5.17 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. New GAP and supporting information were evaluated by the JMPR in 2012, 2014 and 2015, with a number of additional maximum residue levels being recommended.

Residue definitions recommended by the 2010 JMPR are:

Definition of the residue (for compliance with the MRL and for the estimation of dietary exposure) for plant commodities*: fluopyram*

Definition of the residue (for compliance with the MRL) for animal commodities*: Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram*

Definition of the residue (for the estimation of dietary exposure) for animal commodities*: Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues of 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 trial data, additional analytical sample storage stability studies and environmental fate data were provided by the manufacturer for evaluation by the Meeting.

The following abbreviations are used for the metabolites discussed below:

BZM	-benzamide	2-(trifluoromethyl)benzamide
PAA	-pyridyl-acetic acid	[3-chloro-5-(trifluoromethyl)pyridin-2-yl]acetic acid
PCA [a]	-pyridyl-carboxylic acid	3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid
7-OH	-7-hydroxy	N-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]-2-hydroxyethyl}-2-trifluoromethyl) benzamide
	-methyl sulfoxide	3-(methylsulfinyl)-5-(trifluoromethyl) pyridine-2-carboxylic acid

[a] Also a metabolite of fluopicolide (M05)

Environmental fate

The Meeting reviewed information on the behaviour of fluopyram in soil under anaerobic conditions and in water/sediment systems, to determine whether the existing fluopyram residue definitions for plant commodities were also appropriate for paddy rice.

Under aerobic soil conditions, fluopyram slowly degraded, with identified metabolites being 7-OH, -BZM, -PCA and methyl sulfoxide (each less than 5% AR). Under anaerobic soil conditions, fluopyram is essentially stable, with no transformation products being detected.

In water/sediment systems under aerobic conditions, fluopyram steadily partitioned into the sediment with four unknown degradates found, each at less than about 2% applied radioactivity. Under anaerobic aquatic conditions, only one unknown degradate was found (at up to 1.5% AR).

Based on the above, the Meeting concluded that the fluopyram degradates formed in soil under aerobic conditions are not expected in anaerobic soils or in water/sediment systems, and while

several unknown degradates were formed in soil under anaerobic conditions, these were only present at low levels and not expected to be taken up by paddy rice.

In addition, analysis of paddy rice grain and straw for the metabolites found in other plants and in aerobic soil showed a similar pattern to that found in other treated and rotational crops, with fluopyram being the predominant residue and significant levels of the 7-OH and the BZM metabolites also found in rice straw and to a much lesser extent in grain.

The Meeting concluded that the residue profile in paddy rice is similar to that in other treated or rotational crops and that the current plant commodity residue definitions would also cover paddy rice.

Methods of analysis

The Meeting received information on the use of a modified QuEChERS method of analysis (as BCS 01207), together with validation studies for the analysis of fluopyram and its -benzamide (BZM), -pyridyl-acetic acid (PAA) and -pyridyl-carboxylic acid (PCA) metabolites in tomato, wheat (forage and grain), grape, potato, pea seed and oilseed rape. The LOQ for all analytes in all matrices was 0.01 mg/kg and mean recovery rates were within the range of 77–114% (RSDs of 0.8–10%). The Meeting concluded that this method was suitable for both data generation and enforcement.

Stability of pesticide residues in stored analytical samples

The 2012 JMPR concluded that, residues of fluopyram and its -benzamide, -pyridyl-acetic acid and -pyridyl-carboxylic acid metabolites were all stable for up to 36–37 months in 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) stored frozen for up to 36–37 months (6 months for the -pyridyl-acetic acid metabolite in orange). In the supervised trials considered by the Meeting, the frozen storage periods were all less than 36 months.

The Meeting received information on the short-term stability of fluopyram, fluopyram-benzamide and fluopyram-7-hydroxy residues in conditions reflecting field sampling practices. In representative substrates covering those with a high water content (tomato and wheat forage), a high starch content (wheat grain and potato), a high protein content (dry pea seed), a high oil content (rape seed) and a high acid content (grape) residues were stable following storage for 8 hours at +1 °C followed by 7 days at -7 °C.

Results of supervised residue trials on crops

The Meeting received new GAP information and/or new supporting residue information from the manufacturer for citrus, mango, peppers, Witloof chicory, potato, Globe artichoke, barley, wheat, maize, rice, sunflower seed, peanut, hops, dill and herbs. The Meeting agreed to use the data provided to JMPR in 2010, 2012 and 2015 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 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.

Citrus fruits

The critical GAP in the USA for fluopyram on citrus fruit is 2× 0.25 kg ai/ha (foliar applications), PHI of 7 days, with a maximum seasonal rate of 0.5 kg ai/ha.

In 11 independent trials on oranges from the USA matching this GAP, fluopyram residues were: 0.056, 0.084, 0.1, 0.13, 0.15, 0.15, 0.16, 0.27, 0.3, 0.31 and 0.35 mg/kg. The highest residue of replicate samples was 0.37 mg/kg.

Based on the data set for oranges, the Meeting estimated a subgroup maximum residue level of 0.6 mg/kg, an STMR of 0.15 mg/kg and an HR of 0.37 mg/kg for fluopyram on the Subgroup of Oranges, Sweet, Sour.

In two independent trials on mandarins from USA matching this GAP, fluopyram residues were: 0.064 and 0.21 mg/kg.

The Meeting agreed to combine the data sets for oranges and mandarins to mutually support subgroup maximum residue limits for oranges and mandarins. The combined data set is: 0.056, 0.064, 0.084, 0.1, 0.13, 0.15, 0.15, 0.16, 0.21, 0.27, 0.3, 0.31 and 0.35 mg/kg.

