Fludioxonil (211)

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EXPLANATION

Fludioxonil was evaluated for the first time by the JMPR in 2004 when an acceptable daily intake (ADI) of 0–0.4 mg/kg bw was established. An acute reference dose (ARfD) was considered not necessary. In 2006, 2010, 2012 and 2013 the JMPR evaluated the compound for residues and recommended a number of maximum residue levels.

The current Meeting received additional analytical methods, processing data for carrots, a ruminant feeding study, GAP information and residue trial data from uses on blueberry, currant, guava, avocado, pomegranate, pineapple, bulb onion, green onion, mustard greens, pea, soya bean, carrot and celery.

RESIDUE ANALYSIS

Methods of residue analysis

The Meeting received one new analytical method for the determination of parent fludioxonil in soya bean.

Method POPIT MET.073.Rev11 and POPIT MET.073.Rev16. (Casallanova, 2009, FLUDIOX_001; Casallanova, 2010, FLUDIOX_002)

Residues of fludioxonil were extracted from soya bean by shaking with methanol. The resulting extract was further diluted with methanol and filtered prior to analysis. Fludioxonil residues were determined by LC-MS/MS, monitoring the transition m/z 247→180.

Table 1 Recovery data for method POPIT MET.073 measuring fludioxonil in soya bean using LC-MS/MS

Commodity	Fortification level (mg/kg)	No. of analyses (n)	Mean recovery (%)	RSD (%)
Soya bean (Casallanova, 2009, Fludioxnil_001)	0.01	7	95	7
	0.1	5	85	4
Soya bean (Casallanova, 2010, Fludioxnil_002)	0.01	7	82	4
	0.05	5	95	4
	0.1	5	90	1

USE PATTERN

In the following table GAP information on all crops supported with residue data are summarized.

Table 2 List of uses of fludioxonil

Crop/ Commodity	Country	Formulation		Application				PHI (days)
		Active substance content	Type	Method	Rate	Water volume	No or Seasonal max. (interval)	
Bushberry [b]	Canada	250 g ai/kg	WG	Foliar spray	194–244 g ai/ha	200–900 L/ha	1–3 (7–10 days)	1
Black currants, Red currants White currants	Ireland	250 g ai/kg	WG	Foliar spray	250 g ai/ha	100 L/ha	3 (1st and 2nd: 10 days; 2nd and 3rd: 28 days)	7
Guava	USA	250 g ai/kg	WG	Foliar spray	193–245 g ai/ha	200 L/ha	4 (7–10 days)	0
Avocado	Australia	239 g/L	SC	Post-harvest dip/drench/ flood spray for 30–60 seconds	60 g ai/hL	n/a	1	n/a

Crop/ Commodity	Country	Formulation		Application				PHI (days)
		Active substance content	Type	Method	Rate	Water volume	No or Seasonal max. (interval)	
Pomegranate	USA	250 g ai/kg	WG	Post-harvest dip/drench for 30 seconds	36 g ai/hL	n/a	2	n/a
Pineapple	USA	240 g ai/L	SE	Post-harvest, drench and spray	60 g ai/hL	n/a	1 of each [a]	n/a
Onions and garlic bulb vegetables (bulb onion, garlic, green onion)[c]	USA	250 g ai/kg	WG	Foliar spray	245 g ai/ha	47 L/ha	4 (7–10 days)	7
Onions, garlic, shallots, green onions	Italy	250 g ai/kg	WG	Foliar spray	250 g ai/ha	1000 L/ha	3 (10 day)	7
Brassica leafy vegetables [d]	USA	250 g ai/kg	WG	Foliar spray	193–245 g ai/ha	94 L/ha	4 (7–10 days)	7
Lentils and Beans (dried and succulent, except cowpea)[e]	Canada	250 g ai/kg	WG	Foliar spray	194–244 g ai/ha	175–225 L/ha	3 (7 day)	7
Soya beans	Brazil	250 g ai/kg	WG	Foliar spray	125–250 g ai/ha	150–200 L/ha	2 (7–14 days)	30
Carrot	USA	230 g ai/L	SC	Post-harvest dip/drench for 30 seconds	29 g ai/hL	n/a	1	n/a
Carrot	Germany	250 g ai/kg	WG	Foliar spray	250 g ai/ha	400–600 L/ha	3 (7–14 days)	7
Celery	USA	250 g ai/kg	WG	Foliar spray	193–245 g ai/ha	94 L/ha	4 (7–10 days)	0

[a] One application is defined as a drench and a directed peduncle spray

[b] Blueberry (highbush and lowbush), Saskatoon berry, Currant (black and red), Elderberry, Gooseberry, Huckleberry, Aronia berry, Buffalo currant, Chilean guava, Europeam barberry, Highbush cranberry, Honeysuckle (edible), Jostaberry, Lingonberry, Native currant, Salal, Sea buckthorn

[c] Bulb Onion: Chinese onion; Dry Bulb onion; Daylilly bulb; Fritillaria bulb; Garlic; Great-headed garlic; Lily bulb; Pearl onion; Potato onion; Serpent garlic; Shallot; Green Onion: Beltsville bunching onion; Chinese chive fresh leaves; Fresh chive leaves; Fritillaria leaves; Fresh onion; Green onion; Hosta elegans; Kurrat; Lady's leek; Leek; Macrostem onion; Shallot fresh leaves; Tree tops onion; Welsh onion tops; Wild leek

[d] Broccoli; Broccoli, Chinese; Broccoli raab; Brussels, sprouts; Cabbage; Cabbage, Chinese; Cauliflower; Cavalo broccoli; Collards; Kale; Kohlrabi; Mizuna;Mustard greens; Mustard spinach; Rape greens; Turnip greens

[e] Including: chickpea (garbanzo bean), beans (Lupinus spp. including grain lupin, sweet lupin, white lupin, white sweet lupin), beans (Phaseolus spp. including kidney bean, lima bean, mung bean, navy bean, pinto bean, snap bean, wax bean), broad bean (fava bean), beans (Vigna spp. asparagus bean, black-eyed pea)

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Residue levels were reported as measured. Application rates were always reported as fludioxonil equivalents. When residues were not detected they are shown as below the LOQ, e.g., < 0.01 mg/kg. Application rates, spray concentrations and mean residue results have generally been rounded to the even with two significant figures. HR and STMR values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. These results are underlined.

Laboratory reports included method validation including batch recoveries with spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analyses or duration of residue sample storage were also provided. Field

reports provided data on the sprayers used and their calibration, plot size, residue sample size and sampling date. Although trials included control plots, no control data are recorded in the tables except where residues in control samples exceeded the LOQ. Residue data are recorded unadjusted for % recovery.

Fludioxonil – supervised residue trials

Commodity	Indoor/Outdoor	Treatment	Countries	Table
Blueberry	Outdoor	Foliar spray	Canada	Table 3
Black currants, Red currants and White currants	Outdoor	Foliar spray	Germany	Table 4
Guava	Outdoor	Foliar spray	United States	Table 5
Avocado	Outdoor	Post-harvest: dip or spray	Australia	Table 6
Pomegranate	Outdoor	Post-harvest: dip or dip/drench	United States	Table 7
Pineapple	Outdoor	Post-harvest: dip/drench and spray treatment	United States	Table 8
Bulb onion	Outdoor	Foliar spray	United States	Table 9
Green onion	Outdoor	Foliar spray	Italy, Switzerland, The Netherlands, The UK and Spain	Table 10
Mustard greens	Outdoor	Foliar spray	United States	Table 12
Dry pea	Outdoor	Foliar spray	Canada	Table 13
Soya beans	Outdoor	Foliar spray	Brazil	Table 14
Carrot	Outdoor	Post-harvest: dip or drench	Canada	Table 15
Carrot	Outdoor	Foliar spray	France, Italy, Spain and Switzerland	Table 16
Celery	Outdoor	Foliar spray	United States	Table 17

Berries & other small fruits

Blueberries

Two supervised residue trials were conducted on blueberries in Canada in the 2006 growing season (Tout, 2007, FLUDIOX_003). Blueberries received three foliar applications of fludioxonil at a nominal rate of 244 g ai/ha with a 7–8 day interval between applications and a 1-day PHI. Samples of blueberries were collected at 1 DALT.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.01 mg/kg. However, the method was modified to enable LC-MS/MS analysis. Overall mean method verification and procedural recoveries in blueberries spiked with fludioxonil at 0.01, 0.05, 0.1 and 2 mg/kg were 84±3.6% (n=7) and 90±15% (n=4), respectively.

Table 3 Residues of fludioxonil in blueberries following foliar treatment (cGAP: 3 × 244 g ai/ha; 1 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue found (mg/kg)	Report/Trial No., Reference Storage period
Canada St. Andrews, PEI 2006	Foliar spray	248 247 257	Not reported	1	Fruit	0.88	Study: CER04160/06 Trial: T163, Plot 2 & 3 Tout, 2007,

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue found (mg/kg)	Report/Trial No., Reference Storage period
(Wild lowbush)		243 254 236	Not reported	1	Fruit	0.86	FLUDIOX_003 Max. frozen storage: 6 month
Canada Riverton, PEI 2006 (Wild lowbush)	Foliar spray	245 248 251	Not reported	1	Fruit	1.7	Study: CER04160/06 Trial: T164, Plot 2 & 3 Tout, 2007, FLUDIOX_003 Max. frozen storage: 9 month
		247 260 244	Not reported	1	Fruit	1.4	

Currants

Five trials on currants (blackcurrant: four trials; redcurrant: one trial) performed in Germany during the 1999 and 2000 growing seasons were submitted to the 2004 JMPR, but no European label was provided. However, the Meeting received a GAP from Ireland. Hence the trials were re-evaluated (Simon, 2001, FLUDIOX_004; Smith, 2000, FLUDIOX_005, Simon, 2001, FLUDIOX_006; Simon, 2001, FLUDIOX_007; Smith, 2001, FLUDIOX_008).

Currants received three foliar applications of fludioxonil at a nominal rate of 250 g ai/ha with a 7–12 day interval between the 1st and 2nd application and a 27–50 day interval between the 2nd and 3rd application. Samples of blueberries were collected at 0, 7, 10, 14 and 21 DALT.

Residues of fludioxonil were determined using method REM 133.04, already evaluated by the 2004, 2006, 2010 and 2012 JMPR, with a limit of quantification at 0.02 mg/kg. Overall procedural recoveries in currants spiked with fludioxonil at 0.02 and 0.2 mg/kg were 82±22% (n=8).

Table 4 Residues of fludioxonil in black- and red currant following foliar treatment (cGAP: 3 × 250 g ai/ha; 7 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)	Report/Trial No., Reference Storage period
Germany Mecklenburg-Vorpommern Dodow 2000 (Ben Alder)	Foliar spray	3×250	BBCH 85	0 7 10 14 21	Fruit	0.57 0.60 0.46 0.55[a] 0.56	Study: gr 30800 Simon, 2001, FLUDIOX_004 Max. frozen storage: 7 month
Germany Lauffen 1999 (Titania)	Foliar spray	3×250	BBCH 85	0 7 10 14	Fruit	0.63 0.24 0.26 0.16	Study: gr 92999 Smith, 2000, FLUDIOX_005 Max. frozen storage: 7 month
Germany Sachsen Ablass 2001 (Ojebin)	Foliar spray	3×250	BBCH 81	0 7 10 14 21	Fruit	0.83 0.62 0.59 0.43[a] 0.30	Study: gr 37800 Simon, 2001, FLUDIOX_006 Max. frozen storage: 8 month
Germany Lauffen 2000 (Titania)	Foliar spray	3×250	BBCH 81–85	0 7 10 14 21	Fruit	0.79 0.55 0.63 0.53[a] Control: 0.02 0.33	Study: gr 38900 Simon, 2001, FLUDIOX_007 Max. frozen storage: 9 month
Germany Sachsen Ablass 1999 (Rondom)	Foliar spray	3×250	BBCH 81	0 7 10 14	Fruit	2.7 1.4 0.97 0.45	Study: gr 91899 Smith, 2001, FLUDIOX_008 Max. frozen storage: 8 month

[a] Mean of duplicate analysis.

