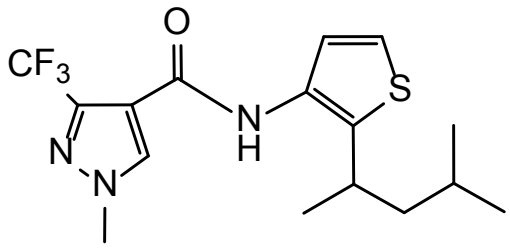
5.25 PENTHIOPYRAD (253)

RESIDUE AND ANALYTICAL ASPECTS

Penthiopyrad (ISO common name) is a carboxamide fungicide used to control a broad spectrum of diseases on large varieties of crops. Penthiopyrad inhibits fungal respiration by binding to mitochondrial respiratory complex II. It was considered for the first time by the 2011 JMPR for toxicology, establishing an acceptable daily intake (ADI) of 0–0.1 mg/kg bw and an acute reference dose (ARfD) of 1 mg/kg bw.

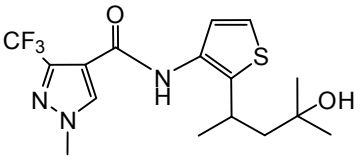


The IUPAC name of penthiopyrad is (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl) pyrazole-4-carboxamide and the CA name is N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (9CI).

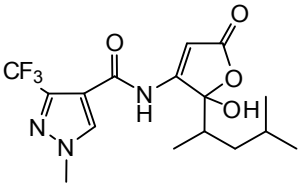
Penthiopyrad labelled either in the pyrazole- (P-label) or thienyl-moiety (T-label) was used in the metabolism and environmental fate studies.

The following abbreviations are used for the metabolites discussed below:

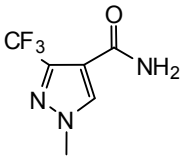
753-A-OH



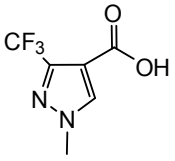
753-F-DO



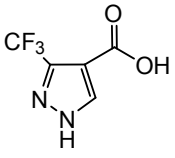
PAM



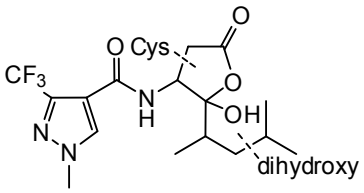
PCA



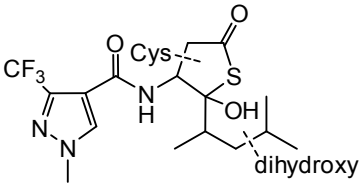
DM-PCA



dihydroxy-cys-F-DO



dihydroxy-cys-T-DO



Animal metabolism

Information was available on metabolism of penthiopyrad in laboratory animals, lactating goats and laying hens.

Rats

In the 2011 JMPR Report on penthiopyrad the following conclusions were drawn by the WHO Experts regarding the metabolism of the active substance in rats:

"The absorption, distribution, metabolism and excretion of penthiopyrad were investigated in rats. ^{14}C labelled penthiopyrad was rapidly and extensively absorbed from the gastrointestinal tract of rats following oral dosing. The extent of absorption was approximately 80–90% of the administered dose, independent of dose and sex.

Very little penthiopyrad was retained in the tissues.

Faecal excretion was the primary route of elimination, and excretion was rapid, with the majority excreted by all routes 24 hours after dosing (74.8–85.0%).

Extensive metabolism occurred at numerous positions within the molecule, including thienyl ring oxidation and conjugation with glutathione, thienyl ring opening, N-demethylation and alkyl side-chain hydroxylation, followed by oxidation to carboxylic acids and glucuronidation. The most abundant metabolite in both urine and faeces was formed as the result of N-demethylation and oxidation of the methyl moiety of the alkyl side-chain. The most abundant metabolites found in bile were formed as a result of thienyl ring oxidation to 753-F-DO, followed by its conjugation with glutathione and the catabolism of this product. Other significant metabolites in bile were glucuronic acid conjugates of the intermediate demethylated and hydroxylated metabolites. Four metabolites containing the pyrazole moiety following cleavage from the thienyl moiety were excreted in both urine and faeces. The two acids, 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid (PCA) and 3-trifluoromethyl-1H-pyrazole-4-carboxylic acid (DM-PCA) are likely formed by amide hydrolysis from 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM) and DM-PAM. PAM and subsequent metabolites account for less than 1% of the administered dose. The thienyl ring appears to be completely degraded."

Goats

Two studies on metabolism in goats were available. In the first study on lactating goats radiolabelled penthiopyrad was administered at a rate equivalent to 20 ppm in the feed, less than 1% of the total dose was recovered from milk or tissues of the animals. Most of the radioactivity was excreted via faeces and urine.

In muscle and fat TRR levels were 0.011–0.038 mg eq./kg and 0.015–0.028 mg eq./kg, respectively. For muscle only PAM and PCA were identified present at 51% and 7% of the TRR. In fat unchanged penthiopyrad (32% TRR, 0.009 mg eq./kg) and PAM (12% TRR, 0.003 mg eq./kg) were the only structures identified.

For kidney (TRR: 0.11–0.33 mg eq./kg) PAM was the major component for the P-label accounting for 19% of the TRR (0.062 mg eq./kg). Unchanged penthiopyrad was detected in traces only (3% TRR, 0.011 mg eq./kg). For the T-label only 753-A-OH was identified, being present at 6% of the TRR (0.007 mg eq./kg). The remaining radioactivity for both labels could not be attributed to specific reference compounds.

In liver TRR levels were 1.9 mg eq./kg for P- and 0.99 mg eq./kg for the T-label. Of the TRR 2% (0.037 mg eq./kg, T-label only) could be attributed to penthiopyrad. The radioactivity recovered was distributed between numerous analytical peaks accounting less than 10% of the TRR each. Identified metabolites were PAM (3% TRR, 0.053 mg eq./kg), PCA (9% TRR, 0.17 mg eq./kg), 753-F-DO (1% TRR, 0.02 mg eq./kg) and 753-A-OH (0.5% TRR, 0.005 mg eq./kg).

In the second study on lactating goats the animals were administered radiolabelled penthiopyrad at rates equivalent to 10 ppm in the feed. TRR levels found were 0.66–0.74 mg eq./kg in liver, followed by kidney (0.15–0.17 mg eq./kg). In muscle, fat and milk the TRR was between 0.013 to 0.072 mg eq./kg.

In muscle PAM was identified as major metabolite being present at levels of 46% of the TRR (0.012 mg eq./kg). In addition traces of DM-PAM were detected (12% TRR, 0.003 mg eq./kg). In fat only DM-PAM, PAM and penthiopyrad were detected at traces up to 0.005 mg eq./kg.

In milk PAM was the major residue at 30% of the TRR (0.013 mg eq./kg) for the P-label, followed by cys-T-DO-isomer with 16% of the TRR (0.007 mg eq./kg). For the T-label the degradation was more extensive, showing unattributed analytical peaks at levels of 8% of the TRR or less (0.008 mg eq./kg or less) each.

In liver solvent extraction with ACN/water released approx. 40% of the TRR, characterised as numerous unassigned analytical peaks present at < 10% of the TRR each. Only hydroxy-penthiopyrad was found in the T-label sample at or above 10% of the TRR (10% TRR, 0.069 mg eq./kg). Following protease, acid and base hydrolysis 97–99% of the TRR could be released. Identification of the residue again gave mainly unassigned chromatographic peaks quantified at rates of < 4% of the TRR each. Only PCA and PAM were identified at levels of 13% (0.10 mg eq./kg) and 8% (0.063 mg eq./kg) of the TRR, respectively.

For kidney solvent extraction with ACN/water gave numerous single metabolites each below 10% of the TRR (0.017 mg eq./kg and less). For the T-label only PAM and the dihydroxy-cys-F-DO isomer were present at amounts of 10% (0.016 mg eq./kg) and 11% (0.017 mg eq./kg) of the TRR, respectively. After protease, acid and base hydrolysis 97–103% of the TRR were released. A large number of substances at individual levels all below 4% of the TRR (0.006 mg eq./kg or less) were found. Additional major metabolites at levels > 10% of the TRR could not be identified.

Laying hens

For laying hens radiolabelled penthiopyrad equivalent to 10 ppm in the diet was administered for 14 consecutive days. For both the P- and the T-label TRR levels in egg yolk (0.28–0.37 mg eq./kg) were higher than in the egg white (0.05–0.06 mg eq./kg). In tissues TRR levels were 0.021–0.049 mg eq./kg in fat, 0.038–0.052 mg eq./kg in muscle, 0.053–0.059 mg eq./kg in skin and 0.6–0.68 mg eq./kg in liver.

In egg white PAM was the major residue present following administration of the P-label, being present up to 50% of the TRR. Unchanged penthiopyrad was identified in all samples, but near the LOQ (0.001 mg/kg). In addition minor levels of 753-A-OH (5–7% TRR) were found.

For egg yolk PAM was the major residue (24–28% of the TRR) following solvent extraction. Hydrolysis released additional 10% of the TRR as PAM. Penthiopyrad was found at levels of 2–15% of the TRR following hydrolysis. Additional minor metabolites all being present at levels of < 10% of the TRR each could be attributed to known reference substances.

For hens' liver also numerous metabolites were present at individual levels of 13% of the TRR and less (0.079 mg eq./kg and less). The only substances identified were PCA with 1.4% TRR

(0.009 mg eq./kg) and PAM with 8% TRR (0.05 mg eq./kg). Following hydrolysis, releasing the major part of the radioactivity, PCA and PAM gave additional amounts of 2% TRR (0.012 mg eq./kg) and 7% TRR (0.043 mg eq./kg), respectively.

In a second study laying hens were administered radiolabelled penthiopyrad equivalent to 10 ppm in the diet. TRR levels found were 0.062–0.094 mg eq./kg in whole eggs, 0.014–0.022 mg eq./kg in muscle, 0.014–0.02 mg eq./kg in fat and 0.24–0.35 mg eq./kg in liver. Further investigation on the nature of residues was performed for eggs and liver only.

For eggs a broad pattern of metabolites all being present below 0.01 mg eq./kg (less than 16% of the TRR) was found. PAM was identified as major residue (0.007 mg eq./kg, 11% TRR) followed by DM-PAM (0.004 mg eq./kg, 7% TRR). Hydrolysis released some additional radioactivity too low for further identification. Only two major chromatographic peaks attributed to PAM were detected, adding 0.01 mg eq./kg for the P-label and 0.008 mg eq./kg for the T-label.

In liver numerous metabolites were found mainly being present at individual levels of < 10% of the TRR for both labels. PAM was the major residue in hens' liver for the P-label with a total amount of 0.046 mg eq./kg parent equivalents (19% of the TRR). For the T-label dihydroxy-cys-T-DO was identified following digestion at a total of 0.042 mg eq./kg parent equivalents (12% of the TRR).

No unchanged penthiopyrad could be identified in hens liver or eggs.

