BIFENTHRIN (178)

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EXPLANATION

Bifenthrin is a pyrethroid insecticide and miticide. It was first evaluated for residues and toxicology by the JMPR in 1992 and re-evaluated in 2009 (T) and 2010 (R). The 46th Session of the CCPR (2014) listed bifenthrin for the evaluation of additional MRLs.

Currently, an ADI of 0–0.01 mg/kg bw and an ARfD of 0.01 mg/kg bw are established. The residue definition for compliance with the MRL and for estimation of dietary intake (for animal and plant commodities) is bifenthrin (sum of isomers). The residue is fat-soluble.

The Meeting received information on supervised residue trials for blueberries, grapes, head lettuce, spinach, celery, peas, snap beans and lima beans.

Analytical methods

Grape, Head lettuce (IR-4 trial), Spinach (manufacturer), Celery, Peas, Snap bean, Lima bean

Analytical methods used for analysis of bifenthrin residues involved an extraction with acetone, an aqueous/acetone partition, a clean-up using florisil and analysis by GC-ECD (Ref. method, Ridler 1989, Report P-2132M; evaluated acceptable for recoveries of the residue in maize samples by 2010 JMPR). For spinach, 4'-hydroxy bifenthrin was analysed as well as bifenthrin using the analytical method. For lima bean (seed), methylene chloride was used instead of hexane in the partition step. The limit of quantification (LOQ) of bifenthrin was 0.05 mg/kg in all matrices. The recoveries and CV (%) values at various fortification levels were in an acceptable range of 70–120% and 20%, respectively, with exceptions of head lettuce 23% CV and celery 25% CV at a fortification level of 0.05 mg/kg. The LOQ of 4'-hydroxy bifenthrin in spinach was 0.05 mg/kg and recoveries at fortification levels of 0.05–2.0 mg/kg were in a range of 79–100% (in total, n=9).

Blueberry, Spinach (IR-4 trial)

Bifenthrin residues were extracted with hexane in an automated extraction unit. The extract was cleaned up on a florisil column and subjected to GC-ECD for analysis. For spinach, the hexane extract was subjected to GC-ECD, omitting the florisil clean-up step. The LOQ was 0.05 mg/kg in the matrices. Recoveries at fortification levels of 0.05, 0.5 and 2.0 or 5.0 mg/kg were in a range of 80–100% (CV, < 5.3%).

Head lettuce (manufacturer)

Bifenthrin residues in head lettuce were extracted with acetone after adding sodium chloride. The extract was partitioned with hexane and cleaned up using an aminopropyl SPE cartridge. GC-MSD was used for determination of the analyte and the LOQ was 0.05 mg/kg. At four fortification levels in the range of 0.05–1.0 mg/kg, recoveries of bifenthrin were 90–120% (in total, n=6; CV, 16%).

A summary of recovery data with the methods used for residue trial samples in this submission are shown in Table 1.

Table 1 Analytical recoveries of bifenthrin in some plant commodities

Matrix	Fortification, mg/kg	n	Range of recoveries, %	Mean recovery, %	CV, %	Ref. method
Blueberry	0.05	3	90–100	96	5.3	
	0.5	4	84–94	89	5.2	

Matrix	Fortification, mg/kg	n	Range of recoveries, %		Mean recovery, %		CV, %		Ref. method
	5.0	3	93–96		94		2.1		
Grape [a]	0.05	7	73–112, 63 (one value)		94		20		Report P-2132M
	0.1	1	110		110		–		
	0.5	6	89–112		100		11		
	1.0	1	98		98		–		
	5	6	73–99		90		14		
	12	1	121		121		–		
Head lettuce (IR-4) [b]	0.05	6	77–111, 152 (one value)		104		23		Report P-2132M
	0.1	4	71–104		87		16		
	0.5	1	96		–		–		
	1.0	4	78–97		90		11		
	5.0	1	95		–		–		
Head lettuce (manufacturer) [b]	0.05	3	90–120		102		16		
	0.1	1	110		–		–		
	0.2	1	95		–		–		
	1.0	1	94		–		–		
Spinach(IR-4) [b]	0.05	3	80–82		81		1.2		
	0.5	3	84–91		88		3.4		
	2.0	3	92–94		93		1.1		
Spinach (manufacturer) [b, c]	0.05	2	101, 103	91, 100	102	96	–	–	Report P-2132M[d]
	0.25	2	100, 107	79, 97	104	88	–	–	
	0.5	2	91, 99	79, 90	95	80	–	–	
	1.0	2	93, 107	61 (90), 81	100	71 (86)	–	–	
	2.0	1	97	94	97	94	–	–	
Celery (IR-4)	0.05	6	77–86		80		2.9		Report P-2132M
	0.5	3	88–99		95		6.4		
	5.0	3	94–100		97		3.1		
Celery (IR-4)	0.04	3	92–118		106		12		Report P-2132M
	0.05	3	69–109		84		25		
	0.4	3	89–94		91		3.3		
	4.0	3	78–103		89		13		
Peas with pods [b]	0.05	5	83–90		86		3.3		Report P-2132M
	0.5	2	79, 106		93		–		
	1.0	2	71, 76		74		–		
	2.0	3	88–91		90		1.7		Report P-2132M
Peas without pods [b]	0.05	2	84, 86		85		–		
	0.2	1	75		75		–		
	0.5	3	76–79		78		1.9		
Snap bean with pods [b]	0.05		105–119		109		8.0		Report P-2132M