Assorted tropical and sub-tropical fruits – edible peel

Guava

A total of five supervised residue trials were conducted on guava in the USA during the 2010 and 2011 growing seasons (Leonard, 2013, FLUDIOX_009). Guava received four foliar applications of fludioxonil at a nominal rate of 245 g ai/ha with application intervals of 7–8, 20–21 and 7–8 days between the first and second, second and third and third and fourth applications, respectively, and a 0-day PHI. Samples of guava were collected at 0 DALT.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.01 mg/kg. However, the method was modified to enable LC-MS/MS analysis. Overall mean recoveries in guava spiked with fludioxonil at 0.02, 0.2 and 2 mg/kg were 87%, RSD = 6% (n=6), 93%, RSD = 10% (n=6), 94%, RSD = 2% (n=3), respectively.

Table 5 Residues of fludioxonil in guava fruit following foliar treatment (cGAP 4 × 245 g ai/ha; 0 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
USA Florida Homestead 2010[c] (Homestead)	Foliar spray	291 246 265 262	Fruiting	0	Fruit	0.11 [0.13; 0.095]	Study: IR-4 PR No.: 07127 Trial: 10-FL11 Leonard, 2013, FLUDIOX_009 Max. frozen storage: 11 month
USA Florida Homestead 2010[c] (Homestead)	Foliar spray	246 265 282 275	Fruiting	0	Fruit	0.13 [0.11; 0.14]	Study: IR-4 PR No.: 07127 Trial: 10-FL12 Leonard, 2013, FLUDIOX_009 Max. frozen storage: 11 month
USA Florida Homestead 2011 (Homestead)	Foliar spray	244 245 244 244	Fruiting	0	Fruit	0.19 [0.19; 0.18]	Study: IR-4 PR No.: 07127 Trial: 10-FL13 Leonard, 2013, FLUDIOX_009 Max. frozen storage: 11 month
USA Hawaii Hilo 2011[b] (Beaumont)	Foliar spray	247 246 294 248	Bearing	0	Fruit	0.12 [0.13; 0.10]	Study: IR-4 PR No.: 07127 Trial: 10-HI01 Leonard, 2013, FLUDIOX_009 Max. frozen storage: 11 month
USA Hawaii Hilo 2011[b] (Beaumont)	Foliar spray	246 247 249 241	Bearing	0	Fruit	0.11 [0.11; 0.11]	Study: IR-4 PR No.: 07127 Trial: 11-HI09 Leonard, 2013, FLUDIOX_009 Max. frozen storage: 11 month

[a] Mean of replicate field samples [individual values]

[b] Trials can be considered independent since actual treatment days differed by 52 days

[c] Trials were not considered independent as they were conducted at the same location and time

Assorted tropical and sub-tropical fruits – inedible peel

Avocado

A total of eight supervised residue trials were conducted on avocado in Australia in the 2015 growing season (Frost, 2016, FLUDIOX_010). Avocado fruit received one post-harvest dip or spray treatment within 6 hours of harvest with fludioxonil at a concentration of 30 g ai/hL, 60 g ai/hL or 120 g ai/hL.

Residues of fludioxonil were determined using method REM 133.06, already evaluated by the 2012 JMPR, with a limit of quantification at 0.01 mg/kg. Overall procedural recoveries in avocado flesh and peel spiked with fludioxonil at 0.02–0.5 mg/kg were 85±13% (n=11) and 89±10% (n=11).

Table 6 Residues of fludioxonil in avocado following one post-harvest dip or spray treatment (cGAP: 1×60 g ai/hl)

Location, Year (variety)	Treatment method	Application Rate	Growth Stage at Application	DALT	Crop Part	Residue Found (mg/kg)	Report/Trial No., Reference Storage period
Australia Queensland Walkamin 2015 (Shepard)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	Study: SF061B4-2015AU Trial: 150140 Frost, 2016, FLUDIOX_010 Max. frozen storage: 2 month
					Peel	1.0	
					Whole fruit*	0.21	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	
					Peel	2.6	
					Whole fruit*	0.52	
		120 g ai/hl (min. 60 s)	Mature fruit		Flesh	0.01	
					Peel	4.0	
					Whole fruit*	0.80	
Australia Queensland Mutchilba 2015 (Shepard)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	Study: SF061B4-2015AU Trial: 150141 Frost, 2016, FLUDIOX_010 Max. frozen storage: 2 month
					Peel	0.76	
					Whole fruit*	0.16	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	
					Peel	1.26	
					Whole fruit*	0.26	
		120 g ai/hl (min. 60 s)	Mature fruit		Flesh	0.01	
					Peel	1.6	
					Whole fruit*	0.34	
Australia Queensland Carbalah 2015 (Hass)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	Study: SF061B4-2015AU Trial: 150142 Frost, 2016, FLUDIOX_010 Max. frozen storage: 4 month
					Peel	1.8	
					Whole fruit*	0.37	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	
					Peel	2.9	
					Whole fruit*	0.59	
Australia Queensland Hampton 2015 (Hass)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	Study: SF061B4-2015AU Trial: 150143 Frost, 2016, FLUDIOX_010 Max. frozen storage: 4 month
					Peel	1.4	
					Whole fruit*	0.29	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	
					Peel	2.3	
					Whole fruit*	0.47	
		120 g ai/hl (min. 60 s)	Mature fruit		Flesh	0.01	
					Peel	3.5	
					Whole fruit*	0.70	
Australia New South Wales Barham 2015 (Hass)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	Study: SF061B4-2015AU Trial: 150144 Frost, 2016, FLUDIOX_010 Max. frozen storage: 3 month
					Peel	0.56	
					Whole fruit*	0.12	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	
					Peel	2.0	
					Whole fruit*	0.41	
Australia South Australia Renmark West 2015 (Hass)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	Study: SF061B4-2015AU Trial: 150145 Frost, 2016, FLUDIOX_010 Max. frozen storage: <1 month
					Peel	1.4	
					Whole fruit*	0.28	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	
					Peel	3.8	

Location, Year (variety)	Treatment method	Application Rate	Growth Stage at Application	DALT	Crop Part	Residue Found (mg/kg)	Report/Trial No., Reference Storage period
					Whole fruit*	0.76	
	Flood spray	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	
					Peel	3.0	
					Whole fruit*	0.59	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	
					Peel	4.00	
					Whole fruit*	0.80	
Australia Northern Victoria Kenley 2015 (Hass)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	Study: SF061B4-2015AU Trial: 150146 Frost, 2016, FLUDIOX_010 Max. frozen storage: 3 month
					Peel	0.79	
					Whole fruit*	0.16	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	0.01	
					Peel	1.20	
					Whole fruit*	0.25	
		120 g ai/hl (min. 60 s)	Mature fruit		Flesh	0.01	
					Peel	1.6	
					Whole fruit*	0.32	
Australia South Australia Renmark West 2015 (Hass)	Dip	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	Study: SF061B4-2015AU Trial: 150147 Frost, 2016, FLUDIOX_010 Max. frozen storage: <1 month
					Peel	1.7	
					Whole fruit*	0.33	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	
					Peel	2.2	
					Whole fruit*	0.43	
	Flood spray	30 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	
					Peel	1.8	
					Whole fruit*	0.36	
		60 g ai/hl (min. 60 s)	Mature fruit	0	Flesh	<0.01	
					Peel	3.1	
					Whole fruit*	0.62	

*Whole fruit basis is calculated from relative proportions of flesh and peel in whole avocado fruit

Pomegranate

A total of four post-harvest residue trials were conducted on pomegranate in the USA during the 2011 growing season (Leonard, 2013, FLUDIOX_011). Mature pomegranates received either 1× dip application, 2x dip applications or 1× dip plus 1× drench application at 36 g ai/hL for 30 seconds each.

Residues of fludioxonil were determined using the method REM 133.06, already evaluated by the 2012 JMPR, with a limit of quantification at 0.02 mg/kg. Overall mean recoveries in pomegranate spiked with fludioxonil at 0.02, 0.2 and 10 mg/kg were 90%, RSD = 13% (n=6), 85%, RSD = 1% (n=3), 86%, RSD = 8% (n=6), respectively.

Table 7 Residues of fludioxonil in pomegranate following post-harvest dip and/or drench treatment (cGAP: 2×36 g ai/hl)

Location, Year (variety)	Treatment method	Application Rate	Growth Stage at Application	DALT	Crop Part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
USA California Lost Hills 2011 (Wonderful)	1x dip, min. 30 s	2×36 g ai/hl (0.28% Decco Lustr 231)	Mature fruit	0	Fruit	0.82 (0.86; 0.78)	Study: IR-4 PR No.: 10613 Trial: 11-CA58 Leonard, 2013, FLUDIOX_011
	2x dip, min.	2×36 g ai/hl	Mature fruit	0	Fruit	1.3 (1.2; 1.4)	

Location, Year (variety)	Treatment method	Application Rate	Growth Stage at Application	DALT	Crop Part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
	30 s each	(dip 1: 0.28% Decco Lustr 231; dip 2: no wax)					Max. frozen storage: 16 month
	1x dip + 1x drench, min. 30 s each	2×36 g ai/hl (dip: 0.34% Decco Lustr 231; drench (no wax)	Mature fruit	0	Fruit	0.72 (0.71; 0.73)	
USA California Ivanhoe 2011 (Wonderful)	1x dip, min. 30 s	2×36 g ai/hl (0.28% Decco Lustr 231)	Mature fruit	0	Fruit	0.63 (0.61; 0.64)	Study: IR-4 PR No.: 10613 Trial: 11-CA59 Leonard, 2013, FLUDIOX_011 Max. frozen storage: 16 month
	2x dip, min. 30 s each	2×36 g ai/hl (dip 1: 0.28% Decco Lustr 231; dip 2: no wax)	Mature fruit	0	Fruit	1.7 (1.7; 1.7)	
	1x dip + 1x drench, min. 30 s each	2×36 g ai/hl (dip: 0.34% Decco Lustr 231; drench (no wax)	Mature fruit	0	Fruit	0.88 (0.86; 0.89)	
USA California Lost Hills 2011 (Wonderful)	1x dip, min. 30 s	2×36 g ai/hl (0.28% Decco Lustr 231)	Mature fruit	0	Fruit	0.81 (0.78; 0.84)	Study: IR-4 PR No.: 10613 Trial: 11-CA60 Leonard, 2013, FLUDIOX_011 Max. frozen storage: 16 month
	2x dip, min. 30 s each	2×36 g ai/hl (dip 1: 0.28% Decco Lustr 231; dip 2: no wax)	Mature fruit	0	Fruit	2.0 (2.1; 2.0)	
	1x dip + 1x drench, min. 30 s each	2×36 g ai/hl (dip: 0.34% Decco Lustr 231; drench (no wax)	Mature fruit	0	Fruit	1.0 (1.1; 1.0)	
USA California Parlier 2011 (Wonderful)	1x dip, min. 30 s	2×36 g ai/hl (0.28% Decco Lustr 231)	Mature fruit	0	Fruit	0.50 (0.50; 0.50)	Study: IR-4 PR No.: 10613 Trial: 11-CA61 Leonard, 2013, FLUDIOX_011 Max. frozen storage: 16 month
	2x dip, min. 30 s each	2×36 g ai/hl (dip 1: 0.28% Decco Lustr 231; dip 2: no wax)	Mature fruit	0	Fruit	1.8 (1.7; 1.9)	
	1x dip + 1x drench, min. 30 s each	2×36 g ai/hl (dip: 0.34% Decco Lustr 231; drench (no wax)	Mature fruit	0	Fruit	0.92 (0.92; 0.92)	

