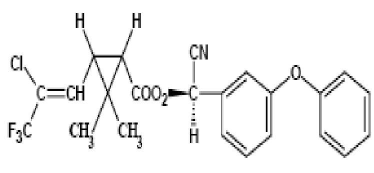
5.8 LAMBDA-CYHALOTHRIN (146)

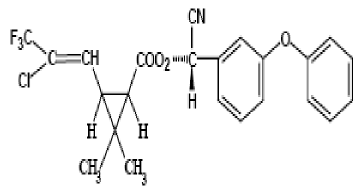
RESIDUE AND ANALYTICAL ASPECTS

Lambda-cyhalothrin was scheduled as a priority compound under the periodic re-evaluation programme at the 34th Session of the CCPR as a replacement for cyhalothrin. The toxicological evaluation for lambda-cyhalothrin was conducted at JMPR 2007. The isomeric mixture cyhalothrin was evaluated several times by JMPR for residues (1984, 1986 and 1988) and once for toxicology (1984). The Meeting received information on lambda-cyhalothrin metabolism and environmental fate, methods of residue analysis, freezer storage stability, national registered use patterns, supervised residue trials, farm animal feeding studies and fate of residues in processing.

Although cyhalothrin and lambda-cyhalothrin are isomers, only lambda-cyhalothrin is supported by the manufacturer and therefore intended as a replacement for cyhalothrin. For cyhalothrin as a mixture of all isomers only limited information on the metabolism and the environmental fate were submitted. No information on registered uses and/or supervised residue trial data was available to the Meeting.



lambda-cyhalothrin (R) (Z)-(1S)-cis-isomer



lambda-cyhalothrin (S)-(Z)-(1R)-cis-isomer

The following abbreviations are used for the metabolites discussed below:

cyhalothrin	3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyano(3-phenoxyphenyl)methyl cyclopropanecarboxylate
lambda-cyhalothrin	1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl) -2,2-dimethylcyclopropane carboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane carboxylate
Compound Ia	(Z)-3-(2-chloro-3,3,3-trifluoro-propenyl)-2,2-dimethylcyclo-propane carboxylic acid
Compound Ib	(1RS)-trans-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethyl-cyclopropane carboxylic acid
Compound III	(RS)-α -cyano-3-phenoxy-benzyl alcohol
Compound IV	3-phenoxybenzaldehyde
Compound V	3-phenoxybenzoic acid
Compound IX	(RS)-3-phenoxymandelamide
Compound XI	3-(2-chloro-3,3,3-trifluoro-prop-1-enyl)-2-hydroxy-methyl-2-methyl-cyclo-

	propane carboxylic acid
Compound XV	(RS)-α -cyano-3-(4-hydroxy-phenoxy)benzyl (Z)-(1RS)-cis-3-(2-chloro-3,3,3-trifluoro-propenyl)-2,2-dimethyl-cyclopropane carboxylate
Compound XXIII	3-(4'-hydroxy)-phenoxy-benzoic acid
R157836	enantiomeric pair A, cis 1RαR and cis 1SαS enantiomers of cyhalothrin

Animal metabolism

The Meeting received animal metabolism studies with cyhalothrin in rats and lambda-cyhalothrin in laying hens and lactating goats. In these studies lambda-cyhalothrin was [^{14}C]labelled at the acid moiety in most cases. Additional information on the metabolism of cypermethrin in cows and laying hens was submitted which shares the structure of the alcohol moiety with lambda-cyhalothrin and has only a slightly lower log K_{ow} of 5.3–5.6 compared to the log K_{ow} of 7.0 for lambda-cyhalothrin. Corresponding to lambda-cyhalothrin the cleavage of the ester bond is the first metabolism step resulting in a comparable alcohol-moiety metabolite which follows a similar pathway subsequently.

