FLUDIOXONIL (211)

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EXPLANATION

Fludioxonil, a fungicide to control plant-pathogenic fungi such as *Botrytis cinerea,* was first evaluated at the 2004 JMPR Meeting. The Meeting established an ADI of 0.0–0.4 mg/kg bw, the establishment of an ARfD was considered unnecessary. The Meeting concluded that the residue definition for plant commodities, for compliance with the MRL and for consumer risk assessment was fludioxonil only. In 2004, no maximum residue level was recommended for the post-harvest use on pomegranates or yams. At that time no GAP was available for pomegranates and the number of trials at the critical GAP for yams was considered insufficient. A maximum residue level for citrus fruit was recommended based on post-harvest uses. However, since the last evaluation a new GAP has been introduced for post-harvest applications of fludioxonil to citrus fruits, in which the maximum application rate has been doubled and additional residue studies have been completed. Furthermore, additional data has been submitted by the manufacturer to support the use of fludioxonil on pomegranates and tropical root and tuber vegetables.

METHODS OF RESIDUE ANALYSIS

Analytical methods for plant materials used in study reports

In the newly submitted supervised residue trials, fludioxonil was analysed by either method REM 133.04 or AG-597B, or slight modifications thereof. JMPR 2004 concluded the following on these methods:

- '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.
- Method REM-133 involves high-performance liquid chromatography (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 solubilised, 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.'

Stability of pesticide residues in stored analytical samples

Additional storage stability studies were available, one on citrus, one on sweet potato and one on yam.

Commodity	Storage time (days)	% remaining mean, range, ± RSD_r	concurrent recovery	reference, method
Whole grapefruit	427	93 (91–95) ± 2%	98%	Thompson 2003a
Canned lemon juice	289	94 (93–95) ± 1%	90%	Thompson 2003a
Lemon pulp	303	79 (77–82) ± 3%	87%	Thompson 2003a
Sweet potato	312	93 (90–96) ± 3%	98%	Thompson 2007
Yam	159	84 (81–88) ± 3%	87%	Thompson, 2003c

USE PATTERNS

Fludioxonil is registered as a fungicide on a wide variety of crops. The information available to the Meeting on registered uses relevant to the supervised trial data are summarised below in Table 1, which is based on approved labels provided by the manufacturer.

Table 1 Registered post-harvest uses of fludioxonil

Crop	Country	Form	Application				Waiting time, days
			Method	Rate g ai/t	Spray conc, g ai/L	Number	
Citrus fruit	USA	SCHOLAR SC	Dip Drench Spray	– – 2–4	60–120 60–120 –	2, in any combination of the methods	NS
Pomegranate	USA	SCHOLAR SC	Dip Drench	– –	60 60	1 1	NS
Sweet potato	USA	SCHOLAR SC	Dip Spray	– 1.2	30–60 –	1 1	NS
True yam	USA	SCHOLAR SC	Dip		30–60	1	NS

NS = not specified

RESIDUES RESULTING FROM SUPERVISED TRIALS

The Meeting received information on fludioxonil supervised trials on the following crops. Data considered relevant for MRL purposes from these trials are underlined.

Commodity	Application	Country	Table no.
Citrus fruits	post-harvest	Spain	2
	post-harvest	USA	3
Pomegranate	post-harvest	USA	4
Sweet potato	post-harvest	USA	5
True yam	post-harvest	Puerto Rico	6

Citrus fruits

For disease control it is recommended that the product be applied once before storage and once after storage, just before marketing. The product should be mixed in appropriate water, wax/oil emulsion, or aqueous dilution of wax/oil emulsion. In dip applications, fruit is placed in a tray containing the application solution, for drench applications, the application solution as poured over the fruit. For low volume spray, fruit is sent through a packing line equipped with low volume applicators.

Trials on Oranges and Mandarins conducted in the European Union

Two trials on oranges and four trials on mandarins have been conducted in Spain.

Trial TRC04-7R1, TRC04-6R1 and TRC04-6R2 were decline trials in which fruit was sampled at intervals (0, 7 and 15 days) after the post-harvest treatments. Trial TRC04-7R2, TRC04-6R3 and TRC04-6R4 were "harvest" trials in which fruit was sampled once, immediately after the postharvest treatments. Samples from trial TRC04-7R2 were further processed into juice and marmalade. The fruit was harvested the day before the application and maintained at ambient temperature until use. Each trial contained four treatment regimes: 1) single drench, 2) single spray, 3 and 4) drench + spray, at different application rates. Fruits were treated with a commercial finishing wax either after application of fludioxonil (drench treatment) or simultaneously by mixing (spray treatment). Fruit was sampled after the post-harvest treatments had dried. When dry, fruits were randomly collected from the top layer of the crates. The three crates that entered first in the line and the three that entered last in the line were disregarded, so samples were only taken from the middle crates. Samples for analysis were frozen on the day of sampling, and maintained deep frozen awaiting dispatch to the analytical laboratory by freezer truck.

Fludioxonil was determined with analytical method REM 133.04 (JMPR 2004), with two modifications: the two-columns system was replaced by a one-column system (NH_2 5 µm 250 mmx 4.6 mm Adsorbosphere) and the ultraviolet detection was replaced by fluorescence detection (exc: 265 nm/ emm: 312 nm). The method was validated in the range of 0.02 to 2 mg/kg. The LOQ was 0.02 mg/kg. Samples were stored frozen for a maximum of 2 months before analysis. The supervised residue trials in citrus fruits in the EU are summarised in Table 2.

Table 2 Residues of fludioxonil after post-harvest application to citrus in Europe

Commodity, Country, Year (Variety)	Application rate					DAT	Fludioxonil residue (mg/kg)	Author, Date Trial Ref No
	Form	no. appl. (interval)	method	g ai/ tonne	g ai/hL			
Oranges, Spain, 2004 (Navel Lane Late)	SC20	1	drench	–	60	0 7 15	0.15[a] 0.21 0.28	Solé, 2005a Trial TRC04-7R1
Oranges, Spain, 2004 (Valencia Late)	SC20	1	drench	–	60	0	0.30[a]	Solé, 2005a Trial TRC04-7R2
Oranges, Spain, 2004 (Navel Lane Late)	SC20	1	LV spray	2.3	–	0 7 15	0.77[a] 0.91 0.96	Solé, 2005a Trial TRC04-7R1
Oranges, Spain, 2004 (Valencia Late)	SC20	1	LV spray	2.5	–	0	0.86[a]	Solé, 2005a Trial TRC04-7R2
Oranges, Spain, 2004 (Navel Lane Late)	SC20	2 (2 d)	drench LV spray	– 1.3	30 –	0 7 15	0.73[a] 1.0 0.88	Solé, 2005a Trial TRC04-7R1
Oranges, Spain, 2004 (Valencia Late)	SC20	2 (2 d)	drench LV spray	– 1.3	30 –	0	0.34[a]	Solé, 2005a Trial TRC04-7R2
Oranges, Spain, 2004 (Navel Lane Late)	SC20	2 (2 d)	drench LV spray	– 2.3	60 –	0 7 15	1.1[a] 1.5 1.2	Solé, 2005a Trial TRC04-7R1
Oranges, Spain, 2004 (Valencia Late)	SC20	2 (2 d)	drench LV spray	– 2.7	60 –	0	1.3[a]	Solé, 2005a Trial TRC04-7R2
Mandarin, Spain, 2004 (Ortanique)	SC20	1	drench	–	60	0 7 15	0.32[a] 0.54 0.50	Solé, 2005b Trial TRC04-6R1
Mandarin, Spain, 2004 (Ortanique)	SC20	1	drench	–	60	0 7 15	1.1[a] 1.5 1.5	Solé, 2005b Trial TRC04-6R2
Mandarin, Spain, 2004 (Ortanique)	SC20	1	drench	–	60	0	0.40[a]	Solé, 2005b Trial TRC04-6R3

