5.16 PENDIMETHALIN (292)

RESIDUE AND ANALYTICAL ASPECTS

Pendimethalin is a meristematic inhibitor herbicide that interferes with plant cellular division or mitosis. Pendimethalin was first evaluated for toxicology and residues by the JMPR in 2016. The compound has an ADI of 0–0.1 mg/kg bw and an ARfD of 1 mg/kg bw. The residue definition for both plant and animal commodities for compliance with the MRL and dietary risk assessment is pendimethalin. The residue is fat soluble.

It was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 Extra JMPR. The current Meeting received information on storage stability, use patterns and supervised residue trials for berries and herbs.

Storage stability of residues

The 2016 JMPR confirmed that pendimethalin residues in high water, high starch and high acid content matrices were stable for at least 24 months. In soya bean and almond nutmeat, pendimethalin was stable for up to 18 and 12 months, respectively. The frozen storage periods of samples in the trials submitted to the current Meeting were less than 18 and 24 months after sampling for berries and herbs, respectively.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for soil applications of pendimethalin on cane berries, blue berries, strawberries and mint.

Cane berries, subgroup of

The critical GAP for pendimethalin on cane berries in the USA is one soil application at a rate of 6.7 kg ai/ha and a PHI of 30 days.

Six supervised field trials were conducted on cane berries in the USA matching the critical GAP for soil application.

Residues of pendimethalin in blackberry were (n=4): < 0.05 (4) mg/kg.

Residues of pendimethalin in raspberry were (n=2): < 0.05 (2) mg/kg.

Noting that the US GAP covers the cane berries subgroup, the Meeting decided to estimate a maximum residue level of 0.05(*) mg/kg, STMR of 0.05 mg/kg and HR of 0.05 mg/kg for the cane berries subgroup.

Bush berries, subgroup of

The critical GAP for pendimethalin on bush berry in the USA is one soil application at a rate of 6.7 kg ai/ha and a PHI of 30 days.

Seven trials on blueberries were conducted in the USA matching the GAP.

In blueberries, residues of pendimethalin in these trials were (n=7): < 0.05 (7) mg/kg.

The Meeting noted that the US GAP is for bush berries, and decided to estimate a maximum residue level of 0.05(*) mg/kg, STMR of 0.05 mg/kg and HR of 0.05 mg/kg for the bush berries subgroup.

Strawberry

The critical GAP in Ireland and UK is one soil application at 1.3 kg ai/ha after flower initiation but before flower truss emergence. In six European trials at 1 kg ai/ha, residues of pendimethalin were

< 0.01 (6) mg/kg. In four other trials, with higher application rates of 1.6 kg ai/ha, residues were found from < 0.01 to 0.016 mg/kg.

The critical GAP for pendimethalin in low growing berries including strawberry in the USA is 1 soil application at 3.2 kg ai/ha and a PHI of 35 days. In eight trials approximating the US GAP conducted in the USA, residues of pendimethalin were < 0.05 (8) mg/kg.

The Meeting decided to estimate a maximum residue level of 0.05(*) mg/kg, an STMR of 0.05 mg/kg, and an HR of 0.05 mg/kg for strawberry on basis of the trial data from the USA.

Mint

The critical GAP for pendimethalin on mint in the USA is 1 soil application of 2.24 kg ai/ha and a PHI of 90 days.

In four independent trials conducted in the USA on mint approximating the US GAP, residues of pendimethalin were (n=4): < 0.05, 0.054, < 0.1 and < 0.1 mg/kg.

The Meeting decided to estimate a maximum residue level of 0.2 mg/kg, STMR of 0.077 mg/kg and HR of 0.1 mg/kg for mint.

Fate of residues during processing

Four studies were submitted on processing of mint to mint oil. In two trials with finite residue in mint leaves, residues in mint leaves were 0.076 and 0.219 mg/kg, and the residues in mint oil were 1.88 and 7.84 mg/kg. Processing factors were calculated to be 24.7 and 35.8. The best estimation of processing factor was 30.

The Meeting estimated a maximum residue level of 6 mg/kg and an STMR-P of 2.3 mg/kg for mint oil.

Residues in animal commodities

None of the commodities or their by-products for which supervised trial data were submitted to the current Meeting are fed to animals. The Meeting confirmed its previous recommendations for animal commodities.

RECOMMENDATIONS

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

Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: *pendimethalin.*

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for pendimethalin is 0–0.1 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for pendimethalin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 Extra JMPR Report.

The IEDIs were 0% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of pendimethalin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for pendimethalin is 1 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for pendimethalin were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 Extra JMPR Report.

The IESTIs were 0% of the ARfD for children and the general population. The Meeting concluded that acute dietary exposure to residues of pendimethalin from uses considered by the present Meeting is unlikely to present a public health concern.

Dietary risk of metabolites previously evaluated by the Meeting against their threshold of toxicological concern

The 2016 JMPR concluded that the dietary exposure to the metabolites M455H025, M455H029 and M455H030 are below the threshold of toxicological concern (TTC) of 1.5 µg/kg bw per day for a Cramer Class III compound.

Based on the uses evaluated by the current Meeting, the estimated dietary exposure to M455H025 increased from 1.30 to 1.32 µg/kg bw per day while the estimated dietary exposures to M455H029 (found in animal commodities) and M455H030 (found in rotated root crops only) remained unchanged.

The Meeting confirmed its previous conclusion that dietary exposure to the metabolites M455H025, M455H029 and M455H030 are unlikely to present a public health concern.