5.19 FLUOPYRAM (243)

RESIDUE AND ANALYTICAL ASPECTS

Fluopyram, a pyridylethylamide broad spectrum fungicide was evaluated for the first time by the 2010 JMPR, where an ADI of 0–0.01 mg/kg bw and an ARfD of 0.5 mg/kg bw were established, residue definitions were proposed and maximum residue levels were recommended for a number of uses where GAP information was available.

Residue definitions recommended by the 2010 JMPR are:

- For compliance with the MRL and for dietary intake estimation for plant commodities: *fluopyram*
- For MRL-compliance for animal commodities: s*um of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram*
- For dietary intake estimation for animal products: *sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues N-{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide and N-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide, all expressed as fluopyram*

The residue is not fat-soluble.

New GAP information, supporting residue data and additional analytical sample storage stability studies were provided by the manufacturer for evaluation by the Meeting.

Stability of residues in stored analytical samples

The Meeting received updated information on the stability of residues in frozen analytical samples of representative substrates covering those with a high water content (lettuce), a high starch content (wheat grain), a high protein content (dry pea seed), a high oil content (rape seed) and a high acid content (orange).

Residues of fluopyram and its -benzamide, -pyridyl-acetic acid and -pyridyl-carboxylic acid metabolites were all stable in these representative substrates (except orange) stored frozen for up to 36–37 months. In orange, levels of the -pyridyl-acetic acid metabolite decreased from about 80% of the spiked level after 6 months to about 50% after 36 months storage.

Results of supervised residue trials on crops

The Meeting received new supervised trial data for foliar applications of fluopyram (SC formulations) on apples, wine grapes and peppers and agreed to use the data provided to the 2010 JMPR to estimate maximum residue levels for commodities for which new GAP information was available.

The results from these new trials and those previously reported by the 2010 JMPR and either matching critical GAP or where the results can be proportionally adjusted (scaled) to reflect GAP application rates were used to estimate maximum residue levels, STMRs and HRs for a number of commodities. The approach used to scale the results from trials where the application rates range from 0.33 × GAP to 5 × GAP (but otherwise match the critical GAP) is described in the Report of the 2010 JMPR (Section 2.8).

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 all relevant factors related to each data set in arriving 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 from that recommended by the Meeting, a brief explanation of the deviation was supplied.

Pome fruit

Results from supervised field trials on apples and pears conducted in Europe and North America were provided to the 2010 JMPR and the results from additional trials on apples in North America were provided to the Meeting.

The critical GAP for pome fruit is in Germany, a maximum of 4 applications of 0.05 kg ai/ha/metre of canopy height, PHI 14 days (equivalent to 0.15 kg ai/ha for 3m canopy trees). In trials on apples (6) and pears (2) from northern Europe, reported by the 2010 JMPR and matching the GAP in Germany, fluopyram residues were: 0.11, 0.11, 0.12, 0.12, 0.15, 0.2, 0.21 and 0.28 mg/kg.

The Meeting estimated a group maximum residue level of 0.5 mg/kg, an STMR of 0.135 mg/kg and an HR of 0.28 mg/kg for fluopyram on pome fruits.

Stone fruit

Results from supervised field trials on cherries conducted in USA and peaches conducted in Europe and USA were provided to the 2010 JMPR.

Cherries

The critical GAP for cherries is in Canada, up to 3 applications of 0.125 kg ai/ha, 14 days apart, PHI 0 days and a maximum seasonal rate of 0.375 kg ai/ha. None of the trials reported by the 2010 JMPR matched this GAP.

GAP for cherries in USA is 0.1 kg ai/ha, PHI 0 days, a 5–7 day spraying interval and a maximum of 0.21 kg ai/ha/season. In trials from USA reported by the 2010 JMPR, where cherries were treated with 2 × 0.25–0.26 kg ai/ha fluopyram, residues at 0 DAT (days after the last treatment) were: 0.07, 0.15, 0.21, 0.28, 0.35, 0.51, 0.51, 0.57, 0.63, 0.64 and 1.2 mg/kg. When proportionally adjusted to the 0.1 kg ai/ha GAP application rate (scaling factors of 0.38–0.4), fluopyram residues in cherries from these trials were: 0.03, 0.06, 0.08, 0.11, 0.14, 0.20, 0.21, 0.22, 0.22, 0.25, 0.26 and 0.47 mg/kg (n=12).