Matrix	Fortification, mg/kg	n	Range of recoveries, %	Mean recovery, %	CV, %	Ref. method
	0.5		88–116	103	14	
	0.6		98	–	–	
	5.0		101–111	105	5.2	
Lima bean, seed	0.05		87–105	93	11	Report P-2132M
	0.5		104–108	106	1.9	

LOQs, < 0.05 mg/kg

[a] Including concurrent recoveries

[b] Concurrent recoveries

[c] Recoveries underlined are for 4'-hydroxy bifenthrin. The value in parenthesis is from a repeat analysis.

[d] In the study report, P-2715 was mentioned as a reference method, however, the used method was very similar to the P-2132M.

Stability of residues in stored analytical samples

The 2010 JMPR evaluated that bifenthrin residues were stable for the period of at least 18 months in oranges, 49 months in apples, 7 months in strawberries, 24 months in bananas, 36 months in lettuce, potatoes and pecans, 15 months in peas, dry, 34 months in maize grain and up to 24 months in cotton seed.

In this Meeting, additional information was available that showed the residues were stable for at least 176 days in grapes, 300 days in head lettuce, 561 days in celery, 210 days in peas with pods, 142 days in snap beans and up to 196 days in lima beans. In these storage stability tests, zero-day residues were not determined, except for lima beans.

Based on the available information, it is considered that residues in all samples relevant to this submission were stable under frozen conditions until extraction and analysis. Table 2 includes results of storage stability tests and actual storage days for field trial samples.

Table 2 Storage stability of bifenthrin in some plant matrices

Matrix	Fortification level, mg/kg	Tested storage days	Residue in fortified samples, mg/kg	Procedural recoveries, %	Actual max. storage days
Blueberry	–	–	–	–	81
Grape	0.10	176	0.080	110	172
	10	176	8.7	121% at 12 ppm	
Head lettuce	0.05	300	0.062	152	280 days or 11 months
	0.1	300	0.11	104	
	0.5	300	0.55	97% at ca. 1 ppm	
Spinach	–	–	–	–	57 days or 4 months
Celery	0.5	561	0.38, 0.38, 0.30 (60%)	69, 76, 109% at 0.05 ppm	229 or 349
Peas with pods	0.05	192	0.030 (58%), 0.049	88	178
	0.5	192	0.34 (68%), 0.39	106	
	0.16 [a]	210	0.17	[b]	
	0.17 [a]	210	0.15	[b]	
Snap bean	0.5	142	0.38, 0.47, 0.36	98% at 0.6 ppm	135 or 150
Lima bean, seed	0.5	1	0.52, 0.53, 0.54	81% at 0.05 ppm	61
		35	0.54, 0.54	81% at 0.05 ppm	
		68	0.49, 0.50, 0.50	87% at 0.05 ppm	
		98	0.42, 0.46, 0.46	61% at 0.05 ppm	

Matrix	Fortification level, mg/kg	Tested storage days	Residue in fortified samples, mg/kg	Procedural recoveries, %	Actual max. storage days
		117	0.48, 0.48, 0.48	195 at 0.05 ppm	
		196	0.40, 0.43, 0.46	120% at 0.05 ppm	

[a] Pea samples from a field residue trial were analysed again seven months after the initial analysis. The initial residue concentrations were 0.16 mg/kg and 0.17 mg/kg, with overall concurrent recoveries of 79–91% at fortification levels of 0.05, 0.5 and 2.0 mg/kg.

[b] Mean procedural recoveries were 88% and 106% at fortification levels of 0.05 mg/kg and 0.5 mg/kg, respectively. At the same date, fortified sample at 192 days and field trial sample at 210 days were analysed.

USE PATTERNS

Bifenthrin is registered in many countries for control of insect pests on fruit, vegetables, cereals, oilseeds and forage crops. This Meeting received information on registered uses from the USA regarding the submitted residue trial, which is summarized in the Table 3.

Table 3 Registered uses of bifenthrin in the USA on crops relevant to this submission

Crop	Form.	Method	Application			
			Rate, kg ai/ha	Max. no.	Interval days	PHI, days
Bushberries (blueberry)	WSB, 2EC	Foliar, G or A [a]	0.11 (0.56 kg ai/ha/season)		7	1
Grapes	WSB, 2EC	Foliar, G or A	0.11 (0.11 kg ai/ha/season)			30
Leafy petiole vegetables (celery)	WSB, 2EC	Foliar, G or A	0.11 (0.56 kg ai/ha/season)		7	7
Lettuce, head	WSB, 2EC	Foliar, G or A	0.11 (0.56 kg ai/ha/season)		7	7
Spinach	WSB, 2EC	Soil at planting; foliar, G or A	0.11 (0.45 kg ai/ha/season)	4	7	40
Succulent peas and beans (pea, snap bean, lima bean)	WSB, 2EC	At planting time [b]; foliar use, G or A [b]	0.11 (0.22 kg ai/ha/season)			3

Succulent peas and beans include as follows: pea (Pisum spp.: dwarf pea, English pea, garden pea, etc.), bean (Phaseolus spp.: broadbean, succulent, lima bean, green, snap bean, etc.), bean (Vigna spp.: asparagus bean, cowpea, moth bean, etc.), jackbean, soybean, immature seed and sword bean.

