavia	2		
Juneberry	USA	2		
Kiwi	USA	(20)		IR-4 proposed
Lingonberry	USA	2		
Longan	USA	1		
Lychee	USA	1		
Mango	Taiwan	2		
Nectarine	Canada	2		
Nectarine	Japan	0.5		
Nectarine	USA	5		
Peach	Austria	0.5		Draft publication
Peach	Canada	2		
Peach	France	0.5		
Peach	Germany	0.5		IT, German conciliation procedure
Peach	Italy	0.5		
Peach	Japan	0.5		
Peach	USA	5		
Pear	Austria	0.5		Draft publication
Pear	Italy	0.5		

	Country	MRL (mg/kg)	Commodity	Notes
Pear	Spain	0.5		
Pear	USA	(5)		IR-4 proposed
Plum	Austria	(0.5)		Draft publication
Plum	Canada	2		
Plum	France	0.2		
Plum	Italy	0.5		
Plum	Japan	0.5		Including prune
Pomegranate	USA	(2)		IR-4 proposed. A time-limited tolerance exists at 5 mg/kg.
Pululan	USA	1		
Rambutan	USA	1		
Raspberry	Germany	1		
Raspberry	Slovenia	1		
Raspberry	Switzerland	1		
Raspberry	USA	2		
Spanish lime	USA	1		
Strawberry	Austria	1		
Strawberry	Belgium	0.5		
Strawberry	Bolivia	1		
Strawberry	Canada	2		
Strawberry	Finland	0.5		
Strawberry	France	1		
Strawberry	Germany	1		
Strawberry	Israel	0.5		
Strawberry	Italy	2		
Strawberry	Japan	5		
Strawberry	Korea (South)	2		
Strawberry	Luxembourg	0.5		
Strawberry	Netherlands	2		
Strawberry	Norway	0.5		
Strawberry	Paraguay	1		
Strawberry	Portugal	1		Published in Portaria 1101/99 on 21/12/99
Strawberry	Spain	1		
Strawberry	Switzerland	1		
Strawberry	USA	2		
Strawberry	Uruguay	1		
VEGETABLES				
Brassica, leafy greens	USA	10		
Bulb vegetable Group (except onion)	USA	0.02		
Cucurbit Group	Spain	0.3		
Cucurbit Group	USA	0.01		
Fruiting vegetable Group	USA	0.01		Excluding cucurbits
Leafy Vegetable Group	USA	0.01		
Legume vegetable Group (except Brassica)	USA	0.01	Foliage	
Legume vegetable Group	USA	0.01	Whole plant	
Root/tuber vegetable Group	USA	0.02	Foliage and root	
Bean	Austria	(0.5)		Draft publication
Bean	Brazil	0.04		
Bean	France	0.2		
Bean	Germany	0.2	Pod	
Bean	Japan	0.2		Including kidney bean, cow pea
Bean	Spain	0.2		

	Country	MRL (mg/kg)	Commodity	Notes
Bean	Switzerland	0.1		
Pepper (Bell pepper)	Austria	1		
Pepper (Bell pepper)	Germany	1		
Pepper (Bell pepper)	Italy	1		
Pepper	Paraguay	1		
Pepper	Spain	1		
Brassica, head and stem	USA	2		
Broad bean	Japan	0.1		
Carrot	USA	0.75		
Cucumber	Austria	0.2		Draft publication
Cucumber	Bolivia	0.5		
Cucumber	Germany	0.2		
Cucumber	Greece	0.3		
Cucumber	Italy	1		
Cucumber	Japan	2		
Cucumber	Slovenia	1		
Cucumber	Spain	0.3		
Cucumber	Switzerland	0.5		
Cucumber	Uruguay	1		
Egg plant (aubergine)	Austria	0.2		
Egg plant (aubergine)	Germany	1		
Egg plant (aubergine)	Greece	0.4		
Egg plant (aubergine)	Italy	1		
Egg plant (aubergine)	Japan	2		
Egg plant (aubergine)	Slovenia	1		
Egg plant (aubergine)	Spain	0.5		
Egg plant (aubergine)	Switzerland	0.5		
Lettuce	Austria	2		Draft publication
Lettuce	Bolivia	1		
Lettuce	France	10		
Lettuce	Italy	10		
Lettuce	Japan	1		Including Tisya and Salad-na
Lettuce	Paraguay	1		
Lettuce	Slovenia	10		
Lettuce	Spain	2		
Lettuce	Switzerland	3		
Lettuce	Uruguay	1		
Onion	Canada	0.2	Dry bulb	
Onion	Canada	7	Green	
Onion	Germany	0.3		
Onion	Switzerland	0.05		
Onion	USA	0.2	Dry bulb	
Onion	USA	7	Green	
Onion	Japan	0.1		
Pea	France	0.05		Green peas and protein peas
Pea	Germany	0.5	Pod	fresh pea with pod
Pea	Japan	0.1		
Pea	Japan	0.1		
Pea	UK	(0.05)	Seed	NCP proposed UK name: peas, pulses
Pea,	UK	(0.05)	Pea	NCP proposed: UK name: peas, green
Potato	Australia	0.02		Seed treatment
Potato	Brazil	0.02	tuber	Seed treatment
Potato	Canada	0.02		Seed treatment
Potato	Czech Republic	0.05		Seed treatment
Potato	Japan	0.02		Seed treatment
Potato	Korea (South)	0.1		Seed treatment
Potato	Russia	0.02		

	Country	MRL (mg/kg)	Commodity	Notes
Summer squash (Zucchini)	Austria	(0.2)		Draft publication
Summer squash (Zucchini)	Italy	1		
Summer squash (Zucchini)	Slovenia	1		
Tomato	Austria	(0.5)		Draft publication
Tomato	Bolivia	1		
Tomato	Greece	0.4		
Tomato	Israel	0.3		
Tomato	Italy	1		
Tomato	Japan	2		
Tomato	Paraguay	1		
Tomato	Portugal	1		Published in Portaria 1101/99 on 21/12/99
Tomato	Slovenia	1		
Tomato	Spain	0.5		
Tomato	Switzerland	0.5		
Tomato	Turkey	1		
Tomato	Uruguay	1		
Turnip greens	USA	10		
Watercress	USA	7		
OILSEED				
Cotton	Brazil	0.04		Seed treatment
Cotton	USA	0.05	By-products	Seed treatment
Cotton Group	Venezuela	0.05		Seed treatment
Cotton, undelinted seed	USA	0.05		Seed treatment
Mustard	Canada	0.05		
Peanut	Brazil	0.02	Nut	Seed treatment
Peanut	Japan	0.1		
Peanut	USA	0.01	Nut	
Rape	Canada	0.01		
Rape	Estonia	0.05		Seed treatment
Rape	USA	0.01	Seed	Seed treatment
Safflower, seed	USA	0.01		
Soya	Brazil	0.04		
Soya	Japan	0.1		
Sunflower	USA	0.01	Seed	Seed treatment
Yam	USA	(8)		IR-propsed
CEREALS				
Cereals	Austria	0.05		Seed treatment
Cereals	Belarus	0.02		Seed treatment
Cereals	Czech Republic	0.05		Seed treatment
Cereals	Japan	0.02		Seed treatment
Cereals	Russia	0.02		Seed treatment
Cereals	Switzerland	0.02		Seed treatment
Cereals	USA	0.01		Seed treatment
Cereals	USA	0.02		Seed treatment
Barley	Estonia	0.05		Seed treatment
Barley	Italy	0.05		Seed treatment
Barley	Japan	0.02		Seed treatment
Barley	Slovenia	0.02		Seed treatment
Barley	UK	0.02		Seed treatment
Buckwheat	Japan	0.02		Seed treatment
Corn, sweet	France	0.05		
Grass	USA	0.01	Foliage	
Maize	Brazil	0.04		Seed treatment
Maize	France	0.05		Seed treatment
Maize	Italy	0.05		Seed treatment
Maize	Japan	0.02		Seed treatment

	Country	MRL (mg/kg)	Commodity	Notes
Maize	Moldavia	0.02		Seed treatment
Maize	Russia	0.02		Seed treatment
Maize	Spain	0.05		Seed treatment
Maize	Venezuela	0.05		Seed treatment
Oat	UK	0.02		Seed treatment
Rice	Italy	0.05		Seed treatment
Rice	Japan	0.02		Seed treatment
Rice	Korea (South)	0.1		
Rice	Venezuela	0.05		
Rye	Denmark	0.02		Seed treatment
Rye	Japan	0.02		Seed treatment
Rye	Norway	0.1		Seed treatment
Sorghum	Venezuela	0.05		Seed treatment
Wheat	Denmark	0.02		Seed treatment
Wheat	France	0.02		Seed treatment
Wheat	Italy	0.05		Seed treatment
Wheat	Japan	0.02		Seed treatment
Wheat	Norway	0.1		Seed treatment
Wheat	Slovenia	0.2		Seed treatment
Wheat	Slovenia	0.2		Seed treatment
Wheat	UK	0.02		Seed treatment
TREE NUTS				
Peanut, meat (hulls removed)	USA	0.01		
Pistachio	USA	0.1		
HERBS AND SPICES				
Spice Group	USA	0.02		
Herb, fresh	USA	10		
Herb, dried	USA	65		
Salal	USA	2		
MAMMALIAN PRODUCTS				
Cow	Australia	0.05	Edible offal	
Cow	Australia	0.01	Meat	
Cow	Australia	0.01	Milk	
ANIMAL FEED				
Forage, fodder & straw of cereals	USA	0.01		
Forage, fodder and hay of grass	USA	0.01		
Non-grass animal feed	USA	0.01		
Peanut hay	USA	0.01		
Rape seed forage	USA	0.01		

[1]As provided by the manufacturer. Values in parentheses have not been finalized as of 06/2004.

APPRAISAL

Fludioxonil, or 4-(2,2-difluorobenzo[1,3]dioxol-4-yl)-1*H*-pyrrole-3-carbonitrile, is a fungicide that belongs to the chemical class phenylpyrroles. It functions by blocking the protein kinase which catalyses the phosphorylation of a regulatory enzyme of glycerol synthesis. It is specific for a limited number of fungi. It was evaluated for the first time by the 2004 Joint Meeting.

