

5.14 IMIDACLOPRID (206)

RESIDUE AND ANALYTICAL ASPECTS

Imidacloprid was evaluated by the JMPR in 2001 for toxicology and in 2002 and 2006 for residues. An ADI of 0–0.06 mg/kg bw/day and an ARfD of 0.4 mg/kg bw/day were established, and numerous maximum residue levels were estimated. The residues were defined by the 2002 JMPR as the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety for both regulatory and dietary intake assessment purposes.

Imidacloprid was scheduled by the 39th session of the CCPR for residue evaluation of additional crops. The Interregional Research Project No. 4 (IR-4) in the USA provided residue data for avocado, banana, blueberry, caneberry, carrot, coffee, pea, peanut, pomegranate, radish, strawberry, sugar apple, sunflower and tree nuts. Japan supplied information on use patterns of imidacloprid on agricultural and horticultural crops and the manufacturer provided labels of products registered in the USA.

Results of supervised residue trials on crops

Berries and other small fruits (except cranberries, grapes and strawberries)

The registered GAP in the USA for blueberries is soil application at a maximal rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of five foliar applications at a maximum rate of 0.112 kg ai/ha with an interval of 7 days and a PHI of 3 days.

Eleven field trials were conducted, two on low bush blueberry and nine on high bush blueberry. Each of the field trial sites consisted of one untreated control plot and one treated plot, but the three Michigan trials on high bush blueberry used two treated plots each, one for a soil-directed application and the other for foliar applications. Eight of the nine trials on high bush blueberry matched the registered use in the USA. After soil application, the residues were <0.05 (4), 0.09 mg/kg. After foliar spray, the residues were: 0.38, 0.49, 0.52, 0.89, 1.1, 2.2 and 2.8 mg/kg.

The registered GAP on caneberries (raspberries, blackberries, boysenberries, marionberries) in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of three foliar applications at a maximum rate of 0.112 kg ai/ha with an interval of 7 days and a PHI of 3 days. Four field trials were conducted on raspberries which matched the registered use in the USA; the residues were 0.48, 0.49, 0.59, 0.96 mg/kg.

Three field trials with foliar treatment were conducted on blackberries and matched the registered use in the USA; the residues were 0.38, 0.69, 0.70 mg/kg.

One field trial each with foliar treatment was conducted on boysenberries and marionberries and matched the registered use in the USA; the residues were 1.5 and 1.7 mg/kg, respectively.

Based on the blueberry foliar spray residue data, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 0.89 mg/kg and an HR of 2.8 mg/kg for the group of berries and other small fruits except cranberries, grapes and strawberries.

Strawberry

The registered GAP on strawberry in the USA is soil application at a maximal rate of 0.56 kg ai/ha with a PHI of 14 days, and/or a maximum of three foliar applications at a maximal rate of 0.053 kg ai/ha with an interval of 5 days and a PHI of 7 days. Nine field trials were conducted; a combination of one soil application matching the registered soil application GAP and three foliar

applications matching the registered foliar application GAP was used. Residues were 0.12, 0.14, 0.15 (2), 0.17 (2), 0.21, 0.32, 0.35 mg/kg.

The Meeting estimated an STMR of 0.17 mg/kg and an HR of 0.35 mg/kg, and recommended a maximum residue level of 0.5 mg/kg in strawberry for imidacloprid.

Avocado

The registered GAP on avocado in the USA is soil application at a maximal 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 0.112 kg ai/ha with an interval of 10 days and a PHI of 7 days. Five field trials were conducted with soil application at 98–104% GAP rate, but with a PHI of 50–69 days, no trials matched the registered GAP in the USA.

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

Banana

The 2002 JMPR evaluated trials from Africa and Central America with an application rate 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.

New GAP and residue data for banana were submitted in 2008. The GAP in the USA is for a 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 0.112 kg ai/ha with a treatment interval of 14 days and a 0 day PHI. Five field trials 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 0.44 (2), 0.50, 0.53 mg/kg for unbagged bananas and 0.13 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 and that the previous recommendation of 0.05 mg/kg should be maintained.

Pomegranate

The registered GAP on pomegranate in the USA is for a soil application at a maximum rate of 0.56 kg ai/ha with a 0 day PHI, and/or a maximum of three foliar applications at a maximum rate of 0.112 kg ai/ha with an interval of 7 days and a PHI of 7 days. Three field trials were conducted, a combination of one soil application at 57–63% of the GAP rate and three foliar applications matching the registered foliar application GAP. Residues in whole fruit were 0.42, 0.43, 0.55 mg/kg. The Meeting considered three trials adequate for estimation of a maximum residue level for this minor crop.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in pomegranate of 1, 0.43 and 0.55 mg/kg, respectively.

