5.2 BENTAZONE (172)

RESIDUE AND ANALYTICAL ASPECTS

Bentazone is a selective herbicide belonging to the thiadiazine group of chemicals. Bentazone was first evaluated for toxicology and residues by JMPR in 1991, and was re-evaluated in 2012 and 2013, as part of the periodic review programme of the CCPR. The 2012 Meeting established an ADI for bentazone of 0–0.09 mg/kg bw, and the 2016 Meeting established an ARfD of 0.5 mg/kg bw. The residue definition for compliance with the MRL and for dietary risk assessment for plant and animal commodities is the parent bentazone. The residue is not fat-soluble.

Bentazone was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The Meeting received a dairy cow feeding study, GAP information and supervised residue trials on dry peas.

Methods of analysis

Analytical methods for determining bentazone residues in various raw agricultural commodities, feed commodities and animal commodities were evaluated by JMPR in 2013. The methods typically use an initial extraction and a further conjugate hydrolysis step, followed by clean-up and GC-MS, or LC-MS/MS determination. LOQs of 0.01 mg/kg were achievable in most matrices.

The analytical method used to determine bentazone residues in kidney and fat matrices was evaluated previously by JMPR in 2013.

The available methods are sufficiently validated and are suitable to measure bentazone in the commodities being considered.

Stability of pesticide residues in stored analytical samples

The 2013 JMPR concluded that bentazone residues were stable at -20 °C for at least 24 months in representative plant matrices.

The current Meeting received residue stability data in animal commodities performed alongside the dairy cow feeding study. Bentazone was shown to be stable in incurred samples of liver after 316 days and kidney after 305 days in frozen storage. In other animal matrices including milk, cream, muscle and fat bentazone residues were stable for at least 120 days.

The Meeting agreed that the demonstrated storage stability in various representative plant and animal commodities covered the residue sample storage intervals used in the studies.

Results of supervised residue trials on crops

The Meeting received information on supervised residue trials for bentazone in dry peas.

Dry peas

The critical GAP for bentazone in pulses (including dry pea) in the USA is for two foliar application at 1.12 kg ai/ha with a PHI of 30 days.

In six trials conducted in the USA and matching cGAP, abamectin residues in dry peas were (n = 6): < 0.01, 0.052, 0.12, 0.17, 0.19 and 0.29 mg/kg.

The 2013 JMPR reviewed field trials on dry peas, concluding that two trials with residue levels less than < 0.02 mg/kg met the GAP of 2×1.12 kg ai/ha. There were insufficient trials to recommend maximum residue levels at the 2013 JMPR. These two trials were considered alongside the submitted data.

The combined data set were (n = 8): < 0.01, < 0.02(2), 0.052, 0.12, 0.17, 0.19 and 0.29 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, and STMR of 0.09 mg/kg for bentazone in the subgroup of Dry peas. As the USA GAP is also applicable to the subgroup of dry beans, the Meeting decide to extrapolate the recommendations to subgroup Dry beans, and withdraw the previous recommendations of 0.04 mg/kg for dry beans, and 0.01(*) mg/kg for soya bean.

Residues in animal commodities

Farm animal feeding studies

The Meeting received a dairy cow feeding study. Bentazone was administered orally once daily to dairy cows for 28 days at levels equivalent to 11.6, 37.2 and 118.1 ppm dry weight in the feed. The cows in the control group received placebos (empty capsules) concurrently with the treated animals. Three additional cows from the high dose group were maintained for up to 7 days after the 28 day dosing period to provide depuration information.

Bentazone residues were observed in liver at up to 0.011 mg/kg and 0.049 mg/kg in the mid and high dose groups, respectively. Bentazone residues were observed in kidney at up to 0.010, 0.040 and 0.144 mg/kg in the low-, mid- and high-dose groups respectively. In all other matrices, including milk, residues were less than LOQ (0.01 mg/kg) in each dose group and (for milk) at all time points. The only bentazone residue detected above LOQ in any matrix, including milk, during the 7 day depuration phase was 0.016 mg/kg after 2 days in kidney.

Estimation of livestock dietary burdens

The 2013 JMPR estimated the animal burden resulting from feed commodities however decided not to estimate maximum residue levels for mammalian tissues and milk. In the current evaluation, new recommendations are made for dry peas and dry beans. The addition of these items did not significantly add to the estimated burden therefore the Meeting decided to use the livestock dietary burdens calculated by the 2013 JMPR and the dairy cow feeding study to estimate potential residues in mammalian tissues and milk.

Animal commodity maximum residue levels

The calculations used in estimating maximum residue levels, STMR and HR values in mammalian tissues and milk are shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
maximum residue level beef or dairy cattle							
Feeding study [a]	11.6	< 0.01	11.6	< 0.01	< 0.01	0.010	< 0.01
	37.2	< 0.01	37.2	< 0.01	0.011	0.040	< 0.01
Dietary burden and high residue	**21.8**	< 0.01	**32.0**	< 0.01	0.011	0.035	< 0.01
STMR beef or dairy cattle							
Feeding study [b]	11.6	< 0.01	11.6	< 0.01	< 0.01	0.010	< 0.01
	37.2	< 0.01	37.2	< 0.01	0.010	0.028	< 0.01
Dietary burden and median residue estimate	**0.76**	< 0.01	**0.80**	< 0.01	< 0.01	< 0.01	< 0.01

[a] highest residues for tissues and mean residues for milk

[b] mean residues for tissues and mean residues for milk

The Meeting estimated maximum residue levels of 0.01(*) mg/kg for milks, mammalian meat and mammalian fats (except milk fats). The meeting estimated a maximum residue level of 0.04 mg/kg for edible offal (mammalian).

The Meeting estimated STMRs of 0 mg/kg for milk, mammalian meat and mammalian fats (except milk fats). The meeting estimated a STMR of 0.01 mg/kg for edible offal (mammalian).

The Meeting estimated HRs of 0 mg/kg, 0 mg/kg, and 0.035 mg/kg for mammalian muscle, mammalian fat, and edible offal (mammalian), respectively.

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 in plant and animal commodities: *bentazone.*

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for bentazone is 0–0.09 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for bentazone 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 0–1% of the maximum ADI.

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

Short-term dietary exposure

The ARfD for bentazone is 0.5 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for bentazone 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 were 0% of the ARfD.

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