Metabolism

Animals

The metabolism of ^{14}C-pyrrole-labelled fludioxonil was studied in goats and laying hens. Two goats were given radiolabelled fludioxonil orally at a level equivalent to 100 ppm in the feed for 4 consecutive days. The levels of radioactive residue, calculated as fludioxonil, were: 0.07 mg/kg in tenderloin muscle, 0.19 mg/kg in fat, 5.8 mg/kg in liver, 2.9 mg/kg in kidney and 2.2 mg/kg in milk on day 4. Organic solvents released 35% of the TRR in liver, 76% in muscle, 50% in kidney, 35% in liver, 87% in fat and 90% in milk. Protease treatment of the solid residues from solvent extraction of liver, kidney and muscle released 75–91% of the remaining activity. Less than half of this released activity was characterised as proteins by derivatization with 2,4-dinitrofluorobenzene.

The main component identified in muscle was fludioxonil, representing 24% and 43% of the TRR in the two goats. Likewise, fludioxonil was the main component of the residue in omental fat, representing 83% TRR. The main identified metabolite in muscle was the sulfate conjugate of the 2-hydroxy or 5-hydroxy derivative of fludioxonil (22% or 2% TRR). Minor metabolites identified in muscle (<10% TRR) included the 2-*O*-glucuronide derivative of fludioxonil and the 5-*O*-glucuronide derivative of fludioxonil. (The position numbers refer to the pyrrole ring.) About 50% of the residue in muscle and 83% of the residue in fat were identified.

Multiple components were found in kidney and liver. The following were identified in kidney: 2-*O*-glucuronide derivative of fludioxonil (23% TRR); 7´-*O*-glucuronide derivative (8% TRR); 5-*O*-glucuronide derivative (15% TRR); fludioxonil (2% TRR); and 2- or 5-*O*-sulfate ester (0.7% TRR), for a total identification of 48%. In liver, only fludioxonil was identified (14% TRR). Two labile compounds (24% TRR) were also encountered. No compounds without the pyrrole–phenyl linkage were identified.

On the basis of the identified and characterised residues, the Meeting concluded that the metabolism of fludioxonil via the oral route in goats involves oxidation of the pyrrole ring at the 2 and 5 positions, followed by rapid conversion to sulfate and glucuronide conjugates. A minor route involves oxidation of the benzodioxol ring at the 7´ position and conversion to the glucuronide conjugate. Evidence was also found for substantial incorporation into natural products, including proteins, in kidney and liver.

Five laying hens were given gelatin capsules containing [^{14}C-pyrrole]fludioxonil for 8 consecutive days at a rate equivalent to about 89 ppm in the feed. The vast majority of the radiolabelled residue was eliminated in the excreta (88–102% of the total administered dose). The levels of radioactive residues, calculated as fludioxonil, in the tissues and eggs were as follows: liver, 8.9 mg/kg; muscle, 0.12 mg/kg; skin with fat, 0.25 mg/kg; peritoneal fat, 0.17 mg/kg; egg yolk, 1.8 mg/kg (day 7); egg white, 0.054 mg/kg (day 7).

A series of organic solvent extractions released 61% TRR in liver, 33% in kidney, 62% in muscle, 42% in skin with fat, 74% in egg white and 83% in egg yolk. The solids remaining after solvent extraction of liver (33% TRR), kidney (54%) and muscle (34%) were solubilized with protease and characterised by treatment with 2,4-dinitrofluorobenzene. Protease solubilized 54% of the unextracted activity in liver, 63% of that in kidney and 67% of that in muscle. About 25% of the released radioactivity (<10% TRR) was derivatized by 2,4-dinitrofluorobenzene at pH 2, indicating the terminal amino group of amino acids.

Alkaline hydrolysis (15% KOH, 95 °C) released all the remaining radioactivity from the solvent-extracted liver (33% TRR), but it could be characterised only as acidic, polar compounds.

About 69% of the TRR in eggs, 24% in liver, 14% in kidney, 44% in muscle and 29% in skin with fat were identified. The main metabolites identified in eggs were the sulfate conjugate of the 1-hydroxy derivative of fludioxonil (40% TRR) , the succinamic acid derivative (10% TRR) and the sulfate conjugate of the 2-hydroxy or 5-hydroxy derivative (13% TRR). Fludioxonil was a minor component (2.1% TRR) in eggs. The succinamic acid derivative was the only significant metabolite identified in liver, at about 6% TRR. The metabolites identified in kidney were the glucuronide conjugate of the 2-hydroxy or 5-hydroxy derivative (4.7% TRR), fludioxonil (2.6% TRR) and the 7´-

hydroxy derivative (2.8% TRR). The main components identified in breast muscle were fludioxonil (29% TRR) and the sulfate conjugate of the 1-hydroxy derivative. A similar situation existed for skin with attached fat, which contained fludioxonil (9.8%) and the sulfate conjugate of the 1-hydroxy derivative (14%).

On the basis of the characterisations and identifications made in the study of metabolism in hens, the Meeting concluded that metabolism in poultry involves oxidation at the C-2, C-5 and N-1 positions in the pyrrole ring and at the C-7´ of the benzodioxol ring. This is followed by the formation of sulfate or glucuronide conjugates. The C-2 hydroxypyrrole further oxidizes to the 2,5-dioxo-2,5-dihydro pyrrole and succinamic acid derivatives. The last two compounds are unique to poultry. The remaining metabolites found in the hen and all the metabolites in ruminants were also found in rats. The studies of metabolism in rats were reviewed by the WHO Expert Group of the 2004 JMPR.

Plants

The metabolism of radiolabelled fludioxonil resulting from its foliar application has been studied in grape, tomato, peach, green onion and head lettuce. Grape vines were sprayed three times at 3-week intervals with [pyrrole-4-^{14}C] fludioxonil at a rate of 500 g ai/ha per application. Samples of grapes and leaves were taken at intervals, immediately after the first application, up to grape maturity 35 days after the final application. Grapes at maturity contained 2.5–2.8 mg/kg of radiolabelled residue, calculated as fludioxonil. About 57% of the TRR was a surface residue, released by a methanol–water rinse; another 32% of the TRR was released by solvent extraction. The leaves at maturity contained 5.2 mg/kg of radiolabelled residue, 52% as a surface residue and 44% solvent extracted.

The residues in grapes and leaves were extensively identified. In grapes at maturity, seven compounds were identified, but only fludioxonil at 70% TRR exceeded 2% TRR. The metabolites included the succinamic acid derivative (<1% TRR), the 3-hydroxy succinamic acid derivative (<1% TRR), the glucose conjugate of 2-hydroxyacetamide benzodioxol (<1% TRR), 2-hydroxyacetamide benodioxol (<1% TRR), the 2-hydroxy-5-oxo derivative (2% TRR), the 2,5-dioxo derivative (<1% TRR) and the 1-hydroxy-2,5-dioxo derivative (<1% TRR). Similar metabolites were identified in leaves, fludioxonil representing 69% of the TRR; no other metabolite exceeded 6% TRR.

The metabolism of [pyrrole-4-^{14}C]fludioxonil was studied in greenhouse tomato plants that were sprayed three times at 2-week intervals with a wettable powder formulation at a single application rate of 750 g ai/ha. Forty days after the last application, leaves and tomatoes were sampled. The leaves contained a fludioxonil-equivalent radiolabelled residue level of 7.0 mg/kg, and the tomatoes contained 0.28 mg/kg. Of the residue on tomatoes, 41% was on the surface. Rinsing and solvent extraction released 95% of the residues in tomatoes and 95% of those in leaves. About 73% of the tomato residue and 69% of the leaf residue was fludioxonil. Five metabolites, representing 3.6% of the TRR in tomato, were identified. These were the same metabolites as in grapes, except that the 2,5-dioxopyrrole derivative was not found and the benzodioxole-4-carboxylic acid derivative was present but at below the LOQ (<0.001 mg/kg).

The metabolism of [phenyl-U-^{14}C]fludioxonil was studied in peaches. Three foliar applications at 30-day intervals were made at 130 and 1300 g ai/ha, starting at petal fall. Mature fruit was collected 28 days after the second treatment. In a second trial, two applications, 950 and 2860 g ai/ha, were made at a 35-day interval, starting at petal fall. Samples of immature and mature fruits were taken 30 and 114 days after the second application. The radiolabelled residue level, calculated as fludioxonil, was 0.083 mg/kg and 0.98 mg/kg in the first trial after application at 130 and 1300 g ai/ha respectively. The residue level on mature peaches in the second trial was 0.26 mg/kg (114-day PHI).

Extraction with acetonitrile:water:acetic acid (80:20:1) released ≥ 88% TRR in all cases. Analyses were conducted on extracts from 28-day peaches treated at 130 and 1300 g ai/ha in the first trial and on 114-day peaches from the second trial. Fludioxonil was the main component in all cases, ranging from 22% TRR to 62% TRR. Eight metabolites were identified in the 114-day PHI peaches, of which four are also grape or tomato metabolites (succinamic acid derivative, 3% TRR; 2-hydroxy-

5-oxo derivative, 1.4% TRR; 2-hydroxy-5-oxo derivative, 1% TRR; benzodioxole-4-carboxylic, 1% TRR). The other metabolites included oxidized fludioxonil glucose conjugates at 7% TRR and an oxirane-2-carboxylic acid derivative at 3% TRR. About 54% of the TRR in peach was identified.

The metabolism of [phenyl-U-^{14}C]fludioxonil on green onions was studied after radiolabelled fludioxonil was applied twice at a 14-day interval at a rate of 560 or 680 g ai/ha and at 2800 or 3380 g ai/ha. Samples were taken at maturity (14-day PHI) and at other intervals. TRR as fludioxonil represented 1.6 mg/kg on the onions given the 560 or 680 kg ai/ha treatment and 10 mg/kg on those given the 2800 or 3380 g ai/ha treatment. After the 2800 or 3380 g ai/ha treatment, 51% of the TRR was souble in organic solvents and 21% in water.

The metabolitic profiles were qualitatively similar at the two treatment levels and at the various sampling intervals. In the onions treated at 2800 or 3380 g ai/ha at mature harvest (14-day PHI), fludioxonil comprised 49% of the TRR. Six metabolites were identified, but none represented >2% TRR. These were the same metabolites identified in the studies of grape, tomato and peach metabolism.