Sugar apple

The registered GAP on sugar apple in the USA is a maximum of five foliar applications at a maximum rate of 0.112 kg ai/ha with a treatment interval of 10 days and a PHI of 7 days. Three field trials were conducted with a PHI of 14/15 days and did not match the registered GAP in the USA

The Meeting decided that the trials submitted were inadequate for the purpose of estimating a maximum residue level for pomegranate.

Radish leaves (including tops)

The registered GAP on radish in the USA is one soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 21 days, and/or one foliar application at a maximal rate of 0.049 kg ai/ha with a PHI of 7 days. Five field trials were conducted, a combination of one soil application matching the registered soil application GAP and one foliar application matching the registered foliar application GAP. Residues in radish leaves (including tops) were 0.53, 0.67, 0.70, 1.8 and 2.7 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in radish leaves of 5, 0.7 and 2.7 mg/kg, respectively.

Peas (pods and succulent, immature seeds)

The registered GAP on pea in the USA is seed treatment at a maximal rate of 1.116 g ai/kg seeds, and/or soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg ai/ha with an interval of 7 days and a PHI of 7 days. Four field trials were conducted, a combination of one seed treatment with 200% GAP rate, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. Residues were 0.20, 0.27, 0.92, 3.8 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in peas (pods and succulent, immature seeds) of 5, 0.60 and 3.8 mg/kg, respectively.

Peas, shelled (succulent seeds)

The registered GAP on pea in the USA is seed treatment at a maximal rate of 1.116 g ai/kg seeds, and/or soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg ai/ha with an interval of 7 days and a PHI of 7 days. Six field trials were conducted, a combination of one seed treatment with 200% GAP rate, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. Residues were 0.31, 0.42, 0.54, 0.62, 0.88 and 1.1 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in peas (succulent, shelled) of 2, 0.58 and 1.1 mg/kg, respectively.

Peas (dry)

The registered GAP on pea in the USA is seed treatment at a maximal rate of 1.116 g ai/kg seeds, and/or soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximum rate of 0.049 kg ai/ha with an interval of 7 days and a PHI of 7 days. Six field trials were conducted, a combination of one seed treatment at 2× GAP rate, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. Residues were 0.14, 0.2, 0.32, 0.91, 0.94, and 1.0 mg/kg in dry shelled peas.

The Meeting estimated a maximum residue level for imidacloprid in peas (dry) of 2 mg/kg and an STMR of 0.62 mg/kg, respectively.

Root and tuber vegetables

The 2002 JMPR evaluated residue supervised trials data for imidacloprid on potatoes and sugar beet. New residue data were submitted to the current Meeting for carrots and radish.

Carrot

The registered GAP on carrot in the USA is for soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg

ai/ha with an interval of 5 days and a PHI of 7 days. Six field trials were conducted involving a combination of one soil application, matching the registered soil application GAP (with trial 96-TX*27 an exception at 168% GAP rate), and one foliar application matching the registered foliar application GAP (with trial 96-OH*20 an exception at 135% GAP rate). The data from these trials were used for the evaluation and the residues were < 0.05 (5), 0.09 mg/kg.

Radish

The registered GAP on radish in the USA is one soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or one foliar application at a maximal rate of 0.049 kg ai/ha with a PHI of 7 days. Five field trials were conducted, a combination of one soil application matching the registered soil application GAP and one foliar application matching the registered foliar application GAP. Residues were < 0.05 (4), 0.13 mg/kg in roots.

Potato

The 2002 JMPR estimated a maximum residue level, an STMR and an HR for imidacloprid in potatoes of 0.5, 0.05 and 0.28 mg/kg, respectively.

Sugar beet

The 2002 JMPR estimated a maximum residue level and an STMR for imidacloprid in sugar beet of 0.05* mg/kg and 0.05 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR for imidacloprid in root and tuber vegetables of 0.5, 0.05 and 0.28 mg/kg, respectively, based on the potato residue data, i.e., commodity with the highest residues in the crop group. The Meeting agreed to withdraw its previous recommendations for potatoes of 0.5 mg/kg and for sugar beet of 0.05* mg/kg.

Tree nuts

The registered GAP on tree nuts in the USA is for a soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of four foliar applications at a maximal application (per season) of 0.403 kg ai/ha with an interval of 6 days and a PHI of 7 days. Ten field trials each were conducted on almonds and pecans. These trials matched the registered GAP in the USA. Residues were < 0.01 (19) and 0.01 mg/kg in the almond and pecan nutmeat (kernels).