The Meeting agreed to use the proportionally adjusted data matching the GAP of the USA for cherries to estimate a maximum residue level of 0.7 mg/kg, an STMR of 0.205 mg/kg and an HR of 0.47 mg/kg for fluopyram on cherries.

Peaches

The critical GAP for peaches is in Turkey, 0.005 kg ai/hL, PHI 3 days. In trials from Southern Europe reported by the 2010 JMPR, where peaches were treated with 3 × 0.01–0.018 kg ai/hL fluopyram, residues at 3 DAT were: 0.11, 0.15, 0.2, 0.24, 0.26, 0.33, 0.34 and 0.34 mg/kg. When proportionally adjusted to the 0.005 kg ai/hL GAP application rate (scaling factors of 0.28–0.5), fluopyram residues in peaches from these trials were: 0.03, 0.06, 0.10, 0.12, 0.14, 0.16, 0.16 and 0.17 mg/kg (n=9).

The Meeting agreed to use the Southern European trial results, proportionally adjusted to match the GAP in Turkey to estimate a maximum residue level of 0.4 mg/kg, an STMR of 0.13 mg/kg and an HR of 0.17 mg/kg for fluopyram on peach.

Berries and small fruit

Grapes

Results from supervised field trials on wine and table grapes conducted in Europe and on table grapes in USA were provided to the 2010 JMPR and additional trial results on wine grapes from USA were provided to the Meeting.

New GAP information was provided to the Meeting for wine grapes in USA (0.25 kg ai/ha, PHI 7 days with a maximum seasonal rate of 0.5 kg ai/ha) and in North American trials matching this GAP, fluopyram residues in grapes were: 0.1, 0.15, 0.15, 0.19, 0.21, 0.27, 0.32, 0.37, 0.43, 0.47, 0.49, 0.52, 0.57, 0.62, 0.63 and 0.95 mg/kg (n=16).

The Meeting noted that the 2010 JMPR had estimated a maximum residue level of 2 mg/kg, an STMR of 0.58 mg/kg and an HR of 1 mg/kg for fluopyram on grape, based on data from European trials matching the Romanian GAP for table grapes (2 × 0.25 kg ai/ha, PHI 3 days) and that this 2010 recommendation accommodated the new GAP in USA.

Strawberries

Results from supervised field trials on strawberries in USA (foliar applications and drip irrigation treatments) and Europe (foliar applications) to strawberries were provided to the 2010 JMPR.

The critical GAP for strawberries is in Morocco, 2 applications of 0.015 kg ai/hL, PHI 3 days but none of the European trials matched this GAP.

GAP for strawberries in Canada is for a maximum of 2 drip irrigation treatments of up to 0.25 kg ai/ha, PHI 0 days with a maximum seasonal application rate of 0.5 kg ai/ha. In trials from USA, reported by the 2010 JMPR and matching the GAP in Canada, fluopyram residues were: < 0.01, < 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.06, 0.1 and 0.23 mg/kg (n=10).

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.025 mg/kg and an HR of 0.23 mg/kg for fluopyram on strawberries..

Banana

Results from supervised field trials on bagged and unbagged bananas in Mexico, Central and South America were provided to the 2010 JMPR.

The critical GAP for bananas is in Panama, a maximum of 5 foliar applications of 0.1 kg ai/ha, PHI 0 days. In trials on bananas, reported by the 2010 JMPR and matching the GAP in Panama (but involving 6 applications), fluopyram residues in unbagged bananas (whole fruit) were: 0.02, 0.04, 0.04, 0.05, 0.05, 0.06, 0.17, 0.18, 0.18, 0.21, 0.22, 0.25, 0.34 and 0.51 mg/kg (n=14).

The Meeting considered that residue contribution from the first of the six applications, applied at least 30 days before harvest would not significantly influence the final residue.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.175 mg/kg and an HR of 0.51 mg/kg for fluopyram on banana.

