BIFENAZATE (219)

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EXPLANATION

Bifenazate is a carbazate acaricide and insecticide. The compound was evaluated for the first time by the 2006 JMPR (T, R) when an ADI of 0-0.01 mg/kg bw was established and no acute reference dose was considered necessary. The residue was defined for enforcement and dietary intake calculations as *Sum of bifenazate and bifenazate-diazene (diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl-3-yl] 1-methylethyl ester), expressed as bifenazate; the residue is fat soluble.* In addition, the meeting recommended maximum residue levels, supervised trial median and high residue levels for a number of commodities. The compound was listed for additional MRLs by 2010 JMPR at the Forty-first Session of the CCPR.

The manufacturer submitted the residue studies for support additional MRLs for raspberries, blackberries, lychee, papaya, sugar apple, guava, beans (succulent shelled and podded), peas (succulent shelled and podded) and dry bean seeds.

METABOLISM

Metabolism studies on lactating goat and laying hens, oranges, apples, grapes, radish and cotton were reviewed by the 2006 JMPR. No new information was provided.

METHODS OF RESIDUE ANALYSIS

Analytical methods

The analytical methods used in the supervised trials presented for evaluation by the present meeting are all based on the method previously reviewed by JMPR in 2006, where combined residues of bifenazate and bifenazate-diazene are determined as bifenazate using HPLC with oxidative coulometric electrochemical detection, after converting bifenazate-diazene into bifenazate with 1% ascorbic acid.

Homogenized lychee samples were extracted twice using acetonitrile (ACN) containing 0.1% acetic acid. The combined extracts were filtered, brought up to volume with ACN, and partitioned with methylene chloride (lychee, GRL-12167) (succulent beans and peas and immature pods, GRL-FR-11927; GRL-FR-11926, dry beans, GRL-12170), n-hexane (papaya, GRL-12035) and 2% aqueous sodium sulphate. The concentrated methylene chloride phase was cleaned up on an amino propyl column (only for lychee). The resulting eluate was evaporated to near dryness and residues reconstituted in HPLC mobile phase (ACN/sodium acetate pH 4 buffer/acetic acid) with 0.1% ascorbic acid to convert residues of bifenazate-diazene to bifenazate. After at least 2 hours of incubation, the samples were quantified as bifenazate by reversed-phase HPLC with oxidative coulometric electrochemical detection (HPLC/OCECD).

Table 1 Summary of method validation data performed with bifenazate and bifenazate-diazene in fruits and vegetables

Analyte	Fortification (mg/kg)	No. of tests (n)	Recoveries (%)	Mean (%)	RSD (%)
Lychee					
Bifenazate	0.01	6	75.8[a], 76.0[a], 81.3[a], 102, 117, 110	93.8	20

Analyte	Fortification (mg/kg)	No. of tests (n)	Recoveries (%)	Mean (%)	RSD (%)
	0.1	3	98.9, 95.0, 95.2	96.4	2.3
	1	3	92.1, 91.7, 92.6	92.2	0.44
	0.01–1	12	75.8–117	94	13
Bifenazate-diazene	0.01	6	83.6[a], 77.1[a], 89.1[a], 117.3, 113.6, 114.7	99.2	18
	0.1	3	84.2[a], 85.6[a], 83.2[a]	84.3	1.4
	1	3	77.3[a], 80.2[a], 77.1[a]	78.2	2.2
	0.01–1	12	77.1–117.3	90.2	17
Papaya					
Bifenazate	0.01	3	70.4, 70.8, 70.2	70.5	0.43
	0.1	3	94.7, 95.3, 93.2	94.4	1.2
	1	3	102, 97.9, 103	101	2.8
	0.01–1	9	70.2–103	88.6	16
Bifenazate-diazene	0.01	3	91.5, 92.9, 81.6	88.7	6.9
	0.1	3	70.1, 70.3, 74.1	71.5	3.1
	1	3	80.2, 78.9, 78.1	79.1	1.4
	0.01–1	9	70.1–92.9	79.7	10
Succulent beans seeds					
Bifenazate	0.01	3	85, 81, 80	82	3.3
	0.05	3	73, 80, 83	78	6.8
	0.5	3	87, 91, 89	89	2.3
	0.01–0.5	9	73–91	83	6.6
Bifenazate-diazene	0.01	3	75, 89, 73	79	11
	0.05	3	78, 73, 70	74	5.8
	0.5	3	81, 76, 73	76	5.1
	0.01–0.5	9	70–89	76	7.6
Beans in pods					
Bifenazate	0.01	3	107, 91, 84	94	13
	0.5	3	83, 85, 84	84	1.1
	5.1	3	89, 85, 91	88	3.4
	0.01–5.1	9	83–107	89	8.4
Bifenazate-diazene	0.01	3	105, 117, 96	106	10
	0.5	3	80, 81, 81	81	1.3
	5.1	3	86, 89, 92	89	3.6
	0.01–5.1	9	80–117	92	14
Succulent peas					
Bifenazate	0.01	3	70, 76, 74	73	3.8
	0.5	3	85, 88, 95	89	5.7
	5.1	3	95, 94, 92	94	1.7
	0.01–5.1	9	70–95	85	11
Bifenazate-diazene	0.01	3	74, 70, 79	74	5.8
	0.5	3	75, 77, 82	78	4.4
	5.1	3	86, 91, 80	86	6.4
	0.01–5.1	9	70–91	79	8.1
Peas in pods					
Bifenazate	0.01	3	119, 92, 71	94	26
	0.05	3	96, 90, 84	90	6.4
	0.5	3	95, 91, 95	93	2.2
	0.01–0.5	9	71–119	92	14
Bifenazate-diazene	0.01	3	90, 88, 79	85	7.0
	0.05	3	86, 83, 81	83	3.1
	0.5	3	93, 90, 90	91	1.9
	0.01–0.5	9	79–93	87	5.4
Dry beans, shelled					
Bifenazate [b]	0.01	6	111.1, 86.8, 112.6 72.1, 71.7, 75.2	88.2	22
	0.5	3	76.0, 76.6, 87.9	80.2	8.3
	0.01–0.5	9	71.7–112.6	86	19
Bifenazate-diazene	0.01	6	71.1, 76.5, 71.3 84.8, 75.6, 74.9	75.7	6.6
	0.5	3	75.8, 83.6, 84.4	81.3	5.6
	0.01–0.5	9	71.1–84.8	78	6.9

