

**DIFENOCONAZOLE (224)**

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**EXPLANATION**

Difenoconazole was evaluated by the JMPR at the first time in 2007 when an ADI of 0–0.01 mg/kg bw and ARfD of 0.3 mg/kg bw was established. 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, the governments of Republic of Korea, Kenya and Thailand provided residue data for additional commodities which were evaluated by the current meeting.

**METHODS OF RESIDUE ANALYSIS****Analytical methods**

The analytical method reported by the 2007 JMPR were shown to be applicable for other crops and used in supervised trials included in this evaluation.

The method AG-514 (Rodrigues, N.R., Rubbo, P., 1999) was used for the analysis of beans with pods and passion fruit. The validation of the method was carried out with samples of tomatoes and potatoes that were treated with phenyl-<sup>14</sup>C-difenoconazole. The limit of quantification of the method was 0.05 mg/kg, the typical recovery was 93% ± 18% in the residue range of 0.05–0.5 mg/kg.

The method AG-575 (Darnow, J., Sayers, L., 1990) is the modified version of AG 537A. It was used for the analysis of banana, beans with pods and cereal grains with an LOQ of 0.01 mg/kg, average recovery of 87% ± 15%. The AG-575A (Ross J., 1991) and AG-575B (Ross J., 1993) are corrected and updated versions of AG-575. AG-575A was translated and referenced under AGR/MOA/169374-1.

The AG-575A was further modified for determination of difenoconazole residues with GC-ECD (Ryan, J., 2005). The procedural recovery data from several crop residue studies are summarised in Table 1.

Table 1 Recovery data for various crops using Method AG-575A (ECD)

Matrix	Fortification Level (mg/kg)	Recoveries (%)	Mean (%)	Relative Standard Deviation	Number Samples Analysed
Kale	0.02	83, 81	82	N/A	2
	0.20	85, 90	88	N/A	2
	10.0	67	67	N/A	1
		Overall	81	11	5
Head Cabbage	0.01	92	92	N/A	1
	0.02	107, 103, 93, 76, 79	92	15	5
	0.10	91	91	N/A	1
	0.20	108, 102, 97, 84	98	10	4
		Overall	94	12	11
Lettuce	0.04	97, 115, 133, 107, 95, 87	106	16	6
	0.20	83, 90, 91, 84, 81, 92	87	5.4	6
		Overall	96	16	12
Broccoli	0.01	77, 99	88	N/A	2
	0.02	93, 90	92	N/A	2
	0.10	74, 90	82	N/A	2
	0.20	77, 91	84	N/A	2
	4.0	82	82	N/A	1
		Overall	86	10	9

Matrix	Fortification Level (mg/kg)	Recoveries (%)	Mean (%)	Relative Standard Deviation	Number Samples Analysed
Celery	0.04	131, 103, 92, 104	108	15	4
	0.20	93, 88, 94, 98	93	4.4	4
	1.0	96, 93	95	N/A	2
		Overall	99	12	10
Sugar Beet Roots	0.02	76, 92, 94, 96, 87, 100	91	9.3	6
	0.04	72, 82, 85, 94	83	11	4
	0.10	91	91	N/A	1
	0.20	93, 88, 94, 93, 96, 88, 110, 85	93	8.2	8
		Overall	90	9.4	19
Sugar Beet Leaves	0.02	109, 65	87	N/A	2
	0.1	89	89	N/A	1
	0.20	106, 99	103	N/A	2
	1.0	87	87	N/A	1
		Overall	93	17	6
Tomatoes	0.01	71, 107, 95, 107	95	18	4
	0.04	99, 82, 98, 94	93	8.4	4
	0.10	87, 70, 82, 84	81	9.2	4
	0.20	100, 89, 93, 96	95	4.9	4
	0.50	84	84	N/A	1
		Overall	91	12	17
Peaches	0.01	93, 97	95	N/A	2
	0.04	110, 100, 97	102	6.7	3
	0.10	80, 88	84	N/A	2
	0.20	100, 95, 69	88	19	3
		Overall	93	12	10
Strawberry	0.04	90, 99, 96	95	5	3
	0.20	90, 97, 94	94	4	3
		Overall	94	4	6
Pome Fruit	0.01	95, 78, 85, 99, 95, 72, 78, 75, 73, 110, 79, 108	87	16	12
	0.02	78	78	N/A	1
	0.04	93, 131, 90	105	22	3
	0.10	72, 73, 83, 91, 72, 89, 75, 87, 84, 74, 96, 81	81	10	12
	0.20	96, 93, 96, 97	96	1.8	4
	0.30	86	86	N/A	1
	0.50	77, 92	85	N/A	2
		Overall	87	15	35
Oilseed Rape	0.02	85, 69, 86	80	12	3
	0.04	89, 95	92	N/A	2
	0.10	89	89	N/A	1
		Overall	86	10	6
Olive Fruit	0.04	75	75	N/A	1
	0.10	100, 104, 96	100	4.0	3
	0.20	102, 95, 101, 103, 87, 77, 96	94	10	7
	1.0	103, 92, 97, 99	98	4.7	4
		Overall	95	9.5	15

N/A = Not Applicable

In the 0.01–1.0 mg/kg concentration range, the overall recovery of difenoconazole residues from crops of high water content was  $93 \pm 12\%$  ( $n = 81$ ). The recovery for crops of high oil content (0.02–1.0 mg/kg) was  $92 \pm 11\%$  ( $n = 21$ ).

Analytical Method AG-575A was modified for residue quantification with gas chromatography utilizing mass selective detection (Ryan, J., 2005a). Procedural recovery data from a range of high water and high fat content crops are summarised in Table 2.

Table 2 Recovery data for various crops using Method AG-575A (MSD)

Matrix	Fortification Level (mg/kg)	Recoveries (%)	Mean (%)	Relative Standard Deviation	Number Samples Analysed
Peaches	0.01	93, 107, 107, 80, 80	93	14	5
	0.10	99, 89, 89, 88	91	6	4
	0.50	94	94	N/A	1
		Overall	93	10	10
Plums	0.01	96, 108, 71, 71, 71	83	21	5
	0.10	86, 109, 71, 78, 78, 70	82	18	6
		Overall	83	18	11
Cherries	0.01	84, 73, 93, 88, 103	88	13	5
	0.10	81, 99, 99, 76, 88	89	12	5
	0.50	72	72	N/A	1
		Overall	87	12	11
Grapes	0.01	102, 99, 100, 95, 98	99	3	5
	0.10	82, 84, 80, 84, 91	84	5	5
		Overall	92	9	10
Tomatoes	0.01	96, 94, 108, 78, 100	95	12	5
	0.10	104, 109, 89, 93, 102	99	8	5
	0.40	74	74	N/A	1
		Overall	95	12	11
Lettuce	0.01	110, 109, 106, 106, 100	106	4	5
	0.10	89, 93, 89	90	3	3
	5.0	109, 70	90	N/A	2
		Overall	98	13	10
Kale	0.01	95, 103, 106, 94, 90, 105, 116, 116	103	4	5
	0.10	124, 115, 93, 94	107	3	3
	5.0	106, 105	106	N/A	2
		Overall	104	13	10
Fennel	0.01	84, 80, 88, 96, 97	89	8	5
	0.10	74, 77, 75, 84, 82	78	6	5
		Overall	84	10	10
Olives	0.01	96, 74, 79, 84, 75	82	11	5
	0.10	91, 89, 97, 92	92	4	4
	5.0	75			1
		Overall	85	11	10
Oilseed Rape Seed	0.01	101, 103, 98, 101, 95	100	3	5
	0.10	11, 124, 104, 104, 106	110	8	5
		Overall	105	8	10

N/A = Not Applicable

The REM 147.08 (Crook, S.J., 2004) was used for the analysis of beans with pods and tree nuts with an LOQ of 0.01 mg/kg. The recoveries obtained in various crops (Ely, S., Ryan, J., 2004) are summarised in Table 3.