The metabolism of [pyrrole-4-^{14}C]fludioxonil on head lettuce was studied after three foliar treatments at 10-day intervals at 200 g ai/ha. A second experiment was conducted at 600 g ai/ha per application. With a 6-day PHI, the TRR calculated as fludioxonil was 1.3 mg/kg after treatment at 200 g ai/ha and 5.8 mg/kg at 600 g ai/ha treated. Almost 100% of the radioactivity was extracted with methanol:water. Fludioxonil was the main component (68% TRR after the 200 g ai/ha treatment, 80% after the 600 g ai/ha treatment).

Six metabolites, four of which corresponded to metabolites in the studies of tomato, grape and peach, were identified. No metabolite exceeded 3% TRR. Metabolites unique to head lettuce were lactic acid conjugates of fludioxonil (1–2% TRR).

Several studies were also conducted on metabolism after seed treatment. Seed potatoes were treated with [pyrrole-4-^{14}C]fludioxonil at a rate of 2.5 g ai/100 kg seed. The pieces were planted, and mature potatoes were harvested after 95 days. The tuber contained 0.006 mg/kg radiolabelled residue, calculated as fludioxonil. Fludioxonil represented 21% of the TRR.

Rice seeds were soaked in a [pyrrole-4-^{14}C]fludioxonil solution equivalent to 6.5 kg ai/100 kg seed. Rice plants were grown in a glasshouse and harvested at maturity, 152 days after treatment. Stalks, hulls and seeds contained $\leq$ 0.002 mg/kg radiolabelled residue as fludioxonil equivalents.

The metabolism of [pyrrole-4-^{14}C]fludioxonil was studied in field-grown spring wheat plants treated at 7.4 g ai/100 kg seed. Plants were harvested 48 days (ear emergence), 83 days (milky stage) and 106 days (maturity) after treatment. At 48 days, stalks contained 0.005 mg/kg of radioactive residue (calculated as fludioxonil). At 83 days, stalks contained 0.004 mg/kg and ears contained 0.002 mg/kg. At maturity, stalks contained 0.015 mg/kg, husks contained 0.005 mg/kg, and grain contained 0.003 mg/kg.

Cotton-seed was treated at a rate of 2.5 or 5.0 g ai/100 kg seeds with [pyrrole-4-^{14}C]fludioxonil and then planted in sandy loam soil in pots. Plants were sampled at maturity, 186 days after treatment. Cotton-seed treated at 5.0 g ai/100 kg seed contained 0.003 mg/kg TRR, and those treated at 2.5 g ai/100 kg contained 0.012 mg/kg. Only 20–30% of the radioactivity could be extracted.

Soya bean seeds were treated with [pyrrole-4-^{14}C]fludioxonil at a rate of 5.0 g ai/100 kg seed and grown to mature plants in a greenhouse. The plants were sampled at intervals of 28 days after planting (sixth node stage), 38 days (mid- to full bloom stage) and 133 days (maturity). Soya bean forage (sixth node) contained 0.096 mg/kg TRR, calculated as fludioxonil. Soya bean hay (mid-flowering) contained 0.041 mg/kg. At maturity, stalks contained 0.005 mg/kg, dry beans contained 0.015 mg/kg, and dry hulls contained 0.012 mg/kg. The main tentatively identified component in forage and hay was 6-hydroxy-2H-chromeno[3,4-c]pyrrol-4-one, representing 2% TRR.

The metabolism of fludioxonil in and on plants after foliar and seed treatment is adequately understood. Generally, the residue concentrations resulting from seed treatment were too low to

permit extraction and identification. The numerous studies of foliar application indicate a similar metabolic pathway, showing fludioxonil as the main component of the residue.

The pathway is characterised by the generation of a large number of metabolites and proceeds mainly through oxidation. Each metabolite represents <10% TRR. With the exception of oxidation at the 7´-C of the benzoldioxol ring, the oxidations and conjugations occur at the C-2, C-5 and N-1 positions of the pyrrole ring. Ultimately, cleavage of the pyrrole ring, probably via the formation of succinamic acid derivatives, results in formation of 2,2-difluorobenzo[1,3]dioxole metabolites. In studies with pyrrole- or phenyl-labelled ^{14}C -fludioxonil, no metabolites were found, indicating cleavage of the bond between the phenyl and pyrrole ring.

No information was provided on the degradation of fludioxonil when applied post-harvest. Nevertheless, the use of both short and long PHIs in the trial on metabolism in peaches after foliar application provides some indication of the fate of fludioxonil when applied to fruit post-harvest. The study of metabolism in peach shows that the main constituent in the residue is fludioxonil.

Soil

The degradation of fludioxonil on soil exposed to light is rapid, with a half-life of <1 day for the component of fludioxonil on the surface. On the basis of isolated and identified degradates in studies of radiolabelled compound, it would appear that fludioxonil degrades to 4-(2,2-difluorobenzo[1,3]dioxol-4-yl)-2,5-dioxo-2,5-dihyrdo-1H-pyrrole-3-carbonitrile or the 2,5-dioxo derivative of fludioxonil. This metabolite undergoes epoxidation at the C-3 to C-4 position and pyrrole ring opening to give 3-carbamoyl-2-cyano-3-(2,2-difluorobenzo[1,3]dioxol-4-yl)oxirane-2-carboxylic acid. The latter degrades to 2,2-difluoro-benzo[1,3]-dioxole-4-carboxylic acid, a compound found in the studies of rotational crops (see below).

The breakdown of fludioxonil in soil under aerobic conditions with no exposure to light is slow. Mineralization to carbon dioxide is the main route of breakdown (4–45% of applied radioactivity). Some unextractable residues (8–27%) also form. The half-life in sandy loam soil is approximately 250 days.

Four studies of confined rotational crops were conducted with [pyrrole-4-^{14}C]fludioxonil. In the first study, soil was sprayed with [pyrrole-4-^{14}C]fludioxonil at a rate of 750 g ai/ha, and lettuce, winter wheat, sugar beets and maize were planted after intervals of 90, 140, 320 and 345 days respectively. Lettuce at maturity (152 days post-treatment) contained 0.006 mg/kg radiolabelled residue, winter wheat stems and grain contained 0.008 and 0.002 mg/kg 429 days post-treatment, sugar beet roots and tops contained 0.001 and <0.001 mg/kg respectively, and maize stalks and grain contained 0.005 and <0.001 mg/kg respectively, at maturity (519 days after treatment). The concentrations of residue were too low to pursue isolation and identification.

In a follow-up study, spring wheat, mustard and turnips were planted 33 days after application of [pyrrole-4-^{14}C]fludioxonil to bare ground at a rate of 120 g ai/ha. At maturity, the residue levels were <0.01 mg/kg (TRR) in the turnips and mustard greens and 0.006 mg/kg in wheat grain. In 25% mature wheat forage (109 days post-treatment) and in wheat straw (175 days post-treatment), however, the residue levels were 0.058 and 0.12 mg/kg respectively. The following components were identified in immature wheat forage: fludioxonil (2.4% TRR, 0.001 mg/kg), 6-hydroxy-2H-chromeno[3,4-c]pyrrol-4-one (11% TRR, 0.006 mg/kg, tentative identification), 4-hydroxy-2,5-dione derivative (4.2% TRR, 0.002 mg/kg), 2,5-dioxo derivative (<0.001 mg/kg, tentative identification), 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (2.3% TRR, 0.001 mg/kg, tentative identification) and 2-(2,2-difluorobenzo[1,3]dioxol-4-yl)-2-hydroxyacetamide (<0.001 mg/kg, tentative identification). Fludioxonil (<0.001 mg/kg) and similar metabolites at similar concentrations were detected in wheat straw. This work was confirmed by another experiment conducted at 60 g ai/ha.

In a final trial, [phenyl-U-^{14}C]fludioxonil was sprayed onto bare ground at a rate of 1120 g ai/ha. Rotational crops of spring wheat, mustard and radishes were planted 30, 90 and 210 days after treatment and grown to normal maturity. Radish tubers contained 0.14, 0.019 and 0.019 mg/kg of radiolabelled residue at plant-back intervals of 30, 90 and 210 days, about 50% of which could be extracted with organic solvents and water. Mustard greens contained 0.033, 0.044 and 0.050 mg/kg at

30, 90 and 120 days after treatment. Mature wheat straw contained 0.36, 0.14 and 0.11 mg/kg radiolabelled residues, and grain contained 0.058, 0.021 and 0.019 at 30, 90 and 120 days plant-back, of which about 40% from straw and 20% from grain was extractable.

The main metabolite identified in the various commodities was 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid, at levels ranging from 4.4% TRR in mature wheat straw (30-day plant-back) to 38% TRR (radish tuber, 90-day plant-back). Fludioxonil generally represented <4% TRR (≤ 0.001 mg/kg) in all matrices except mature radish tuber (30-day plant-back), in which it represented 12% TRR or 0.016 mg/kg.

Field rotational crop studies were conducted in which fludioxonil was applied four times to bare soil at 280 g ai/ha per application, followed at plant-back intervals of 30, 90, 150 and 210 days by sowing of wheat, turnips and leaf lettuce. The mature crops contained no detectable residues of fludioxonil at any plant-back interval, with a LOQ of 0.01 mg/kg.

The nature and extent of the residue in rotational crops after use of fludioxonil on the primary crop is adequately delineated. Similar patterns were observed with pyrrole- and phenyl-labelled ^{14}C - fludioxonil, although somewhat greater concentrations of residue were encountered with the phenyl label. In these trials, fludioxonil was not taken up into rotational crops at plant-back intervals as short as 30 days. The metabolism of fludioxonil in the crops was apparently the same as that seen in target crop studies, but this conclusion is speculative as little or no residue was generally found. Primarily on the basis of the confined study with [phenyl-U-^{14}C]fludioxonil, the metabolism and degradation of this compound is characterised by oxidation and cleavage of the pyrrole ring. No metabolites of cleavage of the bond between the phenyl and the pyrrole ring were observed. The proposed metabolic and degradation pathway is that suggested for foliar application of fludioxonil.

The Meeting concluded that the presence of fludioxonil residues in succeeding (rotational) crops from foliar applications is unlikely.

Methods of analysis

The Committee concluded that adequate analytical methods exist for both monitoring and enforcing MRLs and for gathering data in supervised field trials and processing studies. Methods REM-133/AG631A and AG-597 are suitable for the determination of fludioxonil in samples of plant origin. The methods are fully validated for a range of crops and crop types. In addition, fludioxonil residues can be determined in samples of plant origin by European multi-residue method DG S17.

