5.22 IMIDACLOPRID (206)

RESIDUE AND ANALYTICAL ASPECTS

Imidacloprid was first evaluated by the JMPR in 2001 for toxicology. The Meeting derived an ADI of 0–0.06 mg/kg bw and an ARfD of 0.4 mg/kg bw. The compound was evaluated for residues in 2002, 2006 and 2008. In 2002, the Meeting agreed that the residue definition for compliance with the MRL and for estimation of dietary intake for plant and animal commodities should be the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid.

Imidacloprid was scheduled by the Forty-third Session of the CCPR for residue evaluation of additional crops. The 2012 JMPR received information on GAP and residue data for artichoke, avocado, banana, beans (dry), celery, guava, litchi and papaya.

Methods of analysis

The Meeting received information on analytical methods used for the determination of imidacloprid residues in samples derived from supervised trials on avocado, artichoke, banana, bean (dry), celery, guava, litchi and papaya. Samples were fortified with an equimolar combination of imidacloprid and its metabolites desnitro-imidacloprid, olefin-imidacloprid, hydroxyl-imidacloprid and 6-chloro-nicotinic acid following conversion to 6-chloronicotinic acid-trimethylsilylester with 6-N-methyl-trimethylsilyl-trifluoroacetamide (MSTFA) and analysed by GC-MS. The LOQ was 0.05 mg/kg (expressed in parent equivalents) for the crops mentioned above, except for dry beans.

The Meeting noted that the mean recoveries for dry beans were at the fortification levels of 0.1 mg/kg 59.9% (RSD 27.8%, n=9), of 0.2 mg/kg 57% (n=2), of 0.5 mg/kg 72% (RSD 22.4%, n=6), of 1 mg/kg 107% (RSD 11%, n=5) and of 5 mg/kg 95.6% (RSD 2.3%, n=3).

The freezer storage stability studies carried out with artichoke and beans, dry showed that the residues were stable for the longest period for which the samples were stored at or below -18 °C. The studies reported by the 2002, 2006 and 2008 JMPR cover the other sample materials evaluated by the present Meeting.

Results of supervised residue trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Avocado

The registered GAP on avocado in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 6 days, and/or a maximum of five foliar applications at a maximal rate of 0.56 kg ai/ha with an interval of 10 days and a PHI of 7 days. Five field trials[1] were conducted with soil application at 98–104 % GAP rate, but a PHI of 50–69 days indicated that no trials matched the registered GAP in the USA.

The Meeting decided that the data were inadequate for the purpose of estimating a maximum residue level for avocado.

[1] These residue trials data on avocado were submitted already to the JMPR in 2008.

Banana

The 2002 JMPR evaluated trials from Africa and Central America with application of 0.25 g ai/plant to the base of the pseudo-trunk or with a single basal drench application of 0.21–0.29 g ai/plant and estimated a maximum residue level of 0.05 mg/kg.

The GAP in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a 0 day PHI and/or a maximum of five foliar applications at a maximum rate of 0.56 kg ai/ha with an interval of 14 days and a 0 day PHI. Five field trials[1] were conducted with foliar application and matched the registered GAP in the USA, four of them with unbagged and one with bagged bananas. Residues in the whole fruit were 0.40, 0.48, 0.52 and 0.60 mg/kg for unbagged bananas and 0.12 mg/kg for bagged bananas.

The Meeting decided that four trials on unbagged and one on bagged bananas were not sufficient to estimate a maximum residue level for such a major crop and that the previous recommendation of 0.05 mg/kg should be maintained.

Litchi

Three trials were conducted on litchi in the USA in 2004 with foliar treatment according to GAP (GAP 5 × 0.11 kg ai/ha, PHI 7 days) resulting in residues of 0.16, 0.21 and 0.26 mg/kg. The data were submitted as separate trials but several of the parameters were identical, i.e., location, variety, treatment time and personnel

The Meeting considered the three trials as not independent and concluded that there were insufficient data to estimate a maximum residue level for imidacloprid in litchi.

Papaya

The GAP in the USA is maximal five foliar applications of 0.11 kg ai/ha at a maximal rate of 0.56 kg ai/ha and a PHI of 7 days. Four trials were conducted on papaya in the USA in 2005 with foliar treatment by 5 × 0.11–0.12 kg ai/ha. Residues were 0.13, 0.35, 0.36 and 0.44 mg/kg in samples taken one day after application.