[a] Corrected for average residue detected in the corresponding control samples.

[b] For the bifenazate sample set (0.01 first three results, and at 0.5), the control samples had an average residue of 0.003 mg/kg. Since this is less than half of the LOQ (of 0.01 mg/kg), all recovery results, averages and % RSD values for this set are uncorrected. For the bifenazate (0.01 last three results), bifenazate-diazene (0.01, 0.5) sample set, the control samples had an average residue of 0.006 mg/kg. Since this is greater than half of the LOQ (of 0.01 mg/kg), all recovery results, averages and %RSD values for this set are corrected for this residue.

Stability of residues in stored analytical samples

The 2006 Meeting received information on the freezer storage stability of residues of bifenazate and bifenazate-diazene in apples, apricots, cantaloupe, cherries, cotton seed, cotton seed hulls, cotton seed meal, cotton seed refined oil, egg yolk, fat, gin trash, grape juice, grapes, kidney, liver, milk, mint, muscle, oranges, peaches, peppers, plums, potatoes, poultry liver, poultry muscle, poultry skin + fat, prunes, tomato, tomato paste and tomato puree.

Residues of bifenazate or bifenazate-diazene measured as the sum of bifenazate and bifenazate-diazene did not decline by more than 30% when spiked into the following substrates and stored in a freezer at temperatures below -18 °C for the interval tested: homogenized tomato 6 months; homogenized peppers 6 months; homogenized mint tops 102 days; sliced plums 4 weeks; tomato paste 4 weeks; tomato puree 4 weeks; cottonseed refined oil 28 days; apples skin surface 224 days; grapes surface 224 days; peaches skin surface 223 days; homogenized oranges 186 days; grape juice 186 days; homogenized prunes 182 days; milk 202 days; fat 95 days.

Estimates were made of the time interval for a 30% decline of residues of bifenazate or bifenazate-diazene measured as the sum of bifenazate and bifenazate-diazene when spiked into the following substrates and stored in a freezer at temperatures below -18 °C: homogenized cherries 2.6 months; homogenized cantaloupe 3.9 months; homogenized apples 106 days; homogenized grapes 22 days; homogenized peaches 92 days; muscle 10 days.

The maximum period of storage prior to analysis of samples was less than 30 days except lychee which was stored for over 300 days.

The stability of residues of bifenazate and bifenazate-diazene in lychee samples under frozen conditions was investigated (GRL-12272). Untreated un-homogenized samples of lychee fruit were fortified with bifenazate at 0.1 mg/kg. Samples were placed in frozen storage at -19.2 to -27 °C and analysed at storage intervals of 0, 0.25, 1, 2, 5, 8, and 10 months. At each sampling period, an untreated control was freshly fortified with bifenazate at 0.1 mg/kg and analysed at the same time as the stored samples with the validated method described in the previous section. The reported LOQ is 0.01 mg/kg for each analyte in/on lychee. Three freshly fortified samples of lychee fruit were analysed at 0 time.

Table 2 Stability of bifenazate residues in lychee following frozen storage at -19.2 to -27 °C

Fortification (mg/kg)	Storage interval (months)	Procedural recovery [a] (%)	Residues in stored fortified samples (mg/kg) [b]	Average uncorrected residues remained (%)	Residues remained [c]
0.10	0	112	0.105, 0.110, 0.115	112	-
	0.25	101	0.061, 0.067, 0.071	67.2	67
	1	76.6	0.041, 0.045, 0.049	45.0	58.7
	2	88.9	0.069, 0.069, 0.218 [d]	68.8	77.4
	5	68.6	0.041, 0.042, 0.047	43.9	64.0
	8	54.3	0.021, 0.028, 0.061	37.0	68.2
	10	79.9	0.047, 0.052, 0.060	54.6	68.4

[a] Average recovery obtained from two freshly spike untreated test portions.

