SPIROTETRAMAT (234)

The first draft was prepared by Professor Mi-Gyung Lee, Andong National University Republic of Korea

EXPLANATION

Spirotetramat was evaluated by the JMPR in 2008 for the first time for toxicology and residues. The Meeting derived an ADI of 0–0.05 mg/kg bw and an ARfD of 1.0 mg/kg bw and recommended maximum residue levels for a range of crops. In 2011 and 2012, the JMPR recommended additional MRLs. The compound was again listed by the Forty-fourth Session of CCPR for the evaluation of 2013 JMPR for additional MRLs.

Residue definitions established by the 2008 JMPR are:

- For compliance with the MRL for plant commodities: *spirotetramat plus spirotetramat enol, expressed as spirotetramat*.
- For dietary intake estimation for plant commodities: *spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat*.
- For compliance with the MRL and for dietary intake estimation for animal commodities: *spirotetramat enol, expressed as spirotetramat*.

The residue is not fat soluble.

The present Meeting received supervised field trial data for berries and other small fruits (blueberries and cranberries), assorted tropical and sub-tropical fruits (bananas, pineapples and pomegranates), bulb vegetables (bulb onions and spring onions), watercress, globe artichokes and coffee beans. Information on analytical methods, storage stability testing results (bananas and coffee) and residue levels in processed products (pineapple juice and process residue, roasted bean coffee and freeze-dried coffee) was also received.

METHODS OF RESIDUE ANALYSIS

Analytical methods

The Meeting received information on analytical methods used for the determination of spirotetramat and its major metabolites in the submitted residues trials. In all trials, method 00857 (Shöning *et. al.,* 2005) or modified 00857 (Coopersmith, 2009) was used as a reference method. These methods are based on LC-MS/MS using isotopically labelled internal standards. Method 00857 was previously reported and evaluated by the 2008 and 2011 JMPR.

Further modifications of the reference method were made and applied to determine spirotetramat, the metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside (enol-Glc) in blueberries, cranberries, bananas, pineapples (including juice and processing residues), pomegranates, blub onions, spring onions, watercress, globe artichokes and coffee beans (including roasted beans and freeze-dried coffee). Residues in samples were extracted with 0.22 mL of formic acid (88%) or 0.20 mL formic acid (98%) in 4:1 acetonitrile:water. The extract was filtered (using Celite or polyethylene frit) or non-filtered (pineapple juice) and cleaned up with C18 SPE cartridge or in tandem with an Envi-Carb SPE (or HLB SPE). Quantitation was made by LC-MS/MS. Conversion factors to parent equivalents were used as follows: enol, $\times$1.239; ketohydroxy, $\times$1.177; monohydroxy, $\times$1.231; and enol-glucoside, $\times$0.806.

Except in some cases (enol-Glc in roasted coffee beans and all analytes in freeze-dried coffee), recovery tests for all analytes in all matrices were conducted at the fortification levels of $\geqslant$ 0.01 mg/kg (as parent equivalents). With the exception of enol-Glc in pineapple juice and the process residues, the recoveries were within 70–120% (RSD below 20%) and the limits of

quantitation were 0.01 mg/kg (as parent equivalents) for each analyte and 0.05 mg/kg for total spirotetramat equivalents. The average recoveries of enol-Glc in pineapple juice and process residues were 134% (range, 98–161%) and 137% (range, 102–159%), respectively, at the fortification levels of 0.01 mg/kg, therefore the method was not considered suitable for the pineapple products.

For enol-Glc in roasted coffee beans, recovery tests were conducted at the fortification levels of ≥ 0.05 mg/kg (as parent equivalents). The average recovery was 98% (range, 82–121%) and the limit of quantification was 0.05 mg/kg.

In recovery tests for each analyte (parent and four metabolites) in freeze-dried coffee, the lowest spiking level was 0.1 mg/kg (as parent equivalents). Some recoveries of parent and enol-Glc were 50, 59 and 67%, and 130, 133 and 139%, respectively, at the fortification level. Overall, the method performance was not considered acceptable.

Results of the method validation and procedural recoveries for commodities for which residues trials are reported are summarized in Table 1.

Table 1 Recovery percentage of spirotetramat and its metabolites obtained with method 00857

Sample	Analyte	Fortification, mg/kg	No.	Range of recoveries, %	Mean recovery, %	Recovery, SD
Blueberries	Spirotetramat	0.01–1.0	15	93–103	99	3
	Enol	0.01–1.0	15	86–103	96	6
	Ketohydroxy	0.01–1.0	15	80–97	86	10
	Monohydroxy	0.01–1.0	15	85–109	95	6
	Enol-Glc	0.01–1.0	15	93–106	99	4
Cranberry	Spirotetramat	0.01–0.50	12	89–103	97	4
	Enol	0.01–0.50	12	91–107	99	5
	Ketohydroxy	0.01–0.50	12	74–91	85	6
	Monohydroxy	0.01–0.50	12	95–111	101	5
	Enol-Glc	0.0–0.50	12	91–101	95	3
Banana ,with peel	Spirotetramat	0.01–5.0	16	79–101	91	6
	Enol	0.01–5.0	16	79–101	92	7
	Ketohydroxy	0.01–5.0	16	80–106	95	6
	Monohydroxy	0.01–5.0	16	88–106	97	5
	Enol-Glc	0.01–5.0	16	76–115, 122	95	12
Banana ,without peel	Spirotetramat	0.01–5.0	15	82–105	94	7
	Enol	0.01–5.0	15	79–104	94	8
	Ketohydroxy	0.01–5.0	15	93–108	98	5
	Monohydroxy	0.01–5.0	15	84–110	100	8
	Enol-Glc	0.01–5.0	14	71–122	95	15
Pineapple	Spirotetramat	0.01	6	95–108	99	5
		0.1	3	99–102	101	2
		1.0	5	101–105	103	2
	Enol	0.01	6	95–98	96	1
		0.1	3	96–101	99	3
		1.0	5	74–95	87	10
	Ketohydroxy	0.01	6	89–115	97	10
		0.1	3	92–99	95	4
		1.0	5	101–111	105	4
	Monohydroxy	0.01	6	86–97	91	4
		0.1	3	101–103	102	1
		1.0	5	85–103	98	7
	Enol-Glc	0.01	6	64, 93–120	100	20
		0.1	3	86–99	93	7
		1.0	5	77–106	96	11
Pineapple, juice	Spirotetramat	0.01	6	93–111	102	9
		0.1	3	99–100	100	1
		1.0	4	101–105	104	2
	Enol	0.01	6	88–102	96	5
		0.1	3	97–99	98	1
		1.0	4	81–94	89	5

Sample	Analyte	Fortification, mg/kg	No.	Range of recoveries, %	Mean recovery, %	Recovery, SD
	Ketohydroxy	0.01	6	81–101	91	7
		0.1	3	100–106	103	3
		1.0	4	93–109	104	7
	Monohydroxy	0.01	6	84–115	96	15
		0.1	3	96–104	101	4
		1.0	4	92–105	98	6
	Enol-Glc	0.01	6	98–116, 138, 143, 149, 161	134	23
		0.1	3	100–111	107	6
		1.0	4	88–97	92	4
Pineapple, process residue	Spirotetramat	0.01	6	87–100	91	5
		0.1	3	92–100	97	4
		1.0	4	97–101	100	2
	Enol	0.01	6	86–101	92	6
		0.1	3	93–95	94	1
		1.0	4	86–87	87	1
	Ketohydroxy	0.01	6	88–100	91	5
		0.1	3	93–96	95	2
		1.0	4	100–106	103	3
	Monohydroxy	0.01	6	89–101	94	4
		0.1	3	94–97	96	2
		1.0	4	96–105	100	4
	Enol-Glc	0.01	6	102, 129, 134, 138, 157, 159	137	21
		0.1	3	100–106	104	3
		1.0	4	80–105	95	11
Pomegranate	Spirotetramat	0.01–2.0	14	93–102	98	3
	Enol	0.01–2.0	14	74–107	92	10
	Ketohydroxy	0.01–2.0	14	73–107	92	11
	Monohydroxy	0.01–2.0	14	87–110	98	7
	Enol-Glc	0.01–2.0	14	70–111	98	12
Bulb onion	Spirotetramat	0.01–1.0	12	85–97	93	3
	Enol	0.01–1.0	12	86–97	92	4
	Ketohydroxy	0.01–1.0	12	85–101	93	4
	Monohydroxy	0.01–1.0	12	78–101	89	7
	Enol-Glc	0.01–1.0	12	89–115	97	7
Spring onion	Spirotetramat	0.01–0.5	12	91–97	94	2
	Enol	0.01–0.5	12	71–96	80	10
	Ketohydroxy	0.01–0.5	12	71–93	82	8
	Monohydroxy	0.01–0.5	12	91–100	95	3
	Enol-Glc	0.01–0.5	12	92–101	96	3
Watercress	Spirotetramat	0.01	9	88–100	92	5
		0.1	5	90–97	93	3
		1	3	94–99	97	3
	Enol	0.01	9	87–104	94	6
		0.1	5	85–95	91	5
		1	3	92–96	94	3
	Ketohydroxy	0.01	9	78–92	88	4
		0.1	5	93–100	95	3
		1	3	96–105	100	5
	Monohydroxy	0.01	9	84–106	93	8
		0.1	5	83–97	92	6
		1	3	90–97	94	4
	Enol-Glc	0.01	6	76–103	89	10
		0.1	5	84–92	87	3
		1	3	88–91	88	3
Artichoke, globe	Spirotetramat	0.01–0.5	12	91–95	92	1
	Enol	0.01–0.5	12	91–102	98	4
	Ketohydroxy	0.01–0.5	12	91–105	97	4

