## 5.17 FENPYROXIMATE (193)

### RESIDUE AND ANALYTICAL ASPECTS

Fenpyroximate is a pyrazole non-systemic acaricide. It was first evaluated by JMPR in 1995 and then in 1999 and 2010 for maximum residue levels, and in 2004 and 2007 for toxicology. The currently standing recommendations of JMPR are as follows:

- ADI: 0–0.01 mg/kg bw (1995)
- ARfD: 0.02 mg/kg bw (2007)
- Residue definition: Fenpyroximate for compliance with the MRL and for estimation of dietary intake (both for animal and plant commodities). The residue is fat soluble. (1999)

The current Meeting received information on the latest use pattern and the supervised residue trials on stone fruits, strawberry, avocado, cucumber, common bean (pods and/or immature seeds and bean fodder), potato and mints conducted in the USA.

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

The Meeting received supervised trial data for fenpyroximate conducted in the USA on stone fruits, strawberry, avocado, cucumber, common bean (pods and/or immature seeds; and bean fodder), potato and mints with foliar applications of the fenpyroximate emulsion concentrate (EC) formulation.

For estimating HR or highest residue, the highest individual residue concentration from the trials conducted in accordance with GAP was used.

*Stone fruits*

The approved use of fenpyroximate on stone fruits in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 748 L/ha of water, the PHI is 7 days. In supervised residue trials, various adjuvants were used with the result that there were no significant difference or trend found between the different adjuvants.

A total of eight supervised trials on cherries were conducted in the USA in 2010. The residues of fenpyroximate in cherries from six independent trials in accordance with US GAP were in rank order: 0.27, 0.34, 0.46, 0.69, 0.81 and 0.87 mg/kg.

The Meeting estimated an STMR of 0.57 mg/kg for cherries.

A total of ten supervised trials on peach were conducted in the USA in 2010. The residues from seven trials in accordance with US GAP were in rank order: 0.08, 0.08, 0.12, 0.13, 0.13, 0.15 and 0.18 mg/kg.

The Meeting estimated an STMR of 0.13 mg/kg for peach.

A total of six supervised trials on plum were conducted in the USA in 2010. The residues from five trials in accordance with US GAP were in rank order:< 0.05, 0.09, 0.13, 0.20 and 0.27 mg/kg.

The Meeting estimated an STMR of 0.13 mg/kg for plum.

The GAP in the USA covers the group of stone fruits; and the STMRs for cherries, peach and plum were within five-fold difference. However, the Meeting decided to estimate two maximum residue levels, one for cherries and the other for stone fruits except cherries, in order to avoid probability of IESTI for children calculated for peach exceeding the ARfD.

The Meeting therefore estimated a maximum residue level, STMR and HR of 2, 0.57 and 0.90 mg/kg, respectively for cherries.

As the residue populations of peach and plum were similar according to the Mann-Whitney U test, the Meeting decided to combine the data to recommend a maximum residue level for stone fruits except cherries. The combined residues were in rank order (n=12): < 0.05, 0.08, 0.08, 0.09, 0.12, 0.13, 0.13, 0.13, 0.15, 0.18, 0.20 and 0.27 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.4, 0.13 and 0.29 mg/kg, respectively, for stone fruits, except cherries.

*Strawberry*

The approved use of fenpyroximate on strawberry in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 234 L/ha of water. PHI is 1 day.

A total of three supervised trials on strawberry were conducted in the USA in 2008. In a trial in Porterville, California, the water volume was less than the minimum specified in GAP. However, as the Meeting considered that difference in spray volume would have little impact on terminal residues, the Meeting used the residue data from this trial for the estimation of maximum residue level.

A total of five supervised trials on strawberry were also conducted in the USA in 2010.

The residues of fenpyroximate in strawberry from eight independent trials in accordance with US GAP were in rank order: 0.07, 0.08, 0.19, 0.19, 0.24, 0.24, 0.28 and 0.53 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.8, 0.215 and 0.59 mg/kg, respectively for strawberry.

*Avocado*

The approved use of fenpyroximate on avocado in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 889 L/ha of water (for ground spray). PHI is 1 day.

A total of five supervised trials on avocado were conducted in the USA in 2008 and 2009. The residues of fenpyroximate in avocado from four independent trials in accordance with US GAP were in rank order: < 0.05 (2), 0.06 and 0.10 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.2, 0.055 and 0.10 mg/kg respectively for avocado.

*Cucumber*

The current approved use of fenpyroximate on field grown cucumber in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 374 L/ha of water (for ground spray). PHI is 1 day.

A total of nine supervised trials on cucumber were conducted outdoor in the USA in 2009. The residues of fenpyroximate in cucumber from nine independent trials in accordance with US GAP were in rank order: < 0.05 (2), 0.06, 0.07, 0.07, 0.08, 0.08, 0.11 and 0.17 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.3, 0.07 and 0.19 mg/kg respectively for cucumber. The new recommendation replaces that of the 2010 JMPR (maximum residue level of 0.03 mg/kg).

