5.14 FENPYROXIMATE (193)

RESIDUE AND ANALYTICAL ASPECTS

Fenpyroximate was evaluated by JMPR in 1995 for the first time and then again in 1999. The 1995 JMPR allocated an ADI of 0–0.01 mg/kg bw. The 2007 JMPR established an ARfD of 0.02 mg/kg.

The 1999 JMPR concluded that the residue definition for compliance with the MRL and for estimation of dietary intake, both for animal and plant commodities should be fenpyroximate and recommended the maximum residue levels for apples, grapes, hops, oranges, cattle kidney, cattle liver, cattle meat and cattle milk.

Following the establishment of an ARfD of 0.02 mg/kg, the Fortieth CCPR decided to advance the MRL for apples to Step 8. Because of acute intake concern, the MRL for grapes was retained at Step 7.

The Meeting received information on the residue analysis, storage stability, use patterns, supervised field trials and fates of residues during processing of citrus, grapes and tomatoes. The supervised field trial information included data on citrus, apples, pears, grapes, cantaloupes, cucumbers, tomatoes, peppers (bell and non-bell) and tree nuts.

Methods of analysis

The analytical methods for fenpyroximate and its Z-isomer were evaluated both in 1995 and in 1999. GC, HPLC and HLPC-MS were suitable for the residues determination in plant materials. HLPC-MS/MS is suitable for animal products.

The Meeting received information on multi-residue analytical methods based on DFG S19 for the determination of fenpyroximate and it's Z-isomer in a range of commodities, processed fractions and some livestock feeds. The limits of quantification being 0.005 mg/kg (apples, citrus, cotton, hops, grapes, peppers, tomatoes, okra, melons and cucumbers); 0.01 mg/kg (apples, grapes, oranges, cotton seed, strawberries, peaches, pears, plums, beans, cucumbers, peppers and tomatoes); 0.02 mg/kg (oranges, orange juice, dry orange pulp and orange oil); 0.05 mg/kg (melons, tomatoes, tomato paste, tomato puree, peppers, pears, almonds and almond hulls) for fenpyroximate and its Z-isomer. Recoveries were within acceptable limits of 70 to 120%, with the exception of some reported recoveries for fenpyroximate in dry orange pulp and orange oil.

Stability of residues in stored analytical samples

The meeting received information on the frozen storage stability of residues of fenpyroximate and its Z-isomer in citrus, cantaloupes, pears, grapes, tomatoes and peppers in the corresponding supervised residues trials. The storage stability data covered the period of storage of field samples for residue analysis.

Incurred residues of fenpyroximate and its Z-isomer were stable under frozen storage conditions in orange RAC for up to 132 days, in orange juice for up to 210 days, in orange dry pulp for up to 196 days and up to 191 days in orange oil. In melons (cantaloupe), fenpyroximate was shown to be stable for up to 12 months and in apples and pears up to 100 days.

Fenpyroximate and its Z-isomer residues were shown to be stable under frozen storage conditions in grapes up to 268 days, in raisins up to 195 days, in raisin waste up to 195 days, in wet and dry pomace up to 177 days, and in grape juice for up to 165 days.

Fenpyroximate residues fortified in peppers were stable under frozen storage (< –20 °C) up to 403 days.

Incurred fenpyroximate and Z-isomer residues were stable under frozen storage conditions (–29 to –10 °C) in tomato whole fruit for up to 626 days, in tomato paste for up to 547 days and in tomato puree for up to 546 days.

Results of supervised field trials on crops

The Meeting received supervised residue trial data following foliar application of fenpyroximate on citrus fruits, cucumbers, melons (cantaloupes), tomatoes, peppers, apples, pears, grapes, and tree nuts.

Residues of fenpyroximate and its Z-isomer were reported in most studies. However as the Z-isomer is not included in the residue definition, it is not included in the estimation of maximum residue levels and not discussed further in this appraisal. Supervised field trials conducted with different formulations at identical varieties, locations and dates were not considered as independent. The highest result according to the corresponding GAP was selected in these cases. Where multiple samples were taken from a single plot, individual results are reported, amongst which the highest result is used for estimation of maximum residue level. Where results from separate plots with distinct characteristics such as different varieties or treatment schedules were reported, results are listed for each plot.