Sample	Analyte	Fortification, mg/kg	No.	Range of recoveries, %	Mean recovery, %	Recovery, SD
	Monohydroxy	0.01–0.5	12	99–110	103	3
	Enol-Glc	0.01–0.5	12	87–106	97	5
Green bean coffee	Spirotetramat	0.01–1.0	19	86–94	91	2
	Enol	0.01–1.0	19	72–94	85	7
	Ketohydroxy	0.01–1.0	19	78–92	87	4
	Monohydroxy	0.01–1.0	19	70–97	87	6
	Enol-Glc	0.01–1.0	19	74–113	91	10
Roasted coffee bean	Spirotetramat	0.01–1.0	18	72–92	84	7
	Enol	0.01–1.0	18	76–103	89	9
	Ketohydroxy	0.01–1.0	18	75–111, 135	93	14
	Monohydroxy	0.01–1.0	18	61, 80–105	88	10
	Enol-Glc	0.05–1.0	15	82–121	98	11
Freeze-dried coffee	Spirotetramat	0.1–1.0	15	50[a], 59[a], 67[a], 71–98	80	14
	Enol	0.1–1.0	15	70–120, 132	109	16
	Ketohydroxy	0.1–1.0	15	66–122	101	15
	Monohydroxy	0.1–1.0	15	77–116	91	12
	Enol-Glc	0.1–1.0	15	70–118, 130[a], 133[a], 139[a]	103	20

Method 00857 (Shöning *et al.,* 2005; Coopersmith, 2009) was further modified for matrices.

For bananas, pineapples, pomegranates, watercress and coffee beans, concurrent recoveries were included.

[a] Recoveries at fortification levels of 0.1 mg/kg.

Stability of residues in stored analytical samples

Storage stability studies were performed on bananas with peel, peeled bananas, green bean coffee, roasted coffee bean and freeze-dried coffee for days 771, 770, 418, 438 and 448, respectively. Actual storage periods of the samples are shown in Table 2. For others, storage periods were as follows: blueberries - 587 days, cranberries - 483 days, pineapples without crown/juice/process residues - 179/119/114 days, pomegranates - 412 days, bulb onions - 434 days, spring onions - 550 days, watercress - 472 days and globe artichokes - 500 days.

As shown in Table 2, the results demonstrated that the residues in the samples are stable for the testing period. In addition, the 2008 JMPR reported frozen storage (-18 °C) stabilities of spirotetramat and its metabolites up to 2 years on various plant commodities. These cover storage stability for the samples in this evaluation.

Table 2 Storage stability of spirotetramat and its metabolites in banana and coffee

Crop	Analyte	Fortification level, mg/kg	Days of storage testing	Actual storage days	Remaining, %	Average spirotetramat equivalents [a] mg/kg
Banana with peel	Spirotetramat	0.1	771	363	0, 0, 0	
	Enol	0.1	771	363	137, 137, 144	0.0487
	Ketohydroxy	0.1	771	363	141, 129, 128	0.033
	Monohydroxy	0.1	771	363	124, 119, 127	0.0287
	Enol-Glc	0.1	771	363	101, 93, 98	< 0.01
Banana, peeled	Spirotetramat	0.1	770	357	0, 0, 0	
	Enol	0.1	770	357	95, 89, 117	< 0.01
	Ketohydroxy	0.1	770	357	151, 164, 161	0.0693
	Monohydroxy	0.1	770	357	133, 120, 133	0.0353
	Enol-Glc	0.1	770	357	100, 108, 108	< 0.01
Green bean coffee	Spirotetramat	1.0	418	355	78, 80, 81	
	Enol	1.0	418	355	68, 73, 74	< 0.01
	Ketohydroxy	1.0	418	355	69, 78, 80	< 0.01
	Monohydroxy	1.0	418	355	97, 1104, 107	< 0.01
	Enol-Glc	1.0	418	355	82, 85, 88	< 0.01

Crop	Analyte	Fortification level, mg/kg	Days of storage testing	Actual storage days	Remaining, %	Average spirotetramat equivalents [a] mg/kg
Roasted coffee bean	Spirotetramat	1.0	438	181	67, 66, 64	
	Enol	1.0	438	181	93, 94, 87	< 0.01
	Ketohydroxy	1.0	438	181	79, 67, 64	< 0.01
	Monohydroxy	1.0	438	181	96, 94, 91	< 0.01
	Enol-Glc	1.0	438	181	104, 89, 100	< 0.05
Freeze-dried coffee	Spirotetramat	1.0	448	174	52, 55, 51	
	Enol	1.0	448	174	117, 113, 120	0.211
	Ketohydroxy	1.0	448	174	95, 87, 81	< 0.1
	Monohydroxy	1.0	448	174	112, 90, 115	0.0738
	Enol-Glc	1.0	448	174	82, 76, 100	< 1

[a] Spirotetramat converted to its metabolites after fortification.

USE PATTERN

Spirotetramat is a systemic insecticide used for the control of a broad spectrum of sucking insects. The authorized uses of spirotetramat on crops, submitted for evaluation by the present JMPR, are summarized in Table 3.

Table 3 Registered use of spirotetramat 240 SC formulation on some crops

Crop	Country	Application [a]			PHI, days
		Rate, kg ai/ha	Interval, days	Total/season, kg ai/ha	
Bush berry (blueberries) and low growing berry (cranberry) [b]	Canada	0.053–0.20	7	0.44	7
Banana and plantain	USA	0.18–0.28	14	1.4	1
Pineapple	USA	0.18	14	0.36	1
Pomegranate	USA	0.15–0.18	14	0.36 per 12-month period	1
Bulb vegetables (bulb onion)	USA	0.090	7	0.18	3
Bulb vegetables (spring onion)	USA	0.090	7	0.18	7
Watercress	USA	0.067–0.22	7	0.45	3
Artichoke, globe	USA	0.090–0.15	7	0.56	3
Coffee	USA	0.15–0.18	21	0.53	14

[a] The spirotetramat 240 SC, w/w, 22.4% (240 g/L) formulation must be tank-mixed with a spray adjuvant /additive.

In trees, tropical and vine crops, minimum application volumes of water are 470 L/ha for conventional ground airblast sprayer, 280 L/ha for high air velocity, low volume or air curtain sprayers and 94 L/ha for aerial application.

In vegetable and potato crops, minimum application volumes of water are 140 L/ha by ground and 47 L/ha by aerial application. The formulation may also be applied through overhead irrigation systems. If needed, repeat application at a 7- to 10 day interval.

[b] Usage is registered as 220–585 mL/ha/application and 1.833 L/ha/crop season.

Apply 200–3000 L total volume/ha by ground. For chemigation (cranberry only), the higher rate of the 240 SC formulation and a maximum spray volume of 3000 L total volume are recommend.

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Supervised residue trials were conducted in the USA and Canada according to GLP principles under IR-4 programmes of the USA. The results of the supervised trials are shown in the following tables:

Crop group	Commodity	Table No.
Berries and other small fruits	Blueberries	4
	Cranberry	5
Assorted tropical and sub-tropical fruits—inedible peel	Banana	6
	Pineapple	7

Crop group	Commodity	Table No.
	Pomegranate	8
Bulb vegetables	Onion, bulb	9
	Spring onion	10
Leafy vegetables (including Brassica leafy vegetables)	Watercress	11
Stalk and stem vegetables	Artichoke, globe	12
Seed for beverages and sweets	Coffee beans	13

Where two replicate field samples were taken and residues were determined in each, a mean value was calculated for estimating a maximum residue level. From trials carried out side-by-side, the higher residue was chosen.

Total spirotetramat equivalents are the sum of all components converted to spirotetramat equivalents by multiplying by the following conversion factors: enol ×1.239, ketohydroxy ×1.177, monohydroxy ×1.231 and enol-glucoside ×0.806. Where a component is reported as <'value', the <'value' is added into the calculation of the total equivalents. The following example illustrates this.

