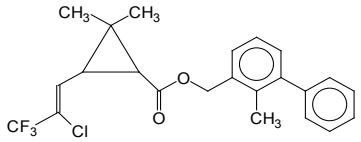
5.2 BIFENTHRIN (178)

RESIDUE AND ANALYTICAL ASPECTS

Bifenthrin is a pyrethroid insecticide and miticide. It was first evaluated by the 1992 JMPR (T, R) and subsequently for residues a number of times. The pesticide was evaluated for toxicology by the 2009 JMPR within the periodic review programme of the CCPR. The periodic review for residues was scheduled at the Forty-first Session of the CCPR for the 2010 JMPR.



Bifenthrin is a mixture of the E- and the Z-isomer with a Z/E-ratio of 99.67% Z-bifenthrin : 0.33% E-bifenthrin and can be present as a cis-isomer and a trans-isomer. The ratio of cis- to trans-isomers is typically 98.65 : 1.35 (specification = 97% cis minimum : 3% trans maximum).

List of metabolites

4'Hydroxy-bifenthrin	3-(4'hydroxyphenyl)-2-methylphenyl-methyl-cis,trans-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropane-carboxylate
Hydroxy-methyl-bifenthrin	2-methyl-[1,1'biphenyl]-3-yl)-methyl-cis-3-(2-chloro- 3,3,3-trifluoro-1-propenyl) trans-2-hydroxy-methyl-2-methyl-cyclopropane-carboxylate
TFP acid	cis-trans-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropane- carboxylic acid
Acetyl-cyclopropane-carboxylic acid	cis-trans-3-acetyl-2,2-dimethyl-cyclopropane-carboxylic acid
Biphenyl alcohol (BP alcohol)	2-methyl-3-phenylbenzyl alcohol
Biphenyl acid (BP acid)	2-methyl-3-phenylbenzoic acid

Animal metabolism

The Meeting received studies on lactating goats and laying hens dosed with either acid cyclopropyl-[^{14}C]-bifenthrin (CP label) or phenyl-^{14}C-bifenthrin (PH label). Studies on rats were reviewed by JMPR during toxicological evaluation in 2009.

Four lactating goats were orally dosed with [^{14}C]-bifenthrin daily for 7 consecutive days at a body weight level of 2.3 mg/kg/day - equivalent to a dietary level of 79 ppm. TRR in milk, liver, fat, kidneys and heart ranged from 0.7–1.5, 1.6-3.9, 1.8–2.8, 0.3–1.0 and 0.4–0.6 mg/kg [^{14}C]-bifenthrin equivalents, respectively. TRR in muscle were relatively lower and amounted to a range of 0.2–0.4 mg/kg. Analysis of ^{14}C in excreta showed that 40–52% and 7.7–17% of the total administered dose was recovered in faeces and urine, respectively.

Bifenthrin was the major product in milk (72–82% of TRR, 0.7–1.1 mg/kg), fat (78–80% of TRR, 1.6–1.8 mg/kg) and muscle (74–88% of TRR, 0.2–0.3 mg/kg). Parent chemical was also found to be a significant residue in kidney and liver tissue, amount to 16–22% of TRR (0.082–0.12 mg/kg) and 19–44% (0.7–0.9 mg/kg), respectively. Biphenyl acid was a significant product identified in kidney and liver tissue (35% of TRR, 0.14 mg/kg and 29% of TRR, 0.5 mg/kg, respectively). Biphenyl alcohol was detected at lower levels relative to parent chemical in milk (13% of TRR) and fat (10% of TRR). TFP acid was detected as a significant metabolite in milk (8.8% of TRR), liver

(4% of TRR) and kidney (14% of TRR). Other metabolites including 4'-hydroxy-bifenthrin, hydroxyl-methyl-TFP acid and biphenyl aldehyde were detected in minor amounts (< 5% of TRR).

Laying hens were dosed by [^{14}C]-bifenthrin for ten days at a body weight level of 1.55 mg/kg/day - equivalent to a dietary level of 31 ppm. The results (values as bifenthrin equivalents) indicated:

- orally administered ^{14}C-bifenthrin is eliminated primarily *via* the excreta (> 90% of the applied radioactivity);
- measurable levels of residues are transferred to tissues of the body, concentrating mostly in the fat (2.1–2.2 mg/kg) and liver (1.4–1.9 mg/kg), the activity in all tissues accounted for less than 0.4% of the applied dose;
- residues in the egg yolk were < 0.8% (max. 3.3 mg/kg) and in egg white < 0.03% (max. 0.05 mg/kg) of the applied radioactivity.

Metabolism of bifenthrin in hens occurred primarily on the cyclopropyl (acid) moiety of the molecule. Hydroxylation on the gem-dimethyl system was followed by formation of organosoluble conjugates with either palmitic or oleic acid. Bifenthrin and these fatty acid conjugates were the major compounds observed in all tissues studied. In egg yolk from the 10 days interval, approximately 40% of TRR (1.4 mg/kg bifenthrin equivalents) was present as bifenthrin. An additional 35% (1.1–1.3 mg/kg) was represented by a mixture of fatty acid conjugates. Unconjugated hydroxyl-methyl-bifenthrin made up another 3.5–4.6% (0.12–0.15 mg/kg) of the residue. Fragmentation products of bifenthrin (or conjugates) were observed as biphenyl alcohol to the extent of 4.2% of TRR (0.15 mg/kg) from hens treated with alcohol (phenyl)-^{14}C-bifenthrin.

In rats, goats and hens, excreta, faeces and urine were shown to be the major route of elimination of bifenthrin and its degradation products. Total radioactivity in excreta amounted in all animals to approximately 92–98 % of all recovered radioactivity. Unchanged bifenthrin was the major residue in the milk and tissues of goat, in the egg yolk and tissues of poultry. Exceptions were goat kidney, where biphenyl acid was the major metabolite with unchanged bifenthrin second and poultry liver, where the TFP acid and fatty acid conjugates of hydroxyl-methyl-bifenthrin were the major residues.

The major routes of metabolism appear to consist in oxidation of one of the gem-dimethyl groups on the cyclopropyl ring to give OH-methyl derivatives, either before or after hydrolysis to TFP acid and biphenyl alcohol and/or oxidation of the biphenyl group. Some of the oxidized or acid derivatives become conjugated.

Although there are qualitative similarities, there appear to be differences, primarily quantitative, between rat, goat and poultry metabolism. In rats and goats the major metabolites result from biphenyl ring oxidation. In poultry the oxidation of the dimethyl-cyclopropane group followed by the formation of fatty acid conjugates with oleic or palmitic acid is the major metabolic pathway which is different from the findings in rats and goats.

Plant metabolism

The metabolism of bifenthrin has been studied on apple (treatment of leaves and fruit surface), potato (treatment of soil, leaves), cotton (treatment of seeds, leaves, soil) and maize (treatment of leaves, husks, soil).

Apple fruits treated with [^{14}C]-bifenthrin (CP label) at a rate equivalent to approximately 24 g ai/hL were harvested and analysed 0, 7, 14 and 21 days following treatment. Most of the residue (> 85%) remained on the peel with little present in the pulp (2–16%, possibly due to contamination during peeling). At 21 days, 93% of the TRR in the whole apple (pulp and peel) was parent bifenthrin.