Based on the combined data set for oranges and mandarins, the Meeting estimated sub-group maximum residue levels of 0.6 mg/kg, STMRs of 0.15 mg/kg and HRs of 0.37 mg/kg for fluopyram on the Subgroup of Mandarins and the Subgroup of Oranges, Sweet, Sour.

In eight independent trials on lemons from USA matching this GAP, fluopyram residues were: 0.24, 0.26, 0.3, 0.32, 0.33, 0.37, 0.42 and 0.48 mg/kg. The highest residue of replicate samples was 0.51 mg/kg.

Based on the data set for lemons, the Meeting estimated a sub-group maximum residue level of 1 mg/kg, an STMR of 0.325 mg/kg and an HR of 0.51 mg/kg for fluopyram on the Subgroup of Lemons and Limes.

In eight independent trials on grapefruit from USA matching this GAP, fluopyram residues were: 0.044, 0.09, 0.1, 0.13, 0.15, 0.16, 0.17 and 0.19 mg/kg. The highest residue of replicate samples was 0.23 mg/kg.

Based on the data set for grapefruit, the Meeting estimated a sub-group maximum residue level of 0.4 mg/kg, an STMR of 0.14 mg/kg and an HR of 0.23 mg/kg for fluopyram on the Subgroup of Pummelo and Grapefruits.

Stone fruits

Cherries

The critical GAP in USA for cherries is 2× 0.25 kg ai/ha (foliar applications), PHI of 0 days and a maximum of 0.5 kg ai/ha/season.

In six independent trials on cherries from USA matching this GAP, fluopyram residues were: 0.16, 0.28, 0.51, 0.63, 0.64 and 1.2 mg/kg.

Based on the data set for cherries, the Meeting estimated a sub-group maximum residue level of 2 mg/kg, an STMR of 0.57 mg/kg and an HR of 1.2 mg/kg for fluopyram on the Subgroup of Cherries to replace the previous recommendation.

Berries and other small fruits

Cane berries

The critical GAP in Canada and USA for fluopyram on small fruit (including cane berries) is 2× 0.25 kg ai/ha, PHI of 0 days and a maximum seasonal rate of 0.5 kg ai/ha.

In five trials from USA matching this GAP, fluopyram residues in raspberries, boysenberries and blackberries were: 0.43, 0.71, 0.83, 1.4 and 2.4 mg/kg. The highest residue of replicate samples was 2.5 mg/kg.

Noting that the GAP in USA included cane berries, the Meeting estimated a sub-group maximum residue level of 5 mg/kg, an STMR of 0.83 mg/kg and an HR of 2.5 mg/kg for fluopyram on the Subgroup of Cane berries to replace the previous recommendation.

Bush berries

The critical GAP in Canada and USA for fluopyram on small fruit (including bush berries) is 2× 0.25 kg ai/ha, PHI of 0 days and a maximum seasonal rate of 0.5 kg ai/ha.

In eight trials from USA (reported by the 2010 JMPR) matching the critical GAP in USA, fluopyram residues in blueberries were: 0.58, 0.88, 1.1, 1.1, 1.2, 1.3, 1.5 and 4.3 mg/kg. The highest residue of replicate samples was 4.9 mg/kg

Noting that the GAP in USA included bush berries the Meeting estimated a sub-group maximum residue level of 7 mg/kg, an STMR of 1.15 mg/kg and an HR of 4.9 mg/kg for fluopyram on the Subgroup of Bush berries.

Assorted tropical and subtropical fruit – inedible peel

Mango

The critical GAP for mango is in Malaysia (2× 0.15 kg ai/hL, PHI of 7-days).

In five trials from Thailand and Peru matching this GAP, fluopyram residues in whole fruit were: 0.1, 0.13, 0.18, 0.44 and 0.48 mg/kg.

In the trials from Peru, fluopyram residues were also measured in mango flesh. Calculated processing factors (flesh:whole fruit ratios) were: 0.04, 0.11 and 0.13).

The Meeting estimated a maximum residue level of 1 mg/kg, and applied the median processing factor (0.11) to the whole fruit median residue (0.18 mg/kg) and the maximum residue (0.48 mg/kg) to estimate an STMR of 0.02 mg/kg and an HR of 0.053 mg/kg for fluopyram on mango.

Bulb vegetables

Spring onions

GAP for bulb vegetables (including green onions) in USA and Canada for fluopyram is 2× 0.25 kg ai/ha, PHI of 0 days and a maximum seasonal rate of 0.5 kg ai/ha.

In three trials conducted in USA and matching the USA GAP for bulb vegetables, residues in spring onions were: 1.2, 5.1 and 6.2 mg/kg. The highest residue of replicate samples was 7.3 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg, an STMR of 5.1 mg/kg and an HR of 7.3 mg/kg for fluopyram for spring onions.

Welsh onion

GAP for Welsh onions in Greece is 1× 0.16 kg ai/ha, PHI of 7 days.

In eight European trials in Europe involving 2 applications of 0.2 kg ai/ha, 7 days apart, residues in samples taken just before the second application (i.e. 7 days after the first application) and thus matching GAP, were: 0.08, 0.08, 0.23, 0.33, 0.49, 0.59, 0.68 and 0.96 mg ai/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.41 mg/kg and an HR of 0.96 mg/kg for fluopyram for Onion, Welsh.

Fruiting vegetables, other than Cucurbits

Peppers

The critical GAP in USA for fruiting vegetables is 2× 0.25 kg ai/ha, PHI of 0 days.

In nine trials conducted in USA matching this GAP, fluopyram residues in sweet peppers and chili peppers were: 0.034, 0.086, 0.12, 0.13, 0.14, 0.17, 0.36, 1.1 and 1.2 mg/kg. The highest residue of replicate samples was 1.4 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.14 mg/kg and an HR of 1.4 mg/kg for fluopyram on the Subgroup of Peppers (except Martynia, Okra and Roselle) to replace the previous recommendation for peppers.

