RECOMMENDATIONS FURTHER WORK OR INFORMATION

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

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

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

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The 2011 JMPR established an Acceptable Daily Intake (ADI) of 0–0.01 mg/kg bw for flutriafol.

The evaluation of flutriafol resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 17 GEMS/Food Consumption Cluster Diets. The results are shown in Annex X.

The IEDIs in the seventeen Cluster Diets, based on the estimated STMRs were 3–10% of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term intake of residues of flutriafol from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2011 JMPR established an Acute Reference Dose (ARfD) of 0.05 mg/kg bw for flutriafol. The International Estimated Short-term Intake (IESTI) for flutriafol was calculated for raw and processed commodities for which maximum residue levels, HR and STMR values were estimated. The results are shown in Annex X to the 2015 Report.

The IESTI represented greater than 100% of the ARfD of 0.05 mg/kg bw in the case of leaf lettuce (360% children; 120% general population), mustard greens (350% children; 140% general population) and spinach (490% children; 150% general population). No alternative GAP was available. On the basis of information provided to the JMPR, the Meeting concluded that the short-term intake of residues of flutriafol from consumption of leaf lettuce, mustard greens and spinach may present a public health concern.

Estimates of intake for the other commodities considered by the 2015 JMPR were within 0–90% of the ARfD. The Meeting concluded that the short-term intake of flutriafol for these other commodities considered is unlikely to present a public health concern when flutriafol is used in ways that considered by the Meeting.

5.17 FLUXAPYROXAD (256)

RESIDUE AND ANALYTICAL ASPECTS

Fluxapyroxad was first evaluated for residues and toxicological aspects by the 2012 JMPR. The 2012 Meeting established an ADI of 0–0.02 mg/kg bw and an ARfD of 0.3 mg/kg bw for fluxapyroxad. The 2012 Meeting recommended a number of maximum residue levels for fluxapyroxad.

The residue definition was established as *fluxapyroxad* for compliance with MRLs for both plant and animal commodities. For estimation of dietary intake, the residue definition was established as *sum of fluxapyroxad, 3-(difluoromethyl)-N-(3',4',5'-trifluoro-1,1'-biphenyl-2-yl)-1H-pyrazole-4-carboxamide (M700F008), and 3-(difluoromethyl)-1-(β-D-glucopyranosyl)-N-(3',4',5'-trifluoro-1,1'-biphenyl-2-yl)-1H-pyrazole-4-carboxamide (M700F048), expressed as fluxapyroxad* for plant commodities and *sum of fluxapyroxad and 3-(difluoromethyl)-N-(3',4',5'-trifluoro-1,1'-biphenyl-2-yl)-1H-pyrazole-4-carboxamide (M700F008),* expressed as *fluxapyroxad* for animal commodities.

Fluxapyroxad was scheduled by the Forty-sixth Session of the CCPR in 2014 for evaluation of residue data for additional crops by the 2015 JMPR.

Methods of analysis

No new methods of analysis were submitted to the Meeting.

Stability of residues in stored analytical samples

No new storage stability studies were submitted to the Meeting.

Results of supervised residue trials on crops

The Meeting received supervised trial data for foliar application of fluxapyroxad to citrus fruit, cherries, grapes, strawberries, blueberries, raspberries, bananas, papaya, mango, bulb vegetables, Brassica vegetables, cucurbits, leafy vegetables, carrots, radish, celery, rice, tree nuts, sugarcane and cotton, as well as data for seed treatment and in-furrow application to potatoes.

It is noted that a number of crops (bulb vegetables, Brassica vegetables, cucurbits, leafy vegetables, celery, rice, sorghum and cotton) for which the critical GAP considered is a foliar application use pattern in the USA also have seed treatment uses registered, and the same crops could be treated with both a seed treatment and foliar application of fluxapyroxad.

All residue data provided was for the foliar use pattern (no seed treatment data was available). The foliar use patterns involve application much closer to harvest, with multiple applications and much shorter pre-harvest intervals. The Meeting noted that residue data for seed treatment of cotton at rates up to 100 g ai/100 kg seed considered by the 2012 Meeting showed no detectable residues of fluxapyroxad in cottonseed or gin by-products at harvest. Seed treatment uses are therefore not expected to contribute significantly to the residues of fluxapyroxad in harvested commodities. The Meeting therefore considered that maximum residue levels recommended based on the foliar use patterns are sufficient to cover residues arising from seed treatment use alone, or combined seed treatment/foliar use.

For dietary intake assessment, the residues are expressed as the sum of fluxapyroxad, M700F008, and M700F048, expressed as fluxapyroxad (total residues). Residues of the metabolites are reported as parent equivalents.

The method LOQ was 0.01 mg/kg for each analyte as measured, or 0.01, 0.02, 0.01 and 0.01 mg/kg as parent equivalents for parent, M700F002, M700F008, and M700F048 respectively. The treatment of residues < LOQ for the purpose of summing residue components is illustrated in the table below.

Residues, mg/kg parent equivalents			Total (sum of fluxapyroxad, M700F008, and M700F048)
Fluxapyroxad	M700F008	M700F048	
0.10	< 0.01	< 0.01	0.10
< 0.01	< 0.01	< 0.01	< 0.01
< 0.01	0.03	< 0.01	0.03

Citrus fruits

The maximum GAP for the citrus fruit group is in Argentina, with 3× 0.0033 kg ai/hL applications, with a maximum spray volume of 5000 L/ha, giving a per hectare rate of 0.165 kg ai/ha, and a pre-harvest interval of 7 days. No trials matching that GAP were available.