Table 3 Recovery data for various crops using Method REM 147.08

Matrix	Fortification Level (mg/kg)	Recoveries (%)	Mean (%)	Relative Standard Deviation	Number Samples Analysed
Oilseed Rape Seed	0.01	84, 81, 83, 94, 93	87	6.9	5
	0.10	91, 91, 90, 94, 93	92	1.8	5
		Overall	89	5.4	10
Olive Fruit	0.01	115, 108, 103, 110, 93	106	7.9	5
	1.0	109, 104, 98, 97, 100	102	4.9	5
		Overall	104	6.6	10
Olive Oil	0.01	94, 97, 103, 98, 96	98	3.4	5
	1.0	81, 94, 92, 84, 87	88	6.2	5
		Overall	93	7.3	10

Matrix	Fortification Level (mg/kg)	Recoveries (%)	Mean (%)	Relative Standard Deviation	Number Samples Analysed
Sugar Beet Leaves	0.01	92, 75, 78, 84, 93	84	10	5
	1.0	96, 102, 95, 90, 95	96	4.5	5
		Overall	90	9.4	10
Sugar Beet Roots	0.01	88, 90, 93, 83, 84	88	4.7	5
	0.20	84, 86, 91, 92, 93	89	4.4	5
		Overall	88	4.4	10
Wheat Grain	0.01	92, 107, 94, 89, 95	95	7.2	5
	0.10	96, 96, 95, 77, 92	91	8.9	5
		Overall	93	8.0	10
Cherry	0.01	81, 84, 85, 90, 90	86	4.6	5
	0.20	95, 84, 82, 91, 94	89	6.6	5
		Overall	88	5.7	10
Apples	0.01	78, 95, 84, 96, 101	91	10	5
	0.30	90, 84, 84, 83, 89	86	3.8	5
		Overall	<b>88</b>	<b>8.1</b>	<b>10</b>
Tomato Fruit	0.01	85, 85, 81, 87, 89	85	3.5	5
	0.50	76, 79, 87, 89, 85	83	6.6	5
		Overall	84	5.1	10
Tomato Puree	0.01	82, 91, 86, 95, 97	90	6.9	5
	1.0	101, 80, 97, 93, 96	93	8.6	5
		Overall	92	7.6	10
Grapes	0.01	92, 99, 100, 101, 115	101	8.3	5
	0.10	120, 119, 100, 99, 96	107	11	5
		Overall	104	9.6	10
Broccoli (Whole Plant)	0.01	119, 90, 80, 88, 104	96	16	5
	0.10	98, 97, 105, 94, 103	99	4.5	5
		Overall	98	11	10
Leeks (Whole Plant)	0.01	93, 86, 84, 83, 86	86	4.5	5
	0.20	89, 78, 89, 89, 89	87	5.7	5
		Overall	87	4.8	10

The method used in a banana study (Xueyan Z., 2007) was based on homogenization in acetonitrile with T25 Ultra-Turrax. The extracted mixture was filtered and partitioned. The upper layer was removed and filtered with sodium sulphate, evaporated to dryness and reconstituted with ethyl acetate: petroleum ether (3:2, v/v). The mixture was cleaned up using an anhydrous sodium sulphate and alumina N column conditioned with ethyl acetate: petroleum ether (3:2, v/v). The eluate was evaporated to dryness and diluted with acetone for determination by gas chromatography with nitrogen phosphorus detection (GC-NPD). The validated quantification limit was 0.02 mg/kg. The recoveries are summarised in Table 4.

Table 4 Recoveries of difenoconazole from banana

Matrix	Fortification Level (mg/kg)	Recoveries (%)	Mean (%)	Relative Standard Deviation	Number Samples Analysed
Banana (whole fruit)	0.02	95.6, 78.7, 87.6, 90.9, 97.0	90.0	8.1	5
	0.5	87.3, 90.0, 99.8, 95.6, 84.9	91.5	6.7	5
		Overall	90.8	7.4	10
Banana (pulp only)	0.02	90.9, 91.6, 91.7, 96.4, 91.8	92.5	2.4	5
	0.5	96.7, 102.5, 102.2, 105.6, 91.5	99.7	5.6	5
		Overall	96.1	4.0	10

Passion fruits were analysed (Ciscato, C.H.P., Gebara, A.B., 1999; Ciscato, C.H.P., Gebara, A.B., 2001) with a method similar to DFG S19 presented in the 2007 Evaluations. The LOQs reported were 0.01–0.02 mg/kg. The recoveries are shown in Table 5.

Table 5 Recovery data from passion fruit (report FHF 017B)

Matrix	Fortification Level (mg/kg)	Recoveries (%)	Mean (%)	Relative Standard Deviation	Number Samples Analysed
Passion fruit	0.01	85	85	NA	1
	0.10	92	92	NA	1
	0.02	96.4	102.8	8.1	3
		100.0			
		111.9			
	1.00	89.1	95.8	5.8	3
		99.1			
99.3					

Fresh ginseng roots were washed with tap water to remove soil particles and ground. These samples were individually packed in polyethylene bags and stored at -20 °C or -70 °C until analysis. The test portions were blended with acetonitrile, the extract diluted with saturated NaCl solution, partitioned with hexane or dichloromethane, cleaned up on Florisil or alumina columns. The residue concentration was determined after elution on capillary column and detection with GC-ECD or GC-MSD. Five recovery tests were performed as part of the validation of the methods. In addition, concurrent recoveries were tested with untreated test portions at the time of the analysis of field treated samples in three replicates from each field (Chae M.Y., 2010; Hur, J.H., 2009); Kyung, K.S., 2009). There was no statistically significant difference between the pre-trial validation data and the concurrent recoveries. The basic methods and their performance parameters are summarised in Table 6.

Table 6 Summary of analytical methods used for determination of fresh ginseng roots and processed ginseng products

Sample material	Fresh ginseng	Dried ginseng	Red ginseng	Dried red ginseng	Ginseng extract
Test portion [g]	20	10	10	10	10
Extraction solvent	100 mL ACN	100 mL ACN	10 mL H <sub>2</sub> O+ 50 ACN	20 mL H <sub>2</sub> O+ 50 ACN	50 mL ACN
Solvent/solvent partition	400 mL water + 100 mL saturated NaCl / 2 × 70 mL hexane	500 mL water+50 mL CH <sub>2</sub> Cl <sub>2</sub> /2 × 50 mL CH <sub>2</sub> Cl <sub>2</sub>	400 mL water+100 mL saturated NaCl + 50 mL CH <sub>2</sub> Cl <sub>2</sub> /2 × 50 mL CH <sub>2</sub> Cl <sub>2</sub>	400 mL water+100 mL saturated NaCl + 50 mL CH <sub>2</sub> Cl <sub>2</sub> /2 × 50 mL CH <sub>2</sub> Cl <sub>2</sub>	
Cleanup	10 g Florisil	5 g SiO <sub>2</sub>		5 g Florisil	
Elution	60 mL CH <sub>2</sub> Cl <sub>2</sub> :ACN=1:1	45 mL hexan:acetone/70:30		50 mL CH <sub>2</sub> Cl <sub>2</sub> :ACN=1:1	
Quantification	GC-ECD	GC/MSD	GC-ECD	GC-ECD	
LOQ					
Fresh ginseng	0.002-0.003	0.02	0.003	0.007	
Dried ginseng		0.04	0.007	0.007	
EtOH extract		0.04	0.007	0.007	
Recovery: n	5	5		5	
0.003 mg/kg	91%			94.6%	
0.007 mg/kg		95-101%			
0.02 mg/kg					
0.03 mg/kg	101.5%				
0.07 mg/kg		103-104%		99.9	
0.2 mg/kg	90.8%	99-105%		89	
1.0 mg/kg		5			
Repeatability	≤ 4%	≤ 7.4%		≤ 3%	

**Stability of residues in stored analytical samples**

Detailed information provided for the 2007 JMPR indicated that difenoconazole residues were stable in the following crop commodities for the intervals tested, some for 1 year, but most for 2 years: banana, cotton seed, cotton seed meal, cotton seed oil, lettuce, potatoes, soya beans, tomatoes, wheat forage, wheat grain and wheat straw stored for one year at ca. -20 °C. Difenoconazole and metabolite CGA 205375 spiked into animal tissues (0.2 mg/kg) and milk (0.05 mg/kg) were stable when stored at or below -18 °C for approximately 10 months.

Untreated test portions of ginseng and ginseng processed products were spiked with difenoconazole solution and stored at or below -20 °C until the analyses of field treated samples. The spiked test portions for testing the stability of residues under deep-frozen conditions were analysed together with the field treated fresh ginseng and various processed products made from them (Chae M.Y., 2010; Hur, J.H., 2009); Kyung, K.S., 2009). The fortification level and the survived residues after the longest storage period are summarised in Table 7.

Table 7 Storage stability of difenoconazole residues in ginseng roots and processed ginseng products

Matrix	Fortification level [mg kg <sup>-1</sup> ]	Residues <sup>a</sup> remained[%]	Relative standard deviation [%]	Days of storage
Fresh ginseng	0.03	95.32	0.98	135
	0.05	98.61	3.53	135
Dried ginseng	0.07	98.88	1.44	135
Red ginseng	0.07	109.43	0.69	135
Dried ginseng extract (ethanol)	0.07	103.56	2.54	135
Dried ginseng extract (water)	0.07	94.94	2.58	135
Red ginseng extract (ethanol)	0.07	98.28	3.10	135
Red ginseng extract (water)	0.07	89.71	4.20	135

<sup>a</sup> Average of 5 replicate analyses

**USE PATTERNS**

The use patterns for protection of crops in which supervised trials had been submitted for evaluation are summarised in Tables 6–8.

