5.16 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 2012 JMPR and a number of additional maximum residue levels were recommended.

Residue definitions established by the 2010 JMPR are:

- For plant products (compliance with MRLs and dietary intake assessment): *fluopyram*
- For animal products (compliance with MRLs*): sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram*
- For animal products (dietary intake assessment): *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.*

New GAP information and supporting residue data were provided by the manufacturer for evaluation by the Meeting.

Results of supervised residue trials in crops

The Meeting received new supervised trial data for foliar applications of fluopyram (SC formulations) on plum, peach, apricot, raspberry, onion, leek, Brussels sprouts, cabbage, cauliflower, melon, lettuce, asparagus and oilseed rape and noted that data for some of these crops had also been provided to the 2010 JMPR. New supervised trial data were also provided for watermelon and currants, but because no GAP information was available for these crops, these data were not considered by the Meeting.

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 for which GAP information was available. The proportionality approach was used to scale the results from trials where the application rates range from 0.33 × GAP to 4 × GAP and where all other parameters matched the critical GAP). Frozen sample storage times in the new trials were within the storage intervals considered acceptable by the 2010 JMPR.

Stone fruit

Results from supervised field trials on apricots, peaches and plums conducted in Europe were considered by the Meeting, including some data for peaches that were also provided to the 2010 JMPR.

Peaches (sub-group 003C)

The critical GAP for apricots is in Greece, up to two applications of 0.15 kg ai/ha, 7–14 days apart with a PHI of 3 days. No trials were available matching this GAP. In trials from Europe where apricots were treated with 2 × 0.21–0.25 kg ai/ha fluopyram, residues at 3 DALA (days after the last application) were: 0.16, 0.2, 0.33, 0.38, 0.43, 0.46, 0.58 and 0.95 mg/kg. When proportionally adjusted to the 0.15 kg ai/hL GAP application rate (scaling factors of 0.6–0.75), fluopyram residues in apricots from these trials were: 0.12, 0.14, 0.22, 0.26, 0.27, 0.28, 0.35 and 0.69 mg/kg (n=8).

For peaches, the 2012 JMPR recommended a maximum residue level of 0.4 mg/kg based trials from Southern Europe proportionally adjusted to the GAP in Turkey (0.005 kg ai/hL, PHI 3 days).

The Meeting was advised that new GAP existed in Europe, with a new critical GAP (Greece) of up to two applications of 0.15 kg ai/ha, 7–14 days apart and a PHI of 3 days. No trials were available matching this new GAP. In trials from Europe where peaches were treated with 2 × 0.21–0.25 kg ai/ha fluopyram, residues at 3 DALA were: 0.2, 0.26, 0.28, 0.28, 0.31, 0.36, 0.63 and 0.73 mg/kg. When proportionally adjusted to the 0.15 kg ai/ha GAP application rate (scaling factors of 0.6–0.75), fluopyram residues in peaches from these trials were: 0.12, 0.16, 0.17, 0.17, 0.19, 0.22, 0.45 and 0.53 mg/kg (n=8).

The Meeting noted that the medians of the data sets for apricots and peaches differed by less than 5-fold and agreed to consider a group maximum residue level for peaches (subgroup 003C) since GAP exists in Europe for all crops within this subgroup. In deciding on the data set to use for estimating a group maximum residue level, since a Mann-Whitney U-test indicated that the residue populations for apricots and peaches were not different it was agreed to combine the results to give a data set of 0.12, 0.12, 0.14, 0.16, 0.17, 0.17, 0.19, 0.22, 0.22, 0.26, 0.27, 0.28, 0.35, 0.45, 0.53 and 0.69 mg/kg (n=16)

The Meeting estimated a group maximum residue level of 1 mg/kg, an STMR of 0.22 mg/kg and an HR of 0.69 mg/kg for fluopyram on peaches (subgroup 003C) and to recommend withdrawal of the previous maximum residue level recommendation of 0.4 mg/kg for peach.

Plums (sub-group 003B)

The critical GAP for plums is in Greece, up to three applications of 0.1 kg ai/ha with a PHI of 3 days. In trials from Europe matching the GAP in Greece, residues were: 0.08, 0.1, 0.1, 0.13, 0.13, 0.14, 0.16, 0.18, 0.2, 0.2 and 0.22 mg/kg (n=11).

The Meeting estimated a sub-group maximum residue level of 0.5 mg/kg, an STMR of 0.13 mg/kg and an HR of 0.22 mg/kg for fluopyram on plums (subgroup 003B).

Berries and small fruit

Results from supervised trials on outdoor and protected raspberries conducted in Europe and outdoor raspberries were provided to the Meeting.