The NAFTA 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 NAFTA 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 supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Citrus fruits

Data were available from supervised trials on oranges, lemons and grapefruits conducted in the USA.

The GAP of fenpyroximate on citrus in the USA is a maximum of two foliar applications at a rate of 0.22 kg ai/ha (not exceeding 0.45 kg ai/ha per growing season), with a PHI of 14 days.

Residues in oranges (whole fruit) from trials in the USA matching critical GAP in rank order were: 0.07, 0.11, 0.18and 0.28 mg/kg.

Residues in lemons (whole fruit) from trials matching critical GAP in the USA in rank order were: 0.17, 0.21 and 0.23 mg/kg.

Residues in grapefruit (whole fruit) from trials matching critical GAP in the USA in rank order were: 0.02, 0.04 and 0.09 mg/kg.

On the basis of the foliar application in the USA, the combined data (whole fruit) in rank order were (n = 10): 0.02, 0.04, 0.07, 0.09, 0.11, 0.17, 0.18, 0.21, 0.23 and 0.28 mg/kg. The Meeting estimated a maximum residue level for the citrus fruit group of 0.5 mg/kg. The previous recommendation of 0.2 mg/kg for fenpyroximate in oranges, sweet and sour, was withdrawn.

The Meeting noted that in trials reported in the evaluation of 1999 JMPR, a reduction factor for residues in whole fruit to pulp of 0.24 can be derived. Taking into account this factor, the Meeting estimated an STMR and HR value of 0.034 and 0.067 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.45 mg/kg, which, when rounded up, was in agreement with the Meeting's estimation.

Apples and pears

Data were available from supervised trials on apples in the EU and pears in the USA and EU.

For apples, the GAP from France, a single application at 8 g ai/100L PHI 21 days, was considered against the field trials from France and Italy from 2001 and 2006. Only one new trial from Germany matched the GAP, with residues of 0.03 mg/kg.

For pears, the critical GAP in the USA is up to two applications at a maximum application rate of 0.11 kg ai/ha (not exceeding 0.11 kg ai/ha per growing season) with a PHI of 14 days. The new data point for pear trials that matched GAP were in rank order: 0.029, < 0.05, 0.052 and 0.10 mg/kg.

From the EU trials, conducted in France, only one trial matched the GAP from Italy, which is a single application at 7 g ai/100L with a PHI of 14 days. This gave a residue value of 0.04 mg/kg.

In the 1999 evaluation of fenpyroximate, the same GAP from France was used to consider residues in apples from French trials, German trials and one Belgian trial which gave the following data in rank order: 0.03, < 0.05, 0.06, 0.06, 0.08, 0.09, 0.09, 0.09, 0.10, 0.11, 0.12, 0.12, 0.15, 0.16, and 0.16 mg/kg. Including the single value from a 2006 trial gives the following data for apples (n = 16): 0.03, 0.03, < 0.05, 0.06, 0.06, 0.08, 0.09, 0.09, 0.09, 0.10, 0.11, 0.12, 0.12, 0.15, 0.16, and 0.16 mg/kg.

The Meeting considered that the EU data from the 1999 evaluation and the residue of 0.04 mg/kg in pears could be combined to recommend a pome fruit MRL of 0.3 mg/kg, with STMR of 0.09 mg/kg and HR of 0.16 mg/kg for apples, also to be used for pears. Use of the NAFTA calculator gives a maximum residue level of 0.31 mg/kg.

The Meeting recommended a maximum residue level of 0.3 mg/kg for pome fruit to replace the current CXL of 0.3 mg/kg for apples.

Grapes

Data were available from supervised field trials on grapes conducted in Southern regions of the EU to support a review of alternative GAP.

The alternative GAP is from Italy which is a single application at a spray concentration of 0.0051 kg ai/hL with a PHI of 28 days.