The GAP in Brazil is 3× 0.0025 kg ai/hL applications at 7-day intervals, with a spray volume of 2000 L/ha (0.05 kg ai/ha), with a 14-day PHI.

Residue trials in oranges, lemons and limes in accordance with the Brazilian GAP were undertaken in Brazil and Argentina.

Residues of fluxapyroxad (parent only) in oranges (whole fruit) at a 14-day PHI were 0.03, 0.04, 0.05 (2), 0.06 (2), 0.07, 0.14 (2), 0.16, and 0.17 mg/kg.

Total residues in whole oranges were 0.03, 0.04, 0.05 (2), 0.06 (2), 0.07, 0.14 (2), 0.16, and 0.17 mg/kg.

Residue data in peel and pulp were available for some of the trials.

Total residues of fluxapyroxad in pulp (edible portion) in oranges (4 trials) and lemons (2 trials) were < 0.01 (6) mg/kg.

The Meeting concluded that there was sufficient edible portion data on which to estimate the STMR and HR for oranges.

The Meeting estimated a maximum residue level of 0.3 mg/kg for fluxapyroxad in oranges, sweet, sour, together with an STMR and an HR of 0.01 mg/kg (based on the edible portion data).

Residues of fluxapyroxad (parent only and total residues) in whole lemons at a 14-day PHI were 0.09 and 0.13 mg/kg.

Residues of fluxapyroxad (parent only and total residues) in limes at a 14-day PHI were 0.04 and 0.06 mg/kg.

The Meeting concluded that there were insufficient data available to estimate maximum residue levels for fruits other than oranges in the citrus fruit group.

Stone fruits

The critical GAP for the stone fruit group is in the USA, with 3× 0.123 kg ai/ha applications at 7-day intervals, and a 0-day pre-harvest interval.

Residue data in peaches, plums and cherries was considered by the 2012 Meeting in conjunction with the above GAP, and a group maximum residue level of 2 mg/kg was estimated for stone fruit.

A request was received by the present Meeting to reconsider the MRL for cherries, with a view to establishing a higher limit to facilitate trade, noting that the highest residue for stone fruit (in cherries) was 1.9 mg/kg. No new data for stone fruit were provided to the current Meeting: two cherry trials were submitted; however, these were considered by the 2012 Meeting. The 2012-submitted stone fruit data are reconsidered in accordance with the 2013 and 2014 JMPR general considerations relating to group MRLs.

Residues of fluxapyroxad (parent compound) in cherries from supervised trials in accordance with GAP were 0.26, 0.31, 0.55, 0.56, 0.59, 0.82, 1.1, and 1.9 mg/kg.

Total residues in cherries were 0.37, 0.50, 0.72, 0.73, 0.78, 1.1, 1.4, and 2.3 mg/kg.

Residues of fluxapyroxad (parent compound) in peaches from supervised trials in accordance with GAP were 0.28, 0.30, 0.32, 0.33, 0.34, 0.43, 0.45, 0.55, 0.57, 0.58, 0.59, and 0.63 mg/kg.

Total residues in peaches were 0.30, 0.31, 0.33, 0.34, 0.35, 0.45, 0.48, 0.58, 0.62, 0.63, and 0.66 (2) mg/kg.

Residues of fluxapyroxad (parent compound) in plums from supervised trials in accordance with GAP were 0.23, 0.24, 0.27, 0.37, 0.38, 0.49, 0.55, 0.56, 0.64, and 0.95 mg/kg.

Total residues in plums were 0.23, 0.24, 0.27, 0.38, 0.39, 0.49, 0.55, 0.56, 0.64, and 0.95 mg/kg.

The Meeting noted the use in the USA is for the stone fruit crop group. Although the median residues for each fruit differed by less than a factor of five, the Meeting decided to recommend maximum residue levels for the individual sub-groups of stone fruit as there are sufficient trials available for each sub-group. The Meeting estimated a maximum residue level for cherries of 3 mg/kg, together with an STMR and an HR of 0.755 and 2.3 mg/kg respectively. The Meeting estimated a maximum residue level of 1.5 mg/kg for the sub-group peaches, together with an STMR and HR of 0.465 and 0.66 mg/kg respectively. The Meeting estimated a maximum residue level of 1.5 mg/kg for the sub-group plums, together with an STMR and an HR of 0.44 and 0.95 mg/kg. The Meeting withdrew its previous recommendation of 2 mg/kg for stone fruit.

Berries and other small fruits (except grapes)

The critical GAP for bushberries, caneberries, low growing berries, and strawberries is in the USA, with 3× 0.2 kg ai/ha applications at 7-day intervals, and a 0-day pre-harvest interval.

A series of trials in blueberries (highbush type) was conducted in the USA. Residues of fluxapyroxad (parent only) immediately after the last of 3× 0.2 kg ai/ha applications were 1.3, 1.7, 2.4 (2), and 3.8 mg/kg.

Total residues were: 1.3, 1.7, 2.4 (2), and 3.8 mg/kg.

A trial in blackberries was conducted in the USA. Residues of fluxapyroxad (parent only and total residues) immediately after the last of 3× 0.2 kg ai/ha applications were 1.4 mg/kg.