Table 8 Registered uses of difenoconazole in banana and passion fruit

Crop	Country	Formulation <sup>a</sup>	Application				PHI (days)	
			Method	Rate (kg ai/ha)	Spray conc. (kg ai/hl)	Spray Interval (days)		Number
Banana	Australia	EC (25% difenoconazole)	Foliar	0.1		14-21	2-3	1
Banana	Bangladesh	EC (25% difenoconazole)	Foliar	0.0625	0.0125		6	
Banana	Belize	EC (25% difenoconazole)	Foliar	0.075-0.1		18-28	4-8	0
Banana	Bolivia	EC (25% difenoconazole)	Foliar (aerial)	0.1	0.02	18-21		1
Banana	Brazil	EC (25% difenoconazole)	Foliar	0.05	0.005-0.01	30	5	7
Banana	Brazil	EC (25% difenoconazole)	Foliar	0.1	0.01-0.02	14-21	5	7
Banana Group	Cameroon	EC (25% difenoconazole)	Foliar	0.1		28	Up to 8	0
Banana	China	EC (25% difenoconazole)	Foliar	-	0.0083 - 0.0125	10	Up to 3	42
Banana	Colombia	EC (25% difenoconazole)	Foliar	0.075-0.1	0.015-0.05			0

Crop	Country	Formulation <sup>a</sup>	Application					PHI (days)
			Method	Rate (kg ai/ha)	Spray conc. (kg ai/hl)	Spray Interval (days)	Number	
Banana	Costa Rica	EC (25% difenoconazole)	Foliar (aerial)	0.1		16-18	Up to 8	0
Banana	Cote d'Ivoire	EC (25% difenoconazole)	Foliar	0.075-0.1		21	6-8	
Banana	Dominican Republic	EC (25% difenoconazole)	Foliar (aerial)	0.1		16-18		0
Banana	Ecuador	EC (25% difenoconazole)	Foliar	0.075-0.1		21-26	2	0
Banana	France	EC (25% difenoconazole)	Foliar	0.1				
Banana	Guatemala	EC (25% difenoconazole)	Foliar	0.1		16-18	Up to 8	0
Banana	Honduras	EC (25% difenoconazole)	Foliar	0.1		16-18	Up to 8	0
Banana	Honduras	EC (25% propiconazole/25% difenoconazole)	Foliar (aerial)	0.075		10-21	Up to 8	0
Banana	Nicaragua	EC (25% difenoconazole)	Foliar (aerial)	0.1		12-18	Up to 8	0
Banana	Panama	EC (25% difenoconazole)	Foliar	0.1			Up to 8	0
Banana	Panama	EC (25% propiconazole/25% difenoconazole)	Foliar (aerial)	0.075		10-21	Up to 8	0
Banana	Philippines	EC (25% difenoconazole)	Foliar (aerial)	0.075-0.1			6-8	
Banana	Taiwan	EC (25% difenoconazole)	Foliar	0.05	0.167	14	1-2	6
Banana	Venezuela	EC (25% difenoconazole)	Foliar	0.075-0.1		18-28	4-8	0
Passion fruit	Brazil	EC (25% difenoconazole)	Foliar spray	0.01-0.04	0.005	15	4	14
Passion fruit	Ecuador	EC (25% difenoconazole)	Foliar spray	0.075		7-15	2	0

<sup>a</sup> percentages are w/v or w/w depending on formulation.

Table 9 Registered uses of difenoconazole in beans with pods

Crop	Country	Formulation <sup>a</sup>	Application					PHI (days)
			Method	Rate (kg ai/ha)	Spray conc. (kg ai/hl)	Spray Interval (days)	Number	
Bean	Chile	EC (25% difenoconazole)	Foliar spray	0.1-0.125	-	10-15	3	14
Bean	Indonesia	EC (25% difenoconazole)	Foliar spray	0.15	0.0125-0.025	7	6-8	7
Bean	Kenya	EC (25% difenoconazole)	Foliar spray	0.125	0.0125-0.125	7-10	4	14
Bean	Malaysia	EC (25% difenoconazole)	Foliar spray	0.075-0.125	-	7-10	4	7
Bean	Morocco	EC (25% difenoconazole)	Foliar spray	0.125	0.0125	10-15	3	14
Bean	Peru	EC (25% difenoconazole)	Foliar spray	0.15	0.019-0.025	7-10	3	14
Bean	Portugal (EU South)	EC (25% difenoconazole)	Foliar spray	0.125	0.0125	12-14	2	7
Bean	South Africa	EC (25% difenoconazole)	Foliar spray	0.0625	0.013-0.021	10-14		14

Crop	Country	Formulation <sup>a</sup>	Application					PHI (days)
			Method	Rate (kg ai/ha)	Spray conc. (kg ai/hl)	Spray Interval (days)	Number	
Bean	Taiwan	EC (25% difenoconazole)	Foliar spray	0.075-0.1	0.00825	10-14	3	3
French bean	Kenya	EC (25% difenoconazole)	Foliar spray	0.125	0.02	14	4	3
French bean	Senegal	EC (25% difenoconazole)	Foliar spray	0.125	0.02	14		3

<sup>a</sup> percentages are w/v or w/w depending on formulation.

Table 10 Registered uses of difenoconazole in tree nuts and ginseng

Crop	Country	Formulation <sup>a</sup>	Application					PHI (days)
			Method	Rate (kg ai/ha)	Spray conc. (kg ai/hl)	Spray Interval (days)	Number	
Pistachio	Turkey	EC (15% difenoconazole, 15% propiconazole)	Foliar spray	0.135	0.0075	15	2-3	21
Coconut	Brazil	EC (25% difenoconazole)	Foliar spray	0.05	0.005	14	4	14
Cashew nut	Vietnam	EC (25% difenoconazole)	Foliar spray	0.045-0.125	0.015-0.025	7-14	2-3	7
Tree nuts	USA	EC (25% difenoconazole)	Foliar spray	0.091-0.128		14-21	2 <sup>b</sup>	14
Ginseng	Republic of Korea	SC (10.7% difenoconazole)	Foliar spray		0.0268	10	max 4	7
Ginseng	Republic of Korea	SC (10.0% difenoconazole)	Foliar spray		0.0535	10	Max 5	14

<sup>a</sup> percentages are w/v or w/w depending on formulation.

<sup>b</sup> Max. 2 sequential applications and max 0.51 kg ai/season

## RESIDUES RESULTING FROM SUPERVISED TRIALS

The Meeting received information on supervised field trials for difenoconazole uses that produced residues on the following commodities.

Crop group	Commodity	Table No.
Tropical subtropical fruits, inedible peel	Banana	11
	Papaya	12
	Passion fruits	13
Legume vegetables	Bean with pod	14
Root and tuber vegetables	Ginseng	15
Tree nuts	Pecans	16
Animal feed	Beans and peas forage	17
	Almond hulls	18

Trial documentation included field and laboratory reports. Laboratory reports included procedural recoveries from spiking at residue levels similar to those occurring in the samples. Dates



of analyses or duration of residue sample storage were also provided. Residue data are recorded unadjusted for recovery. In trials where replicate test portions were analysed the average of the results are included in the following tables. Some of the trials had not been performed in compliance with GLP principles.

### Banana

Difenoconazole formulated as a 250 g/L EC was applied to banana trees (four trials) as a foliar application 3 or 4 times at a rate of 0.125 g/L spray concentration and 3 or 4 times at a spray concentration rate of 0.250 g ai/L. Samples were taken 35 or 42 days after last application (Xueyan Z., 2007). Applications, following the typical Chinese practice, were performed by spraying with manual knapsack equipment, directly upwards to the banana plants.

The average concurrent recovery (n = 10, 0.02–0.5 mg/kg) was  $90.8 \pm 7.4\%$  in whole banana and  $96.1 \pm 4\%$  in banana pulp.

A summary of the data from the trials is given in Table 11.

