BENTAZONE (172)

EXPLANATION

Bentazone was evaluated by the JMPR in 1991, 1994 and 1995. At the CCPR in 1995, the delegations of Germany and France suggested that the definition of the residue for animal products should exclude the metabolite, as no residues of the metabolite had been found.

The 1995 Joint Meeting confirmed the previous recommendation for plant commodities but recommended that the definition of the residue in animal products should be changed to bentazone alone.

In 1997 the CCPR requested the JMPR to consider revising the definition of the residue for plant commodities (ALINORM 97/24A, para 71).

In order to respond to the CCPR request the Meeting considered the information provided in the 1991, 1994 and 1995 JMPR evaluations and that submitted to the manufacturer, which included summaries of new studies on plant metabolism and environmental fate, analytical methods and reports of supervised trials.

METABOLISM AND ENVIRONMENTAL FATE

The 1991 Meeting concluded that the degradation of bentazone in plants, animals, soil, and soil/water suspensions followed similar pathways, but with quantitative differences. In plants the aromatic ring is hydroxylated at the 6 and 8 position of the molecule; 6-hydroxy bentazone is a major part of residue during degradation.

Animal metabolism

Animal metabolism studies showed that bentazone was the main compound eliminated in the urine and faeces, 6-hydroxy-bentazone was present at low levels in the urine and only traces of 8-hydroxy-bentazone were found. Studies on hens and lactating goats evaluated by the 1995 JMPR concluded that the major residue component in meat, milk and eggs was the parent bentazone with smaller amounts of the glucuronide conjugate.

Plant metabolism

New metabolism studies on soya beans, rice, maize, green beans and potatoes were reported.

Soya beans were treated with [^{14}C]bentazone once at 2.24 kg ai/ha or twice at 1.68 and 1.12 kg ai/ha. Forage at long and short pre-harvest intervals, hay and bean samples were collected. The ethanol-extractable residues in forage and hay were up to 62 and 9% of the TRR respectively, and the corresponding total methanol-extractable ^{14}C residues were 4 and 6% of the TRR. When the residue in the methanol extract was hydrolysed with 2N HC1, the hydrolysate contained bentazone and 6- and 8-hydroxy-bentazone. The bound residues (not extracted with methanol) were associated with polysaccharides, hemicellulose fractions and lignin. It was estimated that 57% of the TRR in the beans was associated with protein and 16 % with carbohydrate.

Rice plants were treated by foliar application with 1 kg ai/ha of [^{14}C]bentazone and radioactive residues were determined in whole plants, grain and straw. In grain samples 63 days after

treatment only 6.6% of the TRR was extractable and 93.4% remained in the insoluble fraction. It was shown that the terminal ^{14}C residue consisted predominantly of recycled fragments of bentazone and 6-hydroxy-bentazone taken up into glucose, polysaccharides and lignin. The residues of bentazone and 6-hydroxy-bentazone were below the detection limit (0.02 mg/kg).

The metabolism of bentazone was also investigated in maize grown in outdoor plots and sprayed with an aqueous solution of the sodium salt of [^{14}C]bentazone at a rate equivalent to 1.68 kg ai/ha of bentazone. Samples were taken 0, 1, 2, 3, 6, 9 and 18 weeks (harvest) after application. In forage samples taken 14 and 21 days after treatment only bentazone and 6-hydroxy-bentazone were found in the methanol extract. Analysis of the final harvest grain, cobs, husk and stover showed no residues of bentazone or 6-hydroxy- or 8-hydroxy-bentazone ([0.05mg/kg).

The magnitude and nature of the residues in green beans were determined after one application of [^{14}C]bentazone at 2.24 kg ai/ha or two at 1.68 and 1.12 kg ai/ha. The TRR was determined in forage at 9 and 36 days PHI, and in hay and beans at 79 days (harvest). The residues consisted of bentazone and 6- and 8-hydroxy-bentazone.

The metabolism in potato plants was studied after two foliar spray applications of 1.12 kg ai/ha [^{14}C]bentazone formulation 23 and 44 days after planting. Samples were taken at 41 and 62 days PHI. The identified extractable residues were bentazone (4% of the TRR) and conjugates of 6-hydroxy-bentazone (about 12%). Most of the radioactivity was incorporated into starch.