[b] All residues with the exception of 0-day interval were corrected for apparent residues (0.01 to 0.06 mg/kg).

[c] Corrected for procedural recovery

[d] The report indicated that a sample preparation error was suspected with this sample and therefore its result was not used to determine the mean recovered residues and recoveries.

The results indicate that average bifenazate residue (corrected for apparent residues in untreated samples) remaining after one week storage were significantly lower than the day 0 residues (t-test, equal variances). The average procedural recoveries and the residues measured in stored test portions showed relatively high variation. After one week, the degradation of bifenazate became much slower and after correction for procedural recoveries (54–79.9%) it was around 70% of the day 0 residues.

The storage durations and conditions of samples from the crop field trials evaluated by the present Meeting are summarised below.

Table 3 Summary of storage conditions and durations of samples from supervised field trials

Matrix	Storage Temperature (°C)	Actual Storage Duration	Reference
Cane berries	-28.9 to -18.7	5-13 days	PR 07053
Guava	-26.8 to -19.0	16-23 days	PR -08928
Papaya	-30.4 to -15.8	8-11 days	PR 08270
Sugar apple	~ -20	19 days	PR 08927
Lychee fruit	-28.9 to -19.9	297-308 days	GRL-12272; PR -08768
Bean, Succulent-shelled/ lima beans	-29.3 to -4.7	6-10 days	PR A8275
Bean, Succulent-shelled	-26.0 to -16.6	6-9 days	PR 08275
Bean, Edible-podded	-26.0 to -16.6	5-10 days	PR 08275
Peas, succulent-shelled	-29.7 to -16.6	23 days	
Peas, edible-podded	-29.7 to -16.6	30 days	
Beans, dry shelled	-30.3 to -18.3	29 days	PR 08929

USE PATTERNS

All supervised trials were conducted in the United States. The GAP in the US for the crops for which MRLs are proposed are summarised below.

Table 4 Registered uses of bifenazate in USA

Crop	Country	Formulation (g ai/L or g ai/kg)	Application				PHI Days
			kg ai/ha	Water, L/ha	kg ai/hL	No.	
Cane berries Subgroup [a]	USA	480 SC/ 500 WP	0.40- 0.56	468	0.09- 0.12	1	1
Legume vegetables, 6A (edible podded) and 6B (succulent seeds)[b]	USA	480 SC	0.56- 0.84	187	0.30- 0.45	2	3
Tropical fruits [c]	USA	480 SC/ 500 WP	0.40- 0.56	468	0.09- 0.12	1	1

[a] Blackberry, Loganberry, Red and Black Raspberry, Wild Raspberry

[b] Beans: *Lupinus* spp., *Phaseolus* spp., *Vigna* spp. Peas: *Pisum* spp., Soya beans: immature seeds (*Glycine max)*

[c] Guava, Lychee, Papaya, Star apple, Black sapote, Mango, Sapodilla, Canistel, Mamey, Longan, Spanish lime, Rambutan, Pulasan, Fejioa, Jaboticaba, Wax jambu, Starfruit, Passionfruit, Acerola

RESIDUES RESULTING FROM SUPERVISED TRIALS

Supervised trials on cane berries (raspberries, blackberries), lychee, papaya, sugar apple, guava, beans (succulent seeds and immature pods), peas (succulent seeds and immature pods), and dry beans were conducted in the United States from 2002 to 2006, and two trials on cane berries were conducted in Canada during 2004. The trials used either a formulation of wettable powder in water soluble bags containing 500 g ai/kg (referred to as 500 WP) or a suspension concentrate containing 480 g ai/L formulation (referred to as 480 SC).

The reports submitted were well documented and contained all the necessary information for the evaluation of residues. Each report included details of the field trials and analytical methods, a summary of the method validation, procedural recoveries, and details of storage of samples and where relevant, concurrent recoveries in stored frozen samples.

Although trials included control plots, no control data are recorded in the summary tables unless residues in control samples exceeded the LOQ. Results, expressed as bifenazate including bifenazate-diazene, reported have not been corrected for concurrent method recoveries unless indicated. The concurrent recoveries and those carried out during method validation were comparable.

In the trials, where multiple samples were taken from a single plot, the highest residue value is selected for the estimation of the MRL and STMR. Where results from separate plots with distinguishing characteristics such as different formulations, varieties or treatment schedules were reported, results are listed for each plot.

Residues and application rates have generally been rounded to two significant figures or, for residues near the LOQ, to one significant figure. Residue values from the trials conducted according to the ± 25% of maximum GAP has been used for the estimation of maximum residue levels. Those results included in the tables are underlined.

