5. Evaluation of data for acceptable daily intake and acute reference dose for humans, maximum residue levels and supervised trials median residue values

5.1 ABAMECTIN (177)

RESIDUE AND ANALYTICAL ASPECTS

Abamectin is used to control insect and mite pests of a wide range of crops. Abamectin was first evaluated for toxicology and residues by the 1992 JMPR and was reviewed by the 2015 JMPR as part of the periodic review program of CCPR. The compound has an ADI of 0–0.001 mg/kg bw and an ARfD of 0.003 mg/kg bw. The residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities is avermectin B1a. The residue is fat-soluble.

Abamectin was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses in 2018 JMPR. The current Meeting received information on GAP and supervised residue trials on various crops; processing studies for soya bean, herbs, mint and citrus fruit; and storage stability data for cane berries.

Methods of analysis

The methods of analysis for abamectin residues in various plant and animal commodities were reviewed by the 2015 JMPR. The current Meeting received concurrent recovery data for the crops considered at by the Meeting.

Stability of pesticide residues in stored analytical samples

The 2015 JMPR concluded that abamectin residues in a variety of crop samples except raisins, when stored under frozen conditions were stable for at least 12 months. The current Meeting received storage stability data for cane berry spiked at 0.02 mg/kg and stored concurrently with residue trial samples. The stability of abamectin residues in stored samples of cane berry was demonstrated for at least 978 days.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for foliar applications of abamectin on grape, cane berries, pineapple, spring onion, dry bean, soya bean, sweet corn, basil, chives and mint.

Berries and other small fruits

Grapes

The critical GAP for abamectin on grapes in Brazil is 2 foliar applications of 0.0108 kg ai/ha with a re-treatment interval (RTI) of 7 days and a PHI of 7 days.

Trials were conducted on grapes in Brazil with 3–5 foliar applications at 0.0144 or 0.018 kg ai/ha, a PHI of 7 days. Residue decline data demonstrated that residues dissipate extensively over seven days, and as a result the first applications would be unlikely to affect the final residue at harvest. Therefore, the Meeting agreed to use the proportionality approach to estimate the residues at cGAP.

In six trials conducted at higher application rates the residues of abamectin in grapes were: < 0.002(3), < 0.004, 0.007 and 0.022 mg/kg. Using the proportionality approach (with scaling factors of 0.75 or 0.6) the residues of abamectin in grapes were (n = 6): 0.0012 (3), 0.003, 0.0042 and 0.016 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg, a STMR of 0.0021 mg/kg and a HR of 0.016 mg/kg for abamectin in grapes. This estimation replaces the previous of 0.01 mg/kg for abamectin in grapes.

Cane berries

The critical GAP for abamectin on cane berries in the USA, is 2 foliar applications at 0.0213 kg ai/ha, a RTI of 7 days and a PHI of 7 days.

Seven trials were conducted on blackberry and raspberry in the USA with 3 foliar applications at 0.021 kg ai/ha with a re-treatment interval of 7 days and a PHI of 7 days. Based on residue decline data the first application is unlikely to contribute significantly to the residue level at harvest and therefore the Meeting considered that these trials approximated GAP. The residues of abamectin in cane berries were (n = 7): 0.0047, 0.0064, 0.015, 0.018, 0.024, 0.050 and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a STMR of 0.018 mg/kg and a HR of 0.11 mg/kg for abamectin in the subgroup of Cane berries.

The Meeting withdraw the previous recommendation of 0.05 mg/kg for abamectin in Blackberries and Raspberries, Red, Black.

Pineapple

The critical GAP for abamectin on pineapple in the USA is 2 foliar applications of 0.0261 kg ai/ha, a 7 day RTI and a PHI of 112 days.

In six trials matching the GAP, the residues of abamectin in pineapples were (n = 6): < 0.002 mg/kg.

The Meeting estimated a maximum residue level of 0.002(*) mg/kg, a STMR of 0 mg/kg, and a HR of 0 mg/kg for abamectin on pineapple.

