5. EVALUATION OF DATA FOR ACCEPTABLE DAILY INTAKE AND ACUTE DIETARY INTAKE FOR HUMANS, MAXIMUM RESIDUE LEVELS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES

5.1 BIFENAZATE (219)

RESIDUE AND ANALYTICAL ASPECTS

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.

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.