Table 11 Difenoconazole residues in banana from supervised trials performed with 250g/L EC formulation in Yunnan province of China in 2005

Location	Application			PHI days	Crop Part	Difenoconazole Residue (mg/kg)
	g ai/hl	No	Interval, day			
GAP in China: apply 8.33-12.5 g/hl spray solution maximum 3 times at 10-day intervals. PHI: 42 days						
Yunnan, 2005	12.5	3	10–14	35	Whole fruit	0.25
					Pulp	0.081
				42	Whole fruit	<u>0.18</u>
		Pulp	0.051			
		4	10–14	35	Whole fruit	0.38
					Pulp	0.048
	42			Whole fruit	0.30	
		Pulp	0.037			
	25	3	10 - 14	35	Whole fruit	0.48
					Pulp	0.095
				42	Whole fruit	0.52
		Pulp	0.095			
4		10–14	35	Whole fruit	0.68	
				Pulp	0.099	
	42		Whole fruit	0.47		
Pulp		0.093				
Yunnan, 2006	12.5	3	10–14	35	Whole fruit	0.25
					Pulp	0.067
				42	Whole fruit	<u>0.12</u>
		Pulp	0.052			
		4	10–14	35	Whole fruit	0.27
					Pulp	0.052
	42			Whole fruit	0.25	
		Pulp	0.039			
	25	3		35	Whole fruit	0.32
					Pulp	0.11
				42	Whole fruit	0.3
		Pulp	0.064			
4			35	Whole fruit	0.52	
				Pulp	0.098	
	42		Whole fruit	0.36		
Pulp		0.075				
Guangdong, 2005	12.5	3		35	Whole fruit	0.51
					Pulp	0.052
				42	Whole fruit	<u>0.33</u>
					Pulp	0.045

Location	Application			PHI days	Crop Part	Difenoconazole Residue (mg/kg)				
	g ai/hl	No	Interval, day							
	12.5	4		35	Whole fruit	0.61				
					Pulp	0.036				
				42	Whole fruit	0.29				
					Pulp	0.039				
	25	3		35	Whole fruit	0.80				
					Pulp	0.036				
				42	Whole fruit	0.45				
					Pulp	0.029				
		4		35	Whole fruit	0.80				
					Pulp	0.03				
				42	Whole fruit	0.74				
					Pulp	0.26				
				Guangdong, 2006	12.5	3		35	Whole fruit	0.59
									Pulp	0.12
42	Whole fruit	0.41								
	Pulp	0.11								
12.5	4		35		Whole fruit	0.84				
					Pulp	0.13				
			42		Whole fruit	0.47				
					Pulp	0.11				
25	3		35		Whole fruit	0.87				
					Pulp	0.094				
			42		Whole fruit	0.66				
					Pulp	0.091				
		4		35	Whole fruit	1.2				
					Pulp	0.12				
				42	Whole fruit	1.4				
					Pulp	0.11				

### Papaya

As part of a comprehensive supervised trial programme carried out at two sites in Côte d'Ivoire to detect pesticide residues in papaya in order to provide data for import tolerance in the European Union, difenoconazole was applied 6 times during the growing season at a rate of 60 g ai/ha at about 14 days intervals (PIP, 2004). Papaya is harvested continuously for several months. Pesticides were applied after harvest. Samples consisting of 12-14 fruits and amounting to about 4 kg were packed in cool boxes and sent to the Central Science Laboratory, Sand Hutton, York, UK, for residue analysis.

The summary of the trials is given in Table 12.

Table 12 Difenoconazole residues in papaya fruits treated with 25% EC formulation

Location	Application			PHI days	Residues <sup>a</sup> mg/kg
	kg ai/ha	No. of treatment	Interval day		
Tiassalé SCB	0.06	6	14	3	0.05
				3	0.06
				3	< 0.05
Azaguié	0.06	6	14	3	0.12
				3	0.07
				3	0.13
Tiassalé SCB	0.06	6	14	7	< 0.05
				7	< 0.05
				7	< 0.05
Azaguié	0.06	6	14	7	0.06
				7	< 0.05
				7	0.10

<sup>a</sup> Ready to harvest fruits were picked after the last three applications from the same field.

*Passion fruit*

Difenoconazole was applied as EC formulation alone or in combination with azoxystrobin in Brazil at the recommended and higher rate. Average recoveries, were in the range of 85% and 102.8% at 0.01 and 1.0 mg/kg spike levels. In the latter trials the growth stages at applications were between BBCH 75 and 89. The results are shown in Table 13.

Table 13 Difenoconazole residues in passion fruit from supervised residue trials in Brazil

Location crop variety	Application					Residue (mg/kg)	Reference
	Formulation	Rate (g ai/ha)	Conc (g ai/hl)	Interval (days)	PHI (days)		
GAP in Brazil: 10-40 g ai/ha, spray concentration: 5 g ai/hl, up to 4 times at 15 days, PHI: 14 days							
Morretes – PR not stated	EC 125 g/L	30	-	NA	0	< 0.01	M08078 Trial: M08078-DMO F: A13703G- 10304
					1	0.01	
					3	< 0.01	
					5	< 0.01	
					7	ND	
Uberlandia – MG not stated	EC 125 g/L	30	-	NA	0	0.01	M08078 Trial: M08078-JJB F: A13703G- 10304
					1	0.01	
					3	< 0.01	
					5	< 0.01	
					7	< 0.01	
Piedade - SP not stated	EC 125 g/L	30	-	NA	0	0.08	M08078 Trial: M08078-LZF1 F: A13703G- 10304
					1	0.07	
					3	0.04	
					5	0.04	
					7	0.04	
Santa Amelia – PR not stated	EC 125 g/L	30	-	NA	0	0.02	M08078 Trial: M08078-JJB F: A13703G- 10304
					1	0.03	
					3	< 0.01	
					5	< 0.01	
					7	< 0.01	
São Paulo Amarelo	EC 250 g/L	100	10	-	14	< 0.01	FHF 017B Trial: FHF 017B X 14 F:A7402T-10007
São Paulo Amarelo	EC 250 g/L	200	20	-	7	< 0.01	FHF017B Trial: FHF017B2X7 F:A7402T-10007
São Paulo Amarelo	EC 250 g/L	200	20	-	14	< 0.01	FHF017B Trial: FHF017B2X14 F:A7402T-10007
São Paulo Amarelo	EC 250 g/L	100 (x4)	10 (x4)	7–9 days	0	< 0.05	FHF 017/98 Trial: FHF 017B 2X14 F:A7402T-10008
					3	< 0.05	
					7	< 0.05	
					10	< 0.05	
					14	< 0.05	
São Paulo Amarelo	EC 250 g/L	200 (x4)	20 (x4)	7–8 days	14	< 0.05	FHF 017/98 F:A7402T-10008
São Paulo Azedo	EC 250 g/L	100 (x4)	10 (x4)	7 days	0	< 0.02	M00164 Trial:M00164 F:A7402T-10009
					3	< 0.02	
					7	< 0.02	
					10	< 0.02	
					14	< 0.02	
São Paulo Azedo	EC 250 g/L	200 (x4)	20 (x4)	7 days	0	0.38	M00164 Trial: M00164 F:A7402T-10009
					3	< 0.02	
					7	< 0.02	
					10	< 0.02	
					14	< 0.02	

*Beans with pod*

Difenoconazole formulated as a 25% EC was applied to beans (eight trials) and peas with pods (one trial) as a foliar application in Italy and South France. Samples were taken from 0 to 28 days after last application.

A summary of the residue data from the trials is given in Table 14.

Table 14 Difenoconazole residues in beans and peas following foliar treatments

Country/ Crop/ Variety	Application				Sampling			Report/study reference						
	Conc g ai/ha	Volume (L/ha)	Interval (days)	Growth Stage	PHI (days)	Crop Part (Harvest)	Residue (mg/kg)							
GAP in Portugal: 0.125 kg ai/ha (0.0125 kg ai/hl) 2 applications at 14–21 days, PHI 7 days														
Italy Bean Goldrush	0.125	600	13	Za <sup>a</sup> 19-20	0	Pods	0.27	2057-90 Study: RR 2057/90						
	0.125	600	10	Za 33-35	7		<u>0.07</u>							
	0.125	600			14		< 0.02							
					21		< 0.02							
					28		< 0.02							
Italy Bean (Borlotto)	0.140	1400	16	Pre harvest	0	Pods <sup>b</sup>	1.0	RR-2179-88 Study: 2179/88						
	0.140	1400	15	harvest	7		<u>0.50</u>							
	0.140	1400		harvest	13		0.05							
					21		0.13							
28	0.04													
Italy Bean (Bob)	0.125	700	11		0	Pods	1.02	2058-90						
	0.125	800	11		7		<u>0.31</u>							
	0.125	900			13		0.08							
					21		0.04							
					28		0.02							
France Bean (Inter)	0.127	1019	12	BBCH 69	0*	Bean + Pod	0.01	05-0510 Trial: AF/8562/SY/1						
	0.124	991		BBCH 73	0*	Remaining plant <sup>c</sup>	0.44							
					0	Bean + Pod	0.28							
					0	Remaining plant	6.00							
					3	Bean + Pod	0.04							
					3	Remaining plant	0.53							
					7	Bean + Pod	<u>0.01</u>							
					7	Remaining plant	0.28							
					10	Bean + Pod	< 0.01							
					10	Remaining plant	0.23							
					14	Bean + Pod	< 0.01							
					14	Remaining plant	0.15							
					France Bean (Booster)	127	1013		12	BBCH 65	0*	Bean + Pod	0.01	05-0510 Trial: AF/8562/SY/2
						126	1004			BBCH 77	0*	Remaining plant	0.19	
0	Bean + Pod	0.25												
0	Remaining plant	3.06												
3	Bean + Pod	0.16												
3	Remaining plant	1.02												
7	Bean + Pod	<u>0.09</u>												
7	Remaining plant	0.76												
10	Bean + Pod	0.04												
10	Remaining plant	0.42												
14	Bean + Pod	0.04												
14	Remaining plant	0.31												
France Beans with pods (Booster)	130	300	--	BBCH 59				<u>7</u>			Beans with pods	<u>0.05</u>	T013977-05 Trial: FR-FR- 06-0250	
	129	300	12	BBCH 73				7			Remaining plant	0.85		
France Beans with pods (Booster)	129	300	--	BBCH 64	<u>7</u>	Beans with pods	<u>0.04</u>	T013977-05 Trial: FR-FR- 06-0251						
	129	300	12	BBCH 76	7	Remaining plant	0.31							
France Beans with	128	316	--	BBCH	<u>7</u>	Beans with pods	<u>0.03</u>	T013977-05 Trial: Trial:						
	127	316	12	62-63		Remaining plant	0.75							

