5.20 PYRACLOSTROBIN (210)

RESIDUE AND ANALYTICAL ASPECTS

Pyraclostrobin was first evaluated by JMPR in 2003 when an ADI of 0–0.03mg/kg bw and an ARfD of 0.05 mg/kg bw were established, and subsequently evaluated in 2004 and 2006 for the estimation of a number of maximum residue levels. The 2004 JMPR proposed pyraclostrobin as the residue definition for compliance with MRLs and for dietary intake, for both plant and animal commodities.

At the Forty-second Session of the CCPR, pyraclostrobin was scheduled for the evaluation of 2011 JMPR for additional maximum residue levels.

Analytical methods

The Meeting received descriptions and validation data for analytical methods for residues of pyraclostrobin in raw agricultural commodities, processed commodities and feed commodities. Numerous recovery data on a wide range of substrates were provided from validation testing of the methods, which showed that the methods were valid over the relevant concentration ranges. Pyraclostrobin was determined by LC-MS-MS and the reported LOQs ranged from 0.01 mg/kg to 0.02 mg/kg in plant matrices and 0.05 mg/kg in poultry tissues.

Results of supervised trials on crops

The Meeting received supervised trials data for pyraclostrobin uses on citrus fruits, cherries, plums, peaches, blackberries, raspberries, blueberries, currants, strawberries, avocado, papaya, onions, summer squash, cucumber, cantaloupe, artichoke, oat, rye, wheat, sorghum, pecan, almond, canola, cotton, sunflower and alfalfa.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from the supervised trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

Citrus fruits

The 2004 JMPR evaluated numerous trials carried out in Argentina and the USA and estimated maximum residue levels for citrus fruits (1 mg/kg). New data were available from supervised trials on grapefruit, lemons, mandarins and oranges from Spain and the USA.

Grapefruit

The US GAP for citrus fruits allows a maximum of three spray applications at 0.147–0.245 kg ai/ha with a 0 day PHI.

Six grapefruit trials at maximum GAP, where residues found, median underlined, were: 0.06, 0.07, <u>0.09</u>, <u>0.11</u>, 0.24, and 0.59 mg/kg.

Lemon

The US GAP for citrus fruits allows a maximum of three spray applications at 0.147–0.245 kg ai/ha, 0 day PHI.

Five lemon trials at maximum GAP, where residues found, median underlined, were: 0.52, 0.54, <u>0.56</u>, 0.74 and 0.90 mg/kg.

Mandarin

Spanish GAP allows a maximum of four spray applications at 0.075–0.225 kg ai/ha, with a 7 day PHI.

Six mandarin trials at maximum GAP, where residues found, median underlined, were: 0.25, 0.52, 0.54, 0.76, 0.87, and 1.15 mg/kg.

Oranges

Spanish GAP allows a maximum of four spray applications at 0.075–0.225kg ai/ha, 7 day PHI; the GAP of the US for citrus fruits allows four foliar spray applications at 0.075–0.225 kg ai/ha, 0 day PHI.

In eight orange trials from Spain with application conditions in line with GAP, the ranked order pyraclostrobin residues, median underlined, were 0.24, 0.29, 0.34, 0.39, 0.58, 0.60, 1.10 and 1.31 mg/kg.

In thirteen orange trials from the USA, matching GAP conditions, pyraclostrobin residues were 0.17, 0.19, 0.23, 0.24, 0.25, 0.26, 0.28, 0.30, 0.42, 0.47, 0.61, 0.79 and 1.13 mg/kg.

The ranked order of pyraclostrobin residues in orange pulp, from the US trials, median underlined, were: < 0.02(7), 0.02(3), 0.05 and 0.07(2) mg/kg.

On the basis of the median ratio of 0.077 between pulp and whole fruit, corresponding calculated pyraclostrobin residues in orange pulp from the Spanish trials, median underlined, were: 0.02, 0.02, 0.03, 0.03, 0.04, 0.05, 0.08 and 0.10 mg/kg.

The Meeting noted that oranges had the highest residues in this citrus group and decided to recommend a maximum residue level of 2 mg/kg for pyraclostrobin in citrus fruits, an STMR of 0.035 mg/kg and an HR of 0.10 mg/kg on the basis of Spanish residue data in the pulp for dietary intake calculations, and estimate an STMR of 0.485 mg/kg for the estimation of STMR-P for processed commodities of oranges.

The Meeting agreed to withdraw the previous recommendation of 1 mg/kg for citrus fruits.

Stone fruits

The 2004 JMPR evaluated numerous trials carried out in US and estimated maximum residue levels for stone fruits (1 mg/kg). New data were available from supervised trials on cherries conducted in the USA and for peach and plum from Canada and the USA.