A trial in raspberries was conducted in the USA. Residues of fluxapyroxad (parent only and total residues) immediately after the last of 3 × 0.2 kg ai/ha applications were: 2.0 mg/kg.

In a series of trials in strawberries conducted in the USA, residues of fluxapyroxad (parent only) immediately after the last of 3 × 0.2 kg ai/ha applications were: 0.21, 0.26, 0.76 (2), 0.87, 0.97, 1.0, and 2.3 mg/kg.

Total residues were: 0.22, 0.26, 0.76 (2), 0.87, 0.97, 1.0, and 2.4 mg/kg.

The Meeting noted that the GAPs for the subgroups bushberries, caneberries and low growing berries, and strawberries are the same, and noted that the medians for blueberries and strawberries differed by less than 5× (2.9×) and agreed to consider a group MRL. In determining which datasets to use for estimating the MRL, the Meeting noted that the datasets for blueberries and strawberries were not statistically similar (Mann-Whitney), and, based on the blueberries data set, estimated a maximum residue level of 7 mg/kg for berries and other small fruits (except grapes), together with an STMR and an HR of 2.4 and 3.9 mg/kg (based on the highest residue of duplicate samples) respectively.

Grapes

The critical GAP for grapes is in the USA, with 3× 0.2 kg ai/ha applications at 10-day intervals, and a 14-day pre-harvest interval.

A series of trials was conducted in the USA. Residues of fluxapyroxad (parent only) at a 14-day PHI after 3× 0.2 kg ai/ha applications were 0.11, 0.13, 0.23, 0.43, 0.51, 0.62, 0.71, and 1.4 mg/kg.

Total residues were: 0.11, 0.13, 0.23, 0.43, 0.51, 0.62, 0.71, and 1.4 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg for fluxapyroxad in grapes, together with an STMR and an HR of 0.47 and 1.4 mg/kg respectively.

Tropical fruit—inedible peel

Banana

The critical GAP in bananas is 4× 0.15 kg ai/ha applications at 8-day intervals, with a 0-day pre-harvest interval, in Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Panama. Trials matching GAP and conducted in Brazil, Colombia, and Ecuador were available. Results were reported for both bagged and unbagged fruit for each trial plot; the results for unbagged bananas were considered for estimation of the maximum residue level and dietary risk assessment.

Residues of fluxapyroxad (parent compound) in unbagged bananas (whole fruit) after treatment in accordance with GAP were 0.06, 0.07, 0.08, 0.10, 0.14, 0.15, 0.16, 0.36, 0.66, 0.77, and 1.6 mg/kg.

Total residues of fluxapyroxad in banana pulp (edible portion) were 0.03 (2), 0.05, 0.06, 0.09, and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg for bananas, based on the whole fruit data, and an STMR and an HR of 0.055 and 0.10 mg/kg, based on the edible portion data.

Mango

The critical GAP for mango is in Brazil, with 4× 0.0067 kg ai/hL applications at 7-day intervals, a spray volume of up to 1000 L/ha (giving a maximum per-hectare rate of 0.067 kg ai/ha), and a pre-harvest interval of 7 days.

In trials conducted at GAP in Brazil, residues of fluxapyroxad (parent compound) at a 7-day PHI were 0.14, 0.16, 0.21, and 0.39 mg/kg. Total residues were 0.14, 0.16, 0.21, and 0.39 mg/kg.

The Meeting concluded that there was insufficient data to estimate a maximum residue level for mango.

Papaya

The critical GAP for papaya is in Mexico, with 2× 0.1 kg ai/ha applications at 14-day intervals, and a 7-day pre-harvest interval.

The Meeting concluded that the residue data did not match the GAP (maximum two sprays GAP versus four sprays in the trials).

Bulb vegetables

The critical GAP for the bulb vegetables group is in the USA (3× 0.2 kg ai/ha applications at 7-day intervals and a 7-day pre-harvest interval).

Residue trials were conducted in bulb onions (dry) and green onions.

Residues of fluxapyroxad (parent only) at a 7-day PHI in bulb onions were 0.03, 0.16, 0.23 (2), and 0.27 mg/kg.

Total fluxapyroxad residues were 0.03, 0.16, 0.23 (2), and 0.27 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg for bulb onions, together with an STMR and an HR of 0.23 and 0.28 mg/kg respectively.

The Meeting agreed to extrapolate the maximum residue level, STMR and HR values estimated for bulb onions to garlic and shallot.

Residues of fluxapyroxad (parent only) at a 7-day PHI in green onions were 0.24 and 0.56 mg/kg.

Total fluxapyroxad residues were 0.24 and 0.56 mg/kg.

The Meeting concluded that there were insufficient data to estimate maximum residue levels for other crops in the bulb vegetables group.

Brassica vegetables

The critical GAP for Brassica vegetables is in the USA (3× 0.1 kg ai/ha applications, a re-treatment interval of 7 days, and a pre-harvest interval of 3 days).

Residue data in cabbage and broccoli from trials conducted in the USA in accordance with GAP were available to the Meeting.

Fluxapyroxad was accidentally applied at double the label application rate for one of the broccoli trials. The Meeting noted that the application rate was within the acceptable range of 0.3–4× GAP and that other parameters were in accordance with GAP. The Meeting agreed that this result could be scaled to GAP using proportionality.

Residues of fluxapyroxad (parent only) in broccoli (unscaled results) at a 3-day PHI were 0.17, 0.32, 0.35, 0.57, and 1.2 mg/kg. Total residues were 0.17, 0.34, 0.36, 0.61, and 1.5 mg/kg.

