FLUDIOXONIL (211)

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EXPLANATION

Fludioxonil is a phenylpyrrole fungicide that was reviewed by the JMPR in 2004 (T, R), 2010 (R) and 2012 (R). The compound was listed by the Forty-fourth Session of CCPR for the evaluation by the 2013 JMPR. Residue studies were submitted for pineapple, tomato, fresh peas, dry beans and potato, and processing studies on pineapple, tomato and potato. Additionally, a farm hen feeding study and analytical method to analyse fludioxonil and its metabolites in poultry tissues and eggs were also submitted.

Definition of residue for compliance with the MRLs and estimation of dietary intake in plant commodities: fludioxonil. Definition of residue for compliance with the MRLs and estimation of dietary intake: sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobeno[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil. The residue is fat-soluble.

METHODS OF RESIDUE ANALYSIS

Method GRM025.03A determines fludioxonil and its metabolites oxidisable to CGA192155 (2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid) in poultry tissues and eggs (Sole 2008, 2008a). Samples of muscle, liver and kidney are homogenised and extracted by refluxing with ammonium hydroxide:acetonitrile (80:20 v/v). After filtration, the aqueous phase is acidified and partitioned with toluene following addition of sodium chloride. Conversion of fludioxonil and its metabolites to CGA192155 is carried out by heating in the presence of potassium permanganate and aqueous sodium hydroxide; the oxidation is then quenched with sodium metabisulfite, the extracts are filtered, acidified, and partitioned into dichloromethane:ethyl acetate (80:20 v/v). After evaporation, the residues are dissolved in acetonitrile:water (50:50 v/v) and determined as total fludioxonil by LC-MS/MS. A molecular weight correction factor of 1.23 is applied when calculating procedural recovery values and quantifying residues of CGA192155. The recoveries obtained are shown in Table 1.

Table 1 Recovery of CGA192155 (2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid) expressed as fludioxonil obtained during method validation

Matrix	Level (mg/kg)	Recovery (%)	Mean (%)	RSD (%)	Range (%)
MRM transition 201> 157 m/z					
Eggs	0.01	110, 107, 108, 113, 107	109	2	107-113
	0.1	97, 95, 99, 97, 99	97	2	95-99
	Overall		103	6	95-113
Milk	0.01	74, 84, 92, 98, 87	87	11	74-98
	0.1	78, 78, 79, 76, 80	78	2	76-80
	Overall		83	9	74-98
Muscle	0.01	82, 70, 77, 75, 80	77	6	70-82
	0.1	80, 75, 78, 78, 80	78	3	75-80
	Overall		78	4	70-82
Liver	0.01	86, 86, 85, 85, 89	86	2	85-89
	0.1	88, 87, 88, 87, 87	87	1	87-88
	Overall		87	1	85-89
Kidney	0.01	77, 74, 82, 78, 82	79	4	74-82
	0.1	80, 80, 81, 84, 84	82	3	80-84
	Overall		80	4	74-84
Fat	0.01	78, 81, 78, 76, 77	78	2	76-81
	0.1	77, 79, 81, 78, 80	79	2	77-81
	Overall		78	2	76-81
MRM transition 201>91 m/z					
Eggs	0.01	103, 103, 99, 104, 105	103	2	99-105
	0.1	96, 95, 99, 97, 100	97	2	95-100
	Overall		100	3	95-105
Milk	0.01	80, 82, 85, 92, 81	84	6	80-92

Matrix	Level (mg/kg)	Recovery (%)	Mean (%)	RSD (%)	Range (%)
MRM transition 201> 157 m/z					
	0.1	79, 81, 81, 77, 80	80	2	77-81
	Overall		82	5	77-92
Muscle	0.01	82, 74, 80, 78, 80	79	4	74-82
	0.1	80, 76, 79, 80, 80	79	2	76-80
	Overall		79	3	74-82
Liver	0.01	86, 88, 88, 88, 89	88	1	86-89
	0.1	87, 86, 87, 86, 87	87	1	86-87
	Overall		87	1	86-89
Kidney	0.01	76, 73, 83, 82, 83	79	6	73-83
	0.1	80, 80, 80, 83, 83	81	2	80-83
	Overall		80	4	73-83
Fat	0.01	72, 75, 65, 73, 73	72	5	65-75
	0.1	77, 79, 81, 79, 80	79	2	77-81
	Overall		75	6	65-81

Matrix effects (enhancement or suppression) were greater than 10% for several matrices, and the use of matrix-matched standards is recommended. Standard solutions containing CGA192155 at concentrations ranging from 0.0005 to 0.05 µg/mL (equivalent to 5 to 500 pg of analyte injected on column based on a 10 µL injection) were analysed. The response of the LC-MS/MS system was shown to be linear for CGA192155 primary transition (201.0>157.0 m/z) and the confirmatory transition (201.0>91.0 m/z) over the concentration range tested. The relative standard deviations (RSDs) of recoveries at each fortification level and overall for each matrix tested during method validation were < 20% and therefore according to the EU Guidance (SANCO 3029/99 rev 4. 11/07/00) demonstrate the method has satisfactory repeatability.

The validated limit of quantification for fludioxonil and metabolites as CGA192155 in animal tissues was 0.01 mg/kg for fludioxonil (= 0.0081 mg/kg for CGA192155) when measured as CGA192155 for all animal matrices tested. The stability of CGA192155 was assessed by storing the extracts of representative animal matrices (eggs and liver) refrigerated at 0-9°C and re-analysing them (in quintuplet) after 7 and 9 days of storage. The results showed that the residues were stable in the extracts over these time periods.

USE PATTERNS

All the supervised trials submitted by the manufacturer were conducted in the United States or in Canada. Table 2 shows the registered uses of fludioxonil in USA for the crops relevant to this submission.

Table 2 Use patterns of fludioxonil in USA

Crop	Formulation	Application				DAT (days)
		Method	Maximum Rate	Number	Interval (days)	
Avocado	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	0
Beans, dried and succulent, except cowpeas	25%	Foliar spray application	0.245 kg ai/ha	4/year	7	7
Brassica (cole) leafy vegetables	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	7
Carrot	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	7
Chives	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	7
Cucurbits	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	1
Ginseng	50%	Drench application or via drip irrigation	0.28 kg ai/ha	4/year	14	14
Herbs, dried and flesh	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	7
Kiwifruit	230 g ai/L	In-Line Dip/Drench or aqueous or fruit coating spray application	0.057 kg ai/hL (dip/drench) or 0.24 kg ai/L100,000 kg fruit (spray)	1	na	na

Crop	Formulation	Application				DAT (days)
		Method	Maximum Rate	Number	Interval (days)	
Leafy greens	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	0
Lemon	25%	Foliar spray application	0.245 kg ai/ha	1	na	0
Lychee	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	0
Pineapple	230 g ai/L	Post-harvest high volume drench and/or directed peduncle spray	0.057 kg ai/hL	1	na	Na
Peas, fresh	479 g ai/L	Seed treatment	0.005 kg ai/L100 kg seed	1	na	Na
Pepper (Bell & Non-Bell)	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	0
Potato	230 g ai/L	In-line aqueous spray	0.0045 kg ai/1000 kg tubers	1	na	Na
		High-volume spray	0.005 kg ai/hL	1		
Radish	25%	Foliar spray application	0.245 kg ai/ha	2/crop	7–10	7
Spinach	25%	Foliar spray application	0.245 kg ai/ha	4/year	7–10	0
Tomato	230 g ai/L	In-line drip/drench [a]	0.057 kg ai/hL	1	na	-
	230 g ai/L	High volume, dilute spray [b]	0.0044 kg ai/L1000 kg tomato	1	na	-

Na: not applied;

[a]. Dip for approximately 30 seconds and allow fruit to drain.