Cherries

Canadian GAP allows five spray applications at 0.134 kg ai/ha with a 10 day PHI. The GAP for the USA allows five spray applications at 0.134 kg ai/ha with a 0 day PHI.

Twelve sour or sweet cherry trials from the US and one sour cherry trial from Canada matched the US GAP. Residues found, in rank order, median underlined, were: 0.03, 0.27, 0.38, 0.42, 0.47, 0.50, 0.51, 0.56, 0.63, 0.82, 1.06, 1.08 and 1.57 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.51 mg/kg and HR of 1.57 mg/kg for pyraclostrobin in cherries.

Peaches

Canadian GAP consists of five spray applications at 0.134 kg ai/ha with a 10 day PHI. The GAP of France allows two spray applications at 0.05 kg ai/ha and a 3 day PHI. Germany GAP consists of three spray applications at 0.0168 kg ai/ha, 7 days PHI. For Italy and Spain the current GAP is three

spray applications at 0.04–0.05 kg ai/ha, 3 days PHI. The GAP of the USA is five spray applications at 0.134 kg ai/ha and a 0 day PHI.

Ten supervised trials were conducted on peaches in France, Italy and Spain in 2003 and 2004. The Meeting agreed to combine all data from France (5), Italy (2) and Spain (3) against the Italian or Spanish GAP, pyraclostrobin residues, median underlined, were: < 0.02, 0.03, 0.04, 0.05, 0.07 (2), 0.08, 0.11, 0.12and 0.13 mg/kg.

In 19 peach trials, at maximum US GAP, residues found, in ranked order, median underlined, were: 0.08, 0.11, 0.15, 0.15, 0.16 (2), 0.21, 0.23, 0.28, 0.31, 0.31, 0.34, 0.35, 0.41, 0.43, 0.48, 0.53, 0.61 and 1.75 mg/kg.

The US GAP would lead to an estimated maximum residue level of 2 mg/kg, an STMR of 0.31 mg/kg and an HR of 1.75 mg/kg for peaches. This residue level would result in an estimated intake of 150% of the ARfD.

Consequently, in accordance with the principles of alternative GAP, the Meeting considered the next lowest GAP and used the residues in European trials complying with Italian or Spanish GAP for the estimation of maximum residue level of 0.3 mg/kg, an STMR of 0.07 mg/kg and an HR of 0.13 mg/kg for peaches and nectarines.

Plums

The GAP of the USA consists of five spray applications at 0.134 kg ai/ha and a 0 day PHI.

Fifteen trials were carried out on plums in Canada (2) and the US (13) matching the US GAP. The residues found in rank order, median underlined, were: 0.02(2), 0.04, 0.05, 0.06, 0.07, 0.09 (2), 0.12, 0.19, 0.22, 0.34, 0.38 and 0.40(2) mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.09 mg/kg and HR of 0.40 mg/kg for pyraclostrobin in plums.

The Meeting decided to withdraw its previous recommendations made for stone fruits (1 mg/kg).

Berries and other small fruits

The 2004 and 2006 JMPR evaluated numerous trials in blueberries, raspberries and strawberries carried out in the USA and Canada, and estimated maximum residue levels for blueberry (1 mg/kg), raspberry (2 mg/kg) and strawberry (0.5 mg/kg). New data were available for assessment from supervised trials on blackberry, blueberry, raspberry and strawberry conducted in Canada and the US.

Blackberries

The US GAP consists of five spray applications at 0.196 kg ai/ha, 0 day PHI.

From four blackberries trials, at GAP, residues found were: 0.35, 0.51, 0.87 and 1.32 mg/kg.

Raspberries

The Canadian GAP allows five spray applications at 0.166–0.205 kg ai/ha, 0 days PHI. The US GAP is for five spray applications at 0.196 kg ai/ha, 0 day PHI.

From nine raspberries trials (one trial in Canada and eight trials in the USA) at GAP, pyraclostrobin residues found, in ranked order, were: 0.40, 0.63, 0.78, 0.86, 0.88, 0.88, 1.04, 1.10 and 1.23 mg/kg.

The Meeting noted that residue levels from the same GAP were similar for blackberry and raspberry and agreed to combine all data to support a maximum residue level for blackberry and

raspberry. The ranked order of concentrations, median underlined, was 0.35, 0.40, 0.51, 0.63, 0.78, 0.86, 0.87, 0.88, 0.88, 1.04, 1.10, 1.23 and 1.32 mg/kg. The Meeting estimated a maximum residue level, an STMR and an HR value for pyraclostrobin in blackberry and raspberry of 3, 0.87 and 1.32 mg/kg, respectively. The recommendation for a maximum residue level of 3 mg/kg for raspberries replaces the previous recommendation of 2 mg/kg.