Bushberries include blueberry, high-bush and low-bush, currant, elderberry, gooseberry and huckleberry.

Leafy petiole vegetables include celery, cardoon, Chinese celery, celtuce, Florence fennel, rhubarb, Swiss chard.

The formulation, WSB (water soluble bags; ai, 10%) is a type of wettable powder. The formulation 2EC is a type of emulsifiable concentrate (ai, 25.1%).

[a] By ground or air

[b] Apply in-furrow with the seed or transplant

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Supervised residue trials were conducted in the USA for the following crops: blueberry, grape, head lettuce, spinach, celery, peas, snap bean and lima bean. The results of these residue trials are summarized in the following tables.

Crop group	Commodity	Table No.
Berries and other small fruits	Blueberry	4
	Grape	5
Leafy vegetables	Head lettuce	6
	Spinach	7

Crop group	Commodity	Table No.
Stalk and stem vegetables	Celery	8
Legume vegetables	Peas	9, 10
	Snap bean	11
	Lima bean	12

In all trials, there were no residues detected above the LOQ, 0.05 mg/kg, in control samples. Procedural recoveries of bifenthrin residues were satisfactory in all analytical sets. Bifenthrin residues were demonstrated to be stable for the period of frozen storage for all samples (See section of stability of residue in stored analytical samples).

For estimation of a maximum residue level, residue values from the trials conducted according to the maximum GAP were used. In cases where multiple samples were taken from a single plot, the mean residue from that plot was selected. In cases where separate plots were found not to be independent, the highest residue value was selected for estimating a maximum residue level. Those selected values are underlined in the tables.

Berries and Other Small Fruit

Bushberries—Blueberry

Nine trials were conducted in the USA (CA, ME, MI, NC, NJ and OR) in 2004. At each trial, five foliar applications, 6–8 days apart, were made with the 2 EC formulation (emulsifiable concentrate, 240 g/L), except in Trial ID, NJ10 (in which two of the applications were made at 4-day intervals because the crop was maturing rapidly). In four of the trials (ME01, MI06, NC10, and OR06), separate plots received treatments with the 10 WP formulation (10% wettable powder) as five foliar applications, 6–8 days apart. In all treatments, the application rate was 0.11–0.12 kg ai/ha (0.55–0.57 kg ai/ha/season). Samples of blueberries were collected 1 day after the last application.

Table 4 Residues resulting from bifenthrin application to blueberries in the USA (Report: IR-4 PR No. 08736)

Location (Variety) Year	Application				DALA	Residue, mg/kg			Trial ID
	Form.	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
GAP, USA		0.11 (0.56 kg ai/ha /season)		7	PHI, 1 days				
Tulare, CA (Misty) 2004	2 EC	0.11–0.12	5	7	1	0.50	0.36	0.43	CA33
Jonesboro, ME (Lowbush) 2004	2 EC	0.11	5	6–8	1	1.1	1.6	1.4	ME01
	10 WP	0.11	5	6–8	1	0.64	1.0	0.84	
Fennville, MI (Rubel) 2004	2 EC	0.11	5	7	1	0.95	0.88	0.92	MI06 [a]
	10 WP	0.11	5	6–7	1	1.1	0.76	0.91	
Fennville, MI (Rubel) 2004	2 EC	0.11	5	7	1	0.87	1.4	1.2	MI07 [a]
Fennville, MI (Rubel) 2004	2 EC	0.11	5	6–8	1	0.80	0.96	0.88	MI08 [a]
Castle Hayne, NC (Croatan) 2004	2 EC	0.11	5	7	1	0.42	0.54	0.48	NC10

Location (Variety) Year	Application				DALA	Residue, mg/kg			Trial ID
	Form.	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
	10 WP	0.11	5	7	1	0.48	0.39	0.44	
Bridgeton, NJ (Blueray) 2004	2 EC	0.11–0.12	5	6	1	0.71	0.60	0.66	NJ09 [b]
Bridgeton, NJ (Duke) 2004	2 EC	0.11–0.12	5	4–6	1	0.79	0.89	0.84	NJ10 [b]
Aurora, OR (Bluecrop) 2004	2 EC	0.11–0.12	5	6–8	1	0.52	0.48	0.50	OR06
	10 WP	0.11	5	6–8	1	0.43	0.37	0.40	

2 EC (emulsifiable concentrate; ai, 25.1%), 10 WP (wettable powder, 10%)

Duplicate sampling in each trial was made.

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

Small fruit vine climbing—Grapes

Seven trials on grapes were conducted in the USA (NC, MI, WA, NJ, NY and OH) from 1994 to 1996. One foliar application (2 EC) was made at the rate of 0.10 or 0.11 kg ai/ha. Grape samples were harvested 28 to 32 days after the application.