Cucumber

The 2010 JMPR evaluated residue trial data and GAP information on the use of fluopyram as a foliar spray on cucumber in China (3 × 0.075 kg ai/ha, 2-day PHI) and estimated an STMR of 0.11 mg/kg, an HR of 0.19 mg/kg and recommended a maximum residue level of 0.5 mg/kg for fluopyram on cucumbers.

New information was provided to the Meeting on the GAP in Turkey for cucumbers grown under cover (0.006 kg ai/hL, 3 day PHI). None of the trials in Europe, reported by the 2010 JMPR, matched the GAP in Turkey.

Fruiting vegetables, other than Cucurbits

Peppers

The critical GAP for peppers is in Turkey, 0.006 kg ai/hL, 3 day PHI. In the two new trials provided to the Meeting on peppers grown under cover in Turkey and matching the GAP in Turkey, fluopyram residues were 0.23 and 0.24 mg/kg.

In trials reported by the 2010 JMPR, where fluopyram was applied 2 × 0.025–0.03 kg ai/hL to peppers grown under cover, residues 3 DAT were: 0.16, 0.25, 0.29, 0.31, 0.42 and 0.58 mg/kg. When proportionally adjusted to the 0.006 kg ai/hl GAP application rate in Turkey (scaling factors of 0.2–0.3), residues of fluopyram in peppers were: 0.03, 0.05, 0.08, 0.08, 0.09 and 0.13 mg/kg (n=6).

The combined data set of results from the pepper trials matching the GAP in Turkey, including the proportionally scaled results were: 0.03, 0.05, 0.08, 0.08, 0.09, 0.13, 0.23 and 0.24 mg/kg (n=8).

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.085 mg/kg and an HR of 0.24 mg/kg for fluopyram on peppers.

For dried chili peppers, using the data set for peppers and a dehydration factor of 10, the Meeting estimated an STMR of 0.85 mg/kg, an HR of 2.4 mg/kg and recommended a maximum residue level of 5 mg/kg for fluopyram on peppers chili, dried.

Tomato

The critical GAP for tomato is in Morocco, up to 2 applications/season of 0.0125 kg ai/hL, 3 day PHI. None of the trials on tomatoes in Europe, reported by the 2010 JMPR, matched the GAP in Morocco and the Meeting decided to assess the results of the trials on indoor-grown tomatoes against the Moroccan GAP. In these trials, where fluopyram was applied 2 × 0.02 or 0.03 kg ai/hL (2 × 0.3 kg ai/ha), residues 3 DAT were: 0.13, 0.15, 0.15, 0.15, 0.16, 0.19, 0.19, 0.24, 0.28, 0.36, 0.44 and 0.62 mg/kg. When proportionally adjusted to the 0.0125 kg ai/hl GAP application rate (scaling factors of 0.31–0.63), fluopyram residues in tomatoes were: 0.05, 0.06 (3), 0.08, 0.08, 0.1, 0.15, 0.18, 0.19, 0.22 and 0.23 mg/kg (n=12).

Based on the results of the trials on indoor-grown tomatoes, the Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.09 mg/kg and an HR of 0.23 mg/kg for fluopyram on tomato.

Beans (dry)

The critical GAP for dry beans (except soya beans) is in USA, 0.15 kg ai/ha, at 7-10 day intervals, 14 day PHI with a maximum seasonal rate of 0.3 kg ai/ha. None of the trials reported by the 2010 JMPR matched the USA GAP but in trials in USA on dry beans where fluopyram was applied 2 × 0.24–0.26 kg ai/ha, residues 14 DAT were: < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.03, 0.05 and 0.07 mg/kg. When proportionally adjusted to the 0.15 kg ai/ha GAP application rate (scaling factors of 0.58-0.63), fluopyram residues in beans (dry) from these trials were: < 0.01 (6), 0.02, 0.03 and 0.04 mg/kg (n=9).

The Meeting noted that the GAP in USA for 'dry beans' crop group includes lupins, chick-pea and lentil, which are not covered by the Codex 'beans (dry)' crop group and agreed to extrapolate the data for dry beans to these commodities.