In summary penthiopyrad is effectively degraded in goats and hens into a large number of minor metabolites following hydrolysis, oxidation, N-demethylation and conjugation. Major metabolites were mainly PAM, formed by cleavage of the molecule, or the hydroxylation product 753-A-OH. Unchanged parent substance was found in several samples; however, individual levels were normally below 10% of the TRR. The metabolites dihydroxy-cys-F-DO in goats' kidney (11%TRR, 0.017 mg eq./kg) and dihydroxy-cys-T-DO in hens liver (12%TRR, 0.042 mg eq./kg) wer not identified in rats. All other major metabolites identified were also found in rats.

Plant metabolism

The Meeting received plant metabolism studies for penthiopyrad following foliar application to grapes, cabbage, tomatoes, wheat and rape using a mixture of both radiolabelled active substances.

Grapes

Two plots of grapes were treated with a 1:1 mixture of P- and T-radiolabelled penthiopyrad at rates equivalent to 0.4 kg ai/ha each. Samples of grapes and leaves were collected after either 30 of 60 days. Total radioactive residues in grapes were 0.20–0.24 mg eq./kg after 30 days and 0.083–0.21 mg eq./kg after 60 days. In leaves TRR levels of 5.1 mg eq./kg were found 30 day after treatment (DAT) and of 3.3 mg eq./kg 60 DAT.

Rinsing of grapes released 24% and 12% of the TRR from 30 DAT and 60 DAT samples, respectively. In the rinse unchanged parent penthiopyrad was the major residue (11% TRR for 30 DAT and 2.4% TRR for 60 DAT). In the rinsed fruits penthiopyrad amounts of 9% TRR for 30 DAT and 2.4% TRR for 60 DAT were found. Besides PAM in grapes after 60 DAT (13% TRR) no further metabolites present at relative amounts > 10 of the TRR were identified. Additional attempts for identification using acid hydrolysis released minor amounts of 753-A-OH.

Cabbage

Cabbage plants were treated with a SC formulation using application rates equivalent to either 0.2 or 1 kg ai/ha. After 21 days samples of outer leaves, inner heads and roots were samples and analysed for residues. Total radioactive residues were 1.4 mg eq./kg and 7.9 mg eq./kg for outer leaves, 0.045 mg eq./kg and 0.16 mg eq./kg for inner heads and 0.48 mg eq./kg and 2.6 mg eq./kg for roots, following the lower or higher application rate, respectively.

Rinsing of the outer leaves recovered 44% of the TRR for both application rates. Rinsing the inner leaves additionally recovered 8–11% of the TRR. In the rinses and extracts of leaves penthiopyrad was identified as the major residue, represent at 20–34% of the TRR. Metabolites DM-753, 753-F-DO, 753-A-OH, PCA and PAM were identified, however only PAM was present at amounts higher than 10% of the TRR (10–11% TRR).

Tomatoes

Field grown tomatoes were treated with a 1:1 mixture of P- or T-radiolabelled penthiopyrad at rates equivalent to either 0.3 kg ai/ha or 1.5 kg ai/ha. Total radioactive residues for the low and high rate plots found in fruits after 14 days were 0.014 mg eq./kg and 0.46 mg eq./kg and after 21 days 0.022 mg eq./kg and 0.28 mg eq./kg, respectively. In leaves (21 DAT) TRR levels of 0.65 mg eq./kg for the low rate and 4.8 mg eq./kg for the high rate samples were found.

Rinsing of fruits treated with the higher application rate recovered 76% of the TRR after 14 days and 68% of the TRR after 21 days. In the 14 DAT samples 45% of the TRR (combined rinse and extract) were identified as penthiopyrad, decreasing to 23–38% TRR after 21 days of the TRR. Other metabolites identified were PAM (4–6% TRR), PCA (4–8% TRR), 753-A-OH (1% TRR) and 753-F-DO (3–4% TRR).

In leaves treated with low or high rates penthiopyrad was the major residue with levels ranging from 37% to 55% (0.24 and 2.7 mg eq./kg), respectively. Identified metabolites were PCA (8% TRR or 0.053 mg eq./kg; 3% TRR or 0.14 mg eq./kg), PAM (4% TRR or 0.027 mg eq./kg; 5% TRR or 0.24 mg eq./kg) and 753-F-DO (2% TRR or 0.014 mg eq./kg; 5% TRR or 0.22 mg/kg).

Wheat

Wheat plants were treated with a 1:1 mixture of P- and T-radiolabelled penthiopyrad in the field at application rates equivalent to 2× 0.25 kg ai/ha or 2× 0.75 kg ai/ha. The applications were conducted at stem elongation and the end of flowering (BBCH 59). Samples of forage (7 days after 1st application), hay (5 days after 2nd application), wheat and straw (32 days after 2nd application) were collected. TRR levels found were 6.5 mg eq./kg and 22 mg eq./kg for forage, 4.0 mg eq./kg and 17 mg eq./kg for hay, 9.4 mg eq./kg and 42 mg eq./kg for straw and 0.34 mg eq./kg and 0.87 mg eq./kg for grain following low or high rate treatment, respectively. Only low rate samples were further analysed.

In forage and hay unchanged penthiopyrad was the major residue being present at 75% and 44% of the TRR. Other metabolites identified (PAM, PCA, F-DO and 753-T-DO) each amounted less than 5% of the TRR in forage and hay. In straw penthiopyrad also contributed most to the TRR (19%). Identified metabolites were identical to forage and hay; however PCA and PAM were found at slightly higher levels of 9% and 6% of the TRR, respectively.

In grain penthiopyrad was found at 8% of the TRR, representing the major residue. Both PAM and PCA were present at 4% of the TRR. No further metabolites were identified in grain.

Rape seed

Rape seed (canola) was treated with a 1:1 mixture of P- or T-radiolabelled penthiopyrad in the field two times with 0.4 kg ai/ha at stem elongation and the end of flowering. Forage was collected 14 days after the first application, mature seeds 34 days after the second application. TRR levels in forage and seeds were 12 mg eq./kg and 0.14 mg eq./kg, respectively.

In forage the major residue was 753-A-OH malonyl glucoside (25% TRR, 3.0 mg eq./kg). Unchanged penthiopyrad was found at 11% of the TRR (1.4 mg eq./kg). Other metabolites were all below 10% of the TRR remained mainly unidentified except PAM (1 % TRR, 0.16 mg eq./kg), PCA (0.5% TRR, 0.062 mg eq./kg) and DM-A-OH malonyl glucoside (9%TRR, 1.1 mg eq./kg).

In seeds penthiopyrad and PCA were identified at the LOQ of 0.001 mg/kg (0.7% TRR) in the organic phase following extraction. Approximately 27% of the TRR (0.038 mg eq./kg) was indistinguishable from natural lipids. In the aqueous phase DM-PAM and PAM were attributed to 2

chromatographic peaks at levels of 5% TRR (0.007 mg eq./kg) and 8% TRR (0.011 mg eq./kg), respectively. Additional PCA was found with 2% TRR (0.003 mg/kg). No further metabolites were identified in the aqueous phase.

Summary

In summary the plant metabolism of penthiopyrad is extensive. Following hydroxylation of the dimethyl-butyl-side chain, 753-A-OH is formed as the first stable intermediate. Subsequently conjugation with glucose or glucose malonyl occurs. In case of a hydroxylation at the thienyl moiety, the metabolite 753-F-DO is formed after substitution of the sulphur by oxygen. This structure is then cleaved, leaving the pyrazole moiety to form PAM, PCA and DM-PCA. All major metabolites identified were also found in rats.

Environmental fate in soil

The Meeting received information on the fate of penthiopyrad after aerobic degradation in soil and after photolysis on the soil surface. In addition, the Meeting received information on the uptake of penthiopyrad soil residues by rotational crops. Experiments were carried out using penthiopyrad ^{14}C labelled in the pyrazole or thienyl moiety.

In aerobic soil metabolism studies the metabolic pattern was more or less comparable to the plant metabolism. In nearly all samples PAM, PCA, 753-A-OH and 753-F-DO were found at levels of 2–10% of the applied radioactivity (AR). DM-PCA was identified as major residue in most samples, although mainly being present at levels below 10% of the AR after 140–269 days (in two samples up to 17% and 28% of the AR). Depending on the soil type remaining levels of penthiopyrad ranged from 11% to 78% of the AR (161–300 d). Estimated half-life times (1st order kinetics) were between 65 to 356 days for penthiopyrad.

Soil photolysis of penthiopyrad resulted in less than 50% remaining after three days. After 15 days only 4% of the initial concentration of the parent was recovered from the soil. According to the underlying study the irradiation of 15 days corresponds to 29 midsummer days at latitude 50°N. Main degradation products were PAM and PCA with 27% and 23% of the initial activity, respectively.

Residues in rotational crops

In a confined rotational crop study, a 1:1 mixture of P- and T-radiolabelled penthiopyrad was applied to bare soil at a rate equivalent to 0.8 kg ai/ha. Rotational crops (spinach, lettuce, radish and wheat) were sown or planted 30, 120 and 360 days later. Radioactive residues above the LOQ of 0.001 mg eq./kg were found in all samples, ranging from 0.011–0.73 mg eq./kg after the first, 0.005–0.16 mg eq./kg for the second and 0.003–0.086 mg eq./kg after the third rotation.

Identification of radioactivity was performed for samples with TRR levels above 0.01 mg/kg parent equivalents. Although extraction released 50–100% of the TRRs, rates of identification were low, showing 753-A-OH as highest residue present in spinach leaves (0.039 mg eq./kg). Parent penthiopyrad was identified in chaff samples from 30 days crops rotation. In addition PCA and DM-PAM were identified in spinach leaves and chaff (0.012–0.014 mg eq./kg). In other samples the radioactivity was present in polar fractions consisting of at least 14 individual components not further identified.

Field rotation studies reflecting authorised application rates are available from Europe and the USA. In Europe either cucumbers (Southern Europe) or barley (Northern Europe) were treated with two sprayings of 0.4 kg ai/ha each. Lettuce, spinach, radish, wheat and barley were planted as rotational crops. In all samples no residues above the LOQ were found for penthiopyrad except one detect at 0.017 mg/kg in radish roots. PCA and DM-PCA were frequently present in lettuce, radish and wheat, ranging up to 0.16 mg/kg for DM-PCA in wheat forage. PAM, 753-A-OH and 753-F-DO were not found above the LOQs of 0.01–0.05 mg/kg.

In USA trials field crops were treated with application rates of four sprayings with 0.25 kg ai/ha each. Radish, lettuce and wheat were planted as rotational crops and grown to maturity.

In none of the samples residues above the LOQ were found for penthiopyrad, 753-A-OH, 753-F-DO and PCA. Several minor results of up to 0.064 mg/kg were found for PAM, while DM-PCA was present in most samples ranging up to 0.12 mg/kg (radish tops).