The 2002 JMPR recommended a maximum residue level of 0.05 mg/kg for pecan based on supervised residue trials from the USA carried out in 1993 and 1998. The residue data of the trials carried out in 1998 were submitted to the 2008 JMPR. The Meeting noted that the LOQ for the determination of imidacloprid in pecan nutmeat from the 1993 trials was 0.05 mg/kg whereas it was 0.01 mg/kg for the 1998 trials and decided to estimate the maximum residue level on the basis of the 1998 residue data only.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in tree nuts of 0.01*, 0.01 and 0.01 mg/kg, respectively. The Meeting agreed the previous recommendation of a maximum residue level of 0.05 mg/kg for pecan should be withdrawn.

Sunflower seed

The registered GAP on sunflower in the USA is as a seed treatment at a maximum rate of 0.5 mg ai/seed equivalent or 9.7 g ai/kg seeds. Five field trials were conducted according to GAP with a treatment of 9.38 g ai/kg seeds. In two further trials the application rate was 46.9 g ai/kg seeds. The residues found in the seeds, following a harvest interval of 119–143 days, were: < 0.05 (7) mg/kg.

The Meeting estimated a maximum residue level and an STMR value for imidacloprid in sunflower seed of 0.05* mg/kg and 0.05 mg/kg.

Peanuts

The registered GAP on peanut in the USA is for a soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 14 days, and/or a maximum of three foliar applications at a maximum rate of 0.049 kg ai/ha with an application interval of 5 days and a PHI of 14 days. Twelve field trials were conducted consisting of a combination of one soil application, matching the registered soil application GAP, and three foliar applications, matching the registered foliar application GAP. Residues in the peanut kernels were < 0.05 (4), 0.10, 0.11, 0.12, 0.15, 0.17, 0.23, 0.26, 0.40 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in peanuts of 1, 0.12 and 0.4 mg/kg, respectively.

Coffee

The registered GAP on coffee in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of five foliar applications at a maximum rate of 0.112 kg ai/ha with an application interval of 7 days and a PHI of 7 days. Five trials were conducted complying with the GAP of the USA. Residues were: 0.19, 0.30, 0.35, 0.37 and 0.48 mg/kg in green coffee beans.

The Meeting recommended a maximum residue level of 1 mg/kg for imidacloprid in green coffee beans. The Meeting also estimated an STMR of 0.35 mg/kg.

Primary animal feed commodities

Almond hulls

The registered GAP on tree nuts (almond) in the USA is soil application at a maximal rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of four foliar applications at a maximal application (per season) of 0.403 kg ai/ha with an interval of 6 days and a PHI of 7 days. Ten field trials were conducted on almonds. These trials matched the registered GAP in the USA. The residues were in rank order 0.23, 1.0, 1.1, 1.4 (2), 1.5, 1.9, 2.4, 2.5 and 2.6 mg/kg in almond hulls (fresh weight basis).

Allowing for the standard 90% dry matter, the Meeting estimated a maximum residue level and an STMR value for imidacloprid in almond hulls of 5 mg/kg and 1.7 mg/kg, respectively.

Peanut fodder

The registered GAP on peanut in the USA is soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 14 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg ai/ha with an interval of 5 days and a PHI of 14 days. Twelve field trials were conducted, consisting of a combination of one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. The residues were in rank order 0.95, 1.1, 4.0, 4.1, 7.0, 7.9, 9.5, 12 (2), 21, 23 and 24 mg/kg in peanut fodder (fresh weight basis).

Allowing for the standard 85% dry matter, the Meeting estimated a maximum residue level, an STMR value and highest residue for imidacloprid in peanut fodder of 30 mg/kg, 10.2 mg/kg and 28 mg/kg, respectively.

Residues in animal commodities*Estimated maximum and mean dietary burdens of farm animals*

Dietary burden calculations based on the feed items evaluated by the JMPR in 2002 and 2008 for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

Livestock dietary burden, imidacloprid, ppm of dry matter diet						
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	8.29	2.64	2.29	0.78	18.01	6.07
Dairy cattle	7.16	2.30	2.38	0.93	18.01 ^a	6.14 ^b
Poultry - broiler	0.18	0.28	0.46	0.26	0.12	0.12
Poultry - layer	0.19	0.28	1.02 ^c	0.37 ^d	0.09	0.12

^a Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat and milk

^b Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat and milk

^c Highest maximum poultry broiler or layer burden suitable for MRL estimates for poultry meat and eggs

^d Highest mean poultry broiler or layer burden suitable for STMR estimates for poultry meat and eggs

Animal commodity maximum residue levels

Because of the changes in the animal dietary burden, the residue concentrations in animal products were re-calculated by the 2008 JMPR.