Residues as spirotetramat equivalents (mg/kg)

Spirotetramat	enol	keto-hydroxy	mono-hydroxy	enol-glucoside	total residue	Spirotetramat + enol
0.15	0.30	< 0.012	< 0.012	< 0.008	0.48	0.45
0.55	0.68	0.012	0.022	0.010	1.3	1.2
< 0.01	< 0.012	< 0.012	< 0.012	< 0.008	< 0.055	< 0.022

Berries and other small fruits

Blueberries

Eleven residue trials were conducted in the USA (seven trials) and Canada (four trials) during the 2009 growing season. Four trials were conducted on low-bush blueberries and seven trials were conducted on high-bush blueberries. Spirotetramat 240 SC (240 g/L) was applied to blueberry as three foliar applications ranging from 0.17–0.19 kg ai/ha, with re-treatment intervals of 5 to 8 days. The total seasonal application rate ranged from 0.52 to 0.56 kg ai/ha. A non-ionic surfactant was included in the spray mixtures at 0.25% with the exception of Trial ID#132 (non-ionic surfactant of 1%) and the spray volume of 115–573 L/ha was used. The blueberry samples were harvested 6 to 8 days after the final application. One decline trial was conducted, with blueberry samples harvested at 1, 3, 7, and 10 days after the last application, to assess the decline in potential residues over time.

Table 4 Spirotetramat and its metabolites in blueberries from 240 SC foliar applications in the USA and Canada (IR-4 PR No. 10194)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, Canada	0.20		7	0.44	7							
Sainte-Anne-de-Kent, NB, Canada 2009	0.17 –0.18	3	5–8	0.52	8	0.33 0.30 **0.31** (mean)	0.37 0.37 **0.37**	0.39 0.37 **0.38**	0.11 0.11 **0.11**	0.035 0.033 **0.034**	1.2 1.2 **1.2**	**0.68**

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
(Lowbush, Wild type) Trial ID #131												
Jonesboro, ME , USA 2009 (Lowbush, Wild type) Trial ID #132	0.17–0.18	3	6–7	0.52	7	0.10 0.16 **0.13**	0.19 0.29 **0.24**	0.21 0.21 **0.21**	0.044 0.075 **0.060**	0.011 0.021 **0.016**	0.56 0.76 **0.66**	**0.37**
Chatsworth, NJ, USA 2009 (Highbush, Bluecrop) Trial ID #133	0.17–0.18	3	7	0.53	7	0.24 0.27 **0.25**	0.067 0.050 **0.059**	0.11 0.10 **0.11**	0.019 0.019 **0.019**	< 0.01 < 0.01 **< 0.01**	0.45 0.45 **0.45**	**0.31**
Sheffield Mills, NS, Canada 2009 (Lowbush, Wild type) Trial ID #134	0.17–0.18	3	7	0.53	1	0.065 0.061 **0.063**	0.27 0.26 **0.27**	0.18 0.19 **0.19**	0.038 0.050 **0.044**	< 0.01 < 0.01 **< 0.01**	0.56 0.56 **0.56**	**0.33**
					3	0.041 0.034 **0.038**	0.21 0.20 **0.21**	0.18 0.19 **0.19**	0.053 0.045 **0.049**	< 0.01 < 0.01 **< 0.01**	0.49 0.48 **0.49**	**0.25**
					7	0.042 0.029 **0.036**	0.092 0.12 **0.11**	0.21 0.17 **0.19**	0.033 0.040 **0.037**	< 0.01 < 0.01 **< 0.01**	0.38 0.38 **0.38**	**0.14**
					10	0.025 0.031 **0.028**	0.096 0.094 **0.095**	0.18 0.17 **0.18**	0.051 0.046 **0.049**	0.015 0.013 **0.014**	0.36 0.36 **0.36**	**0.12**
Rawdon Gold Mines, NS, Canada 2009 (Lowbush, Wild type) Trial ID #135	0.17–0.18	3	6–7	0.52	7	0.083 0.073 **0.078**	0.082 0.095 **0.089**	0.21 0.22 **0.21**	0.046 0.050 **0.048**	0.011 0.012 **0.012**	0.43 0.45 **0.44**	**0.17**
Fennville, MI, USA 2009 (Highbush, Rubel) Trial ID #136 [b]	0.18	3	7	0.54	7	0.27 0.18 **0.23**	0.071 0.060 **0.066**	0.17 0.14 **0.15**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.53 0.40 **0.46**	**0.30**
Fennville, MI, USA 2009 (Highbush, Rubel) Trial ID #137 [b]	0.18	3	7	0.54	7	0.44 0.47 **0.46**	0.067 0.064 **0.066**	0.15 0.14 **0.14**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.68 0.70 **0.69**	**0.53**

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
Jordan Station, ON, Canada 2009 (Highbush, Patriot) Trial ID #138	0.18	3	7	0.54	7	0.10 0.13 **0.12**	0.41 0.40 **0.41**	0.82 0.82 **0.82**	0.17 0.17 **0.17**	0.036 0.040 **0.038**	1.5 1.6 **1.6**	**0.53**
Aurora, OR, USA 2009 (Highbush, Bluecrop) Trial ID #139	0.18–0.19	3	7	0.56	7	0.33 0.50 **0.41**	0.28 0.28 **0.28**	0.25 0.26 **0.25**	0.094 0.097 **0.096**	0.026 0.029 **0.028**	1.0 1.2 **1.1**	**0.69**
Castle Hayne, NC, USA 2009 (Highbush, Croatan) Trial ID #140	0.17–0.18	3	7–8	0.52	6	0.08 0.11 **0.10**	0.098 0.12 **0.11**	0.21 0.25 **0.23**	0.030 0.041 **0.036**	0.014 0.020 **0.017**	0.43 0.54 **0.49**	**0.21**
Castle Hayne, NC, USA 2009 (Highbush, Summit) Trial ID#141	0.17–0.18	3	7	0.53	6	0.30 0.28 **0.29**	0.097 0.097 **0.097**	0.18 0.18 **0.18**	0.027 0.023 **0.025**	< 0.01 0.011 **0.011**	0.61 0.59 **0.60**	**0.39**

[a] Mean value of residues is expressed in bold

[b] The two trials were conducted at the same site with the same variety, on 1st application 8 days apart, thus they were not independent.

Cranberry

Six trials were conducted in the USA (five trials) and Canada (one trial) during the 2009 growing season. Five trials were conducted in the US and one trial in Canada. Spirotetramat 240 SC formulation was applied to cranberries as three foliar applications ranging from 0.17 to 0.19 kg ai/ha, with re-treatment intervals of 6 to 8 days. The total seasonal application rate ranged from 0.52 to 0.55 kg ai/ha. A non-ionic surfactant was included in all spray mixtures at a rate of 0.25% and the spray volume of 240–555 L/ha was used. One decline trial was conducted, with cranberry samples harvested at 1, 4, 7 and 11 days after the last application, to assess the decline in potential residues over time.

Table 5 Spirotetramat and its metabolites in cranberry from 240 SC foliar applications in the USA and Canada (IR-4 PR No. 10198)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, Canada	0.20		7	0.44	**7**							
Chatsworth, NJ, USA 2009 (Early Black) Trial ID#143 [b]	0.17–0.18	3	7	0.53	7	0.014 0.016 **0.015**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.054 0.056 **0.055**	**0.025**
Plymouth, MA, USA 2009 (Stevens) Trial ID#144	0.17–0.18	3	7–8	0.53	7	0.036 0.033 **0.035**	0.011 0.011 **0.011**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.077 0.074 **0.076**	**0.046**
Warrens, WI, USA 2009 (Ben Lear) Trial ID#145	0.18	3	7–8	0.55	8	0.012 0.013 **0.013**	< 0.01 < 0.01 **< 0.01**	0.011 0.011 **0.011**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.053 0.054 **0.054**	**0.023**
Warrens, WI, USA 2009 (Stevens) Trial ID#146	0.18–0.19	3	7–8	0.55	7	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.05 < 0.05 **< 0.05**	**< 0.02**
Langley, BC, Canada 2009 (Stevens) Trial ID#14	0.18	3	7–8	0.54	1	0.23 0.28 **0.26**	0.042 0.043 **0.043**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.30 0.35 **0.33**	**0.30**
					4	0.24 0.21 **0.23**	0.048 0.045 **0.047**	0.024 0.027 **0.026**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.33 0.30 **0.32**	**0.28**
					7	0.077 0.084 **0.081**	0.040 0.039 **0.040**	0.015 < 0.01 **< 0.013**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.15 0.15 **0.15**	**0.12**
					11	0.057 0.067 **0.062**	0.038 0.037 **0.038**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.13 0.13 **0.13**	**0.10**
Langlois, OR, USA 2009 (Pilgrim) Trial ID#148	0.17	3	6–8	0.52	8	0.044 0.036 **0.040**	0.018 0.017 **0.018**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.092 0.083 **0.088**	**0.058**

[a] Mean value of residues expressed in bold

Assorted tropical and sub-tropical fruits - Inedible peel

Banana

Spirotetramat is used to control banana aphids (*Pentalonia nigronervosa*) in banana production. In Hawaii, USA, five trials (HI05, HI06, HI09, HI10 and HI14) were conducted during the 2008 and 2009 growing seasons. In each trial, the test substance (spirotetramat 240 SC) was applied in five foliar directed applications of approximately 0.28–0.30 kg ai/ha each, for a total of approximately 1.4–1.5 kg ai/ha. An organosilicone surfactant was included in each tank mix and the spray volume of approximately 500 L/ha was used.