Eight trials conducted in Italy, France and Spain matched with the GAP from Italy. Residues found in ranked order were (n = 8): < 0.01, < 0.01, 0.01, 0.02, 0.02, 0.03, 0.05 and 0.05 mg/kg. Including data from the 1995 and 1999 evaluations of fenpyroximate with the current data set, with trials from Italy and France matching the same GAP gives residues in rank order (n = 11): < 0.01, < 0.01, 0.01, < 0.02, 0.02, 0.02, 0.03, 0.04, 0.04, 0.05, and 0.05 mg/kg.

The Meeting considered a value of 0.1 mg/kg to be appropriate as a maximum residue level. Use of the NAFTA calculator resulted in a value of 0.1 mg/kg. The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR of 0.02 mg/kg and HR of 0.05 mg/kg for fenpyroximate in grapes.

The Meeting agreed to withdraw its previous recommendation of a maximum residue level of 1 mg/kg in grapes.

Fruiting vegetables, Cucurbits

Data were available from supervised trials on cucumbers grown under protected cover in the EU and melons (cantaloupes), grown in the field in the USA.

Cucumber

The GAP of fenpyroximate on greenhouse cucumbers in the USA is a single foliar application at maximum rate of 0.11 kg ai/ha with a PHI of 7 days (not exceeding 0.11 kg ai/ha per growing season).

Residues on greenhouse cucumbers in Europe matching representative GAP in the USA were in ranked order: (n = 9): < 0.01, < 0.01, < 0.01, < 0.01, ≤ 0.01, 0.01, 0.02, 0.02 and 0.02 mg/kg.

The Meeting recommended 0.03 mg/kg as a maximum residue level for cucumbers. Using the NAFTA calculator gave an estimate of 0.03 mg/kg. The corresponding STMR is 0.01 mg/kg and HR value is 0.02 mg/kg.

Melons

The GAP of fenpyroximate on melons in the USA is up to two foliar applications at a maximum rate of 0.11 kg ai/ha with a PHI of 3 days (not exceeding 0.22 kg ai/ha per growing season).

Data from eight residue trials on melons in the USA matched this GAP giving residues in rank order: (n = 8): < 0.05, < 0.05, < 0.05, ≤ 0.05, ≤ 0.05, < 0.05, < 0.05 and < 0.05 mg/kg.

The Meeting agreed to recommend a maximum residue level of 0.05(*) mg/kg for melons. The corresponding STMR and HR values are 0.05 (*) mg/kg.

The NAFTA calculator was not used to derive an estimate as all residue values were below the LOQ, making its application unsuitable.

Fruiting vegetables, other than Cucurbits

Data were available from supervised trials (field and greenhouse) on tomatoes conducted in the USA, Spain, Greece, the UK and France and on peppers in the USA.

Tomatoes

The critical GAP in the USA is up to two sprays at an application rate of 0.11 kg ai/ha (not exceeding 0.22 kg ai/ha per growing season) with a PHI of 1 day for both field and greenhouse tomatoes.

Nineteen trials (16 fields including two cherry tomatoes and three greenhouses) were conducted in the USA which matched USA GAP. Residues from fields in rank order were: < 0.05(7), 0.05, 0.05, 0.06, 0.07, 0.07, 0.08, 0.09, 0.11 and 0.12 mg/kg. Residues from greenhouses were: 0.08, 0.08 and 0.14 mg/kg. This combined data set was used for maximum residue level estimation.

Nine trials (four fields and five greenhouses) were conducted in EU (Greece—one, Spain—five, the UK and France—one) matched Spain GAP. Residues from fields were: 0.02, 0.02, 0.04 and 0.04 mg/kg. Residues from greenhouses were: 0.03, 0.04, 0.04, 0.04 and 0.09 mg/kg.

The Meeting recommended 0.2 mg/kg as a maximum residue level using USA data. Using the NAFTA calculator gives an estimate of 0.15 mg/kg using the USA data. The corresponding STMR is 0.06 mg/kg and HR value is 0.14 mg/kg.

Peppers

The critical GAP in the USA is up to two applications at a rate of 0.11 kg ai/ha (not exceeding 0.22 kg ai/ha per growing season) with a PHI of 1 day.