Country/ Crop/ Variety	Application				Sampling			Report/study reference
	Conc g ai/ha	Volume (L/ha)	Interval (days)	Growth Stage	PHI (days)	Crop Part (Harvest)	Residue (mg/kg)	
Pods (Angers)				BBCH 75	7			FR-FR-06- 0252
France <sup>d</sup> Pea (Messire)	100 100	400 400	22	BBCH 51–55 BBCH 65–73	0  7 14 21 28	Pod + Seed  Pod + Seed Pod + Seed Seed	< 0.02, 0.24 Mean=0.13  0.17 0.03 0.03 < 0.02	OF95121/LD28 Trial: LD28

<sup>a</sup> Za = Zadoks

<sup>b</sup> The average of two recovery tests was 132%

<sup>c</sup> Remaining plant part

<sup>d</sup> The crops were treated with 62.5 ai/kg WG formulation

### Ginseng

Ready to harvest ginseng plantations of 4–6 years old were treated with difenoconazole EC formulation 4 times at 10-day intervals in three typical ginseng growing area of Republic of Korea. Three root samples were collected 14 days after last application from each field. The roots were washed with water to remove soil particles, packed in plastic bags and stored deep-frozen until analyses which were performed latest 135 days after sampling. Part of the crop was processed.

The residues measured in fresh ginseng roots are summarised in Table 15.

Table 15 Difenoconazole residues in fresh ginseng roots treated 4 times with an EC formulation

Location crop variety	Application			Sample material	PHI (days)	Residue <sup>a</sup> (mg/kg)	Study No
	Rate (g ai/hl)	No	Interval (days)				
GAP in Korea: 0.0268 kg ai/hL, maximum 4 times at 10 days intervals, PHI 7 days 0.0535 kg ai/hL, maximum 4 times at 10 days intervals, PHI 14 days							
Gongju, Chungcheongnam-do	0.0535	4	10	Fresh ginseng	14	0.362 0.348 0.339	09072-945
Wonju, Gangwon	0.0535	4	10	Fresh ginseng	14	< 0.02 <sup>b</sup>	08072-051
Icheon, Gyunggi	0.0535	4	10	Fresh ginseng	14	< 0.02 <sup>b</sup>	08072-051
Wonju, Gangwon	0.0535			Dried ginseng		0.067 0.067 0.063	08072-051
Icheon, Gyunggi	0.0535	4	10	Dried ginseng		0.11 0.113 0.113	08072-051
Wonju, Gangwon	0.0535	4	10	Red ginseng	14	< 0.02 <sup>b</sup>	08072-051
Icheon, Gyunggi	0.0535	4	10	Red ginseng	14	0.097 0.10 0.097	08072-051
Wonju, Gangwon				Ethanol extract of dried ginseng		0.07 0.07 0.073	08072-051
Icheon, Gyunggi				Ethanol extract of dried ginseng		0.277 0.367 0.363	08072-051
				Water extract of dried ginseng		< 0.04 <sup>c</sup>	

Location crop variety	Application			Sample material	PHI (days)	Residue <sup>a</sup> (mg/kg)	Study No
	Rate (g ai/hl)	No	Interval (days)				
Wonju, Gangwon				Ethanol extract of red ginseng		0.1	
						0.103	
						0.097	
Icheon, Gyunggi				Ethanol extract of red ginseng		0.213	
						0.223	
				Water extract of dried red ginseng		0.20	
						< 0.04 <sup>c</sup>	
Chungju, Chuncheongbuk-do	0.0535	4	10	Fresh ginseng	14	0.006	09072-944
						0.006	
						0.0063	
				Dried ginseng	0.012	09072-944	
					0.012		
0.013							
Chungju, Chuncheongbuk-do	0.0535	4	10	Red ginseng		0.011	09072-944
						0.011	
				Ethanol extract of dried ginseng		0.011	
						0.017	09072-944
						0.017	
				Water extract of dried ginseng		0.016	
						0.016	09072-944
						0.015	
0.014							
				Ethanol extract of red ginseng		0.012	09072-944
						0.011	
						0.012	
						0.012 <sup>b</sup>	
Goesan, Chuncheongbukdo	0.0535	4	10	Fresh ginseng	14	0.04	
						0.04	
						0.04	
				Dried ginseng		0.072	
						0.067	
						0.068	
				Red ginseng		0.037	
						0.035	
				0.038			
				Ethanol extract of dried ginseng		< 0.007 <sup>b</sup>	
						< 0.007 <sup>b</sup>	
				Water extract of dried ginseng		< 0.007 <sup>b</sup>	
						< 0.007 <sup>b</sup>	
Ethanol extract of red ginseng	< 0.007 <sup>b</sup>						
	< 0.007 <sup>b</sup>						
Water extract of red ginseng	< 0.007 <sup>b</sup>						
	< 0.007 <sup>b</sup>						

<sup>a</sup> Average of three replicate analyses;

<sup>b</sup> All three plots;

<sup>c</sup> All 6 plots

*Almonds*

Difenoconazole formulated as a 25% EC was applied to almonds in five trials in California, USA, as a foliar application four times at a rate of 0.127 kg ai/ha, with a PHI of 14 days. Treatments were made in varying post foliar spray volumes ranging from low volume (concentrated, 84 L/ha) to high volume (dilute, 3742 L/ha) application. At one trial site two spray volumes were applied for a comparison giving two results for this trial. For all trials the mature almonds were picked 14 days after last application and air dried for 1 week. The nuts were then split to hulls and nutmeat.

The residues of parent compound and its main metabolites (1,2,4-triazole, triazole alanine and triazole acetic acid) were determined and detected separately. The average concurrent recoveries of difenoconazole in nutmeat and almond hulls were 79% and 84%, respectively.

The difenoconazole residues were below LOQ (0.01 mg/kg) in all nutmeat samples. The trial conditions are reported in Table 18.

*Pecans*

Difenoconazole formulated as a 25% EC was applied to pecans in different states of USA as a foliar application four times at a rate of 0.129 kg ai/ha, with a PHI of 14 days. Treatments were made with varying spray volumes ranging from low volume (concentrated, 94 L/ha) to high volume (dilute, 1439 L/ha) application. At one trial a comparison of spray volumes was made giving two results for this trial. For all trials the mature pecans were picked 14 days after last treatment, then split to obtain the nutmeat. The average recovery in nutmeat was 94% at spike levels of 0.01-0.5 mg/kg

A summary of the residue data from the trials is given in Table 16.

Table 16 Difenoconazole residues in pecan nutmeat 14 days after the treatments with 25%EC formulation in USA

GLP and Trial Details	Foliar Application				Sampling	Difenoconazole Residue <sup>a</sup> (mg/kg)	Study reference
	Conc (kg ai/ha)	Volume (L/ha)	Spray Interval (days)	Growth Stage	PHI (days)		
US GAP: max 0.091-0.128 kg/ha (0.085 kg ai/hl) with max 2 sequential applications at 14-21 days, max. seasonal rate is 0.51 kg ai/ha, PHI 14 days							
Pecans/ Sumner Georgia	0.129 <sup>b</sup>	1139	14		14	< 0.01	T004710-06 E14GA078001/GA
	0.129 <sup>c</sup>	1242				< 0.01	
	0.129 <sup>d</sup>	1220					
	0.129 <sup>e</sup>	1206					
Pecans/ Sumner North Carolina	0.129	95	14	75	14	< 0.01	T004710-06 E13NC078002/NC
	0.129	94		83		< 0.01	
	0.129	94		85			
	0.129	94		89			
Pecans/ Sumner Louisiana	0.129	723	14	79	14	< 0.01	T004710-06 E17LA078003/LA
	0.129	720		81		< 0.01	
	0.129	711		88			
	0.129	755		93			
Pecans/ Shawnee Texas	0.129	413	14	71	0	0.02	T004710-06 W07TX078004/TX
	0.129	434		85	7	< 0.01	
	0.129	379		89	14	< 0.01	
	0.129	442		89	14	< 0.01	
					21	< 0.01	
	0.129	1272	14	71	0	< 0.01	
	0.129	1439		85	7	< 0.01	
	0.129	1224		89	14	< 0.01	
0.129	1372		89	14	< 0.01		
				21	< 0.01		
Pecans/ Berkett New Mexico	0.129	1037	14	79	14	0.02	T004710-06 W01NM078005/NM
		1041		80		0.02	
		1042		81			
		1062		89			

<sup>a</sup>. Untreated control samples did not contain detectable residues.