[b]. Must be used in tank mixture with propiconazole

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Supervised residue trials (149) conducted with fludioxonil in Canada and USA were submitted to the Meeting. Studies were conducted according to GLP, and specified concurrent determination of residues in untreated crops gave residues < LOQ. Residues of fludioxonil arising from use patterns where rate or PHI or ± 25% of GAP are underlined and considered for estimation of maximum residue levels and STMRs. In the tables, DAT means days after treatment. In all trials, unless specified, two samples were analysed and the mean residues reported.

Lemon

Five supervised residue trials were conducted in the USA during the 2004-2005 growing season. After harvest, samples were dried and stored deep-frozen for less than 22 months. The results are summarized in Table 3.

Table 3 Residues resulting from fludioxonil application to lemon in USA and Canada (Report: IR-4 PR No. 08297) [a]

State	Crop (Var)	Application			Residue, mg/kg	Trial
		No. (date)	kg ai/ha	DAT		
California, Orange core	Lemon (Lisbon)	1 (11/03/2004)	0.257	0	0.12	08297.04-CA122
California, Orange core	Lemon (Lisbon)	1 (11/10/2004)	0.251	0	0.12	08297.04-CA123
California, Riverside	Lemon (Lisbon)	1 (01/13/2005)	0.245	0	0.12	08297.04-CA124
California, Riverside	Lemon (Lisbon)	1 (03/17/2005)	0.245	0	0.16	08297.04-CA125
California, Porteville	Lemon (Pryor)	1 (03/08/2005)	0.244	0	0.16	08297.04-CA126

Avocado

Six supervised residue trials were conducted in USA in 2003. The results from analysis of treated samples are summarized in Table 4.

Table 4 Residues resulting from fludioxonil application to avocado in USA (Report: IR-4 PR No. 07338)

State	Crop (Var)	Application			Residue, mg/kg	Trial
		No.	kg ai/ha	DAT		
Florida, Homestad	Avocado (Miguel)	4	0.246–0.251	0	0.06	07338.03-FL22
Texas, Monte Alto	Avocado (Lula)	4	0.241 – 0.245	0	0.02	07338.03-TX*14
California, Porteville	Avocado (Zutano)	4	0.245 – 0.248	0	0.04	07338.03-CA35
California, Nipomo	Avocado (Gwen & Bacon)	4	0.245 – 0.248	0	0.19	07338.03-CA36
California, Irvine	Avocado (Hass)	4	0.245 – 0.250	0	0.11	07338.03-CA37
California, Orosi	Avocado (Hass)	4	0.246 – 0.247	0	0.02	07338.03-CA38

Pineapple

Eight supervised residue trials were conducted in the USA (Hawaii) in 2009. From each site, pineapple fruit were treated twice post-harvest with the test substance in either a dip plus wax followed by a spray directed to the peduncle or a drench plus wax followed by a spray directed to the peduncle. The fruit was allowed to air dry between applications, and samples of pineapple fruit without crowns were collected following the second application, after the test substance had dried. Samples were stored deep-frozen for a maximum of 18 months. The results are summarized in Table 5.

Table 5 Residues of fludioxonil in pineapple after post-harvest treatment (Report: IR-4 PR No. 10203)

Crop (variety)	Application rate, kg/hL	DAT	Residues, mg/kg	Trial
Pineapple (Maui Gold)	0.06 (drench) + 0.87 (spray)	0	6.4	10203.09-HI02
	0.06 (dip) + 0.87 (spray)	0	4.8	
Pineapple (Mg-3)	0.06 (dip) + 0.87 (spray)	0	5.4	10203.09-HI03
	0.06 (drench) + 0.87 (spray)	0	6.1	
Pineapple (Mg-3)	0.06 (drench) + 0.87 (spray)	0	6.6	10203.09-HI04
	0.06 (dip) + 0.87 (spray)	0	5.4	
Pineapple (Maui Gold)	0.06 (dip) + 0.87 (spray)	0	5.4	10203.09-HI05
	0.06 (drench) + 0.87 (spray)	0	5.2	

Cucurbits

Eighteen supervised residue trials were conducted in the USA in 2004 on cantaloupe, cucumber, and squash plants The results from analysis of treated samples are summarized in Table 6.

Table 6 Residues resulting from fludioxonil application to cucurbits in USA (Report: No. T002039-03)

State	Crop (Var)	Application			Residue, mg/kg	Trial
		No.	kg ai/ha	DAT		
Illinois, Champaign	Cantaloupe (Super Star)	4	0.238–0.250	1 8	0.02 0.02	4A-FR-04-5178
Texas, Wharton	Cantaloupe (Earligold)	4	0.239–0.257	1 8	0.07 0.02	SA-FR-04-5188
Georgia, Chula	Cantaloupe (Edisto 47)	4	0.241–0.247	1 7	0.09 0.02	SI-FR-04-5177
California, Madera	Cantaloupe (Top Net)	4	0.241–0.247	1 7	0.20 0.14	WC-FR-04-5180
California, Live Oak[a]	Cantaloupe (Top Mark)	4	0.245–0.248	1 7	0.36 0.09	WD-FR-04-5182
California, Live Oak[a]	Cantaloupe (Durango)	4	0.245–0.246	1 7	0.13 0.12	WD-FR-04-5181
Wisconsin, Delavan	Cucumber (Marketmore 86)	4	0.243–0.251	1 7	0.03 < 0.01	NI-FR-04-5174
Michigan, Conklin	Cucumber (Marketmore 76)	4	0.243–0.245	1 7	0.04 0.01	NL-FR-04-5173
Texas, Wharton	Cucumber (Slice Master Select)	4	0.245–0.250	1 8	0.06 0.03	SA-FR-04-5175
Georgia, Chula	Cucumber (Lightning)	4	0.244–0.250	1 7	0.04 < 0.01	SI-FR-04-5170

State	Crop (Var)	Application No.	Application kg ai/ha	Application DAT	Residue, mg/kg	Trial
N. Carolina, Rose Hill	Cucumber (Poinsett 79)	4	0.246–0.248	1 7	0.09 < 0.01	SJ-FR-04-5171
Florida, Vero Beach	Cucumber (Straight Eight)	4	0.238–0.248	1 7	0.13 0.02	VF-FR-04-5172
California, Hikman	Cucumber (Poinsett 76)	4	0.243–0.246	1 7	0.05 0.02	WC-FR-04-5176
Illinois, Champaign	Squash, Summer (Lemondrop)	4	0.243–0.268	1 6	0.01 < 0.01	4A-FR-04-5186
New York, Hudson	Squash, Summer (Yellow Straight)	4	0.233–0.252	1 7	0.04 0.01	5E-FR-04-5183
S. Carolina, Elko	Squash, Summer (Lemondrop L)	4	0.244–0.248	1 6	0.08 < 0.01	SJ-FR-04-5184
Florida, Vero Beach	Squash, Summer (Burpee Hybrid Zucchini)	4	0.248–0.252	1 7	0.08 0.02	VF-FR-04-5185
California, Visalia	Squash, Summer (Black Beauty)	4	0.248–0.245	1 7	0.04 < 0.01	WC-FR-04-5187

[a]. independent trials, different application dates

Tomato

Twelve post-harvest trials were conducted in the USA in 2008/2009. A food-grade adjuvant was included in each tank mix. Samples were stored deep-frozen for a maximum of 9 months and analysed using Method No. AG-597B. The results are summarized in Table 7.