The test substance was applied to bagged bunches in the HI05 trial. The bunches were not bagged in the other trials. All applications were made approximately 14 days apart and timed so that marketable-sized bananas could be collected 1 day after the final application. For decline determination, banana samples were collected additionally from HI14 trial at 3, 7, and 14 days after last application. In HI06 and HI10 trials, the bananas were cut in half lengthwise, retaining one half as samples for the banana fruit with peel samples. From the HI06 trial, the samples were additionally collected at 1-day PHI to determine residues in peeled fruits where a whole fruit was peeled and retained as a sample.

Table 6 Spirotetramat and its metabolites in banana from 240 SC foliar applications in the USA [a] (IR-4 PR No. 10042)

Location Year (Variety) Trial No.	Application				PHI (d)	Matrix	Residue (mg/kg) expressed as spirotetramat equivalents						
	kg ai/ha		Int. days	Total/ season, kg ai /ha			spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.28	1	14	1.4									
Hilo, HI 2008 (Williams) 08-HI05 [b]	0.28–0.30	1		1.5		Whole fruit	0.035 0.044 **0.040**	0.12 0.12 **0.12**	0.016 0.018 **0.017**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.20**	**0.16**
Waialua, HI 2009 (Williams) 08-HI06	0.28–0.29	5		1.4	1	Whole fruit	0.38 0.20 **0.29**	0.28 0.24 **0.26**	0.060 0.046 **0.053**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.62**	**0.55**
Waialua, HI 2009 (Williams) 08-HI06						Pulp	0.013 0.017 **0.015**	0.12 0.12 **0.12**	0.033 0.033 **0.033**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.19**	**0.14**
Waianae, HI 2009 (Brazilian Dwarf Apple) 08-HI09	0.28	5		1.4	1	Whole fruit	1.5 0.97 **1.2**	0.55 0.42 **0.49**	0.068 0.034 **0.051**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**1.8**	**1.7**
Hilo, HI 2009 (Williams) 08-HI10	0.28–0.29	5		1.4	1	Whole fruit	0.51 0.37 **0.44**	0.59 0.61 **0.60**	0.092 0.081 **0.087**	< 0.01 < 0.01 **< 0.01**	0.014 0.015 **0.015**	**1.2**	**1.0**
Waimanalo, HI 2009 (Dwarf Apple) 09-HI14	0.29–0.30	5		1.4	1	Whole fruit	0.97 1.3 **1.1**	0.21 0.30 **0.26**	0.035 0.061 **0.048**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**1.4**	**1.4**
					3	Whole fruit	0.88 1.0 **0.94**	0.19 0.32 **0.26**	0.056 0.102 **0.079**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**1.3**	**1.2**
					7	Whole fruit	0.27 0.28 **0.28**	0.16 0.15 **0.16**	0.040 0.035 **0.038**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.50**	**0.44**
					14	Whole fruit	0.50 0.35	0.093 0.10	0.114 0.058	< 0.01 < 0.01	< 0.01 < 0.01		

Location Year (Variety) Trial No.	Application				PHI (d)	Matrix	Residue (mg/kg) expressed as spirotetramat equivalents						
	kg ai/ha		Int. days	Total/ season, kg ai /ha			spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
							0.43	**0.097**	**0.086**	**< 0.01**	**< 0.01**	**0.63**	**0.53**

[a] Mean value of residues was expressed as a bold letter. Portion analysed was a whole banana with peel.

[b] Test substance was applied to bagged bunches. In the other trials, the bunches were not bagged.

Pineapple

Spirotetramat is needed to control grey mealybugs and pink mealybugs (vectors of pineapple mealybug wilt virus) in pineapple production. Five field trials (HI01-HI05) were conducted in Hawaii, USA during 2011. At each trial, two foliar broadcast applications of the test substance (spirotetramat 240 SC) 13–14 days apart were made. The application rates were in the range 0.17–0.18 kg ai/ha per application for a total rate range of 0.35–0.36 kg ai/ha per season. All applications were made using appropriate spray equipment with an adjuvant in the tank mix, and the spray volumes of 830–1900 L/ha were sufficient to provide adequate dispersal of the test substance.

At the HI02 trial, duplicate samples were collected 0, 3, 7, and 14 days after the last application. Additional samples taken from the HI01 trial were subjected to processing into pineapple juice and process residue.

HI01, HI02 and HI05 trials were conducted on different plantations at the same site with the same variety, the 1st application 36–106 days apart. HI03 and HI04 were also conducted on different plantations at the same site with the same variety, the 1st application 40 days apart. These five trials were considered as independent.

At all trials, samples were harvested one day after the last application. Crowns were removed from the sampled fruit and were cut into quarters longitudinally, retaining one quarter of each for the sample. In field site, sample size reduction should be avoided. These trials are not appropriate for evaluation.

Table 7 Spirotetramat and its metabolites in pineapple from 240 SC foliar applications in the USA (IR-4 PR No. 10635)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.18		14	0.36	1							
Wahiawa, HI 2011 (Tropical Gold, MG-3) HI01	0.17–0.18	2	14	0.36		0.038 0.045 **0.042**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.082**	**0.052**
Wahiawa, HI 2011 (Tropical Gold, MG-3) HI02	0.18	2	14	0.36	0	0.034 0.039 **0.037**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.077**	**0.047**
					1	0.015 0.013 **0.014**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.054**	**0.024**
					3	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.05**	**0.02**

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
					7	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.05**	**0.02**
					14	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.05**	**0.02**
Makawao, HI 2011 (Maui Gold) HI03	0.18	2	14	0.35	1	0.065 0.054 **0.060**	0.016 0.016 **0.016**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.11**	**0.076**
Makawao, HI 2011 (Maui Gold) HI04	0.18	2	14	0.36	1	0.023 0.017 **0.020**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.060**	**0.030**
Wahiawa, HI 2011 (Tropical Gold, MG-3) HI05	0.17–0.18	2	13	0.35	1	0.030 0.030 **0.030**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.070**	**0.040**

[a] Mean value of residues was expressed in bold. Portion analysed was fruit crown removed.

Pomegranate

Spirotetramat is used to control aphids, whiteflies, and grape mealybug in pomegranate production. In California, USA, four field trials were conducted during the 2009 growing season. In each trial, the test substance (spirotetramat 240 SC) was applied in two foliar directed applications of approximately 0.35–0.36 kg ai/ha each, for a total of approximately 0.17–0.18 kg ai/ha. An adjuvant was included in each tank mix and the spray volume of 550–1060 L/ha was applied. The applications were made 14 days apart and timed so that marketable-sized pomegranates could be collected 1 day after the final application. Additional samples for decline determination were collected from one trial, CA69 at 3, 7, and 14 days. Each fruit was cut into quarters, retaining opposite quarters as samples. Cutting of samples in field site was not appropriate.

Table 8 Spirotetramat and its metabolites in pomegranate from 240 SC foliar applications in the USA (IR-4 PR No. 10113)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.18		14	0.36 per 12-month	1							
Gridley, CA 2009 (Wonderful) 09-CA71 [b]	0.17–0.18	2	14	0.35	1	0.058 0.061 **0.060**	0.079 0.066 **0.073**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.024 0.019 **0.022**	**0.18**	**0.13**
Gridley, CA 2009 (Wonderful) 09-CA72 [b]	0.17–0.18	2	14	0.35	1	0.041 0.052 **0.047**	0.055 0.085 **0.070**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.018 0.021 **0.020**	**0.16**	**0.12**
Reedley, CA 2009 (Wonderful) 09-CA69 [c]	0.18	2	14	0.35	1	0.13 0.090 **0.11**	0.038 0.027 **0.033**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.011 < 0.01 **0.011**	**0.17**	**0.14**
					3	0.096	0.028	< 0.01	< 0.01	< 0.01		

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
						0.10 **0.098**	0.025 **0.027**	< 0.01 **< 0.01**	< 0.01 **< 0.01**	< 0.01 **< 0.01**	**0.16**	**0.13**
					7	0.10 0.075 **0.088**	0.025 0.020 **0.023**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.14**	**0.11**
					14	0.035 0.016 **0.026**	0.021 0.015 **0.018**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.013 < 0.01 **0.012**	**0.076**	**0.044**
Reedley, CA 2009 (Wonderful) 09-CA70 [c]	0.18	2	14	0.36	1	0.032 0.025 **0.029**	0.019 0.015 **0.017**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.076**	**0.046**

[a] Mean value of residues was expressed in bold

[b] The two trials were conducted at the same site with the same variety, on the same dates of application. Thus they were not independent.

[c] The two trials were conducted at the same site with the same soil type and maintenance, with the same variety, on 1st application 21 days apart. They were not considered as independent.

Bulb vegetables

Onion, bulb

Twelve field trials were conducted in Canada (four trials) and in the USA (eight trials) during 2008 and 2009 growing season. Two foliar broadcast applications of spirotetramat 240 SC formulation were made at a rate of application ranged from 0.084 to 0.094 kg ai/ha. The spray volumes ranged from approximately 205 to 533 L/ha and the PHI was 2 to 4 days, with a 6 to 8 day retreatment interval between applications. A non-ionic surfactant (Agral 90 or Dyne-Amic), at the target rate of 0.25% v/v in the spray mixture was included with each application. Two residue decline trials were conducted with samples collected at 1, 6–7, and 9–10 days after the last application, in addition to the samples collected at the target PHI of 3 to 4 days.