Commodity, Country, Year (Variety)	Application rate					DAT	Fludioxonil residue (mg/kg)	Author, Date Trial Ref No
	Form	no. appl. (interval)	method	g ai/ tonne	g ai/hL			
Mandarin, Spain, 2004 (Ortanique)	SC20	1	drench	–	60	0	0.41[a]	Solé, 2005b Trial TRC04-6R4
Mandarin, Spain, 2004 (Ortanique)	SC20	1	LV spray	2.4	–	0 7 15	0.70[a] 0.93 0.76	Solé, 2005b Trial TRC04-6R1
Mandarin, Spain, 2004 (Ortanique)	SC20	1	LV spray	2.2	–	0 7 15	0.58[a] 0.68 0.71	Solé, 2005b Trial TRC04-6R2
Mandarin, Spain, 2004 (Ortanique)	SC20	1	LV spray	2.5	–	0	0.83 [a]	Solé, 2005b Trial TRC04-6R3
Mandarin, Spain, 2004 (Ortanique)	SC20	1	LV spray	2.2	–	0	0.68[a]	Solé, 2005b Trial TRC04-6R4
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 2.5	60 –	0 7 15	1.8[a] 1.7 1.8	Solé, 2005b Trial TRC04-6R1
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 2.2	60 –	0 7 15	2.2[a] 2.1 2.2	Solé, 2005b Trial TRC04-6R2
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 2.5	60 –	0	1.9[a]	Solé, 2005b Trial TRC04-6R3
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 2.1	60 –	0	1.5[a]	Solé, 2005b Trial TRC04-6R4
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 1.3	30 –	0 7 15	0.84[a] 1.2 1.2	Solé, 2005b Trial TRC04-6R1
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 1.3	30 –	0 7 15	0.61[a] 1.2 1.2	Solé, 2005b Trial TRC04-6R2
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 1.3	30 –	0	0.83[a]	Solé, 2005b Trial TRC04-6R3
Mandarin, Spain, 2004 (Ortanique)	SC20	2 (2 d)	drench LV spray	– 1.1	30 –	0	0.40[a]	Solé, 2005b Trial TRC04-6R4

[a] calculated residue value for whole fruit based on residue determined for flesh and peel and the recorded masses

Trials on Oranges, Mandarins, Lemons and Grapefruit conducted in the USA

Twenty-one trials have been performed in the USA.

In dip applications, the fruit was placed in a bucket, tray or tub containing the application solution. The fruit was gently agitated in solution for approximately one minute. For drench applications, the application solution was poured over the fruit. Low volume applications were achieved by sending the fruit through a packing line equipped with low volume applicators such as Controlled Droplet Applicator (CDA), brushes, belts, rollers, wig-wag, or dribble applicators. Fruits were treated with a commercial finishing wax either after application of fludioxonil (drench treatment) or simultaneously by mixing (spray treatment). After application, the fruit was allowed to dry at ambient temperature. Treated samples were taken and stored frozen on the day of treatment.

Fruits were treated with a commercial finishing wax, either after the last application of fludioxonil or simultaneously by mixing. Analytical method AG-597B (HPLC-UV, JMPR 2004) with some minor modifications was used to determine fludioxonil in citrus fruits. The method was validated in the range of 0.02 to 5.2 mg/kg (grapefruit), 0.02 to 1.0 mg/kg (lemons) and 0.02 to 20 mg/kg (oranges and mandarins). The LOQ was 0.02 mg/kg, except in Thompson 2003a trials, where the LOQ was 0.04 mg/kg. Samples were stored frozen for a maximum of 11 months before analysis.

Table 3 Residues of fludioxonil after post-harvest application to citrus in the USA

Commodity (Variety) Country, Year	Application rate					DAT	Fludioxonil residue (mg/kg)	Author, Date Trial Ref No
	Form	no. appl. (interval)	method	g ai/ tonne	g ai/hL			
Orange, sweet (Valencia) CA, 2004	SC20	1	dip	–	60	0	0.70, 1.0	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia) CA, 2004	SC20	1	dip	–	60	0	0.85, 1.1	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia) CA, 2004	SC20	1	LV spray	2	–	0 6 14	0.58, 0.74 0.62, 0.63 0.63, 0.83	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia) CA, 2004	SC20	1	LV spray	2	–	0 8 15	0.37, 0.50 0.35, 0.50 0.46, 0.51	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia) CA, 2004	50WP	1	LV spray	2	–	0 0	0.63, 0.85 0.03, 0.07	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia) CA, 2004	50WP	1	LV spray	2	–	0	0.62, 0.82	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia) CA, 2004	50WP	1	LV spray	4	–	0	0.90, 1.0	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia) CA, 2004	SC20	2 (0 d)	drench LV spray	– 1	30 –	0 6 14	0.38, 0.53 0.45, 0.58 0.44, 0.60	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia) CA, 2004	SC20	2 (0 d)	drench LV spray	– 1	30 –	0 8 15	0.32, 0.33 0.33, 0.34 0.35, 0.40	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia) CA, 2004	SC20	2 (0 d)	drench LV spray	– 2	60 –	0 6 14	0.84, 0.86 0.68, 0.71 0.20, 0.63	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia) CA, 2004	SC20	2 (0 d)	drench LV spray	– 2	60 –	0 8 15	0.75, 0.77 0.53, 0.57 0.52, 0.72	Ediger, 2005a Trial 2B-FR-04-5276
Grapefruit (Marsh) CA, 2004	SC20	1	dip	–	60	0	0.60, 0.72	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh) CA, 2004	SC20	1	dip	–	60	0 0	0.78, 0.95	Ediger, 2005a Trial 2B-FR-04-5278
Grapefruit (Marsh) CA, 2004	SC20	1	LV spray	2	–	0	0.66, 0.67	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh) CA, 2004	SC20	1	LV spray	2	–	0	0.07, 0.16	Ediger, 2005a Trial 2B-FR-04-5278
Grapefruit (Marsh) CA, 2004	50WP	1	LV spray	2	–	0	0.90, 0.92	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh) CA, 2004	50WP	1	LV spray	2	–	0	0.05, 0.08	Ediger, 2005a Trial 2B-FR-04-5278
Grapefruit (Marsh) CA, 2004	50WP	1	LV spray	4	–	0	1.5, 1.5	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh) CA, 2004	SC20	2 (0 d)	drench LV spray	– 1	30 –	0	0.25, 0.34	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh) CA, 2004	SC20	2 (0 d)	drench LV spray	– 1	30 –	0	0.14, 0.25	Ediger, 2005a Trial 2B-FR-04-5278