In general lambda-cyhalothrin is cleaved at the ester bond as the first step of metabolism followed by hydroxylation at various sites of both breakdown products. These products are further conjugated with sulfate or glucose and excreted via the urine. Parent lambda-cyhalothrin is fat-soluble (log K_{OW} = 7.0) since residue concentrations in fat are approximately 5 to 10 times higher than in the muscle. While unchanged parent compound contributed most to fatty tissues radioactivity, the residues found in liver and kidney at comparable TRR-levels consisted of cleaved and conjugated metabolites of higher polarity.

In rats oral doses of cyhalothrin were readily but incompletely absorbed (30–40% of radiolabel was recovered in urine). Most (70%) of the administered material was excreted in the faeces and urine within 24 h. After 7 days, 2–3% of the cyhalothrin administered persisted as unchanged residue in fat. Metabolism in rats involved initial cleavage of the molecule at the ester bond. In rats dosed with cyhalothrin, major metabolites identified in urine were the sulfate conjugate of compound XXIII and glucuronide conjugate of compound Ia. Minor metabolites identified were the unconjugated compound XXIII and compound V. (See the toxicology report for more details of laboratory animal metabolism)

For lactating goats dosed orally with [cyclopropyl-^{14}C]lambda-cyhalothrin at a rate equivalent to 10.8 mg/kg in the total diet for seven consecutive days, about 71% of the TRR was excreted (faeces 29.3%, urine 41.7%). Residues in milk reached a maximum after five days at a level of 0.27 mg/kg, mostly consisting of lambda-cyhalothrin (> 95%). Muscle gave relatively low total radioactive residues of 0.024–0.028 mg/kg compared to fat ranging from 0.13 to 0.44 mg/kg (0.32 mg/kg in average). Most of the radioactivity (> 88%) was identified as unchanged parent compound. In liver and kidney residues at a level of 0.34 and 0.2 mg/kg respectively were found. Lambda-cyhalothrin contributed to less than 7% of the TRR. Most of the residue was identified as the labelled cleavage metabolite Ia and its hydroxylated form (compound XI).

To investigate the fate of the alcohol-moiety, cows (non-lactating) were dosed orally with [benzyl-^{14}C-cypermethrin at a rate equivalent to 10 mg/kg of total diet for seven consecutive days. In liver and kidney the investigated radioactivity showed that analogous to lambda-cyhalothrin in goats the cleavage of the molecule is the initial breakdown reaction. The labelled alcohol-moiety fragment (compound V) was the dominant residue at levels of about 60% of the TRR, followed by its hydroxylation product compound XXIII at levels of 3.6 to 16% of the TRR (kidney and liver respectively). Due to the low total radioactivity in muscle no further identification was conducted while in fat more than 80% of the TRR consisted of unchanged [benzyl-^{14}C]cypermethrin.

In laying hens dosed orally with [cyclopropyl-^{14}C]lambda-cyhalothrin at a rate equivalent to 10.8 mg/kg of total diet for 14 consecutive days more than 98% of the administered dose was recovered from the excreta. In muscle tissues no TRR above 0.01 mg/kg was found and no further characterisation was possible. In the fat radioactive residues were between 0.17 to 0.46 mg/kg with unchanged lambda-cyhalothrin contributing more than 80% of the radioactivity. In the liver extensive metabolism occurred resulting mainly in the cleavage product compound Ia (51% of the TRR) and its hydroxylated product compound XI (9.5% of the TRR). No parent lambda-cyhalothrin was found in the liver of laying hens. In egg yolk about 60% of the TRR consisted of unchanged parent compound. Further radioactivity was characterized in the polar and hexane fraction amounting less than 10% of TRR. Unextractable residues were at 12.6% of the TRR.

For laying hens dosed orally with [phenoxy-^{14}C]labelled cypermethrin at a rate equivalent to approximately 10 mg/kg in the total diet (1.52 mg per bird and day) for 14 consecutive days similar results to the study with lambda-cyhalothrin were obtained. The labelled alcohol-moiety cleavage product compound V and its hydroxylated products compound XXIII were the main metabolites identified in liver. A subsequent transfer of these metabolites into other animal tissues or the eggs was observed in small amounts only (compound V in egg yolk at 1.2% of the TRR).