Green onions

The critical GAP for abamectin on green onions (includes chives) in the USA is 2 foliar applications of 0.0213 kg ai/ha, a 7 day RTI and a PHI of 7 days.

Eight trials were conducted in the USA on spring onions with 4 foliar applications at 0.021–0.023 kg ai/ha. Two decline studies indicated that abamectin residues dissipated quickly in spring onions. The earlier applications were considered unlikely to contribute significantly to the residue level at harvest and therefore the Meeting considered that these trials approximated GAP. In six trials, where samples were harvested at a 7 day PHI, the residues of abamectin in spring onions were < 0.002(3), 0.002, 0.003 and 0.004 mg/kg.

In three trials matching GAP, and conducted in the USA, on chives residues of abamectin were < 0.002 (2) and 0.002 mg/kg.

Based on the residue data on spring onion, the Meeting estimated a maximum residue level of 0.01 mg/kg, a STMR of 0.002 mg/kg, and a HR of 0.004 mg/kg and for abamectin on the subgroup of Green onions.

The Meeting withdraw the previous recommendation of 0.005 mg/kg for abamectin in leek.

Beans without pods

The critical GAP for abamectin on beans, shelled in the USA is 2 foliar applications of 0.0213 kg ai/ha, a 6 day RTI and a PHI of 7 days.

Seven trials were conducted in the USA with 3–4 foliar applications at 0.021 kg ai/ha. Based on the rapid decline of abamectin residues in other crops the Meeting considered that these trials approximated GAP. The residues of abamectin in shelled beans at a 7 day PHI were (n = 7): < 0.002 mg/kg.

The Meeting estimated a maximum residue level of 0.002(*) mg/kg a STMR of 0.002 mg/kg, and a HR of 0.002 mg/kg and for abamectin on beans without pods.

Soya bean (dry)

The critical GAP for abamectin on soya bean in the USA is 2 foliar applications of 0.0213 kg ai/ham a 7 day RTI and with a PHI of 28 days.

In 19 trials conducted on soya bean in the USA a seed treatment followed by 2 foliar applications at 0.021 kg ai/ha were applied. Based on the rapid decline of abamectin residues in other crops the Meeting considered that these trials approximated GAP. The residues of abamectin in soya bean at a 28 day PHI were (n = 19): < 0.002 mg/kg.

The Meeting estimated a maximum residue level of 0.002(*) mg/kg, and a STMR of 0.002 mg/kg for abamectin on soya bean (dry).

Sweet corns

The critical GAP for abamectin on sweet corn in the USA is 2 foliar applications of 0.0213 kg ai/ha, a 7 day RTI and a PHI of 7 days.

In twelve trials conducted on sweet corn in the USA matching cGAP, the residues of abamectin in sweet corn (kernels+cobs with husks removed) were (n = 12): < 0.002 mg/kg .

The Meeting estimated a maximum residue level of 0.002(*) mg/kg, a STMR of 0.002 mg/kg and a HR of 0.002 mg/kg for abamectin on sweet corns (whole kernel with husk removed).

Herbs

The critical GAP for abamectin on herbs in the USA is 2 foliar applications of 0.0213 kg ai/ha (7 days RTI) and a PHI of 14 days.

In five trials conducted in the USA on basil (3) and mint (2) 3 foliar applications at 0.021 kg ai/ha were applied with samples collected at a PHI of 14 days. Based on the rapid decline of abamectin residues in other crops the Meeting considered that these trials approximated GAP. The residues of abamectin in basil and mint at a PHI of 14 days were: < 0.002, 0.002, 0.003 and 0.007 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg, a STMR of 0.003 mg/kg and a HR of 0.008 mg/kg (highest individual) for abamectin on herbs.

Animal feed commodities

The GAP in the USA does not permit the grazing of livestock on treated crops or harvesting of treated soya bean forage, straw or hay as feed for meat or dairy animals. As a result, the animal feed items from soya bean were not considered in the animal dietary burden calculations.