Commodity (Variety) Country, Year	Application rate					DAT	Fludioxonil residue (mg/kg)	Author, Date Trial Ref No
	Form	no. appl. (interval)	method	g ai/ tonne	g ai/hL			
Grapefruit (Marsh) CA, 2004	SC20	2 (0 d)	drench LV spray	– 2	60 –	0	0.47, 0.59	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh) CA, 2004	SC20	2 (0 d)	drench LV spray	– 2	60 –	0	0.17, 0.19	Ediger, 2005a Trial 2B-FR-04-5278
Lemon (Eureka) CA, 2004	SC20	1	drench	–	68	0 30 66 122	1.0, 1.2 0.52, 0.87 0.77, 0.86 1.2, 1.2	Ediger, 2005b Trial 2B-FR-04-5280
Lemon (Eureka) CA, 2004	SC20	1	drench	–	60	0 31 61 123	0.80, 0.89 0.72, 0.86 1.1, 1.4 1.3, 1.5	Ediger, 2005b Trial 2B-FR-04-5281
Lemon (Eureka) CA, 2004	SC20	1	drench	–	60	0 30	0.91, 1.1 1.1, 1.4	Ediger, 2005b Trial 2B-FR-04-5280
Lemon (Eureka) CA, 2004	WP	1	drench	–	60	0 31	0.80, 0.94 0.72, 0.86	Ediger, 2005b Trial 2B-FR-04-5281
Lemon (Eureka) CA, 2004	SC20	1	LV spray	2	–	0 31 61 123	0.93, 1.1 0.81, 0.92 0.85, 1.5 0.81, 1.2	Ediger, 2005b Trial 2B-FR-04-5281
Lemon (Eureka) CA, 2004	SC20	1	LV spray	2	–	0	0.97, 1.2	Ediger, 2005b Trial 2B-FR-04-5282
Lemon (Eureka) CA, 2004	SC20	1	LV spray	4	–	0 30 66 122	1.6, 1.7 0.74, 1.4 1.1, 1.3 1.5, 1.9	Ediger, 2005b Trial 2B-FR-04-5280
Lemon (Eureka) CA, 2004	SC20	2 (0 d)	drench LV spray	– 2	60 –	0 14	1.9, 2.4 1.0, 1.1	Ediger, 2005b Trial 2B-FR-04-5281
Lemon (Eureka) CA, 2004	SC20	2 (0 d)	drench LV spray	– 2	60 –	0	3.2, 3.2	Ediger, 2005b Trial 2B-FR-04-5282
Lemon (Eureka) CA, 2004	SC20	2 (14 d)	drench LV spray	– 2	68 –	0 14	1.2, 1.3 1.7, 1.7	Ediger, 2005b Trial 2B-FR-04-5280
Lemon (Eureka) CA, 2004	SC20	2 (14 d)	drench LV spray	– 2	60 –	0 14	1.3, 1.3 1.2, 1.3	Ediger, 2005b Trial 2B-FR-04-5281
Lemon (Eureka) CA, 2004	WP	2 (14 d)	drench LV spray	– 2	60 –	0 14	1.3, 1.5 1.8, 1.8	Ediger, 2005b Trial 2B-FR-04-5280
Lemon (Eureka) CA, 2004	WP	2 (14 d)	drench LV spray	– 2	60 –	0 14	1.6, 1.7 1.6, 1.7	Ediger, 2005b Trial 2B-FR-04-5281
Lemon (Eureka) CA, 2004	WP	2 (0 d)	drench LV spray	– 2	60 –	0 14	2.1, 2.1 1.2, 1.5	Ediger, 2005b Trial 2B-FR-04-5281
Lemon (Eureka) CA, 2004	WP	2 (0 d)	drench LV spray	– 4	60 –	0 14	2.0, 2.5 2.1, 2.1	Ediger, 2005b Trial 2B-FR-04-5280
Lemon (Eureka) CA, 2004	SC20	2 (0 d)	drench LV spray	– 4	68 –	0 14	3.0, 3.9 2.9, 3.2	Ediger, 2005b Trial 2B-FR-04-5280
Lemon (Eureka) CA, 2004	SC20	3 (0d)	drench drench LV spray	– – 1	60 30 –	0 14	1.1, 1.3 0.82, 0.88	Ediger, 2005b Trial 2B-FR-04-5281

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	Form	no. appl. (interval)	method	g ai/ tonne	g ai/hL			
Lemon (Eureka) CA, 2004	SC20	3 (0d)	drench drench LV spray	– – 1	60 30 –	0	2.4, 2.8	Ediger, 2005b Trial 2B-FR-04-5282
Lemon (Eureka) CA, 2004	SC20	3 (0d)	drench drench LV spray	– – 2	68 34 –	0 14	1.7, 2.1 1.6, 1.8	Ediger, 2005b Trial 2B-FR-04-5280
Mandarin (Satsuma) CA, 2006	SC20	2 (0 d)	dip LV spray	– 4	120 –	0	4.1, 7.0	Hampton, M., 2008a Trial 2B-FR-06-7230
Mandarin (Satsuma) CA, 2006	SC20	2 (0 d)	dip LV spray	– 4	120 –	0	5.4, 5.6	Hampton, M., 2008a Trial 2B-FR-06-7231
Mandarin (Dancy Tangerine) CA, 2007	SC20	2 (0 d)	dip LV spray	– 4	120 –	0	2.4, 2.9	Hampton, M., 2008a Trial 2B-FR-06-7232
Mandarin (Satsuma) CA, 2006	SC20	2 (0 d)	dip dip	– –	120 120	0	5.2, 7.8	Hampton, 2008a Trial 2B-FR-06-7230
Mandarin (Satsuma) CA, 2006	SC20	2 (0 d)	dip dip	– –	120 120	0	4.7, 5.6	Hampton, 2008a Trial 2B-FR-06-7231
Mandarin (Dancy Tangerine) CA, 2007	SC20	2 (0 d)	dip dip	– –	120 120	0	5.3, 5.8	Hampton, 2008a Trial 2B-FR-06-7232
Mandarin (Sunburst Tangerine) TX, 2006	SC20	2 (0 d)	dip dip	– –	120 120	0	6.4, 7.3	Hampton, 2008a Trial 2B-FR-06-7233
Orange (Valencia) CA, 2007	SC20	2 (0 d)	dip LV spray	– 4	120 –	0	3.4, 4.0	Hampton, 2008b Trial W34CA078175
Orange (Valencia) CA, 2007	SC20	2 (0 d)	dip LV spray	– 4	120 –	0	3.4, 4.6	Hampton, 2008b Trial W34CA078176
Orange (Washington Navel) CA, 2007	SC20	2 (0 d)	dip LV spray	– 4	120 –	0	2.0, 2.9	Hampton, 2008b Trial 2B-FR-06-7242
Orange (Valencia) CA, 2007	SC20	2 (0 d)	dip dip	– –	120 120	0	5.0, 5.0	Hampton, 2008b Trial W34CA078175
Orange (Valencia) CA, 2007	SC20	2 (0 d)	dip dip	– –	120 120	0	6.1, 7.2	Hampton, 2008b Trial W34CA078176
Orange (Washington Navel) CA, 2007	SC20	2 (0 d)	dip dip	– –	120 120	0	4.2, 4.4	Hampton, 2008b Trial 2B-FR-06-7242
Orange (Ruby Blood Orange) TX, 2006	SC20	2 (0 d)	dip dip	– –	120 120	0	3.3, 3.5	Hampton, 2008b Trial 2B-FR-06-7243
Orange, sweet (Valencia) CA, 2001	50WP	1	Dip + st	–	120	0	2.2, 3.4	Thompson, 2003a Trial 07947.01-CA108
Orange, sweet (Valencia) CA, 2001	50WP	1	LV spray + st	3.8	–	0	0.91, 1.1	Thompson, 2003a Trial 07947.01-CA108