Plant metabolism

The Meeting received plant metabolism studies with [^{14}C]cyhalothrin and [^{14}C]lambda-cyhalothrin in apples, cabbage, wheat, cotton and soya beans. Parent substance labelled either as [cyclopropyl-^{14}C]- (cotton, wheat, soya beans), [phenyl-^{14}C]- (wheat) or [benzyl-^{14}C]lambda-cyhalothrin (cotton, soya beans) as well as [cyclopropyl-^{14}C]cyhalothrin (apples, cabbage) were used in the metabolism studies.

In general, the metabolism of cyhalothrin is limited to a few transformation steps. The cleavage of the ester bond is normally the first step followed by hydroxylation of the breakdown products. Translocation of the radioactivity within the plants investigated was not observed.

In the study on wheat both labelled test substances were applied at rates of 0.22 kg ai/ha. The wheat was treated in three variations: two treatments with a PHI of 14 days, two treatments with a PHI of 85 days or three treatments with a PHI of 30 days. Depending on the treatment, TRR values in grain differed significantly.

For two treatments with a PHI of 14 days only minor total residues were detected in wheat grain ranging from 0.002–0.007 mg/kg. Wheat grain with a PHI of 85 days (treated twice) also gave relatively low TRR values, i.e., from 0.005 to 0.018 mg/kg. An investigation of the radioactivity gave detectable residues of unchanged lambda-cyhalothrin, but these residues were below the LOQ of 0.001 mg/kg. The majority of the radioactivity was present in the water soluble phase but could not be further identified. For three applications and a PHI of 30 days the highest residues of the study were detected in the grain, which ranged from 0.112 to 0.131 mg/kg. More than 75% of the TRR was identified as lambda-cyhalothrin. Depending on the label the first products of the cleavage of the ester bond (compound Ia and V) were the only metabolites identified at levels below the LOQ.

For wheat foliage only the samples obtained from short PHIs (14 and 30 days) were analysed. After two treatments and a PHI of 14 days TRR values for both labels of 0.45 to 1.8 mg/kg were found. Three treatments and a PHI of 30 days led to higher radioactive residues ranging from 7.95 up to 10 mg/kg. In all samples, unchanged parent lambda-cyhalothrin was the main residue at levels > 80% of the TRR. Again the initial products of the ester bond cleavage and their hydroxylated metabolites were the only metabolites found at levels < 2% of the TRR each.

In soya beans both labels were applied as two treatments at rates of 0.02 kg ai/ha each. Samples of leaves and soya beans were taken 39 and 51 days after the last treatment respectively. In soya beans very low total radioactive residues ranging from 0.003 to 0.01 mg/kg were found. No further characterisation or identification of the radioactivity was achieved. In soya bean plants residues were higher (TRR 1.2–1.9 mg/kg). About half of the radioactivity was identified as lambda-cyhalothrin (43–52% of the TRR). For the [cyclopropyl-^{14}C]-label compound Ia was the major metabolite with 25% of the TRR. Further breakdown products were the hydroxylated cleavage products at levels below 7% of the TRR.

Two cotton studies were conducted to investigate the residues of lambda-cyhalothrin in leaves and seeds. After three applications of 0.066 kg ai/ha, cotton leaves were sampled at a PHI of 80 days and analysed. Total radioactive residues were quite comparable for both labels ranging from 2.9 to 4.1 mg/kg. Depending on the label, 37–52% of the TRR was identified as unchanged lambda-cyhalothrin. Further metabolites were identified as the initial cleavage products and their hydroxylated metabolites. Except compound Ia (17.6% of the TRR) all metabolites were at levels below 10% of the total radioactivity in the cotton leaves.