Table 7 Residues resulting from fludioxonil post-harvest application to tomato in the USA (IR-4 PR No. 10182)

Crop (Variety)	Application rate	DAT	Residues, mg/kg	Trial
Tomato (Shady Lady)	0.06 kg ai/hL; drench/dip	0	0.25/0.28	09-CA98
	0.005 kg ai/1000 kg fruit; in-line spray	0	0.18	
Tomato (Agri-Set 761)	0.06 kg ai/hL; dip	0	0.48	09-FL06
Cherry tomato (Il-7108)	0.06 kg ai/hL; dip	0	0.77	09-FL68
Tomato (Amelia)	0.005 kg ai/1000 kg fruit; in-line spray	0	0.66	09-NC19
	0.06 kg ai/hL, drench/dip	0	0.73/0.47	
Tomato, Cherry (Red Cherry)	0.06 kg ai/hL; drench/dip	0	1.0/1.1	
	0.005 kg ai/1000 kg fruit; in-line spray	0	1.8	
Tomato (Polbig)	0.06 kg ai/hL; dip	0	0.43	09-NY2

Peppers (Bell and Non-Bell)

Nineteen supervised residue trials were conducted in the field and in greenhouse on bell and non-bell peppers in USA and Canada in 2005/2006. The results from analysis of treated samples are summarized in Table 8.

Table 8 Residues resulting from fludioxonil application to pepper (bell & non-bell) in USA and Canada

Country, region	Crop (Var)	Field/ greenhouse	Application No.	Application kg ai/ha	Application DAT	Residue, mg/kg	Trial
CA, Ontario, Harrow[a]	Bell Pepper (Revolution)	Field	4	0.256 – 0.264	0	< 0.02	IR-4 PR No. 09567.06-ON02
CA, Ontario, Harrow[a]	Bell Pepper (Aristotle)	Field	4	0.249 – 0.286	0	< 0.02	IR-4 PR No. 09567.06-ON03
CA, Ontario, Delhi	Bell Pepper (Crusdaer)	Field	4	0.241 – 0.248	0	0.09	IR-4 PR No. 09567.06-ON04
CA, Quebec	Bell Pepper (Redstart)	Field	4	0.243 – 0.250	0	0.28	IR-4 PR No. 09567.06-QC01
USA, California, Holtville	Bell Pepper (Macabi)	Field	4	0.246 – 0.248	0	0.12	IR-4 PR No. 09567.06-CA45
USA, California, Parlier	Bell Pepper (Baron)	Field	4	0.242 – 0.248	0	0.08	IR-4 PR No. 09567.06-CA46

Country, region	Crop (Var)	Field/ greenhouse	Application			Residue, mg/kg	Trial
			No.	kg ai/ha	DAT		
USA, Florida, Citra	Bell Pepper (Camelot X3R)	Field	4	0.246 – 0.253	0	0.16	IR-4 PR No. 09567.06-FL19
USA, N. Carolina, Raleigh	Bell Pepper (Revolution)	Field	4	0.242 – 0.246	0	0.16	IR-4 PR No. 09567.06-NC07
USA, Florida, Citra	Non-Bell Pepper (Mesilla 242)	Field	4	0.243 – 0.259	0	0.31	IR-4 PR No. 09567.06-FL20
USA, N. Mexico, Las Cruces[a]	Non-Bell Pepper (Joe E. Parker)	Field	4	0.245 – 0.249	0	0.06	IR-4 PR No. 09567.06-NM03
USA, N. Mexico, Las Cruces[a]	Non-Bell Pepper (Joe E. Parker)	Field	4	0.244 – 0.246	0	0.14	IR-4 PR No. 09567.06-NM04
USA, Ohio, Wooster	Non-Bell Pepper (San Ardo)	Field	4	0.244 – 0.245	0	0.07	IR-4 PR No. 09567.06-OH*06
USA, Texas, Weslaco	Non-Bell Pepper (Sonora Anaheim)	Field	4	0.244 – 0.245	0	0.12	09567.06-TX*16
USA, Texas, Weslaco	Bell Pepper (Capistrano)	Field	4	0.244 – 0.248	0	0.13	IR-4 PR No. 09567.06-TX17
Canada, Ontario, Harrow[a]	Pepper (Striker) (bell)	Greenhouse	4	0.245 – 0.247	0	0.21	IR-4 PR No. 09140.05-ON01
Canada, Ontario, Harrow[a]	Pepper (Zamboni) (bell)	Greenhouse	4	0.244 – 0.245	0	0.10	IR-4 PR No. 09140.05-ON06
USA, New Jersey	Pepper (King Arthour) (bell)	Greenhouse	4	0.233 – 0.255	0	0.22	IR-4 PR No. 09140.05-NJ01
USA, Tennessee, Jakson	Pepper (Spartacus F1) (bell)	Greenhouse	4	0.238 – 0.252	0	0.20	IR-4 PR No. 09140.05-TN01
USA, Texas, Weslaco	Pepper (TAM veracruz) (non bell)	Greenhouse	4	0.247 – 0.249	0	0.20	IR-4 PR No. 09140.05-TX01

[a]. independent trials, different application days

Lettuce (Head and Leaf)

Fourteen supervised residue trials were conducted in USA in 2001. The results from analysis of treated samples are summarized in Table 9.

Table 9 Residues resulting from fludioxonil application to lettuce in USA (Report: IR-4 PR No. 07131)[a]

State	Crop (Var)	Application			Residue, mg/kg	Trial
		No.	kg ai/ha	DAT		
New York, Freeville	Head Lettuce	4	0.234 – 0.259	0	1.2 (w/ wrapper); < 0.02 (w/o wrapper)	07131.01-NY11[a]
Florida, Gainesville	Head Lettuce	4	0.243 – 0.247	0	4.6 (w/ wrapper); 0.25 (w/o wrapper)	07131.01-FL15[a]
New Mexico, Mesilla	Head Lettuce	4	0.235 – 0.248	0	2.0 (w/ wrapper); 0.07 (w/o wrapper)	07131.01-NM04[a]
Oregon, Aurora	Head Lettuce	4	0.245 – 0.247	0	1.4 (w/ wrapper); 1.4 (w/o wrapper)	07131.01-OR06[a]
Ohio, Willard	Head Lettuce	4	0.240 – 0.253	0	2.2 (w/ wrapper); 0.50 (w/o wrapper)	07131.01-OH*06[a]
California, Salinas	Head Lettuce	4	0.244 – 0.252	0	2.0 (w/ wrapper); 1.6 (w/o wrapper)	07131.01-CA*27[a]
California, Holtville	Head Lettuce	4	0.239 – 0.263	0	0.42 (w/ wrapper); 0.06 (w/o wrapper)	07131.01-CA29[a]
California, Parlier	Head Lettuce	4	0.247 – 0.252	0	2.8 (w/ wrapper); 0.68 (w/o wrapper)	07131.01-CA31[a]
Maryland, Salisbury	Leaf lettuce	4	0.245– 0.249	0	22	07131.01-MD08
Florida, Live Oak	Leaf lettuce	4	0.243 – 0.251	0	16	07131.01-FL16
New Mexico, Mesilla	Leaf lettuce	4	0.251 – 0.262	0	6.7	07131.01-NM05

State	Crop (Var)	Application No.	kg ai/ha	DAT	Residue, mg/kg	Trial
California, Salinas	Leaf lettuce	4	0.251 – 0.360	0	4.8	07131.01-CA*28
California, Clay Loam	Leaf lettuce	4	0.243 – 0.245	0	10	07131.01-CA30
California, Parlier	Leaf lettuce	4	0.247 – 0.265	0	6.5	07131.01-CA32

[a] Only one sample analysed in each case

Spinach

Eleven supervised residue trials were conducted in USA and Canada in 2008. The results from analysis of treated samples are summarized in Table 10.