Commodity (Variety) Country, Year	Application rate					DAT	Fludioxonil residue (mg/kg)	Author, Date Trial Ref No
	Form	no. appl. (interval)	method	g ai/ tonne	g ai/hL			
Orange, sweet (Valencia) CA, 2001	50WP	1	dip	–	120	0	1.4, 1.9	Thompson, 2003a Trial 07947.01-CA108
Orange, sweet (Valencia) CA, 2001	50WP	1	LV spray, sh	3.9	–	0	0.48, 0.49	Thompson, 2003a Trial 07947.01-CA108
Orange, sweet (Valencia) CA, 2001	50WP	1	st, dip	– –	– 120	0	2.9, 3.0	Thompson, 2003a Trial 07947.01-CA108
Orange, sweet (Valencia) CA, 2001	50WP	1	st, cl, LV spray, sh	– 3.9	– –	0	0.41, 0.70	Thompson, 2003a Trial 07947.01-CA108
Lemon, (Eureka) CA, 2001	50WP	1	Dip + st	–	120	0	3.0, 3.3	Thompson, 2003a Trial 07947.01-CA109
Lemon, (Eureka) CA, 2001	50WP	1	LV spray + st	4.0	–	0	1.0, 1.1	Thompson, 2003a Trial 07947.01-CA109
Lemon, (Eureka) CA, 2001	50WP	1	dip	–	120	0	1.0, 1.1	Thompson, 2003a Trial 07947.01-CA109
Lemon, (Eureka) CA, 2001	50WP	1	LV spray, sh	4.0	–	0	0.46, 0.47	Thompson, 2003a Trial 07947.01-CA109
Lemon, (Eureka) CA, 2001	50WP	1	st, dip	– –	– 120	0	2.6, 3.1	Thompson, 2003a Trial 07947.01-CA109
Lemon, (Eureka) CA, 2001	50WP	1	st, cl, LV spray, sh	– 4.1	– –	0	0.65, 1.0	Thompson, 2003a Trial 07947.01-CA109
Grapefruit (Marsh) CA, 2001	50WP	1	Dip + st	–	120	0	3.4, 4.2	Thompson, 2003a Trial 07947.01-CA110
Grapefruit (Marsh) CA, 2001	50WP	1	LV spray + st	4.0	–	0	0.61, 1.3	Thompson, 2003a Trial 07947.01-CA110
Grapefruit (Marsh) CA, 2001	50WP	1	dip	–	120	0	0.92, 0.98	Thompson, 2003a Trial 07947.01-CA110
Grapefruit (Marsh) CA, 2001	50WP	1	LV spray, sh	4.0	–	0	0.40, 0.62	Thompson, 2003a Trial 07947.01-CA110
Grapefruit (Marsh) CA, 2001	50WP	1	st, dip	–	120	0	4.3, 4.6	Thompson, 2003a Trial 07947.01-CA110
Grapefruit (Marsh) CA, 2001	50WP	1	st, cl, LV spray, sh	4.0	–	0	0.50, 0.55	Thompson, 2003a Trial 07947.01-CA110
Lemon, (Eureka) CA, 2001	50WP	1	Dip + st	–	120	0	2.5, 3.3	Thompson, 2003a Trial 07947.01-CA113
Lemon, (Eureka) CA, 2001	50WP	1	LV spray	3.7	–	0	0.53, 0.65	Thompson, 2003a Trial 07947.01-CA113
Lemon, (Eureka) CA, 2001	50WP	1	dip	–	120	0	0.64, 1.4	Thompson, 2003a Trial 07947.01-CA113
Lemon, (Eureka) CA, 2001	50WP	1	st, dip	–	120	0	2.0, 4.3	Thompson, 2003a Trial 07947.01-CA113

Commodity (Variety) Country, Year	Application rate					DAT	Fludioxonil residue (mg/kg)	Author, Date Trial Ref No
	Form	no. appl. (interval)	method	g ai/ tonne	g ai/hL			
Grapefruit (Ruby Red) TX, 2001	50WP	1	Dip + st	–	120	0	3.5, 6.8	Thompson, 2003a Trial 07947.01-TX29
Grapefruit (Ruby Red) TX, 2001	50WP	1	dip	–	120	0	1.3, 1.4	Thompson, 2003a Trial 07947.01-TX29
Grapefruit (Ruby Red) TX, 2001	50WP	1	st, dip	–	120	0	5.3, 6.9	Thompson, 2003a Trial 07947.01-TX29
Orange, sweet (Valencia) FL, 2001	50WP	1	Dip + st	–	110	0	1.3, 1.6	Thompson, 2003a Trial 07947.01-FL41
Orange, sweet (Valencia) FL, 2001	50WP	1	dip	–	110	0	0.85, 0.96	Thompson,, 2003a Trial 07947.01-FL41
Orange, sweet (Valencia) FL, 2001	50WP	1	st, dip	–	110	0	1.4, 2.0	Thompson, 2003a Trial 07947.01-FL41

st = storage wax; cl.= wash with cleaner; sh = shipping wax;

dip + st = simultaneous treatment st; dip = dip in storage wax, followed by dip in fludioxonil

Pomegranates

Four trials have been conducted, all in the USA, in which pomegranates were treated with fludioxonil as a post-harvest treatment. Mature pomegranates were treated by dipping in solutions made at 60 g ai/hL with or without additive finishing wax. The pomegranates were analysed for residues of fludioxonil when dried. For analysis of fludioxonil, method AG-597B was used with some minor modifications. The method was validated in the range of 0.02 to 20 mg/kg. The LOQ was 0.03 mg/kg (trials 2001) or 0.02 mg/kg (trials 2007). Samples were stored frozen at -28 to -4 °C for a maximum of 11 months before analysis.

Table 4 Residues of fludioxonil after post-harvest application to pomegranates in the USA

Commodity, location, year, (variety)	Form	No	method	g ai/hL	DAT	residues, mg/kg	reference
Pomegranates, CA, 2001 (Wonderful)	50WP	1	dip	60	0	0.50, 0.80	Thomson, 2003b Trial 02-CA01, Lot A
Pomegranates, CA, 2001 (Wonderful)	50WP	1	dip	60	0	0.71, 1.1	Thomson, 2003b Trial 02-CA01, Lot B
Pomegranates, CA, 2007 (Wonderful)	SC20	1	dip, with wax	60	0	1.1, 1.3	Hampton, 2008c Trial W34CA078275
Pomegranates, CA, 2007 (Wonderful)	SC20	1	dip, with wax	60	0	0.72, 0.83, 1.1, 1.2	Hampton, 2008c Trial W34CA078276

Sweet potato

Four trials were conducted in the USA in which sweet potatoes were treated with fludioxonil as a post-harvest treatment. Mature sweet potatoes were treated by dipping in solutions without any additives. Following treatment, the potatoes were allowed to dry out of the sunlight. Samples (taken after drying) were shipped and stored frozen at approximately –29 to –15 °C until analysis. For analysis of fludioxonil, method AG-597B was used with some minor modifications. The method was validated in the range of 0.02 to 5.0 mg/kg. The LOQ was 0.02 mg/kg. Samples were stored frozen for a maximum of 11 months before analysis.

Table 5 Residues of fludioxonil after post-harvest application to sweet potatoes in the USA

Commodity, location, year, (variety)	Form	No	method	g ai/hL	DAT	residues, mg/kg	reference
Sweet potatoes (Beauregard) CA, 2004	SC20	1	dip	30	4	1.8, 2.2	Thompson, 2007 Trial 04-CA42
Sweet potatoes (Beauregard) NC, 2004	SC20	1	dip	30	4	1.2, 1.6	Thompson, 2007 Trial 04-NC06
Sweet potatoes (Beauregard) CA, 2004	50WP	1	dip	60	4	2.4, 2.5	Thompson, 2007 Trial 04-CA42
Sweet potatoes (Beauregard) NC, 2004	50WP	1	dip	60	4	2.2, 2.8	Thompson, 2007 Trial 04-NC06

Yams

Two trials were carried out in Puerto Rico in which yam tubers were treated with fludioxonil. The yams were treated either as whole tubers or after first cutting into pieces, by dipping into a solution without any additives. Following treatment, the yams were allowed to dry out of the sunlight. Samples were taken only after the yams had dried. Samples were shipped and stored frozen until analysis. Sample analysis for residues of fludioxonil was conducted according a slightly modified method AG-597B. The method was validated in the range of 0.04 to 10.5 mg/kg. The LOQ for fludioxonil residues in yams was 0.04 mg/kg. Samples were stored for 5.3 months before analysis.