Table 5 Residues resulting from bifenthrin application to grapes in USA (Report: IR-4 PR No. 05335)

Location (Variety) Year	Application		DALA	Residue, mg/kg [a]			Trial ID
	kg ai/ha	No.		Repl.1	Repl. 2	Mean	
GAP, USA	0.11 (0.11 kg ai/ha/season)		PHI, 30 days				
Raleigh, NC (Muscadine) 1994	0.11	1	29	0.11	0.14	0.13	NC14
Fennville, MI (Concord) 1994	0.11	1	30	< 0.05	< 0.05	< 0.05	MI30
Prosser, WA (Concord) 1994	0.11	1	28	< 0.05	0.070	0.060	WA50
Ferrell, NJ (Concord) 1995	0.11	1	32	0.050	0.050	0.050	NJ29
Mattituck, NY (Chardonnay) 1995	0.11	1	31	0.10	0.13	0.12	NY14
Wooster, OH (Ives) 1995	0.11	1	29	0.060	0.060	0.060	OH*25
Riverhead, NY (Lemberger) 1996	0.10	1	29	0.070	0.070	0.070	NY02

[a] 2 EC was applied and duplicate sampling in each trial was made.

Leafy vegetables

Lettuce, head

Six residue trials were conducted in the USA (CA, OH, NJ, FL and TX) in 1993 and 1994. At each trial, five applications (six at TX*25) timed 5–11 days apart were made with the 2 EC formulation.

The rate of application was approximately 0.11 kg ai/ha (0.55 kg ai/ha/season; 0.66 kg ai/ha/season for TX*25 trial). Head lettuce samples with and without wrapper leaves were taken 7–8 days after the last treatment.

The 'Mesa' variety used in Trial NJ17 has a 'frilled' morphology, which suggests that the leaf edges may not stay as close to the head as in other varieties, perhaps resulting in water and residues being retained.

In 2004, four additional trials were conducted in California and Arizona. At each trial, five foliar applications were made at a rate of 0.11 kg ai/ha (0.55 kg ai/ha/season), 5–10 days apart, with the 2 EC formulation. Samples with and without wrapper leaves were collected 6–8 days after the last treatment. In Trial 04, additional samples were collected at 1, 3 and 14 days after the last application to determine the residue decline pattern of bifenthrin.

Table 6 Residues resulting from bifenthrin application to head lettuce in the USA (Report: IR-4 PR No. 05274; P-3723)

Location (Variety) Year	Application			DALA	Portion analysed	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days			Repl.1	Repl. 2	Mean	
GAP, USA	0.11 (0.56 kg ai/ha /season)		7	PHI, 7 days					
Salinas, CA (Salinas) 1993	0.11	5	6–7	7	w/ w. leaves	0.78	0.84	0.81	CA*46
					wo/ w. leaves	< 0.05	0.09	0.070	
Willard, OH (Ithaca) 1993	0.11	5	6–8	7	w/ w. leaves	0.38	0.51	0.45	OH*12
					wo/ w. leaves	< 0.05	< 0.05	< 0.05	
Bridgeton, NJ (Mesa) [a]1993	0.11	5	7–9	7	w/ w. leaves	1.7	1.8	1.8	NJ17
					wo/ w. leaves	0.48	0.85	0.67	
Zellwood, FL (South Burg) 1993	0.11	5	6–9	8	w/ w. leaves	0.56	0.85	0.71	FL42
					wo/ w. leaves	< 0.05	< 0.05	< 0.05	
Weslaco, TX (Golden State) 1993	0.11	6	7–11	8	w/ w. leaves	1.6	1.9	1.7	TX*25
					wo/ w. leaves	< 0.05	< 0.05	< 0.05	
Holtville, CA (Empire) 1994	0.11	5	5–10	7	w/ w. leaves	0.33		0.33	CA19
					wo/ w. leaves	< 0.05		< 0.05	
San Ardo, CA (Shape Shooter) 2003	0.11	5	5–6	8	w/ w. leaves	< 0.05	< 0.05	< 0.05	01
					wo/ w. leaves	< 0.05	< 0.05	< 0.05	
Hughson, CA (Bayview) 2003	0.11	5	5	6	w/ w. leaves	0.21	0.25	0.23	02
					wo/ w. leaves	0.20	0.24	0.22	
Yuma, AZ (Telluride) 2004	0.11	5	5–10	7	w/ w. leaves	0.54	0.58	0.56	03
					wo/ w. leaves	0.38	0.41	0.40	

Location (Variety) Year	Application			DALA	Portion analysed	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days			Repl.1	Repl. 2	Mean	
Visalia, CA (Salinas M.I.) 2004	0.11	5	7	1	w/ w. leaves	0.39	0.43	0.41	04
					wo/ w. leaves	0.40	0.41	0.41	
				3	w/ w. leaves	0.14	0.16	0.15	
					wo/ w. leaves	0.14	0.14	0.14	
				7	w/ w. leaves	0.11	0.14	0.13	
					wo/ w. leaves	0.14	0.14	0.14 [b]	
				14	w/ w. leaves	0.070	0.080	0.075	
					wo/ w. leaves	0.070	0.080	0.075	

2 EC formulation was used and duplicate sampling in each trial was made.

Residues were analysed for heads with wrapper leaves and heads without wrapper leaves.

[a] Variety with a “frilled” appearance

[b] Higher residue value was selected.