The results of these supervised trials are summarised in the following tables:

Crop Group or Subgroup	Commodity	Table No.
Cane berries subgroup	Raspberries and blackberries	Table 5
Tropical fruits, inedible peel	Lychee	Table 6
	Papaya	Table 7
	Sugar apple	Table 8
Tropical fruits, edible peel	Guava	Table 9
Legume vegetables	Beans	Table 10
	Peas	Table 11
Pulses	Beans, dry	Table 12

Cane berries subgroup

Table 5 Residues of bifenazate resulting from supervised trials on cane berries carried out with 500 WP formulations in 2004.

Corp/Location,	Application kg ai/ha	L/ha	kg ai/hL	No.	RTI	PHI days	Residue mg/kg	Reference/ Field ID
US GAP: 500 WP/ 480 SC, at 0.40-0.56 kg ai/ha (0.09-0.12 kgai/hL), number of applications 1, PHI 1 day								
Raspberry/Reveille Bridgeton, USA,NJ	0.56	193	0.29	2	29	0	2.2, 1.6	PR 07053 04-NJ16
Raspberry/ Royalty Madera, USA, CA	0.56	652	0.09	2	29	0	3.2, 3.3	PR 07053 04-CA67
Raspberry/ Malahat Aldergrove, CAN, BC	0.58	697	0.08	2	31	0	1.7, 1.4	PR 07053 04-BC02
Raspberry/Cascade Delight Abbotsford, CAN, BC	0.57	678	0.08	2	31	0	1.4, 1.5	PR 07053 04-BC03
Raspberry/Kilarme Quebec, CAN	0.63	786	0.08	2	30	0	2.6, 1.4	PR 07053 04-QC03
Raspberry/ Isabel Camarillo, USA, CA	0.57	767	0.07	2	35	0	1.2, 1.4	PR 07053 04-CA149
Blackberry/ Marion Wilsonville, USA, OR	0.56	458	0.12	2	32	0	2.3, 2.3	PR 07053 04-OR09

Corp/Location,	Application kg ai/ha	L/ha	kg ai/hL	No.	RTI	PHI days	Residue mg/kg	Reference/ Field ID
Blackberry/ Evergreen Wilsonville, USA, OR	0.57	383	0.13	2	29	0	2.5, 4.6	PR 07053 04-OR10

RTI: retreatment interval

Assorted tropical and subtropical fruit, inedible peel

Table 6 Residues of bifenazate resulting from supervised trials on lychee carried out with 500 WP formulations in USA in 2004

Corp/Location,	Application kg ai/ha	L/ha	kg ai/hL	No.	RTI	PHI days	Residue [a] mg/kg	Reference/ Field ID
US GAP: 500 WP/ 480 SC, at 0.40-0.56 kg ai/ha (0.09-0.12 kgai/hL), number of applications 1, PHI 1 day								
Mauritius Homestead, FL	0.56 0.57	1188	0.05	2	20	1	2.0 2.9 1.9 2.8	PR 08268 04-FL33
Mauritius Homestead, FL	0.57 0.57	1193	0.05	2	21	1	2.6 3.6 2.6 3.7	PR 08268 04-FL34
Mauritius Homestead, FL	0.57 0.57	1193	0.05	2	21	1	2.3 3.3 1.5 2.2	PR 08268 04-FL35

RTI: retreatment interval

[a] The residues reported are corrected for the loss during storage.

Table 7 Residues of bifenazate resulting from supervised trials on papaya carried out with 500 WP formulations in USA in 2003

Corp variety/Location,	Application kg ai/ha	L/ha	kg ai/hL	No.	RTI	PHI days	Residue [a] mg/kg	Reference/ Field ID
US GAP: 500 WP/ 480 SC, at 0.40-0.56 kg ai/ha (0.09-0.12 kgai/hL), number of applications 1, PHI 1 day								
Red Lady Homestead, FL	0.57	1393	0.04	2	21	1	0.11 0.14	PR 08270 03-FL19
Gold Haleiwa, HI	0.57	477	0.12	2	21	1	0.62 1.9	PR 08270 03-HI01
Kapoho Keaau, HI	0.58	963	0.06	2	22	1	0.81 0.76	PR 08270 03-HI02

RTI: retreatment interval

[a] All harvested samples were cut into fractions (1/8 to 1/2) to reduce sample size, put into bags in the field, transferred to frozen storage and kept frozen until analysis. Note, that this practice is not permitted by the Codex Guideline on Good Laboratory Practice (ftp://ftp.fao.org/codex/alinorm03/al03_41e)

Table 8 Residues of bifenazate resulting from supervised trials on sugar apple carried out with 500 WP formulations in USA in 2006.

Crop variety/Location,	Application kg ai/ha	L/ha	kg ai/hL	No.	RTI	PHI days	Residue[1] mg/kg	Reference/ Field ID
US GAP: 500 WP/ 480 SC, at 0.40-0.56 kg ai/ha (0.09-0.12 kgai/hL), number of applications 1, PHI 1 day								
Red Homestead, FL	0.55	1609	0.03	2	21	1	0.99 0.34	PR 08927 06-FL03
Red Homestead, FL	0.56	1646	0.03	2	21	1	0.21 0.15	PR 08927 06-FL04
Green Homestead, FL	0.58	617	0.09	2	21	1	0.23 0.09	PR 08927 06-FL05

Results are the average of two replicate analyses. The analyses of samples were repeated 6 days later due to the outlier concurrent recoveries in the first run. The relative difference of the results of repeated measurements ranged between 21 and 143%.