In soil the degradation pathway is similar to plants, although no conjugates were observed. The translocation of residues into rotational crops was limited mainly to PCA and DM-PCA, latter being found in concentrations up to 0.09 mg/kg in food commodities, but without a tendency for accumulation. Based on the current use pattern from the USA, the submitted field rotation studies provide a realistic estimate for potential residues arising. For penthiopyrad, PAM, 753-A-OH and 753-F-DO no significant uptake via the roots occurred.

Methods of analysis

The Meeting received a number of analytical methods have for the analysis of penthiopyrad, PAM, PCA, 753-A-OH, 753-F-DO and DM-PCA in plant and animal matrices. The basic principle employs extraction by homogenisation with acetone/water or acetonitrile/water. After partitioning against an organic solvent (normally ethyl acetate) the extracts were cleaned with GPC or directly used for analysis. Residues are determined by liquid chromatography (LC) in combination with tandem mass spectroscopy (MS/MS). Validated LOQs for all analytes were 0.01 mg/kg for plant and animal matrices.

For the application of multi-residue methods the DFG S-19 was tested with satisfactory recoveries for parent penthiopyrad. The metabolites PAM, PCA and DM-PCA did not give acceptable recoveries using the DFG S-19 method.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of penthiopyrad, PAM, PCA, 753-A-OH, 753-F-DO and DM-PCA in plant and animal matrices. The results confirmed the stability of residues for all analytes for at least 18 months in plant matrices.

In animal matrices the percentage of recoveries were measured after a period of one month. Within this timeframe, which covers the storage period of animal metabolism and feeding studies submitted, no significant degradation of the analytes was observed. For bovine milk the storage stability of penthiopyrad, 753-A-OH, PAM and PCA was tested for up to 6 months without significant degradation.

Definition of the residue

Livestock animal metabolism studies were conducted on laying hens (10 ppm) and lactating goats (10 and 20 ppm). In lactating goats penthiopyrad was seldom present, normally near the LOQ amounting 2–3% of the TRR in liver and kidney. In fat 32% of the TRR were present as penthiopyrad, however absolute levels were low (0.009 mg eq./kg). The major residue in goats was PAM, being present at 10% TRR in milk, 3% TRR in liver, 19 % TRR in kidney, 8% TRR in muscle and 12% TRR in fat. Except for dihydroxy-cys-F-DO in goats kidney (11%TRR, 0.017 mg eq./kg) other metabolites were only identified at minor levels less than 10% TRR or less than 0.01 mg eq./kg in tissues and milk, even following acidic, basic or enzymic hydrolysis.

For laying hens parent penthiopyrad was only detected in eggs (up to 0.038 mg eq./kg or 15% TRR in egg yolk). The major residue identified was PAM with levels of 50% TRR in egg white, 24% TRR in egg yolk and 15% TRR in liver (sum of extracts). Except for dihydroxy-cys-T-DO found in one hen's liver sample (0.042 mg eq./kg, 12% TRR) all other metabolites were present at less than 10% of the TRR or less than 0.01 mg eq./kg in tissue and eggs even following acidic, basic or enzymic hydrolysis..

The Meeting concluded that penthiopyrad and PAM were the major residues found in all animal matrices. While parent penthiopyrad was more associated with fatty compartments, PAM was the dominant residue found in tissues, milk and eggs. Analytical methods are capable of measuring both analytes.

Concerning the toxicological relevance of penthiopyrad and its metabolites, PAM was identified to be of higher acute toxicity compared to the parent substance. However PAM was also identified in rats and is covered by the toxicological endpoints of the parent penthiopyrad. The major metabolites dihydroxy-cys-F-DO in goats' kidney and dihydroxy-cys-T-DO in hens' liver were not found in the rat. Dihydroxy degradates would be derived from the monohydroxy-F and –T-DO metabolites, which are found in rats and have very little toxicity concern. Any further metabolism would result in non-toxic products and they would be readily excreted in the body. Other metabolites (PCA, 753-F-DO, 753-A-OH and DM-PCA) are also of lower acute toxicity than penthiopyrad.

For MRL compliance and for dietary intake assessment the Meeting recommended use of the sum of penthiopyrad and PAM, expressed as penthiopyrad, in animal matrices. Although the parent substance was found at higher levels in fat than in muscle, the overall residue including PAM was evenly distributed, suggesting that the residue is not fat-soluble.

The fate of penthiopyrad in plants was investigated following foliar application to grapes, cabbage, tomatoes, wheat and rape. The parent substance was the major residue, being present at levels of 21% TRR in grapes, 20–34% TRR in cabbage, 45–46% TRR in tomatoes, 19% TRR in wheat grain and 11% TRR in rapeseeds. The only other major metabolite found was PAM (14% TRR in grapes, 11% TRR in cabbage, 6% TRR in tomato, 6% TRR in wheat grain and 1% TRR in rapeseeds). Further minor metabolites identified (PCA, 753-F-DO, 753-A-OH, DM-PCA) were normally below 10% of the TRR and often below the limit for identification.

Data from supervised field trials confirmed the results of the plant metabolism studies. Parent penthiopyrad was the highest residue of all analytes, followed by PAM and PCA. 753-F-DO and 753-A-OH were normally not present above the LOQ (0.01 mg/kg). DM-PCA was found in soil and may be taken up by following crops, resulting in detectable residues above the LOQ up to 0.09 mg/kg in food items under field conditions. However, DM-PCA is of lower acute toxicity than the parent substance and its residues make an insignificant contribution to the overall exposure compared to penthiopyrad and PAM.

Based on the overall data in plants the Meeting concluded that parent penthiopyrad is a suitable marker substance for compliance of MRLs for plant commodities. Penthiopyrad can be analysed using established analytical methods.

For dietary intake purposes PAM is covered by the toxiological reference values for penthiopyrad. Other metabolites (PCA, 753-F-DO, 753-A-OH and DM-PCA) were of lower acute toxicity compared to parent penthiopyrad and contributing insignificantly to the overall exposure compared to concentrations found for penthiopyrad and PAM.

The Meeting recommends that for MRL compliance the residue definition for plant commodities should be penthiopyrad. For dietary intake purposes the residue is defined as sum of penthiopyrad and PAM, expressed as penthiopyrad.

Definition of the residue for compliance with MRL for plant commodities: *penthiopyrad.*

Definition of the residue for compliance with MRL for animal commodities and (for the estimation of dietary intake) for plant and animal commodities: *sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad.*

The residue is not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for applications of penthiopyrad on a range of crops (fruits, vegetables, oilseed and cereal grains), conducted in Europe and North America. The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical

calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the mean sample was taken as the best estimate of the residue from the plot.

Labels (or translation of labels) were available from Japan and the USA, describing the registered uses of penthiopyrad.

Supervised field trial data for penthiopyrad conducted in Europe were submitted for various crops. However authorisations in European Member states are still pending, not allowing an assessment of these field trials.

For dietary intake assessment the residue is defined as the sum of penthiopyrad and PAM, expressed as penthiopyrad (referred to as "total"). Since residue data were expressed in mg of the specific analyte per kg sample, PAM needs to be converted into penthiopyrad equivalents. The corresponding factor is: PAM → penthiopyrad = 359.42 g/mol ÷ 193.13 g/mol = 1.86. In supervised field trials PAM residues were normally found at much lower levels than parent penthiopyrad. Therefore no adjustment of PAM or addition of LOQs was conducted, if both analytes were below the LOQ. For all other purposes of calculation < LOQ values were handled as their numeric value (e.g., < 0.01 mg/kg as 0.01 mg/kg). This is illustrated below:

Penthiopyrad [mg/kg]	PAM [mg/kg]	Total [mg/kg]* (Sum of penthiopyrad and PAM, expressed as penthiopyrad equivalents)
< 0.01	< 0.01	< 0.01
0.1	< 0.01	0.12 (0.1 + 1.86 × 0.01)
< 0.01	0.1	0.2 (0.01 + 1.86 × 0.1)
0.1	0.1	0.29 (0.1 + 1.86 × 0.1)

Pome fruits

Penthiopyrad is registered in Canada and the USA for the use on pome fruit at rates of 3–4 × 0.3 kg ai/ha with a PHI of 28 day. Supervised field trials conducted in the USA on apples and pears according to these GAPs were submitted.

Residues of parent penthiopyrad in apple were (n=17): < 0.01, 0.076, 0.099, 0.12(4), 0.13, 0.14, 0.14, 0.15, 0.16, 0.21, 0.22 and 0.23(3) mg/kg.

The total residues in apples were (n=17): < 0.01, 0.10, 0.12, 0.13, 0.13, 0.14, 0.14, 0.15, 0.15, 0.16, 0.17, 0.17, 0.22, 0.24, 0.24, 0.25 and 0.26 mg/kg.

Residues of parent penthiopyrad in pears were (n=10): < 0.01, 0.035, 0.064, 0.097, 0.12, 0.17, 0.18, 0.19, 0.22 and 0.25 mg/kg.

The total residues in pears were (n=10): < 0.01, 0.05, 0.09, 0.12, 0.13, 0.19, 0.20, 0.22, 0.24 and 0.27 mg/kg.

The Meeting noted that corresponding GAP is for all pome fruits and decided to make recommendations for the whole group. Residues in apples and pears treated according to the US GAP for pome fruits were not significantly different and may be combined.

Residues of parent penthiopyrad in pome fruits were (n=27): < 0.01, < 0.01, 0.035, 0.064, 0.076, 0.097, 0.099, 0.12(5), 0.13, 0.14, 0.14, 0.15, 0.16, 0.17, 0.18, 0.19, 0.21, 0.22, 0.22, 0.23(3) and 0.25 mg/kg.

The total residues in pome fruits were (n=27): < 0.01, < 0.01, 0.05, 0.09, 0.10, 0.12, 0.12, 0.13(3), 0.14, 0.14, 0.15, 0.15, 0.16, 0.17, 0.17, 0.19, 0.20, 0.22, 0.22, 0.24(3), 0.25, 0.26 and 0.27 mg/kg.

Based on the combined dataset for apples and pears the Meeting estimated a maximum residue level, an STMR and an HR of 0.4 mg/kg, 0.15 mg/kg and 0.27 mg/kg for penthiopyrad in pome fruits, respectively.

Stone fruits

Residue data were provided to the Meeting from trials in USA on cherries, peaches and plums. GAP for stone fruits is for a maximum of four foliar applications of up to 0.3 kg ai/ha in Canada and for a maximum of three foliar applications of up to 0.35 kg ai/ha in the USA with a PHI of 0 days, respectively.

Residues of parent penthiopyrad in cherries (whole fruits) were (n=9): 0.38, 0.44, 0.9, 0.96, 1.1, 1.1, 1.3, 1.6 and 1.7 mg/kg.

The total residues in cherries (pitted fruits) were (n=9): 0.71, 0.8, 1.0, 1.0, 1.3, 1.3, 1.4, 1.8 and 1.9 mg/kg.

Residues of parent penthiopyrad in peaches (whole fruits) were (n=13): 0.18, 0.2, 0.28, 0.35, 0.44, 0.47, 0.56, 0.58, 0.61, 0.61, 0.69, 0.7 and 1.4 mg/kg.