<sup>b</sup> Dough stage;<sup>c</sup> Late dough stage early split;<sup>d</sup> 40% shuck split;<sup>e</sup> 70% shuck split**Animal feed commodities***Beans and peas forage*

Table 17 Difenoconazole residues in beans and peas forage treated with 25EC formulation

Country/ Crop/ Variety	Application				Sampling			Report/study reference
	Conc kg ai/ha	Volume (L/ha)	Interval (days)	Growth Stage	PHI (days)	Crop Part (Harvest)	Residue (mg/kg)	
GAP in Portugal: 0.125 kg ai/ha (0.0125 kg ai/hl 2 applications at 14-21 days, PHI 7 days								
France Bean (Inter)	0.127	1019	12	BBCH 69	0*	Remaining plant <sup>a</sup>	0.44	05-0510 Trial: AF/8562/SY/1
	0.126	1004			0	Remaining plant	6.00	
					3	Remaining plant	0.53	
					7	Remaining plant	<u>0.28</u>	
					10	Remaining plant	0.23	
					14	Remaining plant	0.15	
France Bean (Booster)	0.127	1013	12	BBCH 65 BBCH 77	0*	Remaining plant	0.19	05-0510 Trial: AF/8562/SY/2
	0.126	1004			0	Remaining plant	3.06	
					3	Remaining plant	1.02	
					7	Remaining plant	<u>0.76</u>	
					10	Remaining plant	0.42	
					14	Remaining plant	0.31	
France Bean (Booster)	0.130	300	--	BBCH 59 BBCH 73	7	Remaining plant	<u>0.85</u>	T013977-05 Trial: FR-FR- 06-0250
	0.129	300	12					
France Beans (Booster)	0.129	300	--	BBCH 64 BBCH 76	7	Remaining plant	<u>0.31</u>	T013977-05 Trial: FR-FR- 06-0251
	0.129	300	12					
France Beans (Angers)	0.128	316	--	BBCH 62-63 BBCH 75	7	Remaining plant	<u>0.75</u>	T013977-05 Trial: FR-FR- 06-0252
	0.127	316	12					

<sup>a</sup> Remaining plant part without beans in pod*Almond hulls*

Table 18 Difenoconazole residues in almond hulls following treatments with 25%EC formulation in USA in 2006

Location/ variety	Foliar Application			PHI (days)	Crop Part (Harvest) <sup>3</sup>	Residue <sup>a</sup> (mg/kg)	Report/trial number
	Conc (kg ai/ha)	Volume (L/ha)	Spray Interval (days)				
US GAP: application rate 0.091-0.128 kg ai/ha with max 2 sequential applications at 14-21 days, max. seasonal rate is 0.51 kg ai/ha, PHI 14 days							
Hanford, CA Fritz (Soft Shell)	0.127	84-103	14	14	Hulls Hulls	Treated:	T014337-05 Trial: 09620.06- CA47/CA
	0.127					1.41	
	0.127					<u>1.44</u>	
	0.127						
Parlier, CA Mission (Hard Shell)	0.127	468- 935	14	14	Hulls Hulls	Treated:	T014337-05 Trial: 09620.06- CA48/CA
	0.127					2.94	
	0.127					<u>3.22</u>	
	0.127						



Location/ variety	Foliar Application			PHI (days)	Crop Part (Harvest) <sup>3</sup>	Residue <sup>a</sup> (mg/kg)	Report/trial number
	Conc (kg ai/ha)	Volume (L/ha)	Spray Interval (days)				
Hanford, CA Nonpariel (Soft Shell)	0.127	468- 935	14	14	Hulls Hulls	Treated: 0.49 <u>0.83</u>	T014337-05 Trial:09620.06- CA49/CA
	0.127						
	0.127						
	0.127						
	0.127	945- 3742	14	14	Hulls Hulls	<u>0.53</u> 0.24	
	0.127						
	0.127						
	0.127						
Arbuckle, CA Butte (Hard Shell)	0.127	945- 3742	14	14	Hulls Hulls	Treated: <u>1.93</u> 1.74	T014337-05 Trial:09620.06- CA50/CA
	0.127						
	0.127						
	0.127						
Arbuckle, CA Nonpariel (Soft Shell)	0.127	945- 3742	14	14	Hulls Hulls	Treated: <u>1.04</u> 0.65	T014337-05 Trial:09620.06- CA51/CA
	0.127						
	0.127						
	0.127						

<sup>a</sup> Untreated control samples did not contain detectable residues. The residues of difenoconazole alone are given.

## FATE OF RESIDUES IN STORAGE AND PROCESSING

### *Fresh ginseng*

Fresh ginseng was harvested 14 days after the application of pesticide at each test site and washed with tap water to remove soil particles.

Fresh ginseng roots were blended. These samples were individually packed in a 20 g pack and stored at -20 °C or -70 °C until processing.

### *Dried ginseng*

The washed fresh ginseng was dried in hot air drying machine set to 60 °C to reduce the water content below 14%. Dried ginseng was blended. Analytical samples were individually packed in polyethylene bags and stored at -20 °C until analysis.

### *Fresh red ginseng*

The washed fresh red ginseng was steamed for 3 hours at 98 °C. The steamed samples were dried in hot air drying machine set to 65 °C to reduce the water content to 50~55%. The smaller roots were removed from the dried samples and further drying processes were carried out under the sunlight to reduce the water content below 14%. The dried samples were blended. Analytical samples were individually packed in 10 g polyethylene bags and stored at -20 °C or -70 °C until analysis.

### *Dried ginseng ethanol extract*

Dried or red ginsengs were cut to about 1 cm in size and extracted three times in refluxing extractor with 70% EtOH at 70 °C about 18 hours. The solvents were then evaporated in vacuum rotary evaporator to reach the 65° Brix. Analytical samples were packed in plastic bottle and stored at -20 °C until analysis.

### *Dried red ginseng water extract*

Dried or red ginsengs were cut to about 1 cm in size and extracted three times in refluxing extractor with water at 85 °C about 18 hours. The solvents were then evaporated in vacuum rotary evaporator to reach the 65° Brix. Analytical samples were packed in plastic bottom and stored at -20 °C until analysis.

Water content of fresh ginseng and its products were determined according to the method in the Korean Food Code (KFDA, Republic of Korea). 10 g or 5 g of analytical samples were dried in drying oven set at  $105 \pm 1$  °C for 5 hours and cooled in desiccators for 30 minutes and weighed.

The residues measured in fresh ginseng and in the processed products made from them are summarised in Table 15. The processing factors, calculated as residues in processed product/residues in fresh ginseng, are summarised in Table 19. The water contents of fresh and processed ginseng products are given in Table 20.

Water contents of fresh ginseng and its products were  $5.56 \pm 0.25\% \sim 66.97 \pm 1.04\%$ .

Table 19 Processing factors estimated for ginseng products

Matrix	Site	Processing factor	Best estimate
Dried ginseng	Field 1	3.28	3.28
	Field 2	5.67	
	Field 3	2.04	
	Field 4	1.15 <sup>a</sup>	
	Overall		
Dried ginseng extract(EtOH)	Field 1	3.56	
	Field 2	18.44	
	Field 3	2.70	
Dried ginseng extract(water)	Field 1	2 <sup>b</sup>	2
	Field 2	2 <sup>b</sup>	
	Field 3	2 <sup>b</sup>	
Red ginseng extract (EtOH)	Field 1	5.0	
	Field 2	10.6	
	Field 3	1.1	
Red ginseng extract (water)	Field 1	2	1.1
	Field 2	2	
	Field 3	1.09	

<sup>a</sup> The application rate was 170 g/ha compared to the recommended maximum rate of 280 g/ha

<sup>b</sup> LOQ values (0.02, 0.04) used when residues were lower than LOQ

Table 20 Water content of fresh and processed ginseng

Matrix	Location	Water content (%)	Field 3	Field 4
Fresh ginseng	Field 1	66.97±1.04	72.8±3.05	72.19 ±0.03
	Field 2	65.59±0.65		
Dried ginseng	Field 1	5.56±0.25	8.24±1.38	7.79 ± 2.12
	Field 2	8.44±0.31		
Red ginseng	Field 1	12.57±0.42	9.04±1.02	8.88 ± 0.11
	Field 2	10.60±0.30		
Dried ginseng extract (EtOH)	Field 1	21.73±0.10	38.1±2.53	48.94 ± 2.64
	Field 2	21.87±0.09		
Dried ginseng extract (water)	Field 1	16.69±0.16	47.5±3.94	48.41±0.31
	Field 2	18.89±0.39		
Red ginseng extract (EtOH)	Field 1	24.35±0.11	37.8±3.05	59.26 ± 0.77
	Field 2	24.19±0.10		
Red ginseng extract (water)	Field 1	16.58±0.37	53.1±4.83	39.5 ± 1.6
	Field 2	11.77±0.23		

## RESIDUES IN ANIMAL COMMODITIES

The 2007 JMPR evaluated two animal transfer studies carried out with Holstein dairy cows administering difenoconazole at 1 ppm (1×), 3 ppm (3×) 5 ppm (5×) 10 ppm (10×) and 15 ppm (15×) in the dry-weight diet for 29-30 consecutive days. The Meeting concluded that the transfer factors were generally in good agreement in the two feeding studies, and decided to use the study with the 1 and 3 ppm feeding levels as most closely bracketing the dietary burdens.

