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), 2010 (R) and 2015 (R).

An ADI of 0–0.01 mg/kg bw and an ARfD of 0.01 mg/kg bw was established by the 2009 JMPR. The residue definition for compliance with MRLs and for estimation of dietary intake (for animal and plant commodities) is bifenthrin (sum of isomers). The residue is fat-soluble.

At the Fiftieth Session of the CCPR (2018), bifenthrin was scheduled for evaluation of additional uses. The current Meeting received new residues data and GAP information for mango, cucumber, okra and barley. In addition, new GAP information was provided for strawberry.

Methods of Analysis

Residues were determined in the crops using several different analytical methods. In general, the data generation methods considered by this Meeting involved extraction with either acetone or ethyl acetate. Final determination was achieved using GC-MS, GC-MS/MS or GC-ECD. The validated LOQs for okra and barley grain were 0.01 mg/kg. For cucumber the validated LOQ was 0.1 mg/kg. For mango the validated LOQs for the different methods used ranged from 0.02–0.1 mg/kg.

The meeting concluded that suitable methods are available for the determination of bifenthrin in mango, cucumber, okra and barley.

Stability of residues in stored analytical samples

The 2010 and 2015 JMPR concluded that residues of bifenthrin were stable for at least 18 months when stored at ≤ -18 °C (high acid), 49 months (high water), 36 months (high oil), 36 months (high starch) and 15 months (high protein).

The Meeting agreed that the new storage stability data for head cabbage, barley grain and barley straw confirms the stability of bifenthrin when stored at ≤ -18 °C. The Meeting concluded that the new storage data for cucumber and okra were of limited use owing to missing information in the studies.

The overall data were sufficient to support the storage intervals in the residue trials.

Results of supervised residue trials on crops

The meeting received residue trial data and GAP information for strawberry, mango, cucumber, okra and barley.

Strawberry

A new GAP was provided for strawberry. The GAP is for the USA and involves four applications of 0.11 kg ai/ha with a PHI of 3 days.

The Meeting received information that confirmed that the more critical use considered by the 2010 JMPR is still authorized in the USA. The application rate is 0.045–0.22 kg ai/ha per application with a total dose not exceeding 0.56 kg ai/ha. No PHI was defined.

The Meeting confirmed its previous recommendation of a maximum residue level of 3 mg/kg, STMR of 0.46 mg/kg and a HR of 2.3 mg/kg.

The Meeting noted that the ARfD was exceeded for children (380% of the ARfD) and the general population (210% of the ARfD).

No alternative GAP was available from another country.

Mango

The critical GAP for mango is in Brazil with 1 application of 0.003 kg ai/hL with a PHI of 7 days.

Trials were available from Brazil, Mali, the Philippines and Senegal. The three trials conducted in Brazil matched the GAP.

Residues in mango at a PHI of 7 days were (n = 3): < 0.02 (2) and < 0.04 mg/kg.

The Meeting concluded that three trials were insufficient to estimate a maximum residue level for mango.

Cucumber

The critical GAP for cucurbits is in the USA with three applications at 110 g ai/ha with a minimum interval between applications of 7 days and a PHI of 3 days.

One trial supports the GAP.

Residues in cucumber at a PHI of 3 days from trials approximating the GAP were (n = 1): < 0.1 mg/kg.

The Meeting concluded that one trial is insufficient to estimate a maximum residue level for cucumber.

Okra

The critical GAP for okra is in the USA with two applications at 110 g ai/ha, an interval between applications of 7 days and a PHI of 7 days.

The residue trials evaluated by the 2010 JMPR do not reflect the GAP. However, the Meeting agreed that three of the trials could be scaled to the GAP using the proportionality principle.

The unscaled residues in okra at a PHI of 7 days were (n = 3): 0.01, 0.02 and 0.04 mg/kg.

The scaled residues (scaling factor of 2.75) in okra at a PHI of 7 days (in rank order) were (n = 3): 0.028, 0.055, 0.11 mg/kg

The Meeting agreed that three trials were insufficient to estimate a maximum residue level for okra.

The GAP in India is one application of 59 g ai/ha followed by a second application of 62 g ai/ha. The retreatment interval is not stated. The PHI is 5 days.

This Meeting received trials from India approximating the GAP.

Residues in okra at a PHI of 5 days in rank order were (n = 4): < 0.01 (2), 0.014, 0.018 mg/kg.

The Meeting concluded that four trials were insufficient to estimate a maximum residue level for okra.