[a] Mean of replicate field samples [individual values]

Pineapple

A total of four post-harvest residue trials were conducted in the USA on pineapples obtained from Costa Rica during the 2012 growing season (Devine & Cenni, 2013, FLUDIOX_012). Mature pineapples received either 1× dip + 1× peduncle targeted spray or 1x drench + 1× peduncle targeted spray applications at 60 g ai/hL each.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.01 mg/kg. However, the method was modified to enable LC-MS/MS analysis. Overall mean recoveries in pineapple spiked with fludioxonil at 0.01, 1.0 and 5.0 mg/kg were 93% (n=2), 86% (n=2) and 88% (n=1), respectively.

Table 8 Residues of fludioxonil in pineapple following post-harvest dip/drench and spray treatment (cGAP: 2×60 g ai/hl)

Location, Year (variety)	Treatment method	Application Rate	Growth Stage at Application	DALT	Crop Part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
USA California Sanger 2012 (MD-2)	Dip (incld 6% wax) for 30 s + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	2.0 (1.9; 2.1)	Study: TK0061924 Trial: TK0061924-01 Devine & Cenni, 2013, FLUDIOX_012 Max. frozen storage: 2 month
	Drench (incld 6% wax) + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	2.1 (1.9; 2.3)	
USA California Sanger 2012 (Montelirio)	Dip (incld 6% wax) for 30 s + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	1.7 (1.7; 1.8)	Study: TK0061924 Trial: TK0061924-02 Devine & Cenni, 2013, FLUDIOX_012 Max. frozen storage: 2 month
	Drench (incld 6% wax) + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	2.8 (3.0; 2.7)	
USA Alabama Auburn 2012 (MD-2)	Dip (incld 6% wax) for 30 s + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	1.2 (1.2; 1.2)	Study: TK0061924 Trial: TK0061924-03 Devine & Cenni, 2013, FLUDIOX_012 Max. frozen storage: 1 month
	Drench (incld 6% wax) + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	1.4 (1.2; 1.6)	
USA Alabama Auburn 2012 (Montelirio)	Dip (incld 6% wax) for 30 s + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	2.2 (2.3; 2.1)	Study: TK0061924 Trial: TK0061924-04 Devine & Cenni, 2013, FLUDIOX_012 Max. frozen storage: 1 month
	Drench (incld 6% wax) + peduncle spray (4 mL/fruit)	2×60 g ai/hl	Mature fruit	0	Fruit	1.9 (2.0; 1.8)	

[a] Mean of replicate field samples [individual values]

Bulb vegetables

Bulb onion

Supervised residue trials on bulb onions were previously reviewed by the 2004 JMPR and a current Codex MRL of 0.5 mg/kg is set for bulb onions. There is no Codex MRL for fludioxonil on garlic, as the previously provided label did not include garlic. Here additional trials on bulb onions were provided to propose a Codex MRL on garlic.

A total of three supervised residue trials with bulb onion were conducted in the USA in the 2004 growing season (Oakes, 2005, FLUDIOX_013). Onions received four foliar applications of fludioxonil at a nominal rate of 245 g ai/ha with a 7-day interval between applications and were harvested at 7 DALT.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.01 mg/kg. However, the method was modified to enable LC-MS/MS analysis. Overall mean recoveries in onions spiked with fludioxonil at 0.01–1.0 mg/kg were 79%, RSD = 9.1% (n=6).

Table 9 Residues of fludioxonil in onions following foliar treatment (cGAP 4 × 245 g ai/ha; 7 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth Stage at final Application	DALT	Crop Part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
USA New York North Rose 2014 (Bastille)	Foliar spray	246 249 245 254	BBCH 79	7	Bulb	0.10 (0.09; 0.10)	Study: T006628-04 Trial: 5A-FR-04-5169 Oakes, 2005, FLUDIOX_013 Max. frozen storage: 2.2 month
USA Illinois Champaign 2014 (Yellow Sweet Spanish)	Foliar spray	240 252 241 255	BBCH 79	7	Bulb	<0.01 (<0.01, <0.01)	Study: T006628-04 Trial: 4A-FR-04-5660 Oakes, 2005, FLUDIOX_013 Max. frozen storage: 3.7 month
USA Washington Burlington 2014 (Walla Walla Sweet)	Foliar spray	248 246 247 245	BBCH 47	7	Bulb	0.02 (0.01; 0.02)	Study: T006628-04 Trial: WF-FR-04-5661 Oakes, 2005, FLUDIOX_013 Max. frozen storage: 5.3 month

[a] Mean of replicate field samples [individual values]

Green onion

A total of eight supervised residue trials were conducted in Italy, the Netherlands, Spain, Switzerland and the UK during the 2004/05 growing seasons (Pointurier, 2005, FLUDIOX_014; Pointurier, 2005, FLUDIOX_015; Pointurier, 2005, FLUDIOX_016; Bour, 2005, FLUDIOX_017; Bour, 2005, FLUDIOX_018). Plants received three foliar applications of fludioxonil at a nominal rate of 250 g ai/ha with a 10–15 day interval between applications. Samples of green onion were collected at 0, 3, 6/7, 10 and 14 DALT.

Residues of fludioxonil were determined using method REM 133.04, already evaluated by the 2004, 2006, 2010 and 2012 JMPR, with a limit of quantification at 0.02 mg/kg. Overall procedural recoveries in green onion spiked with fludioxonil at 0.02, 0.2, 2 and 5 mg/kg were 91%, RSD = 12% (n=8), 83%, RSD = 6.5% (n=7), 75%, (n=1) and 73% (n=1), respectively.

Table 10 Residues of fludioxonil in green onions following foliar treatment (cGAP 4 × 245 g ai/ha; 7 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth Stage at final Application	DALT	Crop Part	Residue Found (mg/kg)	Report/Trial No., Reference Storage period
Italy Bologna 2004 (Blanca Dura)	Foliar spray	246 254 248 RTI: 11 & 14 days	BBCH 40–41	-0 0 3 7 10 14	Whole plant	<0.02 0.63 0.12 0.05 0.02 <0.02	Study: 04-0417 Trial: AF/7904/SY/1 Pointurier, 2005, FLUDIOX_014 Max. frozen storage: 6 month
Italy Tuscany 2004 (Rossa Bastarda)	Foliar spray	253 248 273 RTI: 11 & 11 days	BBCH 43–45	-0 0 3 7 10 14	Whole plant	0.19 0.52 0.76 0.11 0.10 0.05	Study: 04-0417 Trial: AF/7904/SY/2 Pointurier, 2005, FLUDIOX_014 Max. frozen storage: 6 month
Switzerland Chessel 2004 (Top Keeper F1)	Foliar spray	250 270 262 RTI: 10 & 11 days	BBCH 44	-0 0 3 7 10 14	Whole plant	0.11 0.83 0.30 0.17 0.09 0.05	Study: 04-0419 Trial: CH-FR-04-0165 Pointurier, 2005, FLUDIOX_015 Max. frozen storage: 6 month
The Netherland Gravendeel 2004 (Totum)	Foliar spray	273 280 233 RTI: 13 & 15 days	BBCH 35–37	-0 0 3 6 10	Whole plant	0.03 0.61 0.13 0.06 0.11	Study: 04-0420 Trial: NL-FR-04-0169 Pointurier, 2005, FLUDIOX_016 Max. frozen storage: 3

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth Stage at final Application	DALT	Crop Part	Residue Found (mg/kg)	Report/Trial No., Reference Storage period
				14		0.09	month
UK Lincolnshire 2005 (Redmate)	Foliar spray	255 251 253 RTI: 12 & 11 days	BBCH 43–45	-0 0 3 7 10 14	Whole plant	0.07 4.6 2.3 0.47 0.31 0.11	Study: 05-0404 Trial: AF/8556/SY/1 Bour, 2005, FLUDIOX_017 Max. frozen storage: 3 month
UK Warwickshire 2005 (Laser)	Foliar spray	251 252 252 RTI: 12 & 11 days	BBCH 45	-0 0 3 7 10 14	Whole plant	0.06 0.67 0.11 0.20 0.02 <0.02	Study: 05-0404 Trial: AF/8556/SY/2 Bour, 2005, FLUDIOX_017 Max. frozen storage: 3 month
Spain Zaragoza 2005 (Fuentes)	Foliar spray	251 253 245 RTI: 14 & 14 days	BBCH 45	-0 0 3 7 10 14	Whole plant	0.05 0.82 0.27 0.10 0.02 0.02	Study: 05-0405 Trial: AF/8557/SY/1 Bour, 2005, FLUDIOX_018 Max. frozen storage: 3 month
Spain Sevilla 2005 (Lerida Tardia)	Foliar spray	254 254 254 RTI: 10 & 11 days	BBCH 19–41	-0 0 3 7 10 14	Whole plant	0.26 1.2 0.68 0.35 0.21 0.10	Study: 05-0405 Trial: AF/8557/SY/2 Bour, 2005, FLUDIOX_018 Max. frozen storage: 3 month

Brassica vegetables (except brassica leafy vegetables)

Cabbage

A total of five supervised residue trials were conducted on cabbage in the USA during the 2004 growing season (Barney, 2006, FLUDIOX_020). Cabbage received four foliar applications of fludioxonil at a nominal rate of 245 g ai/ha with a 7–8 day interval between the first and the second application, a 19–28 day interval between the second and third application and a 7–8 day interval between the third and fourth application. Samples of cabbage were collected at 6–8 DALT.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.02 mg/kg. Overall mean recovery in cabbage spiked with fludioxonil at 0.02–2 mg/kg was 93%, RSD = 6% (n=7).