## APPRAISAL

Difenoconazole was evaluated by the JMPR for the first time in 2007 when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established, and maximum, supervised trial median and high residue levels were recommended for a range of commodities. Additional studies on residues in banana, passion fruits, beans with pods, papaya, ginseng and almonds were evaluated by the present Meeting.

### *Methods of analysis*

The analytical methods used for the determination of difenoconazole residues in samples derived from supervised trials, submitted for evaluation to the present Meeting, had already been considered by the 2007 JMPR. These methods are based on GC separation and pulse flame photometric detection (PFPD), ECD or MS detection. The validity of the results was supported by validation data on representative crops and results of concurrent recovery studies.

Fresh ginseng root and ginseng processed products were extracted with acetonitrile, partitioned either with dichloromethane or n-hexane, cleaned up on Florisil or silica gel column, and determined applying capillary column GC and ECD. The methods were validated before the analysis of the samples. Additional recovery studies were performed at the same time when the treated or processed samples were analysed. The average recoveries based on minimum 5 replicates ranged between 89 and 105% with repeatability of  $\leq 7.4\%$ . The limits of quantification were between 0.002–0.007 mg/kg for fresh ginseng root, and 0.007–0.04 for various ginseng products.

The freezer storage stability studies carried out with fresh ginseng and ginseng processed products showed that the residue was stable for the longest period (135 days) for which the samples were stored at or below  $-20\text{ }^{\circ}\text{C}$ . The studies reported by the 2007 JMPR cover the other sample materials evaluated by the present Meeting.

### *Results of supervised trials on crops*

The original labels with translation were provided only for the countries where the trials had been carried out.

The reports on supervised trials were made available for the Meeting. Some of the trials had not been conducted according to GLP. However, the documentation of the trials was sufficient for evaluation of the results.

#### *Banana*

A national use pattern in China permits a foliar application of difenoconazole EC 25 (250 g/L) on bananas at a dilution rate of 2000 to 3000 which equates to spray solution concentrations of 8.33 to 12.5 g ai/hL with a PHI of 42 days. Multiple applications are permitted with a maximum of three treatments at 10-day intervals.

Difenoconazole formulated as a 250 g/L EC was applied to banana plants (four trials) as a foliar application 3 or 4 times at the maximum GAP rate of 12.5 g ai/hL (2000 $\times$  dilution) and 3 or 4 times at a spray rate of 25 g ai/hL (double rate) in China. Samples were taken at 35 and 42 days. According to the typical practice in China, the applications were performed by spraying, from the ground using manual knapsack or mechanised equipment, directly upwards to the banana plants.

The difenoconazole residues in whole fruit samples treated according to the maximum GAP rate, in ranked order, were: 0.12, 0.18, 0.33 and 0.41 mg/kg.

Residues from 4 treatments at 12.5 g ai/hL rate were: 0.25, 0.29, 0.3, and 0.47 mg/kg. The residues from 3 or 4 treatments were not significantly different indicating that the first treatment made at least 82 days before sampling did not influence the final residue level. The trials performed with 3

and 4 applications were conducted side-by-side, therefore they are not independent and the results cannot be combined.

The residues in banana pulp derived from the same trials were substantially lower. For the 3 application trials the residues were: 0.045, 0.051, 0.052, and 0.11 mg/kg.

No correlation between the residue in pulp and whole banana could be established based on the results.

The 2007 JMPR evaluated residue data derived from ground and aerial treatments carried out with much lower dosage rate (GAP  $8 \times 0.1$  kg/ha, PHI 0 day) than the Chinese trials, and resulted in lower residue values:  $< 0.02$  (6), 0.02, 0.03, 0.04, 0.06, 0.07 and 0.13 mg/kg.

The two residue populations are significantly different and could not be combined.

The Meeting concluded that four residue trials, reflecting the Chinese GAP and growing conditions, was not sufficient for the estimation of residue levels.

### *Papaya*

To protect fruits from pests and diseases a 3-day PHI is required during harvesting period for continuously fruiting crops like papaya in the Equatorial countries of Africa.

As part of the field trials conducted within the Pesticide Initiative Programme, aiming to provide data for the establishment of import tolerance in the European Union, difenoconazole was applied 6 times during the growing season at 60 g ai/ha at about 14-day intervals at two sites in Côte d'Ivoire. The application conditions (dosage, interval between applications and PHI) were based on the requirement to achieve adequate control of papaya diseases, but were not supported by a label or official declaration of approved use. Samples were collected at 3 and 7 days after the last three applications. The residues measured in samples taken at day 3 were:  $< 0.05$ , 0.05, 0.06, 0.07, 0.12 and 0.13 mg/kg.

Residues in samples taken 7 days after the last treatment were:  $< 0.05$ ,  $< 0.05$ ,  $< 0.05$ ; 0.06,  $< 0.05$  and 0.10 mg/kg.

Taking into account the rapid decrease of residues it is most likely that only the last application affects the residue levels in fruits. The residues taken from the same site after repeated treatments can be considered independent.

Based on the 3-day PHI and 0.06 kg ai/ha application rate which provided efficient control of diseases to protect the crop, the Meeting estimated a maximum residue level, STMR and HR values of 0.3, 0.065 and 0.13 mg/kg, respectively.

### *Passion fruit*

A national use pattern in Brazil permits up to four foliar applications of difenoconazole EC 25 (250 g/L) on passion fruit at a rate of 5 g ai/hL or between 0.01 and 0.04 kg ai/ha with a PHI of 14 days.

In four Brazilian trials the applications were performed within GAP (1 treatment with  $-25\%$  dosage rate) and the samples taken at 7 days after the treatment contained residues below the LOQ of 0.01 mg/kg with one exception (0.04 mg/kg).

Where the trials were conducted at 2.5–5 times maximum GAP rate the residues in all samples taken at 7 or 14 days were below the limit of quantification (0.01–0.05 mg/kg).

The difenoconazole residues in whole fruit collected at 7 or 14 days PHI were, in ranked order:  $< 0.01$  (6),  $< 0.02$  (2), 0.04,  $< 0.05$  (2) mg/kg.

Taking into account that up to 5 times GAP dose rate did not lead to residues at or above 0.05 mg/kg at shorter intervals than the recommended PHI, the Meeting estimated a maximum residue level, an STMR value and HR value of 0.05, 0.01 and 0.04 mg/kg, respectively.

*Legume vegetables*

National use pattern in Portugal permits 2 foliar applications of difenoconazole EC 25 (250 g/L) at 12 to 14 days intervals on beans at a rate of 0.125 kg ai/ha with a PHI of 7 days. Eight trials in beans and one in peas were conducted in Italy and South France.

The results were evaluated against the Portugal GAP. The difenoconazole residues in beans or peas with pods were, in ranked order: 0.01, 0.03, 0.04, 0.05, 0.07, 0.09, 0.17, 0.31 and 0.50 mg/kg.

The Meeting estimated a maximum residue level, STMR value and an HR value for difenoconazole in beans and peas of 0.7, 0.07 and 0.5 mg/kg, respectively.

*Ginseng*

The GAP in Korea permits 4 or 5 foliar applications at 10 day intervals with 0.027 kg ai/hL or 0.053 kg ai/hL spray concentration and 7 or 14 days PHI, respectively.

Ready to harvest ginseng plantations of 4–6 years old were treated with difenoconazole EC formulation (0.053 kg ai/hL) 4 times at 10-day intervals in three typical ginseng growing areas in the Republic of Korea.

Three root samples were collected 14 days after the last application from each field. The residues in fresh ginseng root were: 0.0063, 0.011, < 0.02 (3), 0.038, 0.04, 0.10, and 0.36 mg/kg.

The Meeting estimated a maximum residue level, HR and STMR of 0.5 mg/kg, 0.36 mg/kg and 0.02 mg/kg, respectively.

*Tree nuts*

The US GAP permits up to two foliar applications of difenoconazole EC 250 (232 g/L) on almonds at a rate of 91 to 128 g ai/ha with a PHI of 14 days.

Six trials were conducted with four foliar applications at a rate of 127 g ai/ha. Samples of mature almond were collected at 14 days after the last application. Residues in all almond nutmeat samples were below the limit of quantification (0.01 mg/kg).