For dried chili peppers, using the data set for peppers and a dehydration factor of 10, the Meeting estimated an STMR of 1.4 mg/kg, an HR of 14 mg/kg and recommended a maximum residue level of 30 mg/kg for fluopyram on peppers chili, dried to replace the previous recommendation.

Tomato

The critical GAP in USA for fruiting vegetables is 2× 0.25 kg ai/ha, PHI of 0 days.

In 11 independent trials conducted in USA and matching this GAP, fluopyram residues in tomatoes were: 0.021, 0.06, 0.067, 0.076, 0.11, 0.11, 0.16, 0.17, 0.18, 0.19 and 0.34 mg/kg. The highest residue of replicate samples was 0.37 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.11 mg/kg and an HR of 0.37 mg/kg for fluopyram on tomato (to replace the previous recommendation) and to establish a new maximum residue level of 0.4 mg/kg for cherry tomato based on the previous recommendation for tomato (STMR of 0.09 mg/kg and an HR of 0.23 mg/kg).

Eggplant

Noting that the GAP for fluopyram in USA is for the fruiting vegetables group, including the commodities in the new Codex classification of eggplants and eggplant-like commodities, the Meeting agreed to extrapolate the recommendations for tomatoes to eggplants.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.11 mg/kg and an HR of 0.37 mg/kg for fluopyram on the Subgroup of Eggplants.

Leafy vegetables

Witloof chicory (sprouts)

GAP in Belgium for Witloof chicory in Belgium is for one pre-plant root dip of 0.01 kg ai/hL plus one pre-forcing root collar spray of 0.5 g ai/square metre, PHI of 21 days.

In three trials conducted in Europe matching this GAP, fluopyram residues in sprouts (chicons) were: 0.02, 0.02 and 0.07 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.07 mg/kg for fluopyram on Witloof chicory (sprouts).

Pulses

Dry beans

The GAP in USA and Canada for dried peas and beans (including soya bean) is for foliar applications of up to 0.25 kg ai/ha, PHI of 14 days, with a maximum of 0.5 kg ai/ha/season and that in USA the GAP for soya beans also included a seed treatment of 0.25 mg ai/seed.

In nine trials conducted in USA on dry beans, matching the foliar treatment GAP in USA, fluopyram residues were: < 0.01 (3), 0.011, 0.014, 0.017, 0.027, 0.052 and 0.068 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.014 mg/kg for fluopyram for the Subgroup of Dry beans (except soya bean), to replace the previous recommendations for beans (dry) and lupin (dry).

In 20 trials conducted in USA on soya beans, matching the seed treatment plus foliar treatment GAP in USA, fluopyram residues were: < 0.01 (5), 0.01, 0.012, 0.015, 0.015, 0.019, 0.022, 0.026, 0.028, 0.029, 0.053, 0.069, 0.08, 0.13, 0.15 and 0.21 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.0205 mg/kg for fluopyram for soya bean (dry).

Dry peas

The critical GAP in Canada for dried peas and beans is 2× 0.25 kg ai/ha, PHI of 14 days, with a maximum of 0.5 kg ai/ha/season).

In five trials conducted in USA, fluopyram residues in dry peas were: 0.033, 0.042, 0.058, 0.16 and 0.35 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.058 mg/kg for fluopyram on the Subgroup of Dry peas, to replace the previous recommendations for chick-pea (dry) and lentil (dry).

Root and tuber vegetables

Potato

The critical GAP in USA for tuber and corm vegetables (including potatoes) is for an in-furrow soil treatment (0.25 kg ai/ha) at planting followed by one foliar application of 0.25 kg ai/ha, PHI 7 days, with a total seasonal application rate of 0.5 kg ai/ha.

In 14 USA trials matching this GAP, fluopyram residues were: < 0.01 (4), 0.016, 0.017, 0.018, 0.024, 0.03, 0.031, 0.039, 0.046, 0.056 and 0.069 mg/kg. The highest residue of replicate samples was 0.083 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR of 0.021 mg/kg and an HR of 0.083 mg/kg for fluopyram on potato, to replace the previous recommendation.

Stalk and stem vegetables

Artichoke, globe

GAP in Greece for globe artichoke is 3× 0.075 kg ai/ha and a PHI of 7 days.

In two trials conducted in Europe on globe artichokes matching this GAP, fluopyram residues were: 0.1 and 0.15 mg/kg.

In a further six trials matching this GAP but with higher application rates of 0.1 kg ai/ha, residues were: 0.05, 0.09, 0.16, 0.18, 0.21 and 0.29 mg/kg.

When the results of these six trials are proportionally adjusted to match the GAP application rate of 0.075 kg ai/ha rate, the combined data set is: 0.04, 0.07, 0.1, 0.12, 0.14, 0.15, 0.16 and 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.13 mg/kg and an HR of 0.22 mg/kg for fluopyram on Artichoke, globe.

Cereal grains

Barley, oats

The critical GAP for barley and oats in Estonia is one foliar application of 0.078 kg ai/ha, up to BBCH 61 (start of flowering).

In 11 trials, conducted in Europe, on barley matching the GAP in Estonia for barley and oats, fluopyram residues were: < 0.01 (3), 0.012, 0.015, 0.017, 0.025, 0.028, 0.034, 0.079 and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.017 mg/kg for fluopyram on barley and agreed to extrapolate these estimations to oats.

Maize

The critical GAP in USA is for cereal grains (except rice), 2 × 0.25 kg ai/ha foliar applications, PHI of 14 days and a maximum seasonal rate of 0.5 kg ai/ha/season.