Cane berries

The critical GAP for small berries (including blackberries and raspberries) is in South Africa, up to two applications of 0.25 kg ai/ha, 10–14 days apart, with a PHI of 3 days. In trials from Europe where protected raspberries were treated with 2 × 0.2 kg ai/ha fluopyram, residues at 3 DAT were: 0.51, 0.69, 0.7 and 1.2 mg/kg (n=4).

Since the South African GAP does not exclude use on protected crops the Meeting agreed to use the European trial results on protected raspberries matching the GAP in South Africa to estimate a maximum residue level of 3 mg/kg, an STMR of 0.7 mg/kg and an HR of 1.2 mg/kg for fluopyram on raspberries and agreed to extrapolate these estimations to blackberries.

Bulb vegetables

Results from supervised field trials on bulb onions and leeks in Europe and bulb onions in USA were considered by the Meeting, including some data that were also provided to the 2010 JMPR.

Onion (bulb)

The critical GAP in Northern Europe for bulb onions is in Germany, a maximum of two applications of 0.1 kg ai/ha, with a PHI of 7 days. In trials in Europe matching the GAP in Germany, fluopyram residues in onion bulbs were: < 0.01 (3), ≤ 0.01, 0.01, 0.02, 0.03 and 0.04 mg/kg (n=8).

GAP for bulb onions exists in Southern Europe (Greece and Spain), a maximum of one application of 0.2 kg ai/ha with a PHI of 7 days. In trials in Europe matching this GAP, fluopyram residues in onion bulbs were: < 0.01 (6), 0.03 and 0.04 mg/kg (n=8).

The Meeting agreed to use the results matching the GAP in Germany to estimate a maximum residue level, noting that this would accommodate the GAP in Greece and Spain.

The Meeting estimated a maximum residue level of 0.07 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.04 mg/kg for fluopyram on onion (bulb).

Garlic

The Meeting noted that the GAP for onions in Greece and Spain also applied to garlic and agreed to extrapolate the results of the European onion trials matching this GAP to garlic and estimated a maximum residue level of 0.07 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.04 mg/kg for fluopyram on garlic.

Leek

The critical GAP for leeks is in Germany and Switzerland, a maximum of one application of 0.2 kg ai/ha, with a PHI of 21 days. In trials in Europe matching this GAP, fluopyram residues in leeks were: < 0.01 (4),, 0.01, 0.03, 0.06 and 0.07 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.07 mg/kg for fluopyram on leek.

Brassica vegetables

Results from supervised field trials on broccoli, Brussels sprouts, head cabbage and cauliflower in Europe were considered by the Meeting, including some data that were also provided to the 2010 JMPR.

Broccoli

The critical GAP for broccoli (flowerhead brassicas) is in Germany, a maximum of two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. In trials on broccoli in Europe matching this GAP, fluopyram residues in broccoli were: < 0.01, < 0.01, 0.02, 0.03, 0.05, 0.05, 0.06, 0.13 and 0.14 mg/kg (n=9).

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.14 mg/kg for fluopyram on broccoli.

Cauliflower

In trials on cauliflowers in Europe matching the GAP in Germany for cauliflower (flower head Brassicas), up to two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. fluopyram residues were: < 0.01 (4), 0.01 (5), 0.02, 0.05, 0.05 and 0.05 mg/kg (n=13).

The Meeting estimated a maximum residue level of 0.09 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.05 mg/kg for fluopyram on cauliflower.

Brussels sprouts

The critical GAP for Brussels sprouts is in Germany, a maximum of two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. In trials in Europe matching this GAP, fluopyram residues in Brussels sprouts were: 0.01, 0.04, 0.04, 0.04, 0.04, 0.05, 0.07, 0.07, 0.07, 0.09, 0.14 and 0.15 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.06 mg/kg and an HR of 0.15 mg/kg for fluopyram on Brussels sprouts.

Cabbages, head

The critical GAP for head cabbages is in Germany, a maximum of two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. In trials in Europe matching this GAP, fluopyram residues in cabbage heads were: < 0.01 (4), 0.01, 0.01, 0.01, 0.02, 0.02, 0.04 and 0.08 mg/kg (n=11).

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.08 mg/kg for fluopyram on cabbage, head.

Fruiting vegetables, Cucurbits

Results from supervised field trials on protected melons and on field melons in Europe, USA and Australia were considered by the Meeting, including some data that were also provided to the 2010 JMPR.

Melons (except watermelon)

The critical GAP for melons is in South Korea, up to three applications of 0.225 kg ai/ha, 10 days apart, with a PHI of 3 days. Since this GAP does not exclude use on protected crops, the Meeting agreed to consider the data from trials on protected melons in Europe involving three applications of 0.1 kg ai/ha where residues at 3 DAT were < 0.01, 0.02, 0.07 and 0.12 mg/kg. When the results of three of these trials where residues were found above the LOQ are proportionally adjusted to the South Korean GAP (scaling factor of 2.25), fluopyram residues in these trials are: 0.05, 0.06 and 0.27 mg/kg.