The Meeting estimated a maximum residue level of 0.07 mg/kg and an STMR of 0.01 mg/kg for fluopyram on beans (dry), lupin (dry), chick-pea (dry) and lentil (dry).

Root & tuber vegetables

Results from supervised field trials on carrots, potatoes and sugar beet in North America and on carrots in Europe were provided to the 2010 JMPR.

Carrots

GAP for carrots in Ukraine is for a maximum of 2 foliar applications of 0.15 kg ai/ha, 30 day PHI. In carrot trials in Northern Europe matching the GAP in Ukraine and reported by the 2010 JMPR, residues were: 0.03, 0.04, 0.07, 0.08, 0.1, 0.13, 0.15 and 0.19 mg/kg (n=8).

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.09 mg/kg and an HR of 0.19 mg/kg for fluopyram on carrot.

Potato

The critical GAP for potatoes is in USA, 0.2 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.4 kg ai/ha. In potato trials in USA matching the GAP in USA and reported by the 2010 JMPR, residues were: < 0.01 (14), 0.01 and 0.02 mg/kg (n=16).

The Meeting estimated a maximum residue level of 0.03 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.02 mg/kg for fluopyram on potatoes. The OECD Calculator recommended a value of 0.02 mg/kg but the Meeting noted the high level of censored data and proposed a higher level.

Sugar beet

The critical GAP for sugar beet in USA is 0.125 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.25 kg ai/ha. None of the sugar beet trials reported by the 2010 JMPR matched the GAP in USA, but in trials in USA where fluopyram was applied 2 × 0.24–0.26 kg ai/ha, residues 7 DAT in sugar beet roots were: 0.02 (4), 0.03 (3), 0.04 (3) and 0.05 mg/kg. When proportionally adjusted to the 0.125 kg ai/ha GAP application rate (scaling factors of 0.48–0.52), fluopyram residues in sugar beet roots were: < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.02 and 0.02 mg/kg (n=11).

The Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.02 mg/kg for fluopyram on sugar beet roots.

Tree nuts

The critical GAP for tree nuts is in USA, 0.25 kg ai/ha, 14 day PHI with a seasonal maximum rate of 0.5 kg ai/ha.

In almond trials in USA, reported by the 2010 JMPR, matching the GAP for tree nuts in USA, fluopyram residues in almond nutmeat were: < 0.01, < 0.01, < 0.01, 0.01 and 0.02 mg/kg (n=5).

In pecan trials in USA, reported by the 2010 JMPR, matching the GAP for tree nuts in USA, fluopyram residues in pecan nutmeat were: < 0.01, < 0.01, < 0.01, 0.01 and 0.03 mg/kg (n=5).

The Meeting noted that the residue distributions in almonds and pecans were similar and agreed to combine them to support a group maximum residue level. The combined data set is: < 0.01 (6), 0.01, 0.01, 0.02 and 0.03 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.03 mg/kg for fluopyram on tree nuts.

Oilseeds

Peanut

The critical GAP for peanuts is in USA, 0.25 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.5 kg ai/ha..

In peanut trials reported by the 2010 JMPR, matching the GAP in USA, fluopyram residues in peanut (nutmeat) were: < 0.01 (10), 0.01 and 0.02 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for fluopyram on peanut.

Rape seed

The critical GAP for oilseed rape is in Germany, a single application of 0.125 kg ai/ha over the flowering period (from BBCH 57 to BBCH 69, i.e., up to the end of flowering). In the Northern European supervised trials on oilseed rape reported by the 2010 JMPR, one fluopyram application of 0.125 kg ai/ha was made early flowering (about BBCH 63) and a second treatment was applied between 14 and 39 days later, at BBCH 73 (30% pods at full size).

Fluopyram residues in rape seed from these Northern European trials were: 0.02, 0.04, 0.08, 0.09, 0.1, 0.11, 0.11 and 0.19 mg/kg.

The Meeting agreed that these trials did not match the GAP in Germany and could not be used to estimate a maximum residue level for rape seed.