Apple leaves treated with [^{14}C]-bifenthrin (CP and PH label) were harvested and analysed 29 days following treatment. Bifenthrin accounted for 84–88% of the TRR, and biphenyl acid (2.6%) was detected as a metabolite from the PH label.

Bifenthrin metabolism in potato was studied using [^{14}C]-bifenthrin (CP and PH label). It was applied to soil in-furrow at planting and twice foliar to greenhouse-grown potatoes. The application regimen was designed to simulate a field-like application where the soil was treated at the rate of about 0.34 kg ai/ha at the time of planting followed by two foliar applications each at about 0.11 kg ai/ha at 28 and 14 days pre-harvest interval for a total of 0.56 kg ai/ha. The TRR in the mature foliage for CP and PH labels was 2.7 and 1.94 mg/kg, respectively. The TRR in the tubers from the CP and PH labels was very low, < 0.05 mg/kg at 0.047 and 0.038 mg/kg, respectively, indicating radioactivity in the tubers was not significant. Levels of bifenthrin in tubers were negligible from both labels and ranged between 0.031 mg/kg to 0.034 mg/kg for both labels. It also showed very negligible residues of bifenthrin plant metabolites including 4'-OH-bifenthrin, TFP acid, biphenyl alcohol, biphenyl acid, and biphenyl aldehyde none of which reached 0.001 mg/kg. It was concluded that when bifenthrin is applied foliar to leaves or in furrows, very limited translocation of bifenthrin from either leaf or soil to tubers took place. Parent bifenthrin was the major residue in tubers (73–81% of TRR) and was below 0.035 mg/kg.

Three-week old cotton plants were treated with [^{14}C]-bifenthrin (PH label) either by soil application or by treatment of individual leaves. In all cases essentially no radiocarbon was present in untreated leaves, stems, boll husks, lint and seeds. This indicates that there is essentially no translocation of bifenthrin or metabolite from soil or treated leaves into other portions of the plant through maturity. The metabolite profile indicated that biphenyl alcohol, biphenyl acid and TFP acid account individually for less than 1% of the TRR. Six unidentified metabolites were detected with no single metabolite exceeding 5% of the total residue.

In a second study cotton plants were treated individually with [^{14}C]-bifenthrin (PH label) at a rate of 1.3 µg/seed. Parent bifenthrin made was the main product identified (approximately 83–95% the total ^{14}C-residue). In the 28-day sample, 9% of the residue was not extractable. Other metabolites (up to six minor products) had reached 8% of the total residue in the 28-day sample. ^{14}C-residues in untreated bolls from the treated plants were negligible (not detected in lint, seed, stem, 0.08% in bolls, 0.07% in leaves) indicating that bifenthrin does not translocate from treated cottonseeds to other parts of the plant.

The metabolism study on maize demonstrates that bifenthrin is essentially non-systemic when applied either post-emergence to the soil or when applied as a dilute formulation to the leaves and husks of young maize plants. Bifenthrin on treated leaves degrades only to a minor extent. The major metabolite is 4'-hydroxy-bifenthrin, which comprises 11% of the TRR one month after foliar treatment.

In summary, the results of the different bifenthrin plant metabolism studies are consistent: unchanged and unconjugated bifenthrin was shown to be the predominant residue in plants. No cis- to trans-isomerisation was observed in the course of the studies. Studies on apple fruits and leaves, or either by soil application or by treatment of individual leaves on potatoes, cotton and maize show that bifenthrin is essentially non-systemic. Only little translocation from treated soils or plant parts to untreated parts of the plant was observed.

Environmental fate in soil

The Meeting received information on soil aerobic metabolism, soil photolysis, hydrolysis and crop rotation properties of bifenthrin.

In a series of aerobic soil metabolism studies at 25 °C with [^{14}C]-bifenthrin (CP- and PH-label), the percentage parent remaining after 120–180 days was 28–55% of dose (n = 8). The half-lives ranged for CP-^{14}C-bifenthrin from 50 to 205 days and for PH-^{14}C-bifenthrin from 69 to 135 days, depending on soil type. It can be concluded, that parent compound is the only relevant residue

for quantification in soil. The main metabolite, 4'-OH-bifenthrin, is always found in amounts generally lower than 10% of TRR, other metabolites such as TFP acid, biphenyl alcohol or biphenyl acid mostly occurred in traces only.

The measured half-lives for bifenthrin in two soil surface photolysis studies were 84 and 124 days. No major metabolite was formed, TFP acid reflecting the most predominant identifiable minor metabolite peaking at 3.8% on day 30.

Because of the highly insoluble nature of bifenthrin in water, no hydrolysis of the compound occurred at any of the pH tested (5.05, 7.08, 8.97).

In a confined rotational crop study with lettuce, sugar beet and wheat, soil was spiked with [^{14}C]-bifenthrin (CP- and PH-label), at the equivalent of 0.56 kg ai/ha. The crops were sown at 30, 60 and 120 days later. The maximum TRR (as bifenthrin equivalents) were 0.029 mg/kg in lettuce, 0.065 mg/kg in sugar beets (whole plant) and 0.053 mg/kg in wheat (whole plant). In wheat grain, TRR up to 0.049 mg/kg were determined. In wheat straw, higher TRR up to 0.31 mg/kg were detected.

In a second confined rotational study, only wheat was sowed 30 days, 120 days, 7 months and 12 months following application of [^{14}C]-bifenthrin (CP- and PH-label) at the equivalent of 0.56 kg ai/ha to the soil. Bifenthrin was present in the 30-day straw at 0.064–0.12 mg/kg. The 120 day straw samples had levels of 0.022 mg/kg bifenthrin, and even lower values were found from the 7 and 12 month sowings. The results of those studies are comparable and demonstrated that the translocation of bifenthrin residues is very low.

The residue data from a field crop rotation study showed that wheat planted 30 to 32 days after harvest of a primary crop (cotton, maize or sweet corn) treated with total 0.56 kg ai/ha yielded no bifenthrin residues. This adequately supports the fact that residues in soils resulting from recommended uses should not contribute to the residues in succeeding crops.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of bifenthrin in plant and animal commodities.

Residue analytical methods for bifenthrin rely on GC-ECD and GC-MSD. Typical LOQs achieved for plant and animal commodities fall in the range of 0.01–0.05 mg/kg. Methods have been subjected to independent laboratory validation.

Stability of residues in stored analytical samples

Information was received on the freezer storage stability of bifenthrin residues in plant and animal commodities. Residues were apparently stable at freezer temperature for the intervals tested.

Definition of the residue

The parent compound bifenthrin is the dominant component of the residue in plant commodities.

Unchanged bifenthrin was the major residue in the milk and tissues of goat, in the egg yolk and tissues of poultry. Exceptions were goat kidney, where biphenyl acid was the major metabolite with unchanged bifenthrin second and poultry liver, where the TFP acid and fatty acid conjugates of hydroxyl-methyl-bifenthrin were the major residues. The Meeting noted that the only compound of toxicological relevance in animal commodities is bifenthrin.