Residues of fluxapyroxad (parent only) in broccoli at a 3-day PHI were 0.17, 0.29 (s), 0.32, 0.35, and 1.2 mg/kg, where (s) indicates a result that was scaled to the proposed GAP.

Total residues in broccoli were 0.17, 0.31 (s), 0.34, 0.36, and 1.5 mg/kg.

Residues of fluxapyroxad (parent only) in cabbage (heads with wrapper leaves) at a 3-day PHI were 0.07, 0.11, 0.13, 0.14, 0.22, and 1.2 mg/kg.

Total residues in cabbage (head with wrapper leaves) were 0.07, 0.11, 0.14 (2), 0.22, and 1.3 mg/kg.

Total residues in cabbage heads (without wrapper leaves) were < 0.01, 0.01, 0.04 (2), 0.05, and 0.07 mg/kg.

The Meeting noted that the GAP was for the Brassica vegetables group and considered a group MRL. The Meeting further noted the similarity of the datasets (median for broccoli was 2.6× the median for cabbage, and agreed to consider a group MRL. In determining which datasets to use for estimating the MRL, the datasets were confirmed to be similar by the Mann-Whitney U test) and it was agreed to combine the datasets for the purpose of estimating a group maximum residue level.

Combined dataset for fluxapyroxad (parent only) in broccoli and cabbage (with wrapper leaves): 0.07, 0.11, 0.13, 0.14, 0.17, 0.22, 0.32, 0.35, 0.57, and 1.2 (2) mg/kg.

Combined dataset for total residues in broccoli and cabbage (with wrapper leaves): 0.07, 0.11, 0.14 (2), 0.17, 0.22, 0.31, 0.34, 0.36, 1.3, and 1.5 mg/kg.

The Meeting estimated a maximum residue level for Brassica vegetables of 2 mg/kg. Based on the data for total residues in cabbages with wrapper leaves removed, the Meeting estimated an STMR and an HR of 0.04 and 0.07 mg/kg respectively for cabbage. Based on the combined total residues data set, the Meeting estimated an STMR and an HR of 0.22 and 1.7 mg/kg respectively.

Fruiting vegetables, Cucurbits

The critical GAP for cucurbit fruiting vegetables is in the USA (3× 0.1 kg ai/ha, with a 7-day retreatment interval and a 0-day pre-harvest interval). Residue trials in excess of GAP (3× 0.2 kg ai/ha applications) were conducted in the USA in cucumber, melon (cantaloupe), and summer squash. Trials in melons, including watermelons were also conducted in Brazil, but these did not match the critical GAP (four applications rather than three, and the rate differed by more than ±30%).

Residue data for the crops at the appropriate PHI are summarised below.

Residues of fluxapyroxad (parent only and total residues) in cucumber: 0.03, 0.17 (2), and 0.24 mg/kg.

Residues of fluxapyroxad (parent only and total residues) in whole melons (other than watermelons): 0.05 (2), 0.08, 0.21, and 0.24 mg/kg.

Residues of fluxapyroxad (parent only and total residues) in summer squash: 0.05, 0.07, 0.10, 0.11, and 0.14 mg/kg.

Data for the three crops when scaled to the US GAP (divide by 2) are summarised below:

Residues of fluxapyroxad (parent only and total residues) in cucumber: 0.015, 0.085 (2), and 0.12 mg/kg.

Residues of fluxapyroxad (parent only and total residues) in melons (other than watermelons): 0.025 (2), 0.04, 0.105, and 0.12 mg/kg.

Residues of fluxapyroxad (parent only and total residues) in summer squash: 0.025, 0.035, 0.05, 0.055, and 0.07 mg/kg.

The Meeting noted that the GAP is for the cucurbit fruiting vegetables group and further noted that the datasets are similar (maximum difference in the median was 2.1×). In determining which datasets to use for estimating the MRL, the similarity of the datasets was confirmed by the Kruskal-Wallis test. The Meeting decided to combine the scaled datasets for the purpose of estimating a group maximum residue level.

The combined dataset for residues of fluxapyroxad (parent only) in cucumber, melon and summer squash is 0.015, 0.025 (3), 0.035, 0.04, 0.05, 0.055, 0.07, 0.085 (2), 0.105, and 0.12 (2) mg/kg.

The combined dataset for total residues in cucurbits (whole fruit) is 0.015, 0.025 (3), 0.035, 0.04, 0.05, 0.055, 0.07, 0.085 (2), 0.105, and 0.12 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for fruiting vegetables, cucurbits, together with an STMR and an HR of 0.0525 and 0.13 mg/kg respectively.

Leafy vegetables

Brassica leafy vegetables

The critical GAP for Brassica leafy vegetables is in the USA (3× 0.1 kg ai/ha applications, a 7-day retreatment interval, and a 3-day pre-harvest interval).

Residue trials in mustard greens were conducted in the USA in accordance with GAP.

Residues of fluxapyroxad (parent only) at a 3-day PHI were 0.48, 0.57, 0.90, 1.7, and 1.9 mg/kg.

Total residues were 0.93, 1.3, 1.7, 2.7, and 3.1 mg/kg.

The Meeting agreed to extrapolate the residue data for mustard greens to the Brassica leafy vegetables subgroup. The Meeting estimated a maximum residue level of 4 mg/kg for brassica leafy vegetables, together with an STMR and an HR of 1.7 and 3.1 mg/kg respectively.