The total residues in peaches (pitted fruits) were (n=13): 0.2, 0.31, 0.32, 0.4, 0.54, 0.60, 0.63, 0.67, 0.67, 0.71, 0.73, 0.76 and 1.6 mg/kg.

Residues of parent penthiopyrad in plums (whole fruits) were (n=12): 0.047, 0.076, 0.08, 0.089, 0.1, 0.11, 0.12, 0.13, 0.15, 0.29, 0.51 and 0.77 mg/kg.

The total residues in plums (pitted fruits) were (n=12): 0.068, 0.072, 0.099, 0.10, 0.12, 0.12, 0.13, 0.14, 0.14, 0.24, 0.33 and 0.83 mg/kg.

The Meeting noted that the corresponding GAP is for all stone fruits and decided to make recommendations on the whole group. However the Meeting recognized that datasets for individual commodities within the group were significantly different and could not be combined. Therefore recommendations on stone fruits will be based on cherries, representing the commodity resulting in highest residues within the group.

Based on cherries the Meeting estimated a maximum residue level, an STMR and an HR of 4 mg/kg, 1.3 mg/kg and 1.9 mg/kg for stone fruits, respectively.

Strawberries

Penthiopyrad is registered in Canada and the USA for the use on strawberries at rates of 3× 0.36 kg ai/ha with a PHI of 0 day. Supervised field trials conducted in the USA on strawberries according to these GAPs were submitted.

Residues of parent penthiopyrad in strawberry fruits were (n=9): 0.37, 0.41, 0.46, 0.62, 0.77, 0.87, 1.0, 1.4 and 1.8 mg/kg.

The total residues in strawberry fruits were (n=9): 0.39, 0.43, 0.47, 0.64, 0.80, 0.89, 1.1, 1.4 and 1.8 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.8 mg/kg, and 1.8 mg/kg for penthiopyrad in strawberries, respectively.

Bulb vegetables

Residue data were provided to the Meeting from trials in Canada and the USA on bulb and green onions. GAP for bulb vegetables is for a maximum of three foliar applications of up to 0.36 kg ai/ha with a PHI of 3 days.

Residues of parent penthiopyrad in bulb onions were (n=11): 0.01, 0.014, 0.043, 0.05, 0.054, 0.064, 0.065, 0.13, 0.14, 0.36 and 0.45 mg/kg.

The total residues in bulb onions were (n=11): 0.029, 0.033, 0.062, 0.068, 0.072, 0.082, 0.085, 0.14, 0.15, 0.37 and 0.72 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.7 mg/kg, 0.074 mg/kg and 0.72 mg/kg for penthiopyrad in onions, bulb, respectively.

Residues of parent penthiopyrad in onions, green were (n=6): 0.21, 0.23, 0.55, 0.93, 1.4 and 1.8 mg/kg.

The total residues in onions, green were (n=6): 0.35, 0.66, 0.68, 1.1, 1.4 and 2.0 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 4 mg/kg, 0.89 mg/kg and 2.0 mg/kg for penthiopyrad in onions, Welsh and spring onions.

Flowerhead brassica

Residue data were provided to the Meeting from trials in Canada and the USA on broccoli and cauliflower. GAP for flowerhead brassica is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in broccoli were (n=7): 0.65, 0.87, 1.4, 1.4, 1.9, 1.9 and 2.4 mg/kg.

The total residues in broccoli were (n=7): 0.67, 0.89, 1.4, 1.4, 1.9, 1.9 and 2.4 mg/kg.

Residues of parent penthiopyrad in cauliflower were (n=3): 0.11, 0.5 and 0.5 mg/kg.

The total residues in cauliflower were (n=3): 0.13, 0.51 and 0.52 mg/kg.

The Meeting noted that the corresponding GAP is for all flowerhead brassica and decided to make recommendations on the whole group. However the Meeting recognized that datasets for individual commodities within the group were significantly different and could not be combined. Therefore recommendations on flowerhead brassica will be based on broccoli, representing the commodity resulting in highest residues within the group.

Based on broccoli the Meeting estimated a maximum residue level, an STMR and an HR of 5 mg/kg, 1.4 mg/kg and 2.4 mg/kg for penthiopyrad in flowerhead brassicas, respectively.

Cabbages, Head

Residue data were provided to the Meeting from trials in Canada and the USA on head cabbage. GAP for head cabbages is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in head cabbage were (n=10): 0.024, 0.089, 0.19, 0.22, 0.29, 0.48, 1.0, 1.3, 1.5 and 2.3 mg/kg.

The total residues in head cabbage were (n=10): 0.043, 0.11, 0.21, 0.24, 0.31, 0.49, 1.0, 1.3, 1.5 and 2.4 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 4 mg/kg, 0.4 mg/kg and 2.4 mg/kg for penthiopyrad in head cabbages, respectively.

Fruiting vegetables, Cucurbits

Residue data were provided to the Meeting from trials in Canada and the USA on summer squash, cucumber, melon and winter squash. GAP in the field for cucurbits (cucumbers, melons, watermelons, squashes) is for a maximum of four foliar applications of up to 0.3 kg ai/ha and a PHI of 1 days.

Residues of parent penthiopyrad in summer squash were (n=4): 0.01, 0.13, 0.18 and 0.19 mg/kg.

Residues of parent penthiopyrad in cucumber were (n=10): 0.012, 0.015, 0.029, 0.034, 0.043, 0.047, 0.065, 0.086, 0.11 and 0.13 mg/kg.

Residues of parent penthiopyrad in melon (whole fruit) were (n=8): 0.098, 0.17, 0.17, 0.18, 0.22, 0.26, 0.26 and 0.27 mg/kg.

Residues of parent penthiopyrad in winter squash were (n=5): 0.067, 0.1, 0.12, 0.18 and 0.21 mg/kg.

The Meeting noted that Canadian and US GAP are for all members of the cucurbits group and decided to make recommendations for the whole group. Residues of penthiopyrad in summer squash, cucumber, melon, and winter squash (whole fruits) treated according to the US GAP for cucurbits were not significantly different and may be combined.

The combined residues for penthiopyrad in cucurbits (whole fruits) were (n=27): 0.01, 0.012, 0.015, 0.029, 0.034, 0.043, 0.047, 0.065, 0.067, 0.086, 0.098, 0.1, 0.11, 0.12, 0.13, 0.13, 0.17, 0.17, 0.18(3), 0.19, 0.21, 0.22, 0.26, 0.26 and 0.27 mg/kg.

Based on the combined dataset the Meeting estimated a maximum residue level of 0.5 mg/kg for penthiopyrad in fruiting vegetables, cucurbits.

The total residues in summer squash were (n=4): 0.029, 0.14, 0.2 and 0.21 mg/kg.

The total residues in cucumber were (n=10): 0.031, 0.033, 0.048, 0.052, 0.061, 0.066, 0.084, 0.10, 0.13 and 0.15 mg/kg.

The total residues in melon (whole fruit) were (n=8): 0.12, 0.18, 0.19, 0.19, 0.24, 0.28, 0.29 and 0.3 mg/kg.

The total residues in melon (pulp) were (n=8): < 0.01(8) mg/kg.

The total residues in winter squash were (n=5): 0.086, 0.12, 0.14, 0.21 and 0.22 mg/kg.

For dietary intake purposes the Meeting noted that residues in cucurbits, whole fruits and in the pulp (based on melons) differ significantly.

Therefore the Meeting decided to extrapolate all data on whole fruits to cucurbits with edible peel, also accommodating large varieties within the group like pumpkins with edible peel. The combined total residues in cucurbits (whole fruits) were (n=27): 0.02, 0.025, 0.031, 0.039, 0.044, 0.053, 0.057, 0.075, 0.077, 0.096, 0.11, 0.12, 0.12, 0.13, 0.14, 0.15, 0.18, 0.19(3), 0.2, 0.21, 0.22, 0.24, 0.28, 0.29 and 0.3 mg/kg.

For dietary intake purposes of cucurbits with edible peel, the Meeting estimated an STMR and an HR of 0.13 mg/kg and 0.3 mg/kg, based on the combined dataset for the total residue in all cucurbits (whole fruits).

The Meeting also decided to extrapolate data on melon pulp to the edible portion of all cucurbits with inedible peel, to reflect to the much lower residue situation in these commodities.

For dietary intake purposes of cucurbits with inedible peel, the Meeting estimated an STMR and an HR of 0.01 mg/kg and 0.01 mg/kg, based on the total residue in melon pulp.

Fruiting vegetables, other than cucurbits (except sweet corn and mushroom)

Residue data were provided to the Meeting from trials in Canada and the USA on peppers (sweet and chili) and tomatoes. GAP for fruiting vegetables is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in sweet peppers were (n=11): 0.15, 0.15, 0.17, 0.17, 0.18, 0.19, 0.19, 0.21, 0.22, 0.68 and 0.77 mg/kg.

The total residues in sweet peppers were (n=11): 0.16, 0.16, 0.18, 0.19, 0.2(3), 0.22, 0.23, 0.70 and 0.79 mg/kg.

Residues of parent penthiopyrad in chili peppers were (n=9): 0.17, 0.2, 0.33, 0.36, 0.41, 0.57, 0.71, 0.88 and 1.6 mg/kg.

The total residues in chili peppers were (n=9): 0.19, 0.23, 0.35, 0.38, 0.43, 0.59, 0.73, 0.92 and 1.6 mg/kg.

Residues of parent penthiopyrad in tomatoes were (n=20): 0.085, 0.15, 0.16, 0.17, 0.17, 0.18, 0.22, 0.24, 0.25, 0.27, 0.28, 0.36(3), 0.4, 0.41, 0.42, 0.7, 1.3 and 1.4 mg/kg.

The total residues in tomatoes were (n=20): 0.10, 0.17, 0.17, 0.18, 0.18, 0.2, 0.24, 0.26, 0.27, 0.29, 0.30, 0.37, 0.38, 0.38, 0.42, 0.42, 0.43, 0.72, 1.3, 1.4 mg/kg.

The Meeting noted that the corresponding GAP is for all fruiting vegetables other than cucurbits, except sweet corn and mushroom and decided to make recommendations for the whole group. Based on the Kruskal-Wallis test the dataset for sweet peppers, chili peppers and tomatoes were not significantly different and may be combined.

Residues of parent penthiopyrad in fruiting vegetables, other than cucurbits except sweet corn and mushroom were (n=40): 0.085, 0.15(3), 0.16, 0.17(5), 0.18, 0.19(3), 0.2, 0.21, 0.22, 0.22, 0.24, 0.25, 0.27, 0.28, 0.33, 0.36(4), 0.4, 0.41, 0.41, 0.42, 0.57, 0.68, 0.7, 0.71, 0.77, 0.88, 1.3, 1.4 and 1.6 mg/kg.

The total residues in fruiting vegetables, other than cucurbits except sweet corn and fungi were (n=40): 0.095, 0.16(3), 0.17, 0.18(5), 0.2(4), 0.22, 0.23(3), 0.25, 0.26, 0.28, 0.29, 0.34, 0.37, 0.37, 0.38, 0.38, 0.41, 0.42, 0.43, 0.44, 0.58, 0.69, 0.71, 0.73, 0.78, 0.92, 1.3, 1.4 and 1.6 mg/kg.