Therefore, from the metabolism studies on plants and animals presented, the proposed definition of the residue is parent bifenthrin only.

In animal metabolism and feeding studies, bifenthrin displays the properties of a fat-soluble compound.

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

The residue is fat soluble.

Results of supervised trials on crops

Supervised trials were available on the following crops: oranges, grapefruit, lemons, raspberries, blackberries, bananas, mangos, papaya, Brussels sprouts, head cabbage, cauliflower, egg plant, peppers, okra, sweet corn, tomatoes, mustard greens, green beans, peas, beans (pulses), peas (pulses), soya beans (pulses), carrots, potatoes, radish, sugar beet, barley, maize, oats, triticale, wheat, tree nuts, cotton, rape, hops and tea.

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. 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 NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided. Some common factors that may lead to rejection of the statistical estimate include those situations where the number of data points is less than 15 or where there are too many values below LOQ.

Citrus fruits

Supervised trials were available for lemon, oranges and grapefruit from Brazil and the USA. Furthermore, residue data were submitted from Italy and Spain, but currently no registered use exists in the European Union.

In Brazil, bifenthrin is registered for foliar spray use on citrus fruits at an application rate of 0.014–0.036 kg ai/ha with a PHI of 7 days. One trial each on lemon and oranges is matching the maximum GAP (0.038 kg ai/ha, 7 days PHI). The residues were < 0.05 and 0.05 mg/kg.

In the USA, bifenthrin is registered by ground application to bare soil beneath citrus trees at a rate of 0.11–0.56 kg ai/ha and a PHI of 1 day. In 36 US trials in line with GAP, seven on lemon, 21 on oranges and eight on grapefruit, the residues were: < 0.005, 0.0082, < 0.05 mg/kg (34).

The Meeting estimated a maximum residue level, an STMR and an HR of 0.05 mg/kg for citrus fruits. The previous recommendation of 0.05* mg/kg for grapefruit, lemon and oranges is withdrawn.

Statistical calculations were not possible, since most of the values are below the LOQ.

Pear

Bifenthrin is registered for foliar spray treatment on pears in Australia with 0.0025–0.004 kg ai/hL (PHI 14 days) and in Japan with 0.001–0.002 kg ai/hL (PHI 1 day). No residue data for pears were submitted.

The Meeting withdrew the previous recommendation of 0.5 mg/kg for pear.

Berries and other small fruits

Supervised trials were available for raspberries, blackberries and strawberries from the USA. Furthermore, residue data on strawberries were submitted from Belgium, France, Italy, the Netherlands, Poland, Spain and the UK, but currently no registered use exists in the European Union.

Caneberries

In the USA, bifenthrin may be used as foliar spray on caneberries (blackberry, dewberry, loganberry and raspberry) with an application rate of 2 × 0.056–0.11 kg ai/ha and a PHI of 3 days.

Five US trials (four on raspberries, one on blackberries) were carried out according to GAP. The residues in ranked order were: < 0.05, 0.25, 0.29, 0.34 and 0.51 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR for bifenthrin in blackberries, dewberries (including boysenberry and loganberry) and raspberries (red, black) of 1 mg/kg, 0.29 mg/kg and 0.51 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.81 mg/kg, which when rounded up, was in agreement with the Meeting's estimation.

Strawberry

Bifenthrin is registered in the USA for foliar spray use on strawberries at an application rate of 0.045–0.22 kg ai/ha, maximum 0.56 kg ai/ha per season (PHI not specified).

One US trial was conducted with 2 spray applications (interval 14 days) of 0.22 kg ai/ha resulting in a residue of 0.59 mg/kg at the day of the treatment.

Eighteen US trials were carried out with 4 spray treatments (interval 14 days) of 0.22 kg ai/ha. The maximum application rate of 0.56 kg ai/ha per season was exceeded (0.88 kg ai/ha). Samples were taken at 0, 1, 3 and 5 days. Because no PHI is specified, the highest value of each trial from all sampling days was selected.

The Meeting noted that the number of applications is not relevant because of the large treatment interval of 14 days and used all US trials for the evaluation. The residues, in ranked order, were (n = 19): 0.27, 0.30, 0.31, 0.33, 0.33, 0.34, 0.34, 0.36, 0.41, 0.46, 0.46, 0.48, 0.51, 0.59, 0.86, 0.86, 0.88, 2.1 and 2.3 mg/kg.

The Meeting estimated a maximum residue level for bifenthrin in strawberries of 3 mg/kg to replace the previous recommendation of 1 mg/kg. The Meeting estimated an STMR of 0.46 mg/kg and an HR of 2.3 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 2.39 mg/kg, which when rounded up, was in agreement with the Meeting's estimation.

The Meeting noted that the ARfD is exceeded for children (430%) and the general population (230%) by the dietary intake calculation. No alternative GAP is available.

Assorted tropical and sub-tropical fruits – inedible peel

Supervised trials were available for banana from France, Puerto Rico, Spain and the USA. Data for mango and papaya were submitted as part of the field trials conducted within the Pesticide Initiative Programme aiming to provide data for establishing import MRLs in the European Union.

Banana

In Central America (Columbia, Costa Rica, Ecuador, Guatemala, Honduras, Panama), tree bags with 1% bifenthrin are placed over the banana bunch before flower stalk shows first hand until harvest.

Four trials from France (Martinique) and two from Spain (Canary Islands) in line with Central American GAP showed from 1–132 days no residues in the pulp (< 0.01 mg/kg, n = 6); data on whole fruit were not submitted.

Samples were taken after 43–112 days in six trials from Puerto Rico and three from the USA. No residues were detected in the pulp (< 0.01 mg/kg, n = 9). In the whole fruits, the residues were: < 0.05 (7), 0.057 and 0.074 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg for bifenthrin in banana. Based on data on pulp, the Meeting estimated an STMR and an HR of 0.01 mg/kg.

Statistical calculations were not possible, as the majority of the values were below the LOQ.

Mango

Bifenthrin was applied as foliar spray treatment with 0.05 kg ai/ha and a PHI of 7 days in two trials each in Mali and Senegal. The application conditions were based on the requirement of appropriate control of diseases of mango, but they were not supported by label or official declaration of approved use.

The residues in whole fruit were: 0.066, 0.13, 0.15 and 0.23 mg/kg. In two trials, peel and pulp from day 7 an 14 were analysed separately. No residues were found in flesh (< 0.01 mg/kg).

The Meeting estimated a maximum residue level for bifenthrin in mango of 0.5 mg/kg. The estimated STMR and HR values were 0.01 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.44 mg/kg, which when rounded up, was in agreement with the Meeting's estimation.

Papaya

Bifenthrin was applied as foliar spray treatment with 4 × 0.05 kg ai/ha and a PHI of 3 days in eight trials carried out in Ghana and the Ivory Cost. The application conditions were apparently based on the requirement to achieve appropriate disease control in papaya. However, the data provided was not supported by a label or official declaration indicating the use had regulatory approval.

The residues in whole fruit were (n = 8): 0.095, 0.13, 0.13, 0.14, 0.16, 0.17, 0.20 and 0.30 mg/kg.