Table 10 Residues resulting from fludioxonil application to spinach in USA and Canada (Report: IR-4 PR No. 10006)[a]

Country/Region	Crop (Var)	Application No.	kg ai/ha	DAT	Residue, mg/kg	Trial
USA/Maryland, Salisrbury	Spinach (Melody)	4	0.245 – 0.247	0	4.6	10006.08-MD22
USA/New York, Ithaca	Spinach (Tyee)	4	0.243 – 0.247	0	1.9	10006.08-NY30
USA/Texas, Weslaco[a]	Spinach (Samish)	4	0.246	0	12	10006.08-TX*02
USA/Texas, Weslaco[a]	Spinach (Space F1)	4	0.243 – 0.247	0	7.5	10006.08-TX03
USA/S. Carolina, Charleston	Spinach (Skookam hybrid)	4	0.239 – 0.246	0	3.4	10006.08-SC*07
USA/Colorado, Fort Collins	Spinach (Spinner)	4	0.247 – 0.260	0	8.3	10006.08-CO13
USA/California, Holtville	Spinach (1B12A)	4	0.236 – 0.251	0	9.8	10006.08-CA18
USA/California, Salinas	Spinach (Whale)	4	0.243 – 0.251	0	4.9	10006.08-CA*17
CAN/Ontario	Spinach (Unipack 151)	4	0.244 – 0.253	0	4.9	10006.08-ON13
CAN/British Columbia	Spinach (Unipack)	4	0.248 – 0.251	0	16	10006.08-BC02
CAN/Quebec	Spinach (Unipack 151)	4	0.235 – 0.258	0	5.8	10006.08-QC04

[a.] independent trials, different application days

Potato

Five post-harvest trials were conducted in the United States and Canada during 2009 and 2010. From each site, potato tubers were treated as a spray directed to tubers falling from a conveyor belt or moving along a roller table. Samples were stored deep-frozen for a maximum of 11.3 months before analysis. The results are summarized in Table 11.

Table 11 Residues resulting from fludioxonil post-harvest application to potato in Canada and USA (Report: TK0003297)

Country	Crop (Variety)	kg ai/L ton	Sample	DAT	Residues, mg/kg	Trial
Canada	Potato (Ac Chaleur)	0.0045	Roller table	0	2.5	09-ON14 [a,b]
				14	3.2	
				31	2.9	
				59	2.9	
USA	Potato (Russet Burbank)	0.0045	Conveyor belt	0	2.9	09-ID19 [b]
				30	0.63	
				231	1.0	
			Surface	0	1.0	[c]
			Spray chamber	0	3.2	[d]
			Brush table	0	1.7	[e]
USA	Potato (Frito Lay 1533)	0.005	Conveyor belt	0	0.66	09-ME04 [b]
USA	Potato (Russet Burbank)	0.0045	Conveyor belt	0	1.5	09-WA32 [b]
				13	1.0	
				32	1.1	
				61	1.1	

Country	Crop (Variety)	kg ai/L ton	Sample	DAT	Residues, mg/kg	Trial
	Potato (Russet Burbank)	0.0046	Conveyor belt	0	1.1	09-WI19 [b]

[a]. potato samples were cut in half in the field;

[b]. spray directed to tubers falling from conveyor belt or moving along a roller table;

[c]. spray directed to tubers placed on a flat surface (i.e. tarp) close together, allowed to dry, turned over, and sprayed again;

[d]. spray directed to tubers placed close together inside a spray chamber, allowed to dry, turned over, and sprayed again;

[e]. spray directed to tubers placed on a brush table that rolled the potatoes under the spray.

Radish

Six supervised residue trials were conducted in USA in 2004. The results from analysis of treated samples are summarized in Table 12.

Table 12 Residues on radish tops resulting from fludioxonil application to radish in USA (Report: IR-4 PR No. 09019)

State	Crop (Var)	Application			Sample	Residue, mg/kg	Trial
		No.	kg ai/ha	DAT			
New York, Freevile	Radish (Cheriette F1)	2	0.257 – 0.268	7	Tops	4.6	09019.04-NY06
					Root	0.10	
Florida, Citra [a]	Radish (Fireball)	2	0.248 – 0.454	7	Tops	5.8	09019.04-FL14
					Root	0.04	
Florida, Citra [a]	Radish (Fireball)	2	0.245 – 0.250	7	Tops	10	09019.04-FL15
					Root	0.10	
California, Salinas	Radish (Cheriette)	2	0.251 – 0.254	7	Tops	3.0	09019.04-CA*08
					Root	0.08	
Ohio, Willard	Radish (Cabernet)	2	0.251 – 0.256	7	Tops	2.5	09019.04-OH*01
					Root	< 0.02	
Washington Moxee	Radish (Crunchy Royale)	2	0.238 – 0.240	8	Tops	0.45	09019.04-WA*02
					Root	< 0.02	

[a]. independent trials, different application days

Peas

Twenty supervised residue trials were conducted on fresh peas with pods in the USA in 1997 after seed treatment at different rates. The results are summarized in Table 13.

Table 13 Residues resulting from fludioxonil seed application at planting to succulent peas with pods in USA (Report: ABR-97097)

State	Crop (Variety)	Rate kg/100 kg seed	DAT	Residues, mg/kg	Trial
Wisconsin, Portage	Pea (Knight)	0.0025	61	< 0.01	MW-SR-705-97
	Pea (Knight)	0.005	61	< 0.01	
	Pea (Knight)	0.012	61	< 0.01	
	Pea (Knight)	0.025	61	< 0.01	
Virginia, Isle of Wight	Pea (Knight)	0.0025	66	< 0.01	NE-SR-308-97
	Pea (Knight)	0.005	66	< 0.01	
	Pea (Knight)	0.012	66	< 0.01	
	Pea (Knight)	0.025	66	< 0.01	
New York, Wayne	Pea (Knight)	0.0025	58	< 0.01	NE-SR-805-97
	Pea (Knight)	0.005	58	< 0.01	
	Pea (Knight)	0.012	58	< 0.01	
	Pea (Knight)	0.025	58	< 0.01	
Washington, Whitman	Pea (Scout)	0.0025	71	< 0.01	OW-SR-632-97
	Pea (Scout)	0.005	71	< 0.01	
	Pea (Scout)	0.125	71	< 0.01	
	Pea (Scout)	0.25	71	< 0.01	

State	Crop (Variety)	Rate kg/100 kg seed	DAT	Residues, mg/kg	Trial
Oregon, Washington	Pea (SP173)	0.005	69	≤ 0.01	OW-SR-633-97
	Pea (SP173)	0.125	69	< 0.01	
	Pea (SP173)	0.25	69	< 0.01	
	Pea (SP173)	0.25	69	< 0.01	

Snap bean

Eight supervised residue trials were conducted in USA in 2001. The results from analysis of treated samples are summarized in Table 14.

Table 14 Residues in mature snap bean pods resulting from fludioxonil application to snap beans in USA (Report: IR-4 PR No. 07614)[a]

State	Crop (Var)	Application No.	kg ai/ha	DAT	Residue, mg/kg	Trial
New York, Ithaca	Snap Bean	4	0.245	8	0.04	07614.01-NY09
Maryland, Salisbury	Snap Bean	4	0.245	7	0.03	07614.01-MD05
Florida, Gainesville	Snap Bean	4	0.245	7	0.05	07614.01-FL18
Michigan, East Lansing	Snap Bean	4	0.245	7	0.03	07614.01-MI09
Wisconsin, Madison	Snap Bean	4	0.245	7	< 0.02	07614.01-WI08
California, Holtville	Snap Bean	4	0.245	6	0.38	07614.01-CA34
Idaho, Twin Falls	Snap Bean	4	0.245	8	0.05	07614.01-ID05
Ohio, Madison	Snap Bean	4	0.245	6	0.04	07614.01-OH*09

Lima Bean

Eight supervised residue trials were conducted in USA in 2001. The results from analysis of treated samples are summarized in Table 15.