Table 11 Residues of fludioxonil in cabbage following foliar treatment (cGAP 4×245 g ai/ha; 7 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
USA New York Freeville 2004 (Amtrak)	Foliar spray	250 259 251 251	Vegetative	6	Head with wrapper leaves	0.09 (0.08; 0.10)	Study: : IR-44 No. 09126 Trial: NY05 Barney, 2006, FLUDIOX_020 Max. frozen storage: 5 month
USA Maryland Salisbury 2004 (Early Green)	Foliar spray	248 248 245 247	nearly mature	7	Head with wrapper leaves	0.08 (0.09; 0.06)	Study: : IR-44 No. 09126 Trial: MD01 Barney, 2006, FLUDIOX_020 Max. frozen storage: 2 month
USA Michigan Holt	Foliar spray	258 268 251	Vegetative	6	Head with wrapper	0.21 (0.21; 0.20)	Study: : IR-44 No. 09126 Trial: MI04

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
2004 (Blue Lagoon F1)		261			leaves		Barney, 2006, FLUDIOX_020 Max. frozen storage: 5 month
USA Florida Citra 2004 (Bravo)	Foliar spray	247 247 246 246	heading	7	Head with wrapper leaves	0.99 (1.11; 0.87)	Study: : IR-44 No. 09126 Trial: FL13 Barney, 2006, FLUDIOX_020 Max. frozen storage: 6 month
USA California Salinas 2004 (Red Express)	Foliar spray	245 245 253 251	small to medium heads	8	Head with wrapper leaves	0.35 (0.48; 0.21)	Study: : IR-44 No. 09126 Trial: CA*05 Barney, 2006, FLUDIOX_020 Max. frozen storage: 4 month

[a] Mean of replicate field samples [individual values]

Leafy vegetables (including brassica leafy vegetables)

Mustard greens

A total of eight supervised residue trials were conducted on mustard greens in the USA during the 2000 growing season (Arsenovic, 2002, FLUDIOX_019). Mustard greens received four foliar applications of fludioxonil at a nominal rate of 245 g ai/ha (apart from one trial which was treated at an exaggerated rate of 385–402 g ai/ha) with a 6–7 day interval between the first and the second application (except one trial which had 13 days), a 13–23 day interval between the second and third application and a 6–8 day interval between the third and fourth application. Samples of mustard greens were collected at 6–8 DALT.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.02 mg/kg. Overall mean recovery in mustard greens spiked with fludioxonil at 0.02, 0.2, 1.0 and 10 mg/kg was 88%, RSD = 10% (n=20).

An additional trial with mustard seed was conducted in the USA during the 2004 growing season (Barney, 2006, FLUDIOX_020) under the same condition as described above. The interval between applications was 8, 23 and 4 days.

Table 12 Residues of fludioxonil in mustard greens following foliar treatment (cGAP 4×245 g ai/ha; 7 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
USA New Jersey Bridgeton 2000 (Southern Giant Curled)	Foliar spray	245 241 238 236	Vegetative	8	Whole plant	7.1 (7.7; 6.5)	Study: IR-44 No. 07622 Trial: 00-NJ26 Arsenovic, 2002, FLUDIOX_019 Max. frozen storage: 4 month
USA Tennessee Crossville 2000 (Southern Giant Curled)	Foliar spray	240 243 248 248	Vegetative	7	Whole plant	0.54 (0.45; 0.64)	Study: IR-44 No. 07622 Trial: 00-TN15 Arsenovic, 2002, FLUDIOX_019 Max. frozen storage: 13 month
USA Florida Gainesville 2000 (Florida Broadleaf)	Foliar spray	243 253 246 243	Vegetative	7	Whole plant	6.6 (6.9; 6.4)	Study: IR-44 No. 07622 Trial: 00-FL49 Arsenovic, 2002, FLUDIOX_019 Max. frozen storage: 2 month
USA	Foliar spray	255	Vegetative	7	Whole	0.06 (0.06, 0.06)	Study: IR-44 No. 07622

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
North Carolina Clinton 2000 (Southern Giant Curled)		250 250 250			plant		Trial: 00-NC17 Arsenovic, 2002, FLUDIOX_019 Max. frozen storage: 4 month
USA Texas Weslaco 2000 (India)	Foliar spray	243 244 248 250	Mature plants	6	Whole plant	0.49 (0.48; 0.50)	Study: IR-44 No. 07622 Trial: 00-TX*35 Arsenovic, 2002, FLUDIOX_019 Max. frozen storage: <1 month
USA California Salinas 2000 (Southern Giant Curled)	Foliar spray	247 247 239 243	Mature plants	7	Whole plant	0.76 (1.2; 0.33)	Study: IR-44 No. 07622 Trial: CA*16 Arsenovic, 2002, FLUDIOX_019 Max. frozen storage: 3 month
USA Michigan Lansing 2000 (Southern Giant Curled)	Foliar spray	402 401 398 385	8–10 leaves	7	Whole plant	1.2*, (1.1; 1.3)	Study: IR-44 No. 07622 Trial: 00-MI05 Arsenovic, 2002, FLUDIOX_019 Max. frozen storage: 3 month
USA California Salinas 2004 (India Red Giant)	Foliar spray	248 244 244 251	Vegetative, mature growth	8	Greens	1.0 (1.0; 1.0)	Study: : IR-44 No. 09126 Trial: CA*06 Barney, 2006, FLUDIOX_020 Max. frozen storage: 3 month

[a] Mean of replicate field samples [individual values]

(*): Residues were scaled based on a calculated scaling factor of 0.6. Scaling factor = intended GAP rate (245 g ai/ha) ÷ trials/GAP rate (400 g ai/ha). [a] Mean of replicate field samples [individual values]

Pulses

Dry Pea

A total of seven supervised residue trials were conducted with pea in Canada in the 2015 growing season (Sagan, 2017, FLUDIOX_021). Peas received three foliar applications of fludioxonil at a nominal rate of 244 g ai/ha with a 6–8 day interval between applications. In two decline trials, samples of dry peas were collected at 3/4, 6, 9/10 and 13 DALT, while in all other trials samples were collected at 7±1 DALT.

Residues of fludioxonil were determined using method REM 133.06, already evaluated by the 2012 JMPR, with a limit of quantification at 0.01 mg/kg. Overall procedural recoveries in dry pea spiked with fludioxonil at 0.01 and 0.1 mg/kg were 92±1.5% (n=3) and 89±1.5% (n=3), respectively.

Table 13 Residues of fludioxonil in dry peas following foliar treatment (cGAP 3×244 g ai/ha; 7 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
Canada Saskatchewan Zealandia 2015 (CDC Amarillo)	Foliar spray	237 242 243	BBCH 88–89	3 6 9 13	Seed	0.19 0.13 (0.082; 0.17) 0.075 0.082	Study: TK0256751 Trial: T769-D Sagan, 2017, FLUDIOX_021 Max. frozen storage: 8.6 month
Canada Saskatchewan	Foliar spray	234 249	BBCH 79–83	4 6	Seed	0.087 0.046 (0.041; 0.050)	Study: TK0256751 Trial: T770-D

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
Delisle 2015 (CDC Amarillo)		254		10 13		0.038 0.030	Sagan, 2017, FLUDIOX_021 Max. frozen storage: 8.7 month
Canada Saskatchewan Dundern 2015 (CDC Meadow)	Foliar spray	247 254 246	BBCH 83–84	7	Seed	0.018 (0.018; 0.017)	Study: TK0256751 Trial: T771 Sagan, 2017, FLUDIOX_021 Max. frozen storage: 8.5 month
Canada Saskatchewan Moon Lake 2015 (CDC Amarillo)	Foliar spray	251 242 243	BBCH 79–82	6	Seed	0.11 (0.097; 0.12)	Study: TK0256751 Trial: T772 Sagan, 2017, FLUDIOX_021 Max. frozen storage: 7.8 month
Canada Saskatchewan Blaine Lake 2015 (CDC Amarillo)	Foliar spray	240 239 241	BBCH 84–85	7	Seed	0.11 (0.090; 0.13)	Study: TK0256751 Trial: T774 Sagan, 2017, FLUDIOX_021 Max. frozen storage: 8.4 month
Canada Saskatchewan Hague 2015 (CDC Amarillo)	Foliar spray	247 253 241	BBCH 81–84	7	Seed	0.046 (0.048, 0.043)	Study: TK0256751 Trial: T775 Sagan, 2017, FLUDIOX_021 Max. frozen storage: 8.7 month
Canada Manitoba Glenboro 2015 (CDC Meadow)	Foliar spray	245 247 244	BBCH 82–83	6	Seed	0.17 (0.23, 0.11)	Study: TK0256751 Trial: T776 Sagan, 2017, FLUDIOX_021 Max. frozen storage: 8.7 month

[a] Mean of replicate field samples [individual values]

Soya beans

A total of eight supervised residue trials were conducted on soya beans in Brazil. Four were performed in the 2008/09 growing season (Casallanovo, 2009, FLUDIOX_001) and another four trials in the 2010 growing season (Casallanovo, 2010, FLUDIOX_002). Soya beans received two foliar applications of fludioxonil at a nominal rate of 250 g ai/ha with a 7 or 14 day interval between applications. Samples of soya beans were collected 25, 30 and 35 DALT.

Residues of fludioxonil were determined using the validated analytical method POPIT MET.073 with a limit of quantification at 0.01 mg/kg. The method is described in the analytical methods section.

Table 14 Residues of fludioxonil in soya bean following foliar treatment (cGAP: 2×250 g ai/ha; 30 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	PHI (days)	Crop part	Residue found (mg/kg)	Report/Trial No., Reference Storage period
Brazil Bandeirantes – PR 2009 (CD 202)	Foliar spray	2×250	BBCH 81	25 30 35	Seed	0.01 0.02 0.02	Study: M09160 Trial: LZF Casallanovo, 2009, FLUDIOX_001 Max. frozen storage: 2 month
Brazil Goiania-GO 2009	Foliar spray	2×250	BBCH 82	25 30 35	Seed	<0.01 <0.01 <0.01	Study: M09160 Trial: MFG Casallanovo, 2009,

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	PHI (days)	Crop part	Residue found (mg/kg)	Report/Trial No., Reference Storage period
(NK 9074)							FLUDIOX_001 Max. frozen storage: 2 month
Brazil Carambei - PR 2009 (BRS 230)	Foliar spray	2×250	BBCH 61–65	25 30 35	Seed	0.07 0.01 0.03	Study: M09160 Trial: DMO1 Casallanovo, 2009, FLUDIOX_001 Max. frozen storage: 3 month
Brazil Uberlandia - MG 2009 (NK 9074 RR)	Foliar spray	2×250	BBCH 82	25 30 35	Seed	<0.01 <0.01 <0.01	Study: M09160 Trial: JJB Casallanovo, 2009, FLUDIOX_001 Max. frozen storage: 3 month
Brazil Engenheiro Coelho - SP 2010 (Valiosa)	Foliar spray	2×250	BBCH 77	25 30 35	Seed	0.01 <0.01 <0.01	Study: M10115 Trial: LZF Casallanovo, 2010, FLUDIOX_002 Max. frozen storage: 3 month
Brazil Planaltina - OF 2010 (NK 7074 RR)	Foliar spray	2×250	BBCH 86	25 30 35	Seed	0.06 0.03 0.03	Study: M10115 Trial: MFG Casallanovo, 2010, FLUDIOX_002 Max. frozen storage: 2 month
Brazil Carambei - PR 2010 (SYN 1049 RR)	Foliar spray	2×250	BBCH 85–86	25 30 35	Seed	0.01 <0.01 <0.01	Study: M10115 Trial: DMO Casallanovo, 2010, FLUDIOX_002 Max. frozen storage: 3 month
Brazil Uberlandia - MG 2010 (NK 9074)	Foliar spray	2×250	BBCH 81	25 30 35	Seed	0.07 0.13 0.08	Study: M10115 Trial: JJB Casallanovo, 2010, FLUDIOX_002 Max. frozen storage: 1 month

Root and tuber vegetables

Carrot (post-harvest treatment)

A total of two post-harvest residue trials were conducted in Canada with carrots from the 2009 growing season (Subedi, 2012, FLUDIOX_022). Carrots received either one dip or one drench application at 30 g ai/hL each.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.01 mg/kg. However, the method was modified to enable LC-MS/MS analysis. Overall mean method validation recoveries in carrot spiked with fludioxonil at 0.01–4.0 mg/kg were 88±10% (n=15). Mean concurrent recoveries at 0.01 and 1.0 mg/kg were 91±14% (n=12).