Method REM-133 involves HPLC with ultraviolet detection (268 nm). Only fludioxonil is determined. Samples are extracted and then placed on a phenyl solid-phase extraction cartridge and eluted with the appropriate solvent. The samples are analysed by HPLC with column switching (C-18 and phenyl). The validated LOQ is 0.01–0.04 mg/kg. In some European field trials, method REM 133 was modified by the use of only one HPLC column (amino) with a fluorescence detector (excitation, 265 nm; emission, 312 nm). The method was radiovalidated. In this method, 89% of the total radioactivity was solubilized, and 66% of the fludioxonil determined in the metabolism study was identified.

Method AG-597 is another HPLC method with ultraviolet detection (268 nm). Only fludioxonil is determined. Samples are extracted and then cleaned up by silica solid-phase extraction. Analysis is usually conducted on an amino or a C18 column. The method was validated with a wide array of commodities, with limits of determination of 0.01–0.02 mg/kg, except for sorghum grain, for which the limit was 0.05 mg/kg. The method was validated by the US Environmental Protection Agency. Liquid chromatography with mass spectrometry can be used for confirmation, with quantification on ion 247.

A European multi-residue method based on DFG S19 was developed for an array of plant commodities. Extracts are separated by gel permeation chromatography and analysed by capillary gas chromatography with a mass selective detector, monitoring ions 248, 154 and 127. The method was

validated for fludioxonil only at 0.02 mg/kg for tomato, orange, wheat and rape and at 0.01 mg/kg for grape wine.

The Meeting concluded that an adequate method exists for the determination of fludioxonil and certain metabolites in livestock commodities (meat, milk, poultry, eggs). In the HPLC method, fludioxonil and metabolites are converted to 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid. The resulting residue is quantified by external calibration against standards of this conversion product, with HPLC and a ultraviolet detector (230 nm). Column switching is used, and alternate columns are specified as a confirmatory procedure. The method was validated at 0.01 mg/kg for muscle and milk and at 0.05 mg/kg for eggs, fat, liver and kidney.

Stability of residues in stored analytical samples

The Meeting concluded that fludioxonil is stable in an array of stored frozen commodities. No degradation of fludioxonil was observed in any frozen commodity throughout the duration of the studies. Fludioxonil is stable for at least 24 months in frozen samples of the following commodities: cereal grains, cereal straw, apple, tomato, grape, pea, rape-seed, maize grain, maize meal, sorghum hay, potato tuber and potato flake. Fludioxonil is stable for at least 12 months in frozen broccoli, cabbage and carrots and for 9 months in frozen chives. Fludioxonil is also stable for at least 3 months in frozen peach, plum, cherry and blueberry.

The Meeting also concluded that fludioxonil and metabolites, determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid, are stable for at least 12 months in frozen muscle and for at least 18 months in frozen liver, milk and eggs.

Definition of the residue

The results of the studies of metabolism after both seed treatment and foliar treatment show that the main identified component of the radiolabelled residue is fludioxonil. The identified metabolites generally represent <10% of the TRR. The toxicological evaluation did not reveal any metabolites of special concern relative to the parent. The Meeting concluded that the residue definition for plant commodities for compliance with MRLs and for estimation of dietary intake is fludioxonil.

In the analytical methods for plant commodities, HPLC with ultraviolet detection or gas chromatography with mass spectrometry detection, only fludioxonil is determined.

The results of the studies of metabolism in goats and hens were similar. In goats, the main identified metabolite in meat, fat and liver was fludioxonil, representing 33%, 83% and 14% TRR respectively. The main metabolite in milk and kidney was the pyrrole carbonitrile-*O*-glucuronide, representing 65% and 31% TRR respectively, and the parent was absent. In hens, fludioxonil was present in muscle (7.9–28% TRR) and skin plus attached fat (9.8%). It accounted for 1.2% of the TRR in liver, 2.6% in kidney and 2.2% in egg yolk (equivalent to 2.1% egg TRR). The main identified component of the radioactive residue in eggs and fat was the sulfate conjugate of 4-(2,2-difluorobenzo[1,3]dioxol-4-yl)-1-hydroxy-1*H*-pyrrole-3-carbonitrile. The benzene–pyrrole linkage was intact in all the identified metabolites. The toxicological evaluation did not reveal any metabolites of particular concern relative to the parent.

The P_{ow} for fludioxonil is 4.1, suggesting that fludioxonil is fat-soluble. In goats, the radioactive residue represented 0.07 mg/kg TRR in muscle and 0.26 mg/kg in fat. The main component in muscle and fat was fludioxonil (24–43% TRR in muscle and 83% in fat). The Meeting concluded that the fludioxonil residue is fat-soluble, but it also noted the lack of information on milk fat from both the metabolism and the feeding study.

In the validated analytical method for fludioxonil, fludioxonil and pyrrole-derivative metabolites are converted to 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid.

The Meeting concluded that the residue definition of the residue for livestock commodities (for compliance with MRLs and for estimation of dietary intake) is the sum of fludioxonil and its

benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil.

Results of supervised trials on crops

Supervised trials were conducted with foliar treatment, seed treatment and post-harvest treatment of a variety of crops worldwide.

Citrus fruit

Citrus (orange, lemon, grapefruit) was treated by post-harvest dip (120 g ai/hl) or spray (1000 g ai/250 000 kg fruit) in 28 trials conducted in the USA. GAP specifies a maximum of two treatments, one on entering storage and a second on exit of storage for market distribution, at a single application rate of 500 g ai/250 000 kg fruit (2 mg/kg; 0.85 kg ai/hl for droplet-type applications with a low-volume concentrate, 0.24 kg ai/hl for high-volume jet-type sprays) and 0.06 kg ai/hl for 30-s dip treatments. All trials were conducted at twice GAP in a single-application dip or high-volume spray, and nine of the trials included a second application at twice GAP with a re-treatment interval of 0 days. In the absence of data on residue level decrease during storage of citrus, the Meeting considered application at twice GAP an approximation of the practical situation of two treatments at GAP with a variable interval between applications.

The residue levels on orange (six trials; one treatment at twice GAP), in ranked order, were: 0.48, 0.90, 1, 1.4, 2.2 and 2.8 mg/kg. The levels on lemon (seven trials; one treatment at twice GAP) were: 0.46, 0.54, 1., 1.1 (two), 2.9 and 3.2 mg/kg, and those on grapefruit (six trials; one treatment at twice GAP) were: 0.51, 0.94, 0.95, 1.4, 3.8 and 5.2 mg/kg. The nine trials consisting of two sequential applications, each at twice the GAP application rate, were considered exaggerations and were not used; the residue levels ranged from 0.52 mg/kg to 6.0 mg/kg.

The Meeting decided to combine the data; the residue levels on citrus (19 trials; one treatment at twice GAP single rate), in ranked order, were: 0.46, 0.48, 0.51, 0.54, 0.90, 0.94, 0.95, 1 (two), 1.1 (two), 1.4 (two), 2.2, 2.8, 2.9, 3.2, 3.8 and 5.2 mg/kg. Data on residues in pulp were available from only one trial on oranges, in which flesh and peel contained approximately equal concentrations of fludioxonil. The Meeting estimated a maximum residue level for whole citrus of 7 mg/kg and an STMR of 1.1 mg/kg.

Pome fruit

Apples were treated by post-harvest dip or spray in the USA with a 50% wettable powder formulation. GAP specifies a maximum of two treatments, one on entering storage and a second on exit from storage for market distribution, at a single application rate of 500 g ai/250 000 kg fruit (2 mg/kg; 0.85 kg ai/hl for droplet-type applications with a low-volume concentrate, 0.24 kg ai/hl for high-volume jet-type sprays) and 0.06 kg ai/hl for dip treatments of approximately 30 s. Seven trials were conducted at approximately the GAP rate (single application), and two trials were conducted at the GAP rate with two sequential applications: dip at 0.06 kg ai/hl, followed by packing-line spray at 2.5 mg/kg (125% GAP). As GAP specifies two treatments, the Meeting regarded the two trials conducted with two applications as an approximation of GAP. The residue levels were 2.0 and 2.2 mg/kg. The Meeting considered two trials inadequate for estimating a maximum residue level.

Pears were treated by post-harvest dip or spray treatment in the USA with a 50% wettable powder formulation. GAP is identical to that for apples. Twelve trials were conducted, but only two were conducted with two applications: 0.048 kg ai/hl drench (80% dip GAP), followed by a packing-line spray at 0.2–0.6 kg ai/hl or 2.2–6.6 mg/kg fruit (110–300% GAP). As GAP specifies two treatments, the Meeting regarded the two trials conducted with two applications as an approximation of GAP. The residue levels (with an exaggerated rate for the second application) were 1.6 and 2.8 mg/kg. The Meeting considered two trials insufficient for estimating a maximum residue level.

The Meeting considered combining the post-harvest trials on pear and apple (same GAP) for mutual support, but considered four trials insufficient for these commodities.

Pears received foliar treatment with a 25% water-dispersible granule formulation in seven trials conducted at GAP (three in Italy , three in Spain and one in France). The GAPs are as follows: Italy, 0.02 kg ai/hl, 0.25 kg ai/ha, three applications, 14-day PHI; Spain, 0.025 kg ai/ha, 0.25 kg ai/ha, three applications, 7-day PHI. No GAP was available for France, and the GAP of Spain was applied to all trials (7-day PHI). The residue levels, in ranked order, were: 0.14, 0.15, 0.18, 0.21, 0.28, 0.32 and 0.36 mg/kg. The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.21 mg/kg.

Stone fruit

In seven post-harvest treatment trials (spray or dip), *peaches* were treated at the GAP of 0.06 kg ai/hl with a 50% wettable powder formulation. The residue levels on peaches after treatment (no storage interval), in ranked order, were: 0.37, 0.42, 1.6, 2.2, 2.8, 3.4 and 3.6 mg/kg

Trials of foliar application of fludioxonil (62.5% water-dispersible granules, 25% fludioxonil) were conducted in France, Italy and Spain. The relevant GAPs are: France, 0.015 kg ai/hl, 14-day PHI; Italy, 0.015 kg ai/hl, 0.25 kg ai/ha, two applications, 14-day PHI. No GAP was available for Spain, and the GAP of Italy was applied. The residue levels in 11 trials at GAP, in ranked order, were: 0.02, 0.04 (two), 0.08 (two), 0.11, 0.23 (two), 0.29 and 0.33 mg/kg. The data set on post-harvest treatment contained the highest residue values and was used to estimate the maximum residue level and the STMR.