Spinach

Five trials were conducted in the USA (MD, NJ and TX) in 1999. At each trial, foliar spray was made once at a rate of 0.45–0.47 kg ai/ha with the 2 EC formulation. A single treatment was made because spinach in some areas developed too rapidly to accommodate a use pattern of four applications and a 40-day PHI. Spinach samples were taken 36–41 days after the application.

Three additional trials were conducted in California and Arizona in 1999. The 2 EC formulation was applied to spinach as four foliar sprays (aerial or ground spray) 4–13 days apart. Each application was at 0.11 kg ai/ha (0.55 kg ai/ha/season), and spinach samples were collected 20, 39 or 40 days after the last application. In these three trials, the metabolite 4'-hydroxy bifenthrin was also analysed along with bifenthrin.

Table 7 Residues resulting from bifenthrin application to spinach in the USA (Report: IR-4 PR No.07088; P-2839)

Location (Variety) Year	Application			DALA	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
GAP, USA	0.11 (0.45 kg ai/ha/season)		7	PHI, 40 days				
Salisbury, MD (Vienna) 1999	0.454	1		37	< 0.05	< 0.05	< 0.05	MD01
Bridgeton, NJ (Melody) 1999	0.448	1		36	< 0.05	< 0.05	< 0.05	NJ07
Weslaco, TX (Olympia) 1999	0.448	1		41	< 0.05	< 0.05	< 0.05	TX07
Weslaco, TX (Fall Green) 1999	0.448	1		39	< 0.05	< 0.05	< 0.05	TX*08
Weslaco, TX (Olympia) 1999	0.467	1		39	< 0.05	< 0.05	< 0.05	TX24
Yuma, AZ (St. Helens) 1999	0.11	4	7–13	20	0.89	1.4	1.1	01

Location (Variety) Year	Application			DALA	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
			4–10	40	0.14	0.16	0.15	
Imperial, CA (St. Helens) 1999	0.11 aerial spray	4	5–8	20	0.44	0.50	0.47	02
Imperial, CA (St. Helens) 1999	0.11 ground spray	4	5–8	20	1.0	1.1	1.0	03
			4–7	39	0.040	0.060	0.050	

2 EC formulation was used and duplicate sampling in each trial was made.

For Trial ID, 01, 02 and 03, the metabolite, 4'-hydroxy bifenthrin was analysed as well as bifenthrin. The metabolite was not determined in any samples, i.e., less than LOQ, 0.05 mg/kg.

Stalk and stem vegetables

Celery

Four trials were conducted in the USA (Florida and California) in 1997 and 1998. Celery plots were treated five times with the 2 EC formulation 6–8 days apart. Foliar application was made at a rate of 0.11–0.12 kg ai/ha (0.55–0.57 kg ai/ha/season). Samples were taken 6–8 days after the last treatment. In one trial (CA*03), additional samples were taken 1, 5, 9 and 14 days after the last treatment.

In 2004, four additional trials were conducted in California, Florida and Ohio. Each trial included two treated plots treated with the 2EC or 10 WP formulation. Five foliar applications, 6–8 days apart, were made at the rate of 0.11–0.12 kg ai/ha (0.56–0.58 kg ai/ha/season). Samples were harvested 6–7 days after the last application.

Table 8 Residues resulting from bifenthrin application to celery in the USA (Report: IR-4 PR No. A4945, B4945)

Location (Variety) Year	Application				DALA	Residue, mg/kg			Trial ID
	Form.	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
GAP, USA		0.11 (0.56 kg ai/ha/ season)		7	PHI, 7 days				
Gainesville, FL (June Belle) 1997	2 EC	0.11	5	6–7	6	0.26	0.31	0.29	FL03
Holtville, CA (Conquistador) 1997–98	2 EC	0.11	5	6–8	8	0.87	0.91	0.89	CA04
Salinas, CA (Conquistador) 1997	2 EC	0.11	5	6–8	1	1.2	2.3	1.8	CA*03
					5	0.74	1.1	0.91	
					7	0.28	0.61	0.45	
					9	0.81	1.1	0.97	
					14	0.66	1.6	1.1	
Salinas, CA (52–75) 1998	2 EC	0.11–0.12		7–8	7	0.11	0.22	0.17	CA*45
Irvine, CA (Conquistador 1703) 2004	2 EC	0.11–0.12	5	6–8	7	1.8	1.2	1.5	CA31

Location (Variety) Year	Application				DALA	Residue, mg/kg			Trial ID
	Form.	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
	10 WP	0.11–0.12		6–8	7	0.97	1.2	1.1	
Salinas, CA (Conquistador) 2004	2 EC	0.11–0.12	5	6–8	6	0.65	0.71	0.68	CA*32
	10 WP	0.11–0.12		6–8	6	0.43	0.47	0.45	
Citra, FL (M9) 2004	2 EC	0.11	5	6–8	7	0.69	0.73	0.71	FL21
	10 WP	0.11		6–8	7	0.58	0.69	0.64	
Celeryville, OH (Ventura) 2004	2 EC	0.11–0.12	5	6–7	7	0.11	0.15	0.13	OH05
	10 WP	0.11–0.12		6–7	7	0.06	0.13	0.095	

2 EC (emulsifiable concentrate, 240 g/L), 10 WP (wettable powder, 10%)

Two sampling in each trial was made and duplicate sampling in each trial was made.