Based on the combined dataset for sweet pepper, chili pepper and tomatoes the Meeting estimated a maximum residue level, an STMR and an HR of 2 mg/kg, 0.27 mg/kg and 1.6 mg/kg for penthiopyrad in fruiting vegetables, other than cucurbits except sweet corn and mushroom, respectively.

The Meeting noted that residues in chili pepper and in other commodities within the group of fruiting vegetables, except sweet corn and mushroom do not differ significantly. Since the group maximum residue level of 2 mg/kg is expected to provide a reliable estimate for chili peppers also, the default dehydration factor of 7 for chili pepper instead of the default factor of 10 for peppers was used to estimate a maximum residue level of 14 mg/kg for dried chili peppers.

Sweet corn (corn-on-the-cob)

For sweet corn GAP is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 30 days.

Residues of parent penthiopyrad in sweet corn (corn-on-the-cob) were (n=11): < 0.01(11) mg/kg.

The total residues in sweet corn (corn on the cob) were (n=11): < 0.01(11) mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.01 mg/kg, 0.01 mg/kg and 0.02 mg/kg for penthiopyrad in sweet corn (corn on the cob), respectively. The Meeting noted the in maize treated identically as sweet corn following processing finite residues in processed products occur, also precluding a zero-residue situation for sweet corn.

Brassica leafy vegetables

Residue data were provided to the Meeting from trials in Canada and the USA on mustard greens and turnip leaves. GAP from the US for brassica, leafy vegetables is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in mustard greens were (n=9): 7.6, 8.3, 8.7, 8.75, 11, 16, 17, 23 and 30 mg/kg.

The total residues in mustard greens were (n=9): 7.7, 8.4, 8.9, 9.0, 11, 16, 17, 23 and 30 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 50 mg/kg, 11 mg/kg and 30 mg/kg for penthiopyrad in mustard greens, respectively.

The Meeting noted that for mustard greens the IESTI exceeds the ARfD by 150%. No alternative GAP for mustard greens is available.

Residues of parent penthiopyrad in turnip greens were (n=6): 4, 4.8, 6.1, 13, 20 and 23 mg/kg.

The total residues in turnip greens were (n=6): 4.1, 4.9, 6.4, 13, 20 and 23 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 50 mg/kg, 9.4 mg/kg and 23 mg/kg for penthiopyrad in turnip greens, respectively.

Leafy vegetables, except brassica leafy vegetables

Residue data were provided to the Meeting from trials in Canada and the USA on lettuce and spinach. GAP for leafy vegetables is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 3 days.

Residues of parent penthiopyrad in head lettuce were (n=12): < 0.01, 0.37(3), 0.41, 0.49, 0.6, 1.6, 2.0, 2.3, 2.8 and 3.5 mg/kg.

The total residues in head lettuce were (n=12): < 0.01, 0.38, 0.38, 0.41, 0.42, 0.52, 0.68, 1.7, 2.2, 2.3, 2.8 and 3.5 mg/kg.

Residues of parent penthiopyrad in leaf lettuce were (n=12): 1.1, 1.2, 1.2, 1.8, 1.8, 2.0, 3.5, 4.1, 4.4, 5.3, 7.4 and 11 mg/kg.

The total residues in leaf lettuce were (n=12): 1.2, 1.2, 1.4, 2.0, 2.2, 2.3, 3.5, 4.2, 4.6, 5.4, 7.5 and 11 mg/kg.

Residues of parent penthiopyrad in spinach were (n=10): 0.81, 1.2 1.5, 2, 2.7, 2.8, 2.8, 8.1, 11 and 15 mg/kg.

The total residues in spinach were (n=10): 0.95, 1.4, 1.8, 2.9, 3.1, 3.2, 3.9, 8.3, 12 and 15 mg/kg.

The Meeting notes that the corresponding GAP is for all leafy vegetables, except brassica leafy vegetables, and decided to make recommendations on the whole group. However the Meeting recognized that datasets for individual commodities within the group were significantly different and could not be combined. Therefore recommendations on leafy vegetables, except brassica leafy vegetables, will be based on spinach, representing the commodity resulting in highest residues within the group.

Based on the critical use on spinach the Meeting estimated a maximum residue level, an STMR and an HR of 30 mg/kg, 3.15 mg/kg and 15 mg/kg for penthiopyrad in leafy vegetables, except brassica leafy vegetables, respectively.

Celery

Residue data were provided to the Meeting from trials in Canada and the USA on celery. GAP for celery is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 3 days.

Residues of parent penthiopyrad in celery were (n=11): 1.7, 2, 2.1, 2.5, 2.8, 3, 3.1, 5.3, 5.3, 5.8 and 8.7 mg/kg.

The total residues in celery were (n=11): 1.7, 2.0, 2.3, 2.6, 2.9, 3.1, 3.2, 5.4, 5.6, 6.1 and 8.8 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 15 mg/kg, 3.1 mg/kg and 8.8 mg/kg for penthiopyrad in celery, respectively.

Legume vegetables, immature with pods

Residue data were provided to the Meeting from trials in Canada and the USA on succulent beans and peas. GAP for legume vegetables is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in green beans with pods were (n=8): 0.13, 0.16, 0.36, 0.47, 0.77, 0.9, 0.99 and 1.5 mg/kg.

The total residues in green beans with pods were (n=8): 0.14, 0.17, 0.38, 0.49, 0.79, 0.92, 1.1 and 1.5 mg/kg.

Residues of parent penthiopyrad in green peas with pods were (n=4): 0.88, 1.0, 1.3 and 1.5 mg/kg.

The total residues in peas with pods were (n=4): 0.90, 1.1, 1.3 and 1.6 mg/kg.

The Meeting decided that residues in green beans with pods and in green peas with pods are similar and can be combined for mutual support. Residues of parent penthiopyrad in green beans with pods and peas with pods were (n=12): 0.13, 0.16, 0.36, 0.47, 0.77, 0.88, 0.9, 0.99, 1.0, 1.3, 1.5 and 1.5 mg/kg.

The total residues in green beans with pods and peas with pods were (n=12): 0.14, 0.178, 0.37, 0.49, 0.78, 0.89, 0.91, 1.1, 1.1, 1.3, 1.5 and 1.6 mg/kg.

Based on the combined dataset of the Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.9 mg/kg and 1.6 mg/kg for penthiopyrad in beans, except broad bean and soya bean (green pods and immature seeds) and in peas (pods and succulent), respectively.

Legume vegetables, shelled

Residue data were provided to the Meeting from trials in Canada and the USA on shelled succulent beans and peas. GAP for legume vegetables is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in shelled beans were (n=7): 0.011, 0.024, 0.025, 0.035, 0.052 and 0.056, 0.13 mg/kg.

The total residues in shelled beans were (n=7): 0.029, 0.043, 0.043, 0.054, 0.071, 0.075 and 0.16 mg/kg.

Residues of parent penthiopyrad in shelled peas were (n=7): 0.04, 0.05, 0.067, 0.069, 0.077, 0.09 and 0.14 mg/kg.

The total residues in shelled peas were (n=7): 0.059, 0.068, 0.085, 0.088, 0.095, 0.11 and 0.16 mg/kg.

The Meeting decided that residues in shelled beans and in shelled peas without pods are similar and can be combined for mutual support. Residues of parent penthiopyrad in shelled beans and peas without pods were (n=14): 0.011, 0.024, 0.025, 0.035, 0.04, 0.05, 0.052, 0.056, 0.067, 0.069, 0.077, 0.09, 0.13 and 0.14 mg/kg.

The total residues in shelled beans and peas without pods were (n=14): 0.021, 0.034, 0.035, 0.045, 0.05, 0.06, 0.062, 0.075, 0.077, 0.079, 0.087, 0.1, 0.15 and 0.16 mg/kg.

Based on the combined dataset the Meeting estimated a maximum residue level, an STMR and an HR of 0.3 mg/kg, 0.0685 mg/kg and 0.16 mg/kg for penthiopyrad in beans, shelled and in peas, shelled, respectively.

Pulses, except soya beans

Residue data were provided to the Meeting from trials in Canada and the USA on beans and peas as pulses. GAP for pulses except soya beans is for a maximum of three foliar applications of up to 0.35 kg ai/ha and a PHI of 21 days.

Residues of parent penthiopyrad in beans were (n=14): < 0.01(10), 0.011, 0.026, 0.033 and 0.2 mg/kg.

The total residues in beans were (n=14): < 0.01(10), 0.029, 0.030, 0.045 and 0.29 mg/kg.

Residues of parent penthiopyrad in peas were (n=14): < 0.01(7), 0.011, 0.012, 0.014, 0.014, 0.032, 0.034 and 0.088 mg/kg.

The total residues in peas were (n=14): < 0.01(7), 0.030, 0.031, 0.033, 0.033, 0.051, 0.052 and 0.12 mg/kg.

The Meeting noted that corresponding GAP is for all pulses, except soya beans and decided to make recommendations for the whole group. The Meeting also noted that beans and peas treated according to the same GAP result in comparable residues and could be combined.

Combined residues of parent penthiopyrad in beans and peas were (n=28): < 0.01(17), 0.011, 0.011, 0.012, 0.014, 0.014, 0,026, 0.032, 0.033, 0.034, 0.088 and 0.2 mg/kg.

The total residues in beans and peas were (n=28): < 0.01(17), 0.029, 0.030, 0.030, 0.031, 0.033, 0.033, 0.045, 0.051, 0.052, 0.12 and 0.29 mg/kg.

Based on the combined dataset of the Meeting estimated a maximum residue level and an STMR of 0.3 mg/kg and 0.01 mg/kg for penthiopyrad in pulses, except soya beans, respectively.

Soya beans

Residue data were provided to the Meeting from trials in Canada and the USA on soya beans. GAP for soya beans is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in soya beans were (n=21): < 0.01(9), 0.012, 0.013, 0.014, 0.022, 0.022, 0.024, 0.025, 0.049, 0.056, 0.068, 0.1 and 0.21 mg/kg.

The total residues in soya beans were (n=21): < 0.01(9), 0.030, 0.031, 0.033, 0.041, 0.042, 0.043, 0.043, 0.069, 0.074, 0.087, 0.12 and 0.23 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.3 mg/kg and 0.032 mg/kg for penthiopyrad in soya beans, respectively.

Carrots

Residue data were provided to the Meeting from trials in Canada and the USA on carrots. GAP for carrots in the USA is for a maximum of two foliar applications of up to 0.39 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in carrots were (n=9): 0.021, 0.025, 0.047, 0.051, 0.071, 0.085, 0.12, 0.1 and, 0.4 mg/kg.

The total residues in carrots were (n=9): 0.039, 0.044, 0.066, 0.070, 0.09, 0.10, 0.14, 0.18 and 0.41 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.6 mg/kg, 0.09 mg/kg and 0.41 mg/kg for penthiopyrad in carrots, respectively.