Blueberries

The Canadian GAP allows five spray applications at 0.166–0.205 kg ai/ha, 0 days PHI. The GAP of the USA consists of five spray applications at 0.196 kg ai/ha, and a 0 day PHI.

From 11 blueberries trials (three trials in Canada and eight trials in the US) at GAP, residues found, median underlined, were: 0.19, 0.30, 0.33, 0.35, 0.57, 0.78, 1.16, 1.37, 1.62, 2.02 and 2.08 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 0.78 mg/kg and HR of 2.08 mg/kg for pyraclostrobin in blueberries. The recommendation for a maximum residue level of 4 mg/kg for blueberries replaces the previous recommendation of 1 mg/kg.

Currants

The GAP of Germany allows a maximum of three spray applications at 0.067 kg ai/ha, with a PHI of 14 days. The GAP of Italy consists of two spray applications at 0.10 kg ai/ha, and a 3 day PHI.

A total of 16 trials on currants were available from France (2), Germany (12), Italy (1) and the UK (1).

Two trials from France and one trial from Italy were conducted on currants matching Italian GAP. The ranked order of residues was 0.25, 0.58 and 0.62 mg/kg.

Pyraclostrobin residues from German trials matching the GAP of that country, median underlined, were: 0.03, 0.04, 0.08, 0.10, 0.11, 0.17, 0.20, 0.20, 0.22, 0.27, 0.73 and 1.30 mg/kg.

Based on the German data, the Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.185 mg/kg and an HR of 1.30 mg/kg.

Strawberries

The GAP of the USA allows a maximum of five spray applications at 0.168–0.196 kg ai/ha, with a 0 day PHI.

From 11 strawberries trials, at GAP, residues found, median underlined, were: 0.06, 0.12, 0.13, 0.15, 0.16, 0.20, 0.24, 0.31, 0.43, 0.73 and 0.75 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.20 mg/kg and HR of 0.75 mg/kg for pyraclostrobin in strawberries. The Meeting agreed to withdraw the previous recommendation of 0.5 mg/kg on strawberries.

Assorted tropical and sub-tropical fruits-inedible peel

Avocados

The US GAP allows two spray applications at 0.148 kg ai/ha, with a 0 day PHI.

No residue trials matching the GAP of the USA were available. Consequently, the Meeting agreed that a maximum residue level for avocado could not be recommended.

Papaya

The GAP of Brazil allows four spray applications at 0.010 kg ai/hL with a 7 day PHI.

From eight trials on papaya available from Brazil, residues found, median underlined, were: < 0.05 (7) and 0.06 mg/kg.

The Meeting agreed to estimate a maximum residue level of 0.15 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.06 mg/kg. The recommendation for a maximum residue level of 0.15 mg/kg for papaya replaces the previous recommendation of 0.05* mg/kg. The Meeting agreed to withdraw the previous recommendation of 0.05* mg/kg on papaya.

Bulb vegetables

The 2004 JMPR evaluated numerous trials carried out in the USA and estimated maximum residue levels for bulb onion (0.2 mg/kg) and garlic (0.05* mg/kg). New data were available from supervised trials on bulb onion and spring onions conducted in Canada and the USA.

Bulb onions

The GAP of Canada allows a maximum of six spray applications at 0.128–0.166 kg ai/ha, at a PHI of 7 days. The US GAP consists of six spray applications at 0.112–0.168 kg ai/ha, with a 7 day PHI.

From 12 bulb onions trials (five trials in Canada and seven trials in US) at GAP, residues found, median underlined, were: < 0.02, 0.02(4), 0.03, 0.09, 0.11, 0.42, 0.43, 0.61 and 0.62 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.06 mg/kg and HR of 0.62 mg/kg for pyraclostrobin in bulb onions. The Meeting agreed to withdraw the previous recommendation of 0.2 mg/kg.

Garlic

The GAP of Brazil consists of four spray applications at 0.12 kg ai/ha with a 7 day PHI.

Seven trials on garlic were available from Brazil complying with the GAP of that country. Residues found, median underlined, were: < 0.02(4), 0.03, 0.05 and 0.09 mg/kg.

The Meeting agreed to estimate a maximum residue level of 0.15 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.09 mg/kg, respectively. The Meeting agreed to withdraw the previous recommendation of 0.05* mg/kg on garlic.