Table 6 Residues of fludioxonil after post-harvest application to Yams in Puerto Rico

Commodity, location, year, (variety)	Form	No	method	g ai/hL		DAT	residues, mg/kg	reference
Yams (Guinea) Puerto Rico, 2000	50WP	1	dip	60	RAC tuber- pieces	6 6	3.4, 4.2 4.5, 4.7	Thompson, 2003c Trial 08107.01-PR01
Yams (Guinea) Puerto Rico, 2000	50WP	1	dip	60	RAC tuber- pieces	7 7	4.2, 5.7 2.5, 4.0	Thompson, 2003c Trial 08107.01-PR02

FATE OF RESIDUES IN STORAGE AND PROCESSING

The Meeting received information on the fate of incurred residues of fludioxonil during the processing of citrus fruits into washed fruit, peel, pulp, juice, pomace, marmalade and oil.

Industrial processing

For industrial processes, two trials were available, one in oranges for juice, wet and dry pomace, and marmalade, and one trial in lemons for juice, oil and pulp. Orange and lemon fruit were treated once, post-harvest, with Scholar (SC20) at an application rate of ca. 60 g ai/hL fludioxonil. Fruit samples were taken for processing on the day of application. The fruit was sampled by hand, washed by spraying with water and sub-samples taken for further processing.

Orange juice

Oranges were crushed and pressed generating raw juice and wet pomace. Wet pomace was dried in an oven at 60 °C to give dry pomace. The orange juice was pasteurised by heating to 85 °C for one minute.

Marmalade

Washed oranges were peeled, with part of the shredded peel added, and the fruit was boiled in water for 40 minutes. The fruits were sieved, mixed with the cooking water and cooked zests. After addition

of sugar, the mixture was reduced by heating in a double jacket saucepan to obtain a Brix degree of 62%.

Lemon juice

Lemons were abraded and sprayed with water in an abrasion peeler. Once abraded, the lemons were processed through a juice extractor and then a finisher to remove the pomace. Wet pomace was dried in an oven at 60 °C to give dry pomace. The lemon juice was pasteurised by heating to approximately 93 °C before bottling.

Lemon oil

The water, oil and peel emulsion taken from the abrasion peeler was treated with a pectolytic enzyme and left overnight at 20 °C. The emulsion/peel mixture was passed through a screen separator to separate the peel solids from the emulsion. The solids were combined with the other pulp and peel fractions. The oil emulsion was centrifuged to separate solids, water and oil. The solids were combined with the other pulp and peel fractions, the water discarded and the oil was again centrifuged. The oil was placed in a freezer for at least 16 hours and then filtered. Anhydrous sodium sulphate was added to remove any remaining water from the oil. The oil was re-filtered and bottled. The residual solids were shredded in a grinder and neutralised with lime-slurried water to form a neutralized pulp. This was pressed to remove water to leave a wet pulp which was dried for 5–6 hours at ± 60 °C.

Residues in (processed commodities of) citrus were determined using method REM133.04. Samples were stored frozen at or below –18 °C for a period of about two months from sampling to analysis. Recoveries were acceptable for all investigated fractions. The method was validated in the range of 0.02 to 0.20 mg/kg (flesh and marmalade), 0.02 to 2 mg/kg (fruit, juice and dry pomace), 0.02 to 8.0 mg/kg (peel) and 0.02 to 1.0 mg/kg (wet pomace). The LOQ was 0.02 mg/kg for all commodities. Samples were stored frozen for a maximum of 2.3 months before analysis.

Residues in (processed commodities of) lemon were determined using method AG-597B with some minor modifications. Samples were stored frozen at or below –18 °C for a maximum of ten months from sampling to analysis. Recoveries were acceptable for all investigated fractions. The method was validated in the range of 0.04 to 5.2 mg/kg (lemon fruit), 0.54 to 54 mg/kg (oil), 0.11 to 5.4 mg/kg (pulp), and 0.02 to 5.4 mg/kg (juice). The LOQ was 0.04 mg/kg for lemon fruit, 0.54 kg/mg for oil, 0.02 mg/kg for juice and 0.11 mg/kg for pulp. Samples were stored frozen for a maximum of 11 months before analysis.

Residues of fludioxonil determined in the processed fractions are shown in Table 7.

Table 7 Fludioxonil residues and processing factors for industrial processing of citrus fruits

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	Fludioxonil residue (mg/kg)	PF	Author, Date Trial Ref No
Oranges (Valencia Late)	SC20 1× drench 60 g ai/hL DAT = 0	Whole fruit Dry pomace Orange juice Marmalade	0.22 2.3 0.04 0.12	– 10 0.18 0.55	Solé, 2005a TRC04-7R2
Oranges (Valencia Late)	SC20 1× drench 60 g ai/hL DAT = 0	Whole fruit Dry pomace Orange juice Marmalade	0.41 2.1 0.03 0.20	– 5.1 0.07 0.49	Solé, 2005a TRC04-7R2
Oranges (Valencia Late)	SC20 1× drench 60 g ai/hL DAT = 0	Whole fruit Dry pomace Orange juice Marmalade	0.25 2.1 0.03 0.11	– 8.4 0.12 0.44	Solé, 2005a TRC04-7R2

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	Fludioxonil residue (mg/kg)	PF	Author, Date Trial Ref No
Lemon, (Eureka) CA, 2001	50WP 1× LV spray 3.7 g ai/tonne DAT =0	Whole fruit Juice Oil Dried pomace	0.65 < 0.02 39.7 1.39	– < 0.03 61 2.1	Thompson, 2003a 07947.01-CA113
Oranges (Valencia Late)	SC20 1× drench 60 g ai/hL DAT: 0	Whole fruit JUICE PRODUCTION Washed fruit Wash water Wet pomace Raw juice Dry pomace Orange juice MARMALADE Washed fruit Wash water Peeled fruit Peel Cooked fruit Cooked peel (zest) Cooking water Sieved fruit Waste Marmalade (raw) Marmalade (finish)	0.29 0.22 0.06 0.64 0.04 1.8 0.04 0.36 0.05 < 0.02 0.59 0.05 0.89 0.11 0.02 0.09 0.12 0.13	– 0.76 0.21 2.21 0.14 6.2 0.14 1.2 0.17 < 0.07 2.0 0.17 3.1 0.38 0.07 0.31 0.41 0.45	Solé, 2005a TRC04-7R2

Residues in the edible portion of food commodities

For household processing (peeling and washing), data were collected on residues in peel, pulp and washed fruit in a number of the supervised residue trials summarised above. The residue data on the processed commodities from these trials (peel, pulp and washed fruit) are summarised in Table 8.

Table 8 Fludioxonil residues and processing factors for pulp, peel and washed whole citrus fruits

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	DAT	Fludioxonil residue (mg/kg)	mean residue (mg/kg)	PF	Author, Date Trial Ref No
Oranges (Navel Lane Late)	SC20, 1× drench 60 g ai/hL	RAC peel pulp	0 0 0	0.15[a] 0.40 < 0.02		– 2.7 < 0.13	Solé, 2005a Trial TRC04-7R1
Oranges (Valencia Late)	SC20, 1× drench 60 g ai/hL	RAC peel pulp	0 0 0	0.30[a] 0.89 < 0.02		– 3.0 < 0.07	Solé, 2005a Trial TRC04-7R2
Oranges (Navel Lane Late)	SC20, 1× LV spray 2.3 g ai/tonne	RAC peel pulp	0 0 0	0.77[a] 2.0 < 0.02		– 2.6 < 0.03	Solé, 2005a Trial TRC04-7R1
Oranges (Valencia Late)	SC20, 1× LV spray 2.5 g ai/tonne	RAC peel pulp	0 0 0	0.86[a] 2.9 < 0.02		– 3.4 < 0.02	Solé, 2005a Trial TRC04-7R2
Oranges (Navel Lane Late)	SC20, 2× (2 d) drench & LV spray 30 g ai/hL & 1.3 g ai/tonne	RAC peel pulp	0 0 0	0.73[a] 1.9 < 0.02		– 2.6 < 0.03	Solé, 2005a Trial TRC04-7R1