Post-harvest treatment of *plums* was investigated in two trials in the USA. GAP is spray application at 0.06 kg ai/hl of a 50% wettable powder formulation. The results were 0.10 and 0.92 mg/kg. As the results for post-harvest treatment of plums were not statistically significantly different from those for peaches with the same GAP, the populations can be combined for mutual support.

Trials of foliar application of fludioxonil (22.5% water-dispersible granules, 25% fludioxonil) to plums were conducted in France, Italy, Germany and Switzerland. The relevant GAPs are: France, 0.012 kg ai/hl, 0.12 kg ai/ha, three applications, 14-day PHI; Italy, 0.025 kg ai/hl, 0.25 kg ai/ha, two applications, 14-day PHI; Switzerland, 0.3 kg ai/ha, two applications, PHI not specified. GAP in Germany was not available, and the GAP of Italy was applied. In 12 trials at GAP, the residue levels, in ranked order, were: <0.02, 0.03, 0.04, 0.05, 0.06 (two), 0.065, 0.07, 0.09, 0.10, 0.11 and 0.17 mg/kg. The data set on post-harvest treatment contained the highest residue values and was used to estimate the maximum residue level and the STMR.

Post-harvest treatment of *cherries* was investigated in two trials in the USA. GAP is spray application at 0.06 kg ai/hl of a 50% wettable powder formulation. The reside levels were 0.19 and 0.68 mg/kg. As the results for post-harvest treatment of cherries were not statistically significantly different from those for peaches, with the same GAP, the populations can be combined for mutual support.

A 25% water-dispersible granule formulation of fludioxonil was applied as a foliar spray to cherries in Europe. In six trials, the residue levels ranged from 0.16 to 0.43 mg/kg after a treatment rate of 0.019 kg ai/hl and a PHI of 7 days. No GAP was provided for any country in Europe.

The results for post-harvest treatment (GAP, dip or spray at 0.06 kg ai/hl) of peaches, plums and cherries were combined. The residue levels in the 11 trials, in ranked order, were: 0.10, 0.19, 0.37, 0.42, 0.68, 0.92, 1.6, 2.2, 2.8, 3.4 and 3.6 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.80 mg/kg for stone fruit.

Berries and other small fruit

Grape

Trials on foliar treatment of grape vines were available from Chile, France, Germany, Greece, Italy , South Africa, Spain and Switzerland. The relevant GAPs (25% water-dispersible granules) are: Chile, 0.25 kg ai/ha, two applications, 7-day PHI; France, 0.3 kg ai/ha, two applications, 60-day PHI; Germany, 0.015 kg ai/hl, 0.24 kg ai/ha, two applications, 35-day PHI; Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, two applications, 21-day PHI; Spain, 0.25 kg ai/ha, two applications, 21-day PHI; Switzerland, 0.3 kg

ai/ha, one application, early season. The residue values at the GAP of Chile, in ranked order, were: 0.18, 0.24 and 0.28 (two) mg/kg. The trials in France (northern), Germany and Switzerland were evaluated against the GAP of Germany, resulting in six trials in Germany (0.17, 0.20, 0.21, 0.24, 0.28, 0.31 mg/kg) and five trials in Switzerland (0.90, 0.99, 1.4, 1.6 (two) mg/kg) at GAP and combined: 0.17, 0.20, 0.21, 0.24, 0.28, 0.31, 0.90, 0.99, 1.4 and 1.6 (two) mg/kg. The GAP of Spain was used to evaluate the trials in Greece, Italy and Spain. The residue levels in two trials in Spain and one in Italy at this GAP were 0.22, 0.41 and 0.43 mg/kg. The Meeting combined the 18 values for Chile, Germany and Switzerland, Spain and Italy (same population) and found a ranked order of: 0.17, 0.18, 0.20, 0.21, 0.22, 0.24 (two), 0.28 (three), 0.31, 0.41, 0.43, 0.90, 0.99, 1.4 and 1.6 (two) mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.28 mg/kg.

Strawberry

Foliar applications of a 50% wettable powder formulation were made to strawberries in the USA, and of a 25% water-dispersible granule formulation in Europe (glasshouse and outdoor). The relevant GAPs are: France, 0.25 kg ai/ha, one application, 3-day PHI; Germany, 0.125 kg ai/hl, 0.25 kg ai/ha, three applications, 7-day PHI; Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.25 kg ai/ha, three applications, 7-day PHI; Switzerland, 0.025 kg ai/hl, 0.3 kg ai/ha, two applications, 14-day PHI; USA, 0.25 kg ai/ha, four applications, 0-day PHI. The values from the eight trials in the USA in ranked order were: 0.22, 0.43, 0.54, 0.62, 1.0, 1.2 (two) and 1.3 mg/kg. At GAP of Spain and Germany (0.25 kg ai/ha, three applications, 7-day PHI), the values from outdoor trials in Germany were 0.04 and 0.05 (two) mg/kg; those in Switzerland were 0.13 (two) mg/kg; those in France were 0.09, 0.25, 0.61 and 0.77 mg/kg; that in Italy was 0.14 mg/kg; those in Spain were 0.64 and 0.83 mg/kg; and that in the UK was 0.11 mg/kg. These 13 values may be combined: 0.04, 0.05 (two), 0.09, 0.11, 0.13 (two), 0.14, 0.25, 0.61, 0.64, 0.77 and 0.83 mg/kg. When the European and US populations were combined, the residue levels, in ranked order, were: 0.04, 0.05 (two), 0.09, 0.11, 0.13 (two), 0.14, 0.22, 0.25, 0.43, 0.54, 0.61, 0.62, 0.64, 0.77, 0.83, 1.0, 1.2 (two) and 1.3 mg/kg.

Indoor trials were also conducted in France, Italy, Spain and Switzerland. The ranked order of residue values evaluated against the GAP of Italy was: 0.11, 0.21, 0.27 and 1.9 mg/kg.

When the results of the indoor and outdoor trials were combined, the residue levels in the 25 trials, in ranked order, were: 0.04, 0.05 (two), 0.09, 0.11 (two), 0.13 (two), 0.14, 0.21, 0.22, 0.25, 0.27, 0.43, 0.54, 0.61, 0.62, 0.64, 0.77, 0.83, 1.0, 1.2 (two), 1.3 and 1.9 mg/kg. The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.27 mg/kg.

Raspberry

Foliar applications of a 25% water-dispersible granule formulation of fludioxonil were made to raspberries in Germany and the USA. The relevant GAPs are: Switzerland, 0.025 kg ai/hl, 0.32 kg ai/ha, two applications, 14-day PHI; and USA, 0.25 kg ai/ha, four applications, 0-day PHI. The residue levels, in ranked order, were: 0.19, 0.24 (two) and 0.30 mg/kg in Germany and 0.96, 1.0 (three) and 3.6 mg/kg in the USA.

The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 1.0 mg/kg for raspberries and extrapolated the values to blackberry and dewberry on the basis of the trials in the USA, which had the highest values.

Blueberry

Foliar applications of a 25% water-dispersible granule formulation of fludioxonil were made to blueberries in Germany and the USA. The relevant GAP is: USA, 0.25 kg ai/ha, four applications, 0-day PHI. No GAP was available for Germany or other European countries. The residue levels in ranked order at GAP in the USÂ were: <0.05, 0.14, 0.26, 0.52, 0.68, 0.84, 0.90 and 1.4 mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.60 mg/kg.

Black and red currant

Foliar application of a 25% water-dispersible granule formulation of fludioxonil was made to black currants in four trials and to red currants in one trial in Germany. As no GAP is available for Germany or other European countries, the Meeting could not estimate an STMR or maximum residue level.

Assorted tropical andsubtropical fruits

Lychee

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to lychee in the USA, where GAP is: 0.25 kg ai/ha, four applications, 0-day PHI. The residue levels in ranked order were: 0.81, 0.92 and 1.4 mg/kg. The Meeting noted that five or seven applications were made at about 7-day intervals and that the extra one or three applications would have been made ≤ 21 days before harvest. On the basis of studies of decline in other fruit crops, they might have made a significant contribution (about 25%) to the final residue level. Therefore, the Meeting did not estimate a maximum residue level or an STMR.

Kiwi

Kiwi fruit in the USA were treated post-harvest at 0.06 kg ai/hl with a wettable powder formulation. GAP specifies application of a 50% wettable powder formulation as a dip at 0.06 kg ai/hl for 30 s or as a low-volume application with a control droplet-type application at 0.24 kg ai/hl or 2.5 mg/kg fruit. Trials were conducted, with two methods (dip, spray) at two locations and a single method (dip) at a third. The ranked order of residue levels in the five trials was: 1.6, 5.2, 7.2, 8.6 and 9.0 mg/kg. The Meeting estimated mg/kg a maximum residue level of 15 mg/kg and an STMR of 7.2 mg/kg for kiwi fruit.

Pomegranate

Pomegranate in the USA were treated post-harvest at 0.06 kg ai/hl with a wettable powder formulation. The residue levels were 0.65 and 0.95 mg/kg; however, there is no GAP, and the Meeting could not estimate a maximum residue level or an STMR.

Bulb vegetables

Green (spring) onions

Fludioxonil was applied as a foliar spray of a wettable powder formulation to green onions in the USA. The relevant GAP is 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in ranked order were 0.14, 0.59 and 3.0 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.59 mg/kg.

Bulb onion

Fludioxonil (wettable powder formulation) was applied as a foliar spray to onions in France, Italy, Germany and Switzerland and in the USA. The relevant GAPs are: Austria, 0.25 kg ai/ha, three applications, 7-day PHI; Switzerland, 0.25 kg ai/ha, two applications, unspecified PHI; and USA, 0.25 kg ai/ha, four applications, 7-day PHI. GAP in Switzerland (assumed 0-day PHI) was applied to the other European countries in the absence of a GAP for southern Europe. The residue levels in trials on bulb onions (fresh) at the Swiss GAP were: France, <0.02, 0.05 and 0.06 mg/kg; and Italy, <0.02, 0.04, 0.07 and 0.34 mg/kg. The levels in three trials on bulb onions (dry) in the USA at US GAP were: <0.02 (three), 0.04 (two) and 0.06 mg/kg. The Meeting combined the data sets for Europe and the USA and found a ranked order of residue levels of: <0.02 (five), 0.04 (three), 0.05, 0.06 (two), 0.07 and 0.34 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.04 mg/kg.