The metabolism and distribution of [^{14}C]bentazone were studied in leafy vegetable, root and grain rotational crops grown in confined plots, after soil was treated at a nominal application rate of 2.24 kg ai/ha. Cropping intervals were 39 days to represent emergency replanting, 102 to 145 days for autumn planting and 316 to 369 days for annual planting of rotational crops. The residues of bentazone and the metabolites 6-hydroxy- and 8-hydroxy-bentazone were quite low in emergency replant crops (0.005-0.04 mg/kg) and essentially absent in autumn and annual crops (0.001-0.02 mg/kg).

Residues in succeeding crops

Field trials were carried out with alfalfa, maize, lettuce, mustard, radishes, snap beans, sorghum, spinach, sugar beets, turnips and wheat, representing cereal, root, legume, leafy and oil crops.

The rates applied to the preceding crop, soya beans in all the trials, reflected a “worst-case” situation: 2 applications at 1.12 kg ai/ha each with an interval of 14 days (GAP: 1.44-1.99 kg ai/ha, 1 application). Soil samples collected before and after each application to the soya beans and at planting and harvest of the rotational crops were analysed. The residues of bentazone and 6-hydroxy- and 8-hydroxybentazone in the replanted crops were all below the LOD (0.05 mg/kg).

METHODS OF RESIDUE ANALYSIS

Analytical methods

The analytical method described in the 1991 evaluation (BASF, method No. 197) was modified to extend its range, and the modified method was described in the 1994 monograph. The reported LOD was 0.05 mg/kg. The method determines bentazone and the hydroxy metabolites.

Definition of the residue

New metabolism studies on plants and supervised trials showed that the main residues in food or feed of plant origin were bentazone and one or both of its conjugated metabolites, 6-hydroxy- and 8-hydroxy-bentazone, depending whether a monocotyledonous or dicotyledonous crop was treated.

Animal metabolism studies showed that the parent bentazone was the major component of the residue.

Analytical methods are suitable for the determination of bentazone and both hydroxy metabolites.

The Meeting noted that existing and proposed MRLs for plant commodities are based on the sum of bentazone and its hydroxy metabolites, agreed that it was necessary to review all the studies on metabolism before taking a decision and recommended that the definition of the residue should be considered at the next periodic review.

USE PATTERN

Detailed information on national use patterns was given in the 1994 evaluation.

RESIDUES RESULTING FROM SUPERVISED TRIALS

Supervised field trials were evaluated by the JMPR in 1991 and 1994. Bentazone and its hydroxy metabolites were determined in all the trials. A summary of the results is given below.

Crop	No. of trials	Applic. rate, kg ai/ha	PHI, days	bentazone, 6-OH- and 8-OH-bentazone, mg/kg	Recommended MRL, mg/kg
Onion	8	0.7-2.0	48-95	Bent <0.02-0.05 6-OH <0.02 8-OH <0.02	0.1 (1991) (CXL, 1995)
Beans, dry		1.44	21-35	Bent <0.02 6-OH <0.02 8-0H <0.02	0.05 (1991)
Common bean		1.44	21-35	6-OH <0.02 8-OH <0.02	0.2 (1991)
Broad bean, dry		1.44	21-35	6-OH <0.02 8-OH <0.02	0.05(1991)
Field pea (dry)	6	0.96- 1.44	30-40	Bent <0.05 6-OH <0.05 (3 trials); 0.06-0.43 (3 trials) 8-OH 0.31 (1 trial); <0.05 (5 trials)	1 (1994)
Lima bean	3	1.1		Bent, 6-OH and 8-OH<0.05	0.05 (1991) (CXL 1995)
Soya beans, dry		0.9-1.4	30-90	Bent, 6-OH and 8-OH < 0.02	0.05 (1991) (CXL, 1995
Barley		0.5-2.0	40-90	Bent, 6-OH and 8-OH <0.02	0.1 (1994)
Oats		1.0-2.0		Bent, 6-OH and 8-OH < 0.02	0.1 (1994)
Rye	4	1.0-1.9	64-91	Bent, 6-OH and 8-OH < 0.02	0.1 (1994)
Sorghum	9	1.0	97-134	Bent, 6-OH and 8-OH<0.02	0.1 (1994)
Wheat	15	1.0-1.9	60-110	Bent, 6-OH and 8-OH<0.02 6-OH B = 0.06 (1 sample)	0.1 (1994)
Maize	12	0.7 - 1.9	69-110	6- OH > Bentaz. (2 trials, 1991)	0.2 (1994)