Assorted tropical and subtropical frui, edible peel

Table 9 Residues of bifenazate resulting from supervised trials on guava carried out with 500 WS formulations in USA in 2004.

Crop variety/Location,	Application					PHI	Residue	Reference/
	kg ai/ha	L/ha	kg ai/hL	No.	RTI	days	mg/kg	Field ID
US GAP: 500 WP/ 480 SC, at 0.40-0.56 kg ai/ha (0.09–0.12 kgai/hL), number of applications 1, PHI 1 day								
Homestead Homestead, FL	0.58	1330	0.04	2	21	1	0.26 0.30	PR 08928 04-FL36
Homestead Homestead, FL	0.58	1330	0.04	2	21	1	0.04 0.18	PR 08928 04-FL37
Homestead Homestead, FL	0.58	1330	0.04	2	27	1	0.21 0.14	PR 08928 04-FL38

Legume vegetables

Table 10 Residues of bifenazate resulting from supervised trials on beans carried out with 480 SC formulations in USA in 2002-2003.

Crop variety/Location,	Application					PHI	Residue	Reference/
	kg ai/ha	L/ha	kg ai/hL	No.	RTI	days	mg/kg	Field ID
US GAP: 500 WP/ 480 SC, at 0.56–0.84 kg ai/ha (0.30-0.45 kgai/hL), number of applications 2, PHI 3 days								
Edible podded beans (Immature pods)								
Snap beans/ Labrador Freeville, NY	0.83	367	0.22	2	15	3	1.8 1.8	PR 08275 02-NY11
Snap beans/Strike Strike Clinton, NC	0.85	283	0.30	2	14	2	1.4 2.0	PR 08275 02-NC12
Snap beans/ Blue Lake 274 Citra, FL	0.87	337	0.26	2	15	4	0.24 0.15	PR 08275 02-FL30
Snap beans/ Hystyle Arlington, WI[a]	0.85	300	0.28	2	14	3	0.58 0.54	PR 08275 02-WI05
Snap beans/ Bush Blue Lake 156 Arlington, WI[a]	0.84	301	0.28	2	14	3	0.70 0.64	PR 08275 02-WI06
Snap beans/ Florence Prosser, WA	0.85	283	0.30	2	14	3	1.0 1.3	PR 08275 02-WA*51
Succulent – Shelled Beans (Seeds)								
Lima beans/ Fordhook 242 Salisbury, MD[a]	0.83	386	0.22	2	13	2	0.11 0.18	PR 08275 02-MD04
Lima beans/ Burpee Improved Bush Salisbury, MD[a]	0.83	386	0.21	2	13	2	0.13	PR 08275 02-MD05
Lima beans/ Improved Kinston Hancock, WI	0.84	319	0.26	2	13	3	0.02 0.02	PR 08275 02-WI07
Lima beans/ Mezcla Parlier, CA	0.85	323	0.27	2	14	3	0.06 0.15	PR 08275 02-CA59
Lima Beans/Henderson Kimberly, ID	0.84	188	0.45	2	14	4	0.09 0.04	PR 08275 02-ID04
Lima beans/ Burpee improved bush Salisbury, MA	0.85	325	0.26	2	16	3	0.05 0.07	PR A8275 03-MD22
Lima beans/ Cangreen Tifton, GA	0.85	454	0.19	2	8	2	0.18 0.26	PR A8275 03-GA*20

[a] The two trials were performed at the same site with different varieties.

Table 11 Residues of bifenazate resulting from supervised trials on peas carried out with 480 SC formulations in USA in 2002

Crop variety/Location,	Application kg ai/ha	L/ha	kg ai/hL	No.	RTI	PHI days	Residue mg/kg	Reference/ Field ID
US GAP: 500 WP/ 480 SC, at 0.56-0.84 kg ai/ha (0.30-0.45 kg ai/hL), number of applications 2, PHI 3 days								
Edible podded peas (Immature pods)								
Sugar sprint Salisbury, MD	0.84	363	0.23	2	13	2	0.91 3.7	PR 08276 02-MD07
Sugar Daddy Prosser, WA	0.86	362	0.24	2	14	4	2.7 3.4	PR 8276 02-WA15
Progress No. 9 Potterville, CA	0.84	448	0.19	2	12	3	1.2 1.4	PR 08276 02-CA60
SP704 Arlington, WI	0.85	280	0.31	2	12	2	1.6 2.2	PR 08276 02-WI29
Sugar sprint Arlington, WI	0.86	284	0.31	2	12	2	1.4 1.5	PR 08276 02-WI30
Succulent – shelled peas (Seeds)								
Progress No. 9 Salisbury, MD	0.84	364	0.23	2	13	2	0.03 0.03	PR 08276 02-MD06
Pinkeye Purplehull Southern Tifton, GA	0.88	481	0.18	2	12	2	0.09 0.17	PR 08276 02-GA*06
Progress No. 9 Moxee, WA	0.83	392	0.21	2	14	4	0.03 0.04	PR 08276 02-WA*16
Knight Aurora, OR	0.86	224	0.39	2	14	2	0.03 0.03	PR 08276 02-OR17
Galant Arlington, WI	0.84	280	0.30	2	12	2	0.04 0.08	PR 08276 02-WI27
Dual Arlington, WI	0.85	280	0.31	2	12	2	0.05 0.09	PR 08276 02-WI28