Brassica vegetables

Broccoli

Fludioxonil (water-dispersible granule formulation) was applied as a foliar spray to broccoli in Canada and the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in seven trials at US GAP, in ranked order, were: 0.07, 0.10, 0.18, 0.23, 0.26, 0.34 and 0.36 mg/kg. The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.23 mg/kg.

Cabbage

Fludioxonil (water-dispersible granule formulation) was applied as a foliar spray to cabbage in the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in ranked order on cabbage with wrapper leaves in six trials at GAP were: 0.17, 0.17, 0.21, 0.27, 0.5 and 1.2 mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.24 mg/kg.

Fruiting vegetables

Cucumber

A 25% water-dispersible granule formulation of fludioxonil was applied as a foliar spray (glasshouse and field) to cucumbers in Greece, Spain and Switzerland. The relevant GAPs are: Italy, 0.02 kg ai/hl, 0.20 kg ai/ha, three applications, 7-day PHI; Spain, 0.025 kg ai/hl, three applications, 7-day PHI; Switzerland, 0.025 kg ai/hl, 3-day PHI. GAP for Greece was not available, and that of of Italy and Spain was used. The results from the 10 glasshouse trials (seven in Spain, one in Greece, two in Switzerland) in ranked order were: <0.02, 0.02 (two), 0.06 (two), 0.07, 0.08 (two), 0.11 and 0.14 mg/kg. The results from the field trials (one in Greece, two in Spain) were: <0.02, 0.02 and 0.03 mg/kg. The populations are not statistically significantly different, and the combined results are: <0.02 (two), 0.02 (three), 0.03, 0.06 (two), 0.07, 0.08 (two), 0.11 and 0.14 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.06 mg/kg.

Summer squash (zucchini)

Two indoor trials were conducted on zucchini in Italy. The relevant GAP is: 25% water-dispersible granule, 0.02 kg ai/hl, 0.20 kg ai/ha, three applications, 7-day PHI. The residue levels were 0.05 and 0.06 mg/kg. The Meeting agreed to use the results for cucumber as support for summer squash. The residue levels in ranked order were: <0.02 (two), 0.02 (three), 0.03, 0.05, 0.06 (three), 0.07, 0.08 (two), 0.11 and 0.14 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.06 mg/kg.

Cantaloupe

A 50% wettable powder formulation was applied to cantaloupe vines (three times 0.28 kg ai/ha, 0.84 kg ai/ha total, 14-day PHI) in the USA by drip irrigation. GAP specifies drip irrigation application of a 50% wettable powder formulation at a rate of 0.28 kg ai/ha. The total seasonal application is limited to 0.84 kg ai/ha, and the PHI is 14 days. The residue levels in ranked order were: <0.02 (two) and 0.02 (two) mg/kg. The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.02 mg/kg for whole melon. No information was available on the residue in pulp.

Tomato

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray in glasshouses (11 trials) and in the field (two trials) in Greece, Spain, Switzerland and the UK. The relevant GAPs are: Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.025 kg ai/hl, three applications, 7-day PHI; Switzerland, 0.25 kg ai/ha, two applications, 3-day PHI. GAPs were not available for Greece or the UK. As three applications were used in all trials, the GAPs of Italy and

Spain were used (7-day PHI). The residue levels in the 14 glasshouse trials at this GAP in ranked order were: 0.05, 0.08, 0.09 (two), 0.10 (two), 0.13 (two), 0.14 (two), 0.16, 0.21, 0.28 and 0.32 mg/kg. The levels in the outside trials in Switzerland were: 0.04 and 0.07 mg/kg. The two groups were statistically the same population, and the combined levels from the 16 trials were: 0.04, 0.05, 0.07, 0.08, 0.09 (two), 0.10 (two), 0.13 (two), 0.14 (two), 0.16, 0.21, 0.28 and 0.32 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.12 mg/kg.

Bell pepper

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to bell (sweet) peppers in eight glasshouse trials and two field trials in Spain and Switzerland. The relevant GAPs are: Austria, 0.025 kg ai/hl, 0.25 kg ai/ha, three applications, 7-day PHI; Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.25 kg ai/ha, three applications, 7-day PHI. The GAP of Austria and Italy was used. The ranked order of residue levels in the eight glasshouse trials (six in Spain, two in Switzerland) at GAP was: 0.08, 0.10, 0.14, 0.22, 0.29, 0.46, 0.56 and 0.60 mg/kg. The ranked order in field trials at GAP (one in Italy, one in Spain) was: 0.06 and 0.13 mg/kg. As the two groups are from the same population, they were combined to give levels of: 0.06, 0.08, 0.10, 0.13, 0.14, 0.22, 0.29, 0.46, 0.56 and 0.60 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.18 mg/kg.

Egg plant

Fludioxonil formulated as 25% water-dispersible granule was applied to Egg plant as a foliar spray three times in glasshouse trials in Italy and Spain. The relevant GAPs are: Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.025 kg ai/hl, three applications, 7-day PHI. The results at GAP in ranked order were: 0.03, 0.06, 0.06 and 0.08 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.06 mg/kg.

Sweet corn (corn-on-the-cob)

Fludioxonil (flowable concentrate) was applied to sweet corn seed in the USA before planting. The relevant GAP is 5 g ai/1000 kg seed. The residue levels were <0.01 in three trials at three to five times GAP. The Meeting recognized the similarity of sweet corn and maize (see below) and decided to translate the field trial data for seed treatment of maize (same GAP as sweet corn) to sweet corn seed treatment. The residue levels in the eight trials were all <0.01 mg/kg. The Meeting estimated a maximum residue level of 0.01 (*) mg/kg and an STMR 0.01 mg/kg.

Leafy vegetables

Lettuce, head

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to lettuce in 11 glasshouse and 17 field trials in France, Germany, Italy, Spain and Switzerland. The relevant GAPs are: France, 0.15 kg ai/ha, four applications, 14-day PHI; Italy, 0.018 kg ai/hl, 0.18 kg ai/ha, three applications, 14-day PHI; Spain, 0.15 kg ai/ha, three applications, 14-day PHI; Switzerland, 0.12 kg ai/ha, two applications, early season. No GAP was available for Germany. The GAP of Italy was used to evaluate the trials. The ranked order of residue levels in the glasshouse trials was: 0.72, 0.98, 1.1, 2.4, 2.5, 2.7 (two), 3.4 (two), 4.7 and 6.0 mg/kg. The ranked order of residue levels in the field trials was: <0.02 (six), 0.02 (two), 0.04 (three), 0.07, 0.11, 0.17, 0.29, 1.2 and 1.2 mg/kg. The two sets are not from the same population. In the basis of the indoor trials, the Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 2.7 mg/kg.

Watercress

Watercress was treated with fludioxonil (25% water-dispersible granules) as a foliar spray in the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 0-day PHI. In the two trials at GAP,

the residue levels were 4.2 and 4.5 mg/kg. The OECD York Workshop recommended a minimum of three trials for commodities that are not significant in trade or in the diet. (See mustard greens.)

Mustard greens

Supervised trials were conducted on mustard greens in the USA. The relevant GAP is: 0.24 kg ai/ha, water-dispersible granules, four applications, 7-day PHI. The ranked order of residue levels in the seven trials at GAP was: 0.06, 0.49, 0.54, 0.76, 1.2, 6.6 and 7.1 mg/kg. The Meeting decided to combine the results of the trials on watercress and mustard greens (same GAP) for mutual support. The ranked order of levels in the nine trials was 0.06, 0.49, 0.54, 0.76, 1.2, 4.2. 4.5, 6.6 and 7.1 mg/kg. The Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 1.2 mg/kg for both watercress and mustard greens.

Legume vegetables and pulses

Bean pod with seed (common bean, French bean, edible podded bean)

Fludioxonil (water-dispersible granules) was applied as a foliar spray to beans in pod in 22 field and glasshouse trials in France, Spain and Switzerland. The relevant GAPs are: France, 0.083 kg ai/hl, 0.25 kg ai/ha, number of applications not specified, 14-day PHI; Spain, 0.025 kg ai/hl, three applications, 14-day PHI. No GAP was available for Switzerland, and the GAP of France was applied. The ranked order of residue levels from the 15 field trials was: <0.02, 0.02 (two), 0.03 (five), 0.04 (two), 0.06 (three), 0.09 and 0.13 mg/kg. The ranked order in the seven glasshouse trials was: 0.03, 0.04 (two), 0.06, 0.09, 0.17 and 0.20 mg/kg. The two groups are not from different populations and were therefore combined to give residue levels of: <0.02, 0.02 (two), 0.03 (six), 0.04 (four), 0.06 (four), 0.09 (two), 0.13, 0.17 and 0.20 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.04 mg/kg for beans (pods and/or immature seeds). This maximum residue level and STMR are extended to peas with pod.

Trials were also conducted on the seed treatment of broad bean and French bean seeds (flowable concentrate) at 5 g ai/100 kg seed in Denmark and Germany. The residue levels were <0.02 mg/kg on bean seed in all six trials, but no GAP was available.

Peas (succulent)

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to pea vines in France and Switzerland. The relevant GAP is that of France for legume vegetables: 0.083 kg ai/hl, 0.25 kg ai/ha, number of applications not specified, 14-day PHI. No GAP was available for Switzerland, and the GAP of France was applied. The ranked order of residue levels in the trials at GAP was: <0.02 (10) and 0.02 mg/kg.

Trials were also conducted of seed treatment of peas with a flowable concentrate or water-dispersible granule formulation in France and the UK. The residue levels were <0.02 mg/kg in the six trials conducted at the GAP of the UK (5% water-dispersible granules, 10 g ai/100 kg seed).

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.02 mg/kg for peas, shelled (succulent seeds) on the basis of the trials with foliar application. Nevertheless, the maximum residue level and STMR also accommodate seed treatment use and are extended to succulent beans without pod.