The US GAP permits up to two foliar applications of difenoconazole EC 250 (232 g/L) on pecans at a rate of 91 to 128 g ai/ha with a PHI of 14 days.

Trials were conducted with four applications at a rate of 0.129 kg ai/ha. Residues in 6 pecan nutmeat samples were < 0.01 (5) and 0.02 mg/kg.

Based on the mutually supporting residue data, the Meeting estimated a maximum residue level, STMR value and an HR value for difenoconazole in tree nuts of 0.03, 0.01 and 0.02 mg/kg, respectively.

*Animal feed commodities**Beans and peas forage*

Residues in bean forage following the treatments according to GAP (2 × 0.125 kg/ha, PHI 7 days) were: 0.28, 0.31, 0.75, 0.76, and 0.85 mg/kg.

The Meeting estimated an STMR value and high residue for difenoconazole in bean forage 0.75 and 0.85 mg/kg, respectively.

*Almond hulls*

The residues in almond hulls derived from trials complying with the total seasonal rate as specified by US GAP (0.51 kg/ha) in ranked order, were: 0.53, 0.83, 1.04, 1.44, 1.93 and 3.22 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and high residue for difenoconazole in almond hulls of 6, 1.24 and 3.22 mg/kg, respectively. Estimated derived from use of the NAFTA and OECD calculators was 6 mg/kg.

#### *Fate of residues during processing*

Fresh ginseng roots were dried or extracted with ethanol to produce powdery material. The processing was carried out independently from samples obtained from three plots treated at each of the three different sites. The average processing factors were calculated from the results obtained from the three replicate plots. The best estimate for the processing factor for dried ginseng is 3.28. The ethanol extract of dried ginseng resulted in a wide range of processing factors (2.7–18.44) which made the obtaining of a single best estimate impossible. The apparent numerical processing factor for the water extract is 2. However, this estimate is very uncertain as it is based on the LOQ values of processed and fresh ginseng. In one study where the LOQ value was sufficiently low the results indicated a processing factor of 1.1

Consequently the Meeting could only estimate a processing factor of 3.3 for dried ginseng.

#### *Residues in animal commodities*

The 2007 JMPR evaluated two animal transfer studies carried out with Holstein dairy cows administering difenoconazole at 1 ppm (1×), 3 ppm (3×), 5 ppm (5×), 10 ppm (10×) and 15 ppm (15×) in the dry-weight diet for 29–30 consecutive days. The Meeting concluded that the two feeding studies were generally in good agreement of transfer factors, and decided to use the study with the 1 and 3 ppm feeding levels as most closely bracketing the dietary burdens.

#### *Livestock dietary burden*

The residues in almond hull and bean forage evaluated by the present Meeting contributed substantially to the beef and dairy cattle dietary burden calculation based on the maximum portion of agricultural commodities in animal feed (FAO, 2009). Dietary burden calculations for beef cattle, and dairy cattle are provided in Annex 6. The Japanese animal diet contained only soya bean seed of those commodities for which the JMPR estimated highest and median residues. The residues in soya bean seed resulted in an animal dietary burden of 0.00 ppm on dry matter bases, therefore those values are not included in the summary below.

	Livestock dietary burden, difenoconazole, ppm of dry matter diet					
	US/CAN		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	0.62	0.48	1.85	0.81	2.0	1.77 <sup>b</sup>
Dairy cattle	0.80	0.31	2.42 <sup>a</sup>	1.15	2.14	1.82 <sup>c</sup>

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat and milk.

<sup>b</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

<sup>c</sup> Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

#### *Animal commodities, MRL estimation*

For MRL estimation, the residues in the animal commodities are the sum of difenoconazole and CGA 205375 (1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol-1-yl)-ethanol)) expressed as difenoconazole.

#### *Cattle*

For maximum residue level estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden of 2.42 ppm (in 2007 it was 2.10 ppm) between the

relevant feeding levels (1 and 3 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups.

The STMR values for the tissues were calculated by taking the STMR dietary burden (1.82 ppm) between the relevant feeding levels (1 and 3 ppm) from the dairy cow feeding study and using mean residue of the 3 animals.

In the following table, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding study are shown in square brackets [] and estimated concentrations related to the dietary burdens are shown without brackets.

Dietary burden (ppm)					
Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
MRL					
	Mean	highest	highest	highest	highest
MRL dairy cattle (2.42)	< 0.005	0.021	0.121	0.0178	0.031
[1, 3]	[< 0.005, < 0.005]	[< 0.01, 0.026]	[0.051, 0.15]	[< 0.01, 0.021]	[0.015, 0.038]
STMR					
	Mean	mean	mean	mean	mean
STMR dairy cattle (1.82)	< 0.005	< 0.01	0.041	< 0.01	0.012
[0, 1, 3]	[0, < 0.005, < 0.005]	[0, < 0.01]	[0, 0.045]	[0, < 0.01]	[0, 0.013]

The data from the cattle feeding studies were used to support mammalian meat and milk maximum residue levels.

Residues in the milk were below LOQ (0.005 mg/kg) for all samples from the 1 ppm and 3 ppm feeding groups, so the dietary burdens (2.42 and 1.82 ppm) were taken as a proportion of the 3 ppm to calculate the residues resulting from the dietary burdens.

For muscle, the residue arising from a dietary burden of 2.42 ppm was 0.021 mg/kg, while the residue resulting from a dietary burden of 1.82 ppm was < 0.01 mg/kg. For fat, the residue arising from a dietary burden of 2.42 ppm was 0.031 mg/kg, while the residue resulting from a dietary burden of 1.82 ppm was 0.012 mg/kg.

The Meeting confirmed its previous recommendation for a maximum residue level for difenoconazole in mammalian meat (fat) of 0.05 mg/kg. The Meeting estimated STMR and HR values for meat (fat) of 0.012 and 0.031 mg/kg respectively. The Meeting estimated STMR and HR values for meat (muscle) of 0.01 and 0.021 mg/kg respectively.

The residues in milk were below the limit of quantification at 1 and 3 ppm feeding level. The Meeting estimated a maximum residue level of 0.005\* mg/kg and STMR value of 0.005 mg/kg for milk.

For liver, the residue arising from a dietary burden of 2.42 ppm was 0.121 mg/kg, while the residue resulting from a dietary burden of 1.82 ppm was 0.041 mg/kg. The Meeting confirmed its recommendation for a maximum residue level of 0.2 mg/kg, and estimated an STMR value and an HR value for difenoconazole in liver of 0.041 and 0.12 mg/kg, respectively.

For kidney, the residue arising from a dietary burden of 2.42 ppm was 0.018 mg/kg, while the residue resulting from a dietary burden of 1.82 ppm was < 0.01 mg/kg. Although the residue levels in kidney were somewhat below those in liver, the Meeting decided that it was preferable to have an animal offal MRL which would be supported by the liver data.

The Meeting estimated a maximum residue level, an STMR value and an HR value for difenoconazole in mammalian edible offal of 0.2, 0.041 and 0.12 mg/kg, respectively.

The Meeting withdrew its previous recommendations for STMR values of 0.043 mg/kg and HR values of 0.11 mg/kg for edible offal (mammalian), and HR values of 0.019 for meat (muscle) and 0.028 mg/kg meat (fat).

## 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 the MRL and for estimation of dietary intake) for plant commodities: *difenoconazole*.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol, expressed as difenoconazole*.

*The residue is fat soluble.*

Commodity		Recommended MRL, mg/kg		STMR/STMR-P mg/kg	HR/HR-P mg/kg
CCN	Name	New	Previous		
AM 0660	Almond hulls		-	1.24	3.22
VD 0061	Bean and peas in pod	0.7		0.07	0.5
AL 1030	Bean forage (green)			0.75	0.85
MO 0105	Edible offal (Mammalian)	0.2		0.041	0.12
	Ginseng root, fresh	0.5		0.02	0.36
MM 0095	Meat (from mammals other than marine mammals)	0.05(fat) <sup>a</sup>		0.01 muscle 0.012 fat	0.021 Muscle 0.031 fat
ML 0106	Milks	0.005* <sup>a</sup>		0.001	
FI 0350	Papaya	0.3 <sup>b</sup>		0.065	0.13
TN 0095	Tree nuts	0.03		0.01	0.02
FI 4132	Passion fruits	0.05		0.01	0.04

<sup>a</sup> The maximum residue limits recommended by the 2007 JMPR remained the same.

<sup>b</sup> The recommendation is based on reported use conditions provided appropriate protection of the crop, but it is not supported by official information on use.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The evaluation of difenoconazole 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 for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3 of the 2010 JMPR Report.

The IEDIs in the thirteen Cluster Diets, based on estimated STMRs were 1–10% 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*

The IESTI of difenoconazole calculated on the basis of the recommendations made by the JMPR represented 0–3 % of the maximum ARfD (0.3 mg/kg bw) for children and 0–2 % for the general population.



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

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