Pulses

Table 12 Residues of bifenazate resulting from supervised trials on dry beans carried out with 480 SC formulations in USA in 2004-2005.

Crop variety/Location,	Application kg ai/ha	L/ha	kg ai/hL	No.	RTI	PHI days	Residue mg/kg	Reference/ Field ID
US GAP: 500 WP/ 480 SC, at 0.56-0.84 kg ai/ha (0.30-0.45 kg ai/hL), number of applications 2, PHI 8 days								
Cabernet Freeville, NY	0.84	286	0.30	2	13	8	0.01, < 0.01	PR 08929 04-NY10
California Red Kidney Arlington, WI	0.84	184	0.46	2	13	8	< 0.01, < 0.01	PR 08929 04-WI09
White marrow Arlington, WI	0.84	182	0.47	2	13	8	0.02, < 0.01	PR 08929 04-WI10
Maverick Velva, ND	0.85	186	0.46	2	14	7	0.09, 0.04	PR 08929 04-ND01
Navigator Navy Fargo, ND	0.85	113	0.75	2	14	7	< 0.01, < 0.01	PR 08929 04-ND02
Northern Beryl Scottsbluff, NE	0.85	203	0.41	2	15	8	0.07, 0.20	PR 08929 04-NE01
Kenearly Yellow Eye Freemont, OH	0.84	346	0.25	2	13	7	< 0.01, < 0.01	PR 08929 04-OH07
Othello Moxee, WA	0.81	341	0.25	2	14	7	0.01, < 0.01	PR 08929 04-WA05
Othello Fort Collins, CO	0.84	187	0.45	2	14	7	< 0.01, 0.01	PR 08929 04-CO05
Bill Z Fort Collins, CO	0.87	192	0.45	2	14	7	0.02, 0.02	PR 08929 04-CO06
California Early Light Red Kidney Davis, CA	0.84	280	0.30	2	15	7	0.04, 0.03	PR 08929 05-CA03

FATE OF RESIDUES IN STORAGE AND PROCESSING

No information was provided.

RESIDUES IN ANIMAL COMMODITIES

No information was provided.

APPRAISAL

Bifenazate was first evaluated by the 2006 JMPR when an ADI of 0–0.01 mg/kg bw was established and an acute reference dose was considered unnecessary. The 2006 Meeting recommended maximum and median residue levels for a number of commodities. The residue was defined for the purposes of undertaking enforcement and dietary intake calculations as the s*um of bifenazate and bifenazate-diazene (diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl-3-yl] 1-methylethyl ester), expressed as bifenazate.* The residue is considered fat-soluble. The current Meeting evaluated results of supervised trials for certain berry fruit, tropical fruit, legume vegetables and pulses.

Metabolism in animals and plants

The Meeting did not received additional metabolism studies, however those studies evaluated by the 2006 Meeting were deemed sufficient to cover the additional commodities.

Analytical methods

The analytical methods used in the supervised trials presented for evaluation by the present meeting are all based on the method previously reviewed by JMPR in 2006. The individual recoveries for residue concentration of 0.01–1 mg/kg ranged between 70 and 117% for lychee, papaya, succulent bean seeds, beans in pods, succulent peas, and peas in pods with relative standard deviations of 6–19%.

Stability of residues in samples stored under deep-frozen conditions was evaluated by the 2006 JMPR.

The maximum period of storage prior to analysis of samples evaluated by the present Meeting was less than 30 days except for lychee. Therefore no storage stability studies were conducted for these crops according to current guidelines. As the lychee samples were stored over 300 days, a storage stability study was carried out with the fortification of aliquots of un-homogenized samples to more accurately reflect application of bifenazate to whole fruit. The residues corrected for concurrent recoveries remained after the storage interval of one week and 10 months ranged between 59 to 64%. The results indicate a rapid decline during the first week and remained stable afterwards.

Results of supervised trials on crops

Supervised trial reports on cane berries, lychee, papaya, sugar apple, guava, legume vegetables, pulses were submitted for evaluation by the present Meeting.

Cane berries subgroup

The US GAP specifies one application at maximum 0.56 kg ai/ha with a PHI of 1 day.

