5.17 Penthiopyrad (253)

RESIDUE AND ANALYTICAL ASPECTS

Penthiopyrad is a locally systemic carboxamide fungicide used for the control of foliar and soil-borne plant diseases. Penthiopyrad was first evaluated in 2011 for toxicology, and an ADI of 0–0.1 mg/kg bw and an ARfD of 1 mg/kg bw were established. For residues, penthiopyrad was first evaluated by the 2012 JMPR. The residue definition for compliance with the MRL for plant commodities is penthiopyrad. For compliance with the MRL for animal commodities and dietary risk assessment for plant and animal commodities, the residue definition is the sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad. The residue is not fat-soluble. Additional uses were evaluated by the 2013 JMPR.

Penthiopyrad was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received information on supervised residue trials and GAP information for caneberry and blueberry.

Methods of analysis

Residues of penthiopyrad and its metabolites (PAM and PCA, 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid) were analysed by the method evaluated by the 2012 JMPR. The current Meeting received additional method validation and concurrent recovery data on caneberry and blueberry. The method involving extraction and partitioning with organic solvent and determination by LC-MS/MS, was sufficiently validated for caneberry and blueberry. Mean recoveries ranged from 80–115% (RSDs ≤ 15%). The LOQs for the analytes were 0.01 mg/kg.

Stability of residues in stored analytical samples

The 2012 JMPR agreed that penthiopyrad, PAM and PCA are stable for at least 18 months in frozen plant matrices. The residue sample storage intervals used in the field trials considered by the current Meeting were covered by the demonstrated stability period.

Results of supervised residue trials on crops

Supervised trials were available for the use of penthiopyrad on caneberry and blueberry. Product labels were available from Canada.

For dietary risk assessment, the sum of penthiopyrad and PAM (conversion factor into penthiopyrad, 1.86) is referred to as "total". If both analytes were below LOQs (< 0.01 mg/kg), the total residues were assumed to be < 0.01 mg/kg, and for all other cases, <LOQ values were handled as their numeric value (e.g. < 0.01 mg/kg as 0.01 mg/kg).

Cane berries, Subgroup of

Blackberry and raspberry

The critical GAP for penthiopyrad on caneberries in Canada is 3 foliar spray applications of 0.35 kg ai/ha each with a minimum retreatment interval of 7 days and a PHI of 0 days. One field trial on blackberry conducted in the USA and four independent field trials on raspberry conducted in Canada or the USA matched the critical GAP. Noting that the cGAP was for caneberries, the Meeting decided to combine the data from raspberries and blackberries to consider a group maximum residue level.

For the purposes of maximum residue level estimation penthiopyrad residues in raspberries and blackberries from trials matching the Canadian GAP were (n = 5): 2.0, 3.4, 3.7, 3.7 and 4.3 (blackberry) mg/kg.

For the dietary risk assessment purposes the total residues in caneberry were (n = 5): 2.0, 3.4, 3.7, 3.8 and 4.3 mg/kg (highest individual value was 4.8 mg/kg).

The Meeting estimated a maximum residue level of 10 mg/kg, a STMR of 3.7 mg/kg and a HR of 4.8 mg/kg for penthiopyrad in the Subgroup 004A Caneberries.

Blueberries

The critical GAP for penthiopyrad on bushberries is 3 spray applications at a rate of 0.35 kg ai/ha with a minimum retreatment interval of 7 days and a PHI of 0 days. Seven independent trials on highbush blueberry conducted in Canada or the USA matched the critical GAP.

For the purposes of maximum residue level estimation penthiopyrad residues in blueberry were (n = 7): 0.57, 1.2, 1.5, 1.7, 1.7, 2.6 and 3.9 mg/kg.

For the dietary risk assessment purposes the total residues in blueberry were (n = 7): 0.59, 1.3, 1.5, 1.7, 1.7, 2.6 and 4.0 mg/kg.

Noting that blueberry is a representative crop for bushberries, the Meeting estimated a maximum residue level of 7 mg/kg, a STMR of 1.7 mg/kg and a HR of 4.0 mg/kg for penthiopyrad in the Subgroup 004B Bush berries.

The Meeting noted that the Canadian bushberries group includes highbush cranberries, listed in The Codex Classification as Guelder rose (*Vibernum opulus* L.) and Elderberries (*Sambucus* spp.) in the subgroup of large shrub/tree berries, and agreed to extrapolate the maximum residue level of 7 mg/kg, the STMR of 1.7 mg/kg and the HR of 4.0 mg/kg for penthiopyrad to Guelder rose and Elderberries.

Residues in animal feeds

The additional uses submitted to the current Meeting are not relevant to animal feeds.

RECOMMENDATIONS

On the basis of the data obtained 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 for plant commodities: *penthiopyrad*

Definition of the residue for compliance with the MRL for animal commodities and for dietary risk assessment for plant and animal commodities: *sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

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

The IEDIs ranged from 1–8% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of penthiopyrad from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for penthiopyrad is 1 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for penthiopyrad were calculated for the food commodities for which HRs 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 0–5% of the ARfD for children and general population. The Meeting concluded that acute dietary exposure to residues of penthiopyrad from uses considered by the present Meeting is unlikely to present a public health concern.