In 14 trials conducted in USA matching this GAP, fluopyram residues were: < 0.01 (13) and 0.018 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg for fluopyram on the Subgroup of Maize cereals.

Sweet corn (corn-on-the-cob)

GAP for maize and sweet corn in Hungary is 2 foliar applications of 0.125 kg ai/ha up to the end of flowering (BBCH 69), and a PHI of 14 days.

In European maize trials matching this GAP, residues of fluopyram were all < 0.01 mg/kg (n=16) in samples of cobs+kernels (without husks) taken at about the milk stage (i.e. to represent sweetcorn), 20–51 days after the last application.

The Meeting estimated maximum residue levels of 0.01 (*) mg/kg, an HR of 0.01 mg/kg and an STMR of 0.01 mg/kg for fluopyram for sweet corn (corn-on-the-cob).

Rice

GAP for rice in Thailand is 2 foliar applications of 0.024 kg ai/hL between booting and the start of flowering (up to BBCH 59).

In eight trials conducted in Thailand and Vietnam, matching this GAP, fluopyram residues in rice grain were: 0.3, 0.34, 0.35, 0.56, 0.67, 0.7, 0.9 and 2.7 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg and an STMR of 0.615 mg/kg for fluopyram on rice.

Wheat, rye, triticale

The critical GAP in USA for cereal grains (except rice) is 2× 0.25 kg ai/ha, PHI of 14 days and a maximum seasonal rate of 0.5 kg ai/ha.

In 15 trials conducted in USA matching this GAP, fluopyram residues were: 0.021, 0.038, 0.13, 0.13, 0.15, 0.15, 0.17, 0.19, 0.19, 0.19, 0.22, 0.24, 0.25, 0.3 and 0.72 mg/kg.

The Meeting estimated a maximum residue level of 0.9 mg/kg and an STMR of 0.19 mg/kg for fluopyram on wheat.

The Meeting agreed to extrapolate the wheat results to rye and triticale and estimated maximum residue levels of 0.9 mg/kg and STMRs of 0.19 mg/kg for fluopyram on rye and triticale.

Oilseeds

Cotton seed

The critical GAP in USA for cotton seed is a seed treatment of 0.35 mg ai/seed and an in-furrow soil treatment at planting (0.25 kg ai/ha) followed by one foliar spray of 0.25 kg ai/ha, PHI 30 days, with a total maximum rate of 0.5 kg ai/ha/season.

In 10 trials from USA matching this GAP (seed treatment + in-furrow soil treatment + foliar spray), but using a higher seed treatment rate of 0.5 mg ai/seed), fluopyram residues were: < 0.01, < 0.01, 0.016, 0.023, 0.036, 0.081, 0.14, 0.16, 0.29 and 0.47 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg and an STMR of 0.0585 mg/kg for fluopyram on cotton seed to replace the previous recommendation.

Peanut

The USA GAP for peanut includes options for a pre-plant in-furrow soil treatment (0.25 kg ai/ha), a seed treatment (0.35 mg ai/seed) and/or foliar treatments (0.25 kg ai/ha), a PHI of 7 days and a total seasonal application rate of 0.5 kg ai/ha. The label also states that treated crops must not be fed to livestock.

In trials from USA comparing these treatment options, highest residues of fluopyram were 0.018 mg/kg following 2 foliar treatments (14 trials), 0.06 mg/kg following the in-furrow + foliar treatments (15 trials), 0.11 mg/kg in the seed + in-furrow treatments (12 trials).

In the trials matching the critical USA GAP (seed treatment + foliar spray), but with a higher seed treatment rate of 1.1 mg ai/seed), fluopyram residues in peanut (nutmeat) were (n=9): 0.012, 0.015, 0.032, 0.032, 0.033, 0.042, 0.042, 0.046 and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.033 mg/kg for fluopyram on peanut to replace the previous recommendation.

Sunflower seed

The critical GAP in Canada and USA for sunflower seed is 2 × 0.25 kg ai/ha, PHI of 14 days and a maximum of 0.5 kg ai/ha/season.

In eight independent trials from USA matching this GAP, fluopyram residues in sunflower seeds were: 0.011, 0.02, 0.053, 0.056, 0.076, 0.22, 0.25 and 0.38 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.066 mg/kg for fluopyram on sunflower seed.

Herbs, dried herbs and spices

Basil

The critical GAP in Canada for Herbs (including basil) is 2× 0.25 kg ai/ha, PHI of 0 days and a maximum seasonal rate of 0.5 kg ai/ha.

In three trials conducted in USA and matching the GAP in Canada, fluopyram residues in fresh basil leaves were: 19, 19 and 30 mg/kg. The highest residue of replicate samples was 32 mg/kg.

The Meeting estimated a maximum residue level of 70 mg/kg, an STMR of 19 mg/kg and an HR of 32 mg/kg for fluopyram on basil.

Basil, dry

The critical GAP in Canada for Herbs (including basil) is 2× 0.25 kg ai/ha, PHI of 0 days and a maximum seasonal rate of 0.5 kg ai/ha.

In three trials conducted in USA and matching this GAP, fluopyram residues in dried basil leaves (i.e. after drying in the field for up to 9 days) were: 90, 96 and 180 mg/kg. The highest residue of replicate samples was 187 mg/kg.

The Meeting estimated a maximum residue level of 400 mg/kg, an STMR of 96 mg/kg and an HR of 187 mg/kg for fluopyram on basil, dry.

Dill (seed)

The critical GAP in USA for dill seed is 2× 0.25 kg ai/ha, PHI of 14 days and a maximum seasonal rate of 0.5 kg ai/ha.

In four trials conducted in USA and matching this GAP, fluopyram residues in dill seed were: 9.2, 20, 27 and 30 mg/kg.