Leafy vegetables (except Brassica leafy vegetables)

The critical GAP for leafy vegetables other than Brassica leafy vegetables is in the USA (3× 0.2 kg ai/ha applications with a retreatment interval of 7 days, and a 1-day pre-harvest interval).

Residue trials in head lettuce, leaf lettuce, and spinach were conducted in the USA in accordance with the cGAP for leafy vegetables (except Brassica leafy vegetables).

Residues of fluxapyroxad (parent only and total residues) at a 1-day PHI in head lettuce were 0.14, 0.47, 0.51, 0.66, and 1.9 mg/kg.

Residues of fluxapyroxad (parent only) in leaf lettuce at a 1-day PHI were 2.7 and 4.4 mg/kg.

Total residues in leaf lettuce were 2.7 and 4.4 mg/kg.

Two of the residue trials reported as leafy lettuce were for cos lettuce varieties.

Residues of fluxapyroxad (parent only) in cos lettuce at a 1-day PHI were 3.3 and 6.2 mg/kg.

Total residues in cos lettuce were 3.4 and 6.2 mg/kg.

Residues of fluxapyroxad (parent only) in spinach at a 1-day PHI were 5.2, 6.0, 6.7, 8.3, and 11.5 mg/kg.

Total residues in spinach were 5.2, 6.3, 6.8, 8.8, and 12.2 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg for head lettuce, together with an STMR and an HR of 0.51 and 2.0 mg/kg respectively.

The Meeting noted that there were insufficient leafy and cos lettuce data for estimation of maximum residue levels.

The Meeting estimated a maximum residue level of 30 mg/kg for spinach, together with an STMR and an HR of 6.8 and 13 mg/kg respectively.

Residue data for radish tops were also available from trials conducted on radish in the USA, in accordance with the GAP for root vegetables (3× 0.1 kg ai/ha, with a 7-day PHI).

Residues of fluxapyroxad (parent only) in radish tops at a 7-day PHI were 0.2 (2), 0.7, 1, and 4 mg/kg.

Total residues in radish tops were 0.4, 0.6, 1.2, 1.7, and 5 mg/kg.

The Meeting estimated a maximum residue level of 8 mg/kg for radish leaves, together with an STMR and HR of 1.2 and 6 mg/kg (based on the highest residue of duplicate samples) respectively.

Short term intake assessment showed that residues in spinach exceed the acute reference dose of 0.3 mg/kg bw, at 180% of the ARfD, for children.

Root and tuber vegetables

The 2012 Meeting considered residue data for potato and sugar beet, in accordance with GAP in the USA (3× 0.1 kg ai/ha foliar applications with 7-day retreatment interval and a 7-day PHI, and maximum residue levels of 0.03 and 0.15 mg/kg were estimated for potato and sugar beet respectively.

The current Meeting received residue data for potato (soil application at planting), carrots and radish (both for foliar applications).

Carrot

The critical GAP for carrots (for the group root and tuber vegetables except sugar beet) is in the USA, at 3× 0.1 kg ai/ha foliar applications, with a 7-day retreatment interval and a 7-day pre-harvest interval.

Trials were conducted in the USA in accordance with GAP.

Residues of fluxapyroxad (parent only and total residues) in carrots at a 7-day PHI were 0.04, 0.05, 0.06, 0.1, and 0.5 mg/kg.

Potato

A series of residue trials was conducted in northern and southern Europe involving a single, at planting, in-furrow application at 0.24 kg ai/ha. However, there are currently no registrations for that GAP. The Meeting therefore was unable to estimate a maximum residue level for potatoes based on at planting soil application.

The 2012 Meeting considered residue data for foliar application to potatoes from trials conducted in accordance with the US GAP for root and tuber vegetables (except sugar beet) group (3× 0.1 kg ai/ha foliar applications, with a 7-day pre-harvest interval).

Residues of fluxapyroxad (parent only and total residues) in potatoes at a 7-day PHI were < 0.01 (17), and 0.02 (2) mg/kg.

Radish

The critical GAP for radish (for the group root and tuber vegetables except sugar beet) is in the USA, at 3× 0.1 kg ai/ha foliar applications, with a 7-day retreatment interval and a 7-day pre-harvest interval.

Trials were conducted in the USA in accordance with GAP.

Residues of fluxapyroxad (parent only and total) in radish roots at a 7-day PHI were 0.03, 0.04, 0.05, and 0.1 (2) mg/kg.

Sugar beet

The critical GAP for sugar beet is in the USA, at 3× 0.1 kg ai/ha foliar applications, with a 7-day retreatment interval and a 7-day pre-harvest interval. Residue data for this GAP was considered by the 2012 Meeting.

Residues of fluxapyroxad (parent only and total residues) in sugar beet roots at a 7-day PHI were 0.01 (2), 0.03 (3), 0.04 (3), 0.05 (2), and 0.06 (2) mg/kg.

The Meeting noted that the critical GAPs for root and tuber vegetables (except sugar beet) and sugar beet were the same, and considered a group maximum residue level.

The Meeting noted that the median residue for potatoes differed from those carrot and radish by > 5-fold (> 6× and > 5× respectively) and concluded that a group maximum residue level was not appropriate. The Meeting confirmed the 2012 recommendation for a maximum residue level, STMR and HR of 0.03, 0.01 and 0.02 mg/kg respectively for fluxapyroxad in potatoes. The Meeting confirmed the 2012 recommendation for a maximum residue level, STMR and HR of 0.15, 0.04, and 0.06 mg/kg respectively for fluxapyroxad in sugar beet.