*Common beans (pods and/or immature seeds)*

The approved use of fenpyroximate on common beans (US GAP for snap beans) in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 281 L/ha of water (for ground spray). PHI is 1 day.

A total of eight supervised trials on common beans were conducted in the USA in 2008. The residues of fenpyroximate in common beans (pods and/or immature seeds) from seven independent trials in accordance with US GAP were in rank order: < 0.05, 0.09, 0.09, 0.09, 0.15, 0.18 and 0.19 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.4, 0.09 and 0.19 mg/kg respectively for common beans (pods and/or immature seeds).

*Potato*

The approved use of fenpyroximate on potato in the USA consists of up to two foliar spray applications with an interval of 7 days at a maximum rate of 0.117 kg ai/ha and a minimum of 187 L/ha of water (for ground spray). PHI is 7 days.

A total of sixteen supervised trials on potato were conducted in the USA. The residues of fenpyroximate in potato from fourteen independent trials in accordance with US GAP were in rank order: < 0.05 (14) mg/kg. The residues of fenpyroximate from one trial in which the application rate was 5 times the GAP rate were also < 0.05 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.05 *, 0 and 0 mg/kg respectively for potato.

*Mints*

The approved use of fenpyroximate on mint in the USA consists of up to two foliar spray applications with an interval of 7 days at a maximum rate of 0.117 kg ai/ha and a minimum of 234 L/ha of water (for ground spray). PHI is 1 day.

A total of six supervised trials on mint were conducted in the USA. As the method used analyses fenpyroximate and M-1 as M-1, no information was available on the concentrations of fenpyroximate alone. In general, the concentrations of M-1 in food commodities were much lower than those of fenpyroximate but the data from supervised residue trials provided to JMPR so far indicate that M-1 can be present up to 30% of fenpyroximate. The Meeting considered that the information was insufficient to estimate a maximum residue level for mints.

***Legume animal feeds***

*Bean forage*

Common bean plants with pods were sampled by cutting the whole plant at soil level.

The residues of fenpyroximate in foliage of common bean plant from seven independent trials in accordance with US GAP were in rank order: < 0.05, 0.90, 1.87, 1.92, 2.45, 3.42 and 5.80 mg/kg on a fresh weight basis.

The Meeting estimated a median residue and highest residue at 1.92 and 6.50 mg/kg respectively for bean forage (on a fresh weight basis) for the purpose calculating livestock dietary burdens.

***Fate of residues during processing***

The Meeting received information on the processing of plum into dried plums; potato into potato flakes, chips and wet peels; and mint into mint oils.

As concentration of fenpyroximate was observed in the processing of plums, there was a need to estimate a maximum residue level for dried plum. Using the processing factor of 1.73 shown below, a maximum residue level for dried plum was estimated to be 0.7 mg/kg.

| Commodity | Fenpyroximate mg/kg | Processing factor for Fenpyroximate | STMR-(P) | HR-(P) |
|---|---|---|---|---|
| Fresh plum | 1.84 | - | 0.11 | 0.29 |
| Dried plum | 3.18 | **1.73** | **0.18** | **0.50** |

As for processing of potato, no processing factors could be calculated as the residues of fenpyroximate were all below the LOQ of 0.05 mg/kg in fresh potato and processed potato products (flakes, chips and wet peels).

As for processing of mint, since no information was available for the concentration of fenpyroximate alone was available, processing factor of fenpyroximate could not be calculated. The best estimate of processing factor for the sum of fenpyroximate and M-1 in the processing of mint to mint oil was 0.20.

### *Residues in animal commodities*

*Estimation of dietary burdens*

Among commodities reviewed by the 1999, 2010 and the current JMPR, apple wet pomace (STMR-P, 0.05 mg/kg), dry citrus pulp (STMR-P, 0.64 mg/kg), wet grape pomace (STMR-P, 0.06 mg/kg), wet tomato pomace (STMR-P, 0.03 mg/kg), bean forage (median residue, 1.89 mg/kg; and highest residue, 3.415 mg/kg on a fresh weight basis) and potato wet peel (STMR-P, 0.05 mg/kg) can be fed to beef and dairy cattle. There have been no feed items for poultry.

The maximum and mean dietary burdens were calculated using the highest residue and STMR/median residue of fenpyroximate in the above-mentioned commodities on a basis of the OECD Animal Feeding Table. The summary of calculated dietary burdens of fenpyroximate is shown in the following table.