Residues in stalks and leaves were analysed.

Legume vegetables

Peas

Six trials were conducted in the USA (MN, WI, MD, NY and WA) from 1992 to 1994. At each trial, two foliar applications (2 EC) were made with a 7-day retreatment interval at a rate of 0.11 kg ai/ha (0.22 kg ai/ha/season). Peas and shelled pea samples were collected 3 days after the second application. In three of the six trials, forage samples were collected (one trial for hay), however, residues were not analysed.

Table 9 Residues resulting from bifenthrin application to peas (with pods) in the USA (Report: IR-4 PR No. 05237)

Location (Variety) Year	Application			DALA	Portion analysed	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days			Repl.1	Repl. 2	Mean	
GAP, USA	0.11 (0.22 kg ai/ha /season)			PHI, 3 days					
Springfield, MN (Del Monte 5063) 1992	0.11	2	7	3	w/ pods	0.16	0.17	0.17	MN02
Columbus, WI (DLM 2601) 1992	0.11	2	7	3	w/ pods	0.19	0.48	0.34	WI20
Salisbury, MD (Rigo) 1993	0.11	2	7	3	w/ pods	0.17	0.17	0.17	MD06
Geneva, NY (Wando) 1993	0.11	2	7	3	w/ pods	0.47	0.50	0.49	NY17
Yakima, WA (Puget) 1993	0.11	2	7	3	w/ pods	0.18	0.22	0.20	WA*22
Yakima, WA (Puget) 1994	0.11	2	7	3	w/ pods	0.25		0.25	WA*17

2 EC formulation was used and duplicate sampling in each trial was made.

Table 10 Residues resulting from bifenthrin application to peas (pea, shelled) in the USA (Report: IR-4 PR No. 05237)

Location (Variety) Year	Application			DALA	Portion analysed	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days			Repl.1	Repl. 2	Mean	
GAP, USA	0.11 (0.22 kg ai/ha /season)			PHI, 3 days					
Springfield, MN (Del Monte 5063) 1992	0.11	2	7	3	wo/ pods	< 0.05	< 0.05	< 0.05	MN02
Columbus, WI (DLM 2601) 1992	0.11	2	7	3	wo/ pods	< 0.05	< 0.05	< 0.05	WI20
Salisbury, MD (Rigo) 1993	0.11	2	7	3	wo/ pods	< 0.05	< 0.05	< 0.05	MD06
Geneva, NY (Wando) 1993	0.11	2	7	3	wo/ pods	< 0.05	< 0.05	< 0.05	NY17
Yakima, WA (Puget) 1993	0.11	2	7	3	wo/ pods	< 0.05	< 0.05	< 0.05	WA*22
Yakima, WA (Puget) 1994	0.11	2	7	3	wo/ pods	< 0.05	< 0.05	< 0.05	WA*17

2 EC formulation was used and duplicate sampling in each trial was made.

Snap bean

Six residue trials on snap beans (beans with pods) conducted in the USA (1996 and 1997), previously evaluated by the 2010 JMPR were re-submitted for evaluation by this Meeting. The 2010 JMPR did not estimate a maximum residue level as the trials submitted were not in accordance with the GAP.

At each trial, three foliar applications (2EC) were made, with 7-day intervals, at a rate of 0.090, 0.090, and 0.045 kg ai/ha for the 1st, 2nd and 3rd applications, respectively. The total rate was 0.23 kg ai/ha during growing the season. The bean samples were harvested 2-4 days after the last application.

Table 11 Residues resulting from bifenthrin application to snap bean in the USA (Report: IR-4 PR No. 06423)

Location (Variety) Year	Application			DALA	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
GAP, USA	0.11 (0.22 kg ai/ha/season)			PHI, 3 days				
Live Oak, FL (Magnum) 1996	0.090, 0.090, 0.045	3	7	3	0.12	0.15	0.14	FL50
Kimberly, ID (Idelif) 1996	0.090, 0.090, 0.045	3	7	3	< 0.05	0.05	0.050	ID11
West Lafaytte, IN (Espada) 1996	0.090, 0.090, 0.045	3	7	3	0.050	0.060	0.055	IN04
Geneva, NY (Labrador) 1996	0.090, 0.090, 0.045	3	7	3	0.090	0.13	0.11	NY09
Plower, WI (Del Monte 0488) 1996	0.090, 0.090, 0.045	3	7	3	< 0.05	0.05	0.050	WI16
Charleston, SC	0.090, 0.090, 0.045	3	7	4	< 0.05	< 0.05	< 0.05	SC*09

Location (Variety) Year	Application			DALA	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
(Bush Blue Lake) 1997								

Re-submitted data to this Meeting.

2 EC formulation was used and duplicate sampling in each trial was made.

Residues in snap bean with pods were analysed.

Lima bean

Seven residue trials on lima beans, without pods, conducted in the USA (1997), previously evaluated by the 2010 JMPR, were re-submitted for evaluation by this Meeting. The 2010 JMPR did not estimate a maximum residue level as the trials submitted were not in accordance with the GAP.