The Meeting estimated a maximum residue level of 1 mg/kg for fluxapyroxad in carrot, together with an STMR and an HR of 0.06 and 0.5 mg/kg respectively. The Meeting agreed to extrapolate these values to parsnips.

The Meeting estimated a maximum residue level of 0.2 mg/kg for fluxapyroxad in radish, together with an STMR and an HR of 0.05 and 0.1 mg/kg respectively.

Celery

The critical GAP for celery is in the USA, at 3× 0.2 kg ai/ha applications, with a 7-day retreatment interval, and a 1-day pre-harvest interval.

Residues of fluxapyroxad (parent only and total residues) in US trials matching GAP were 1.3, 1.4, 1.8, and 5.2 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg for celery, together with an STMR and an HR of 1.6 and 5.5 mg/kg respectively.

Cereals

Rice

The critical GAP for rice is in the USA, with 2× 0.15 kg ai/ha applications, a 7-day retreatment interval, and a 28-day pre-harvest interval. Residue trials matching the GAP were conducted in the USA.

Residues of fluxapyroxad (parent only) in paddy rice (with husks) at a 28-day PHI were 0.26, 0.34, 0.37, 0.59, 0.60, 0.61, 0.80, 0.92 (2), 0.94, 1.1, 1.2 (2), 1.7, and 3.7 mg/kg.

Total residues were 0.35, 0.37, 0.49, 0.59, 0.61, 0.62, 0.83, 0.94, 0.95, 0.96, 1.1, 1.2 (2), 1.7, and 3.7 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg for rice, together with an STMR of 0.94 mg/kg.

Sorghum

Residue data for sorghum were provided to the 2012 Meeting, however at the time no maximum residue level was estimated as the data did not match any label GAP. GAPs have now been provided to the Meeting for consideration against the previously submitted data.

The GAP for sorghum in Mexico is 2× 0.1 kg ai/ha applications 14 days apart, with a 10-day pre-harvest interval. No data matching that GAP is available to the Meeting.

The GAP for sorghum in the USA is 2× 0.1 kg ai/ha applications, with a 21-day pre-harvest interval. Data from trials conducted in the USA and submitted to the 2012 Meeting match the US GAP for sorghum.

Residues of fluxapyroxad (parent only) in sorghum at a 21-day PHI were 0.13, 0.15 (2), 0.17, 0.19, 0.21, 0.24, 0.31, and 0.40 mg/kg.

Total residues in sorghum were 0.13, 0.15, 0.17, 0.19, 0.20, 0.22, 0.30, 0.32, and 0.40 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for sorghum, together with an STMR of 0.2 mg/kg.

Sugar cane

The critical GAP for sugarcane is in the USA, with 2× 0.125 kg ai/ha applications, a 14-day retreatment interval, and a 14-day pre-harvest interval. Residue trials matching GAP were conducted in the USA.

Residues of fluxapyroxad (parent only) in sugarcane at a 14-day PHI were 0.06, 0.26, 0.56, and 1.3 mg/kg.

Total residues were 0.06, 0.26, 0.58, and 1.4 mg/kg.

The Meeting concluded that there was insufficient data to estimate a maximum residue level for sugarcane.

Tree nuts

The critical GAP for fluxapyroxad in tree nuts is in the USA, with 3× 0.125 kg ai/ha applications, a 7-day retreatment interval, and a 14-day PHI.

Residue trials conducted in the USA in almonds and pecans and matching the US GAP were available to the Meeting.

Residues of fluxapyroxad (parent compound and total residues) in almond kernels at a 14-day PHI were < 0.01 (3), 0.01 and 0.02 mg/kg.

Residues of fluxapyroxad (parent compound and total residues) in pecan kernels at a 14-day PHI were < 0.01 (4), and 0.03 mg/kg.

The Meeting noted that the US GAP was for the tree nuts group and noted the similarity of the datasets for almonds and pecans (the medians were identical at 0.01 mg/kg). The Meeting decided to combine the datasets for almonds and pecans for the purpose of estimating a group maximum residue level.

Parent compound and total residues in almond and pecan kernels were: < 0.01 (7), 0.01, 0.02, and 0.03 mg/kg.

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

Cotton

The 2012 Meeting considered a USA GAP and residue trials for seed treatment application to cotton, and estimated a maximum residue level of 0.01* mg/kg, together with an STMR of 0.

Residue data for foliar application to cotton was presented to the current Meeting.

The GAP for foliar application of fluxapyroxad to cotton in Brazil is 4× 0.058 kg ai/ha applications, with a 12-day retreatment interval and a 14-day pre-harvest interval. No data matching that GAP was available to the Meeting.

The USA GAP for cotton is 3× 0.1 kg ai/ha, with a 7-day retreatment interval and a 30-day pre-harvest interval. A series of trials conducted in the USA in accordance with the GAP was available to the Meeting.

Residues of parent compound in cottonseed after treatment in accordance with GAP were < 0.01, 0.01 (2), 0.03, 0.07, 0.09, 0.11 (2), and 0.13 mg/kg.

Total residues in cottonseed were < 0.01, 0.01 (2), 0.03, 0.07, 0.09, 0.11, 0.12, and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for cottonseed, together with an STMR of 0.07 mg/kg. The Meeting withdrew the previous maximum residue level recommendation of 0.01* mg/kg for fluxapyroxad in cottonseed.