Potatoes

Residue data were provided to the Meeting from trials in Canada and the USA on potatoes.

GAP for potatoes in the USA is for a maximum of three foliar applications of up to 0.31 kg ai/ha and a PHI of 7 days.

Residues of parent penthiopyrad in potato tubers were (n=22): < 0.01(15), 0.011, 0.011, 0.014, 0.015, 0.017, 0.025 and 0.033 mg/kg.

The total residues in potato tubers were (n=22): < 0.01(15), 0.029, 0.030, 0.033, 0.03, 0.036, 0.044 and 0.051 mg/kg.

The OECD Calculator suggests a maximum residue level of 0.04 mg/kg for penthiopyrad in potatoes; however, a high uncertainty due to the limited number of results above the LOQ was

indicated. The Meeting decided to estimate a maximum residue level at the next higher MRL-step of 0.05 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.05 mg/kg, 0.01 mg/kg and 0.051 mg/kg for penthiopyrad in potatoes, respectively.

Radish

Residue data were provided to the Meeting from trials in Canada and the USA on radishes.

GAP for radish in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in radish roots were (n=6): < 0.01, 0.14, 0.22, 0.33, 0.92 and 1.2 mg/kg.

The total residues in radish roots were (n=6): < 0.01, 0.15, 0.24, 0.35, 0.93 and 1.2 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.305 mg/kg and 1.2 mg/kg for penthiopyrad in radish roots, respectively.

Sugar beet

Residue data were provided to the Meeting from trials in Canada and the USA on sugar beets.

GAP for sugar beets in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 7 days.

Residues of parent penthiopyrad in sugar beet roots were (n=12): 0.015, 0.017, 0.019, 0.033, 0.042, 0.085, 0.090, 0.13, 0.18, 0.19, 0.2 and 0.27 mg/kg.

The total residues in sugar beet roots were (n=12): 0.033, 0.035, 0.037, 0.051, 0.060, 0.1, 0.11, 0.15, 0.20, 0.20, 0.21 and 0.29 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.5 mg/kg and 0.105 mg/kg for penthiopyrad in sugar beets, respectively.

Barley and oats

Residue data were provided to the Meeting from trials in Canada and the USA on barley grain. GAP for barley and oats in the USA is for a maximum of two foliar applications before flowering (BBCH 59) of up to 0.36 kg ai/ha without a specified PHI for the grain (covered by growth stage).

Residues of parent penthiopyrad in barley grain were (n=13): < 0.01(7), 0.01, 0.011, 0.02, 0.024, 0.03 and 0.11 mg/kg.

The total residues in barley grain were (n=13): < 0.01(7), 0.029, 0.029, 0.038, 0.042, 0.048 and 0.14 mg/kg.

The Meeting recognized that barley and oats share an identical GAP and normally show comparable residues. It was therefore decided to extrapolate residue data from barley to oats.

The Meeting estimated a maximum residue level and an STMR of 0.15 mg/kg and 0.01 mg/kg for penthiopyrad in barley and oats, respectively.

Rye, triticale and wheat

Residue data were provided to the Meeting from trials in Canada and the USA on wheat grain. GAP for rye, triticale and wheat in the USA is for a maximum of two foliar applications before flowering (BBCH 59) of up to 0.36 kg ai/ha without a specified PHI for the grain (covered by growth stage).

Residues of parent penthiopyrad in wheat grain were (n=29): < 0.01(24), 0.011, 0.012, 0.017, 0.019 and 0.034 mg/kg.

The total residues in wheat grain were (n=29): < 0.01(24), 0.030, 0.033, 0.036, 0.037 and 0.053, mg/kg.

The Meeting recognized that wheat, triticale and rye share an identical GAP and normally show comparable residues. It was therefore decided to extrapolate residue data from wheat to rye and triticale.

The Meeting estimated a maximum residue level and an STMR of 0.04 mg/kg and 0.01 mg/kg for penthiopyrad in rye, triticale and wheat, respectively.

Maize

Residue data were provided to the Meeting from trials in Canada and the USA on maize. GAP for maize in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 30 days.

Residues of parent penthiopyrad in maize grain were (n=14): < 0.01(14) mg/kg.

The total residues in maize grain were (n=14): < 0.01(14) mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.01 mg/kg and 0.01 mg/kg for penthiopyrad in maize, respectively. The Meeting noted the in maize processing finite residues in processed products occur, precluding a zero-residue situation for maize grain.

Millet and sorghum

Residue data were provided to the Meeting from trials in Canada and the USA on sorghum. GAP for sorghum and millet in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 30 days.

Residues of parent penthiopyrad in sorghum grain were (n=9): 0.06, 0.093, 0.12, 0.16, 0.18, 0.28, 0.3, 0.39 and 0.43 mg/kg.

The total residues in sorghum grain were (n=9): 0.084, 0.13, 0.14, 0.2, 0.22, 0.34, 0.4, 0.45 and 0.69 mg/kg.

The Meeting recognized that sorghum and millet share an identical GAP and normally show comparable residues. It was therefore decided to extrapolate residue data from sorghum to millet.

The Meeting estimated a maximum residue level and an STMR of 0.8 mg/kg and 0.22 mg/kg for penthiopyrad in millet and sorghum grain, respectively.

Tree nuts

Residue data were provided to the Meeting from trials in Canada and the USA on almonds and pecans. GAP for tree nuts in the USA is for a maximum of four foliar applications of up to 0.3 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in almond nutmeat were (n=6): < 0.01(4), 0.01 and 0.037 mg/kg.

The total residues in almond nutmeat were (n=6): < 0.01(4), 0.029 and 0.056 mg/kg.

Residues of parent penthiopyrad in pecan nutmeat were (n=6): < 0.01(6) mg/kg.

The total residues in pecan nutmeat were (n=6): < 0.01(6) mg/kg.

The Meeting noted that corresponding GAP is for all tree nuts and decided to make recommendations for the whole group. The Meeting concluded that the dataset for almonds and pecan treated according to US GAP for tree nuts are not significantly different and can be combined.

Residues of parent penthiopyrad in almond and pecan nutmeat were (n=6): < 0.01(10), 0.01 and 0.037 mg/kg.

The total residues in almond and pecan nutmeat were (n=6): < 0.01(10), 0.02 and 0.047 mg/kg.

Based on the combined dataset of the Meeting estimated a maximum residue level, an STMR and an HR of 0.05 mg/kg, 0.01 mg/kg and 0.047 mg/kg for penthiopyrad in tree nuts, respectively.

Cotton

Residue data were provided to the Meeting from trials in the USA on cotton. GAP for cotton in the USA is one in-furrow spray and a maximum of two foliar applications of up to 0.35 kg ai/ha each and a PHI of 21 days.

Residues of parent penthiopyrad in cotton seeds were (n=13): < 0.01, < 0.01, 0.011, 0.036, 0.04, 0.091, 0.093, 0.11, 0.13, 0.13, 0.14, 0.23 and 0.25 mg/kg.

The total residues in cotton seeds were (n=13): 0.035, 0.036, 0.043, 0.060, 0.083, 0.12, 0.17, 0.17, 0.22, 0.22, 0.37, 0.39 and 0.39 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.5 mg/kg and 0.17 mg/kg for penthiopyrad in cotton seeds, respectively.

Rape seed

Residue data were provided to the Meeting from trials in Canada and the USA on oilseed rape. GAP for rape in the USA is for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 21 days.

Residues of parent penthiopyrad in rape seeds were (n=21): < 0.01(7), 0.011, 0.017, 0.024, 0.025, 0.028, 0.033, 0.052, 0.054, 0.065, 0.08, 0.081, 0.085, 0.13 and 0.42 mg/kg.

The total residues in rape seeds were (n=21): < 0.01(5), 0.03, 0.046, 0.048, 0.071, 0.073, 0.074, 0.083, 0.084, 0.087, 0.094, 0.099, 0.12, 0.13, 0.15, 0.15 and 0.44 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.5 mg/kg and 0.084 mg/kg for penthiopyrad in rape seeds, respectively.

Peanuts

Residue data were provided to the Meeting from trials in the USA on peanuts. GAP for peanuts in the USA is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in peanut nutmeat were (n=13): < 0.01(12) and 0.034 mg/kg.

The total residues in peanut nutmeat were (n=13): < 0.01(12) and 0.055 mg/kg.

The OECD Calculator suggests a maximum residue level of 0.04 mg/kg for penthiopyrad in peanuts; however, a high uncertainty due to the limited number of results above the LOQ was indicated. The Meeting decided to estimate a maximum residue level at the next higher MRL-step of 0.05 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.05 mg/kg and 0.01 mg/kg for penthiopyrad in peanuts, respectively.

Sunflowers

Residue data were provided to the Meeting from trials in Canada and the USA on sunflowers. GAP for sunflowers in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in sunflower seeds were (n=9): < 0.01, 0.078, 0.079, 0.079, 0.1, 0.28, 0.34, 0.44 and 0.81 mg/kg.

The total residues in sunflower seeds were (n=9): < 0.01, 0.097, 0.097, 0.098, 0.12, 0.32, 0.51, 0.57 and 0.94 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 1.5 mg/kg and 0.12 mg/kg for penthiopyrad in sunflower seeds, respectively.

Animal feeds

Alfalfa, forage and hay

Residue data were provided to the Meeting from trials in Canada and the USA on alfalfa. GAP for alfalfa in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 14 days.

The total residues in alfalfa forage were (n=15): 0.1, 0.21, 0.45, 0.47, 0.59, 0.62, 0.7, 0.73, 0.95, 1.0, 1.4, 1.8, 2.0, 2.1 and 4.6 mg/kg.

Residues of parent penthiopyrad in alfalfa hay were (n=15): 0.11, 0.28, 0.58, 0.77, 0.97, 1.6, 1.6, 1.8, 1.8, 1.9, 3.2, 3.6, 4.7, 4.9 and 14 mg/kg.

The total residues in alfalfa hay were (n=15): 0.6, 1.2, 1.9, 2.3, 2.5(3), 2.9, 3.3, 3.4, 4.5, 4.9, 5.9, 6.4 and 16 mg/kg.

The Meeting estimated STMR values of 0.73 mg/kg and 2.9 mg/kg and highest residue values of 4.6 mg/kg and 16 mg/kg for alfalfa forage and hay (fresh weight basis), respectively.

The Meeting also estimated a maximum residue level of 20 mg/kg for penthiopyrad in alfalfa fodder (DM basis, 89% dry-matter content).

Pea vines and hay

Residue data were provided to the Meeting from trials in Canada and the USA on pea vines. GAP for peas in the USA are for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 0 days for vines and hay.

The total residues in pea vines were (n=7): 4.5, 5.3, 6.1, 6.2, 6.3, 12 and 23 mg/kg.

Residues of parent penthiopyrad in pea hay were (n=7): 3.7, 8.7, 9.4, 11, 14, 15 and 30 mg/kg.

The total residues in pea hay were (n=7): 3.9, 8.9, 11, 12, 14, 15 and 31 mg/kg.