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	DAT	Fludioxonil residue (mg/kg)	mean residue (mg/kg)	PF	Author, Date Trial Ref No
Oranges (Valencia Late)	SC20, 2× (2 d) drench & LV spray 30 g ai/hL & 1.3 g ai/tonne	RAC peel pulp	0 0 0	0.34[a] 1.3 < 0.02		– 3.8 < 0.06	Solé, 2005a Trial TRC04-7R2
Oranges (Navel Lane Late)	SC20, 2× (2 d) drench & LV spray 60 g ai/hL & 2.3 g ai/tonne	RAC peel pulp	0 0 0	1.1[a] 3.3 < 0.02		– 3.0 < 0.02	Solé, 2005a Trial TRC04-7R1
Oranges (Valencia Late)	SC20, 2× (2 d) drench & LV spray 60 g ai/hL & 2.7 g ai/tonne	RAC peel pulp	0 0 0	1.3[a] 3.5 < 0.02		– 2.7 < 0.02	Solé, 2005a Trial TRC04-7R2
Mandarin (Ortanique)	SC20, 1× drench 60 g ai/hL	RAC peel pulp	0 0 0	0.32[a] 1.2 < 0.02		– 3.8 < 0.06	Solé, 2005b Trial TRC04-6R1
Mandarin, (Ortanique)	SC20, 1× drench 60 g ai/hL	RAC peel pulp	0 0 0	1.1[a] 3.5 < 0.02		– 3.2 < 0.02	Solé, 2005b Trial TRC04-6R2
Mandarin, (Ortanique)	SC20, 1× drench 60 g ai/hL	RAC peel pulp	0 0 0	0.40[a] 1.5 < 0.02		– 3.8 < 0.05	Solé, 2005b Trial TRC04-6R3
Mandarin, (Ortanique)	SC20, 1× drench 60 g ai/hL	RAC peel pulp	0 0 0	0.41[a] 1.2 < 0.02		– 2.9 < 0.05	Solé, 2005b Trial TRC04-6R4
Mandarin (Ortanique)	SC20, 1× LV spray 2.4 g ai/tonne	RAC peel pulp	0 0 0	0.70[a] 2.2 < 0.02		– 3.1 < 0.03	Solé, 2005b Trial TRC04-6R1
Mandarin (Ortanique)	SC20, 1× LV spray 2.2 g ai/tonne	RAC peel pulp	0 0 0	0.58[a] 1.8 < 0.02		– 3.1 < 0.03	Solé, 2005b Trial TRC04-6R2
Mandarin (Ortanique)	SC20, 1× LV spray 2.5 g ai/tonne	RAC peel pulp	0 0 0	0.83 [a] 3.0 < 0.02		– 3.6 < 0.02	Solé, 2005b Trial TRC04-6R3
Mandarin (Ortanique)	SC20, 1× LV spray 2.2 g ai/tonne	RAC peel pulp	0 0 0	0.68[a] 2.1 < 0.02		– 3.1 < 0.03	Solé, 2005b Trial TRC04-6R4
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 60 g ai/hL & 2.5 g ai/tonne	RAC peel pulp	0 0 0	1.8[a] 6.9 0.05		– 3.8 0.03	Solé, 2005b Trial TRC04-6R1
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 60 g ai/hL & 2.2 g ai/tonne	RAC peel pulp	0 0 0	2.2[a] 7.4 < 0.02		– 3.4 < 0.01	Solé, 2005b Trial TRC04-6R2
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 60 g ai/hL & 2.5 g ai/tonne	RAC peel pulp	0 0 0	1.9[a] 6.9 0.02		– 3.6 0.01	Solé, 2005b Trial TRC04-6R3
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 60 g ai/hL & 2.1 g ai/tonne	RAC peel pulp	0 0 0	1.5[a] 4.6 < 0.02		– 3.1 < 0.01	Solé, 2005b Trial TRC04-6R4
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 30 g ai/hL & 1.3 g ai/tonne	RAC peel pulp	0 0 0	0.84[a] 3.0 < 0.02		– 3.6 < 0.02	Solé, 2005b Trial TRC04-6R1

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	DAT	Fludioxonil residue (mg/kg)	mean residue (mg/kg)	PF	Author, Date Trial Ref No
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 30 g ai/hL & 1.3 g ai/tonne	RAC peel pulp	0 0 0	0.61[a] 2.0 < 0.02		– 3.3 < 0.03	Solé, 2005b Trial TRC04-6R2
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 30 g ai/hL & 1.3 g ai/tonne	RAC peel pulp	0 0 0	0.83[a] 3.1 < 0.02		– 3.7 < 0.02	Solé, 2005b Trial TRC04-6R3
Mandarin (Ortanique)	SC20, 2× (2 d) drench & LV spray 30 g ai/hL & 1.1 g ai/tonne	RAC peel pulp	0 0 0	0.40[a] 1.2 0.02		– 3.0 0.05	Solé, 2005b Trial TRC04-6R4
Orange, sweet (Valencia)	SC20, 1× dip 60 g ai/hL	RAC pulp	0 0	0.70, 1.0 0.05, 0.08	0.85 0.065	– 0.08	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia)	SC20, 1× dip 60 g ai/hL	RAC pulp	0 0	0.85, 1.1 0.06, 0.08	0.975 0.07	– 0.07	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia)	SC20, 1× LV spray 2 g ai/tonne	RAC washed pulp	0 0 0	0.58, 0.74 0.07, 1.10 0.05, 0.07	0.66 0.585 0.06	– 0.89 0.09	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia)	SC20, 1× LV spray 2 g ai/tonne	RAC washed pulp	0 0 0	0.37, 0.50 0.27, 0.35 < 0.02 (2×)	0.445 0.31 0.02	– 0.70 < 0.04	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia)	50WP, 1× LV spray 2 g ai/tonne	RAC pulp	0 0	0.63, 0.85 0.03, 0.07	0.74 0.05	– 0.07	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia)	50WP, 1× LV spray 2 g ai/tonne	RAC pulp	0 0	0.62, 0.82 0.07, 0.08	0.72 0.075	– 0.10	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia)	50WP, 1× LV spray 4 g ai/tonne	RAC washed pulp	0 0 0	0.90, 1.0 0.06, 0.19 0.05, 0.11	0.95 0.125 0.08	– 0.13 0.08	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia)	SC20, 2× (0 d) drench & LV spray 30 g ai/hL & 1 g ai/tonne	RAC washed pulp	0 0 0	0.38, 0.53 0.13, 0.16 0.04, 0.05	0.455 0.145 0.045	– 0.32 0.10	Ediger, 2005a Trial 2B-FR-04-5275