The Meeting estimated a maximum residue level of 70 mg/kg and an STMR of 23.5 mg/kg for fluopyram on dill seed.

Hops (dry)

The critical GAP in USA for hops in USA is 2× 0.25 kg ai/ha, PHI of 7 days and a maximum seasonal rate of 0.5 kg ai/ha).

In four trials conducted in USA and matching this GAP, fluopyram residues in dried hops (i.e. oven-dried for 12 hours, hot-air dried for 3.5 hours or air-dried for 24 hours) were: 5.8, 6.7, 14 and 25 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 10.35 mg/kg for fluopyram on hops (dry).

Animal feeds

Bean forage and fodder

The critical GAP for dry beans (except soya beans) in Canada (2× 0.25 kg ai/ha, with a maximum seasonal rate of 0.5 kg ai/ha) includes a statement that except for soya beans, legume forage and vines may be grazed or harvested for livestock feed on the day of application.

In nine trials conducted in USA and matching this GAP, fluopyram residues in bean forage sampled the day of the last application were: 10, 13, 13, 13, 14, 14, 15, 21 and 25 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 14 mg/kg and a highest residue of 25 mg/kg for fluopyram on bean forage.

In these same trials, fluopyram residues in bean hay (i.e. after drying for up to 18 days in the field) fluopyram residues were: 4.1, 8.9, 12, 17, 19, 23, 27, 27 and 29 mg/kg.

The Meeting estimated a median residue of 19 mg/kg, a highest residue of 29 mg/kg and based on a dry matter content of 85% (OECD Livestock Feed Table – soya bean hay), estimated a maximum residue level of 70 mg/kg for fluopyram on bean fodder.

Pea vines and hay

The critical GAP in Canada for dry peas (2× 0.25 kg ai/ha, PHI of 14 days with a maximum seasonal rate of 0.5 kg ai/ha) includes a statement that except for soya beans, legume forage and vines may be grazed or harvested for livestock feed on the day of application.

In five trials conducted in USA and matching this GAP, fluopyram residues in pea vines sampled the day of the last application were: 2.7, 4.6, 5.6, 5.9 and 10 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 5.6 mg/kg and a highest residue of 10 mg/kg for fluopyram on peavines.

In these same trials, fluopyram residues in pea hay (i.e. after drying for up to 10 days in the field) residues were: 14, 17, 18, 30 and 48 mg/kg.

The Meeting estimated a median residue of 18 mg/kg, a highest residue of 48 mg/kg and based on a dry matter content of 88% (OECD Livestock Feed Table), estimated a maximum residue level of 100 mg/kg for fluopyram on pea hay or pea fodder (dry).

Soya bean forage and fodder

The critical GAP in Canada for soya beans is 2× 0.25 kg ai/ha with a maximum of 0.5 kg ai/ha/season and a 7-day livestock withholding period.

In 19 trials conducted in USA and matching the GAP in Canada, fluopyram residues in soya bean forage sampled 7 days after the last application were: 0.36, 1.1, 1.1, 1.1, 1.2, 1.3, 1.9, 2.1, 2.3, 2.3, 2.6, 2.6, 3.2, 3.3, 3.3, 3.7, 4.6, 5.6 and 5.7 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 2.3 mg/kg and a highest residue of 5.7 mg/kg for fluopyram on soya bean forage.

In these same trials, fluopyram residues in soya bean hay (i.e. dried in the field for up to 6 days) were: 1.8, 2.2, 3.0, 3.2, 3.4, 3.6, 4.6, 5.6, 5.9, 6.1, 6.2, 6.5, 7.4, 9.1, 11, 11, 14, 16 and 20 mg/kg.

The Meeting estimated a median residue of 6.1 mg/kg, a highest residue of 20 mg/kg and based on a dry matter content of 85% (OECD Livestock Feed Table), estimated a maximum residue level of 35mg/kg for fluopyram on soya bean fodder.

Barley, oat forage and fodder

In 12 trials conducted in Europe on barley, matching the GAP in Estonia (1 foliar application of 0.078 kg ai/ha up to BBCH61, with no specified livestock withholding interval, fluopyram residues in barley forage sampled on the day of application were: 0.27, 1.0, 1.3, 1.3, 1.5, 1.7, 1.8, 2.0, 2.0, 2.0, 2.0 and 2.1 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 1.75 mg/kg and a highest residue of 2.1 mg/kg for fluopyram on barley forage and agreed to extrapolate these estimations to oat forage.

In barley straw from these same trials, fluopyram residues in samples taken at maturity (35–69 days after treatment) were: 0.018, 0.024, 0.025, 0.054, 0.058, 0.095, 0.097, 0.4, 0.77, 0.81 and 1.1 mg/kg.

The Meeting estimated a median residue of 0.095 mg/kg, a highest residue of 1.1 mg/kg and based on a dry matter content of 89% (OECD Livestock Feed Table), estimated a maximum residue level of 2 mg/kg for fluopyram on barley straw and fodder, agreed to extrapolate these estimations to oat straw and fodder, dry.

Maize forage and fodder

In the trials conducted in USA on maize, matching the GAP in USA for cereal grains except rice (0.25 kg ai/ha, maximum seasonal rate of 0.5 kg ai/ha) and with a livestock withholding interval of 14 days, fluopyram residues in maize forage following treatments up to about the soft dough stage (BBCH 73–87) were (n=3): 1.5, 2 and 3.9 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 2 mg/kg and a highest residue of 3.9 mg/kg for fluopyram on maize forage.

In maize fodder (stover) fluopyram residues in samples taken at maturity, 12-14 days after the last application were (n=14): 1.0, 1.1, 1.1, 1.2, 1.2, 1.5, 1.8, 1.9, 2.1, 2.3, 2.8, 3.0, 4.1 and 13 mg/kg.