Spring onions

The GAP of the US allows a maximum of six spray applications at 0.112–0.168 kg ai/ha, with a 7 day PHI.

Seven spring onions trials (one trial in Canada and six trials in US) complied with the US GAP. Residues found were: 0.05(2), 0.33, 0.42, 0.52, 0.58 and 0.60 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.42 mg/kg and HR of 0.60 mg/kg for pyraclostrobin in spring onions. Use of the OECD calculator resulted in a value of 1.5 mg/kg.

Fruiting vegetables, Cucurbits

The 2004 and 2006 JMPR evaluated numerous trials carried out in Brazil and the USA, and estimated maximum residue levels for cucumber (0.5 mg/kg) and summer squash (0.3 mg/kg). New data were available from supervised trials on cucumbers and summer squash from the USA. The US GAP for

cucurbits (including cucumber, summer squash and melons) consists of four spray applications at 0.112–0.224 kg ai/ha, with a 0 day PHI.

Cucumbers

The data from four field cucumbers trials conducted in the USA and complying with US GAP, were available. Residues found were: 0.02, 0.05, 0.06 and 0.10 mg/kg.

The 2004 and 2006 JMPR reported cucumber trials carried out in Brazil and US in line with GAP. The ranked order residues in cucumbers from US were 0.02, 0.03, 0.05, 0.06, 0.07, 0.09, 0.12, 0.14 and 0.41 mg/kg. Taking into account the new supervised trials from the USA, the ranked order of residues from US supervised trials, median underlined, were: 0.02(2), 0.03, 0.05(2), <u>0.06</u>(2), 0.07, 0.09, 0.10, 0.12, 0.14 and 0.41 mg/kg.

Squash, Summer

Data from four summer squash trials, complying with US GAP, were available. Residues found were: 0.09, 0.09, 0.12 and 0.22 mg/kg.

The 2004 JMPR reported US trials conducted with the maximum GAP. The residues in summer squash, in ranked order, were: 0.03, 0.07, 0.14, 0.17 and 0.18 mg/kg. Taking into account new supervised trials from the USA, in ranked order the combined residues were: 0.03, 0.07, 0.09(2), 0.12, 0.14, 0.17, 0.18 and 0.22 mg/kg.

Melons, except Watermelon

The 2006 JMPR evaluated eight trials carried out in US, and estimated a maximum residue levels for cantaloupe (0.2 mg/kg). New data were available from supervised trials on cantaloupe from the USA.

Six cantaloupe trials at GAP, where residues found were: 0.05, 0.09, 0.10, 0.12, 0.14 and 0.28 mg/kg.

The 2006 JMPR reported cantaloupe trials carried out in US in line with US GAP. The ranked order residues in cantaloupe from the USA were: 0.05, 0.08, 0.09, 0.10, 0.11, 0.12 (2) and 0.13 mg/kg. Taking into account the new supervised trials from US, the ranked order of residue concentrations were: 0.05(2), 0.08, 0.09(2), 0.10(2), 0.11, 0.12(3), 0.13, 0.14 and 0.28 mg/kg.

On the basis of the median ratio of 0.50 between flesh and whole fruit, from Spanish trials corresponding calculated pyraclostrobin residues in melon flesh from US trials, median underlined, were: 0.025 (2), 0.04, 0.045(2), <u>0.05</u> (2), <u>0.055</u>, 0.06(3), 0.065, 0.07, and 0.14 mg/kg.

The Meeting agreed to replace the previous the maximum residue level recommendation of 0.5 mg/kg on cucumber, and the previous recommendation of 0.3 mg/kg on cantaloupe (melon except watermelon) and 0.3 mg/kg on summer squash with a crop group estimate. Based on the cucumber residue data, the Meeting estimated a maximum residue level of 0.5 mg/kg for cucurbits.

For dietary intake calculation, the Meeting agreed to estimate an STMR of 0.06 mg/kg and HR of 0.41 mg/kg for fruiting vegetables, cucurbits edible peel and an STMR of 0.0525 mg/kg and HR of 0.14 mg/kg for fruiting vegetables, cucurbits-inedible peel, respectively.

Artichoke, globe

The GAP of France consists of 2 applications at a rate of 0.10 kg ai/ha and a 3 day PHI.

A total of 19 artichoke trials were available from France (7), Germany (2), Greece (1), Italy (3), the Netherlands (3) and Spain (3) complying with the French GAP. Residues found, median underlined, were: 0.04, 0.08, 0.13(3), 0.19, 0.22(2), 0.24, <u>0.25</u>, 0.27(2), 0.32, 0.33, 0.34, 0.36, 0.49, 0.60 and 1.44 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.25 mg/kg and an HR of 1.44 mg/kg, for pyraclostrobin in globe artichoke.