Sweet corn forage

The critical GAP for abamectin on sweet corn in the USA is for up to 2 foliar applications of 0.0213 kg ai/ha applied at a 7 day RTI and with a PHI of 7 days.

In twelve trials conducted on sweet corn in the USA matching the cGAP, residues of abamectin in sweet corn forage were(n = 12): 0.011, 0.015, 0.021, 0.027, 0.051, 0.053, 0.06, 0.061, 0.062, 0.067, 0.096 and 0.098 mg/kg.

The Meeting estimated a median and a highest residue of 0.056 mg/kg and 0.10 mg/kg (highest individual), respectively, for abamectin in sweet corn forage.

Fate of residues during processing

The Meeting received processing studies for soya bean, herbs, mint, and citrus fruit. The 2015 JMPR also considered processing studies on grape. In two processing studies on soya bean, residues in seed were < 0.002 mg/kg, therefore, no processing factors could be estimated. In one processing study conducted on chives residues were 0.002 mg/kg in fresh leaves and 0.010 mg/kg in dried leaves, leading to a processing factor of 5. In three processing studies on mint abamectin residues in fresh mint leaves were 0.0055, 0.034 and 0.032 mg/kg while residues in mint oil were < 0.002 (3) mg/kg; the median processing factor was 0.06. In three processing studies on citrus fruit abamectin residues in citrus fruits were 0.0092, 0.0099 and 0.017 mg/kg while residues in orange oil were 0.054, 0.087 and 0.118 mg/kg; the median processing factor was 5.5.

The estimated processing factors with the respective recommendations for STMR-Ps are shown in the following table.

RAC	Matrix	Processing factor	Median Processing Factors	STMR RAC (mg/kg)	STMR-P (mg/kg)
Chives	Chives, dried	5	5	0.003	0.015
Mint	Mint oil	< 0.06, < 0.06, < 0.36	0.06	0.003	0.00002
Citrus fruits	Orange oil	4.3, 5.5, 9.7	5.5	0.005	0.0275
Grapes	dried grape (= currants, raisins and sultanas)		2.8	0.0021	0.0059
	Grape juice		1.4		0.0029
	Grape pomace	4.75			0.01

Based on the estimated maximum residue level of 0.015 mg/kg for herbs, the Meeting estimated a maximum residue level of 0.08 mg/kg for abamectin in chives, dried.

Based on the recommended maximum residue level of 0.02 mg/kg for citrus fruits, the Meeting estimated a maximum residue level of 0.1 mg/kg for abamectin in orange oil.

Based on processing data on raisin and grape juice considered by the 2015 JMPR, the current Meeting recommended a maximum residue level of 0.1 mg/kg for dried grape (= currants, raisins and sultanas), to replace the previous recommendation of 0.03 mg/kg and recommended a maximum residue level of 0.05 mg/kg for grape juice, to replace the previous recommendation of 0.015 mg/kg.

Residues in animal commodities

The additional animal feed commodities considered by the present Meeting (soya beans, sweet corn forage and grape pomace) do not significantly impact the dietary burden estimated by the 2015 JMPR. The Meeting confirmed its previous conclusions for abamectin in animal commodities.

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 assessment.

Definition of the residue for -compliance with the MRL and dietary risk assessment for plant and animal commodities: *avermectin B1a.*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for abamectin is 0–0.001 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for abamectin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged 1–6% of the maximum ADI.

The Meeting concluded that the long-term dietary exposure to residues of abamectin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for abamectin is 0.003 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for abamectin were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the current JMPR and for which consumption data were available. The results are shown in Annex 4 of the 2018 JMPR Report. The IESTIs varied from 0–40% of the ARfD for children and 0–30% for the general population.

The Meeting concluded that the acute dietary exposure to residues of abamectin from uses considered by the current JMPR is unlikely to present a public health concern.