Animal feeds

Bean forage and fodder

The critical GAP for dry beans (except soya beans) is in USA, 0.15 kg ai/ha, at 7–10 day intervals, 14 day PHI with a maximum seasonal rate of 0.3 kg ai/ha, but as the GAP includes a restriction that livestock should not be grazed on or fed hay or threshings from treated crops, the Meeting did not estimate a median residue for livestock dietary burden estimation.

Sugar beet tops

The critical GAP for sugar beet in USA is 0.125 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.25 kg ai/ha. None of the sugar beet trials reported by the 2010 JMPR matched the GAP in USA, but in trials in USA where fluopyram was applied 2 × 0.24–0.26 kg ai/ha, residues 7 DAT in sugar beet tops were: 0.35, 0.38, 0.67, 0.69, 0.7, 0.89, 1.8, 3.2, 4.7, 9.4 and 16.5 mg/kg. When proportionally adjusted to the 0.125 kg ai/ha GAP application rate (scaling factors of 0.48-0.52), fluopyram residues in sugar beet tops were: 0.18, 0.19, 0.34, 0.35, 0.37, 0.46, 0.89, 1.6, 2.3, 4.7 and 8.3 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 0.46 mg/kg and a highest residue of 8.3 mg/kg for fluopyram on sugar beet tops.

Almond hulls

The critical GAP for tree nuts is in USA; 0.25 kg ai/ha, 14 day PHI with a seasonal maximum rate of 0.5 kg ai/ha. In almond trials in USA, reported by the 2010 JMPR, matching the GAP for tree nuts in USA, fluopyram residues in almond hulls were: 2.4, 3.2, 3.6, 4.3 and 5.4 mg/kg.

For animal dietary burden estimation, the Meeting estimated a median residue of 3.6 mg/kg for fluopyram on almond hulls.

Peanut forage and fodder

The critical GAP for peanuts is in USA; 0.25 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.5 kg ai/ha but as the GAP includes a restriction that livestock should not be grazed on or fed hay or threshings from treated crops, the Meeting did not estimate a median residue for livestock dietary burden estimation.

Fate of residues during processing

The 2010 JMPR reported that fluopyram was stable under conditions simulating pasteurisation, boiling and sterilisation and also estimated processing factors and STMR-Ps for a range of commodities. Relevant processing factors and STMR-Ps for the commodities considered at this Meeting and used for dietary intake risk assessment or for estimating livestock animal burdens are summarized below.

Summary of relevant processing factors and STMR-P values for fluopyram residues.

Raw agricultural commodity	Processed commodity	Processing factor [a] (mean or median)	RAC STMR (HR) (mg/kg)	STMR-P (HR-P) (mg/kg)
Tomato	Juice	0.36	0.09	0.03
Tomato	Pomace (wet)	0.1	0.09	0.01
Tomato	Preserve	0.21	0.09	0.02
Tomato	Puree	0.73	0.09	0.07

Raw agricultural commodity	Processed commodity	Processing factor [a] (mean or median)	RAC STMR (HR) (mg/kg)	STMR-P (HR-P) (mg/kg)
Tomato	Paste	0.46	0.09	0.04
Potato	Peeled tubers	< 0.64	0.01 (0.02)	< 0.006 (< 0.013)
Potato	Chips (crisps)	< 0.64	0.01	< 0.006
Potato	Flakes	1	0.01	0.01
Potato	Wet peel (process waste)	4.3	0.01	0.04
Sugar beet	Sugar	1.3	0.01	0.01
Sugar beet	Thick juice (Molasses)	0.92	0.01	0.01
Sugar beet	Dried pulp	1.3	0.01	0.01
Apples	Dried fruit	0.64 (median)	0.135	0.09
Apples	Sauce	0.36 (median)	0.135	0.05
Apples	Juice	< 0.09 (median)	0.135	< 0.01
Apples	Pomace (wet)	2.3 (median)	0.135	0.31
Peanut	Meal	0.19	0.01	0.002
Peanut	Butter	0.22	0.01	0.002
Peanut	Oil	0.01	0.01	0.0001
Strawberry	Preserve	0.31	0.025	0.008
Strawberry	Jam	0.65	0.025	0.02

[a] The processing factor is the ratio of the total residue in the processed item divided by the total residue in the RAC.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of fluopyram in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops).