Table 15 Residues of fludioxonil in carrot following post-harvest dip or drench treatment (cGAP: 1×29 g ai/hL)

Location, Year (variety)	Treatment method	Application Rate	Growth Stage at Application	DALT	Crop Part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
Canada Nova Scotia	Dip, 30 s	30 g ai/hL	Mature	0	Root	2.6 (3.5; 2.6; 2.3; 1.9)	Study: AAFC08-013R Trial: 554

Location, Year (variety)	Treatment method	Application Rate	Growth Stage at Application	DALT	Crop Part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
Kentville 2009 (Pronto)	Drench, 21 s	30 g ai/hL	Mature	0	Root	1.9 (2.1; 2.0; 1.8; 1.6)	Subedi, 2012, FLUDIOX_022 Max. frozen storage: 5.4 month
Canada British Columbia Summerland 2009 (Bolero)	Dip, 30 s	30 g ai/hL	Mature	0	Root	2.4 (3.0; 2.6; 2.3; 1.9)	Study: AAFC08-013R Trial: 555 Subedi, 2012, FLUDIOX_022 Max. frozen storage: 4.2 month
	Drench, 21 s	30 g ai/hL	Mature	0	Root	2.0 (2.0; 1.8; 2.4; 1.9)	

Carrot (foliar treatment)

A total of 15 supervised residue trials were conducted in carrots in France, Italy, Spain and Switzerland in the 2005 and 2006 growing seasons (Bour, 2006, FLUDIOX_023; Bour, 2006, FLUDIOX_024; Sole, 2007, FLUDIOX_025; Royer, 2007, FLUDIOX_026; Bour, 2006, FLUDIOX_027, Bour, 2006, FLUDIOX_028; Bour, 2006, FLUDIOX_029; Royer, 2007, FLUDIOX_030). Carrots received three foliar applications of fludioxonil at a nominal rate of 250 g ai/ha with a 14-day interval between applications. Samples of carrots were collected at 0, 3, 6–8, 13–15 and 20–23 DALT.

Residues of fludioxonil were either determined by method REM 133.04 or REM 133.06 with LOQs of 0.02 mg/kg and 0.01 mg/kg, respectively. Both methods have been previously evaluated by the JMPR. For method REM 133.04, overall procedural recoveries in carrots spiked with fludioxonil at 0.02, 0.2, 0.5 and 1.0 mg/kg were 87±8.8% (n=14), 82±7.0% (n=13), 80% (n=1) and 70% (n=1), respectively. For method REM 133.06 overall procedural recoveries in carrots spiked with fludioxonil at 0.01 and 0.1 mg/kg were 84% (n=2) and 95% (n=2), respectively.

Table 16 Residues of fludioxonil in carrot following foliar treatment (cGAP 3×250 g ai/ha; 7 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth Stage at final Application	DALT	Crop Part	Residue Found (mg/kg)	Report/Trial No., Reference Storage period
France (north) Lacrost 2005 (Bolero)	Foliar spray	244 270 246	BBCH 74	-0 0 3 7 14 21	Root	0.16 0.14 0.23 0.19 0.15 0.13	Study: 05-0402 Trial: AF/8554/SY/1 Bour, 2006, FLUDIOX_023 Max. frozen storage: 2 month
France (north) Saint Lambert des Levées 2005 (Chambord)	Foliar spray	244 245 250	BBCH 48	-0 0 3 7 14 21	Root	0.25 0.30 0.37 0.26 0.44 0.28	Study: 05-0402 Trial: AF/8554/SY/2 Bour, 2006, FLUDIOX_023 Max. frozen storage: 2 month
France (north) La Chapelle de Guinchay 2005 (Napoli)	Foliar spray	277 257 254	BBCH 45–47	-0 0 3 7 14 21	Root	0.30 0.35 0.35 0.52 0.46 0.40	Study: 05-0610 Trial: FR-FR-05-0474 Bour, 2006, FLUDIOX_024 Max. frozen storage: 2 month
France (north) Forest Montier 2006 (Solo)	Foliar spray	238 233 257	BBCH 45	-0 0 3 6 14 20	Root	0.37 0.35 0.40 0.54 0.42 0.43	Study: T001818-06-REG Trial: FR·FR·06·0080 Sole, 2007, FLUDIOX_025 Max. frozen storage: 10 month
Switzerland Vouvry[a] 2006 (Nantaise Selma)	Foliar spray	238 258 247	BBCH 45	-0 0 3 7 14 21	Root	0.38 0.38 0.42 0.40 0.40 0.38	Study: T013971-05 Trial: CH~FR~06~0133 Royer, 2007, FLUDIOX_026 Max. frozen storage: 3 month
Switzerland	Foliar spray	252	BBCH 45–47	-0	Root	0.38	Study: T013971-05

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth Stage at final Application	DALT	Crop Part	Residue Found (mg/kg)	Report/Trial No., Reference Storage period
Vouvry[a] 2006 (Dordogne)		253 252		0 3 7 14 21		0.47 0.38 0.41 0.37 0.40	Trial: CH~FR~06~0134 Royer, 2007, FLUDIOX_026 Max. frozen storage: 3 month
France (north) Caudan 2006 (Solo)	Foliar spray	253 252 248	BBCH 42	-0 0 3 6 14 21	Root	0.16 0.17 0.17 0.29 0.27 0.03	Study: T013971-05 Trial: FR·FR~06..0135 Royer, 2007, FLUDIOX_026 Max. frozen storage: 3 month
Spain Villamanrique de la Condesa 2005 (Mocun)	Foliar spray	261 258 262	BBCH 47–48	-0 0 3 7 14 21	Root	0.12 0.19 0.13 0.18 0.12 0.12	Study: 05-0403 Trial: AF/8555/SY/1 Bour, 2006, FLUDIOX_027 Max. frozen storage: 4 month
Italy Lusia 2005 (Nelson)	Foliar spray	253 251 256	BBCH 41	-0 0 3 7 14 21	Root	0.12 0.14 0.09 0.04 0.03 0.05	Study: 05-0403 Trial: AF/8555/SY/2 Bour, 2006, FLUDIOX_027 Max. frozen storage: 4 month
France (south) Saucats 2005 (Maestro)	Foliar spray	237 257 236	BBCH 49	-0 0 3 7 14 21	Root	0.06 0.04 0.04 0.04 0.02 0.03	Study: 05-0606 Trial: FR-FR-05-0473 Bour, 2006, FLUDIOX_028 Max. frozen storage: 2 month
France (south) Bâgé Le Châtel 2005 (Dematro)	Foliar spray	276 262 271	BBCH 43	-0 0 3 7 15 21	Root	0.16 0.25 0.29 0.30 0.25 0.14	Study: 05-0611 Trial: FR-FR-05-0475 Bour, 2006, FLUDIOX_029 Max. frozen storage: 3 month
Spain Chatún 2006 (Maestro)	Foliar spray	264 258 260	BBCH 49–55	-0 0 3 8 13 23	Root	0.06 0.05 0.03 0.06 0.05 0.03	Study: T013972-05 Trial: ES-FR-06-0301 Royer, 2007, FLUDIOX_030 Max. frozen storage: 4 month
Spain Villanueva de Duero 2006 (Maestro)	Foliar spray	273 248 251	BBCH 49-55-91	-0 0 3 7 14 21	Root	0.03 0.04 0.03 0.06 0.02 0.03	Study: T013972-05 Trial: ES-FR-06-0123 Royer, 2007, FLUDIOX_030 Max. frozen storage: 4 month
France (south) Hourtin 2006 (Solo)	Foliar spray	258 259 243	BBCH 47	-0 0 3 7 14 21	Root	0.05 0.05 0.15 0.08 0.09 0.07	Study: T013972-05 Trial: FR-FR-06-0124 Royer, 2007, FLUDIOX_030 Max. frozen storage: 4 month
France (south) Cestas 2006 (Solo)	Foliar spray	266 256 235	BBCH 48	-0 0 3 7 13	Root	0.04 0.08 0.11 0.06 0.07	Study: T013972-05 Trial: FR-FR-06-0125 Royer, 2007, FLUDIOX_030 Max. frozen storage: 4 month

[a] Trials can be considered independent since actual planting dates differed by 2 months.

Stalk and stem vegetables

Celery

A total of eight supervised residue trials were conducted on celery in the USA during the 2009 growing season (Hampton, 2011, FLUDIOX_031). Celery received four foliar applications of fludioxonil at a nominal rate of 246 g ai/ha with a 7-day interval between applications. Samples of celery were collected at 0 DALT, with the exception of one dissipation trial where samples were also taken at 0, 3, 7 and 10 DALT.

Residues of fludioxonil were determined using method AG-597B, already evaluated by the 2006 and 2010 JMPR, with a limit of quantification at 0.02 mg/kg. However, the method was modified to enable LC-MS/MS analysis. Overall mean recoveries in celery spiked with fludioxonil at 0.02, 0.2 and 10 mg/kg were 85%, RSD = 7.5% (n=15), 85%, RSD = 6.8% (n=12) and 85%, RSD = 1.6% (n=3), respectively.

Table 17 Residues of fludioxonil in celery following foliar treatment (cGAP 4×245 g ai/ha; 0 day PHI)

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
USA Florida Bradenton 2009 (Golden Blanch)	Foliar spray	242 242 245 240	Vegetative growth	0	Leaf stalk	7.8 (7.6; 8.0)	Study: T008508-08 Trial: E16-9141 Hampton, 2011, FLUDIOX_031 Max. frozen storage: 5.8 month
USA Florida Belle Glade 2009 (Walt's Pride)	Foliar spray	243 250 252 248	BBCH 49	0	Leaf stalk	3.2 (3.2; 3.2)	Study: T008508-08 Trial: E19-9142 Hampton, 2011, FLUDIOX_031 Max. frozen storage: 1 month
USA Wisconsin Fitchburg 2009 (Tango)	Foliar spray	244 289 251 249	BBCH 49	0	Leaf stalk	5.8 (6.0; 5.4)	Study: T008508-08 Trial: C08-9143 Hampton, 2011, FLUDIOX_031 Max. frozen storage: 2.5 month
USA California Hughson 2009 (Conquistador)	Foliar spray	247 245 248 238	BBCH 49	0	Leaf stalk	5.1 (4.9; 5.2)	Study: T008508-08 Trial: W26-9144 Hampton, 2011, FLUDIOX_031 Max. frozen storage: 4.6 month
USA California Madera 2009 (Salyer Sonora)	Foliar spray	246 246 248 247	BBCH 85	0 3 7 10	Leaf stalk	5.9 (5.4[b]; 6.3[b]) 4.9 (4.7; 5.0) 4.2 (4.2, 4.1) 4.0 (3.9; 4.0)	Study: T008508-08 Trial: W29-9145 Hampton, 2011, FLUDIOX_031 Max. frozen storage: 4.6 month
USA California Gonzales 2009 (SSC1)	Foliar spray	246 251 246 238	Mature fruit	0	Leaf stalk	1.8 (1.8; 1.8)	Study: T008508-08 Trial: W28-9146 Hampton, 2011, FLUDIOX_031 Max. frozen storage: 3.3 month
USA California King City 2009 (Hill's Special)	Foliar spray	252 248 248 252	BBCH 49	0	Leaf stalk	2.3 (2.0[c]; 2.6[c])	Study: T008508-08 Trial: W32-9147 Hampton, 2011, FLUDIOX_031 Max. frozen storage: 7.3 month
USA California Guadalupe 2009	Foliar spray	248 252 247 246	BBCH 85	0	Leaf stalk	4.0 (3.4[c]; 4.5[c])	Study: T008508-08 Trial: W33-9148 Hampton, 2011, FLUDIOX_031

Location, Year (variety)	Treatment method	Application rate (g ai/ha)	Growth stage at final application	DALT	Crop part	Residue Found (mg/kg)[a]	Report/Trial No., Reference Storage period
(Mission)							Max. frozen storage: 7.3 month

[a] Mean of replicate field samples [individual values]

[b] Average of duplicate sub-samples

[c] Average of triplicate sub-samples

FATE OF RESIDUES IN STORAGE AND PROCESSING

Residues after processing

The Meeting received new information on the fate of fludioxonil residues during the processing of carrots.

