

## 5.4 BUPROFEZIN (173)

### RESIDUE AND ANALYTICAL ASPECTS

Buprofezin, insecticide, was evaluated by JMPR in 1991 for the first time and then in 1995 and 1999. It was also reviewed under the Periodic Re-evaluation Programme in 2008 for toxicity and residues. The 2008 JMPR allocated an ADI of 0–0.009 mg/kg bw and ARfD of 0.5 mg/kg bw. It concluded that the residue definition for compliance with the MRL and for estimation of dietary intake, both for animal and plant commodities, should be buprofezin. Buprofezin was further evaluated for additional maximum residue levels in 2009.

At the Forty-third Session, the CCPR included buprofezin in the Priority List for review by the current JMPR for additional MRLs.

The current Meeting received information on supervised trials on banana, coffee and tea. The Meeting also received information on method validation and storage stability studies additional to those submitted to the 2008 and 2009 JMPR.

#### *Methods of analysis*

The Meeting received information on validation of analytical methods used in the supervised field trial studies for determination of buprofezin in banana, coffee bean or crude green tea.

A number of CG-NPD methods and HPLC-MS-MS methods were validated for determination of buprofezin in banana (pulp and peel), coffee or green tea. Mean recoveries were within the acceptable range of 70–110% with RSDs less than 20%. The reported LOQ was 0.01 mg/kg for the methods used for determination of buprofezin in banana pulp and peel and coffee. For the two GC-NPD methods for determining buprofezin in green tea, reported limit of detection was 0.01–0.05 mg/kg.

#### *Stability of residues in stored analytical samples*

The current Meeting received information on the storage stability studies on banana, coffee and tea to determine the stability of buprofezin following frozen storage.

Buprofezin was demonstrated to be stable when stored frozen at -20 °C for at least the longest storing periods in studies: 70 days in whole banana (0.01 mg/kg), 656 days in green coffee beans (0.50 mg/kg), 658 days in roasted coffee beans (0.50 mg/kg) and 680 days in freeze-dried coffee (0.50 mg/kg) and 75 days in crude green tea (2 mg/kg). The storage duration of samples in supervised trials was within the above mentioned period for each commodity.

#### *Results of supervised residue trials on crops*

The Meeting received supervised trial data for buprofezin on banana, coffee and tea.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

#### *Banana*

Six supervised trials were conducted in the USA: one in Puerto Rico and four in Hawaii in 1996 and one in Florida in 2003. Four applications were made at around 0.34 kg ai/ha with an exception that in the trial in Puerto Rico the first application rate was 0.84 kg ai/ha. The registered use on banana in the USA allows the maximum of 4 foliar spray applications at the maximum rate of 0.34 kg ai/ha with PHI of 1 day. The maximum spray concentration is 0.24 kg ai/hL.

The Meeting decided that as about three times higher rate applied at the first application (42 days before the last application) in one trial did not seem to contribute significantly to residues in fruits at harvest, it was appropriate to use the residue data from this trial.

In five trials banana fruit was either bagged or unbagged and one half of each sample of bagged or unbagged banana was peeled and analysed with the rest unpeeled and analysed. No residues were found in pulp portion of both bagged and unbagged banana, or in bagged whole banana fruit. Therefore, the Meeting decided to use data set from unbagged banana. Residues in unbagged whole banana from trials conducted in USA following US GAP were in rank order: 0.02, 0.04, 0.05, 0.06, 0.07, and 0.18 mg/kg.

Corresponding residues in pulp were in rank order: < 0.01 mg/kg (5). In the trial in Florida, only whole fruits were analysed.

Additionally four trials were conducted in Spain: two in 2009 and two other in 2010. The registered use on banana in Spain allows the maximum spray concentration of 0.01–0.02 kg ai/hL with PHI of 7 days. The spray concentrations in trials were 0.025–0.04 kg ai/hL.

Residues in unbagged whole banana from trials conducted in Spain following Spanish GAP were: 0.32 mg/kg.

The GAP of the USA and that of Spain are significantly different and the data from trials in Spain were not sufficient for estimating a maximum residue level, the Meeting decided to use the results of S trials as a basis of estimating a maximum residue level, STMR and HR.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.01 mg/kg and HR of 0.01 mg/kg on a basis of US trials.

#### *Coffee bean*

Supervised trials were conducted on coffee in Hawaii in the USA in 2004 with four applications at 1.12–1.23 kg ai/ha. The 2009 JMPR reviewed these data and concluded that data were insufficient to recommend a maximum residue level.

Residues of buprofezin in green coffee beans from trials in the USA conducted following US GAP for coffee (1.12 kg ai/ha × 4, PHI 0 day) were re-evaluated by the current Meeting. These were in rank order: 0.08, 0.12, 0.16 and 0.24 mg/kg.

Additionally three trials were conducted in Brazil in 2011 with four applications at 1.12–1.14 kg ai/ha. These trials were in accordance with US GAP.

As the Meeting does not have sufficient information on normal agricultural practices in coffee cultivation in Brazil or the USA to determine their similarity, it concluded that it was not possible to estimate a maximum residue level for coffee bean.

#### *Green tea*

Supervised trials were conducted on tea in five Prefectures in Japan in 1981 and 1996 with two foliar applications at the spray concentration rate of 0.02 (SC) or 0.025(WP) kg ai/hL. The registered use in Japan allows maximum of two applications at the maximum spray concentration of 0.020 (in case of SC) or 0.025 (in case of WP) kg ai/hL. No maximum rate per ha is specified.

Residues of buprofezin in crude (unblended) green tea from trials in accordance with GAP in Japan were in rank order: 6.9, 7.1, 8.2, 9.8, 11 and 12 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg and STMR of 9.0 mg/kg for tea, green.

As the processing of green tea is significantly different from that of black tea, the Meeting concluded that the estimated maximum residue level should be applicable only to green tea.

**DIETARY RISK ASSESSMENT*****Long-term intake***

The International Estimated Daily Intakes (IEDIs) of buprofezin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMTPs estimated by the 2004, 2006, 2010 and current Meetings (Annex 3). The ADI is 0–0.009 mg/kg bw and the calculated IEDIs were 2–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of buprofezin resulting from the uses considered by the 2008, 2009 and current JMPR is unlikely to present a public health concern.

***Short-term intake***

The International Estimated Short-Term Intakes (IESTI) of buprofezin were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (see Annex 4). The ARfD is 0.5 mg/kg and the calculated IESTIs were 0–7 % of the ARfD. The Meeting concluded that the short-term intake of residues of buprofezin, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.