Eight supervised trials on cane berries were conducted in the United States and Canada during the 2004–2005 growing season. Six of the trials were on raspberries and two on blackberries. Two applications were made with maximum GAP dosage rate at 29–35 days apart. Residues in samples were collected at day 0 were: 1.4, 1.5, 1.7, 2.2, 2.3, 2.6, 3.3 and 4.6 mg/kg.

The Meeting considered the rate of degradation of bifenazate between 7 and 28 days in grape, apple, pear in supervised trials evaluated by the 2006 JMPR and noted that the half-lives of the compound on grape, apple and pear were about 12.2, 10.9 and 13 days, respectively. Considering that the residue is mainly on the surface of the fruits, the similarity in the size of grape berries and raspberries, and the comparable rate of decline on several crops, the Meting assumed that the first treatment performed 29–35 days before the second one did not probably contribute more than 10–15% to the initial residue.

The Meeting estimated maximum residue level, STMR of 7 mg/kg, and 2.25 mg/kg for cane berries.

Lychee

The US GAP specifies one application at maximum 0.56 kg ai/ha with a PHI of 1 day. Three trials were performed at the same site with two pesticide treatments with maximum GAP dosage rate 20–21 days apart. The plots were treated on different days within a short period of time.

The residue levels in/on lychee fruits, corrected for loss during storage, one day after the 2nd application were 2.9, 3.3, and 3.7 mg/kg.

As the trials could not be considered independent and trial conditions did not match the GAP and the instability of residues in stored samples, the residue data available were not sufficient for estimation of residue levels.

Papaya

The US GAP specifies one application at maximum 0.56 kg ai/ha with a PHI of 1 day. Three field trials were conducted on papaya in Florida and Hawaii in the United States during the 2003 growing season. Two pesticide treatments were performed with maximum GAP dosage rate 21–22 days apart. All harvested samples were cut into fractions (1/8 to 1/2) on the fields to reduce sample size. This practice may lead to contamination of the samples and it is against provisions of the Codex Standards on Recommended method of sampling for the determination of pesticide residues for compliance with MRLs, and the Good Laboratory Practice in Residue Analysis as well as the FAO Manual

The residues 1 day after the 2nd pesticide application were: 0.14, 0.81 and 1.9 mg/kg.

Taking into account the uncertainties derived for sample size reduction in the field and the limited data, the Meeting could not recommend residue limits for papaya.

Sugar apple

The US GAP specifies one application at max 0.56 kg ai/ha with a PHI of 1 day. Three field trials performing 2 treatments with maximum GAP dosage rate at 21 days apart were conducted on sugar apple in the United States during the 2006 growing season. The trials were performed at the same site applying the pesticide with the same equipment on different days. These trials could not be considered independent.

The analyses of samples were repeated 6 days later due to the outlier concurrent recoveries in the first run. The relative difference of the results of repeated measurements ranged between 21 and 143% indicating very low reproducibility of the analysis and making the results questionable.

The higher of the replicated residue values in samples taken 1 day after the 2nd application were 0.21, 0.23 and 0.99 mg/kg.

Taking into account the trials were not independent and the large uncertainty of the results the Meeting considered the residue data unsuitable for estimation of residue levels for sugar apple.

Assorted tropical and sub-tropical fruits – Edible peel

Guava

The US GAP specifies one application at max 0.56 kg ai/ha with a PHI of 1 day. Three field trials were conducted on guava with two treatments with maximum GAP dosage rate at 21–27 days apart in the United States during the 2004 growing season. The trials were performed at the same site applying the pesticide with the same equipment on different days.

Residues 1 day after the second application were 0.18, 0.21 and 0.30 mg/kg.

As the trials could not be considered independent, the residue data available were not sufficient for estimation of residue levels.

Legume vegetables

The US GAP specifies two application at 0.56–0.84 kg ai/ha (0.30–0.45 kg ai/hL) with a PHI of 3 days.

Eleven supervised field trials on beans were conducted in the United States during the 2002 growing season according the US GAP. Five field trials were conducted on succulent-shelled beans and six on beans with edible pod. Two additional trials on lima beans were conducted during the 2003 growing season. These trials were performed at the same site with different varieties.

The samples of beans in pod collected 3 days after 2nd pesticide treatment contained residues: of 0.58, 0.7, 1.3 and 1.8 mg/kg. The residues in samples taken at day 2 and 4 were 2 mg/kg and 0.24 mg/kg, respectively.

Succulent shelled bean samples collected 3 days after 2nd pesticide treatment contained residues of: 0.02, 0.07 and 0.15 mg/kg, while the samples collected 2 days after 2nd pesticide application contained residues of 0.13, 0.18 and 0.26 mg/kg. Sample taken at day 4 contained residue of 0.09 mg/kg

Eleven supervised field trials on peas were conducted in the United States during the 2002 growing season according the US GAP. Six field trials were conducted on succulent-shelled peas and five on peas with pod. Only one sample, containing 1.4 mg/kg bifenazate residues, was taken from peas in pod at the registered PHI of 3 days. The residue content of samples of peas in pod taken at day 2 was 1.5, 2.2 and 3.7 mg/kg. The residue in a sample taken at day 4 was 3.4 mg/kg.