Table 9 Spirotetramat and its metabolites in bulb onion from 240 SC foliar applications in the USA and Canada (IR-4 PR No. 09983)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.09		7	0.18	3							
Delhi, ON, Canada 2008 (Nebula) #141	0.092–0.093	2	7	0.18	3	< 0.01 < 0.01 **< 0.01**	0.068 0.062 **0.065**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.11**	**0.075**
Delhi, ON, Canada 2008 (Milestone) #142	0.091–0.093	2	8	0.18	4	< 0.01 < 0.01 **< 0.01**	0.087 0.083 **0.085**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.13**	**0.095**
Sainte-Clotilde, QC, Canada 2008 (Hybrid Centennial) #143[b]	0.086–0.088	2	7	0.17	1	< 0.01 < 0.01 **< 0.01**	0.20 0.17 **0.19**	0.013 < 0.01 **0.012**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.23**	**0.20**
					3	< 0.01 < 0.01 **< 0.01**	0.22 0.21 **0.22**	0.014 0.013 **0.014**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.26**	**0.23**
					6	< 0.01 < 0.01	0.21 0.19	< 0.01 < 0.01	< 0.01 < 0.01	< 0.01 < 0.01		

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
						< 0.01	**0.20**	**< 0.01**	**< 0.01**	**< 0.01**	**0.24**	**0.21**
					9	< 0.01 < 0.01 **< 0.01**	0.22 0.21 **0.22**	0.014 < 0.01 **0.012**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.26**	**0.23**
Sainte-Clotilde, QC, Canada 2008 (Hybrid Champlain) #144[b]	0.084–0.094	2	7	0.18	**3**	< 0.01 < 0.01 **< 0.01**	0.24 0.30 **0.27**	0.014 0.016 **0.015**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.32**	**0.28**
Freeville, NY, USA 2008 (Patterson) #589	0.085–0.089	2	6	0.17	**2**	< 0.01 < 0.01 **< 0.01**	0.045 0.050 **0.048**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.088**	**0.058**
Arlington, WI, USA 2008 (Stutgard yellow) #590	0.090–0.094	2	7	0.18	**3**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**< 0.05**	**< 0.02**
Weslaco, TX, USA 2008 (Super Star F1) #591	0.091–0.090	2	7	0.18	**3**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**< 0.05**	**< 0.02**
Greeley, CO, USA 2008 (Talon, yellow) #592	0.094–0.092	2	6	0.19	1	< 0.01 < 0.01 **< 0.01**	0.032 0.033 **0.033**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.073**	**0.043**
					4	< 0.01 < 0.01 **< 0.01**	0.037 0.048 **0.043**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.083**	**0.053**
					7	< 0.01 < 0.01 **< 0.01**	0.051 **0.042** **0.047**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.087**	**0.057**
					10	< 0.01 < 0.01 **< 0.01**	0.037 0.046 **0.042**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.082**	**0.052**
Salem, OR, USA 2008 (Red Bull) #593	0.091	2	7	0.18	2	< 0.01 < 0.01 **< 0.01**	0.036 0.035 **0.036**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.076**	**0.046**
Holtville, CA, USA 2009 (Serengeti) #594	0.089–0.092	2	7	0.18	4	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**< 0.05**	**< 0.02**
Parlier, CA, USA 2008 (Candy) #595	0.092–0.093	2	7	0.18	3	< 0.01 < 0.01 **< 0.01**	0.041 0.041 **0.041**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.081**	**0.051**
Parma, ID, USA 2008 (Granero) #596	0.089–0.089	2	8	0.18	4	< 0.01 < 0.01 **< 0.01**	0.014 0.019 **0.016**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.056**	**0.026**

[a] Mean value of residues was expressed in bold

[b] The trials were conducted at the same site with the same variety, on the same dates of application.

Spring onion

Two field trials were conducted during the 2009 growing season in Ontario and Quebec of Canada. Spirotetramat 240 SC formulation was applied to green onions as two foliar applications ranging from 0.090 to 0.092 kg ai/ha each, with re-treatment intervals of six to seven days, for maximum seasonal rates of 0.18 kg ai/ha. A non-ionic surfactant was included at 0.25% in the spray mixtures and the spray volume of approximately 300 L/ha was applied. Samples were harvested 6 to 7 days after the final application. One decline trial was conducted with additional samples harvested at 1, 4, and 11

days following the last application to assess the decline pattern of spirotetramat and its metabolites residues.

Table 10 Spirotetramat and its metabolites in spring onion from 240 SC foliar applications in Canada (IR-4 PR No. 10942)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.09		7	0.18	7							
Harrow, ON 2009 (Emerald lsle) #113	0.090–0.091	2	7	0.18	1	0.24 0.27 **0.26**	0.26 0.35 **0.31**	0.12 0.11 **0.12**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.71	**0.57**
					4	0.14 0.16 **0.15**	0.20 0.18 **0.19**	0.080 0.084 **0.082**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.44	**0.34**
					6	0.098 0.099 0.096 0.10 **0.098**	0.13 0.12 0.16 0.15 **0.14**	0.075 0.056 0.064 0.063 **0.064**	< 0.01 < 0.01 < 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 < 0.01 < 0.01 **< 0.01**	**0.32**	**0.24**
					11	0.053 0.059 **0.056**	0.067 0.062 **0.065**	0.039 0.034 **0.037**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.18**	**0.12**
St-Jeansur-Richelieu, QC 2009 (Parade)	0.091–0.092	2	6	0.18	7	0.043 0.040 0.040 0.035 **0.039**	0.046 0.060 0.064 0.047 **0.054**	0.059 0.050 0.044 0.046 **0.050**	< 0.01 < 0.01 < 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 < 0.01 < 0.01 **< 0.01**	**0.16**	**0.093**

[a] Mean value of residues was expressed in bold

Leafy vegetables (including Brassica leafy vegetables)

Watercress

Three field trials were conducted in the USA (Florida and Maryland) during 2008 (Trial FL38, FL39, MD27). In the FL39 and MD27 trials, the plots received two applications of spirotetramat 240 SC formulation using conventional broadcast sprayers at the rate of 0.21–0.22 kg ai/ha. In the FL38 trial, additionally, two chemigation applications were made in the different plot using overhead mini-sprinklers at the rate of 0.22 kg ai/ha. The organo-silicone surfactant Dyne-Amic was used with all applications (except application 1 at the FL39 trial) at all the field trials. Applications of the test substance were made at 7–8 day intervals when the watercress was in the vegetative stage with the last application 3 days before the harvest. The foliage (leaves and stems) was cut with a knife/pruners and placed directly into sample bags. Samples were taken from at least 12 separate areas within each plot. For chemigation application of FL38 trial, half of each sample was taken from the plot area where the sprinkler spray overlapped and the other half was taken from areas where the spray did not overlap.

Table 11 Spirotetramat and its metabolites in watercress from 240 SC foliar applications in the USA (IR-4 PR No. 09948)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.22		7	0.45	3							
Fellsmere, FL 2008 (B&W 1)	0.22	2	8	0.44	3	< 0.01 < 0.01	0.13 0.14	0.077 0.083	< 0.01 < 0.01	< 0.01 < 0.01		

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
FL38[b]						**< 0.01**	**0.14**	**0.080**	**< 0.01**	**< 0.01**	**0.25**	**0.15**
						< 0.01 *< 0.01* ***< 0.01***	*0.25* *0.23* ***0.24***	*0.21* *0.18* ***0.20***	*< 0.01* *< 0.01* ***< 0.01***	*< 0.01* *< 0.01* ***< 0.01***	***0.47***	***0.25***
Fellsmere, FL 2008 (B&W 1) FL39[b]	0.22	2	7	0.44	3	0.044 0.054 **0.049**	0.19 0.22 **0.21**	0.21 0.24 **0.23**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.51**	**0.26**
Rocktown, MD 2008 (B&W 47)	0.21	2	7	0.42	3	0.014 0.016 **0.015**	0.27 0.33 **0.30**	0.22 0.22 **0.22**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.56**	**0.32**

[a] Mean value of residues was expressed in bold. Italic values mean residues from chemigation application using overhead mini-sprinklers.

[b] FL 38 trials using backpack sprayer and mini-sprinkler were conducted at the same site with the same variety on the same dates of application. FL38 and FL 39 trials were conducted at the same site and soil type with the same variety, on 1st application 13 days apart. These trials were not considered as independent.

Stalk and stem vegetables

Artichoke, globe

Five trials were conducted in the USA (three trials) and Canada (two trials) during the 2009 and 2010 growing season. Spirotetramat 240 SC formulation was applied to artichoke as four foliar applications ranging from 0.13 to 0.15 kg ai/ha, with re-treatment intervals of 5 to 9 days, and the last application timed for a 3 ± 1 day PHI. The total seasonal application rate ranged from 0.56 kg ai/ha. A non-ionic surfactant was included at 0.25% in the spray mixtures and the pray volumes ranged from 92 to 708 L/ha. The artichoke samples were harvested 2 to 3 days after the final application. One decline trial was conducted, with artichoke samples harvested at 1, 3, 7 and 10 days after the last application, to assess the potential decline in residues over time.