Pulses (dry bean and dry pea)

A water-dispersible granule formulation of fludioxonil was applied as a foliar spray to pea and bean (kidney) vines in France. The relevant GAP is: Austria and Spain, water-dispersible granules, 0.25 kg ai/ha, two applications, 14-day PHI. No GAP was available for France, and the GAP

of Spain was applied. The ranked order of residue levels in dry pea and bean was: <0.02 (two), 0.04 (two) and 0.05 mg/kg.

Supervised trials on the treatment of pea seed in France were also considered. GAP in the UK is application of a 5% water-dispersible granule formulation of fludioxonil (w/w) at a rate of 10 g ai/100 kg pea seed. The residue levels in the seven trials at this GAP were <0.02 mg/kg in dry seed at harvest.

The Meeting estimated a maximum residue level of 0.07 mg/kg and an STMR of 0.02 mg/kg for dry peas and for dry beans after foliar application of fludioxonil. The Meeting noted that this also accommodates use of fludioxonil for seed treatment.

Root and tuber vegetables

Potato

Fludioxonil (flowable concentrate, dustable powder) was applied to potato pieces as seed treatment in six trials in Australia, three in South Africa and 13 in the USA. The available GAPs are: Australia, flowable concentrate, 10%, 2.5 g ai/100 kg seed; USA, flowable concentrate, 2.5 g ai/100 kg seed. The ranked order of residue levels on mature potatoes in trials at GAP in Australia and the USA was: <0.01 (16) and 0.01 (17) mg/kg. The Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg.

Yam

A 50% wettable powder formulation of fludioxonil was applied as post-harvest treatment to yams at 0.06 kg ai/hl in the USA. GAP specifies application of a 50% wettable powder formulation as a single dip application at a rate of 0.06 kg ai/hl for about 30 s. Two trials were conducted at GAP, and in each trial both whole tubers and tuber pieces (cut yams) were tested. The ranked order of residue levels was: 4.6 and 5.0 mg/kg. The Meeting regarded two independent trials as insufficient for estimating a maximum residue level or an STMR.

Carrot

Nine trials were conducted in the USA in which carrot plots were given four foliar applications of fludioxonil at 0.24 kg ai/ha. The relevant GAP is: water-dispersible granules, 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in seven trials at GAP were: 0.04, 0.16, 0.18, 0.20, 0.20, 0.25 and 0.42 mg/kg. The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.20 mg/kg.

Asparagus

In two trials in Germany, asparagus plants were treated with a water-dispersible granule formulation after harvest. This gives a PHI of about 240 days. No GAP was available for Germany. GAP for Austria specifies use of a 25% water-dispersible granule formulation three times with a 14–21-day interval at 0.042 kg ai/hl or 0.25 kg ai/ha per application. No PHI is specified, but treatments are to be made at transplantation from the glasshouse to the field. The residue levels in the two German trials were <0.02 mg/kg. The Meeting considered two trials insufficient for estimating a maximum residue level or an STMR.

Cereal grains

Fludioxonil formulations were applied to wheat in France, Germany and Switzerland as seed treatment. The relevant GAPs are: Austria, Belgium, UK, flowable concentrate formulation, 5 g ai/100 kg seed, one application. In the 48 trials conducted at or above GAP, the residue levels in ranked order were: <0.02 (36) and <0.04 (12) mg/kg.

One trial was reported from Denmark in which rye seed was treated. The relevant GAP is: Austria, flowable concentrate, 5 g ai/100 kg seed. No GAP is available for Denmark. The residue level was <0.02 mg/kg.

Fludioxonil was applied as seed treatment to barley in 30 trials in France, Germany and Switzerland. The relevant GAPs are: Austria, Belgium, UK, flowable concentrate formulation, 5 g ai/100 kg seed. No GAP was available for France, Germany or Switzerland. The residue levels in six trials conducted at or above GAP were <0.02 mg/kg.

Fludioxonil was applied as a seed treatment to maize (field corn) in 27 trials in France, Germany, Greece, Hungary, Italy and Spain, three trials in South Africa and five trials in the USA. The relevant GAP is: USA, flowable concentrate formulation, 5 g ai/100 kg seed. No GAPs were available for Europe or South Africa, and the GAP of the USA was applied. The ranked order of residue values in trials conducted at GAP and at three and five times the GAP rate were <0.01 (five) and <0.02 (seven) mg/kg.

Fludioxonil was applied as seed treatment to sorghum in four trials in the USA. The relevant GAP is flowable concentrate formulation, 5 g ai/100 kg seed. The residue level at three to five times the GAP rate was <0.05 mg/kg.

All residue levels resulting from seed treatment of the five different cereal grains were below the LOQ. The combined results from all the trials, in ranked order, were: <0.01 (five), <u>≤0.02</u> (50), <0.04 (12) and <0.05 (four) mg/kg. The Meeting estimated a maximum residue level of 0.05 (*) mg/kg and an STMR of 0.02 mg/kg for cereal grains.

Pistachio nut

Fludioxonil was applied as a water-dispersible granule formulation to pistachio trees in the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels, in ranked order, were: 0.04, 0.05 and 0.08 mg/kg. The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR 0.05 mg/kg.

Rape-seed

Fludioxonil was applied to rape as seed treatment in trials in France, Germany, Sweden and the UK. GAP in Germany is treatment of seed with a flowable concentrate formulation at 12 g fludioxonil per 100 kg seed. The residue levels in the 15 trials at this GAP were <0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02 (*) mg/kg and an STMR of 0.02 mg/kg.

Cotton-seed

Fludioxonil was applied as seed treatment (flowable concentrate and emulsion formulations) to cotton in Greece and the USA. The relevant GAP is: USA, flowable concentrate, 5 g ai/100 kg seed. No GAP was available for Greece (or any other European country), and the GAP of the USA was applied. The ranked order of residue levels in the trials was: <0.02 (two) and <u>≤0.05</u> (six) mg/kg. The Meeting estimated a maximum residue level of 0.05 (*) mg/kg and an STMR of 0.05 mg/kg for cotton-seed.

Herbs

Fludioxonil was applied as a foliar spray (water-dispersible granules) to chives and basil in the USA. The relevant GAP is 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels were: 1.8 and 3.9 mg/kg on chives and 1.9 and <u>3.0</u> mg/kg on basil. The Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 2.4 mg/kg for fresh basil and a maximum residue level of 10 mg/kg and an STMR of 2.8 mg/kg for fresh chives.

For each herb, one trial included drying. The drying factor for chives is 8 (31/3.9), and that for

basil is also 8 (23/3). Application of this factor to the data from field trials with chives yielded a revised ranked order of residue levels: 14 and 31 mg/kg. Therefore, the Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 22 mg/kg for dried chives. Application of the drying factor for basil yield a revised ranked order of 15 and 24 mg/kg. Therefore, the Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 20 mg/kg for dried basil.

Animal feedstuffs

Straw, fodder and forage of cereal grains and grasses

Trials of residue levels in forage, fodder and straw after application of fludioxonil as seed treatment were conducted with wheat, rye, barley, maize, sweet corn and sorghum. Trials on wheat were conducted in Europe according to the following relevant GAP: Austria, Belgium, UK, flowable concentrate formulation, 5 g ai/100 kg seed, one application. In the 45 trials conducted at or above GAP, the ranked order of residue levels in straw was: <0.02 (eight), <0.04 (14) and <0.05 (23) mg/kg. The ranked order of residue levels in forage was: <0.02 (seven) and <0.04 (11) mg/kg.

A trial on rye was conducted in Denmark according to the GAP for Austria: flowable concentrate, 5 g ai/100 kg seed. The residue level was <0.05 mg/kg in straw and <0.05 mg/kg in forage.

Trials on barley were conducted in Europe according to the GAP for Austria, Belgium and the UK: flowable concentrate formulation, 5 g ai/100 kg seed. In five trials conducted at or above GAP, the ranked order of residue levels were: <0.02 and <0.05 (four) mg/kg in straw and <0.05 (three) mg/kg in forage.

Trials on maize and sweet corn were conducted Europe (maize only) and in the USA. The relevant GAP was: USA, flowable concentrate formulation, 5 g ai/100 kg seed, as no GAP was available for any country in Europe. There were no detectable residues in fodder (<0.01 (five) mg/kg) or forage (<0.01 (seven) mg/kg). Using the default moisture content value of 40% for maize forage (*FAO Manual*, Appendix IX), the Meeting estimated a maximum residue level of 0.03 (*) mg/kg (0.01/0.40) and an STMR of 0 mg/kg (0.00/0.40) for maize forage (dry).

Field trials were conducted on sorghum in the USA, the relevant GAP being flowable concentrate formulation, 5 g ai/100 kg seed. The residue levels after exaggerated application rates were <0.01 (four) mg/kg on fodder and <0.01 (four) mg/kg on forage.

The combined values for fodder and straw in ranked order were: <0.01 (nine), <0.02 (nine), <0.04 (four) and <0.05 (28). As no data were available on the moisture content, the default value of 83% for maize fodder was used (*FAO Manual*, Appendix IX). The Meeting estimated an STMR of 0 mg/kg (0.00/0.83) and a maximum residue level of 0.06 (*) mg/kg (0.05/0.83) for fodder (dry) and straw of cereal grains.

Rape forage and straw

Fludioxonil was applied to rape as seed treatment in trials in France, Germany, Sweden and the UK. The GAP in Germany is treatment of seed with an flowable concentrate formulation at 12 g fludioxonil per 100 kg seed. The residue levels were <0.05 mg/kg in forage (12) and straw (six).

Fate of residues during processing

A study of hydrolysis with [pyrrole-4-^{14}C]fludioxonil showed that fludioxonil is stable under the typical conditions of pasteurization, baking, brewing, boiling and sterilization.

The processing (transfer) factors through commercial-type processes for plums, strawberries,

grapes, citrus and tomato are summarized in the table below. Factors could not be calculated for cereal grains, cotton-seed or potatoes because there were no quantifiable residues in the raw agricultural commodities, even in trials with exaggerated treatment rates.