Table 15 Residues resulting from fludioxonil application to lima beans in USA (Report: IR-4 PR No. 07783)

Region	Crop (Var)	Application No.	kg ai/ha	DAT	Residue, mg/kg	Trial
Maryland, Salisbury[a]	Lima Bean	4	0.245	8	< 0.02	07783.01-MD03
Maryland, Salisbury[a]	Lima Bean	4	0.245	8	< 0.02	07783.01-MD04
N. Carolina, Clinton	Lima Bean	6	0.245	7	0.03	07783.01-NC08
Idaho, Kimberly	Lima Bean	5	0.245	7	0.21	07783.01-ID07
California, Salinas[a]	Lima Bean	4	0.245	6	0.04	07783.01-CA*26
California, Salinas[a]	Lima Bean	5	0.245	8	< 0.02	07783.01-CA*81
Ohio, Freemont	Lima Bean	5	0.245	8	< 0.02	07783.01-OH*11
Georgia, Tifton	Lima Bean	5	0.245	8	0.03	07783.01-GA*08

[a]. independent trials, different application days

Dry beans

Nine supervised residue trials were conducted in USA in 2001 using foliar application. The results are summarized in Table 16.

Table 16 Residues resulting from fludioxonil application to dry beans in USA (Report: IR-4 PR No. 07782)

Region	Crop variety	Application No.	kg ai/ha	DAT	Residue, mg/kg	Trial
California, Salinas	Bean	4	0.245	5	0.22[a]	07782.01-CA*25
Colorado, Fort Collins	Bean Bill Z	4	0.245	7	0.06	07782.01-CO08
Colorado, Wellington	Bean UI 126	4	0.245	6	0.12	07782.01-CO09

Region	Crop variety	Application			Residue, mg/kg	Trial
		No.	kg ai/ha	DAT		
Idaho, Kimberly	Bean Pinto	4	0.245	6	0.04	07782.01-ID06
Michigan, Holt	Bean Strike	4	0.245	6	0.02	07782.01-M110
N. Dakota, Velva	Bean Othello	4	0.245	7	0.04	07782.01-ND07
Ohio, Freemont	Bean	4	0.245	8	0.02	07782.01-OH*10
S. Dakota, Brookings	Bean Vista	4	0.245	7	0.23	07782.01-SD04
S. Dakota, Aurora	Bean Vista	6	0.245	7	0.06	07782.01-SD05

[a.] Residues detected in the "treated samples" were < 0.02 ppm, and in "control samples" were 0.18 ppm and 0.26 ppm from this trial. It is believed that the control & treated samples were inadvertently switched

Parsley

Four supervised residue trials were conducted in USA in 2003. The results from analysis of treated samples are summarized in Table 17.

Table 17 Residues on fresh parsley resulting from fludioxonil application in USA (Report: IR-4 PR No. 07130)[a]

State	Crop (Var)	Application			Sample	Residue, mg/kg	Trial
		No.	kg ai/ha	DAT			
Ohio, Willard	Parsley (Dark Green Italian Flat Leaf)	4	0.241–0.247	6	Fresh	2.3	07130.03-OH*04
				6	dried	23	
California, Salinas	Parsley (Italian Dark Green)	4	0.240–0.251	7	Fresh	1.6	07130.03-CA*34
				8	dried	8.9	
Florida, Citra	Parsley (Italian Dark Green)	4	0.239–0.248	7	Fresh	3.9	07130.03-FL21
				7	dried	18	
Oregon, Aurora	Parsley (Italian Plain Leaf)	4	0.244–0.248	6	Fresh	3.2	07130.03-OR05
				6	dried	15	

[a.] one sample analysed

Ginseng

Four supervised residue trials were conducted in the USA and Canada from 2005 to 2006. Samples of ginseng root were collected 14–15 days after the last application. The results from analysis of treated samples are summarized in Table 18.

Table 18 Residues resulting from fludioxonil application to ginseng in USA and Canada (Report: IR-4 PR No. 09349) [a]

Country	Crop (Var)	Application			Residue, mg/kg	Trial
		No.	kg ai/ha	DAT		
CAN, British Columbia	Ginseng	4	0.182 – 0.287	15	0.16	09349.06-BC06
CAN, Ontario	Ginseng	4	0.280 – 0.282	14	0.18	09349.05-ON18
USA, Michigan, Athens	Ginseng	4	0.270 – 0.289	15	0.40	09349.05-MI22
USA, Wisconsin, Stratford	Ginseng	4	0.277 – 0.291	14	1.7	09349.05-WI18

[a]. highest residue of two samples

RESIDUES IN PROCESSED COMMODITIES

Pineapple

The trial 10203.09-HI05 shown in Table 4 included a processing study. Pineapple fruit (5.62 mg/kg fludioxonil) was processed to juice, that contained residue of 5.40 mg/kg, with a processing factor of 0.96.

Tomato

In one processing study, tomato plants received four foliar applications of fludioxonil (0.24 kg ai/ha), and samples were processed simulating commercial practices (Thompson, 2005; IR-4 PR No. 08124). After washing, the tomatoes were placed in a grinder and the crush was pumped into a hot break system. The crush was heated and processed through a finisher to remove peel and seeds. The resulting juice was concentrated to puree with a vacuum evaporator. After puree sample collection, the remaining puree was condensed into paste. Residues was 0.14 mg/kg in RAC, 0.05 mg/kg in pure (PF=0.36) and 0.15 mg/kg in paste (PF=1.1).

Potato

The trial 09-ID19 shown in Table 8 included a processing study. Residues in tubers were 0.472 mg/kg, in wet peel 0.797 mg/kg (PF=1.69), 0.01 mg/kg in flakes (PF=< 0.02) and 0.018 mg/kg in chips (PF=0.04).

RESIDUES IN ANIMAL COMMODITIES

Farm Animal Feeding Studies

Hen feeding study

A residue transfer study in poultry was carried out with four dosing level groups following a 28-day repeat dose regime via a gelatin capsule (Leslie, 2009; Report No. 1983/108-D2149). Dose levels were 1.54, 4.64 and 15.4 mg/kg feed (AR). Each of the four dosed groups was further sub divided into three sub-groups. Collection of eggs was made in the afternoon following dosing and the following morning immediately prior to dosing, which comprised a single day's sample. Following sacrifice, samples of tissue were homogenised to a fine powder in the presence of dry ice and stored frozen prior to analysis. Samples from the 10× dose group were analysed initially and then those from the lower dose group analysed if residues of fludioxonil were found to be above LOQ. The maximum storage period for eggs and tissues samples was 58 days. Residue levels (sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobeno[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil) in eggs as a function of time from the three dosed groups are shown in Table 19.

Table 19 Fludioxonil residue level in eggs (sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobeno[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil)

Days after dosing	Equivalent Fludioxonil Residue Level (mg/kg)					
	1.54 ppm		4.64 ppm		15.4 ppm	
	Average	Max	Average	Max	Average	Max
0	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
1	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
3	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
5	< 0.01	< 0.01	0.010	0.013	0.024	0.036
7	< 0.01	< 0.01	< 0.01	< 0.01	0.026	0.032
10	< 0.01	< 0.01	< 0.01	0.011	0.032	0.040
14	< 0.01	< 0.01	0.010	0.012	0.035	0.041
16	< 0.01	< 0.01	< 0.01	< 0.01	0.026	0.028
21	< 0.01	< 0.01	< 0.01	0.010	0.029	0.032
24	< 0.01	< 0.01	< 0.01	< 0.01	0.036	0.040
28	< 0.01	< 0.01	0.011	0.013	0.040	0.052

Residue levels in tissues as a function of feeding level from the three dosed groups are summarised in Table 20. Muscle samples from animals treated at 15.4 ppm per day exhibited residues <LOQ and so further analysis of samples from the lower dose groups was not considered necessary.