No residue data for the edible portion were available. Nevertheless, taking into account the results of the apple fruit metabolism study showing that more than 85% of the residue remained on the peel and that no residues were found in supervised residue trials in pulp of banana and mango, the Meeting concluded that no residues higher than 0.01 mg/kg are expected in papaya edible portion.

The Meeting estimated for bifenthrin in papaya a maximum residue level of 0.4 mg/kg and STMR and an HR of 0.0.1 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.35 mg/kg, which when rounded up, was in agreement with the Meeting's estimation.

Brassica vegetables

Supervised trials were available for head cabbage and cauliflower from Japan and the USA. Furthermore, residue data on Brussels sprouts, head cabbage and cauliflower were submitted from France, Germany, Italy, the Netherlands, Poland and the UK, but currently no registered use exists in the European Union.

The registered use of bifenthrin in brassica vegetables in the USA is foliar spray treatment of 5 × 0.034–0.11 kg ai/ha and a PHI of 7 days or as soil treatment in-furrow at seeding or at transplant with 0.06–0.11 kg ai/ha.

Trials on head cabbage were carried out in the USA, three of them were in line with the US GAP (5 × 0.11 kg ai/ha, PHI 7 days). The treatment interval was 7 days. Two further trials had the same treatment rate and PHI, but higher application numbers of 8 and 11. In these trials, cool, wet weather resulted in much slower growth of the plants than expected. In order to collect mature-sized cabbages and to maintain a PHI of 7 days, spraying at weekly intervals was continued. The Meeting noted that the earlier sprays do not influence the terminal residues and considered these trials also as being in GAP. The residues were < 0.04, < 0.04, < 0.04, < 0.05 and 0.19 mg/kg in cabbage without

wrapper leaves. In cabbage with wrapper leaves the residues were 0.70, 0.82, 1.5, 2.3 and 3.1 mg/kg which are relevant for animal dietary burden estimation.

Ten trials on cauliflower were carried out in the USA, four of them were in line with the US GAP (5 × 0.11 kg ai/ha, PHI 7 days). The residues were < 0.05, 0.09, 0.14 and 0.19 mg/kg.

Based on the data for cauliflower, the Meeting estimated a maximum residue level, an STMR and an HR of 0.4, 0.115 and 0.19 mg/kg for brassica vegetables.

Based on the data for head cabbage with wrapper leaves, an STMR of 1.5 mg/kg and a highest residue of 3.1 mg/kg were estimated for animal dietary burden calculation.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.4 mg/kg, which was in agreement with the Meeting's estimation.

Fruiting vegetables, other than Cucurbits

Supervised trials were available for egg plant, peppers, sweet corn and tomato from the USA and European countries as well as for okra from Ivory Coast. No GAP exists currently in the European Union for the use of bifenthrin in fruiting vegetables.

Peppers

The registered use of bifenthrin in peppers in the USA is foliar spray treatment 0.022–0.11 kg ai/ha and a PHI of 7 days. Eleven US trials in line with US GAP were available. The residues were in rank order (n = 11) were: < 0.055, 0.07, 0.09, 0.10, 0.11, 0.14, 0.17, 0.21, 0.23, 0.24 and 0.31 mg/kg.

The Meeting estimated for bifenthrin residues in peppers a maximum residue level, an STMR and an HR of 0.5 mg/kg, 0.14 mg/kg and 0.31 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.5 mg/kg, which was in agreement with the Meeting's estimation.

Okra

As part of the field trials conducted within the Pesticide Initiative Programme aiming to provide data for establishing import MRLs in the European Union, bifenthrin was applied as foliar spray treatment with 2 × 0.05 kg ai/ha and a PHI of 2 days in four trials in Ivory Cost. The application conditions were based on the requirement of appropriate control of diseases of okra, but they were not supported by label or official declaration of approved use. The residues were 0.04, 0.05, 0.09 and 0.11 mg/kg.

The Meeting estimated for bifenthrin residues in okra a maximum residue level, an STMR and an HR of 0.2 mg/kg, 0.07 mg/kg and 0.11 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.2 mg/kg, which was in agreement with the Meeting's estimation.

Sweet corn

The registered use of bifenthrin in sweet corn in the USA is foliar treatment with 0.036–0.11 kg ai/ha (max. 0.34 kg ai/ha per season) and a PHI of 1 day. Thirteen US trials treated with 0.09, 0.09 and 0.04 kg ai/ha showed residues of < 0.05 mg/kg at one day after the last application, but did not match the critical GAP.

The Meeting was not able to estimate a maximum residue level for bifenthrin residues in sweet corn.

Tomato

The registered use of bifenthrin in tomato in the USA is foliar spray treatment 0.022–0.11 kg ai/ha and a PHI of 1 day. None of the 22 US trials submitted was in line with critical US GAP because the samples were taken later than the PHI of 1 day.

In Mexico, bifenthrin is registered as foliar spray treatment of 0.06 kg ai/ha and a PHI of 1 day. Seven outdoor trials according to GAP were received. The residues were 0.03, 0.04, 0.06, 0.06, 0.09, 0.15 and 0.15 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.3 mg/kg, 0.06 mg/kg and 0.15 mg/kg, respectively, for bifenthrin residues in tomatoes.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.3 mg/kg, which was in agreement with the Meeting's estimation.

Egg plant

The registered use of bifenthrin in eggplant in the USA is foliar spray treatment 0.034–0.11 kg ai/ha and a PHI of 7 days. Three US trials in line with US GAP were available. The residues were < 0.05 mg/kg (3). The Meeting noted that three trials are not sufficient to estimate a maximum residue level.

Six trials from the USA on tomato were available carried out about according to the GAP for eggplant (4 × 0.09 kg ai/ha, PHI 6–7 days). The residues in tomatoes were: < 0.05 (4), 0.07 and 0.10 mg/kg.

The Meeting concluded to use the trials on tomatoes to estimate a maximum residue level, an STMR and an HR of 0.3 mg/kg, 0.05 mg/kg and 0.10 mg/kg, respectively, for bifenthrin residues in eggplant.

Statistical calculations were not possible, since most of the values are below the LOQ.

Leafy vegetables (incl. brassica leafy vegetables)

Supervised trials on leafy vegetables were available for mustard greens and radish leaves and tops from the USA.

The registered use of bifenthrin in brassica leafy vegetables in the USA is foliar spray treatment of 0.037–0.11 kg ai/ha and a PHI of 7 days.

Eight US trials on mustards greens in line with US GAP were available. The residues were in rank order (n = 8): 0.08, 0.19, 0.85, 0.91, 1.4, 1.9, 1.9 and 2.1 mg/kg.

The Meeting estimated for bifenthrin residues in mustard greens a maximum residue level, an STMR and an HR of 4 mg/kg, 1.16 mg/kg and 2.1 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 3.52 mg/kg (mean +3SD), which when rounded up, was in agreement with the Meeting's estimation.

Six US trials on radish leaves and tops in line with US GAP for leafy vegetables were available. The residues were in rank order (n = 6): 0.69, 1.2, 1.7, 1.8, 2.0 and 2.3 mg/kg.