Cereals

The critical GAP for cereals is in Switzerland with two applications at 0.016 kg ai/ha and a PHI of 42 days.

Barley

The Meeting noted that the residue trials considered by the 2010 JMPR and the trials considered by this Meeting were conducted at a lower application rate compared to the GAP. However, the trials could be scaled using the proportionality principle, except where residues were reported as < 0.01 mg/kg. It was also noted that the PHI varied within the trials. The Meeting agreed that only trials with samples taken 40–44 DALA could be used to support the GAP. Four trials were considered to support the GAP.

The unscaled residues in barley (in rank order) were (n = 4): 0.01 and 0.02 (3) mg/kg

The scaled residues (scaling factors of 1.45–2.13) in barley were (n = 4): 0.02, 0.03 and 0.04 (2) mg/kg.

The Meeting concluded that four trials were insufficient to estimate a maximum residue level for barley.

Oats, triticale and wheat

The 2010 JMPR evaluated residue trial data on oats, triticale and wheat. Although the trials were all conducted at lower application rates compared to the GAP, the number of applications and the PHI matched the GAP for some of the trials. However, as residues were < 0.01 mg/kg scaling of the residues using the proportionality principle was not possible.

The Meeting concluded that the trials were not suitable for estimating maximum residue levels for oats, triticale and wheat.

Residues in animal feed

Cereal forage

The critical GAP for cereals is in Switzerland. Grazing of forage from cereal grain crops is not common practice in Europe and is precluded in conjunction with agricultural chemical use unless specifically allowed by label instructions. Median and highest residues for barley forage have therefore not been estimated.

Cereal Straw

The critical GAP for cereals is in Switzerland with two applications at 0.016 kg ai/ha and a PHI of 42 days.

Residue trials on barley, oats, triticale and wheat were evaluated by the 2010 JMPR. None of the trials matched the GAP. However, the Meeting agreed that the trials could be scaled using the proportionality principle. The Meeting noted that the DALA varied and the Meeting agreed that only trials with 40–44 DALA could be used to support the GAP.

Thirteen trials conducted on cereal straws support the GAP when the proportionality principle is applied.

The unscaled residues in cereal straw were (n = 13): 0.059, 0.074, 0.09, 0.11 (3), 0.12, 0.18 (2), 0.19, 0.2, 0.21 and 0.24 mg/kg (as received).

The scaled residues (scaling factors of 1.45–2.13) in cereal straw were (n = 13): 0.12, 0.15, 0.19, 0.22, 0.23 (2), 0.26, 0.28, 0.38 (2), 0.39, 0.42 and 0.45 mg/kg (as received).

The Meeting estimated a highest residue of 0.45 mg/kg (as received), a median residue of 0.26 mg/kg (as received) and a maximum residue level of 1 mg/kg (dw), using a correction factor of 90% for dry matter, for straw and fodder (dry) of cereal grains.

Residues in animal commodities

Straw can be fed to livestock.

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO manual[7], are presented in Annex 6.

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[7] http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/

The maximum total dietary burdens calculated in 2010 were 8.3 ppm (beef cattle), 7.4 ppm (dairy cattle), 0.59 ppm (poultry broiler) and 2.0 ppm (poultry layer). The maximum total dietary burdens calculated by the current Meeting using the OECD diets were 8.5 ppm (beef cattle), 7.6 ppm (dairy cattle), 0.59 (poultry broiler) and 1.5 ppm (poultry layer).

The Meeting noted that the contribution of straw to the dietary burden was less than 10% of the maximum total dietary burden estimated by the 2010 JMPR and did not change the estimated residues in milk, eggs and tissues. The Meeting therefore confirmed its previous recommendations for maximum residue levels in animal products.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

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

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for bifenthrin is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) of bifenthrin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR values estimated by the JMPR in this Meeting and in 2010 and 2015. The results are shown in Annex 3 of the 2019 JMPR Report.

The IEDIs ranged from 10–40% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of bifenthrin resulting from the uses considered by the current and previous Meetings are unlikely to present a public health concern.

Acute dietary exposure

The ARfD for bifenthrin is 0.01 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for bifenthrin were calculated for the food commodities and their processed commodities for which HRs and STMRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs varied from 2–380% of the ARfD for children and 1–210% of the ARfD for the general population.

The Meeting concluded that acute dietary exposure to residues of bifenthrin from the consumption of strawberry may present a public health concern.