As a measure of the transfer of residues into processed products, a processing factor was used, which is defined as:

Processing factor = Residue in processed product (mg/kg) ÷ Residue in raw agricultural commodity (mg/kg)

If residues in the RAC were below the LOQ, no processing factor could be derived. In case of residues below the LOQ, but above the LOD in the processed product, the numeric value of the LOQ was used for the calculation. If residues in the processed product were below the LOD, the numeric value of the LOQ was used for the calculation but the PF was expressed as "less than" (e.g. <0.5).

The transfer of residues of fludioxonil was investigated in carrots from one supervised field trial conducted in northern France (Sole, 2007, FLUDIOX_025). The trial was performed with three treatments at exaggerated rates of 750 g ai/ha with harvest at 6 DALT. Carrots were processed into canned carrots, carrot juice, boiled carrots and vacuum packed carrots using common commercial practices. Residues of fludioxonil were determined by method REM 133.06 that has been previously evaluated by the JMPR.

Table 18 Summary of fludioxonil residues in carrots and processed commodities

Trial Identification (City, State/Region, Country, Year)	Form.	Crop/ Variety	Process	Commodity or Matrix	Average Residues (mg/kg)[a]	Processing Factor
FR·FR·06·0080B Forest Montier France (north) 2006	WG	Carrots/ Solo	Canning	Carrot (RAC)	0.52[a]	-
				Waste (peels)	0.75	1.4
				Carrots (washed and peeled)	0.10	0.19
				Carrots (blanched)	0.10	0.19
				Carrots (canned)	0.05	0.10
			Juicing	Carrot (RAC)	0.49[a]	-
				Waste (peels)	0.77	1.6
				Carrots (washed and peeled)	0.24	0.49
				Pulp	0.25	0.51
				Juice (raw)	0.09	0.18
				Juice (pasteurised)	0.08	0.16
			Cooking	Carrot (RAC)	0.34[a]	-
				Waste (peels)	1.4	4.1
				Carrots (peeled)	0.09	0.26
				Carrots (washed and peeled)	0.04	0.12
				Carrots (cooked)	0.03	0.09
			Bagging	Carrot (RAC)	0.40[a]	-
				Waste (peels)	1.40	3.5
				Carrots (peeled)	0.07	0.18
				Carrots (washed and peeled)	0.03	0.08
				Carrots (bagged)	0.02	0.05
FR·FR·06·0080F1 Forest Montier France (north)	WG	Carrots/ Solo	Canning	Carrot (RAC)	0.52[a]	-
				Carrots (canned)	0.07	0.13
			Juicing	Carrot (RAC)	0.49[a]	-

Trial Identification (City, State/Region, Country, Year)	Form.	Crop/ Variety	Process	Commodity or Matrix	Average Residues (mg/kg)[a]	Processing Factor
2006				Juice (pasteurised)	0.08	0.16
			Cooking	Carrot (RAC)	0.34[a]	-
				Carrots (cooked)	0.04	0.12
			Bagging	Carrot (RAC)	0.40[a]	-
				Carrots (bagged)	0.04	0.10
FR·FR·06·0080F2 Forest Montier France (north) 2006	WG	Carrots/ Solo	Canning	Carrot (RAC)	0.52[a]	-
				Carrots (canned)	0.07	0.13
			Juicing	Carrot (RAC)	0.49[a]	-
				Juice (pasteurised)	0.07	0.14
			Cooking	Carrot (RAC)	0.34[a]	-
				Carrots (cooked)	0.04	0.12
			Bagging	Carrot (RAC)	0.40[a]	-
				Carrots (bagged)	0.03	0.08
FR·FR·06·0080F3 Forest Montier France (north) 2006	WG	Carrots/ Solo	Canning	Carrot (RAC)	0.52[a]	-
				Carrots (canned)	0.10	0.19
			Juicing	Carrot (RAC)	0.49[a]	-
				Juice (pasteurised)	0.13	0.27
			Cooking	Carrot (RAC)	0.34[a]	-
				Carrots (cooked)	0.05	0.15
			Bagging	Carrot (RAC)	0.40[a]	-
				Carrots (bagged)	0.02	0.05

[a] Mean of duplicate sample

RESIDUES IN ANIMAL COMMODITIES

Farm animal feeding studies

Lactating cows

The transfer of residues of fludioxonil into animal matrices was investigated in a study with dairy cows (Willard, 2011, FLUDIOX_032). The study was conducted at treatment rates of 20 and 100 ppm for 28 days.

Seven dairy cows were divided into two treatment groups (three animals each), plus one control animal. The cows in the treatment groups were dosed with fludioxonil in gelatine capsules once daily. Milk samples were collected twice daily throughout the dosing period. All cows were killed on day 28 within 22–24 hours after the last dose. Samples of muscle, liver, kidney and fat were collected and taken for analysis.

The total residues of fludioxonil (determined as CGA192155) in milk and tissues were analysed using method GRM025.03A, already evaluated by the 2013 JMPR, with a limit of quantification of 0.01 mg/kg. Maximum storage time of milk samples was 3.4 months, while for tissues the maximum frozen storage period was 2.7 days.

The residue levels in milk and tissues are summarised in

Table 19. In milk, residue levels reached a plateau in the 20 ppm group after approximately 3 days, while for the 100 ppm group a plateau was reached after 14 days (Figure 1).

Table 19 Residues of fludioxonil (total residue as CGA192155) in milk and cow tissues

Commodity	Sampling Interval (days)	Individual residues in mg/kg (mean)	
		20 ppm	100 ppm
Milk	-1	ND[c]	ND[c]
	1	0.029, 0.027, 0.012, 0.013, <0.01, <0.01 (0.015)	0.055, 0.059, 0.10, 0.075, 0.066, 0.072 (0.071)
	3	0.049, 0.044, 0.020, 0.016, 0.012, 0.011 (0.025)	0.092, 0.12, 0.11, 0.13, 0.093, 0.070 (0.10)
	7	0.051, 0.041, 0.018, 0.016, 0.015, 0.015 (0.026)	0.099, 0.090, 0.15, 0.18, 0.081, 0.066 (0.11)
	10	0.037, 0.037, 0.025, 0.014, 0.012, 0.011 (0.023)	0.13, 0.11, 0.17, 0.18, 0.11, 0.081 (0.13)
	14	0.041, 0.038, 0.016, 0.013, 0.012, 0.013 (0.022)	0.16, 0.12, 0.20, 0.22, 0.089, 0.075 (0.14)
	17	0.056, 0.053, 0.023, 0.016, 0.013, 0.012 (0.029)	0.14, 0.12, 0.20, 0.26, 0.10, 0.099 (0.15)
	21	0.054, 0.051, 0.019, 0.016, 0.015, 0.012 (0.028)	0.16, 0.11, 0.15, 0.19, 0.078, 0.084 (0.13)
	24	0.047, 0.046, 0.021, 0.020, 0.017, 0.013 (0.027)	0.14, 0.11, 0.19, 0.22, 0.092, 0.11 (0.14)
	28	0.067, 0.047, 0.020, 0.018, 0.017, 0.013 (0.030)	0.15, 0.12, 0.15, 0.21, 0.092, 0.092 (0.13)
Muscle	28	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01 (<0.01)	0.011, 0.012, 0.010, 0.012, <0.01, <0.01 (0.011)
Liver	28	0.053, 0.049, 0.049, 0.038, 0.079, 0.059 (0.055)	0.31, 0.28, 0.35, 0.26, 0.28, 0.28 (0.29)
Kidney	28	0.082, 0.080, 0.048, 0.048, 0.056, 0.057 (0.062)	0.27, 0.29, 0.29, 0.28, 0.24, 0.24 (0.27)
Fat	28	<0.01, 0.011, <0.01, <0.01, <0.01, <0.01 (0.01)	0.032, 0.031, 0.033, 0.033, 0.031, 0.030 (0.032)

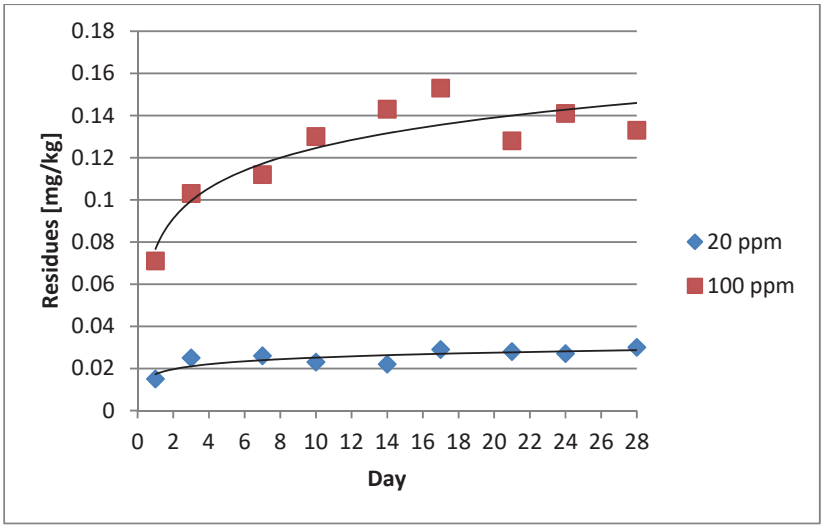

Figure 1 Time course of the concentrations of fludioxonil in milk

APPRAISAL

Fludioxonil was evaluated for the first time by the JMPR in 2004 when an acceptable daily intake (ADI) of 0–0.4 mg/kg bw was established. An acute reference dose (ARfD) was considered unnecessary. In 2006, 2010, 2012 and 2013 the JMPR evaluated the compound for residues and recommended a number of maximum residue levels.

The definition of the residue for compliance with the MRL and for dietary risk assessmentfor plant commodities is parent *fludioxonil.*The definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities is the *sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil*. The residue is fat-soluble.