Cereal grains

The 2004 and 2006 the JMPR evaluated numerous trials carried out in Brazil, Canada, Europe and the USA, and estimated maximum residue levels for barley (0.5 mg/kg), maize (0.02* mg/kg), oats (0.5 mg/kg), spelt (0.2 mg/kg) and wheat (0.2 mg/kg). New data were available from supervised trials on barley, oat, rye, sorghum and wheat from the USA.

Oats

Canadian GAP consists of two spray applications at 0.075–0.10 kg ai/ha not later than the end of flowering. The US GAP allows two spray applications at 0.098–0.147 kg ai/ha not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Residues from eight US trials and four Canadian trials, complying with the GAP of the USA, in ranked order, were: < 0.02, 0.11, 0.14, 0.15, 0.26, 0.30, 0.33, 0.33, 0.36, 0.40, 0.40 and 0.59 mg/kg.

Barley

The GAP of the USA consists of two spray applications at 0.098–0.147 kg ai/ha not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Four additional barley trials were conducted in US at the new GAP, where residues found were: 0.39, 0.50, 0.56 and 0.62 mg/kg.

The Meeting noted that residue levels from trials complying with the same GAP were similar for barley and oats and agreed to combine the data sets to support a maximum residue level for barley and oats. The ranked order of residues, median underlined, were: < 0.02, 0.11, 0.14, 0.15, 0.26, 0.30, 0.33, <u>0.33</u>, <u>0.36</u>, 0.39, 0.40, 0.40, 0.50, 0.56, 0.59 and 0.62 mg/kg. The Meeting estimated a maximum residue level and an STMR for pyraclostrobin in barley and oats of 1 and 0.345mg/kg, respectively. The Meeting agreed to withdraw its previous recommendation for barley and oats of 0.5 mg/kg.

Wheat

The GAP of France GAP allows two spray applications at 0.25 kg ai/ha with a 35 day PHI. German GAP consists of two spray applications at 0.25 kg ai/ha, 35 day PHI. The GAP of the USA consists of two spray applications at 0.147 kg ai/ha not later than 25% flowering.

Four additional wheat trials were conducted in France, Germany, Greece and Spain, but not in line with French or German GAP.

Only one additional wheat trial was conducted in the USA at the new US GAP, where the residue found was < 0.02 mg/kg.

The Meeting noted that the 2004 JMPR recommended a maximum residue level of 0.2 mg/kg accommodates the new residue data from US for wheat grain.

Rye

The Meeting received the data from five supervised trials for rye. The Meeting considered that five trials were not sufficient to allow the estimation of a maximum residue level in rye. However, as rye is a registered crop in Germany with the same GAP as that of wheat and triticale the Meeting agreed to extrapolate the existing maximum residue level (0.2 mg/kg) and STMR (0.02 mg/kg) values of wheat to rye and triticale.

Sorghum

The GAP of the USA allows the use of pyraclostrobin as a seed treatment at 0.01–0.02 kg ai/100 kg seeds, and as a single spray application at 0.098–0.196 kg ai/ha, not later than 25% flowering.

In 12 sorghum trials complying with US GAP, residues found, median underlined, were: < 0.02(2), 0.02(4), 0.03(2), 0.05, 0.08, 0.10 and 0.34 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.025 mg/kg for pyraclostrobin in sorghum.

Tree nuts

The 2004 JMPR evaluated numerous trials carried out in Brazil and US, and estimated maximum residue levels for almond (0.02* mg/kg), pecan (0.02* mg/kg) and pistachio (1 mg/kg). New data were available from supervised trials on almonds from the USA.

Almonds

The US GAP allows four spray application at 0.133 kg ai/ha, with a 25 day PHI.

In ten almond trials complying with US GAP, residues found, median underlined, were: < 0.02 (10) mg/kg.

The 2004 JMPR reported five pecan trials carried out in US in line with GAP. All residue levels in pecan were < 0.02 mg/kg. Noting that the residue levels from the same GAP are similar on almonds and pecans, the Meeting agreed to combine the almond and pecan data in mutual support and estimate a maximum residue level of 0.02* mg/kg, an STMR of 0 mg/kg and an HR of 0.02 mg/kg for tree nuts except pistachio. The Meeting agreed to withdraw the previous recommendations of 0.02* mg/kg on almonds and pecans.

Oilseeds

The 2004 and 2006 JMPR evaluated numerous trials carried out in Brazil and the USA, and estimated maximum residue levels for peanuts (0.05* mg/kg) and sunflower seed (0.3 mg/kg). New data were available from supervised trials on rape seed and sunflowers in Canada and the USA.