The Meeting estimated a median residue of 1.85 mg/kg, a highest residue of 13 mg/kg and based on a dry matter content of 83% (OECD Livestock Feed Table), estimated a maximum residue level of 18 mg/kg for fluopyram on maize fodder (dry).

Rice straw

In 10 trials conducted in Thailand and Vietnam, matching the GAP for rice in Thailand (2 foliar applications of 0.024 kg ai/hL between booting and the start of flowering - BBCH 59), fluopyram residues in rice straw at maturity were: 0.22, 0.74, 0.89, 1.3, 1.6, 3.5, 3.8, 4.0, 6.1 and 6.7 mg/kg.

The Meeting estimated a median residue of 2.55 mg/kg, a highest residue of 6.7 mg/kg and based on a dry matter content of 90% (OECD Livestock Feed Table), estimated a maximum residue level of 17 mg/kg for fluopyram on rice straw and fodder (dry).

Wheat, rye, triticale forage and fodder

In the trials conducted in USA on wheat, matching the GAP in USA for cereal grains except rice (0.25 kg ai/ha, maximum seasonal rate of 0.5 kg ai/ha) and with a livestock withholding interval of 14 days, fluopyram residues in wheat forage following treatments up to the end of stem elongation

(BBCH 21–41) were (n=15): 0.06, 0.14, 0.14, 0.36, 0.51, 0.53, 0.53, 0.56, 0.79, 0.83, 0.94, 1.1, 1.2, 1.3, and 2.9 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 0.56 mg/kg and a highest residue of 2.9 mg/kg for fluopyram on wheat forage and agreed to extrapolate these estimations to rye forage and triticale forage.

In wheat hay, fluopyram residues in samples taken between BBCH 41 and BBCH 83 (to reflect harvesting for hay) but at least 13-15 days after the last application were (n=16): 0.29, 0.32, 0.46, 0.62, 0.7, 0.95, 1.0, 1.5, 2.1, 2.3, 2.6, 3.4, 3.5, 4.9, 5.0 and 5.4 mg/kg.

In wheat straw, fluopyram residues in samples taken at maturity, 13-15 days after the last application were (n=15): 0.85, 0.87, 0.99, 3.2, 3.3, 4.0, 4.7, 4.8, 5.2, 5.3, 5.7, 6.9, 7.3, 8.9 and 12 mg/kg.

Based on the results for wheat straw, the Meeting estimated a median residue of 4.8 mg/kg, a highest residue of 12 mg/kg and based on a dry matter content of 88% (OECD Livestock Feed Table), estimated a maximum residue level of 23 mg/kg for fluopyram on wheat straw and fodder dry and agreed to extrapolate these estimations to rye straw and fodder, dry and to triticale straw and fodder, dry.

Peanut hay

The critical GAP in Canada for peanuts is 2 foliar applications of 0.25 kg ai/ha with a maximum seasonal rate of 0.5 kg ai/ha and with a livestock withholding interval of 7 days.

In 13 trials matching this GAP, residues of fluopyram in peanut hay were: 1.2, 2.7, 2.9, 3.7, 4.1, 4.2, 5.4, 6.7, 9.1, 11, 18, 19 and 21 mg/kg.

The Meeting estimated a median residue of 5.4 mg/kg, a highest residue of 21 mg/kg and based on a dry matter content of 85% (OECD Livestock Feed Table), estimated a maximum residue level of 47 mg/kg for fluopyram on peanut hay.

Cotton gin trash

In six trials conducted in USA matching the critical GAP in USA for cotton seed (seed treatment of 0.35 mg ai/seed plus an in-furrow soil treatment at planting (0.25 kg ai/ha) followed by one foliar spray of 0.25 kg ai/ha, PHI 30 days, with a total maximum rate of 0.5 kg ai/ha/season, residues of fluopyram in cotton gin by-products were: < 0.01, 2.5, 3.9, 6.8, 7.3 and 14 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a maximum residue level of 30 mg/kg, a median residue of 5.4 mg/kg and a highest residue of 14 mg/kg for fluopyram on cotton gin trash.

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.

In addition to the processing studies evaluated by the 2010 JMPR, the Meeting received a processing study on rice. Fluopyram residues decreased during the processing of rice grain (removal of the hulls) to brown rice and after polishing (white rice). Residues in bran were about the same as in the whole grain and higher levels were reported in hulls. Residues in cooked polished rice were also significantly lower than in uncooked polished rice.

Relevant processing factors and STMR-Ps for the commodities considered at this Meeting and used for dietary exposure risk assessment or for estimating livestock animal burdens are summarised below.