At the Forty-ninth Session of the CCPR, fludioxonil was scheduled for the evaluation of additional uses by the 2018 JMPR

The current Meeting received additional analytical methods, GAP information and residue trial data for uses on blueberries, currants, guava, avocado, pomegranate, pineapple, bulb onion, green onion, mustard greens, dry pea, dry soya bean, carrot and celery. In addition, processing data for carrots and a new dairy cow feeding study was received.

Methods of analysis

The Meeting received additional information on analytical methods for fludioxonil in soya bean.

Method POPIT MET.073.Rev11 and POPIT MET.073.Rev16 employ shaking of the sample material with methanol. The resulting extract is further diluted with methanol and analysed by LC-MS/MS with an LOQ of 0.01 mg/kg.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure fludioxonil in soya beans.

Results of supervised residue trials on crops

Blueberries

Blueberries were previously evaluated by the 2004 JMPR where a maximum residue level of 2 mg/kg and a STMR of 0.60 mg/kg was estimated for fludioxonil based on a GAP from the USA using four foliar applications at a rate of 250 g ai/ha and a 0 day PHI. The residue levels from the 2004 trials in ranked order were (n = 8): < 0.05, 0.14, 0.26, 0.52, 0.68, 0.84, 0.90, 1.4 mg/kg.

The 2018 Meeting considered the critical GAP for use on bush berries in Canada that allows three foliar applications at a rate of 244 g ai/ha with a 7 day re-treatment interval and 1 day PHI. Two new trials from Canada matching the GAP were submitted, resulting in residues of 0.88 and 1.7 mg/kg in the fruits.

The Meeting agreed that the existing maximum residue level accommodates for residues of fludioxonil according to the Canadian GAP.

Currants, black, red, white

The use of fludioxonil on currants was previously evaluated by the 2004 JMPR, but as no relevant label was provided, no recommendations could be made.

The current Meeting considered, the critical GAP for use on currants in Ireland that allows three foliar applications at a rate of 250 g ai/ha with a 10 day interval between the 1st and 2nd applications, a 28 day interval between the 2nd and 3rd, and a PHI of 7 days.

Field trials with black- and red currant from Germany, already submitted for the 2004 JMPR, were re-evaluated and residues of fludioxonil following GAP treatment (±25%) were (n = 5): 0.26, 0.60, 0.62, 0.63 and 1.4 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and a STMR of 0.62 mg/kg for fludioxonil in currants, black, red, white.

Guava

The critical GAP for the use on guava in the USA allows for four foliar applications at a rate of 245 g ai/ha with a 7 day re-treatment interval and a PHI of 0 days.

In field trials on guava from the USA, residues of fludioxonil following GAP treatment (±25%) were (n = 4): 0.11, 0.12, 0.13 and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.125 mg/kg for fludioxonil in guava.

Avocado

The use of fludioxonil on avocado as foliar treatment was previously evaluated by the 2013 JMPR where a maximum residue level of 0.4 mg/kg and a STMR of 0.05 mg/kg were estimated, based on trials from the USA.

The current Meeting received GAP information for the use on avocado from Australia, which comprised one post-harvest dip/drench/flood spray application at a rate of 60 g ai/hL.

In trials performed in Australia on avocados receiving a dip treatment, residues of fludioxonil in whole fruits following GAP treatment (±25%) were (n = 8): 0.25, 0.26, 0.41, 0.43, 0.47, 0.52, 0.59 and 0.76 mg/kg.

Corresponding residues in the flesh were: < 0.01(2) and 0.01(6) mg/kg.

In two trials involving a flood spray treatment residues of fludioxonil found were: 0.62 and 0.80 mg/kg. Corresponding residues in the flesh were: < 0.01(2) mg/kg.

The Meeting noted that both treatment resulted in comparable residue levels and decided to combine both data sets (n = 10): 0.25, 0.26, 0.41, 0.43, 0.47, 0.52, 0.59, 0.62, 0.76 and 0.80 mg/kg.

Corresponding combined residues in the flesh were: < 0.01(4), 0.01(6) mg/kg.

The Meeting estimated a STMR of 0.01 mg/kg, based on the flesh, and a maximum residue level of 1.5 mg/kg for fludioxonil in avocado. The Meeting withdrew its previous recommendation for avocado of 0.4 mg/kg.

Pomegranate

Pomegranate was previously evaluated by the JMPR in 2004 and 2010, where a maximum residue level of 2 mg/kg and a STMR of 1 mg/kg were estimated for fludioxonil based on a GAP from the USA of a single dip or drench application at 60 g ai/hL.

The current Meeting considered, the critical GAP for the use on pomegranate in the USA that allows for two post-harvest dip/drench applications at a rate of 36 g ai/hL.

In trials performed in the USA, pomegranates received either 2× dip applications or 1× dip plus 1× drench application at 36 g ai/hL for 30 seconds each. The samples were allowed to dry between treatments. Residues of fludioxonil following 2× dip treatments were (n = 4) 1.3, 1.7, 1.8 and 2.0 mg/kg, while residues after 1× dip plus 1× drench treatment were (n = 4) 0.72, 0.88, 0.92 and 1.0 mg/kg.

As the treatments resulted in appreciably different residues, the Meeting decided to only consider the double dip treatment for the estimation of maximum residue levels as it resulted in the higher residues.

On the basis that the variability of residues from post-harvest treatment is lower the Meeting decided that a lower maximum residue level was sufficient. Hence, the Meeting estimated a STMR of 1.75 mg/kg and a maximum residue level of 3 mg/kg (based on the mean + 4 SD) for fludioxonil in pomegranate (whole fruit). The Meeting withdraws its previous recommendation for pomegranate of 2 mg/kg.

Pineapple

The use of fludioxonil on pineapple was previously evaluated by the 2013 JMPR, but no recommendations were made.

The current Meeting considered, the critical GAP for the post-harvest use on pineapples in the USA that allows one drench treatment and one spray treatment at a rate of 60 g ai/hL.

In trials conducted in the USA, residues of fludioxonil following GAP treatment (±25%) were (n = 4): 1.4, 1.9, 2.1 and 2.8 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg (based on the mean + 4 SD) and a STMR of 2.0 mg/kg for fludioxonil in pineapple.

Bulb onion

Bulb onion was previously evaluated by the 2004 JMPR where a maximum residue level of 0.5 mg/kg and a STMR of 0.04 mg/kg were estimated for fludioxonil based on a GAP of the USA comprising four foliar applications at 245 g ai/ha and a 7-day PHI. The ranked order of residues were (n = 13): < 0.02(5), 0.04(3), 0.05, 0.06(2), 0.07 and 0.34 mg/kg.

For the current Meeting additional trials on onion conducted in the USA based on the same GAP (bulb vegetables) were provided. Residues of fludioxonil matching the GAP were (n = 3): < 0.01, 0.02 and 0.10 mg/kg.

The Meeting decided that its previous recommendations for a maximum residue level of 0.5 mg/kg and a STMR of 0.04 mg/kg also accommodated the residues found in the newly submitted data on bulb onion. However, the Meeting decided to withdraw its previous recommendation for a maximum residue level for bulb onion of 0.5 mg/kg and estimated a maximum residue level of 0.5 mg/kg for the Subgroup of Bulb onions.

Green onion

Green onion was previously evaluated by the 2004 JMPR where a maximum residue level of 5 mg/kg and a STMR of 0.59 mg/kg was estimated for fludioxonil based on a GAP from the USA comprising four foliar applications at 245 g ai/ha and a 7-days PHI. The ranked order of residues was (n = 3): 0.14, 0.59 and 3.0 mg/kg.

The current Meeting considered the critical GAP on green onion in the USA that allows four foliar applications at a rate of 245 g ai/ha with a 7 day re-treatment interval and a 7 days PHI. However, no trials were provided matching this GAP. An alternative GAP from Italy was available that allows three foliar applications at a rate of 250 g ai/ha with a 10 day re-treatment interval and a 7-day PHI.

In field trials with green onion from Europe matching the Italian GAP, residues of fludioxonil were (n = 8): 0.05, 0.10, 0.11(2), 0.17, 0.20, 0.35 and 0.47 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg and a STMR of 0.14 mg/kg for fludioxonil in the subgroup of green onions.

Head cabbage

Head cabbage was previously evaluated by the 2004 JMPR where a maximum residue level of 2 mg/kg and a STMR of 0.24 mg/kg were estimated for fludioxonil based on a GAP from the USA using four foliar applications at 250 g ai/ha and a 7 days PHI. The ranked order of residues matching the GAP was (n = 6): 0.17(2), 0.21, 0.27, 0.50 and 1.2 mg/kg.

The 2018 Meeting considered the critical on brassica leafy vegetables from the USA that allows four foliar applications at 250 g ai/ha and a 7-day PHI. Additional trials on cabbage from the USA were provided. Residues of fludioxonil matching the GAP were (n = 5): 0.08, 0.09, 0.21, 0.35 and 0.99 mg/kg.

The Meeting decided that its previous recommendations of a maximum residue level of 2 mg/kg and a STMR of 0.24 mg/kg also accommodate for residues found in the newly submitted data on cabbage.

Mustard greens

Mustard greens were previously evaluated by the 2004 JMPR where a maximum residue level of 10 mg/kg and a STMR of 1.2 mg/kg were estimated for fludioxonil based on a GAP from the USA comprising of four foliar applications at 240 g ai/ha with a 7 days PHI. The ranked order of residues (combined with watercress) matching the GAP was (n = 9): 0.06, 0.49, 0.54, 0.76, 1.2, 4.2, 4.5, 6.6 and 7.1 mg/kg.

The current Meeting received GAP information for use in brassica leafy vegetables from the USA, which allows four foliar applications at 250 g ai/ha and a 7 days PHI. One additional trial for mustard greens from the USA was provided. Residues of fludioxonil matching the GAP were (n = 1): 1.0 mg/kg.

The Meeting decided that residue levels found in the newly submitted data on mustard greens would be accommodated by its previous recommendations of a maximum residue level of 10 mg/kg and a STMR of 1.2 mg/kg. However, the Meeting decided to withdraw its previous recommendation of a maximum residue level for mustard greens of 10 mg/kg and estimated a maximum residue level of 15 mg/kg for the subgroup of Brassica leafy vegetables.

Lentils and chick-peas

The current Meeting received GAP information on the use in lentils and chick-peas from Canada, which allows for three foliar applications at a rate of 244 g ai/ha with a 7-day re-treatment interval and a PHI of 7 days.

In dry peas, residues of fludioxonil following GAP treatment (±25%) were (n = 7): 0.018, 0.046(2), 0.11(2), 0.13 and 0.17 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.3 mg/kg and 0.11 mg/kg respectively for lentils and chick-peas, based on the data from dry peas.

Soya beans (dry)

Fludioxonil is registered in Brazil for use on soya beans with a GAP comprising two foliar applications at a rate of 250 g ai/ha with a 7-day re-treatment interval and a PHI of 30 days.

In soya beans, residues of fludioxonil following Brazilian GAP treatment (±25%) were (n = 8): < 0.01(4), 0.01, 0.02, 0.03 and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and a STMR of 0.01 mg/kg for fludioxonil in soya beans (dry).

Carrot

Carrot was previously evaluated by the 2004 JMPR where a maximum residue level of 0.7 mg/kg and a STMR of 0.2 mg/kg were estimated for fludioxonil based on a GAP from the USA, comprising of four foliar applications at 250 g ai/ha with a 7 days PHI. The ranked order of residues, matching GAP were (n = 7): 0.04, 0.16, 0.18, 0.20, 0.20, 0.25, 0.42 mg/kg.