Cotton

The US GAP allows three spray applications at 0.098–0.196 kg ai/ha, with a 30 day PHI.

In 12 trials carried out in the USA, treatments consisted of a single at-planting in-furrow application to cotton at 0.22–0.23 kg ai/ha, followed 96–159 days later by three broadcast foliar applications at 0.22–0.27 kg ai/ha. The ranked order of residues found, median underlined, were: < 0.02(3), 0.02(3), 0.03, 0.06(2), 0.08, 0.10 and 0.13 mg/kg.

Rape seed

The US GAP allows two spray applications at 0.222 kg ai/ha, with a 21 day PHI.

Four trials carried out in the USA and 12 trials carried out in Canada matched the US GAP. Residues found, median underlined, were: < 0.02(6), 0.03(2), 0.04(2), 0.06, 0.08, 0.09, 0.10, 0.14 and 0.20 mg/kg.

Sunflower seed

The US GAP allows two spray applications at 0.222 kg ai/ha, with a 21 day PHI.

In eight trials carried out in the USA, matching GAP, residues found, in ranked order with median underlined, were: < 0.04, 0.04, 0.05, 0.06 (2), 0.08, 0.12 and 0.2 mg/kg.

The 2006 JMPR reported eight sunflower trials carried out in the US in line with GAP. The ranked order of residue levels in sunflower seed was: < 0.02, 0.02, 0.04, 0.05, 0.06(2), 0.10 and 0.22 mg/kg. Noting that sunflower had the highest residues in the above oilseed group and the Meeting agreed to estimate a maximum residue level of 0.4 mg/kg and an STMR of 0.055 mg/kg for oil seed except peanuts. The previous recommendation (0.3 mg/kg) for sunflower seed should be withdrawn.

Animal feedstuffs

Alfalfa forage

The GAP of the USA consists of a maximum of three spray applications at 0.098–0.147 kg ai/ha with a 14 day PHI.

Twelve alfalfa trials were available complying with GAP. Residues in alfalfa forage, (median underlined) were: 1.15, 1.22, 1.23, 1.24, 1.56, 1.65, 1.90, 2.73, 3.20, 3.23, 4.70 and 6.61 mg/kg.

The Meeting estimated a median residue of 1.775 mg/kg and a highest residue of 6.61mg/kg for pyraclostrobin in alfalfa forage (fresh weight).

Alfalfa fodder

Supervised trials data were available from alfalfa hay from USA. Residues, in ranked order, on alfalfa hay were: 3.86, 4.23, 4.45, 4.92, 6.81, 7.10, 7.81, 9.49, 9.84, 11.37, 12.87 and 19.83 mg/kg.

On a dry-weight basis (dry matter (DM) = 89%), pyraclostrobin residues in dry alfalfa hay, were: 4.34, 4.75, 5.00, 5.53, 7.65, 7.98, 8.78, 10.66, 11.06, 12.78, 14.46 and 22.28 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg, a median residue of 8.38 mg/kg and a highest residue of 22.28 mg/kg for pyraclostrobin in alfalfa fodder.

Sorghum forage

The US GAP allows a seed treatment at 0.01–0.02 kg ai/100 kg seeds plus one foliar spray application at 0.098–0.196 kg ai/ha, not later than 25% flowering.

Supervised trials data were available for sorghum forage from the USA. The ranked order of concentrations on forage (fresh weight), median underlined, were: < 0.02, 0.12, 0.14, 0.22, 0.26, 0.28, 0.33, 0.44, 0.45, 0.92, 1.08 and 1.33 mg/kg.

The Meeting estimated a median and a highest residue value for pyraclostrobin in sorghum forage (fresh weight) of 0.305 and 1.33 mg/kg, respectively.

Straw and fodder of cereal grain (dry)

Oats straw and fodder

The GAP of the US allows two spray applications at 0.098–0.147 kg ai/ha not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Eight trials were conducted in the US and four trials were conducted in Canada matching US GAP. The ranked order of residues found on oat hay were: 2.12, 2.92, 2.93, 4.40, 4.86, 5.31, 5.50, 6.04, 6.11, 6.81, 7.67 and 12.96 mg/kg.

On a dry-weight basis (DM = 90%), pyraclostrobin residues in dry oats hay, were: 2.36, 3.24, 3.26, 4.89, 5.40, 5.90, 6.11, 6.71, 6.79, 7.57, 8.52and 14.40 mg/kg.