Matching the USA GAP, residues for 13 field trials in rank order were (n = 13): < 0.05(7), 0.057, 0.058, 0.074, 0.075, 0.12 and 0.13 mg/kg, and residues for three greenhouses in rank order were < 0.05, 0.056 and 0.069 mg/kg. This data set was used for maximum residue level estimation.

The Meeting considered a value of 0.2 mg/kg as a maximum residue level. Use of the NAFTA calculator yielded a value of 0.14 mg/kg. The corresponding STMR is 0.053 mg/kg and HR value is 0.13 mg/kg.

On the basis of the STMR and HR for peppers and the default dehydration factor of 7, an STMR and HR for chilli peppers (dry) were calculated to be 0.37 and 0.9 mg/kg respectively. Based on the HR, the Meeting recommended a maximum residue level for chilli peppers (dry) at 1 mg/kg.

On the basis of estimations on tomatoes and peppers, The Meeting agreed to recommend the group MRL 0.2 mg/kg for fruiting vegetables other than cucurbits, except sweet corn and mushroom.

Tree nuts

Data were available from the supervised field trials conducted in the US.

The critical GAP in the USA is two spray applications at a rate of 0.22 kg ai/ha with a PHI of 14 days.

None of the trials matched the GAP as they were conducted at twice the maximum rate. However, all residues (five on almonds, three on walnuts and five on pecans) in nut meat were less than 0.05 mg/kg.

Based on the US residue data for almonds, walnuts and pecans, the Meeting estimated a maximum residue level of 0.05(*) mg/kg, and a STMR value and HR value of 0.05(*) mg/kg for fenpyroximate in tree nuts.

The NAFTA calculator was not used to derive an estimate as all residue values were below the LOQ, making its application unsuitable.

Animal feed commodities

Almond hulls

As the residue data for tree nuts did not match the USA GAP, the data for hulls were not considered appropriate for estimation of a maximum residue level. The Meeting did not make a recommendation for almond hulls.

Fate of residues in processing

The Meeting received information on the fate of incurred residues of fenpyroximate during the processing of citrus, grapes and tomatoes. The processing factors and STMR-P are summarized in Table 1.

Orange dry pulp, apple wet pomace, grape wet/dry pomace and raisins are expected to contain higher residues than respective raw agricultural commodities. The Meeting estimated processing factors of 0.13 for orange juice and 5.3 for orange dry pulp, giving STMR-P values of 0.018 and 0.74 mg/kg for orange juice and dry pulp, respectively. Using the highest residue value of 0.28 mg/kg for oranges and the PF of 5.3 gives a highest value (P) of 1.5 mg/kg.

Multiplying the HR of grapes found in the supervised trials 0.05 mg/kg by the processing factor of 2.7 resulted in an HR-P and proposed MRL estimate of 0.14 and 0.3 mg/kg for dried grapes. The Meeting estimated processing factors of 0.11, 2.8, 9.6 and 2.7 for grape juice, wet pomace, dry pomace and raisins, respectively. Using the HR of 0.05 mg/kg and the PF of 9.6 for dry pomace gives an HR-P of 0.48.

The Meeting estimated processing factors of 0.54 and 0.44 for tomato paste and puree, respectively.

Table 1 Summary of calculated processing factors

Commodity	Processed fraction	Calculated processing factor	Processing factor	STMR/ STMR-P, mg/kg
Orange[a]	RAC			0.14
	Juice	< 0.13, < 0.02, < 0.02	0.13	0.018
	Dry pulp	6.9, 4.75, 5.3	5.3	0.74
Grape	RAC			0.02
	Juice	< 0.11	0.11	0.0022
	Wet pomace	2.8	2.8	0.056
	Dry pomace	9.6	9.6	0.19
	Raisin	2.7	2.7	0.054
Tomato/US	RAC			0.06
	Paste	0.69, 0.38	0.54	0.032
	Puree	0.44, 0.44	0.44	0.026

[a] Based on whole fruit data

Residues of animal commodities

Farm animal studies on dairy cattle were considered by the 1999 JMPR.