Table 20 Fludioxonil residue level in tissues (sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobeno[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil)

		Equivalent Fludioxonil Residue Level (mg/kg)			
Dose Rate	Sub group	Muscle	Skin and Fat	Abdominal Fat	Liver
1.54 ppm	A	na	na	na	0.076
	B	na	na	na	0.036
	C	na	na	na	0.026
	Average	na	na	na	0.046
4.64 ppm	A	na	0.012	< 0.01	0.085
	B	na	< 0.01	< 0.01	0.064
	C	na	0.014	< 0.01	0.209
	Average	na	0.012	< 0.01	0.119
15.4 ppm	A	< 0.01	0.035	0.024	0.284
	B	< 0.01	0.039	0.012	0.282
	C	< 0.01	0.030	0.023	0.283
	Average	< 0.01	0.035	0.020	0.283

na = not analysed

One of the highest dosed group of animals remained on the study after the cessation of dosing to monitor the elimination of fludioxonil from eggs and tissues after dosing had been withdrawn – depuration phase. Commensurate with the dosing phase, egg samples were collected twice daily until twelve days after dosing ceased. From this final group, the three sub groups were sacrificed at three, seven, and eleven days after cessation of dosing and edible tissue samples were retained as for the dosing period. The results are shown in Table 21.

Table 21 Summary of equivalent fludioxonil residue levels in egg samples across sub groups during depuration phase.

Number Days after end of dosing	Equivalent Fludioxonil Residue Level (mg/kg)		
	Sub Group A	Sub Group B	Sub Group C
0	0.024	0.035	0.032
1	0.029	0.032	0.028
3	0.024	0.023	0.022
4	Na	< 0.01	< 0.01
6	Na	< 0.01	< 0.01
8	Na	< 0.01	< 0.01
10	Na	na	< 0.01
11	Na	na	< 0.01

na = not available for analysis – animals sacrificed

Fludioxonil was not detected in any of the muscle, fat and liver samples from the depuration study (< LOQ), suggesting rapid elimination of fludioxonil following completion of dosing.

APPRAISAL

Fludioxonil was reviewed by the JMPR in 2004, 2006, 2010 and most recently in 2012. The ADI for fludioxonil is 0–0.4 mg/kg bw and an ARfD was considered unnecessary. Residue studies were submitted by the manufacturer for various crops, in addition to a hen feeding study and analytical method for poultry tissues and eggs.

The residue definition for fludioxonil for plant commodities for compliance with the MRL and estimation of dietary intakes is fludioxonil. For animal commodities the residue is the sum of fludioxonil and it benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil. The residue is considered fat-soluble.

Methods of analysis

Method GRM025.03A, not previously evaluated by the JMPR, determines fludioxonil and its metabolites oxidisable to 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid (CGA192155) in poultry tissues and eggs. Samples of muscle, liver and kidney are homogenized, extracted by refluxing with ammonium hydroxide:acetonitrile and the aqueous phase is acidified and partitioned with toluene. Fludioxonil and its metabolites are converted to CGA192155 by heating in the presence of potassium permanganate and sodium hydroxide; the oxidation is quenched with sodium metabisulfite, the extracts are filtered, acidified, and partitioned into dichloromethane:ethyl acetate (80:20 v/v). Residues are determined as total fludioxonil by LC-MS/MS. A molecular weight correction factor of 1.23 is applied when calculating procedural recovery values and quantifying residues of CGA192155. The LOQ for fludioxonil and metabolites as CGA192155 in animal tissues was 0.01 mg/kg for fludioxonil (=0.0081 mg/kg for CGA192155). Residues of CGA192155 were shown to be stable at 0–9 °C for at least 7–9 days of storage.

Data evaluated by the 2004 JMPR showed that fludioxonil and CGA192155 are stable for at least 12 months in frozen muscle and for at least 18 months in frozen liver, milk and eggs.

Results from supervised residue trials on crops

Lemon

Five foliar supervised residue trials were conducted in the USA in lemons in 2004–2005 matching US GAP (1 × 0.245 kg ai/ha; 0 day PHI). Residues were 0.12 (3) and 0.16 (2) mg/kg.

Residues on lemons from foliar application are covered by the previous recommendation of maximum residue level of 10 mg/kg (Po) for fludioxonil on citrus

Avocado

Six supervised residue trials were conducted in USA in avocado in 2003 complying with US GAP (4 × 0.245 kg ai/ha; 0 day PHI). Residues were 0.02 (2), 0.04, 0.06, 0.11 and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.05 mg/kg for fludioxonil in avocado.

Pineapple

Fludioxonil is registered in the USA for use in pineapple as a post-harvest high volume drench and/or directed peduncle spray at 1 × 0.06 kg ai/hL. Eight supervised residue trials were conducted in the USA (Hawaii) in 2009 using a dip plus wax or drench application at 0.06 kg ai/hL followed by a spray directed to the peduncle at 0.87 kg ai/hL. Residues ranged from 4.8 to 6.6 mg/kg (n=8).

As no trials were conducted according to GAP, the Meeting could not estimate a maximum residue level for fludioxonil in pineapple.

Fruiting vegetables, Cucurbits

Eighteen supervised residue trials were conducted in the USA in 2004 complying with the US GAP for cucurbits (4 × 0.245 kg ai/ha; 1 day PHI).

Residues in cantaloupe were (n=6) 0.02, 0.07, 0.09, 0.13, 0.20 and 0.36 mg/kg.

Residues in cucumber were: (n=7) 0.03, 0.04 (2), 0.05, 0.06, 0.09 and 0.13 mg/kg.

Residues in summer squash were: (n=5) 0.01, 0.04 (2) and 0.08 (2) mg/kg

The median residues found in the three individual commodities were within a 5 times range, allowing a recommendation to be made for the cucurbits crop group.

As the residue populations are not statistically different, the Meeting agreed they could be combined as (n=18) 0.01, 0.02, 0.03, 0.04 (4), 0.05, 0.06, 0.07, 0.08 (2), 0.09 (2), 0.13 (2), 0.20 and 0.36 mg/kg.

The Meeting recommended a maximum residue level of 0.5 mg/kg and a STMR of 0.065 mg/kg for fludioxonil in fruiting vegetables, cucurbits.

The Meeting withdrew its previous recommendation of 0.03 mg/kg for Melons, except watermelon, and of 0.3 mg/kg for summer squash.

Tomato

Fludioxonil is registered in the USA for use on tomatoes as a post-harvest in line dip/drench at 1 × 0.06 kg ai/hL or high volume spray at 0.0044kg ai/1000 kg tomatoes (combined with propiconazole in a tank mix).

Residues in tomatoes from six trials at GAP using the dip or drench application were: 0.28, 0.43, 0.48, 0.73, 0.77 and 1.1 mg/kg (if drench and drip was used in one trial, only the highest residue was selected). Three trials conducted at GAP using spray application gave residues of 0.18, 0.66 and 1.8 mg/kg.

Residue data from the two application types were similar and could be combined for residues of 0.18, 0.28, 0.43, 0.48, 0.66, 0.73, 0.77, 1.1 and 1.8 mg/kg (n=9).

The Meeting estimated a maximum residue level of 3 mg/kg and a STMR of 0.66 mg/kg for fludioxonil in tomato (Po).

The Meeting withdrew its previous maximum residue level recommendation for fludioxonil in tomato of 0.5 mg/kg.

Peppers (Bell & Non-Bell)

Currently, there is a MRL of 1 mg/kg for fludioxonil in Peppers, sweet, based European trials matching the GAPs of Italy and Austria.

The GAP of the USA consists of 4 × 0.245 kg ai/ha; 0 day PHI. The current Meeting received 14 supervised field residue trials on bell (sweet pepper) and non-bell peppers (including chili pepper) from the USA and Canada and five greenhouse trials matching US GAP.

Residues in the field trials for sweet peppers were < 0.02 (2), 0.08, 0.09, 0.12, 0.13 (2), 0.16 (2) and 0.28 (2) mg/kg. Residues for non-bell peppers were 0.06, 0.07, 0.12 and 0.14 mg.

Residues found in the greenhouse trials were 0.10, 0.20, 0.21 and 0.22 mg/kg for sweet pepper and 0.20 mg/kg for non-bell peppers.

These data indicate that the current MRL of 1 mg/kg would accommodate the expected fludioxonil residues resulting in non-bell peppers when applied according to US GAP. The Meeting agreed to extend the previous recommendation of 1 mg/kg to peppers.