Supervised trials data were available from oat straw from USA. The ranked order of concentrations on oat straw was: 2.32, 2.33, 2.66, 2.98, 3.19, 3.23, 3.57, 4.06, 4.76, 5.02, 6.62 and 11.08 mg/kg.

On a dry-weight basis (DM = 90%), pyraclostrobin residues in oats straw and fodder, dry, were: 2.58, 2.59, 2.96, 3.31, 3.54, 3.59, 3.97, 4.51, 5.29, 5.58, 7.36 and 12.31 mg/kg.

Barley straw

The US GAP allows two spray applications at 0.098–0.147 kg ai/ha, not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Four new barley trials were conducted in US complying with GAP. Residues found were: 1.49, 2.14, 2.26 and 3.00 mg/kg.

Wheat straw

Spanish and Greek GAPs were not available. The GAP of France consists of two spray applications at 0.25 kg ai/ha, 35 day PHI. German GAP is two spray applications at 0.25 kg ai/ha, no later than BBCH 61 (beginning of flowering). US GAP allows two spray applications at 0.147 kg ai/ha not later than 25% flowering.

Four wheat trials were available from France, Germany, Greece and Spain but did not match not French or German GAP.

Only one additional wheat trial was conducted in US matching US GAP, where the residue was 0.14 mg/kg.

The Meeting noted that the additional data submitted were insufficient for the estimation of a new maximum residue level.

Sorghum straw

The US GAP allows seed treatment at 0.01–0.02 kg ai/100 kg seeds, and one spray application at 0.098–0.196 kg ai/ha, not later than 25% flowering.

The ranked order of concentrations on sorghum straw, median underlined, were: < 0.02, 0.04(2), 0.05, 0.06 (2), 0.08(2), 0.09, 0.11, 0.19 and 0.57 mg/kg.

On a dry-weight basis (DM = 88%), pyraclostrobin residues in dry sorghum straw were: < 0.02, 0.05(2), 0.06, 0.07(2), 0.09(2), 0.10, 0.13, 0.22 and 0.65 mg/kg.

The Meeting noted the 2004 JMPR recommended a maximum residue level of 30 mg/kg for dry straw and fodder of cereal grain and that this recommendation covers the highest residue from the data submitted on oats, barley straw, wheat straw and sorghum straw to the current Meeting.

Almonds hulls

The GAP of the US GAP allows four spray application at 0.133 kg ai/ha, 25 day PHI.

Supervised trials data for almond hulls were available from USA. The ranked order of concentrations on hulls, median underlined, were: 1.06, 1.09, 1.14, 1.14, 1.23, 1.56, 1.61, 3.10, 3.12 and 4.79 mg/kg.

On a dry-weight basis (DM = 90%), pyraclostrobin residues in almond hulls, dry, were: 1.18, 1.21, 1.27, 1.27, 1.37, 1.73, 1.79, 3.44, 3.47 and 5.32 mg/kg.

The Meeting estimated a median of 1.55 mg/kg and a highest residue of 5.32 mg/kg for pyraclostrobin in almond hulls. The previous maximum residue level recommendation (2 mg/kg) for almond hulls is withdrawn as the policy is to use the information in dietary burden calculations, but not to propose maximum residue levels for almond hulls which, it is understood, are not traded internationally.

Cotton gin by-products

The US GAP allows three spray applications at 0.098–0.196 kg ai/ha, with a 30 day PHI.

Six trials carried out in the USA in which a single at-planting in-furrow application to cotton was made at 0.22–0.23 kg ai/ha, then followed 96–159 days later by three broadcast foliar applications at 0.22–0.27 kg as/ha. The ranked order of residues, median underlined, were: 0.94, 1.54, 1.56, 1.59, 2.60 and 16.73 mg/kg. Taking into account that a single in-furrow application at planting would not affect the residues and based on the residue data derived from trials performed in accordance with the US GAP, the Meeting estimated a median and highest residue levels of 1.575 mg/kg and 16.73 mg/kg, respectively.

Fate of residues during processing

The Meeting received information on the fate of pyraclostrobin residues during the processing of oranges for juice, pomace and oil; plums for puree and prunes; cherries for canned cherries and juice; strawberries for canned strawberries and jam; barley for brewing malt, malt germ, beer and pearl barley; wheat for flour, bran and germ; rape seed for meal and refined oil; sunflower for meal and refined oil; soya bean for hulls, meal and refined oil.

Calculated processing factors are summarized in the following table. Factors are indicated with a "<" (less than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity).