The Meeting estimated for bifenthrin residues in radish leaves and tops a maximum residue level, an STMR and an HR of 4 mg/kg, 1.75 mg/kg and 2.3 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 4.19 mg/kg, which was in agreement with the Meeting's estimation.

Legume vegetables

Supervised trials on legume vegetables were available for green beans and peas from European countries and the USA. None of the trials submitted was in line with the GAP.

The Meeting was not able to estimate a maximum residue level for bifenthrin in legume vegetables.

Pulses

Supervised trials on pulses were available for dry beans and soya beans from the USA as well as for dry peas from Denmark, France, Germany, Poland, Sweden and the UK, but currently no registered use exists in the European Union.

Bifenthrin is registered on beans and peas in the USA with 0.028–0.11 kg ai/ha and a PHI of 14 days. Nine US trials matching the GAP showed residues in dried beans of < 0.05 (6), 0.07, 0.10 and 0.10 mg/kg. Residues in dried peas were < 0.05 mg/kg (6) in six US trials matching the GAP.

For soya beans, the US GAP is 0.028–0.11 kg ai/ha and a PHI of 18 days. The residues were in 15 US trials in line with US GAP (n = 15): < 0.05 (13), 0.07 and 0.18 mg/kg.

Based on the soya bean data, the Meeting estimated for bifenthrin residues in pulses a maximum residue level and an STMR of 0.3 mg/kg and 0.05 mg/kg, respectively.

Statistical calculations were not possible, since 13 from 15 residue values are below the LOQ.

Root and tuber vegetables

Supervised trials on root and tuber vegetables were available for carrots from European countries and the USA; for potatoes from Brazil, European countries and the USA; for radish from the USA and for sugar beet from France. Currently no registered use exists in the European Union.

The US GAP allows the foliar spray treatment of 0.09–0.11 kg ai/ha with a PHI of 21 days on root and tuber vegetables. In ten US trials on carrots matching US foliar spray GAP, the residues were in roots < 0.05 mg/kg (10).

In 17 US trials on potatoes matching US foliar spray GAP for root and tuber vegetables, the residues were in tubers < 0.05 mg/kg (17).

Bifenthrin is registered on potatoes in Brazil for soil treatment with 0.1 kg ai/ha and a PHI of 35 days. Three residue supervised trials each were carried out with 0.15 and 0.30 kg ai/ha (PHI 35 days). In all trials the residues were lower than the LOQ: < 0.02 mg/kg (6).

The Meeting estimated a maximum residue level, an STMR and an HR of for bifenthrin in root and tuber vegetables of 0.05 mg/kg.

Statistical calculations were not possible, since all levels are below the LOQ.

Cereals

Supervised trials on cereal grains were available for maize from the USA, for wheat after treatment at storage from the European countries and Brazil as well as for barley, oat, triticale and wheat after foliar spray application from European countries, but currently no registered uses exist in the European Union.

The previous recommendation for bifenthrin on barley of 0.05* mg/kg was withdrawn.

Wheat – storage treatment

The registered GAP on stored wheat grain in Brazil is 0.0004 kg ai/ton (withholding period 30 days). One Brazilian trial was in GAP and shows residues of 0.2 mg/kg.

The Meeting received 11 trials from Belgium, France and the UK treated with 0.0003 kg ai/ton (withholding period 30 days). The residues were 0.19, 0.21, 0.22, 0.23, 0.24, 0.25, 0.26, 0.27, 0.28, 0.28 and 0.29 mg/kg. In one further trial from the UK treated with 0.0005 kg ai/ton the residues were 0.40 mg/kg.

The Meeting noted that the storage treatment of the European trials was in line with the Brazilian GAP (±25%) and could be used for the evaluation. The residues of one Brazilian and

twelve European trials, in ranked order, were (n = 13): 0.19, 0.20, 0.21, 0.22, 0.23, 0.24, 0.25, 0.26, 0.27, 0.28, 0.28, 0.29 and 0.40 mg/kg.

Based on the European data and Brazilian GAP for stored wheat grain, the Meeting estimated a maximum residue level of 0.5 mg/kg Po for wheat and confirmed the previous recommendation. The STMR and the HR were 0.25 mg/kg and 0.40 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.39 mg/kg. However, in order to cover residues in wheat after post harvest use, a higher maximum residue level was necessary.

Maize

Bifenthrin is registered on maize in the USA as foliar spray treatment with 0.11 kg ai/ha and a PHI of 30 days. The Meeting received the following residue data from US trials:

- Seven trials treated with 5 × 0.11 kg ai/ha, PHI 29–38 days: < 0.05 mg/kg (7)
- 18 trials treated with 5 × 0.11, kg ai/ha, PHI 39–68 days: < 0.05 mg/kg (18)
- Five overdosed trials treated 4 × 0.11 and 1 × 1.1 kg ai/ha, PHI 31, 33, 39, 54, 65 days: < 0.05 mg/kg (5).

The Meeting estimated a maximum residue level of 0.05* mg/kg for bifenthrin residues in maize and confirmed its previous recommendation. An STMR of 0 mg/kg was derived.

Statistical calculations were not possible, since all levels are below the LOQ.

Tree nuts

Supervised trials on tree nuts were available from the USA. The registered GAP on tree nuts in the USA is foliar spray treatment with 0.056–0.22 kg ai/ha. The PHI is 21 days for pecans and 7 days for others. The Meeting received 30 US trials treated 3 - 8 times with 0.22 kg ai/ha:

- 12 trials on walnuts, PHI 7 days, residues in meat: < 0.05 mg/kg (12)
- Six trials on filberts, PHI 14 days, residues in meat: < 0.05 mg/kg (6)
- 12 trials on pecans, PHI 21–23 days, residues in meat: < 0.05 mg/kg (12).

The Meeting estimated a maximum residue level, an STMR and an HR for tree nuts of 0.05 mg/kg.

Statistical calculations were not possible, since all levels are below the LOQ.

Oilseed

Supervised trials on oil seed were available from Brazil, Canada and the USA with data on cotton seed and rape seed. Furthermore, for cotton seed data from Greece and Spain as well as for rape seed from Germany, Poland and the UK were submitted, but currently no registered use exists in the European Union.

Cotton seed

Bifenthrin is registered in Brazil on cotton with 5 × 0.03 - 0.1 kg a/ha and a PHI of 15 days. Two Brazilian trials were matching the critical GAP. The residues were 0.02 and 0.07 mg/kg.

In the USA, Bifenthrin is registered with 0.11 kg ai/ha (maximum 0.56 kg ai/ha per season) and a PHI of 14 days. The Meeting received US trials treated with 0.1–0.11 kg ai/ha and a PHI of 14 days. Different application numbers in an interval of 7 days were used. The residues were after 3–11 treatments with 0.1–0.11 kg ai/ha (n = 21): < 0.05 (14), 0.06, 0.06, 0.07, 0.07, 0.13, 0.17 and 0.37 mg/kg.

The Meeting estimated a maximum residue level and an STMR for bifenthrin in cotton seed of 0.5 mg/kg and 0.05 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator (after MLE[28]) was 0.34 mg/kg. However, in order to cover residues in cotton seed, a higher maximum residue level was necessary. The number of < LOQ values (13 in 21 trials, > 50%) reduces the reliability of the calculated result.