In the second experiment cotton was either sprayed three times at rates of 0.066 kg ai/ha each with a PHI of 101 days or the cotton seeds were directly treated using a syringe with a PHI of 14 days. After the direct treatment the analysis of the radioactivity showed that all of the lambda-cyhalothrin applied remained unchanged. No degradation on the parent substance was observed. Following foliar application, residues in the seeds were relatively low ranging from 0.01 to 0.027 mg/kg. No further identification of the radioactivity was performed.

Metabolism on cabbage was investigated using cyhalothrin. The cabbage plants were directly spotted with a [^{14}C]cyhalothrin solution. Treated leaves were removed from these plants at intervals of 2, 4, 5, 6 and 7 weeks. Two additional plants were sprayed either four or eight times at rates of 0.055 kg ai/ha with a PHI of 7 days.

The cabbage leaves spotted with [^{14}C]cyhalothrin showed a steady decrease of the parent compound. At 2 weeks after the treatment more than 80% of the TRR was identified as cyhalothrin. This percentage dropped to 54% after 5–6 weeks. The leaves harvested after 6 weeks were further analysed and indicated both isomers of the initial cleavage products compound Ia and Ib as metabolites identified at levels of 4% of the TRR each.

After eight spray applications and a PHI of 7 days cabbage leaves showed total radioactive residues of 0.44 mg/kg. Most of the residues were located on the outer leaves (1.13 mg/kg) while only minor residues could be found within the cabbage head (0.003 mg/kg). In total about 80% of the TRR consisted of unchanged cyhalothrin. Again both isomers of the initial cleavage products (compound Ia and Ib) were identified as metabolites (3.0% and 0.8% of the TRR respectively).

In apples the metabolism was also investigated using the isomeric mixture of cyhalothrin labelled at the cyclopropyl-moiety. Ten apples were directly treated with the active ingredients and exposed to sunlight. At intervals of 0, 7, 14, 28 and 56 days two apples were harvested and analysed for radioactive residues. The results obtained from 0 to 28 days indicated that only very little degradation of cyhalothrin occurred. More than 97% of the TRR was identified as unchanged parent. After 56 days approximately 89% of the remaining TRR was cyhalothrin. Minor amounts of the isomers compound Ia and Ib were detected (< 3% of the TRR). The rest of the radioactivity was characterized as water soluble or unextractable.

Environmental fate in soil

The Meeting received information on aerobic soil metabolism and soil photolysis of lambda-cyhalothrin as well as studies on the behaviour in crop rotations. Due to the fact that mostly acid-labelled lambda-cyhalothrin was used in the aerobic soil metabolism study, additional information on the aerobic soil metabolism of alcohol-labelled cypermethrin was submitted.

The photolysis study conducted with [cyclopropyl-^{14}C]- and [phenyl-^{14}C]lambda-cyhalothrin at a rate of 40 g ai/ha showed no accelerated decrease in the residues under irradiation. The levels of parent compound in the samples were at comparable levels to the dark control samples.

In the aerobic soil metabolism studies conducted with [cyclopropyl-^{14}C]lambda-cyhalothrin at rates of 100–500 g ai/ha, DT_{50} values ranging from 22 to 83 days were reported. After 26 weeks a significant mineralisation was observed (up to 70% evolved $^{14}CO_2$). The main metabolites found after 90 to 181 days were the hydroxylated parent compound (compound XV) and the labelled cleavage products compound Ia, each accounted for less than 12% of the initial dose.

In comparable studies using [benzyl-^{14}C]-cypermethrin compounds III, IV and IX were the predominant metabolites. After the cleavage of the initial molecule into the labelled compound III subsequent oxidation into compound IV and conjugation appear to be the typical reaction pathways in soil.

Rotational crop studies using [cyclopropyl-^{14}C] and [phenyl-^{14}C]lambda-cyhalothrin were conducted on wheat, lettuce and carrots with plant back intervals of 30, 60 and 120 days. After treatment with approximately 0.47 kg ai/ha, samples from each commodity were taken and analysed for the total radioactivity for the phenyl-label and additionally for the nature of residue for the cyclopropyl-label.