Based on the data on non-bell peppers (0.06, 0.07, 0.12, 0.14 and 0.20 mg) and a factor of 10, the Meeting estimates a maximum residue level of 4 mg/kg and a STMR of 1.2 mg/kg for dried chili peppers.

Leafy vegetables

Currently, there is a MRL of 10 mg/kg in Head lettuce, based on indoor trials matching the Italian GAP, and a MRL of 10 mg/kg in Mustard greens based on trials matching the GAP of the USA.

In the USA, GAP in leafy greens is 4 × 0.245 kg ai/ha; 0 day PHI. Twenty five trials were conducted in USA in 2001 in lettuce and spinach according to GAP were submitted to this Meeting. Additionally, trials evaluated by the 2004 JMPR according to GAP were also considered. Six trials conducted in USA in 2004 in radish tops were not at GAP.

Residue in head lettuce (with wrapper leaves) were (n=8) 0.42, 1.2, 1.4, 2.0 (2), 2.2, 2.8 and 4.6, mg/kg.

Indoor trials conducted in Europe in head lettuce at Italian GAP evaluated by the 2004 JMPR gave residues (n=11) ranging from 0.72 to 6 mg/kg, median of 2.7 mg/kg.

Residues in leafy lettuce were (n= 6) 4.8, 6.5, 6.7, 10, 16 and 22 mg/kg.

Residues in spinach were (n= 11) 1.9, 3.4, 4.6, 4.9 (2), 5.8, 7.5, 8.3, 9.8,12 and 16 mg/kg.

Residues in watercress from trials evaluated in 2004 (USA GAP) were 4.2 and 4.5 mg/kg.

Residues in mustard greens from trials evaluated in 2004 (USA GAP) ranged from 0.06 to 7.1 mg/kg, median of 1.2 mg/kg (n=9).

The median residues found in the individual commodities from trials conducted matching USA GAP were outside the 5 times range, not allowing a recommendation for leafy vegetable group.

The Meeting therefore, estimated a maximum residue level of 40 mg/kg and a STMR of 8.3 mg/kg for fludioxonil in leafy lettuce

The Meeting estimated a maximum residue level of 30 mg/kg and a STMR of 5.8 mg/kg for fludioxonil in spinach.

The Meeting agreed that there were insufficient trials to estimate a maximum residue level for watercress.

The Meeting confirmed its previous recommendation of 10 mg/kg for fludioxonil in head lettuce and mustard greens.

Potato

Currently, there is a MRL of 0.02 mg/kg for potato, based on the Australian GAP as a seed treatment.

Fludioxonil is registered in the USA for use in potatoes as a post-harvest in line spray at 0.0045 kg ai/1000 kg tubers. Five trials were conducted in the USA and Canada in 2009/2010 matching the US GAP, giving residues of 0.66, 1.1, 1.5, 1.7 and 2.9 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and a STMR of 1.5 mg/kg for fludioxonil in potato (Po).

The Meeting withdrew its previous recommendation for fludioxonil in potatoes of 0.02 mg/kg.

Radish

Six supervised residue trials were conducted in the USA in 2004 matching US GAP (2 × 0.245 kg ai/ha; 7 days PHI). Residues in the radish tops were: < 0.02 (2), 0.04, 0.08, and 0.10 (2) mg/kg.

The Meeting estimated a maximum residue level of .3 mg/kg and a STMR of 0.06 mg/kg for fludioxonil in radish.

Legume vegetables

Currently, there is a MRL of 0.3 mg/kg for beans, except broad beans and soya beans and for peas (pods and succulent=immature seeds), based on the GAP of France.

The GAP in USA for beans (dried and succulent, except cow beans) is 4 × 0.245 kg ai/ha; 7 days PHI). In eight trials conducted in snap beans (common beans) from the USA, matching US GAP, residues in snap beans pods were: < 0.02, 0.03 (2), 0.04 (2), 0.05 (2) and 0.38 mg/kg.

Based on the US data on snap beans, the Meeting estimated a maximum residue level of 0.6 mg/kg and a STMR of 0.04 mg/kg for fludioxonil in Beans, except broad bean and soya bean. The Meeting withdrew its previous recommendation of 0.3 mg/kg for beans, except broad bean and soya bean.

In seven trials conducted in lima beans in the USA according to US GAP, residues in succulent shelled beans were: < 0.02 (4), 0.03, 0.04 and 0.21 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.02 mg/kg for fludioxonil in Beans, Shelled. The Meeting agreed to withdraw its previous recommendation of 0.03 mg/kg for Beans, Shelled.

Fludioxonil is registered in USA to be used in peas as a seed treatment at 0.005 kg ai/100 kg seed. Five trials conducted at US GAP gave residues in mature fresh peas with pods of < 0.01 (5) mg/kg. Fifteen trials conducted at higher or lower GAP rate gave the same results.

The Meeting confirms its previous recommendation of 0.3 mg/kg for peas (pods and succulent=immature seeds).

Beans (dry)

Currently, there is a Codex MRL of 0.07 mg/kg for beans (dry) based on Spanish GAP.

Seven trials were conducted in USA in 2001 according to US GAP (4 × 0.245 kg ai/ha; 7 days PHI) gave residues in dry beans of 0.02 (2), 0.04 (2), 0.06, 0.12 and 0.23 mg/kg. In two trials harvested earlier or with 6 applications gave residues in the same range.

The Meeting estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.04 mg/kg for fludioxonil in beans (dry) The Meeting withdrew its previous recommendation of 0.07 mg/kg for Beans (dry).

Herbs

Currently, there is a Codex MRL of 10 mg/kg for fludioxonil in fresh basil and chives and of 50 mg/kg for dried basil and chives.

The Meeting received four supervised residue trials in parsley from the USA matching US GAP in herbs (4 × 0.245 kg ai/ha; 7 days PHI). Residues in fresh parsley were 1.6, 2.3, 3.2 and 3.9 mg/kg and in dry parsley 8.9, 15, 18 and 23 mg/kg.

Data submitted to the 2004 JMPR matching US GAP showed residue of 1.8 and 3.9 mg/kg on fresh chives and 1.9 and 3.0 mg/kg on fresh basil, 14 and 31 mg/kg on dry chives and 15 and 24 mg/kg on dry basil.

The residues found in the individual fresh or dried commodities from trials conducted according to USA GAP are in the same range, and they are combined for allowing recommendations for herbs, fresh and dried.

The residues of fludioxonil in fresh parsley, basil and chives were considered similar and could be combined giving residues of 1.6, 1.8, 1.9, 2.3, 3.0, 3.2 and 3.9 (2) mg/kg.

The Meeting recommended a maximum residue level of 9 mg/kg and a STMR of 2.65 mg/kg for fludioxonil in herbs.

The residue data sets of fludioxonil from dried parsley, basil and chives were also considered similar and could be combined giving residues of 8.9, 14, 15 (2), 18, 22, 24 and 31 mg/kg.

The Meeting recommended a maximum residue level of 60 mg/kg and a STMR of 16.5 mg/kg for fludioxonil in dried herbs, except dried hops.

The Meeting agreed to withdraw its previous recommendations for chives and basil of 10 mg/kg and for dried chives and basil of 50 mg/kg.

Ginseng

Four supervised residue trials were conducted in the USA and Canada from 2005 to 2006 according to GAP (4 × 0.245 kg ai/ha; 14 days PHI). Residues were 0.16, 0.18, 0.40 and 1.7 mg/kg.

The Meeting recommends a maximum residue level of 4 mg/kg and a STMR of 0.29 mg/kg for fludioxonil in ginseng.

Residues in processed commodities

Pineapple fruit (5.62 mg/kg fludioxonil) processed to juice contained a residue of 5.40 mg/kg, with a processing factor (PF) of 0.96. However, as no maximum residue level recommendation on the raw commodity was made, the Meeting could not make an assessment of residues for pineapple juice.