Table 12 Spirotetramat and its metabolites in globe artichoke from 240 SC foliar applications in the USA and Canada (IR-4 PR No. 10243)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.15		7	0.56	3							
L'Acadie QC, Canada 2009 (Imperial Star) #125	0.14	4	6-8	0.56	1	0.051 0.058 **0.055**	0.16 0.13 **0.15**	0.077 0.056 **0.067**	< 0.01 < 0.01 **< 0.01**	0.025 0.018 **0.022**	**0.30**	**0.21**
					3	0.020 0.012 **0.016**	0.11 0.11 **0.11**	0.073 0.066 **0.069**	< 0.01 < 0.01 **< 0.01**	0.027 0.024 **0.026**	**0.23**	**0.13**
					7	< 0.01 < 0.01 **< 0.01**	0.044 0.043 **0.044**	0.038 0.025 **0.032**	< 0.01 < 0.01 **< 0.01**	0.021 0.015 **0.018**	**0.11**	**0.054**
					10	< 0.01 < 0.01 **< 0.01**	0.025 0.022 **0.024**	0.028 0.016 **0.022**	< 0.01 < 0.01 **< 0.01**	0.021 0.011 **0.016**	**0.081**	**0.034**
Agassiz, BC, Canada 2010 (Imperial Star) #126	0.13-0.15	4	5-8	0.56	3	0.046 0.038 **0.042**	0.17 0.14 **0.16**	0.099 0.11 **0.10**	< 0.01 < 0.01 **< 0.01**	0.031 0.026 **0.028**	**0.34**	**0.20**

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
Castroville, CA, USA 2009 (F1 1855) #128	0.14	4	7-8	0.56	3	0.25 0.38 **0.31**	0.13 0.19 **0.16**	0.071 0.10 **0.087**	< 0.01 < 0.01 **< 0.01**	0.020 0.051 **0.035**	**0.60**	**0.47**
Marina, CA, USA 2009 (Green Globe) #129	0.14	4	6-8	0.56	3	0.052 0.074 **0.063**	0.21 0.21 **0.21**	0.095 0.095 **0.095**	< 0.01 < 0.01 **< 0.01**	0.033 0.033 **0.033**	**0.41**	**0.27**
Castroville, CA, USA 2009 (Green Globe) #130	0.14	4	6-9	0.56	2	0.28 0.28 **0.28**	0.23 0.19 **0.21**	0.19 0.14 **0.17**	< 0.01 < 0.01 **< 0.01**	0.042 0.026 **0.034**	**0.70**	**0.49**

[a] Mean value of residues was expressed as a bold letter.

Seed for beverages and sweets

Coffee beans

Spirotetramat is used to control green scale (*Coccus viridis*) in coffee production. Five field trials were conducted in Hawaii, USA during the 2009 growing season. In each trial, the test substance (spirotetramat 240 SC) was applied in three foliar directed applications of approximately 0.18–0.19 kg ai/ha each, for a total of approximately 0.54–0.57 kg ai/ha. An organosilicone surfactant was included in each tank mix and the spray volumes ranged from 240 to 470 L/ha.

The applications were made 20 to 22 days apart in HI09, HI10, and HI13 trials. The interval between the second and third application was shortened to 13 days and 7 days, respectively, in HI11 and HI12 because the beans were ripening earlier than expected. Ripe coffee bean "cherries" were collected 13 to 14 days after the final application in all but HI11, where samples were collected at 7 days HI11 because the crop was maturing faster than expected. Additional samples for decline determination were collected from HI13 at 1, 7, and 21 days.

At the field facility, the coffee bean cherries were run through a mechanical pulper and demusilager to remove the flesh from the bean. The beans were then dried in an oven at 50 °C for up to 2 days, hulled, and winnowed. The green bean coffee samples from HI12 were further processed into roasted coffee beans and freeze-dried coffee at a processing facility.

Table 13 Spirotetramat and its metabolites in coffee beans from 240 SC foliar applications in the USA (IR-4 PR No. 10041)

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
GAP, USA	0.18		21	0.53	14							
Kealakekua, HI 2009 (Guatemalan) 09-HI09[b]	0.18–0.19	3	21–22	0.56	13	< 0.01 < 0.01 **< 0.01**	0.033 0.022 **0.028**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.016 0.012 **0.014**	**0.072**	**0.038**
Lahaina, HI 2009 (Yellow Caturra) 09-HI10	0.18	3	20	0.54	14	< 0.01 < 0.01 **< 0.01**	0.025 0.016 **0.021**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.011 < 0.01 **0.011**	**0.062**	**0.031**
Kealakekua, HI 2009 (Guatemalan) 09-HI11 [b]	0.19	3	13 [c]–21	0.57	7[d]	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**< 0.05**	**< 0.02**

Location Year (Variety) Trial No.	Application				PHI (d)	Residue (mg/kg) expressed as spirotetramat equivalents [a]						
	kg ai/ha	n	Int. days	Total/ season, kg ai /ha		spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
Kauai, HI 2009 (Red Caturra) 09-HI12	0.18	3	7 [c]–21	0.54	14	< 0.01 < 0.01 **< 0.01**	0.012 < 0.01 **0.011**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.05**	**0.02**
Kauai, HI 2009 (Yellow Caturra) 09-HI13	0.18	3	20	0.54	1	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**< 0.05**	**< 0.02**
					7	< 0.01 < 0.01 **< 0.01**	0.012 < 0.01 **0.011**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	**0.051**	**0.021**
					14	< 0.01 < 0.01 **< 0.01**	0.020 < 0.01 **0.015**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.010 < 0.01 **0.010**	**0.055**	**0.025**
					21	< 0.01 < 0.01 **< 0.01**	0.021 0.015 **0.018**	< 0.01 < 0.01 **< 0.01**	< 0.01 < 0.01 **< 0.01**	0.011 < 0.01 **0.011**	**0.059**	**0.028**

[a] Mean value of residues was expressed in bold. Analysed sample is green bean coffee.

[b] Trials were conducted at the sites within 3 km with the same variety, 1st application 22 days apart. They were not considered as independent.

[c] Interval between the second and third application was shortened due to an earlier ripening of coffee beans.

[d] Harvested earlier due to the faster maturing of coffee beans.

FATE OF RESIDUES IN STORAGE AND PROCESSING+-

Magnitude of residue in processing

The Meeting received information on the residue levels on the processed products of pineapple and green bean coffee. They are summarized in Table 14.

Pineapple (juice and process residue)

One processing study for pineapple was carried out in Hawaii, USA (HI01, IR-4 PR No. 10635). The trial plot received two foliar broadcast applications with the test substance (spirotetramat 240 SC) 14 days apart. The application rates were in the range 0.17–0.18 kg ai/ha per application for a total rate range of 0.36 kg ai/ha per season. The spray solutions included adjuvant in the tank mix. The fruit samples were harvested one day after the last application.

Crowns were removed from the sampled fruit and the fruits without crown were processed into juice and process residue as follows. Both ends of the fruits were cut and peeled. The peeled fruit, scraped flesh from peels and end cuts were juiced using a commercial juicer. Juice and pulp were collected separately. Antifoam agent was added into the separated juice, mixed and heated in a water bath to 88 ℃. The juice was cooled to 8 ℃. For preparing process residue, the retained pineapple peels were chopped in a food cutter. Pulp left over from juicing was added and stirred to mix thoroughly. Juice and process residue samples were placed in the freezer until shipment to the residue laboratory.

From the results, processing factors for juice and process residue, based on total spirotetramat residues, could not be calculated as valid LOQ values at or below 0.01 mg/kg for enol glucoside were not provided.

Coffee beans (roasted coffee bean and freeze-dried coffee)

One processing study was conducted in Hawaii, USA (09-HI12, IR-4 PR No. 10041). Spirotetramat 240 SC formulation was applied in three foliar directed applications of approximately 0.18 kg ai/ha

each, for a total of approximately 0.54 kg ai/ha. An organosilicone surfactant was included in each tank mix. The applications were made 7 to 21 days apart and ripe coffee bean "cherries" were collected 14 days after the final application.

At the field facility, the coffee bean cherries were run through a mechanical pulper and demusilager to remove the flesh from the bean. The beans were then dried in an oven at 50 °C for up to 2 days, hulled, and winnowed. The green bean coffee (RAC) samples were further processed into roasted coffee beans and freeze-dried coffee at a processing facility.

The green beans were roasted to light to medium roast in the coffee roaster set at 208 ℃. The roasted beans were thoroughly mixed and a portion was moved to freezer storage. The remaining roasted beans were ground fine in a small burr grinder, added to boiling water, steeped at least 10 minutes brewing (1600 g ground coffee per 10 litre water), and filtered. The filtered coffee extract was cooled in an ice water bath and then placed on a tray in a freezer set at approximately -50 °C and frozen overnight. The following day, the frozen coffee grounds were placed in a prepared freeze-dryer for 3 days (shelf temperature, 35 ℃; vacuum chamber pressure, approximately 100 m Torr). Freeze-dried coffee samples were placed in frozen storage until shipment to the analytical laboratory.