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	DAT	Fludioxonil residue (mg/kg)	mean residue (mg/kg)	PF	Author, Date Trial Ref No
Orange, sweet (Valencia)	SC20, 2× (0 d) drench & LV spray 30 g ai/hL & 1 g ai/tonne	RAC washed pulp	0 0 0	0.32, 0.33 0.18, 0.21 < 0.02, 0.02	0.325 0.195 0.02	– 0.60 0.06	Ediger, 2005a Trial 2B-FR-04-5276
Orange, sweet (Valencia)	SC20, 2× (0 d) drench & LV spray 60 g ai/hL & 2 g ai/tonne	RAC washed pulp	0 0 0	0.84, 0.86 0.16, 0.19 0.04, 0.06	0.85 0.175 0.05	– 0.21 0.06	Ediger, 2005a Trial 2B-FR-04-5275
Orange, sweet (Valencia)	SC20, 2× (0 d) drench & LV spray 60 g ai/hL & 2 g ai/tonne	RAC washed pulp	0 0 0	0.75, 0.77 0.39, 0.47 0.03, 0.04	0.76 0.43 0.035	– 0.57 0.05	Ediger, 2005a Trial 2B-FR-04-5276
Grapefruit (Marsh)	SC20, 1× dip 60 g ai/hL	RAC pulp	0 0	0.60, 0.72 0.04, 0.05	0.66 0.045	– 0.07	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh)	SC20, 1× dip 60 g ai/hL	RAC pulp	0 0	0.78, 0.95 < 0.02 (2)	0.865 < 0.02	– < 0.02	Ediger, 2005a Trial 2B-FR-04-5278
Grapefruit (Marsh)	SC20, 1× LV spray 2 g ai/tonne	RAC washed pulp	0 0 0	0.66, 0.67 0.25, 0.38 0.03, 0.04	0.665 0.315 0.035	– 0.47 0.05	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh)	SC20, 1× LV spray 2 g ai/tonne	RAC washed pulp	0 0 0	0.07, 0.16 < 0.02 (2×) < 0.02 (2×)	0.115 < 0.02 < 0.02	– < 0.17 < 0.17	Ediger, 2005a Trial 2B-FR-04-5278
Grapefruit (Marsh)	50WP, 1× LV spray 2 g ai/tonne	RAC pulp	0 0	0.90, 0.92 0.03, 0.04	0.91 0.035	– 0.04	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh)	50WP, 1× LV spray 2 g ai/tonne	RAC pulp	0 0	0.05, 0.08 < 0.02 (2×)	0.065 < 0.02	– < 0.31	Ediger, 2005a Trial 2B-FR-04-5278
Grapefruit (Marsh)	50WP, 1× LV spray 4 g ai/tonne	RAC washed pulp	0 0 0	1.5, 1.5 0.52, 0.58 0.09, 0.09	1.5 0.55 0.09	– 0.37 0.06	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh)	SC20, 2× (0 d) drench & LV spray 30 g ai/hL & 1 g ai/tonne	RAC washed pulp	0 0 0	0.25, 0.34 0.20, 0.23 < 0.02, 0.03	0.295 0.215 0.025	– 0.73 0.08	Ediger, 2005a Trial 2B-FR-04-5277
Grapefruit (Marsh)	SC20, 2× (0 d) drench & LV spray 30 g ai/hL & 1 g ai/tonne	RAC washed pulp	0 0 0	0.14, 0.25 0.16, 0.29 < 0.02 (2×)	0.195 0.225 < 0.02	– 1.2 < 0.10	Ediger, 2005a Trial 2B-FR-04-5278

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	DAT	Fludioxonil residue (mg/kg)	mean residue (mg/kg)	PF	Author, Date Trial Ref No
Grapefruit (Marsh)	SC20, 2× (0 d) drench & LV spray 60 g ai/hL & 2 g ai/tonne	RAC washed pulp	0 0 0	0.47, 0.59 0.43, 0.43 0.02, 0.03	0.53 0.43 0.025	– 0.81 0.05	Ediger, 2005a Trial 2B-FR- 04-5277
Grapefruit (Marsh)	SC20, 2× (0 d) drench & LV spray 60 g ai/hL & 2 g ai/tonne	RAC washed pulp	0 0 0	0.17, 0.19 0.13, 0.14 < 0.02 (2×)	0.18 0.135 < 0.02	– 0.75 < 0.11	Ediger, 2005a Trial 2B- FR-04- 5278
Lemon (Eureka)	SC20, 1× drench 68 g ai/hL	RAC washed RAC washed RAC washed RAC washed	0 0 30 30 66 66 122 122	1.0, 1.2 0.83, 0.87 0.52, 0.87 0.77, 0.81 0.77, 0.86 1.0, 1.0 1.2, 1.2 0.84, 1.1	1.1 0.85 0.695 0.79 0.815 1 1.2 0.97	– 0.77 – 1.1 – 1.2 – 0.81	Ediger, 2005b Trial 2B- FR-04- 5280
Lemon (Eureka)	SC20, 1× drench 60 g ai/hL	RAC washed RAC washed RAC washed RAC washed	0 0 31 31 61 61 123 123	0.80, 0.89 0.49, 0.58 0.72, 0.86 0.52, 0.62 1.1, 1.4 0.43, 0.62 1.3, 1.5 0.58, 0.68	0.845 0.535 0.79 0.57 1.25 0.505 1.4 0.63	– 0.63 – 0.72 – 0.40 – 0.45	Ediger, 2005b Trial 2B-FR- 04-5281
Lemon (Eureka)	SC20, 1× drench 60 g ai/hL	RAC washed RAC washed	0 0 30 30	0.91, 1.1 0.46, 0.55 1.1, 1.4 0.9, 1.1	1.05 0.505 1.25 1	– 0.48 – 0.80	Ediger, 2005b Trial 2B- FR-04- 5280
Lemon (Eureka)	WP, 1× drench 60 g ai/hL	RAC washed RAC washed	0 0 31 31	0.80, 0.94 0.53, 0.54 0.72, 0.86 0.44, 0.55	0.87 0.535 0.79 0.495	– 0.61 – 0.63	Ediger, 2005b Trial 2B- FR-04- 5281
Lemon (Eureka)	SC20, 1× LV spray 2 g ai/tonne	RAC washed RAC washed RAC washed RAC washed	0 0 31 31 61 61 123 123	0.93, 1.1 0.50, 0.58 0.81, 0.92 0.56, 0.67 0.85, 1.5 0.63, 0.66 0.81, 1.2 0.65, 1.0	1.015 0.54 0.865 0.615 1.175 0.645 1.005 0.825	– 0.53 – 0.71 – 0.55 – 0.82	Ediger, 2005b Trial 2B- FR-04- 5281
Lemon (Eureka)	SC20, 1× LV spray 2 g ai/tonne	RAC washed	0 0	0.97, 1.2 0.04, 0.28	1.085 0.16	– 0.15	Ediger, 2005b Trial 2B-FR- 04-5282
Lemon (Eureka)	SC20, 1× LV spray 4 g ai/tonne	RAC washed RAC washed RAC washed RAC washed	0 0 30 30 66 66 122 122	1.6, 1.7 0.31, 0.47 0.74, 1.4 1.7, 1.9 1.1, 1.3 1.5, 1.7 1.5, 1.9 1.3, 1.7	1.65 0.39 1.07 1.8 1.2 1.6 1.7 1.5	– 0.24 – 1.7 – 1.3 – 0.88	Ediger, 2005b Trial 2B- FR-04- 5280

Commodity Country, Year (Variety)	Application Form, no. appl. (interval), method, rate	crop part	DAT	Fludioxonil residue (mg/kg)	mean residue (mg/kg)	PF	Author, Date Trial Ref No
Orange, sweet (Valencia)	50WP, 1× dip 120 g ai/hL	RAC peel pulp	0 0 0	1.4, 1.9 3.0, 3.4 0.55, 0.92	1.65 3.2 0.735	– 1.9 0.45	Thompson, 2003a Trial 07947.01-CA108

[a] calculated residue value for whole fruit based on residue determined for flesh and peel and the recorded masses

Mean processing factors are summarised in table 9.

Table 9 Mean processing factors

Commodity	Processed commodity	N	PF (mean)
citrus fruits	washed whole fruit	35	0.67
	pulp	47	0.07
	peel	25	3.2
orange	orange juice	4	0.13
	wet pomace	1	2.2
	dry pomace	4	7.4
	marmalade	4	0.48
lemon	lemon juice	1	< 0.03
	dry pomace	1	2.1
	oil	1	61

APPRAISAL

Fludioxonil, a fungicide to control plant-pathogenic fungi such as *Botrytis cinerea,* was first evaluated at the 2004 JMPR Meeting. That Meeting established an ADI of 0–0.4 mg/kg bw and considered that an ARfD was unnecessary. The Meeting concluded that the residue definition for plant commodities for compliance with the MRL and for consumer risk assessment was fludioxonil only. A number of maximum residue levels were proposed, but in 2004, no maximum residue level was recommended for the post-harvest use on pomegranate or yam. At that time no GAP was available for pomegranate and the number of trials at the critical GAP for yams was insufficient. A maximum residue level for citrus fruit was recommended based on post-harvest uses. However, since the last evaluation a new GAP has been introduced for post-harvest applications of fludioxonil to citrus fruits, in which the maximum application rate has been doubled and further residue studies have been carried out. Furthermore, additional data has been submitted by the manufacturer to support the use of fludioxonil on pomegranate and root & tuber vegetables.