Rape seed

In the USA, bifenthrin may be used as foliar spray treatment with 0.036–0.045 kg ai/ha and a PHI of 35 days. Four US and two Canadian trials treated with 0.04 kg ai/ha and PHIs of 20–29 days were received. The residues were < 0.05 mg/kg (6).

The Meeting estimated a maximum residue level and an STMR for bifenthrin in rape seed of 0.05 mg/kg.

Statistical calculations were not possible, since all levels are below the LOQ.

Hops, dry

Supervised trials on hops were available from Germany, the UK and the USA. No GAP exists currently in the European Union.

In USA, bifenthrin is registered for use on hops at 0.056–0.11 kg ai/ha and a PHI of 14 days. Three US trials in line with GAP were submitted. The residues were in dried hops 0.85, 1.9 and 5.4 mg/kg.

The Meeting estimated for bifenthrin residues in hops, dry a maximum residue level of 20 mg/kg and an STMR of 1.9 mg/kg. The pervious recommendation of 10 mg/kg was withdrawn.

Statistical calculations for only three data points were not adequate.

Tea, green and black

Supervised trials on green and black tea (dry) were available from China, India, Indonesia and Japan.

In China, the registered use for bifenthrin in tea is foliar spray treatment at 0.0075–0.053 kg ai/ha and a PHI of 7 days. The Meeting received ten Chinese trials treated with 2 × 0.045–0.048 kg ai/ha and a PHI of 7 days which were considered still consistent with Chinese GAP. The residues were in dried tea in ranked order (n = 10): 0.04, 0.07, 0.08, 0.08, 0.08, 0.09, 0.09, 0.11, 1.2 and 4.3 mg/kg.

Three trials from India treated with 0.06 kg ai/ha and a PHI of 7 days were submitted. The application rate was in the limit of ± 25% of Chinese GAP. The residues were in dried tea 0.42, 5.1 and 5.9 mg/kg.

The GAP in Japan is 2 × 0.08 kg ai/ha and a PHI of 14 days. Three Japanese trials according to GAP were submitted. The residues were in dried tea 1.3, 5.2 and 18 mg/kg.

One Indian (1 × 0.08 kg ai/ha, PHI 14 days) and one Indonesian trial (0.06 and 0.10 kg ai/ha, PHI 10 days) were considered still consistent with Japanese GAP. The residues were in dried tea 0.47 and 4.6 mg/kg.

The Meeting agreed to use the Japanese trials supported by the results of the Indian and Indonesian trials to estimate a maximum residue level.

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[28] Note: MLE (Maximum Likelihood Estimate) is the NAFTA process that adjusts the data below LOQ to a lognormal distribution, by applying the distribution based on values at or above the LOQ

The Meeting estimated a maximum residue level and an STMR for bifenthrin in tea, green and black, of 30 mg/kg and 5.2 mg/kg, respectively.

Statistical calculations for only three data points were not adequate.

Primary animal feed commodities

Legume animal feeds

Supervised trials on peas were available from Germany and the UK with data on fodder and forage but no GAP was submitted.

Straw and fodder (dry) of cereal grains (except maize)

Supervised trials on cereals as barley, oats, triticale and wheat were available from European countries with data on straw but no GAP was available.

The Meeting decided to withdraw the previous recommendation for barley straw and fodder, dry and wheat straw and fodder, dry of 0.5 mg/kg.

Forage of cereal grains (except maize)

Supervised trials on cereals as barley, oats, triticale and wheat were available from European countries with data on forage but no GAP was available.

Maize fodder and forage

Supervised trials on maize were available from the USA with data on fodder and forage.

Bifenthrin is registered on maize in the USA as foliar spray treatment with 0.11 kg ai/ha and a PHI of 30 days.

The Meeting received eight US trials treated with 5 × 0.11 kg ai/ha, PHI 29–39 days. The residues in maize straw (fresh weight) were (n = 8): 0.2, < 0.5, 1.3, 1.7, 1.9, 2.0, 2.7 and 4.6 mg/kg.

Based on 83% dry matter (FAO Manual, Table IX.2), the Meeting estimated a maximum residue level for maize fodder of 15 mg/kg (dry weight) to replace the previous recommendation of 0.2 mg/kg. The estimated STMR value was 2.2 mg/kg and the high residue level 5.5 mg/kg, respectively, based on dry weight.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 12.37 mg/kg (fresh weight) or 14.9 mg/kg (dry weight) which was in agreement with the Meeting's estimation.

The Meeting received 24 US trials on maize forage treated with 5 × 0.11 kg ai/ha, samples were taken 10–42 days after the last treatment. The residues in maize forage (fresh weight) were (n = 24): < 0.1, 0.14, 0.16, 0.23, 0.23, 0.29, 0.29, 0.39, 0.49, 0.49, 0.55, 0.57, 0.60, 0.60, 0.76, 0.85, 0.97, 0.97, 1.2, 1.3, 1.4, 1.5, 1.6 and 2.0 mg/kg.

The Meeting estimated STMR and highest residue values for maize forage (fresh weight) of 0.585 mg/kg and 2.0 mg/kg, respectively.

Almond hulls

Supervised trials on almond hulls were available from the USA.

The registered GAP on tree nuts in the USA is foliar spray treatment with 0.056–0.22 kg ai/ha. The Meeting received five US trials where the last treatment was with 0.06–0.11 kg ai/ha. The trials did not match the critical US GAP.

The trials could not used to support recommendations.

Fate of residues during processing

A nature of the residue under simulated processing conditions study was received. The hydrolysis of ^{14}C[phenyl ring] bifenthrin was studied at 90, 100, and 120 °C in sterile buffers. The radio labelled compound was applied to pH 4, 5, and 6 sterile aqueous buffer solutions at an application rate of 0.005 mg/L. The samples were incubated for 20 to 60 minutes at 90, 100, and 120 °C in the dark. The mean material balance was 100.3, 97.6, and 81.3% of the applied radioactivity for the pH 4, 5, and 6 tests, respectively. Under the sterile hydrolysis conditions of the study, bifenthrin was found to be hydrolytically stable at those pH levels.

The Meeting received information on the fate of bifenthrin residues during the processing of tomatoes to paste and puree; of maize to meal, flour, oil and wet milling starch; of soya beans to meal and oil; of cotton seed to oil and of hops to beer. Information is available on processing of wheat to flour, bred, bran and germ and of tea to tea water extract. A potato processing studies could not be used to derive processing factors, as the RAC contained no residues above LOQ and the processed fraction residues were below the LOQ.