No spirotetramat or spirotetramat equivalent residues were observed in coffee green bean (RAC), except spirotetramat enol, 0.011 mg/kg. However, this value is very close to the LOQ (< 0.01 mg/kg). Further, the high LOQ values for enol-Glc in roasted coffee bean and all analytes in freeze-dried coffee made an estimation of processing factors for total spirotetramat residues impossible.

Table 14 Residues on pineapple and coffee processed fractions from the foliar application of spirotetramat (IR-4 PR No. 10635, IR-4 PR No. 10041)

Location Year (Variety) Trial No.	Application				PHI (d)	Portion analysed	Residue (mg/kg) expressed as spirotetramat equivalents						
	kg ai/ha	n	Int. (d)	Total/ season, kg ai /ha			spiro	enol	keto -OH	mono-OH	enol -Glc	total spiro	spiro + enol
Pineapple													
GAP, USA	0.18	(2)	14	0.36	1								
Wahiawa, HI 2011 (Tropical Gold, MG-3) HI01	0.17–0.18	2	14	0.36	1	Fruit without crown	0.042	< 0.01	< 0.01	< 0.01	< 0.01	0.082	0.052
						Juice	0.019	< 0.01	< 0.01	< 0.01	< 0.01[a]		0.029
						Process residue	0.050	0.015	< 0.01	< 0.01	< 0.01[a]		0.065
Coffee bean													
GAP, USA	0.18	(3)	21	0.53	14								
Kauai, HI 2009 (Red Caturra) 09-HI12	0.18	3	7–21	0.54	14	Green bean	< 0.01	0.011	< 0.01	< 0.01	< 0.01	0.05	0.021
						Roasted bean	< 0.01	0.018	< 0.01	< 0.01	< 0.05		0.028
						Freeze-dried coffee	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1		

[a] The analytical method performance was not acceptable due to high recoveries.

APPRAISAL

Spirotetramat was evaluated for the first time by the JMPR in 2008 for toxicology and residues. The Meeting derived an ADI of 0–0.05 mg/kg bw and an ARfD of 1.0 mg/kg bw and recommended

maximum residue levels for a range of crops. In 2011 and 2012, the JMPR recommended additional maximum residue levels. The residue is defined as follows.

For compliance with the MRL for plant commodities: *spirotetramat plus spirotetramat enol, expressed as spirotetramat.*

For dietary intake estimation for plant commodities: *spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat*.

For compliance with the MRL and for dietary intake estimation for animal commodities: *spirotetramat enol, expressed as spirotetramat*.

The residue is not fat soluble.

The present Meeting evaluated supervised field trial data for various crops including their analytical methods, stability of frozen sample and stability tests, and processing studies.

Methods of analysis

Analytical methods used in raw agricultural commodities from field trials were suitable for quantifying spirotetramat residues including the metabolites spirotetramat enol, spirotetramat ketohydroxy, spirotetramat monohydroxy and spirotetramat enol glucoside in the various plant commodities. The methods were based on LC-MS/MS and the reference method used was evaluated by the Meeting in 2008 and 2011. The limits of quantitation for the raw commodities are 0.01 mg/kg (parent equivalents) for each analyte and 0.05 mg/kg for total spirotetramat equivalents.

For the processed products of pineapple and coffee bean, overall, the method performance was not acceptable. In pineapple juice and processing by-products, average recoveries of enol glucoside (0.01 mg/kg as parent equivalents) were not in the allowable range.

In roasted coffee bean, a limit of quantitation for enol glucoside was as high as 0.05 mg/kg. For freeze-dried coffee, the LOQ levels for spirotetramat enol, -ketohydroxy and - monohydroxy were 0.1 mg/kg, i.e., the fortification levels were not sufficiently low enough, further, some recoveries of parent and enol glucoside at the indicated LOQ level were outside the acceptable range, as a result the method performance was not considered satisfactory.

Stability of residues in stored analytical samples

Storage stability studies were performed with banana with peel, peeled banana, green coffee bean, roasted coffee bean and freeze-dried coffee. They indicated that the residues were stable during the frozen storage intervals of field trial samples. Stabilities of residues in commodities not assessed by the present Meeting are covered by the storage stability data evaluated by the 2008 JMPR, which demonstrated stability of all analytes for up to 2 years for a diverse range of commodities.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for the foliar application of spirotetramat as a suspension concentrate formulation (SC) to a variety of crops, i.e., blueberries, cranberry, banana, pineapple, pomegranate, blub onion, spring onion, watercress, globe artichoke and coffee.

In the discussions below, spirotetramat plus enol residues considered first for the estimation of maximum residue levels followed by total residues (spirotetramat plus the metabolites enol, ketohydroxy, monohydroxy, and enol glucoside, expressed as spirotetramat) for estimation of STMR and HR values for the dietary risk assessments.

Berries and other small fruits

Blueberries

In Canada, spirotetramat is registered at a rate of 0.20 kg ai/ha, a 7-day retreatment interval, a total seasonal rate of 0.44 kg, and a 7-day PHI. Eleven residue trials were conducted in the USA (7) and

Canada (4) with three applications at a rate of 0.17–0.19 kg ai/ha, total seasonal rate of 0.52–0.56 kg ai/ha, 5–8 days retreatment intervals and 6–8 days PHIs. Of the trials, two were not considered independent as they were conducted at the same site, with the same variety at very close dates of application.

Residues of spirotetramat plus enol from the trials were (n=10): 0.14, 0.17, 0.21, 0.31, 0.37, 0.39, 0.53, 0.53, 0.68 and 0.69 mg/kg.

Total residues of spirotetramat from the trials were (n=10): 0.38, 0.44, 0.45, 0.49, 0.60, 0.66, 0.69, 1.1, 1.2 and 1.6 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.63 mg/kg and an HR of 1.6 mg/kg for bush berries as blueberry is a representative crop of the subgroup.

Cranberry

In Canada, spirotetramat is registered for the use on cranberry at a rate of 0.20 kg ai/ha, a 7-day retreatment interval, a total seasonal rate of 0.44 kg, and a 7-day PHI. Six residue trials were conducted in the USA and Canada with three applications at a rate of 0.17-0.19 kg ai/ha, total seasonal rate of 0.52–0.55 kg ai/ha, 6–8 days retreatment intervals and 7–8 days PHIs, approximating the Canadian GAP.

Residues of spirotetramat plus enol from the trials were (n=6): < 0.02, 0.023, 0.025, 0.046, 0.058 and 0.12 mg/kg.

Total residues of spirotetramat from the trials were (n=6): < 0.05, 0.054, 0.055, 0.076, 0.088 and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.066 mg/kg and an HR of 0.15 mg/kg for cranberry.

Assorted tropical and sub-tropical fruits-inedible peel

Banana

Five residue trials were conducted using five applications in Hawaii, USA, according to the USA GAP (rate of 0.28 kg ai/ha, 14-day retreatment interval, total seasonal rate of 1.4 kg ai/ha, and 1-day PHI). In one trial, application was made on bagged banana. For the other four trials, banana bunches were not bagged, however, residues in pulp were not analysed, except one trial.

From the trials, residues of spirotetramat plus enol in unbagged whole banana were (n=4): 0.16 0.55, 1.0, 1.4 and 1.7 mg/kg.

From the trials, total residues of spirotetramat in unbagged whole banana were (n=4): 0.2, 0.62, 1.2, 1.4 and 1.8 mg/kg.

In the one trial, residues in pulp were 0.14 mg/kg (0.55 mg/kg for whole) for spirotetramat plus enol and 0.19 mg/kg (0.62 mg/kg for whole) for total spirotetramat.

The Meeting could not estimate a maximum residue level for banana as the number of trials was considered insufficient.

Pineapple

Five trials were conducted in Hawaii, USA with two applications, according to the USA GAP (rate of 0.18 kg ai/ha, 14-day retreatment interval, total seasonal rate of 0.36 kg ai/ha, and 1-day PHI). In these trials the preparation of samples did not comply with the relevant FAO guidelines, i.e., samples underwent cutting/quartering at the field site.

As the handling of samples did not comply with the relevant FAO guidelines on sample preparation, the Meeting decided that residue data could not be used for the estimation of a maximum residue level.

Pomegranate

Four trials were conducted in the USA with two applications, complying with the GAP of the USA (rate of 0.18 kg ai/ha, 14-day retreatment interval, 0.36 kg ai/ha/12-month, and a 1-day PHI). In these trials the preparation of samples did not comply with the relevant FAO guidelines, i.e., samples underwent cutting/quartering at the field site. As a result the residue data could not be used in estimating a maximum residue level.

Bulb vegetables,

Onion, bulb

Twelve trials were performed in Canada and USA with two applications, according to the USA GAP (rate of 0.09 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.18 kg ai/ha, and 3-day PHI). Two trials were not independent as they were conducted at the same site with the same variety with the same dates of application.