Tomatoes containing 0.14 mg/kg of fludioxonil were processed to paste (0.15 mg/kg), giving a PF of 1.1. Processing factors estimated by the 2004 JMPR were 1.1, 1.4, 1.5 and 1.6. The best estimated processing factor for tomato paste is 1.4. Based on a STMR of 0.66 mg/kg for tomato, the Meeting estimated a of STMR-P of 0.924 mg/kg for tomato paste

Tomatoes was also processed to puree (0.05 mg/kg) giving a PF of 0.36. The Meeting estimated a STMR-P of 0.236 mg/kg for tomato puree.

The best estimate PF for tomato juice (2004 JMPR) was 0.22. The Meeting estimated a STMR-P of 0.145 mg/kg for fludioxonil.

Potato tubers containing 0.472 mg/kg fludioxonil were processed into chips. Residues were 0.797 mg/kg in wet peel (PF=1.69), 0.01 mg/kg in flakes (PF < 0.02) and 0.018 mg/kg in chips (PF of 0.04).

The Meeting estimated a STMR-P of 0.06 mg/kg for fludioxonil in potato chips (STMR in potato is 1.5 mg/kg).

Residues in animal commodities

Farm animal dietary burden

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Appendix IX of the FAO manual. The calculations were made according to the animal diets from US-Canada, EU, Australia and Japan in the Table (Appendix IX of the FAO manual). The STMR, STMR-Ps were estimated at the present Meeting. Dietary burden calculations are provided in Annex 5 of the 2013 JMPR Report.

Livestock dietary burden for fludioxonil, ppm of dry mater diet

	US-Canada		EU		Australia		Japan	
Commodity	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.029	0.018	0.56 [a]	0.27 [c]	0.24	0.13	0.017	0.017
Dairy cattle	0.39	0.18	0.57 [a b]	0.27 [d]	0.24	0.11	0.02	0.018
Poultry–broiler	0.017	0.017	0.38 [e]	0.19 [f]	0.035	0.035	0.002	0.002
Poultry–layer	0.017	0.017	0.38	0.19	0.035	0.035	0.002	0.002

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimated for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimated for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimated for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimated for milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimated for poultry tissues

[f] Highest mean poultry dietary burden suitable for maximum residue level estimated for poultry tissues

Animal feeding study

A feeding study on poultry submitted to the current Meeting was conducted with fludioxonil at 1.54, 4.64 and 15.4 mg/kg feed on a 28-day daily dose regime via gelatine capsules.

Residues in eggs from the 15.4 ppm dose level hens were < 0.01 mg/kg 3 days after the initiation of dosing, increased to 0.024 mg/kg fludioxonil eq. (max. of 0.036 mg/kg), and reached 0.04 mg/kg at day 28. The Mean level during the study was 0.025 mg/kg and a maximum of 0.052 mg/kg fludioxonil eq. Eggs from the 4.64 ppm group had a mean and a maximum residue of 0.01 and 0.013 mg/kg fludioxonil eq., respectively. No residues were found in eggs from the 1.54 ppm dose group.

Only liver samples from the 1.54 ppm group were analysed, giving a mean of 0.05 mg/kg eq. (0.03 to 0.08 mg/kg).

In the 4.64 ppm group, residues in skin/fat (including abdominal fat) ranged from < 0.01 to 0.01 mg/kg eq. and residues in liver ranged from 0.06 to 0.21 mg/kg eq. (mean of 0.12 mg/kg).

In the 15.4 mg/kg ppm group, residues in muscle were < 0.01, from 0.01 to 0.04 mg/kg eq. in skin and fat (mean of 0.03 mg/kg) and 0.28 mg/kg eq. in liver.

A depuration study conducted at 15.4 ppm dosing level demonstrated that residues in the eggs ranged from 0.02 to 0.04 mg/kg eq. up to 3 days after termination of the study and were not detected further. Fludioxonil was not detected in any of the muscle, fat or liver samples, suggesting rapid elimination of fludioxonil following completion of dosing.

Animal commodity maximum residue levels

A feeding study in cattle evaluated by the 2004 JMPR showed that residues of fludioxonil and its metabolites found in the highest feeding level dose group (5.5 ppm) were 0.014–0.017 mg/kg in liver, 0.022–0.025 mg/kg in kidney (LOQ of 0.05 mg/kg) and none was detected in fat (< 0.05 mg/kg) or muscle (< 0.01 mg/kg). The highest and median residues in milk were 0.019 and 0.01 mg/kg, respectively (LOQ of 0.01 mg/kg). The feeding level in this study is about 10 times higher than the highest dietary burden estimated for cattle at this Meeting (0.57 ppm).

The Meeting confirmed its maximum residue level recommendation of 0.05* mg/kg for edible offal (mammalian), and 0.01* mg/kg for meat (from mammals other than marine mammals) and milks.

Based on an estimated dietary burden for poultry of 0.07 ppm and a metabolism study, the 2004 JMPR had estimated that residues of fludioxonil and metabolites were unlikely to be found in poultry commodities and recommended maximum residue levels of 0.05* mg/kg for eggs, 0.01* mg/kg for poultry meat and 0.05* mg/kg for poultry edible offal and STMRs of 0 mg/kg for eggs, poultry meat and poultry edible offal.

The highest calculated poultry dietary burden calculated by the current Meeting was 0.38 ppm. As the feeding study showed that no residues are expected at a dietary burden of 1.54 ppm (lowest dose tested), the Meeting confirmed that no residues are expected in poultry commodities.

The Meeting recommended a maximum residue level of 0.01* mg/kg and a STMR of 0 for fludioxonil in poultry edible offal and eggs.

The Meeting confirmed its previous recommendation of 0.01* mg/kg for poultry meat.

RECOMMENDATION

The residue definition: for plant commodities for compliance with the MRL and estimation of dietary intakes: *fludioxonil*.

For animal commodities the residue is the sum of fludioxonil and it benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil.

The residue is fat-soluble.

CCN	Commodity name	Recommended maximum residue level (mg/kg)		STMR (P) mg/kg
		New	Previous	
FI 0326	Avocado	0.4		0.05
HH 0772	Basil	W	10	
DH 0772	Basil, dry	W	50	

CCN	Commodity name	Recommended maximum residue level (mg/kg)		STMR (P) mg/kg
		New	Previous	
VP 0061	Beans, except broad bean and soya bean	0.6	0.3	0.04
VP 0062	Beans (shelled)	0.4		0.02
VD 0071	Beans (dry)	0.5	0.07	0.04
VC 4199	Melons	W	0.03	
HH 0727	Chives	W	10	
DH 0727	Chives, dry	W	50	
	Chili pepper, dry	2		1.2
DH 0092	Dried herbs, except dried hops	60		16.5
PE 0112	Eggs	0.01*	0.05*	0
VC 0045	Fruiting vegetables, Cucurbits	0.5		0.065
VR 0604	Ginseng	4		0.29
HH 0092	Herbs	9		2.65
VL 0483	Lettuce, leafy	40		8.3
VP 0063	Peas (pods and succulent=immature seeds)	0.6	0.3	0.04
VO 0051	Peppers	1		0.18
VO 0445	Peppers, sweet (including pimento or pimiento)	W	1	
VR 0589	Potato	5 (Po)	0.02	1.5
	Potato chips			0.06
PO 0111	Poultry, edible offal of	0.01*	0.05*	0
VR 0494	Radish	20		3.8
VP 4453	Snap beans	0.6		0.04
VL 0502	Spinach	30		5.8
VO 0448	Tomato	3	0.5	0.66
	Tomato purée			0.236
	Tomato juice			0.145
	Tomato paste			0.924

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of fludioxonil based on the STMRs estimated by this and previous Meetings for the 13 GEMS/Food regional diets were 2–6% of the maximum ADI of 0–0.4 mg/kg bw (see Annex 3 of the 2013 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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