The residue content of shelled pea samples taken at 2 days after the 2nd pesticide treatment were: 0.03, 0.03, 0.08, 0.09 and 0.17 mg/kg. The day 4 sample contained residue of 0.04 mg/kg

As the decline of residues is moderate and the residue values in samples taken between 2 and 4 days were in the same range, all residue values were taken into account. The residues in beans and peas were similar and could be considered together.

The residues in samples of beans and peas in pod taken between 2 and 4 days after the second pesticide treatments were 0.58, 0.7, 1.3, 1.4, 1.5, 1.8, 2.2, 3.4 and 3.7 mg/kg.

Taking into account the mutual support, the Meeting estimated maximum residue and STMR values of 7 mg/kg and 1.5 mg/kg, respectively, for legume vegetables.

Pulses

The US GAP specifies two application at 0.56–0.84 kg ai/ha (0.30–0.45 kg ai/hL) with a PHI of 8 days. Eleven supervised field trials on beans (shelled, dry) were conducted in the United States during the 2004–2005 growing season. Samples collected 7–8 days after 2nd pesticide treatment contained residues of: < 0.01 (3), 0.01 (3), 0.02, 0.02, 0.04, 0.09 and 0.2 mg/kg.

The Meeting estimated maximum residue level, and STMR values of 0.3 mg/kg, and 0.01 mg/kg for beans, dry, respectively.

Residues in animal commodities

The 2006 JMPR evaluated a lactating dairy cow feeding study and estimated maximum and median residue levels in animal tissues and milk from residues in the animal diet.

Livestock dietary burden

The 2006 Meeting estimated the dietary burden of bifenazate in farm animals on the basis of the diets listed in Appendix IX of the FAO Manual1st ed. The estimated maximum and mean intakes were for beef (4.4 mg/kg and 1.02 mg/kg) and dairy cattle (4.24 mg/kg and 0.86 mg/kg), respectively.

Of the commodities evaluated by the present Meeting, only dry bean seeds can be considered as animal feedstuff Highest residue is 0.2 mg/kg, median residue 0.01 mg/kg. Dry bean seeds may be fed to cattle and poultry. Based on the new OECD feed table (FAO Manual 2nd ed. Appendix IX) the dietary burden calculations based also on the feed items considered by the 2006 JMPR for beef cattle, dairy cattle and poultry are provided in Annex 6. The Japanese animal dietary burden was 0 for the four animal groups and is therefore not included in the summary below.

	Livestock dietary burden, bifenazate, ppm of dry matter diet					
	US/CAN		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	0.07	0.07	0.21	0.16	0.83 [a]	0.73 [b]
Dairy cattle	0.64	0.64	0.13	0.08	0.67	0.64 [c]
Poultry, broilers	0.00	0.00	0.05	0.00	0.16 [d]	0.01 [e]
Poultry, layers	0.00	0.00	0.05	0.00	0.16	0.01

[a] Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[d] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat, edible offal and eggs.

[e] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat, edible offal and eggs.

Even with the addition of dry bean seeds, the resulting maximum dietary burdens for beef and dairy cattle are lower than those estimated in 2006 (4.4 ppm and 4.24 ppm, respectively), because a different animal feeds table was used then and the percent contribution of feed items in the diet has changed. Similarly, the mean dietary burdens are also lower than the previous estimates (1.02 ppm and 0.86 ppm for beef and dairy cattle, respectively). Therefore, the additional use of bifenazate on dry bean seeds will not affect the current MRLs for milk, milk fats, meat, and edible offal.

The dietary burden for poultry is very low. According to the poultry metabolism study, residues in poultry tissues and eggs are at very low levels even for a dietary burden of 10 ppm. Additional use of bifenazate on dry bean seed is not expected to result in residues in poultry tissues and eggs.

Based on the new dietary burden calculation, the Meeting confirmed its previous estimates for residues in animal commodities.

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 estimating IEDIs.

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

bifenazatediazene (diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl-3-yl] 1-methylethyl ester), expressed as bifenazate.

The residue is fat-soluble.

CCN	Commodity	Recommended Codex MRL (mg/kg)	STMR (mg/kg)
VD 0071	Beans (dry)	0.3	0.01
FB 0264	Blackberries	7	2.25
FB 0266	Dewberries	7	2.25
FB 0272	Raspberries	7	2.25
VP 0060	Legume vegetables	7	1.5

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of bifenazate resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated, including data from the 2006 JMPR Report, for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDIs in the thirteen Cluster Diets, based on estimated STMRs were 3–20 % of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term intake of residues of difenoconazole from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

As the establishment of an ARfD was previously considered unnecessary, the Meeting concluded that the short-term intake of bifenazate residues is unlikely to present a public health concern.

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Dorschner, K	2005	Bifenazate: Magnitude of the Residue on Lima Bean (Succulent Shelled). Chemtura Corporation, Project Number: A8275, A8275/03/UCR02, A8275/03/MD22. GLP; Unpublished.	PR A8275