5.4 BIFENTHRIN (178)

RESIDUE AND ANALYTICAL ASPECTS

Bifenthrin is a pyrethroid insecticide and miticide. It was first evaluated for residues and toxicology by the JMPR in 1992 and re-evaluated in 2009 (T) and 2010 (R) under the periodic review programme of the CCPR. The forty-sixth Session of the CCPR (2014) listed bifenthrin for the evaluation of additional maximum residue levels by the 2015 JMPR.

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

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

Methods of analysis

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

Stability of residues in stored analytical samples

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

Results of supervised trials on crops

Berries and Other Small Fruit

Bushberries-Blueberry

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

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

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

Small fruit vine climbing-Grapes

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

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

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

Leafy vegetables

Lettuce, head

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

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

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

Spinach

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

Bifenthrin residues were 0.05 and 0.15 mg/kg.

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

Stalk and stem vegetables

Celery

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

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

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

Legume vegetables

Peas

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

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

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

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

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

Beans

Data from six trials on snap bean (beans with pods) were re-submitted. The 2010 JMPR did not estimate a maximum residue level as the trials were not conducted in accordance with the US GAP

(0.11 kg ai/ha with a PHI of 3 days; 0.22 kg ai/ha/season). The trials were conducted in the USA in 1996 and 1997 with three applications 7 days apart, 0.090 kg ai/ha (1st), 0.090 kg ai/ha (2nd) and 0.045 kg ai/ha (3rd) and with a 3-day PHI. Residue values in snap beans with pods were < 0.05, 0.050, 0.050, 0.055, 0.11 and 0.14 mg/kg.

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

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

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

RECOMMENDATIONS

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

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

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

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

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

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

Short-term intake

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

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

Estimates of intake for the other commodities considered by the 2015 JMPR were within 0-100% ARfD. The Meeting concluded that the short-term intake of bifenthrin for the other commodities may not(?) present a public health concern when bifenthrin is used in ways that were considered by the Meeting.