The Meeting estimated STMR values of 6.2 mg/kg and 12 mg/kg and highest residue values of 23 mg/kg and 31 mg/kg for pea vines and hay (fresh weight basis), respectively.

The Meeting also estimated a maximum residue level of 60 mg/kg for penthiopyrad in pea hay (DM basis, 88% dry-matter content).

Soya bean, forage and hay

Residue data were provided to the Meeting from trials in Canada and the USA on soya beans. GAP for soya beans in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days for forage and hay.

The total residues in soya forage were (n=16): 4.1, 4.9, 6.4, 11, 14, 14, 15, 16(3), 19, 20, 21, 23, 24 and 24 mg/kg.

Residues of parent penthiopyrad in soya hay were (n=16): 11, 22, 33, 45, 47, 48, 49, 50, 53, 54, 55, 59, 73, 99, 100 and 123 mg/kg.

The total residues in soya hay were (n=16): 11, 22, 33, 45, 48, 49, 50, 51, 54, 55, 55, 61, 73, 100, 102 and 125 mg/kg.

The Meeting estimated STMR values of 16 mg/kg and 52.5 mg/kg and highest residue values of 24 mg/kg and 125 mg/kg for soya forage and fodder (fresh weight basis), respectively.

The Meeting also estimated a maximum residue level of 200 mg/kg for penthiopyrad in soya bean fodder (DM basis, 85% dry-matter content).

Barley, oats, rye, triticale and wheat—straw, fodder and forage of cereals

GAPs for barley, oats, rye, triticale and wheat in the USA are for a maximum of two foliar applications before flowering (BBCH 59) of up to 0.36 kg ai/ha and a 0 day PHI for the forage/hay and an unspecified PHI for the straw (covered by growth stage).

The Meeting concluded that straw, fodder and forage of barley, oats, rye, triticale and wheat are indistinguishable and result in comparable residues following treatment according to the identical US GAPs for these crops. Therefore all estimations on forage, fodder and straw will be based on the combined residue dataset for these crops and applied to each of them.

The total residues in forage based on wheat trials were (n=26): 5.5, 5.8, 6.2, 7.3, 8.3, 8.7, 8.8, 8.9, 9.2, 9.5, 9.8, 10(3), 11, 12, 12, 13(4), 14, 14, 15, 16 and 17 mg/kg (fresh weight basis).

Residues of parent penthiopyrad in hay based on barley and wheat trials were (n=39): 2.6, 3.9, 4.4, 4.5, 4.7, 6.4, 7.0, 7.4, 7.7, 8.2, 8.9, 11, 12, 12, 13, 14, 17, 17, 19, 19, 22, 23, 23, 25, 25, 27, 28(3), 29(3), 30, 34, 35, 38, 40, 44 and 53 mg/kg.

Residues of parent penthiopyrad in straw based on barley and wheat trials were (n=13): < 0.05, < 0.05, 0.051, 0.053, 0.054, 0.058, 0.06, 0.084, 0.088, 0.095, 0.096, 0.11(5), 0.12, 0.12, 0.14, 0.14, 0.15, 0.18, 0.19(3), 0.2, 0.22, 0.22, 0.23, 0.24, 0.24, 0.3, 0.34, 0.36, 0.37, 0.37, 0.4, 0.42 and 0.7 mg/kg.

The total residues in hay based on barley and wheat trials were (n=39): 2.9, 4.2, 4.9, 5.1, 5.7, 7.1, 7.9, 8.1, 9.3, 9.7, 9.8, 13(4), 16, 17, 20, 20, 21, 23, 24, 24, 26, 27, 28, 29(3), 30(3), 31, 36, 36, 39, 42, 47 and 54 mg/kg

The total residues in straw based on barley and wheat trials were (n=39): < 0.1, < 0.1, 0.14, 0.15(3), 0.18, 0.18, 0.19, 0.20(4), 0.21, 0.21, 0.23, 0.23, 0.26, 0.27, 0.27, 0.32, 0.32, 0.34, 0.34, 0.35, 0.40, 0.41, 0.42, 0.42, 0.43, 0.50, 0.54, 0.57, 0.61, 0.61, 0.66, 0.69, 0.81 and 0.97 mg/kg.

The Meeting concluded that residues in hay are significantly higher as in straw and should be used as basis for recommendations on straw, fodder and forage of barley, oats, rye, triticale and wheat.

The Meeting estimated an STMR value of 10 mg/kg and a highest residue value of 17 mg/kg for barley, oats, rye, triticale and wheat forage (fresh weight basis).

The Meeting also estimated a maximum residue level, an STMR value and a highest residue of 80 mg/kg (DM based, 88% dry-matter content), 21 mg/kg (fresh weight basis) and 54 mg/kg (fresh weight basis) for penthiopyrad in barley, oats, rye, triticale and wheat straw and fodder.

Maize, millet and sorghum—forage and fodder

GAP for maize, sorghum and millet in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 0 days for forage and hay and of 30 days for stover.

The total residues in maize forage were (n=13): 3.0, 3.4, 3.4, 3.6, 3.7, 4.3, 4.4, 4.7, 4.9, 5.1, 5.2, 5.3 and 7.3 mg/kg.

The total residues in sorghum forage were (n=9): 3.6, 3.9, 6.2, 6.7, 6.7, 7.0, 7.5, 7.9 and 14 mg/kg.

Residues of parent penthiopyrad in sorghum stover were (n=9): 0.14, 0.19, 0.23, 0.32, 0.44, 0.62, 0.66, 2.5 and 5.5 mg/kg.

The total residues in sorghum stover were (n=9): 0.23, 0.42, 0.47, 0.52, 0.55, 0.75, 0.82, 2.7 and 5.9 mg/kg.

Supervised field trial data on maize stover from the USA was not conducted according to the submitted GAPs.

The Meeting concluded that forage and fodder of maize, millet and sorghum treated according to identical US GAPs result in comparable residues and may be combined for mutual support. Therefore all estimations on forage and fodder will be based on the combined residue dataset for these crops and applied to each of them.

For forage of maize and stover combined total residues were (n=22): 3.0, 3.4, 3.4, 3.6, 3.6, 3.7, 3.9, 4.3, 4.4, 4.7, 4.9, 5.1, 5.2, 5.3, 6.2, 6.7, 6.7, 7.0, 7.3, 7.5, 7.9 and 14 mg/kg.

The Meeting estimated an STMR value of 5 mg/kg and a highest residue value of 14 mg/kg for maize, millet and sorghum forage (fresh weight basis).

The Meeting also estimated a maximum residue level, an STMR value and a highest residue of 10 mg/kg (DM basis, 88% dry-matter content), 0.52 mg/kg (fresh weight basis) and 5.9 mg/kg (fresh weight basis) for penthiopyrad in maize, millet and sorghum fodder.

Sugar beet leaves

GAP for sugar beets in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days for the forage. In Canada GAP for sugar beets is for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 7 days for the forage.

All supervised field trials on sugar beet leaves involve two treatments of 0.45 kg ai/ha and a PHI of 6–8 days. Since neither the Canadian nor the US GAP matched these field trials, the Meeting concluded that for sugar beets leaves no STMR value or highest residue can be estimated.

Oilseed rape forage

GAP for oilseed rape in the USA is for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 21 days.

Supervised field trial data submitted from Europe involve single treatment at 0.3 kg ai/ha. The Meeting noted that the data submitted involving single application probably underestimates the true residue situation according to US GAP and concluded that for rape forage no STMR value or highest residue could be estimated.

Peanut hay

GAP for peanuts in the USA is for a maximum of three foliar applications of up to 0.36 kg ai/ha (maximum annual rate in 1.1 kg ai/ha) and a PHI of 14 days.

Residues of parent penthiopyrad in peanut hay were (n=13): 1.5, 1.8, 1.8, 1.9, 2.9, 4.5, 5.4, 6.8, 6.9, 7.1, 8.6, 8.8 and 17 mg/kg.

The total residues in peanut hay were (n=13): 1.6, 2.0, 2.1, 2.1, 3.6, 4.9, 5.9, 7.3, 7.9, 8.7, 9.2, 9.4 and 18 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an highest residue of 30 mg/kg (DM basis, 85% dry-matter content), 5.9 mg/kg (fresh weight basis) and 18 mg/kg (fresh weight basis) for penthiopyrad in peanut hay(fresh weight basis), respectively.

Almond hulls

GAP for tree nuts in the USA is for a maximum of four foliar applications of up to 0.3 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in almond hulls were (n=6): 0.8, 1.1, 1.4, 2.1, 2.4 and 2.7 mg/kg.

The total residues in almond hulls were (n=6): 0.91, 1.6, 1.9, 2.9, 3.0 and 3.1 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 6 mg/kg (DM basis, 90% dry-matter content) and 2.4 mg/kg (fresh weight basis) for penthiopyrad in almond hulls, respectively.

Cotton gin trash

GAP for cotton in the USA is for a maximum of three foliar applications of up to 0.35 kg ai/ha and a PHI of 21 days.

The total residues in cotton gin trash were (n=4): 3.0, 4.2, 4.9 and 7.8 mg/kg.

The Meeting estimated an STMR of 4.55 mg/kg (fresh weight basis) for penthiopyrad in cotton gin trash.

Fate of residues during processing

The Meeting received information on the hydrolysis of radiolabelled penthiopyrad as well as processing studies using unlabelled material on grown residues in apples, plums, tomatoes, soya beans, potatoes, sugar beet, barley, maize, wheat, oilseed rape and peanuts.

In a hydrolysis study using radiolabelled penthiopyrad (1:1 mixture) typical processing conditions were simulated (pH 4,5 and 6 with 90 °C, 100 °C and 120 °C for 20, 60 and 20 minutes). In duplicate samples of sterile buffer solution no degradation of the parent substance was observed.

In the following table all processing factor relevant for the estimation of the dietary intake or recommendation of maximum residue levels for processed commodities are summarized. Processing factors for additional processed products are reported in the corresponding evaluation for penthiopyrad; however no conclusion could be drawn based on this information. If analytes were present below the LOQ in the RAC for specific commodities, no processing factors were derived.