The Meeting agreed that these data were not sufficient to estimate a maximum residue level for fluopyram on melons (except watermelon).

Leafy vegetables, including brassica leafy vegetables

Lettuce

The critical GAP for lettuce is in Netherlands, up to two applications of 0.25 kg ai/ha, 7 days apart, with a PHI of 7 days.

In outdoor lettuce trials in Europe matching this GAP, fluopyram residues in head lettuce were 0.12, 0.13, 0.57, and 0.63 mg/kg and in leaf lettuce were 0.18, 0.18, 0.25, 0.26, 0.27, 0.53, 0.61, 0.62 and 0.93 mg/kg.

In protected lettuce matching the GAP in Netherlands, fluopyram residues in head lettuce were 0.23, 1.4, 1.9, 2.1, 2.5 and 7.7 mg/kg and in leaf lettuce were 0.16, 0.81, 0.92, 1.2, 2.3, 2.7, 3.8, 4.4, 7.2 and 8.4 mg/kg.

The Meeting noted that highest residues were in protected lettuce and since the data sets for leaf and head lettuce were not from different populations (Mann Whitney), agreed to use the combined data set for protected head and leaf lettuce to estimate maximum residue levels for leaf and head lettuce.

The combined data set of results from the protected lettuce trials matching the GAP in Netherlands is: 0.16, 0.23, 0.81, 0.92, 1.2, 1.4, 1.9, 2.1, 2.3, 2.5, 2.7, 3.8, 4.4, 7.2, 7.7 and 8.4 mg/kg (n=16).

The Meeting estimated maximum residue levels of 15 mg/kg, STMRs of 2.2 mg/kg and HRs of 8.4 mg/kg for fluopyram on lettuce, head and lettuce, leaf.

Stalk and stem vegetables

Asparagus

The critical GAP for asparagus is in Switzerland, up to two applications of 0.2 kg ai/ha, applied to mature ferns prior to senescence, about 6 months or more before the new spears emerge. In four European trials matching this GAP, fluopyram residues in the new spears were all < 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0 mg/kg and an HR of 0 mg/kg for fluopyram on asparagus.

Oilseeds

Rape seed

The critical GAP for oilseed rape is in Ukraine, up to two applications of 0.113 kg ai/ha with a PHI of 30 days. Fluopyram residues in rape seed from European trials matching this GAP were: 0.07, 0.1, 0.14, 0.25, 0.27, 0.27, 0.29, 0.33, 0.34, 0.35, 0.38, 0.38, 0.46, 0.46 and 0.61 mg/kg (n=15).

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.33 mg/kg for fluopyram on rape seed.

Animal feeds

Oilseed rape, forage

The Meeting noted that the GAP for fluopyram in Europe is for use on oilseed rape over the flowering period or at early maturity (up to 30 days before harvest). The use of oilseed rape as a forage crop is normally earlier in the season, up to about BBCH 39, prior to the first application of fluopyram and the Meeting concluded that the reported GAP for fluopyram is not relevant for the use of oilseed rape as an animal forage crop.

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 summarised below.

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

Raw agricultural commodity	Processed commodity	Processing factors [a] (mean or median)	RAC (mg/kg)		STMR-P (mg/kg)	HR-P (mg/kg)
			STMR	HR		
Cabbage			0.01	0.14		
	Cooked washed heads	< 0.36			0.004	0.05
Plums			0.13	0.22		
	Dried fruit	1.1			0.14	0.24

Raw agricultural commodity	Processed commodity	Processing factors [a] (mean or median)	RAC (mg/kg)		STMR-P (mg/kg)	HR-P (mg/kg)
			STMR	HR		
Rape seed			0.33			
	Oil (refined)	0.71			0.23	
	Meal	0.69			0.23	

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

Animal commodity maximum residue levels

Cattle

The two new cattle feed commodities considered by the Meeting (rape meal and cabbage leaves) increased these dietary burdens by less than 1.5% and the Meeting agreed that the maximum residue levels, STMRs and HRs estimated by the 2012 JMPR for animal commodities did not need to be revised.

Poultry

The new poultry feed commodity considered by the Meeting (rape meal) increased the maximum dietary burden by less than 1% and increased the mean dietary burden by 11%. The Meeting agreed that the maximum residue levels and HRs estimated by the 2012 JMPR for poultry commodities did not need to be revised.

RECOMMENDATIONS

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

Definition of the residue for compliance with the MRL and for the estimation of dietary intake 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 intake for animal commodities: *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*.

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 to the 2014 Report.

The International Estimated Daily Intakes of fluopyram for the 17 GEMS/Food regional diets, based on estimated STMRs were 3–20% 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 to the 2014 Report).

For fluopyram the IESTI varied from 0–100% 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.