The dietary burden of fenpyroximate residues in farm animals was estimated from the diets listed in OECD Feedstuff derived from field crops. Among commodities reviewed by the 1999 JMPR and 2010 JMPR, apple wet pomace (STMR-P, 0.05 mg/kg), citrus pulp, dry (STMR-P, 0.64 mg/kg), grape pomace, wet (STMR-P, 0.06 mg/kg) and tomato pomace, wet (STMR-P, 0.03 mg/kg) can be fed to beef and dairy cattle. Poultry were not exposed to fenpyroximate through treated feed items.

The maximum dietary burden of beef cattle and dairy cattle was estimated using apple pomace, wet and citrus pulp, dry, and provided in Annex table 1 and 2 of the present meeting report. The summary of livestock dietary burdens of fenpyroximate is shown in Table 2.

As reported in 1999 JMPR, the animal feeding study was conducted at a level equivalent to 1, 3 or 10 ppm in the feed. The maximum and mean dietary burdens in beef cattle and dairy cattle are 0.24 and 0.24 ppm of dry matter diet, which is below the lowest feeding level in the animal feeding study. So the maximum residue levels and STMR values for relevant animal commodities are estimated by applying the transfer factor at the lowest feeding level to the dietary burden. The results are summarized in Table 3.

Table 2 Summary of livestock dietary burdens (ppm of dry matter diet)

	US/CAN		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.08	0.08	0.06	0.06	0.24[a]	0.24[a]	-	-
Dairy cattle	0.08	0.08	0.16	0.16	0.24[b]	0.24[b]	-	-

[a] suitable for estimating maximum residue levels and STMRs for meat and edible offal.

[b] suitable for estimating a maximum residue level and STMRs for milk.

Table 3 Summary of residues corresponding to the estimated dietary burden

Dietary burden (ppm) Feeding level[ppm]	Milk	Muscle	Liver	Kidney	Fat
MRL					
	mean	highest	highest	highest	highest
MRL beef or dairy cattle					
(0.24)	0.005*F	0.01*	0.01*	0.01*	0.004
[0, 1] for other than milk [0, 3] for milk	[0, 0.011]	[0, < 0.01]	[0, < 0.003]	[0, < 0.003]	[0, 0.018]

Dietary burden (ppm) Feeding level[ppm]	Milk	Muscle	Liver	Kidney	Fat
STMR					
	mean	mean	mean	mean	mean
STMR beef or dairy cattle					
(0.24)	0.001	0	0	0	0.006
[0, 1] for other than milk [0, 3] for milk	[0, 0.011]	[0, < 0.01]	[0, < 0.003]	[0, < 0.003]	[0, 0.015]

The Meeting confirmed the current CXL 0.01 (*) mg/kg for cattle kidney, 0.01(*) mg/kg for cattle liver, 0.02 mg/kg for cattle liver and 0.005(*) mg/kg for cattle milk.

DIETARY RISK ASSESSMENT

Long-term intake

The acceptable daily intake (ADI) of 0–0.01 mg/kg bw/day based on the NOAEL for reduced body weight gain in a 2-year study in rats was allocated by 1995 JMPR.

International Estimated Daily Intake (IEDI) was calculated for commodities of human consumption for which STMRs for fenpyroximate were estimated. Results are presented in Annex Table 3. The IEDI for the 13 GEMS/Food cluster diets were 6% or less of the maximum ADI. The intake of residues of fenpyroximate resulting from its proposed uses is unlikely to present a public health concern.

Short-term intake

The acute reference dose (ARfD) of 0.02 mg/kg bw was established by the 2007 JMPR.

International Estimates of Short-term Intake (IESTI) have been calculated for the general population (Annex 4) and for children aged 1 to 6 years (Annex 4). The results compared to the proposed ARfD of 0.02 mg/kg bw/day show short-term intakes of 20% and 60% for the general population and for children, respectively. The results indicate that short-term intake of fenpyroximate resulting from proposed uses is unlikely to present a public health concern.