Residues of spirotetramat plus enol from the trials were (n=11): < 0.02, < 0.02, < 0.02, 0.026, 0.046, 0.051, 0.057, 0.058, 0.075, 0.095 and 0.28 mg/kg.

Total residues of spirotetramat from the trials were (n=11): < 0.05, < 0.05, < 0.05, 0.056, 0.076, 0.081, 0.087, 0.088, 0.11, 0.13 and 0.32 mg/kg.

Based on the residue values, the Meeting estimated a maximum residue level of 0.4 mg/kg.

The 2011 JMPR recommended a maximum residue level of 0.4 mg/kg, an STMR of 0.11 mg/kg and an HR of 0.27 mg/kg, based on the residues from trials in Australia matching GAP (2 applications at 0.048 kg ai/ha with a PHI of 7 days).

The Meeting therefore confirmed its previous maximum residue level recommendation of 0.4 mg/kg for onion, bulb.

Spring onion

Two trials were performed in Canada with two applications, matching the USA GAP (rate of 0.09 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.18 kg ai/ha, and 7-day PHI). The residues were 0.093 and 0.24 mg/kg as spirotetramat plus enol, 0.16 and 0.32 mg/kg as total residues.

The Meeting considered the number of trials insufficient to estimate a maximum residue level.

Watercress

Three trials were performed in the USA with two applications, according to GAP of the country (rate of 0.22 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.45 kg ai/ha, and 3-day PHI).

Two trials were not independent as they were conducted at the same site with the same variety, with dates of application 13 days apart. In addition, in one trial, two methods of application were utilized, i.e., using a backpack sprayer and overhead mini-sprinkler in a separate plot. These treatments were considered replicates of the trial. As a result one residue value was selected from each of the trials.

Residues from the trials were 0.26 and 0.32 mg/kg for spirotetramat plus enol, 0.51 and 0.56 mg/kg for total residues. The Meeting could not estimate a maximum residue level due to insufficient residue data.

The Meeting noted that the residues from the trials were covered by the previously recommended maximum residue level for leafy vegetables.

Artichoke, globe

Five trials were conducted in Canada and the USA with four applications, according to the USA GAP (rate of 0.15 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.56 kg ai/ha, and 3-day PHI).

Residues of spirotetramat plus enol from the trials were (n=5): 0.13, 0.20, 0.27, 0.47 and 0.49 mg/kg.

Total residues of spirotetramat from the trials were (n=5): 0.23, 0.34, 0.41, 0.60 and 0.70 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.41 mg/kg and an HR of 0.70 mg/kg for artichoke, globe.

Coffee beans

Five trials were conducted in Hawaii, USA with three applications, according to the GAP of that country (rate of 0.18 kg ai/ha, 21-day retreatment interval, total seasonal rate of 0.53 kg ai/ha, and 14-day PHI). Exceptionally, in one trial, a retreatment interval between the second and third application was 7 days due to an earlier ripening of coffee beans. The Meeting considered such a divergence from GAP would have little impact on the final residue level. Two trials were not considered independent as they were carried out at geographically close sites on the same variety within the same growing season.

Residues of spirotetramat plus enol from the four trials available were: 0.020, 0.028, 0.031 and 0.038 mg/kg; and 0.050, 0.059, 0.062 and 0.072 mg/kg for total residues of spirotetramat.

The Meeting considered the number of trials insufficient to estimate a maximum residue level.

Animal feeds

Residue information on animal feeds was not available for this Meeting.

Fate of residues during processing

One processing study for pineapple juice and pineapples processing by-products, roasted coffee bean and freeze-dried coffee were made available. However, the estimation of processing factors was not required as maximum residue levels could not be recommended for pineapple and coffee beans.

Residues in animal commodities

From the evaluations by the present Meeting, no feed items were added to the feed list evaluated by the 2011 JMPR. The Meeting retained the residue levels for animal commodities estimated by the 2011 and 2012 JMPR.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue concentrations listed below are suitable for establishing MRLs and for assessing IEDIs and IESTIs.

Definition of the residue (for compliance with MRL for plant commodities: Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

Definition of the residue (for estimation of dietary intake)for plant commodities: Spirotetramat, enol metabolite 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, ketohydroxy metabolite 3-(2,5-dimethylphenyl)-3-hydroxy-8-methyoxy-1-azaspiro[4.5]decane-2,4-dione, monohydroxy metabolite cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-

methoxy-1-azaspiro[4.5]decan-2-one, and enol glucoside metabolite glucoside of 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal commodities: Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

The residue is not fat-soluble.

CCN	Commodity	Recommended MRL mg/kg New	Previous	STMR or STMR-P mg/kg	HR or HR-P mg/kg
VS 0620	Artichoke, globe	1		0.41	0.70
FB 2006	Bush berries	1.5		0.63	1.6
FB 0265	Cranberry	0.2		0.066	0.15

DIETARY RISK ASSESSMENT

Long–term intake

The ADI for spirotetramat is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for spirotetramat were estimated for the 13 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3 of the 2013 Report. The IEDIs ranged 2–20% of the maximum ADI. The Meeting concluded that the long-term intake of residues of spirotetramat from uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for spirotetramat is 1.0 mg/kg bw. The International Estimate Short Term Intakes (IESTIs) for difenoconazole were calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2013 Report. The IESTIs varied from 0–2% of the ARfD for children and 0–1% for general population.

The Meeting concluded that the short-term intake of residues of spirotetramat from other uses that have been considered by the present Meeting is unlikely to present a public health concern.

REFERENCES

Code	Author	Year	Title, Institute, Report reference
	Coopersmith, H	2009	An Analytical Method for the Determination of Residues of BYI08330, BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono-hydroxy and BYI08330-enol-Glc Metabolites in/on Crop Matrices Using LC/MS/MS. Bayer CropScience, Bayer Method No. FN-007-P08-01, June 5, 2009.
09948	Corley, J	2010	Spirotetramat: Magnitude of the Residue on Watercress. IR-4 Project HQ, Rutgers, The State University of New Jersey, Princeton, NJ 08540; dated: 20 September, 2010.
10042	Dorschner, K	2011	Spirotetramat: Magnitude of the Residue on Banana. IR-4 Project HQ, Rutgers, The State University of New Jersey, Princeton, NJ 08540; dated: 21 November 2011.
10041	Dorschner, K	2011	Magnitude of the Residue on Coffee. IR-4 Project HQ, Rutgers, The State University of New Jersey, Princeton, NJ 08540; dated: 2 December, 2011.
10113	Dorschner, K	2011	Spirotetramat: Magnitude of the Residue on Pomegranate. IR-4 Project HQ, Rutgers, The State University of New Jersey, Princeton, NJ 08540; dated: 29 September, 2011.

Code	Author	Year	Title, Institute, Report reference
10635	Dorschner, K	2011	Spirotetramat: Magnitude of the Residue on Pineapple. IR-4 Project HQ, Rutgers, The State University of New Jersey, Princeton, NJ 08540; dated: 7 December, 2011.
10234	Lonsbary, S	2011	Spirotetramat: Magnitude of the Residue on Artichoke, Globe. Minor Use Pesticide Program, Pest Management Centre, Agriculture and Agri-Food Canada, Ottawa, ON K1A 0C6; dated: 1 December, 2011.
10194	Lonsbary, S	2011	Spirotetramat: Magnitude of the Residue on Blueberry, Lowbush and Highbush. Minor Use Pesticide Program, Pest Management Centre, Agriculture and Agri-Food Canada, Ottawa, ON K1A 0C6; dated: 25 November, 2011.
10198	Lonsbary, S	2011	Spirotetramat: Magnitude of the Residue on Cranberry. Minor Use Pesticide Program, Pest Management Centre, Agriculture and Agri-Food Canada, Ottawa, ON K1A 0C6; dated: 1 December, 2011.
09983	Lonsbary, S	2011	Spirotetramat: Magnitude of the Residue on Onion, Dry Bulb. Minor Use Pesticide Program, Pest Management Centre, Agriculture and Agri-Food Canada, Ottawa, ON K1A 0C6; dated: 7 July, 2011.
10924	Lonsbary, S	2011	Spirotetramat: Magnitude of the Residue on Onion, Green. Minor Use Pesticide Program, Pest Management Centre, Agriculture and Agri-Food Canada, Ottawa, ON K1A 0C6; dated: 1 December, 2011.
	Schöning, R and Wolters, A	2007	Storage stability of BYI08330 and its metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono-hydroxy and BYI08330-enol-glucoside in/on tomato (fruit), tomato (paste), potato (tuber), lettuce (head), climbing French bean (bean with pod), and almond (nutmeat) for 24 months. Bayer CropScience AG, Monheim, Germany, Bayer Report No.: MR-07/268. June 21, 2007.
	Schöning, R, Stuke, S and Billian, P	2005	Analytical Method 00857 for the Determination of Residues of BYI08330 (Parent Compound and Total Residue of BYI08330), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono-hydroxy and BYI08330-enol-Glc Metabolite in/on Plant Material by HPLC-MS/MS. Bayer CropScience AG, Monheim, Germany, Bayer Report No. MR-099/04. June 17, 2005.