The processing factors and the derived STMR-P values are summarized as follows:

RAC	Processed commodity	Calculated processing factors	PF (median or best estimate)	RAC STMR (HR)	STMR-P (HR-P)
Tomato	Paste	< 0.63, < 0.71	< 0.67 (mean)	0.06	0.04
	Puree	< 0.63, < 0.71	< 0.67 (mean)		0.04
Maize	Coarse meal	0.32	0.32	0	0
	Flour	1.1	1.1		0
	Grits	< 0.15	< 0.15		0
	Crude oil	0.77, 1.9	1.9 (highest)		0
	Refined oil	0.92, 2.3	2.3 (highest)		0
	Germ	0.29, 0.52	0.52 (highest)		0
	Hulls	2.9, 1.5	2.9 (highest)		0
	Starch	< 0.15	< 0.15		0
Soya bean	Hulls	1.2, 1.4	≥ 1.3		0.065
	Aspirated grain	140, 240	≥ 190 (mean)		9.5
Wheat	Bran	2.5, 2.6, 2.7, 2.7, 2.7, 2.9, 3.0, 3.0, 3.0, 3.1, 3.1, 3.2, 3.3, 3.3, 3.5, 3.5, 4.4, 4.6, 4.6, 5.0, 5.0, 5.1	3.15 (median, n = 22)	0.25 (0.40)	0.79 (1.26)
	Whole meal flour	0.29, 0.32, 0.37, 0.59, 0.63, 0.64, 0.68, 0.68, 0.69, 0.69, 0.70, 0.71, 0.73, 0.76, 0.76, 0.77, 0.77, 0.78, 0.79, 0.81, 0.81, 0.87, 0.88, 0.92, 0.95, 1.0, 1.0, 1.1, 1.1, 1.1	0.765 (median, n = 30)		0.19 (0.306)
	Whole meal bread	0.11, 0.11, 0.14, 0.15, 0.15, 0.18, 0.19, 0.19, 0.60, 0.69, 0.73, 0.76, 0.76, 0.81, 0.83, 0.85, 0.86, 0.87, 0.88, 0.88, 0.89, 0.97	0.75 (median, n = 22)		0.19 (0.3)
	White flour	0.038, 0.038, 0.071, 0.077, 0.21, 0.21, 0.24, 0.26, < 0.3, 0.3, 0.3, 0.32, 0.32, 0.32, 0.33, 0.34, 0.35, 0.39, 0.42, 0.47, 0.51, 0.52	0.31 (median, n=22)		0.078 (0.124)
	White flour bread	0.036, 0.037, 0.038, 0.038, 0.069, 0.071, 0.074, 0.077, 0.20, 0.24, 0.24, 0.25, 0.25, 0.25, 0.27, 0.28, < 0.29, < 0.30, 0.30, 0.31, < 0.32, 0.32	0.245 (median, n=22)		0.061 (0.098)
	Germ	1.1, 1.2, 1.5, 1.6, 2.0, 2.2, 2.5, 2.7	1.8 (median, n=8)		0.45 (0.72)

RAC	Processed commodity	Calculated processing factors	PF (median or best estimate)	RAC STMR (HR)	STMR-P (HR-P)
Cotton seed	Linters	4.5, 4.2	4.4 (mean)	0.05	0.22
	Hulls	0.27, 0.40	0.34 (mean)		0.017
	Meal	< 0.058, < 0.053	< 0.06 (highest)		0.003
	Refined oil	0.10, 0.084	0.1 (highest)		0.005
Rape seed	Meal	0.54	0.54	0.05	0.027
	Refined oil	1.6	1.6		0.08
Hops	Beer	< 0.0055, < 0.0057	< 0.006	1.9	0.011
Tea	Water extract	0.001, 0.0018, 0.002, 0.002, 0.0021, 0.0023, 0.0023, 0.0025, 0.0026, 0.0027, 0.0027, 0.003, 0.0035, 0.0043, < 0.005, 0.0062, < 0.007, 0.0077, < 0.011, 0.014, < 0.019, < 0.024	0.003 (median, n=22)	5.2	0.0156

On processing, bifenthrin concentrated in maize oil, rape seed oil, wheat germ, wheat bran and in milled by-products as hulls and aspirated grain fractions. The Meeting decided to estimate the following maximum residue levels, STMR-P and HR-P values for processed commodities:

Based on the STMR of 0.05 mg/kg for rape seed and a processing factor of 1.6, the Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR-P of 0.08 mg/kg for rape seed oil, edible.

Based on an HR for wheat of 0.4 mg/kg Po, an STMR of 0.25 mg/kg Po and a processing factor of 1.8, the Meeting estimated a maximum residue level of 1 mg/kg PoP, a STMR-P of 0.45 mg/kg PoP and an HR-P of 0.72 mg/kg PoP for wheat germ.

Based on an HR for wheat of 0.4 mg/kg Po, an STMR of 0.25 mg/kg Po, an HR and a processing factor of 3.15, the Meeting estimated a maximum residue level of 2 mg/kg PoP, an STMR-P of 0.79 mg/kg PoP and an HR-P of 1.26 mg/kg PoP for wheat bran, unprocessed. The previous recommendation was confirmed.

The Meeting was aware that bifenthrin residues concentrated during processing of maize to maize oil. Because the STMR in maize grain is 0 mg/kg, residues in maize oil are not expected above the maximum residue level of 0.05* mg/kg for maize grain. The Meeting estimated an STMR of 0 for maize oil, edible and maize oil, crude, maize flour, maize grits and maize starch.

The Meeting also decided to estimate a maximum residue for chilli pepper (dried) of 5 mg/kg following application of a default dehydration factor of 10 to the estimated maximum residue level of 0.5 mg/kg for sweet pepper (10 × 0.5 = 5 mg/kg). The STMR for residues of bifenthrin in chilli peppers (dry) is estimated to be 10 × 0.14 = 1.4 mg/kg.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of bifenthrin in farm animals on the basis of the diets listed in Appendix X of the FAO Manual (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6.

	Livestock dietary burden, bifenthrin, ppm of dry matter diet							
	US/CAN		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	1.85	1.35	**8.26** [a]	**3.35** [b]	5.2	1.76	0.57	0.57
Dairy cattle	2.68	1.12	**7.41** [c]	**3.21** [d]	5.2	1.76	2.92	1.15
Poultry - broiler	0.59	0.59	0.43	0.43	0.38	0.38	0.11	0.11
Poultry - layer	0.59	0.59	**1.97** [e]	**1.10** [f]	0.35	0.35	0.28	0.28

[a] Highest maximum beef or dairy cattle burden suitable for MRL 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 MRL estimates for milk.

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

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

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

Farm animal feeding studies

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were dosed daily with bifenthrin for 28 days at the equivalent of 0.5, 5, 15 and 50 ppm in the diet. Average residues of bifenthrin in milk for the 5, 15 and 50 ppm dose group were 0.082, 0.15 and 0.65 mg/kg, respectively. Residues in tissues were:

- In the 5 ppm dose group, no residues of bifenthrin above the LOQ of 0.1 mg/kg were detected in muscle, kidney and liver; in fat, the highest residue was 1.7 mg/kg and the mean 0.865 mg/kg.
- In the 15 ppm dose group, the highest residues in muscle, liver, kidney and fat were 0.24, < 0.1, 0.19, and 2.2 mg/kg, respectively. The mean residues in muscle, liver, kidney and fat were 0.154, < 0.1, 0.185 and 1.325 mg/kg.
- In the 50 ppm dose group, the highest residues in muscle, liver, kidney and fat were 0.88, < 0.1, 0.49 and 5.8 mg/kg, respectively. The mean residues in muscle, liver, kidney and fat were 0.37, < 0.1, 0.465 and 3.45 mg/kg.