Raw agricultural commodity STMR [HR] mg/kg	Processed commodity	Calculated processing factors [a]	Processing factor (mean or median)	STMR-P [HR-P] (mg/kg)
Orange	Peel	1.8	1.8	0.27 [0.67]
STMR: 0.15 mg/kg	Flesh	0.16	0.16	0.024 [0.059]
HR: 0.37 mg/kg	Juice	0.01	0.01	0.0015
	Oil	16	16	2.4
Tomato	Washed fruit	0.32, 0.51, 0.67, 0.92, 0.94	0.67	0.074 [0.25]
STMR: 0.11 mg/kg	Juice	0.09, 0.27, 0.42, 0.44, 0.56	0.36	0.04
HR: 0.37 mg/kg	Pulp	0.08, 0.09, 0.11, 0.13	0.1	0.011
	Preserve	0.07, 0.18, 0.21, 0.25, 0.33	0.21	0.023
	Puree	0.18, 0.46, 0.73, 0.94, 2.2	0.73 (median)	0.08
	Paste	0.46	0.46	0.051
Soya bean	Meal	0.05	0.05	0.001
STMR: 0.019 mg/kg	Refined oil	0.02	0.02	0.00041
	Flour	0.04	0.04	0.00082
	Soymilk	< 0.02	< 0.02	0.00041
	Asp grain fraction	223	223	4.6
Potato	Washed tubers	0.7	0.7	0.015 [0.058]
STMR: 0.021 mg/kg	Peeled tubers	< 0.64	< 0.64	0.013 [0.053]
HR: 0.083 mg/kg	Chips	< 0.64	< 0.64	0.013
	Flakes	1	1	0.021
	Wet peel	4.3	4.3	0.09
Maize	Grits	0.51	0.51	0.051
STMR: 0.01 mg/kg	Meal	0.81	0.81	0.0081
	Flour	0.85	0.85	0.0085
	Bran	2.7	2.7	0.027
	Starch	0.36	0.36	0.0036
	Oil (wet milled)	0.58	0.58	0.0058
	Oil (dry milled)	< 0.36	< 0.36	0.0036
	Asp grain fraction	161	161	16
Rice	Brown rice	0.24, 0.34	0.29	0.178
STMR: 0.615 mg/kg	Polished rice	0.1, 0.12	0.11	0.0676
	Cooked rice	0.04, 0.04	0.04	0.0246
	Rice hulls	1.9, 2.2	2	1.23
	Rice bran	1.0, 1.1	1.1	0.68
Wheat	Wheat bran	2.7	2.7	0.51
STMR: 0.19 mg/kg	Middlings	0.34	0.34	0.065
	Shorts	0.75	0.75	0.14
	Flour	0.12	0.12	0.023
	Asp grain fraction	70	70	13
	Wheat germ	2.4	2.4	0.46
Cotton seed	Oil (refined)	< 0.01	< 0.01	0.000585

Raw agricultural commodity STMR [HR] mg/kg	Processed commodity	Calculated processing factors [a]	Processing factor (mean or median)	STMR-P [HR-P] (mg/kg)
STMR: 0.0585 mg/kg	Meal	0.022	0.022	0.001287
Peanut	Nuts (roasted)	0.26	0.26	0.0086
STMR: 0.033 mg/kg	Meal	0.19	0.19	0.0063
	Butter	0.22	0.22	0.0073
	Oil	0.01	0.01	0.00033
Sunflower seed	Oil (refined)	< 0.01	< 0.01	0.00066
STMR: 0.066 mg/kg	Meal	0.02	0.02	0.0013

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

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of fluopyram in farm animals were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual.

	Animal dietary burden, fluopyram, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	4.1	2.8	28	9.5	65[a]	32[c]	4.3	1.8
Dairy cattle	14	6.1	36	14	55[b]	31[d]	5.2	2.7
Poultry – broiler	0.37	0.37	0.41	0.32	0.57	0.57	0.079	0.079
Poultry – layer	0.37	0.37	9.0[eg]	3.1[fh]	0.57	0.57	0.2	0.2

[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 2010 JMPR.

For maximum residue estimation, the high residues of fluopyram and BZM (expressed as fluopyram equivalents) were calculated by interpolating the maximum dietary burden (65 ppm) from the 44:133 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 exposure estimation.

The STMR values for the tissues were calculated by interpolating the STMR dietary burden (32 ppm from the from the 14.4:44 ppm 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 (55 ppm) from the 44:133 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 (32 ppm) from the 14.4:44 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
MRL beef or dairy cattle ((fluopyram + BZM)							
Feeding study (1)	44 133	0.62 1.42	44 133	0.83 1.53	6.0 11	0.93 1.68	0.78 1.81
Dietary burden/residue estimate	55[d]	**0.72**	65[c]	**1**	**7.2**	**1.1**	**1**
High residue beef or dairy cattle (fluopyram + BZM + Total olefins)							
Feeding study [a]			44 133	0.86 1.57	6.13 11.6	0.97 1.83	1.1 2.75
Dietary burden/residue estimate			65[c]	**1**	**7.4**	**1.2**	**1.5**
STMR beef or dairy cattle ((fluopyram + BZM + Total olefins)							
Feeding study [b]	14.4 44	0.27 0.65	14.4 44	0.32 0.64	1.96 4.99	0.41 0.79	0.31 0.91
Dietary burden/residue estimate	31[f]	**0.48**	32[e]	**0.51**	**3.8**	**0.6**	**0.67**

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

[b] Mean residues for tissues and for milk

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

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

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

[f] Highest mean dairy cattle dietary burden suitable for STMR estimates 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: 1 mg/kg (fat), 1 mg/kg (muscle), 7.2 mg/kg (liver) and 1.1 mg/kg (kidney) and the mean residue for milk is 0.72 mg/kg.

The Meeting estimated maximum residue levels of 1.5 mg/kg for fluopyram in meat (from mammals other than marine mammals), 1.5 mg/kg for mammalian fat, 8 mg/kg for edible offal (mammalian) and 0.8 mg/kg for milks to replace the existing recommendations and agreed to withdraw the previous recommendations for meat (from mammals other than marine mammals), liver and kidney of cattle, goats, pigs and sheep, and milks.

Estimated HRs for dietary exposure estimation for fluopyram (and including residues of BZM and total olefins) are 1.5 mg/kg for mammalian fat, 1 mg/kg for mammalian muscle, 7.4 mg/kg for liver and 1.2 mg/kg for kidney.