	Animal dietary burden, fluopyram, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.13	0.12	7.69	0.74	2.97	2.93[c]	-	-
Dairy cattle	0.64	0.55	11.2 [a b]	0.87	2.96	2.92[d]	-	-
Poultry – broiler	0.002	0.002	0.16	0.08	0.008	0.008	-	-
Poultry – layer	0.002	0.002	1.97[e g]	0.18[f h]	0.008	0.008	-	-

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

[g] Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

[h] Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

Farm animal feeding studies

The 2010 JMPR reviewed feeding studies with fluopyram on lactating dairy cows and laying hens and the conclusions from these residue transfer studies were used to estimate residue levels of fluopyram and its metabolites in milk, eggs and livestock tissues, based on the above dietary burdens.

Animal commodity maximum residue levels

Cattle

Maximum and mean residues expected in milk and tissues were obtained by using the residue transfer factors estimated by the 2007 JMPR.

For maximum residue estimation, the high residues of fluopyram and BZM (expressed as fluopyram equivalents) were calculated by interpolating the maximum dietary burden (11.2 ppm) from the 1.5:14.4 ppm feeding levels in the dairy cow feeding study and using the highest tissue concentrations of fluopyram plus BZM (fluopyram equivalents) from individual animals within those feeding groups. The same interpolation was used to calculate the highest tissue concentrations of fluopyram, BZM plus total olefins (fluopyram equivalents) for estimating HRs for dietary intake estimation.

The STMR values for the tissues were calculated by interpolating the STMR dietary burden (2.93 ppm from the same feeding levels and using the mean tissue concentrations of fluopyram, BZM plus total olefins (fluopyram equivalents) from those feeding groups.

For milk MRL estimation, the high residues in the milk were calculated by interpolating the maximum dietary burden for dairy cattle (11.2 ppm) from the 1.5:14.4 ppm feeding levels in the dairy cow feeding study and using the mean milk concentrations of fluopyram and BZM (fluopyram equivalents) from this feeding group.

The STMR value for milk was calculated by interpolating the mean dietary burden for dairy cows (2.92 ppm) from the 1.5:14.4 ppm feeding levels and using the mean milk concentrations of fluopyram, BZM plus total olefins (fluopyram equivalents).

	Feed level for milk (ppm)	Residues in milk (mg/kg)	Feed level for tissues (ppm)	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle ((fluopyram + BZM)							
Feeding study (1)	1.5 14.4	0.02 0.25	1.5 14.4	0.02 < 0.45	0.36 2.88	0.03 < 0.39	< 0.02 0.4
Dietary burden/residue estimate	11.2[b]	0.193	2.43[a]	0.343	2.25	0.301	0.306
High residue beef or dairy cattle (fluopyram + BZM + Total olefins)							
Feeding study (2)			1.5 14.4	0.02 < 0.47	< 0.38 2.94	0.03 < 0.41	< 0.04 0.52
Dietary burden/residue estimate			2.43[a]	0.358	2.305	0.316	0.401
STMR beef or dairy cattle ((fluopyram + BZM + Total olefins)							
Feeding study (2)	1.5 14.4	0.02 < 0.27	1.5 14.4	0.02 < 0.47	0.36 2.92	0.03 < 0.41	< 0.04 0.49
Dietary burden/residue estimate	2.92	0.048	2.93	0.053	0.527	0.061	0.059

[a] Highest residues for tissues and mean residues for milk

[b] Mean residues for tissues and for milk

Combined residues of fluopyram and BZM (expressed as fluopyram equivalents) expected in cattle milk and tissues for use in estimating maximum residue levels are: 0.31 mg/kg (fat), 0.34 mg/kg (muscle), 2.25 mg/kg (liver) and 0.3 mg/kg (kidney) and the mean residue for milk is 0.19 mg/kg.

The Meeting estimated maximum residue levels of 0.5 mg/kg for fluopyram in meat (from mammals other than marine mammals), 3 mg/kg for liver of cattle, goats, pigs and sheep, 0.5 mg/kg for kidney of cattle, goats, pigs and sheep and 0.3 mg/kg for milks and agreed to withdraw the previous recommendations for meat (from mammals other than marine mammals), edible offal (mammalian) and milks.