The current Meting received new GAP information for fludioxonil from the USA which comprised two post-harvest dip/drench applications at a rate of 29 g ai/hL.

In trials conducted in the USA on carrots, residues of fludioxonil matching GAP (±25%) were (n = 2): 2.4 and 2.6 mg/kg.

The Meeting noted that the data submitted for post-harvest treatment was insufficient for a recommendation.

An alternative GAP for the use of fludioxonil on carrots was available from Germany with three foliar applications at a rate of 250 g ai/ha, a 7-day re-treatment interval and a PHI of 7 days.

Residues in carrots from European trials with fludioxonil following GAP (±25%) were (n = 15): 0.04, 0.05, 0.06(2), 0.07, 0.09, 0.18, 0.19, 0.29, 0.30, 0.40, 0.41, 0.44, 0.52 and 0.54 mg/kg. The Meeting noted that the RTI in the trials was 14 days, i.e, twice as long as the GAP. However, as decline studies showed that no significant degradation occurred, the Meeting decided that the trials approximated the German GAP.

The Meeting estimated a STMR of 0.19 mg/kg and a maximum residue level of 1 mg/kg for fludioxonil in carrot. The latter replaces the previous recommendation for carrots (0.7 mg/kg).

Celery

Fludioxonil is registered in the USA for use on celery with four applications at a rate of 245 g ai/ha with a 7-day re-treatment interval and a 0-day PHI.

In celery trials from the USA, residues of fludioxonil matching following GAP (±25%) were (n = 8): 1.8, 2.3, 3.2, 4.0, 5.1, 5.8, 5.9 and 7.8 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and a STMR of 4.55 mg/kg for fludioxonil in celery.

Fate of residues during processing

The Meeting received new information on the fate of fludioxonil residues following the processing of carrots.

Estimated processing factors for the commodities considered at this Meeting are summarised below.

Raw commodity	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = $STMR_{RAC}$ × PF (mg/kg)
Carrot	Carrots (canned)	0.10, 0.13, 013, 0.19	0.14	0.027
	Juice (pasteurised)	0.16, 0.16, 0.14, 0.27	0.18	0.034
	Carrots (cooked)	0.09, 0.12, 0.12, 0.15	0.12	0.023

Residues in animal commodities

Farm animal feeding studies

The Meeting received one new feeding study involving the dosing of lactating cows with fludioxonil. The study was conducted at treatment rates of 20 and 100 ppm for 28 days. Residues were determined as the total residue of fludioxonil.

In milk, residues in the 20 ppm group were up to 0.067 mg/kg (mean 0.030 mg/kg) and in the 100 ppm group up to 0.26 mg/kg (mean 0.15 mg/kg).

In muscle residue were < 0.01 mg/kg at the 20 ppm level and up to 0.012 mg/kg (mean: 0.011 mg/kg) at the 100 ppm level.

In liver at the 20 and 100 ppm feeding levels, residues were up to 0.079 mg/kg (mean 0.055 mg/kg) and 0.35 mg/kg (mean: 0.29 mg/kg), respectively.

In kidney at the 20 and 100 ppm feeding levels, residues were up to 0.082 mg/kg (mean 0.062 mg/kg) and 0.29 mg/kg (mean: 0.27 mg/kg), respectively.

In fat at the 20 and 100 ppm feeding levels, residues were up to 0.011 mg/kg (mean 0.01 mg/kg) and 0.033 mg/kg (mean: 0.032 mg/kg), respectively.

Estimated maximum and mean dietary burdens of farm animals

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

Previous evaluations included the following potential feed items: rape greens, potato culls, cereal grain, dry beans, apple pomace, rape seed meal, sweet corn cannery waste, cotton meal and tomato pomace. Feed items from this evaluation were additionally cabbage, kale, carrot, dry pea and soya bean.

	Livestock dietary burden, Fludioxonil, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max.	Mean	max.	mean	max.	Mean	max.	Mean
Beef cattle	5.2	3.1	15	5.3	6.3	5.6	0.023	0.023
Dairy cattle	2.3	1.6	15	4.6	23[a]	6.4[b]	0.023	0.023
Poultry – broiler	0.029	0.029	1.5	0.78	0.042	0.042	0.023	0.023
Poultry – layer	0.029	0.029	1.9[c]	0.86[d]	0.042	0.042	0.023	0.023

[a] Highest maximum beef or dairy cattle burden suitable for maximum reside level estimates for mammalian tissues and milk

[b] Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian tissues and milk

[c] Highest maximum broiler or laying hen burden suitable for maximum reside level estimates for poultry products and eggs

[d] Highest mean broiler or laying hen burden suitable for STMR estimates for poultry products and eggs

For beef and dairy cattle, a maximum and mean dietary burden of 23 ppm and 6.4 ppm were estimated, respectively.

For maximum residue level estimation, residues were calculated by interpolating between the 20 and 100 ppm dosing levels in the lactating cow feeding study using the maximum dietary burden of 23 ppm.

Maximum residue level beef or dairy cattle	Feed level (ppm) for milk residues	Total residue in milk (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	20	0.030	20	0.079	0.082	< 0.01	0.011
	100	0.15	100	0.35	0.29	0.012	0.033
Dietary burden and highest residue	23	0.035	23	0.089	0.090	0.010	0.012

For the estimation of STMRs the mean dietary burden of 6.4 ppm was used. Although in the previously evaluated feeding study, performed at 5.5 ppm (JMPR 2004) residues were consistently <LOQ (< 0.05 mg/kg), the Meeting decided to extrapolate from the 20 ppm feeding level of the new study, since residues were found.

STMR beef or dairy cattle	Feed level (ppm) for milk residues	Total residue in milk (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	20	0.026	20	0.055	0.062	< 0.01	0.01
Dietary burden and mean residue	6.4	0.008	6.4	0.018	0.020	< 0.01	0.003

Animal commodity maximum residue levels

The Meeting recommended a maximum residue level for milks at 0.04 mg/kg, edible offal (mammalian) at 0.1 mg/kg, mammalian muscle (fat) at 0.02 mg/kg and mammalian fats at 0.02 mg/kg, withdrawing the previous recommendations of 0.05(*) mg/kg for edible offal (mammalian), 0.01 mg/kg for milks and 0.01 mg/kg for meat.

The Meeting estimated STMR values of 0.008 mg/kg in milks, 0.01 mg/kg in muscle, 0.003 mg/kg in fat and 0.020 mg/kg in edible offal (mammalian).

For poultry a maximum and mean dietary burden of 1.9 ppm and 0.86 ppm were estimated, respectively. A feeding study performed with poultry at dosing levels of 1.54, 4.64 and 15.4 ppm was evaluated by the 2013 JMPR. In the relevant dosing group of 1.54 ppm liver samples showed residues of fludioxonil at up to 0.08 mg/kg (mean: 0.05 mg/kg). Other tissues from animals in the 1.54 ppm dose group were not analysed since samples were <LOQ at the higher feeding levels.

For maximum residue level estimation, residues were calculated by interpolating between the 1.54 and 4.64 ppm dosing levels using the maximum dietary burden of 1.9 ppm.

Maximum residue level broiler or layer poultry	Feed level (ppm) for egg residues	Total residue in egg (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)		
				Liver	Muscle	Fat
Feeding study	1.54	< 0.01	1.54	0.080	< 0.01	< 0.01
	4.64	0.013	4.64	0.21	< 0.01	< 0.01
Dietary burden and highest residue	1.9	0.011	1.9	0.095	< 0.01	< 0.01

For the estimation of STMR values for eggs and poultry tissues, the mean dietary burden of 0.86 mg/kg was used and residues estimated by extrapolating from the 1.54 ppm feeding level of the previously submitted poultry feeding study (JMPR, 2013).

STMR broiler or layer poultry	Feed level (ppm) for egg residues	Total residue in egg (mg/kg)	Feed level (ppm) for tissue residues	Total residue of fludioxonil (mg/kg)		
				Liver	Muscle	Fat
Feeding study	1.54	< 0.01	1.54	0.050	< 0.01	< 0.01
Dietary burden and mean residue	0.86	< 0.01	0.86	0.028	< 0.01	< 0.01

The Meeting recommended a maximum residue level of 0.02 mg/kg for eggs and 0.1 mg/kg for poultry edible offal, withdrawing the previous recommendation of 0.01(*) mg/kg for eggs and 0.05 mg/kg for poultry edible offal. The Meeting also recommended a maximum residue level of 0.01(*) mg/kg for poultry fat and confirmed its previous recommendations of 0.01(*) mg/kg for poultry meat.

The Meeting estimated a STMR value of 0.028 mg/kg in poultry edible offal and 0.01 mg/kg for eggs and confirmed the previously estimated STMR values of 0 mg/kg for poultry meat and fat.

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 compliance with the MRL and for dietary risk assessment for plant commodities: *fludioxonil*.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil.

The residue is fat-soluble.

Commodity		MRL, mg/kg		STMR or STMR-P, mg/kg	HR or highest residue, mg/kg
CCN	Name	New	Previous		
FI 0326	Avocado	1.5	0.4	0.01	-
FB 0020	Blueberries	2	2	0.6	-
VA 2031	Bulb onions, Subgroup of (includes all commodities in this subgroup)	0.5	-	0.04	-
VB 0041	Cabbages, head	0.7	0.7	0.24	-
VR 0577	Carrot	1	0.7	0.19	-
VS 0624	Celery	15	-	4.55	-
VD 0524	Chick-pea (dry)	0.3	-	0.11	-
FB 0021	Currants, Black, Red, White	3	-	0.62	-
MO 0105	Edible offal (Mammalian)	0.1	0.05*	0.02	-
PE 0112	Eggs	0.02	0.01*	0.01	-
VA 2032	Green onion, Subgroup of (includes all commodities in this subgroup)	0.8	-	0.14	-
FT 0336	Guava	0.5	-	0.125	-
VL 0054	Leaves of Brassicaceae, subgroup of (includes all commodities in this subgroup)	15	-	1.2	-
VD 0533	Lentils	0.3	-	0.11	-
MF 0100	Mammalian fats (except milk fats)	0.02	-	0.003	-
MM 0095	Meat (from mammals other than marine mammals)	0.02 (fat)	0.01	0.01	-
ML 0106	Milks	0.04	0.01	0.008	-
VL 0485	Mustard greens	W	10		-
VA 0385	Onion, bulb	W	0.5		-
FI 0353	Pineapple	5 Po	-	2	-
FI 0355	Pomegranate	3 Po	2	1.75	-
PF 0111	Poultry fats	0.01*	-	0	-
PM 0110	Poultry meat	0.01*	0.01*	0	-
PO 0111	Poultry, edible offal of	0.1	0.05	0.028	-
VD 0541	Soya bean (dry)	0.2	-	0.01	-
					-
	Carrots (canned)			0.027	-
	Carrots (cooked)			0.023	-
	Carrot Juice (pasteurised)			0.034	

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for fludioxonil is 0–0.4 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fludioxonil were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged from 1–6% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of fludioxonil from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2004 JMPR decided that an ARfD for fludioxonil was unnecessary. The current Meeting therefore concluded that the acute dietary exposure to residues of fludioxonil from the uses considered is unlikely to present a public health concern.

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