At each trial, three foliar applications (2EC) were made with 6–7 day intervals at the rate of 0.087–0.091, 0.089–0.092, 0.043–0.047 kg ai/ha for the 1st, 2nd and 3rd applications, respectively. The total rate was 0.22–0.23 kg ai/ha during the growing season. The bean samples were harvested 2–4 days after the last application.

Table 12 Residues resulting from bifenthrin application to lima bean in USA (Report: IR-4 PR No. 06252)

Location (Variety) Year	Application			DALA	Residue, mg/kg			Trial ID
	kg ai/ha	No.	Inter. days		Repl.1	Repl. 2	Mean	
GAP, USA	0.11 (0.22 kg ai/ha/season)			PHI, 3 days				
Parlier, CA (Jackson Wonder) 1997	0.090, 0.090, 0.045	3	6	3	< 0.05	< 0.05	< 0.05	CA01
Salisbury, MD (Maffei) 1997	0.087, 0.092, 0.045	3	7	3	< 0.05	< 0.05	< 0.05	MD01
Bridgeton, NJ (Baby Fordhook) 1997	0.090, 0.090, 0.047	3	6-7	3	< 0.05	< 0.05	< 0.05	NJ01
Charleston, SC (Henderson Bush) 1997	0.090, 0.090, 0.045	3	6-7	4	< 0.05	< 0.05	< 0.05	SC*05
Moxee, WA (Ford Hook 242) 1997	0.091, 0.090, 0.045	3	6	3	< 0.05	< 0.05	< 0.05	WA*10
Hancock, WI (Improved Kingston) 1997	0.090, 0.089, 0.044	3	7	3	< 0.05	< 0.05	< 0.05	WI03
Arlington, WI (Improved Kingston) 1997	0.091, 0.091, 0.043	3	6	2	< 0.05	< 0.05	< 0.05	WI04

Re-submitted data to this Meeting

2 EC formulation was used and duplicate sampling in each trial was made.

The 3rd application rate was 0.045 kg ai/ha in all trials.

Residues in lima bean without pods, were analysed.

APPRAISAL

Bifenthrin is a pyrethroid insecticide and miticide. It was first evaluated for residues and toxicology by the JMPR in 1992 and re-evaluated in 2009 (T) and 2010 (R) under the periodic review

programme of the CCPR. The forty-sixth Session of the CCPR (2014) listed bifenthrin for the evaluation of additional maximum residue levels by the 2015 JMPR.

Currently, an ADI of 0–0.01 mg/kg bw and an ARfD of 0.01 mg/kg bw are established. The residue definition for compliance with the MRL and for estimation of dietary intake (for animal and plant commodities) is bifenthrin (sum of isomers). The residue is fat-soluble.

The Meeting received information on supervised residue trials for blueberry, grape, head lettuce, spinach, celery, peas, snap bean and lima bean.

Methods of analysis

Acceptable analytical methods were developed and validated for determination of bifenthrin in residue trial samples. All methods involved an analysis by GC-ECD, except one method using GC-MSD. The limit of quantification (LOQ) of bifenthrin was 0.05 mg/kg in all matrices.

Stability of residues in stored analytical samples

At the 2010 JMPR, bifenthrin was shown to be stable in lettuce under frozen storage condition for at least 36 months. This Meeting received additional storage stability studies on grape, head lettuce, celery, peas, snap bean and lima bean, showing that bifenthrin was stable for the period of storage of the supervised trial samples. Bifenthrin residues in blueberry (81 days) and spinach (4 months) were considered to be stable for the storage period based on all available information.

Results of supervised residue trials on crops

Berries and Other Small Fruit

Bushberries-Blueberry

Nine trials were conducted in the USA in 2004, matching the US GAP on bushberries (0.11 kg ai/ha with 7-day intervals and a PHI of 1 day; 0.56 kg ai/ha/season). Six independent trials matched the GAP.

Bifenthrin residues in blueberry were (n=6): 0.43, 0.48, 0.50, 0.84, 1.2 and 1.4 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.67 mg/kg and an HR of 1.6 mg/kg (based on a highest single sample) for blueberries. The Meeting noted that an extrapolation to the group of bushberries was not possible because of a high acute intake resulting from the consumption of currents.

Small fruit vine climbing-Grapes

Seven trials were conducted in the USA from 1994 to 1996 that matched the US GAP on grapes (0.11 kg ai/ha with a PHI of 30 days; 0.11 kg ai/ha/season).

Bifenthrin residues in grapes were (n=7): < 0.05, 0.050, 0.060, 0.060, 0.070, 0.12 and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.060 mg/kg and an HR of 0.14 mg/kg (based on a highest single sample) for grapes.

Leafy vegetables

Lettuce, head

Ten trials were conducted in the USA in 1993–1994 (six trials) and 2003 (four trials), matching the US GAP on lettuce, head (0.11 kg ai/ha with 7-day intervals and a PHI of 7 days; 0.56 kg ai/ha/season).

Bifenthrin residues in head lettuce with wrapper leaves were (n=10): < 0.05, 0.14, 0.23, 0.33, 0.45, 0.56, 0.71, 0.81, 1.7 and 1.8 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg for lettuce, head, an STMR of 0.51 mg/kg and an HR of 1.9 mg/kg (based on a highest single sample). However, this would result in an exceedance of the ARfD and an alternative GAP for head lettuce was not identified.