Cattle

A feeding study on dairy cows dosed with imidacloprid in capsules at the equivalent of 5, 15 or 50 ppm in the diet for 28 days was submitted to the 2002 JMPR. The 2002 Meeting estimated mean transfer factors (concentration of residue ÷ concentration in feed) for cattle tissues and milk as follows: liver 0.01, kidney 0.006, muscle 0.002, fat 0.0012 and milk 0.0029. The Meeting agreed to apply the transfer factors to maximum and mean dietary burdens calculated by the 2008 JMPR (transfer factor × dietary burden in mg/kg feed).

The maximum concentrations of residues expected in tissues and milk based on a dietary burden of 18.01 ppm are: 0.18 mg/kg in liver, 0.11 mg/kg in kidney, 0.04 mg/kg in muscle, 0.02 mg/kg in fat and 0.05 mg/kg in milk.

The mean concentrations of residues expected in tissues and milk based on a dietary burden of 6.14 ppm are: 0.06 mg/kg in liver, 0.04 mg/kg in kidney, 0.012 mg/kg in muscle, 0.007 mg/kg in fat and 0.018 mg/kg in milk.

The Meeting estimated maximum residue levels of 0.1 mg/kg for meat (mammalian), 0.3 mg/kg in edible offal (mammalian) and 0.1 mg/kg in milks. The previous recommendation for 0.02* mg/kg for meat (mammalian) and milks, as well as 0.05 mg/kg for edible offal, should be withdrawn.

The Meeting recommended that the HR values should be 0.04 mg/kg in meat (mammalian), 0.18 mg/kg in edible offal (mammalian), and 0.02 mg/kg in fat (mammalian). The estimated STMR

values are 0.012 mg/kg for meat (mammalian), 0.06 mg/kg for edible offal (mammalian), 0.007 mg/kg for fat (mammalian) and 0.018 mg/kg for milks.

Poultry

A feeding study on laying hens dosed with imidacloprid at the equivalent of 2, 6 or 20 ppm in the diet for 30 days was submitted to the 2002 JMPR. The 2002 Meeting estimated mean transfer factors (concentration of residue ÷ concentration in feed) for poultry tissues and eggs as follows: liver 0.02, muscle 0.0027, fat 0.001 and eggs 0.007. The Meeting agreed to apply the transfer factors to maximum and mean dietary burdens calculated by the 2008 JMPR (transfer factor • dietary burden in mg/kg feed).

The maximum concentrations of residues expected in poultry tissues and eggs based on a maximum dietary burden of 1.02 ppm are: 0.02 mg/kg in liver, 0.003 mg/kg in muscle, 0.001 mg/kg in fat and 0.007 mg/kg in eggs.

The mean concentrations of residues expected in poultry tissues and eggs based on a mean dietary burden of 0.37 ppm are: 0.007 mg/kg in liver, 0.001 mg/kg in muscle, 0.0004 mg/kg in fat and 0.003 mg/kg in eggs.

The Meeting estimated maximum residue levels of 0.02 mg/kg for eggs and poultry meat and confirmed its previous recommendation. For poultry edible offal a maximum residue level of 0.05 mg/kg was estimated. The previous recommendation of 0.02* mg/kg for poultry edible offal should be withdrawn.

The Meeting recommended that the HR values should be 0.003 mg/kg in poultry meat, 0.02 mg/kg in poultry edible offal, 0.001 mg/kg in poultry fat and 0.007 mg/kg in eggs. The estimated STMR values are 0.001 mg/kg for poultry meat, 0.007 mg/kg for edible offal, 0.0004 mg/kg for poultry fat and 0.003 mg/kg for eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of imidacloprid were estimated for the 13 GEMS/Food cluster diets based on 65 commodities. The results are shown in Annex 3.

The IEDI for the 13 GEMS/Food cluster diets was 1–5% of the maximum ADI of 0.06 mg/kg bw. The Meeting concluded that the long-term intake of residues of imidacloprid from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) 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 Meeting noticed the very high consumption for black currants of 1054 g for children in the UK with a body weight of 14.5 kg in the large portion and recommended confirmation of this figure.

The IESTI represented for the general population 0–10% and for children 0–50% 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.