Crop	No. of trials	Applic. rate, kg ai/ha	PHI, days	bentazone, 6-OH- and 8-OH-bentazone, mg/kg	Recommended MRL, mg/kg
Maize fodder	12	0.7-1.9	69 - 110	6-OH> Bent (3 trials) 8-OH> Bent (1 trial)	0.2 (1994)
Linseed	5	0.9-1.4	62 - 77	6-OH > Bent. 8-OH > Bent. (1 sample)	0.1 (1991)
Peanuts		0.75 3.6	20 - 155	Bent., 6-OH and 8-OH <0.05	0.05 (1991)
Potatoes	31	0.96 - 1.44	35 - 84	6- OH >bent. (2 samples)	0.1 (1991)
Alfalfa	3	0.9 - 1.4	32 - 58	8-OH < 0.02 6-OH> Bent in all trials	2 (1991)

APPRAISAL

Bentazone was originally evaluated in 1991 and subsequently in 1994 and 1995. The 29th (1997) Session of the CCPR requested the JMPR to consider revising the residue definition for plant commodities.

In order to respond to the CCPR request the Meeting considered the information provided in the 1991, 1994 and 1995 JMPR evaluations and that submitted by the manufacturer, which included summaries of new studies on plant metabolism and environmental fate, analytical methods and reports of supervised trials.

Metabolism studies in rats showed that bentazone is poorly metabolized. The parent compound was the predominant metabolite, with 6-hydroxy-bentazone identified as a minor metabolite and 8-hydroxy-bentazone found in trace amounts.

Metabolism studies in lactating goats and hens showed that the major residue component in meat, milk and eggs was the parent bentazone with small amounts of 6- or 8-hydroxy-bentazone and their glucuronide and sulfate conjugates.

New metabolism studies on soya beans, rice, maize, green beans and potatoes showed that the main residues in plants were bentazone and one or both of its conjugated metabolites, 6- and 8-hydroxy-bentazone, depending whether a monocotyledonous or dicotyledonous crop was treated. The nature of residues in succeeding crops was also investigated, but residues in replanted crops were all below the LOD. Details of these studies were not provided since bentazone was not scheduled for a full re-evaluation.

Multi-residue analytical methods do not determine residues of bentazone and its hydroxy metabolites. In a specialized analytical method suitable for the determination of bentazone and conjugated 6- and 8-hydroxy-bentazone, each of the residue components can be determined with an LOD of 0.02 mg/kg. The 1995 JMPR recommended a practical limit of determination of 0.05 mg/kg for regulatory purposes for each component.

Residue definitions for national MRLs include bentazone alone and the sum of bentazone and its metabolites.

In most of the supervised trials, residues of the metabolites were below the LOD. Residues of 8-hydroxy-bentazone above the LOD were found in three samples of maize fodder and one of linseed in trials evaluated in 1991. Residues of 6-hydroxy-bentazone were found at higher concentrations than bentazone in some samples of field peas (dry) (1 of 31), potatoes (2 of 31), wheat (1 of 15), maize (3 of 12), maize fodder (3 of 5), linseed (1 of 5) and alfalfa (3 of 3).

The Meeting noted that existing and proposed MRLs are based in the sum of bentazone and its hydroxy metabolites, agreed that it was necessary to review all the studies on metabolism before taking a decision and recommended that the definition of the residue should be considered at the next periodic review.

DIETARY RISK ASSESSMENT

Although no maximum residue levels were estimated, a risk assessment was carried out because the compound was on the agenda of the FAO Panel. The International Estimated Daily Intakes for the five GEMS/Food regional diets were in the range of 0 to 1% of the ADI. The Meeting concluded that the intake of residues of bentazone resulting from its uses that have been considered by the JMPR is unlikely to present a public health concern.

REFERENCES

BASF. Bentazone dossier prepared according to Annex II of Directive 91/414/EC.