Raw agricultural commodity (RAC)	Processed commodity	Median or best estimate	RAC STMR/HR	STMR-P/HR-P
Orange	Peel	4.60	0.485	2.23
	Pomace (wet)	1.41		0.68
	Pomace (dry)	6.95		3.37
	Juice (pasteur.)	0.08		0.04
	marmalade	0.18		0.09
	Canned orange	0.11		0.05
	Oil	6.24	0.34	3.03
Plums	Puree	1.87	0.09	0.17
	Prune	4.59	0.09/0.40	0.41/1.84
Cherries	Canned cherries	1.00	0.51	0.51
	Juice	0.16		0.08
Currants	Juice (pasteurised)	0.035	0.185	0.013
	Currants (canned)	0.375		0.069
	Jame	0.415		0.077
Strawberries	Canned fruit	0.40	0.20	0.08
	Jam	0.21		0.04
Barley	Brewing malt	1.17	0.345	0.40
	Malt germ	2.33		0.80
	beer	< 0.67		0.23
	Pearl barley	< 0.67		0.23
Wheat	Bran	0.91	0.02	0.018
Rape seed (canola)	Meal	1.00	0.04	0.04
	Refined oil	1.33		0.053

Raw agricultural commodity (RAC)	Processed commodity	Median or best estimate	RAC STMR/HR	STMR-P/HR-P
Cotton seed	Meal	0.18	0.025	0.0045
	Hulls	0.18		0.0045
	Refined oil	0.18		0.0045
Soya bean	Hulls	1.67	0.02	0.03
	Meal	< 0.67		0.01
	Refined oil	< 0.67		0.01

The Meeting estimated a maximum residue level of 10 mg/kg and STMR-P of 3.03 mg/kg for pyraclostrobin in orange oil.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of pyraclostrobin in livestock on the basis of the diets listed in OECD Feed Table 2009 (available from the FAO website: http//www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/). Based on new data, the dietary burdens are higher than those by the 2004 JMPR. Calculation from highest residue, STMR and STMP-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and layer are provided in Annex 6.

The summarized calculations and the highest dietary burdens are selected for maximum residue level and STMR estimates on animal commodities.

		Animal dietary burden, pyraclostrobin, ppm of dry matter diet			
		US-CAN	EU	Australia	Japan
Beef cattle	Max	7.73	21.91	26.10 [a]	2.44
	Mean	1.64	11.86	15.59 [b]	1.05
Dairy cattle	Max	12.56	22.44	26.10 [c]	8.02
	Mean	3.83	14.19 [d]	13.63	2.52
Poultry - broiler	Max	0.27	0.26	0.08	0.97
	Mean	0.27	0.26	0.08	0.28
Poultry - layer	Max	0.27	5.70 [e]	0.08	0.02
	Mean	0.27	3.62 [f]	0.08	0.02

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat.

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

[c] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for mammalian milk.

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

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for meat and eggs.

Farm animal feeding

The lactating goat metabolism study was used to evaluate the dietary burden for ruminants by 2004 JMPR. In this metabolism study, in which ^{14}C-pyraclostrobin equivalent to 12–50 ppm in the diet was orally administered to lactating goats for 5 consecutive days, the highest residue (0.082 mg/kg) was found in fat, 0.047 mg/kg in milk, 0.089 mg/kg in muscle, 0.07 mg/kg in liver and 0.074 mg/kg in kidney.

The resulting maximum dietary burdens for beef and dairy cattle with residues in additional feedstuffs were slightly different to those with previous residues in feedstuffs using the OECD animal feeds table. The resulting maximum dietary burdens for poultry using the OECD animal feeds table is much higher than that of previous estimates. However, the Meeting noted that in the study of metabolism in laying hens, pyraclostrobin was not detected in tissues (< 0.002 mg/kg) or eggs (< 0.002 mg/kg) at a feeding level of 12 mg/kg, which was over 2 times higher than the calculated dietary burden (5.70 ppm).

The Meeting agreed that the residues based on new animal dietary burdens were covered by the existing recommendations for animal commodities.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of pyraclostrobin resulted in recommendations for maximum residue level and STMR values for raw and processed commodities. Data on consumption were available for 77 food commodities and were used to calculate dietary intake. The results are shown in Annex 3.

The International Estimated Daily Intakes (IEDIs) of pyraclostrobin, based on the STMRs estimated, were 1–9% of the maximum ADI of 0.03 mg/kg bw for the thirteen GEMS/Food cluster diets. The Meeting concluded that the long-term intake of residues of pyraclostrobin resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

The IESTI of pyraclostrobin calculated on the basis of the recommendations made by the JMPR represented 50% of the ARfD (0.05 mg/kg bw).

The Meeting therefore concluded that the short-term intake of pyraclostrobin residues, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.