Estimated HRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.4 mg/kg for mammalian fat, 0.36 mg/kg for mammalian muscle, 2.3 mg/kg for liver and 0.32 mg/kg for kidney.

Estimated STMRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.06 mg/kg for mammalian fat, 0.05 mg/kg for mammalian muscle, 0.53 mg/kg for liver of cattle, goats, pigs and sheep, 0.06 mg/kg for kidney of cattle, goats, pigs and sheep and 0.05 mg/kg for milks

Poultry

The dietary burdens for poultry broilers are 0.18 ppm (maximum) and 0.08 ppm (mean) but the Meeting decided to estimate residue levels in poultry tissues using the higher mean/maximum dietary burden in poultry layers (1.97 ppm) as they may also be consumed. Tissue concentrations of fluopyram plus BZM (fluopyram equivalents) for maximum residue level estimation and of fluopyram, BZM plus total olefins (fluopyram equivalents) for dietary intake were obtained by interpolation between the 1.6 ppm and the 4.8 ppm feeding levels in the poultry study reported by the 2010 JMPR.

For eggs, for MRL estimation, residue levels in eggs were also estimated by interpolation between the higher dose levels (1.6 ppm and 4.8 ppm) because of the higher poultry layer dietary burden (1.97 ppm) but for estimating the STMR, based on a mean dietary burden of 0.18 ppm for poultry layers, mean residue levels were estimated by interpolation between the 0.05 ppm and the 0.49 ppm feeding levels.

	Feed level for eggs (ppm)	Residues in eggs (mg/kg)	Feed level for tissues (ppm)	Residues (mg/kg)		
				Muscle	Liver	Skin with Fat
Maximum residue level broiler or laying hen (fluopyram + BZM)						
Feeding study (1)	1.6 4.8	0.22 0.72	1.6 4.8	0.1 0.33	0.43 1.6	0.11 < 0.64
Dietary burden/residue estimate	1.97 [b]	0.193	1.97 [a]	0.127	0.565	0.171
High residue broiler or laying hen (fluopyram + BZM + Total olefins)						
Feeding study (2)			1.6 4.8	0.1 0.39	< 0.45 1.8	< 0.14 < 072
Dietary burden/residue estimate			1.97 [a]	0.134	0.585	0.207
STMR broiler or laying hen (fluopyram + BZM + Total olefins)						
Feeding study (2)	0.05 0.49	0 0.8	0.05 0.49	< 0.01 0.03	0.1 0.16	< 0.01 < 0.06
Dietary burden/residue estimate	0.18	0.008	0.18	0.011	0.02	0.013

[a] Highest residues for tissues and mean residues for eggs

[b] Mean residues for tissues and for eggs

Combined residues of fluopyram and BZM (expressed as fluopyram equivalents) expected in poultry eggs and tissues for use in estimating maximum residue levels are: 0.17 mg/kg (fat), 0.13 mg/kg (muscle), 0.56 mg/kg (liver) and 0.19 mg/kg (eggs).

The Meeting estimated maximum residue levels of 0.2 mg/kg for fluopyram in poultry meat, 0.7 mg/kg for poultry edible offal and 0.3 mg/kg for eggs.

Estimated HRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.2 mg/kg for poultry fat, 0.13 mg/kg for poultry muscle and 0.58 mg/kg for poultry edible offal.

Estimated STMRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.01 mg/kg for poultry fat, 0.01 mg/kg for poultry muscle, 0.02 mg/kg for poultry edible offal and 0.008 mg/kg for eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) for fluopyram were calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of fluopyram for the 13 GEMS/Food regional diets, based on estimated STMRs were 2–20% of the maximum ADI of 0.01 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of fluopyram 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 Intakes (IESTIs) for fluopyram were calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available (Annex 4).

For fluopyram the IESTI varied from 0–10% of the ARfD (0.5 mg/kg bw) and the Meeting concluded that the short-term intake of residues of fluopyram from uses considered by the Meeting is unlikely to present a public health concern.