As no trials according to GAP were submitted, the Meeting could not estimate a maximum residue level for imidacloprid in papaya.

Guava

The GAP in the USA is maximum five foliar applications of 0.11 kg ai/ha at a maximum rate of 0.56 kg ai/ha and a PHI of 7 days. Four trials were conducted on guava in the USA in 2000 with foliar treatment by 5 × 0.11 kg ai/ha, samples were taken at a PHI of 14–15 days only. The data were submitted as separate trials but several of the parameters were the same (place, treatment date, personnel). Residues were 0.12, 0.26, 0.28 and 0.38 mg/kg in samples taken 14–15 days after application.

As no trials according to GAP were submitted, the Meeting could not estimate a maximum residue level for imidacloprid in guava.

Artichoke

Three US trials treated in 1997 with foliar application at 2 × 0.28 kg ai/ha and a PHI of 7 days did not match the GAP (0.056–0.14 kg ai/ha, maximum 0.56 kg ai/ha per season, PHI 7 days). Furthermore, the data were submitted as separate trials but several of the parameters were identical, i.e., location, variety, treatment time and personnel.

[1] These residue trials data on banana were submitted already to the JMPR in 2008.

The Meeting concluded that there were insufficient data to estimate a maximum residue level for imidacloprid in artichoke.

Celery

The US labels for imidacloprid in celery allow soil application with 0.18–0.42 kg ai/ha and a 45 day PHI. Twelve trials[1] with different treatment scenarios were conducted in the USA: In six field trials, plant drench application with 0.54–0.59 kg ai/ha was used, 43–46 days prior to harvest. The remaining six other trials were bridging studies to compare the residues arising from various types of soil applications.

In the trials treated with 0.54–0.59 kg ai/ha, the application rate exceeded the maximum GAP rate of 0.42 kg ai/ha for more than 30 % and the residues were 0.13, 0.13, 0.42, 0.57, 1.0 and 4.3 mg/kg. Applying the principle of proportionality (scaling factors of 0.71–0.778), imidacloprid residues in celery were: 0.096, 0.1, 0.3, 0.43, 0.75 and 3.2 mg/kg (n=6).

Tthe Meeting estimated a maximum residue level of 6 mg/kg, an STMR of 0.365 mg/kg and an HR of 3.2 mg/kg for imidacloprid in celery.

Beans, dry

The registered GAP in the USA on dried shelled bean (except soya bean) and dried shelled peas is soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 21 days, and/or maximum of three foliar applications of 0.048 kg ai/ha at a maximal rate of 0.147 kg ai/ha with an interval of 7 days and a PHI of 7 days.

Eleven field trials were conducted with the following use pattern: a combination of one seed treatment with 0.25 kg ai/100 kg seed before sowing, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. The residues were < 0.5 (6), 0.59, 0.69, 0.71, 0.79 and 0.99 mg/kg in dry beans. Using the OECD MRL calculator, a maximum residue level of 1.5 mg/kg is calculated. The Meeting was aware of the high uncertainty of this value because 55% of the data population were censored data.

The Meeting noted that the GAP in the USA is the same for dried shelled pea and bean, except soya bean. For peas, dry the 2008 JMPR estimated a maximum residue level of 2 mg/kg and an STMR of 0.62 mg/kg.

The Meeting agreed to extrapolate from beans, dry and peas, dry to pulses and estimated a maximum residue level of 2 mg/kg and an STMR of 0.62 mg/kg for pulses, except soya beans. The previous recommendation for peas, dry of 2 mg/kg should be withdrawn.

Residues in animal commodities

The 2012 JMPR evaluated residues of imidacloprid in beans, dry, which is listed in the OECD feeding table. The Meeting noted that the estimation did not result in a significant change of the dietary burdens of farm animals. The previous MRL recommendations for animal commodities were maintained.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) of imidacloprid were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2002, 2006, 2008 and 2012. The results are shown in Annex 3.

[1] These residue trials data on celery were already submitted to the 2002 JMPR.

The ADI is 0–0.06 mg/kg bw and the calculated IEDI were 2–5 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of imidacloprid from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intakes (IESTIs) of imidacloprid was calculated for the food commodities for which maximum residue levels, STMRs and HRs were estimated by the current Meeting and for which consumption data was available. The results are shown in Annex 4.

The IESTIs represented 0–30 % of the ARfD (0.4 mg/kg bw). The Meeting concluded that the short-term intake of residues of imidacloprid from uses considered by the current Meeting was unlikely to present a public health concern.