Processing factors and STMR-P values for various commodities

Raw agricultural commodity				Processed commodity			
Commodity	MRL (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Commodity	Processing factor	STMR-P (mg/kg)	HR-P (mg/kg)
Plum[1]	5	0.80	3.6	Prunes (dried plums)	1.91[2]	0.96	4.3
				Juice	0.10	0.080	
				Preserves	0.50	0.40	
				Purée	0.80	0.64	
Strawberry	3	0.38	2.2	Juice	0.16	0.061	
				Preserves	0.62	0.24	
				Jam	0.34	0.13	
Grapes	2	0.28	1.6	Raisins (dried grapes)	1.1[3]	0.31	1.8
				Juice	0.92[4]	0.26	
				Wine	0.30[5]	0.08	
				(<100 days)			
				Wine	0.036[6]	0.010	
				(>100 days			
Lemons				Juice	0.031		
				Oil	61		
				Pulp	2.1		
Tomato	0.5	0.12	0.32	Juice	0.22[7]	0.026	
				Paste	1.4[8]	0.17	
				Pomace (wet)	3.3[9]		

[1] Stone fruit, includes field trial data for cherries and peaches
[2] Four trials, range 1.8–2.7, mean 1.91, median 1.6
[3] 15 trials, range 0.58–1.7, mean 1.1, median 1.1
[4] 12 trials, range 0.58–1.0, mean 0.92, median 0.86
[5] 17 trials, range 0.012–0.86, mean 0.30, median 0.24
[6] 11 trials, range 0.0086–0.11, mean 0.036, median 0.029
[7] Four trials for pasteurized juice, range 0.20–0.24, average 0.22, median 0.22
[8] Four trials for pasteurized paste, range 1.1–1.6, average 1.4, median 1.35
[9]Two trials for wet pomace, 3.0 and 3.6

Residues in animal commodities

A feeding study was conducted in which three groups of three dairy cows received 0.55 ppm, 1.6 ppm or 5.5 ppm fludioxonil in the diet for 28–30 days. Residues of fludioxonil and metabolites, determined as CGA-192155 (2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid), were quantifiable only at the highest feeding level (5.5 ppm). Residues were found in the milk of two of three cows, with maximum values of 0.019 mg/kg and 0.014 mg/kg on days 14 and 21 respectively. At the lowest feeding level, residues were detected in milk on days 3–21 at levels of 0.001–0.004 mg/kg, with maximum detection on day 3.

Only tissue samples from cows fed the 5.5 ppm diet were analysed. No residues of fludioxonil or metabolites were found. The LOQ was 0.01 mg/kg in muscle and 0.05 mg/kg in liver, kidney and fat (perirenal and omental).

The dietary intake of ruminants and poultry can be calculated from the recommended STMRs or HRs and consideration of possible animal feed items. The table below shows the bases for the dietary intake calculation.

Commodity	Group	Maximum or highest residue level (mg/kg)	STMR or STMR-P (mg/kg)	Dry matter (%)	Dietary content (%)			Residue contribution (mg/kg)		
					Beef cattle	Dairy cows	Poultry	Beef cattle	Dairy cows	Poultry
Barley grain	GC	0.05		88	50	40	75			
Barley straw (dry)	AS	0.06			10	60				
Cotton-seed	SO	0.05		88	25	25				
Cotton-seed meal		0.05		89	15	15	20			
Maize grain	GC	0.05		88	80	40	**80**	0.02	0.03	0.05
					25	**40**				
Maize forage (dry)	AF	0.03			40	50				
Maize fodder (dry)	AS	0.06			25	15				
Oat grain	GC	0.05		89	50	40	80			
Oat straw (dry)	AS	0.06		90	10	10				
Potato waste	AB		0.01	15	**75**	**40**		0.05	0.03	
Rape meal		0.02		88	15	15	15			
Rape forage	AM	0.05		30	30	30				
						20				
Rye grain	GC	0.05			40	40	50			
Rye straw (dry)	AS	0.06		88	10	10				
Wheat grain	GC	0.05		89	50	40	80			
Wheat forage	AF	0.05		25						
Wheat straw (dry)	AS	0.06		88	10	10				
Pea seed	VD	0.07		90	20	20	**20**			0.02
Total					**100**	**100**	**100**	**0.07**	**0.06**	**0.07**

The calculated dietary intakes of beef cattle, dairy cows and poultry are 0.07, 0.06 and 0.07 mg/kg respectively.

No quantifiable residue was found in the tissues of ruminants at levels 60 times (cows) and 80 times (beef cattle) the calculated dietary burden. Fludioxonil and metabolites were detected in liver and kidney at concentrations of 0.014–0.017 mg/kg and 0.022–0.025 mg/kg respectively, at the 5.5 ppm feeding level. None was detected in fat or muscle. The Meeting concluded that the maximum residue level is the LOQ, 0.05 (*) mg/kg, for offal and 0.01 (*) mg/kg for muscle and that the STMR values for edible offal and muscle are both 0 mg/kg.

In milk, the highest residue level found was 0.019 mg/kg with the 5.5 ppm diet (60 times).

The Meeting concluded that the maximum residue level is the LOQ, 0.01 (*) mg/kg, and that the STMR value for milk is 0 mg/kg.

No feeding study was available with poultry. The dietary intake calculation shows a possible burden of 0.07 ppm. The study of the nature of the residue in poultry was conducted at 89 ppm (1300 times) for 8 consecutive days. While short of the normal 30-day feeding study, the extreme exaggeration provides some idea of the likelihood of residues of fludioxonil and metabolites occurring in poultry commodities. The identified residue levels in eggs, liver, kidney, muscle and skin with fat were 0.26, 0.046, 0.020, 0.036 and 0.036 mg/kg respectively. This strongly suggests that residues will not be quantifiable in these commodities at a feeding level of 0.07 mg/kg. Therefore, the Meeting estimated MRLs at the LOQ of 0.05 (*) mg/kg for eggs, 0.01 (*) mg/kg for poultry meat and 0.05 (*) mg/kg for poultry offal and STMRs of 0 mg/kg for eggs, poultry meat and poultry offal.

RECOMMENDATIONS

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

Definition of the residue for compliance with MRLs and estimation of dietary intake in plant commodities: fludioxonil

Definition of the residue for compliance with MRLs and estimation of dietary intake in livestock commodities: fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid and calculated as fludioxonil. Fludioxonil is fat-soluble.

Commodity		MRL, mg/kg		STMR or STMR-P, mg/kg
CCN	Name	New	Previous	
HH722	Basil	10		2.4
DH722	Basil (dried)	50		20
VD0071	Beans (dry)	0.07		0.02
VP61	Beans, except broad bean and soya bean (green pods and immature seeds)	0.3		0.04
VP62	Beans, shelled (succulent=immature seeds)	0.03		0.02
FB264	Blackberries	5		1.0
FB20	Blueberries	2		0.60
VB400	Broccoli	0.7		0.23
VB41	Cabbages, head	2		0.24
VR577	Carrot	0.7		0.20
GC80	Cereal grains	0.05(*)		0.02
HH727	Chives	10		2.8
HH727	Chives (dried)	50		22
FC0001	Citrus	7 Po		1.1
SO691	Cotton seed	0.05(*)		0.05
VC424	Cucumber	0.3		0.06

Commodity		MRL, mg/kg		STMR or STMR-P, mg/kg
CCN	Name	New	Previous	
FB266	Dewberries (including Boysenberry and Loganberry)	5		1.0
DF269	Dried grapes (currants, raisins, sultanas)			0.31
MO105	Edible offal	0.05 (*)		0
VO440	Egg plant (aubergine)	0.3		0.06
PE0112	Eggs	0.05 (*)		0
FB269	Grapes	2		0.28
	Grape juice			0.26
FI0341	Kiwifruit	15 Po		7.2
VL482	Lettuce, head	10		2.7
AF645	Maize forage (dry)	0.03 (*)		0
MM95	Meat (from mammals other than marine mammals)	0.01(*)		0
VC0046	Melon	0.03		0.02
ML106	Milks	0.01		0
VL485	Mustard greens	10		1.2
VA385	Onions, bulb	0.5		0.04
VA389	Onions, spring	5		0.59
FP230	Pears	0.7		0.21
VD0072	Peas (dry)	0.07		0.02
VP63	Peas (pods and succulent=immature seeds)	0.3		0.04
VP64	Peas, shelled (immature seed)	0.03		0.02
VO455	Peppers, sweet	1		0.18
TN675	Pistachio nut	0.2		0.05
	Plum juice			0.08
	Plum preserves			0.40
	Plum purée			0.64
VR589	Potato	0.02		0.01
PM0110	Poultry meat	0.01 (*)		0
PO0111	Poultry, edible offal of	0.05 (*)		0
DF14	Prunes (dried plums)			0.96
SO495	Rape seed	0.02(*)		0.02
FB272	Raspberries, red, black	5		1.0
FS12	Stone fruits	5 Po		0.80
AS81	Straw and fodder (dry) of cereal grains	0.06(*)		
FB275	Strawberry	3		0.27
	Strawberry juice			0.06
	Strawberry preserves			0.24
	Strawberry jam			0.13
VC0431	Summer squash (zucchini)	0.3		0.06

Commodity		MRL, mg/kg		STMR or STMR-P, mg/kg
CCN	Name	New	Previous	
VO447	Sweet corn (corn-on-the-cob)	0.01(*)		0.01
VO448	Tomato	0.5		0.12
JF448	Tomato juice			0.026
	Tomato paste			0.17
VL473	Watercress	10		1.2
	Wine (grape)			0.01

DIETARY RISK ASSESSMENT

Long-term intake

The IEDIs of fludioxonil based on the STMRs estimated for 45 commodities for the five GEMS/Food regional diets were 0–1% of the ADI (Annex 3 of the Report). The Meeting concluded that the long-term dietary intake of residues of fludioxonil is unlikely to present a public health concern.

Short-term intake

The 2004 JMPR decided that an ARfD for fludioxinil is unnecessary. The Meeting therefore concluded that the short-term dietary intake of fludioxonil residues is unlikely to present a public health concern.

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Short-term intake

The Meeting set an ARfD of 0.2 mg/kg bw for folpet for women of childbearing age and decided that an ARfD was unnecessary for the general population, including children aged 1–6 years. Women of childbearing age are also part of the general population.

In the absence of relevant studies on the developmental effects of phthalimide (metabolite of folpet), the Meeting was unable to determine whether phthalimide should be excluded from the residue definition for dietary risk assessment. The Meeting was not able to finalize the risk assessment before an evaluation of the residue definition for risk assessment and associated residue values for dietary intake estimation had been completed.