Methods of analysis

In the newly submitted supervised residue trials, fludioxonil (parent only) was analysed by either method REM 133.04 or AG-597B, or slight modifications thereof. JMPR 2004 concluded the following on these methods: '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 the current trials, the methods were validated for the range of LOQ to at least the highest residue value measured, with an LOQ of 0.02 mg/kg for citrus fruits, sweet potato and pomegranate, 0.03 mg/kg for older pomegranate studies and 0.04 mg/kg for yams.

Stability of pesticide residues in stored analytical samples

The 2004 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.

Additional storage stability studies on citrus, sweet potato and yam were available to the Meeting. Fludioxonil is stable for at least 14 months in frozen samples of citrus, and at least 10 months in lemon juice and pulp. Fludioxonil is also stable for at least 10 months in sweet potato and for 5 months in yam. Based on these data, the Meeting concluded, that no storage stability problems are to be expected in these commodities since samples were stored for less than the period tested for in the storage stability studies. Storage of pomegranate samples is covered by results for citrus fruits.

Results of supervised trials on crops

Supervised trials with fludioxonil were conducted with post-harvest treatment of citrus fruit, pomegranate, sweet potato and yam.

Citrus fruits

Since 2004, 27 new trials have been carried out in the USA and in the EU. Citrus fruit was treated with fludioxonil in post-harvest residue trials in oranges (10), lemons (5), grapefruit (4) and mandarins (8). Citrus fruits were treated once, twice or three times by post-harvest dip or drench (30-240 g ai/hL) or spray (1-4 g ai/tonne fruit).

The critical GAP in the US is 2 applications of dip or drench at 120 g ai/hL and/or spray at 4 mg ai/kg fruit. No minimum time for interval between applications is given. As residue decline studies show that the residue is stable in time, interval duration does not significantly influence final residue values. For compliance with worst case GAP, all trials conducted with two applications at worst case GAP-rate (± 25% of overall application rate) were considered, regardless the length of interval between applications.

The selected residue levels on orange (seven trials; two treatments at GAP rate) in ranked order, were: 2.9, 3.5, 4.0, 4.4, 4.6, 5.0 and 7.2 mg/kg. The levels on mandarin (seven trials; two treatments at GAP rate) were: 2.9, 5.6 (2), 5.8, 7.0, 7.3 and 7.8 mg/kg. The residue level on lemon (two trials at 75% of GAP rate) were: 2.5 and 3.9 mg/kg.

No trials that were summarised in JMPR 2004 complied with the newly introduced critical GAP. The Meeting decided to estimate a maximum residue level based on the data from mandarin; the data from orange and lemon are used for support. The Meeting estimated a maximum residue level for whole citrus of 10 mg/kg. In the selected trials, residue in the pulp was not measured. However, in 47 of the other citrus trials residues in peel and pulp were determined and a processing factor of 0.07 for residue in citrus pulp could be derived. An STMR-P of 0.41 (5.8×0.07) mg/kg was estimated, for citrus pulp.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 11 mg/kg. Since the total dose is 8 mg/kg (post-harvest), the Meeting considered that 10 mg/kg was sufficient.

Pomegranates

Since 2004, four post-harvest trials on pomegranate have been conducted according to the critical GAP in the USA, i.e. a single dip or drench application at 60 g ai/hL. Another two trials with the same

applications were summarised in JMPR 2004. All trials are considered appropriate to be included in MRL setting and calculation of STMR.

The residue levels on pomegranate (six trials) in ranked order, were: 0.65, 0.80, 0.95, 1.1, 1.2 and 1.3 mg/kg. The Meeting estimated a maximum residue level for pomegranate 2 mg/kg and an STMR of 1 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 2 mg/kg.

Root and tuber vegetables

Four post-harvest trials on sweet potato tubers have been conducted in the USA and two trials on yam tubers have been conducted in Puerto Rico (also summarised in JMPR 2004, but with some errors). All trials were conducted according to the range specified in the recommended GAP. Two sweet potato trials in the USA (2.5 and 2.8 mg/kg) and two yam trials in Puerto Rico (4.2 and 5.7 mg/kg) comply with the critical GAP, i.e., a single application at 60 g ai/hL.

The residue levels on yams and sweet potatoes (four trials) were used in mutual support. The Meeting estimated a maximum residue level for yams and sweet potatoes of 10 mg/kg and an STMR of 3.5 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 9 mg/kg,

Fate of residues during processing

Post-harvest treatments are normally reserved for high value commodities and it is therefore unlikely that treated crops will undergo industrial processing. However, information on the fate of incurred residues of fludioxonil during the processing of citrus fruits was submitted to the Meeting for completeness. The processed commodities obtained from industrial processing are juice, marmalade, and wet and dry pomace from orange (one trial), and juice, oil, and pomace from lemon (one trial). For household processing (peeling and washing), data on residues in peel, pulp and washed fruit was available in most of the supervised residue trials.

For pulp, the calculated processing factor is very low (0.07) due to the fact that the fruit was peeled on the same day as the day of last application. Therefore, time for translocation of fludioxonil from the peel to the pulp was very limited, explaining the low processing factor for pulp. Only in 3 samples, another application was made 2 days before, as in all other samples, no other application was performed or it was performed at the same day as the last application. If the fruit is stored for longer periods before peeling, the processing factor for pulp will likely be higher. The other way around is the processing factor of 3.2 for peel derived from a worst-case scenario and this factor will likely be lower if fruit is stored for longer periods before peeling. For washed fruit, it can be concluded that the processing factor is not influenced by the period between last treatment and the washing of the fruit. Therefore, all trials are included in the calculation of the overall processing factor for washing (0.67).

Data on different kinds of citrus fruit (lemon, mandarin, orange and grapefruit) can be combined to derive one processing factor for each processed commodity of citrus fruit.

Processing factors and STMR-P values in citrus fruit

Commodity	Processed commodity	PF (mean)	STMR-P
Citrus fruit (STMR = 5.8)	pulp	0.07	0.41
	juice	0.11	0.64
	dry pomace	6.4	37

Residues in animal commodities

Waste pulp (pomace) from processed citrus fruits can contribute to animal diets and is listed on the OECD Dietary Burden Calculator. However, in commercial practice, post-harvest treatment is normally reserved for high value commodities and it is therefore unlikely that pomace from treated fruits would be fed to livestock. As a result of this, the Meeting considered that the proposed MRL and STMR for fludioxonil in citrus crops will not change the dietary burden calculation which was evaluated at the 2004 JMPR meeting.

Pomegranate and tropical root and tuber vegetables are not regarded as crops contributing significantly to animal diets and do not appear on the OECD Dietary Burden Calculator. Therefore the Meeting retained the recommendations for animal commodities as reported in 2004.

RECOMMENDATIONS

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

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

Definition of the residue for livestock commodities (for compliance with MRLs and for estimation of dietary intake): *the sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil*

Fludioxonil is fat-soluble.

Codex Code	Commodity	MRL (mg/kg)		STMR (P) (mg/kg)
		New	Previous	
FC 0001	Citrus fruits	10 Po	7 Po	0.41
FI 0355	Pomegranate	2 Po		1.0
VR 0508	Sweet potato	10 Po		3.5
VR 0600	Yams	10 Po		3.5

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of fludioxonil based on the STMRs for 48 commodities for the 13 GEMS/Food regional diets were 1–2% of the maximum ADI of 0.4 mg/kg bw (see 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 fludioxonil 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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