In a second study, dairy cows were dosed with bifenthrin at levels of 5 and 50 ppm per day for 28 consecutive days. Milk fat was analysed for parent bifenthrin. Additional, milk and tissues were analysed for biphenyl alcohol and tissues for biphenyl acid. The results were:

- Bifenthrin mean residues in milk fat were 0.765 mg/kg in the 5 ppm dose group and 8.81 mg/kg in the 50 ppm dose group.
- Residues of the metabolite biphenyl alcohol were in milk < 0.02 mg/kg of the 50 ppm dose group.
- In tissues, in the 5 ppm dose group, the highest residues of biphenyl alcohol in muscle, liver and kidney were < 0.05 mg/kg and in fat 0.11 mg/kg. The mean residues in muscle, liver, kidney were < 0.05 mg/kg and 0.067 mg/kg in fat.
- In tissues, in the 50 ppm dose group, the highest residues of biphenyl alcohol in muscle, liver, kidney and fat were 0.07, < 0.05, < 0.05 and 1.1 mg/kg, respectively. The mean residues in muscle, liver, kidney were < 0.05 mg/kg and 0.067 mg/kg in fat.
- Residues of the metabolite biphenyl acid were at the 50 ppm feeding level in muscle and fat < 0.05 mg/kg. Highest residues were in liver 0.05 mg/kg and in kidney 0.14 mg/kg. Mean residues were in liver 0.045 mg/kg and in kidney 0.09 mg/kg.

In a third study, dairy cows were dosed with bifenthrin at levels of 5 and 50 ppm per day for 28 consecutive days. Tissue samples of peritoneal fat and subcutaneous fat were analysed for 4'-hydroxy-bifenthrin. No detectable (< 0.01 mg/kg) 4'-hydroxy-bifenthrin residue was found in any of the cow fat samples analysed.

The Meeting also received information on the residue levels arising in tissues and eggs when laying hens were dosed with bifenthrin for 28 days at levels equivalent to 0.0025, 0.025 and 0.25 ppm in the diet. At the high dose residues of bifenthrin and 4'-hydroxy-bifenthrin in eggs were below the LOQ of 0.01 mg/kg. No bifenthrin residues were found in any of the tissue samples of the 0.25 ppm dosing group (< 0.02 muscle, < 0.05 mg/kg liver, fat, gizzard). Biphenyl alcohol could only be detected in subcutaneous fat of the 0.25 ppm dosing group, but was always below LOQ of 0.05 mg/kg. It was not detected at the lower dosing level of 0.025 ppm. No TFP acid residues were found in any of the liver samples of the 0.25 ppm dosing group (< 0.05 mg/kg).

Animal commodity maximum residue level estimation

Cattle

The dietary burdens for the estimation of maximum residue levels for bifenthrin in animal commodities are 8.3 ppm for beef cattle and 7.41 ppm for dairy cattle. The dietary burdens for the estimation of STMR values are 3.35 ppm for beef cattle and 3.21 for dairy cattle.

In the table below, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding study are shown in square brackets [] and estimated concentrations related to the dietary burdens are shown without brackets.

Dietary burden (ppm) Feeding level [ppm]	Milk	Milk fat	Muscle	Liver	Kidney	Fat
MRL	mean	highest	highest	highest	highest	highest
Beef cattle (8.26) [5/15]			0.104 mg/kg [< 0.1/0.24]	< 0.165 mg/kg [< 0.1/0.1]	0.108 mg/kg [0.1/0.19]	1.902 mg/kg [1.7/2.2]
Dairy cattle (7.41) [5/15]	0.088 mg/kg [0.082/0.15]	2.371 mg/kg [1.6/-]				
STMR	mean	mean	mean	mean	mean	mean
Beef cattle (3.4) [0/5]			< 0.068 mg/kg [< 0.1]	< 0.068 mg/kg [< 0.1]	< 0.068 mg/kg [< 0.1]	0.588 mg/kg [0.865]
Dairy cattle (3.21) [0/5]	0.053 mg/kg [0.082]	0.491 mg/kg [0.765]				

The data from the cattle feeding studies were used to support the estimation of maximum residue levels for bifenthrin in mammalian meat, edible offal and milk.

The Meeting estimated STMR values of 0.07 mg/kg for mammalian muscle and 0.59 mg/kg for mammalian fat, and a maximum residue level of 3 (fat) for mammalian meat. The HRs were 0.104 and 1.9 mg/kg for muscle and fat, respectively.

The Meeting estimated an STMR value of 0.07 mg/kg and a maximum residue level of 0.2 mg/kg for mammalian edible offal, based on liver and kidney data. The HR was 0.165 mg/kg.

The Meeting estimated an STMR value of 0.053 mg/kg and a maximum residue level of 0.2 mg/kg for milks.

The Meeting estimated an STMR value of 0.49 mg/kg and for milk fat. The Meeting estimated a maximum residue level of 3 mg/kg for milk fat.

Previous recommendations for cattle meat (fat) (0.5 mg/kg), cattle liver (0.05* mg/kg), cattle kidney (0.05* mg/kg), cattle fat (0.5 mg/kg) and cattle milk (0.05* mg/kg) were withdrawn.

Poultry

The dietary burdens for the estimation of maximum residue levels and STMR values for bifenthrin in poultry commodities are 1.79 ppm and 1.1 ppm, respectively.

An extrapolation from the highest dose level of 0.25 ppm in the laying hen feeding study to the estimated dietary burdens was not made because of the big distance.

The laying hen feeding study submitted is not adequate to estimate maximum residue levels, STMR and HR values for poultry tissues and eggs.

Previous recommendations for chicken eggs (0.01* mg/kg), chicken fat (0.05* mg/kg), chicken meat (fat) (0.05* mg/kg) and chicken, edible offal of (0.05* mg/kg) are withdrawn.

FURTHER WORK OR INFORMATION

The Meeting identified the following data gaps:

An adequate poultry feeding study at the dose level matching the animal dietary burden.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of bifenthrin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.01 mg/kg bw and the calculated IEDIs were 8–20% of the maximum ADI. The Meeting concluded that the long-term intake of residues of bifenthrin resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for bifenthrin was calculated for food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4.

For strawberries, the IESTI represented 230% of the ARfD of 0.01 mg/kg bw for the general population and 430 % of the ARfD for children. The information provided to the JMPR precludes an estimate that the short-term intake of residue of bifenthrin from the consumption of strawberries will below the ARfD. The Meeting noticed that an alternative GAP for strawberries was not available.

For the other commodities considered by the JMPR, the IESTI represented 0–50 % of the ARfD for the general population and 0–90% of the ARfD for children. The Meeting concluded that the short-term intake of residues of bifenthrin, when used in ways that have been considered by the JMPR (except strawberry), is unlikely to present a public health concern.

A concern form regarding the ARfD established by the JMPR in 2009 was received immediately prior to the current Meeting, long after the agreed CCPR deadline (see 3.1). The Meeting decided to defer this item to the next JMPR.