Commodity	Processing factor		Processing factor (median or best estimate)		HR / STMR (mg/kg)		MRL, HR-P / STMR-P (mg/kg)
Apple juice	Total:	< 0.13, < 0.14, 0.14	Total:	0.14	STMR:	0.15	STMR-P: 0.021
Apple pomace (wet)	Total:	4.4, 4.6, 6	Total:	4.6	STMR:	0.15	STMR-P: 0.69
Apple pomace (dry)	Total:	5.9, 8.8, 11	Total:	8.8	STMR:	0.15	STMR-P: 1.3
Prunes	Total:	1.3, 1.4	Total:	1.4	STMR: HR:	1.3 1.9	STMR-P: 1.8 HR-P: 2.7
Tomato juice	Total:	0.26, 0.34, 0.5	Total:	0.34	STMR:	0.27	STMR-P: 0.092
Tomato puree	Total:	1.5, 2.0, 2.0	Total:	2.0	STMR:	0.27	STMR-P: 0.54
Tomato paste	Total:	0.1, 3.4, 3.5	Total:	3.4	STMR:	0.27	STMR-P: 0.92
Tomato pomace (wet)	Total:	4.3, 5.0, 5.5	Total:	5.0	STMR:	0.27	STMR-P: 1.4
Tomato pomace (dry)	Total:	24, 39, 41	Total:	39	STMR:	0.27	STMR-P: 11
Soya beans, meal	Total:	0.23, <1.4	Total:	0.23	STMR:	0.032	STMR-P: 0.007
Soya beans, hulls	Total:	0.44, 4.7	Total:	2.5	STMR:	0.032	STMR-P: 0.08
Soya beans, refined oil	Total:	0.1, 1.8	Total:	1	STMR:	0.032	STMR-P: 0.032
Peeled potatoes (steam peeled and abrasion peeled)	Total:	< 0.21, < 0.45	Total:	< 0.33	STMR: HR:	0.01 0.05	STMR-P: 0.003 HR-P: 0.017
Sugar beet, refined sugar	Total:	0.27, 0.35	Total:	0.31	STMR:	0.105	STMR-P: 0.033
Sugar beet, molasses	Total:	0.20, 0.51	Total:	0.36	STMR:	0.105	STMR-P: 0.038
Sugar beet, dried pulp	Total:	4.9, 5.6	Total:	5.3	STMR:	0.105	STMR-P: 0.56
Barley beer	Total:	< 0.11, < 0.36	Total:	< 0.24	STMR:	0.01	STMR-P: 0.002
Pot barley	Total:	0.67, 0.68	Total:	0.68	STMR:	0.01	STMR-P: 0.007
Maize flour	Penthiopyrad:	2.1	Penthiopyrad:	2.1	MRL:	0.01	MRL: 0.03

Commodity	Processing factor		Processing factor (median or best estimate)		HR / STMR (mg/kg)		MRL, HR-P / STMR-P (mg/kg)
	Total:	1.4	Total:	1.4	STMR:	0.01	STMR-P: 0.014
Maize oil (wet milled)	Penthiopyrad:	5.6	Penthiopyrad:	5.6	MRL:	0.01	MRL: 0.05
	Total:	2.7	Total:	2.7	STMR:	0.01	STMR-P: 0.027
Wheat bran	Penthiopyrad:	1.8	Penthiopyrad:	1.8	MRL:	0.04	MRL: 0.1
	Total:	1.8	Total:	1.8	STMR:	0.01	STMR-P: 0.018
Wheat flour	Total:	0.39	Total:	0.39	STMR:	0.01	STMR-P: 0.004
Wheat germ	Penthiopyrad:	2.1	Penthiopyrad:	2.1	MRL:	0.04	MRL: 0.1
	Total:	1.9	Total:	1.9	STMR:	0.01	STMR-P: 0.019
Oilseed rape crude oil (mechanically extracted)	Penthiopyrad:	0.78, 1.9, 2.5	Penthiopyrad:	1.9	MRL:	0.5	MRL: 1
Oilseed rape refined oil	Penthiopyrad:	0.48, 1.6, 2.5	Penthiopyrad:	1.6	MRL:	0.5	MRL: 1
	Total:	0.39, 1.3, 2.1	Total:	1.3	STMR:	0.084	STMR-P: 0.11
Peanuts, meal	Total:	0.84, 2.5	Total:	1.7	STMR:	0.01	STMR-P: 0.017
Peanut refined oil	Penthiopyrad:	1.4, 18	Penthiopyrad:	9.7	MRL:	0.05	MRL-P: 0.5
	Total:	1.2, 6.7	Total:	4	STMR:	0.01	STMR-P: 0.04

Processing factors, STMR-P, HR-P and, if necessary, maximum residue levels for processed commodities are presented in the table above. Under consideration of penthiopyrad being the major residue in all supervised field trials, the processing factors for the parent substance were selected for the estimations.

For the processing for plums into prunes a processing factor of 1.4 was derived for penthiopyrad. In view of the highest residue of 0.77 mg/kg found in plums, the Meeting concluded that residues in prunes will be covered by the estimated maximum residue level for the stone fruit group.

For maize processed into maize flour and maize oil the Meeting estimated maximum residue levels of 0.05 mg/kg and 0.15 mg/kg, respectively.

For wheat processed into wheat bran and wheat germ the Meeting estimated maximum residue levels of 0.1 mg/kg, respectively.

For rape seed processed into crude and refined oil the Meeting estimated maximum residue levels of 1 mg/kg, respectively.

Peanuts processed into refined peanut oil show an accumulation of residues exceeding the recommended maximum residue for peanuts of 0.05 mg/kg. Under consideration of the derived processing factor of 9.7 the Meeting recommended a maximum residue level of 0.5 mg/kg for penthiopyrad in peanut oil, edible.

Residues in animal commodities

Livestock dietary burden

The Meeting received feeding studies involving penthiopyrad on lactating cows and laying hens.

Three groups of lactating cows were dosed daily at levels of 8.4, 21.4 and 74.6 ppm dry weight feed (0.15, 0.48 and 1.65 mg/kg bw) for 28 consecutive days. Milk was collected throughout the study and tissues were collected on day 29 within 24 hrs after the last dose.

In milk no residues above the LOQ of 0.01 mg/kg were found for the two lower dose groups. Only the 74.6 ppm dose group contained single positive detects of PAM between 0.01 and 0.02 mg/kg. Separation of milk obtained from high dosed animals into cream and skim milk revealed

a slight concentration of parent penthiopyrad in cream (positive detect at 0.01 mg/kg). However, the results were not sufficient to estimate a ratio (< 0.01 to 0.01 mg/kg).

In tissues penthiopyrad was only found for the highest dose group, resulting in residues above the LOQ in liver (0.02–0.03 mg/kg) and fat (0.01–0.02 mg/kg). PAM was present in all dose groups except the lowest, giving residues of 0.01–0.02 mg/kg in liver, < 0.01 mg/kg in muscle, 0.01 mg/kg in kidney and 0.01 mg/kg in fat for the 51.4 ppm dose group and 0.03–0.06 mg/kg in liver, 0.01–0.02 mg/kg in muscle, 0.02–0.03 mg/kg in kidney and 0.01–0.02 mg/kg in fat for the 74.6 ppm dose group.

For laying hens three groups of animals were dosed with rates of 5.85, 17.54 and 58.46 ppm in the dry weight feed (0.4, 1.2 and 1.2 mg/kg bw) for 28 consecutive days. Eggs were collected throughout the study and tissues were collected on day 29 within 6 hrs after the last dose.

In eggs residues were very low showing detectable residues only for the highest dose group. PAM was quantified in all samples from Day 3 until Day 27 at levels ranging from 0.011 to 0.028 mg/kg. Penthiopyrad was measurable in only 7 of the 48 samples with concentration ranging from 0.011 to 0.016 mg/kg.

In tissues again only the highest dose group gave detectable residues above the LOQ. Penthiopyrad was found at levels of < 0.01–0.021 mg/kg in liver, < 0.01 mg/kg in muscle, < 0.01–0.018 mg/kg in skin and 0.016–0.036 mg/kg in fat. PAM was present above the LOQ in liver (0.017–0.019 mg/kg) and in a single sample of muscle (0.01 mg/kg). In other tissues no residues above the LOQ were found.

Estimated maximum and mean dietary burdens of livestock

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU, Australia and Japan in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, ACTIVE-SUBSTANCE, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max.	mean	max.	mean	max.	mean	max.	mean
Beef cattle	12	4.5	56	23	130 [a]	57 [b]	1.9	0.5
Dairy cattle	55	26	43	20	100 [c]	49 [d]	24	7.9
Poultry—broiler	0.2	0.2	0.2	0.2	0.2	0.2	0.8	0.3
Poultry—layer	0.2	0.2	22 [e]	10 [f]	0.2	0.2	0.1	0.1

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

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

[c] Highest maximum dairy cattle burden suitable for MRL estimates for milk

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

[e] Highest maximum broiler or laying hen burden suitable for MRL estimates for poultry products and eggs

[f] Highest mean broiler or laying hen burden suitable for STMR estimates for poultry products and eggs

Animal commodities, MRL estimation

	Feed level (ppm) for eggs and tissues	Total residues (mg/kg)			
		Eggs	Muscle	Liver	Fat
Maximum residue level poultry					
Feeding study	18 58	< 0.02 0.044	< 0.02 0.029	< 0.02 0.045	< 0.02 0.046
Dietary burden and residue estimate	22	0.023	0.021	0.023	0.023
STMR poultry					
Feeding study	5.9	< 0.02	< 0.02	< 0.02	< 0.02

	18	< 0.02	< 0.02	< 0.02	< 0.02
Dietary burden and residue estimate	10	0.02	0.02	0.02	0.02

For beef and dairy cattle the maximum dietary burden (130 ppm) exceeds the highest dose level of 74.6 ppm in the corresponding lactating cow feeding study. The Meeting concluded that based on the available information no recommendation for residues of penthiopyrad in mammalian tissues and milk can be made.

For poultry the maximum calculated dietary burden resulted in HR values for the sum of penthiopyrad and PAM, expressed as penthiopyrad of 0.023 mg/kg in eggs, 0.021 mg/kg in muscle, 0.023 mg/kg in liver and 0.023 mg/kg in fat.

Correlating to this estimation the Meeting recommended maximum residue levels of 0.03 mg/kg for poultry meat, fat and eggs. The Meeting also decided to extrapolate the data on poultry liver to poultry, edible offal of and also recommended a maximum residue level of 0.03 mg/kg for this commodity.

For dietary intake purposes no residues above the LOQ of 0.02 mg/kg were found in samples collected from animals dosed above and below the calculated mean dietary burden. The Meeting estimated STMR values for poultry meat, fat and edible offal of as well as for eggs of 0.02 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The WHO Panel of the 2011 JMPR established an Acceptable Daily Intake (ADI) of 0–0.1 mg/kg bw/day for penthiopyrad.

The evaluation of penthiopyrad 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 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 0–6% of the maximum ADI (0.1 mg/kg bw). The Meeting concluded that the long-term intake of residues of penthiopyrad from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The WHO Panel of the 2011 JMPR established an Acute Reference Dose (ARfD) of 1 mg/kg bw for penthiopyrad.

For mustard greens, the IESTI represented 150% of the ARfD of 1 mg/kg bw. On the basis of the information provided to the JMPR it was not possible to conclude that the estimate of the short-term intake of penthiopyrad, from the consumption of mustard greens, was less than the ARfD. The Meeting noted that an alternative GAP for mustard greens was not available.

For other commodities the IESTI for penthiopyrad calculated on the basis of the recommendations made by the JMPR represented 0–90% of the ARfD (1 mg/kg bw) for children and 0–90% for the general population.

The Meeting concluded that the short-term intake of residues of penthiopyrad resulting from uses that have been considered by the JMPR (other than mustard greens) is unlikely to present a public health concern.