Spinach

Eight trials were conducted in the USA in 1999, two trials of which matched the US GAP on spinach (by ground or aerial spray, a rate of 0.11 kg ai/ha with 7-day intervals and a PHI of 40 days; 0.45 kg ai/ha/season).

Bifenthrin residues were 0.05 and 0.15 mg/kg.

The Meeting did not estimate a maximum residue level as the number of trials was not sufficient.

Stalk and stem vegetables

Celery

Eight trials, including one decline trial, were conducted in 1997 (3 trials), 1998 (one trial) and 2004 (four trials) matching the US GAP on leafy petiole vegetables (0.11 kg ai/ha with 7-day intervals and a PHI of 7 days; 0.56 kg ai/ha/season).

Bifenthrin residues were (n=8): 0.13, 0.17, 0.29, 0.68, 0.71, 0.89, 1.1 and 1.5 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.70 mg/kg and an HR of 1.8 mg/kg (based on a highest single sample). However, this would result in an exceedance of the ARfD and an alternative GAP for celery was not identified.

Legume vegetables

Peas

Six trials were conducted in the USA from 1992 to 1994 that matched the US GAP on succulent peas and beans (0.11 kg ai/ha with a PHI of 3 days; 0.22 kg ai/ha/season).

Bifenthrin residues in peas with pods were (n=6): 0.17, 0.17, 0.20, 0.25, 0.34 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.9 mg/kg, an STMR of 0.23 mg/kg and an HR of 0.50 mg/kg (based on a highest single sample) for peas (pods and succulent=immature seed).

Bifenthrin residues in peas without pods were (n=6): < 0.05 (6) mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg and an STMR of 0 mg/kg for peas, shelled (succulent seeds).

Beans

Data from six trials on snap bean (beans with pods) were re-submitted. The 2010 JMPR did not estimate a maximum residue level as the trials were not conducted in accordance with the US GAP (0.11 kg ai/ha with a PHI of 3 days; 0.22 kg ai/ha/season). The trials were conducted in the USA in 1996 and 1997 with three applications 7 days apart, 0.090 kg ai/ha (1st), 0.090 kg ai/ha (2nd) and 0.045 kg ai/ha (3rd) and with a 3-day PHI. Residue values in snap beans with pods were < 0.05, 0.050, 0.050, 0.055, 0.11 and 0.14 mg/kg.

None of the data matched the GAP and the data were not suitable for application of the proportionality approach.

Data from seven trials on lima bean, without pods (conducted in the USA in 1997) were re-submitted. The 2010 JMPR did not estimate a maximum residue level as the trials were not conducted in accordance with the US GAP. The trials were conducted with three applications (approximately 0.090 kg ai/ha at the 1st and 2nd application, and 0.045 kg ai/ha at the 3rd application), 6–7 days apart, and a 2 to 4-day PHI. Residue concentrations in lima bean, shelled (succulent seeds) were all less than 0.05* mg/kg (n=7).

None of the data matched the GAP and the data were not suitable for application of the proportionality approach.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex I are appropriate for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *bifenthrin (sum of isomers).*

The residue is fat-soluble.

CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
		New	Previous		
FB 0020	Blueberries	3		0.67	1.6
FB 0269	Grapes	0.3		0.06	0.14
VL 0482	Lettuce, Head	4 [a]		0.51	1.9
VS 0624	Celery	3 [a]		0.7	1.8
VP 0063	Peas (pods and succulent=immature seed)	0.9		0.23	0.5
VP 0064	Peas, shelled	0.05*		0	

[a] On the basis of information provided to the JMPR it was concluded that the estimated short-term intake of bifenthrin for the consumption of head lettuce and celery may present a public health concern

DIETARY RISK ASSESSMENT

Long-term intake

The 2009 JMPR established an ADI of 0–0.01 mg/kg bw for bifenthrin.

The International Estimated Daily Intakes (IEDIs) of bifenthrin were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current and previous Meeting. The results are shown in Annex 3 to the 2015 JMPR Report.

The calculated IEDIs were 9–30% of the maximum ADI. The Meeting concluded that the long-term intake of residues of bifenthrin from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2009 JMPR established an ARfD of 0.01 mg/kg bw for bifenthrin. The International Estimated Short Term Intakes (IESTIs) for bifenthrin were calculated for the food commodities using HRs/STMRs estimated by the current Meeting. The results are shown in Annex 4 to the 2015 JMPR Report.

For celery the IESTI represented 600% and 360% of the ARfD for children and general population, respectively. For head lettuce the IESTI represented 430% and 190% of the ARfD for children and general population, respectively. No alternative GAP for celery and head lettuce was available. On the basis of information provided to the JMPR, the Meeting concluded that the short-term intake of residues of bifenthrin from consumption of celery and head lettuce may present a public health concern.

Estimates of intake for the other commodities considered by the 2015 JMPR were within 0-100% ARfD. The Meeting concluded that the short-term intake of bifenthrin for the other commodities is unlikely to present a public health concern when bifenthrin is used in ways that were considered by the Meeting.

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