Summary of livestock dietary burdens (ppm of dry matter diet)

| | US-Canada | | EU | | Australia | | Japan | |
|---|---|---|---|---|---|---|---|---|
| | max | mean | max | Mean | max | mean | Max | mean |
| Beef cattle | 0.15 | 0.15 | 0.18 | 0.18 | 11.35 | 3.50 | - | - |
| Dairy cattle | 0.07 | 0.07 | 3.90 [a] | 1.28 [b] | 13.21 | 4.05 | - | - |

[a] Suitable for estimating maximum residue levels for meat, fat, edible offal and milk of cattle (see below).

[b] Suitable for estimating STMRs for meat, fat, edible offal and milk of cattle (see below).

*Residues in milk and mammalian tissues*

The 1999 JMPR reviewed a cattle feeding study conducted at levels equivalent to 1, 3 and 10 ppm in the feed. In the study, fenpyroximate in milk or tissues was measured together with M-1. No information was available on the concentration of fenpyroximate alone. Nonetheless, the 1999 JMPR and 2010 JMPR used the results of this study as the dietary burdens were lower than 1 ppm and the residue concentrations in the tissues and milk were also very low.

In the animal metabolism study, residues of M-1 in tissues and milk were< 0.001 mg/kg and less than fenpyroximate except in the case of liver in which M-1 was present at much higher concentrations. In the animal feeding study, the sum of fenpyroximate and M-1 in kidney was higher

than that in liver, and as such, the residue in kidney would be the basis for a maximum residue level for edible offal. In kidney, the concentration of fenpyroximate was significantly higher than that of M-1. Therefore, the Meeting decided to use the results of animal feeding study recognizing that it would lead to some overestimate of maximum residue level.

The maximum and mean dietary burdens in cattle were 13.21 and 4.05 ppm of dry matter diet respectively. The Meeting noted that the highest maximum dietary burden in cattle, based on animal feed ration in Australia, was higher than the highest feeding level of 10 ppm in feed in the cattle feeding study by about 30%.

As fenpyroximate has not been authorized for use for common beans in Australia, and bean forage is not generally traded internationally, the Meeting decided to use the second highest maximum dietary burden based on the animal feed ration in Europe, where use of fenpyroximate for common bean has been authorized, together with residue levels in tissues and milk at 1, 3 and 10 ppm dose groups. The maximum dietary burden calculated for cattle using the feed ration in Australia without bean forage was 0.21 ppm in dry matter diet.

| | Feed level (ppm) for milk residues | Fenpyroximate+M-1 (mg/kg) in milk | Feed level (ppm) for Tissue residues | Fenpyroximate+M-1 (mg/kg) in | | | |
|---|---|---|---|---|---|---|---|
| | | | | Muscle | Liver | Kidney | Fat |
| Maximum residue level beef or dairy cattle | | | | | | | |
| Feeding study[a] | 3 | 0.0062 | 3 | 0.017 | < 0.003 | < 0.01 | 0.073 |
| | 10 | 0.013 | 10 | 0.049 | 0.011 | 0.019 | 0.159 |
| Dietary burden and highest residue | 3.90 | 0.007 | 3.90 | 0.021 | 0.004 | 0.011 | 0.084 |
| STMR beef or dairy cattle | | | | | | | |
| Feeding study[b] | 1 | - | 1 | < 0.01 | < 0.003 | < 0.003 | 0.015 |
| | 3 | 0.0062 | 3 | 0.015 | < 0.003 | < 0.003 | 0.056 |
| Dietary burden and mean residue | 1.28 | < 0.005 | 1.28 | 0.011 | < 0.003 | < 0.003 | 0.021 |

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

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

The Meeting estimated STMR of 0.005, 0.011, 0.003, 0.003 and 0.021 mg/kg for milk, muscle, liver, kidney and fat, respectively; and HR of 0.021, 0.004, 0.011 and 0.084 mg/kg for muscle, liver, kidney and fat, respectively.

The Meeting estimated maximum residue levels of 0.01* mg/kg for milks, 0.02 mg/kg for edible offal (mammalian) and 0.2 mg/kg (fat) for meat (from mammals other than marine mammals) and withdrew the existing CXLs for cattle milk, kidney, liver and meat.

## RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for both plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *fenpyroximate*.

The residue is fat soluble.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The International Estimated Dietary Intakes (IEDIs) of fenpyroximate were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 1999, 2010 and current Meetings (Annex 3). The ADI is 0–0.01 mg/kg bw and the calculated IEDIs were 1–7% of the maximum ADI. The Meeting concluded that the long-term intake of residues of fenpyroximate resulting from the uses considered by the JMPR is unlikely to present a public health concern.

### *Short-term intake*

The International Estimated Short-Term Intakes (IESTI) of fenpyroximate were calculated for commodities and their processed commodities using STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.02 mg/kg and the calculated IESTIs were 0–80% of the ARfD. The Meeting concluded that the short-term intake of residues of fenpyroximate, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.