Animal feeds

Rice straw

The critical GAP for rice is in the USA, with 2× 0.15 kg ai/ha applications, and a 28-day pre-harvest interval.

Residues of fluxapyroxad parent compound in rice straw after treatment in accordance with GAP were 1.5, 1.8, 1.9, 2.5, 2.9, 3.1, 3.6, 4.0, 4.2, 5.2, 6.8, 6.9, 7.3, 10, and 42 mg/kg (dry weight basis).

Total residues were 1.5, 1.9 (2), 2.6, 2.9, 3.2, 3.8, 4.2 (2), 5.4, 7.0 (2), 7.4, 10, and 42 mg/kg (dry weight basis).

The Meeting estimated a maximum residue level of 50 mg/kg for rice straw and fodder, dry, together with a median residue and a highest residue of 4.2 and 48 mg/kg respectively.

Sorghum forage and stover

Residue data for sorghum were provided to the 2012 Meeting, but the Meeting was unable to estimate any maximum residue levels due to the data not corresponding with any label GAP. GAPs have now been provided to the Meeting for consideration against the previously submitted data.

The GAP for sorghum in the USA is 2× 0.1 kg ai/ha applications, with a 21-day pre-harvest interval. Data from trials conducted in the USA and submitted to the 2012 Meeting match the US GAP for sorghum.

Residues of fluxapyroxad (parent only) in sorghum forage at a 7-day PHI were 1.5, 1.8, 2.3, 2.7, 2.9, 3.1, 3.5, 6.4, and 7.0 mg/kg (dry weight basis).

Total residues in sorghum forage were 1.6, 2.0, 2.4, 2.8, 3.1, 3.2, 3.5, 6.8, and 7.1 mg/kg (dry weight basis).

The Meeting estimated a median residue and a highest residue of 3.1 and 7.1 mg/kg (dry weight basis) respectively.

Residues of fluxapyroxad (parent only) in sorghum stover at a 21-day PHI were 0.72, 1.3, 1.6 (2), 2.1, 2.5 (2), 2.8, and 3.2 mg/kg (dry weight basis).

Total residues in sorghum stover were 0.72, 1.4,1.8 (2), 2.2, 2.6 (2), 2.9, and 3.3 mg/kg (dry weight basis).

The Meeting estimated a maximum residue level of 7 mg/kg, together with a median residue and a highest residue of 2.2 and 3.3 mg/kg respectively, for sorghum straw and fodder, dry (dry weight basis).

Almond hulls

The critical GAP for fluxapyroxad in tree nuts is in the USA, with 3× 0.125 kg ai/ha applications (maximum two consecutive applications), and a 14-day PHI.

Residues of fluxapyroxad (parent compound and total residues) in almond hulls were 0.88, 0.92, 1.1, 1.4 and 1.7 mg/kg.

The Meeting estimated a median residue of 1.1 mg/kg.

Cotton gin trash

The USA GAP for cotton is 3× 0.1 kg ai/ha, with a 30-day pre-harvest interval.

Residues in cotton gin trash (parent compound) were 6.9 and 8.0 mg/kg, while total residues were 6.9 and 8.1 mg/kg.

The Meeting concluded that there were insufficient data for estimation of a median residue and highest residue for cotton gin trash.

Processing studies

The Meeting received processing studies for oranges, grapes, sugarcane, and cottonseed. The 2012 Meeting received processing studies for plums, rice and sorghum. Processing factors, HR-P, STMR-P and maximum residue levels are summarised in the table below.

Plums

Based on the processing factor of 2.81 for prunes (which was the same for both parent compound and total residues), the STMR and HR of 0.44 and 0.95 mg/kg for plums, the 2012 Meeting estimated an STMR-P, HR-P and maximum residue level of 1.2, 2.7 and 5 mg/kg respectively for prunes. The current Meeting confirmed those recommendations.

Grapes

Based on the processing factor of 4.25 for raisins (for parent compound and total residues), the STMR of 0.47 mg/kg for grapes, and the HR of 1.4 mg/kg for grapes, the Meeting estimated an STMR-P, an HR-P and a maximum residue level of 2.0, 6.0, and 15 mg/kg respectively for dried grapes.

Using the parent compound and total residues processing factor of 5.25 for grape pomace (wet), the OECD guideline value of 15% for the dry matter content of wet grape pomace, and the above STMR value for grapes, the Meeting estimated a maximum residue level and STMR-P of 150 and 16.5 mg/kg respectively for grape pomace, dry.

Rice

Based on the processing factor of 0.07 for polished rice (which was the same for parent and total residues), the maximum residue level of 5 mg/kg for rice, and the STMR of 0.94 mg/kg, the Meeting

estimated a maximum residue level and an STMR-P of 0.4 and 0.066 mg/kg respectively for rice, polished.

Based on the processing factor of 0.59 (for both parent and total residues) for rice, husked produced using the parboiling process, the maximum residue level and STMR of 5 and 0.94 mg/kg respectively, the Meeting estimated a maximum residue level and an STMR-P of 3 and 0.55 mg/kg respectively for rice, husked.

Sugarcane

Although a processing study was provided, there were insufficient data for sugarcane to estimate STMR and HR values, so values for processed commodities were not estimated.