Estimated STMRs for dietary exposure estimation for fluopyram (and including residues of BZM and total olefins) are 0.67 mg/kg for mammalian fat, 0.51 mg/kg for mammalian muscle, 3.8 mg/kg for liver, 0.6 mg/kg for kidney and 0.48 mg/kg for milks

Poultry

The dietary maximum and mean burdens for poultry broilers are 0.57 ppm but the Meeting decided to estimate residue levels in poultry tissues using the higher mean/maximum dietary burden in poultry layers (3.1 pm and 9 ppm respectively) as they may also be consumed.

In the 28-day poultry feeding study evaluated by the 2010 JMPR, in hens dosed with 4.8 ppm fluopyram in the diet, maximum residues of fluopyram+BZM (for estimating maximum residue levels) were 0.72 mg/kg, (eggs), 0.33 mg eq/kg (muscle), 0.64 mg eq/kg (fat) and 1.6 mg eq/kg (liver). Maximum residues of fluopyram+BZM+olefins (for estimating HRs) were 0.95 mg eq/kg (eggs), 0.39 mg eq/kg (muscle), 0.72 mg eq/kg (fat) and 1.6 mg eq/kg (liver). Mean fluopyram-equivalent residues of fluopyram+BZM (for estimating a maximum residue level for eggs) were 0.72 mg eq/kg (eggs) and mean residues of fluopyram+BZM+olefins (for estimating STMRs) were 0.74 mg/kg (eggs), 0.31 mg/kg (muscle), 0.46 mg/kg (fat) and 1.42 mg/kg (liver).

In the 1.6 ppm dose group, mean residues of fluopyram+BZM+olefins (for estimating STMRs) were 0.22 mg/kg (eggs), 0.09 mg eq/kg (muscle), 0.12 mg eq/kg (fat) and 0.41 mg eq/kg (liver).

The Meeting noted that the maximum dietary burden of 9 ppm for poultry layers was about twice the highest dose of 4.8 ppm used in the poultry feeding study and agreed to estimate revised maximum residue levels for poultry tissues and eggs by interpolating between the highest feeding study dose level (4.8 ppm) and the 26 ppm dose used in the 14-day poultry metabolism study (phenyl-label) evaluated by the 2010 JMPR.

In this metabolism study, residues of fluopyram+BZM were 3.47 mg/kg (eggs), 3.23 mg/kg (muscle), 1.17 mg/kg (fat) and 8.74 mg/kg (liver). Total residues (fluopyram+BZM+olefins) were 3.52 mg/kg (eggs), 3.25 mg/kg (muscle), 1.63 mg/kg (fat) and 8.78 mg/kg (liver).

For estimating STMRs, the Meeting agreed to extrapolate the results of the 1.6 ppm and the 4.8 ppm dose groups in the poultry feeding study.

Tissue concentrations of fluopyram plus BZM (fluopyram equivalents) were used for estimating maximum residue levels and concentrations of fluopyram, BZM plus total olefins (fluopyram equivalents) were used for dietary exposure estimation.

	Feed level for eggs (ppm)	Residues in eggs (mg/kg)	Feed level for tissues (ppm)	Residues (mg/kg)		
				Muscle	Liver	Skin with Fat
MRL broiler or laying hen (fluopyram + BZM)						
Feeding study [a]	4.8 26	0.72 3.47	4.8 26	0.33 3.23	1.6 8.74	0.64 1.17
Dietary burden/residue estimate	9[e]	**1.3**	9[c]	**0.91**	**3**	**0.75**
High residue broiler or laying hen (fluopyram + BZM + Total olefins)						
Feeding study [a]	4.8 26	0.95 3.47	4.8 26	0.39 3.25	1.6 8.78	0.72 1.63
Dietary burden/residue estimate	9[c]	**1.4**	9c	**0.93**	**3**	**0.9**
STMR broiler or laying hen (fluopyram + BZM + Total olefins)						
Feeding study [b]	1.6 4.8	0.22 0.74	1.6 4.8	0.09 0.31	0.41 1.42	0.12 0.46
Dietary burden/residue estimate	3.1[f]	**0.46**	3.1[d]	**0.19**	**0.88**	**0.28**

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

[b] Mean residues for tissues and for eggs

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

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

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

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry 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: 0.75 mg/kg (fat), 0.91 mg/kg (muscle), 3 mg/kg (liver) and 1.3 mg/kg (eggs).

The Meeting estimated maximum residue levels of 1.5 mg/kg for fluopyram in poultry meat, 1 mg/kg for poultry fat, 5 mg/kg for poultry edible offal and 2 mg/kg for eggs, to replace the previous recommendations.

Estimated HRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.9 mg/kg for poultry fat, 0.95 mg/kg for poultry muscle, 1.4 mg/kg for eggs and 3 mg/kg for poultry edible offal.

Estimated STMRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.28 mg/kg for poultry fat, 0.19 mg/kg for poultry muscle, 0.88 mg/kg for poultry edible offal and 0.46 mg/kg for eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for compliance with the MRL and for the estimation of dietary exposure for plant commodities: *fluopyram*

Definition of the residue for compliance with the MRL for animal commodities: *Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram*

Definition of the residue for the estimation of dietary exposure for animal commodities: *Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues of 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.

DIETARY RISK ASSESSMENT

Long-term exposure

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 17 GEMS/Food regional diets, based on estimated STMRs were 10–80% of the maximum ADI of 0.01 mg/kg bw (Annex 3). The Meeting concluded that the long-term dietary exposure to residues of fluopyram from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term exposure

The International Estimated Short-term Intakes (IESTIs) for fluopyram were calculated for the food commodities for which STMRs or HRs were estimated by the current and previous meetings and for which consumption data were available (Annex 4).

For fluopyram the IESTI varied from 0–100% of the ARfD (0.5 mg/kg bw) and the Meeting concluded that the short-term dietary exposure of residues of fluopyram from uses considered by the JMPR is unlikely to present a public health concern.