RAC	Processed commodity	PF (parent)	RAC maximum residue level	Processed commodity maximum residue level	PF (total)	RAC STMR	Processed commodity STMR-P	RAC HR	Processed commodity HR-P
Orange	Dried pulp	0.095	0.3	–	0.095	0.06 (whole fruit)	0.006	0.17 (whole fruit)	0.016
	Oil	27.5		–	27.5		1.7		4.7
	Juice	0.045		–	0.045	0.01 (pulp)	0.00045	0.01 (pulp)	0.00045
Plum	Washed plums	0.77	1.5	–	0.77	0.44	0.34	0.95	0.73
	Puree	0.83		–	0.83		0.37		0.79
	Jam	0.41		–	0.41		0.18		0.39
	Dried prunes	2.81		5	2.81		1.23		2.66
Grape	Stalks	5.95	3	–	5.95	0.47	2.8	1.4	8.3
	Grape crush	0.83		–	0.83		0.39		1.2
	Must	0.23		–	0.23		0.11		0.32
	Wet pomace	5.25		–	5.25		2.5		7.4
	Dry pomace	35		150	35		16.5		105
	Must deposit	0.88		–	0.88		0.41		1.2
	Separated must	0.26		–	0.26		0.12		0.36
	Pasteurised juice	0.345		–	0.345		0.16		0.48
	Yeast deposit	2.75		–	2.75		1.3		3.9
	Red wine	0.20		–	0.20		0.094		0.28
	Rosé wine	0.23		–	0.23		0.11		0.32
	Raisins	4.25		15	4.25		2.0		6.0
Rice	Rice, polished (white rice)	0.07	5	0.4	0.07	0.94	0.066	–	–
	Hulls	4.3		–	4.3		4.04		–
	Bran	3.79		–	3.78		3.55		–
	Rice, husked (brown rice)	0.59		3	0.59		0.55		–
	Flour	0.08		–	0.08		0.08		–
Sorghum	Aspirated grain fractions	14.5	0.7	–	13.8	0.2	2.76	–	–
	Syrup	0.135		–	0.13		0.026		–
Sugar cane	Molasses	0.17	–	–	0.17	–	–	–	–
	Raw sugar	0.25		–	0.25		–		–
	Refined sugar	0.04		–	0.04		–		–
Cotton seed	Meal	0.055	0.3	–	0.055	0.07	0.004	–	–

RAC	Processed commodity	PF (parent)	RAC maximum residue level	Processed commodity maximum residue level	PF (total)	RAC STMR	Processed commodity STMR-P	RAC HR	Processed commodity HR-P
	Hulls	0.185		–	0.185		0.013		–
	Refined oil	0.045		–	0.045		0.003		–

Residues in animal commodities

Farm animal dietary burden

Dietary burden calculations incorporating all commodities considered by the current and 2012 Meetings for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations are made according to the livestock diets of the USA/Canada, the European Union, Australia and Japan as laid out in the OECD table.

	US/CAN		EU		AU		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	4.73	2.64	22.8	6.81	45.2	12.7	27.3	3.25
Dairy cattle	19.7	4.63	23.3	7.95	40.9	11.9	14.1	2.43
Poultry—broiler	0.985	0.985	1.27	0.898	1.37	1.37	0.35	0.35
Poultry—layer	0.985	0.985	8.53	2.69	1.37	1.37	0.947	0.947

Animal commodity maximum residue levels

The animal commodity maximum residue levels were estimated by the 2012 Meeting based on the following maximum and mean dietary burdens:

Animal (commodities)	Dietary burden (ppm)	
	Maximum	Mean
Beef cattle (mammalian meat and offal)	40.7 (Australia)	11.4 (Australia)
Dairy cattle (milk)	39.2 (Australia)	9.37 (Australia)
Poultry–layers (poultry meat, offal and eggs)	7.14 (EU)	2.10 (EU)

The Meeting noted that the dietary burdens had not changed significantly from those determined by the 2012 Meeting and confirmed its previous recommendations for meat (from mammals other than marine mammals), edible offal (mammalian), milks, poultry meat, poultry, edible offal of, and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of fluxapyroxad were calculated for the 17 GEMS/food cluster diets using STMRs/STMR-Ps estimated by the current Meeting and by the 2012 JMPR. The results are shown in Annex 3 to the 2015 Report.

The calculated IEDIs of fluxapyroxad were 4–20% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that the long-term intakes of residues of fluxapyroxad, resulting from the uses considered by the current Meeting and by the 2012 JMPR, are unlikely to present a public health concern.

Short-term intake

The 2012 Meeting estimated an ARfD of 0.3 mg/kg bw for fluxapyroxad. The International Estimated Short Term Intakes were calculated for fluxapyroxad using the recommendations for STMRs and HRs for raw and processed commodities in combination with consumption data for the corresponding food commodities. The results are shown in Annex 4 to the 2015 Report.

The IESTI for spinach represented 190% of the ARfD for children. On the basis of the information provided to the JMPR, the Meeting concluded that the short-term intake of fluxapyroxad from consumption of spinach may present a public health concern. The Meeting noted that no data for alternative GAPs in spinach were presented.

For the other commodities, the IESTI for fluxapyroxad calculated on the base of recommendations made by JMPR represented 0–60% of the ARfD for children, and 0–60% for the general population.

The Meeting concluded that except for spinach, the short term intake of residues of fluxapyroxad, from uses considered by the current Meeting is unlikely to present a public health concern.