The samples grown in soil treated with the phenyl-label gave very low residues overall, ranging from 0.002 mg/kg for carrot roots up to the highest concentration of 0.035 mg/kg in wheat straw. Due to the low level of radioactivity no further investigation of the radioactivity was performed.

For the cyclopropyl-label residues were higher ranging from 0.003 mg/kg in carrot roots up to 0.85 mg/kg in wheat straw. The characterisation of the radioactivity showed negligible residues of parent lambda-cyhalothrin in all matrices (< 0.5% of the TRR). Most of the radioactivity was identified as the first cleavage product compound Ia at 40–60% of the TRR. The remaining radioactivity was included in unidentified polar fractions or not extractable.

Methods of analysis

The Meeting received information on analytical methods for the determination of residues of the active substance cyhalothrin, lambda-cyhalothrin (enantiomeric pair B, cis 1RαS and cis 1SαR enantiomers of cyhalothrin), R157836 (enantiomeric pair A, cis 1RαR and cis 1SαS enantiomers of cyhalothrin) and for some metabolites in target crops and animal products (milk, meat, kidney, liver, fat and eggs).

In the methods the macerated samples are typically extracted with acetone:hexane (50:50 v/v) and the extract is cleaned by a solid phase clean-up either with a silica or Florisil column. The final residue is determined by GLC with ECD or MS detection. LOQs are at 0.01 mg/kg for all plant and animal matrices.

Analytical recovery data were satisfactory for cyhalothrin, lambda-cyhalothrin, its epimer R157836 and several metabolites for numerous commodities. Residue methods were tested by independent laboratories unfamiliar with the analysis and were found to have satisfactory recoveries and no background interferences.

Stability of residues in stored analytical samples

Information was received on the freezer storage stability of lambda-cyhalothrin residues in plant and animal commodities. For some commodities the stability for the epimer of lambda-cyhalothrin (R157836) was also investigated.

Lambda-cyhalothrin residues were stable in the commodities apple and cabbage for 16 months and were stable for 26 months in apple, peach, cabbage, pea, potato, rape seeds, wheat grain, sugar beet roots and cotton seed. R157836 was stable in apples and cabbages for at least 16 months.

In animal commodities lambda-cyhalothrin residues were stable for 3 months (bovine muscle, kidney, liver, fat and milk) and 26 months (poultry muscle, liver fat and eggs).

Residue definition

The residue following use of lambda-cyhalothrin on crops is predominantly lambda-cyhalothrin. Epimerisation of lambda-cyhalothrin was measurable, but only at very low levels. Methods are available that can measure cyhalothrin as well as the individual diastereoisomers and epimers.

The ratio of lambda-cyhalothrin to major metabolites differed in the ruminant metabolism and feeding studies. In the feeding study, lambda-cyhalothrin is the major component of the residue in kidney and liver while in metabolism studies conducted with labelled material only minor amounts of the parent substance were detected. In muscle, fat, milk and eggs, lambda-cyhalothrin was the dominant residue.

Based on the actual residue measured (lambda-cyhalothrin), the Meeting recommended that the residue definition for plant and animal commodities for compliance with MRLs and for estimation of dietary intake should be lambda-cyhalothrin. The log K_{ow} of lambda-cyhalothrin of 7.0 and the animal metabolism and feeding studies suggest that lambda-cyhalothrin should be described as fat-soluble. In the ruminant and poultry metabolism studies lambda-cyhalothrin residues were approximately 5–10 times greater in fat than muscle.

For cyhalothrin, sum of isomers MRLs for animal commodities were established by JECFA in 2004. In addition the evaluation for lambda-cyhalothrin in by JMPR 2007 identified all isomers of cyhalothrin to be of toxicological concern in relation to dietary intake. In harmony with the JECFA MRLs established and the toxicological properties of cyhalothrin, a residue definition based on all isomers is recommended.

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

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trials data for lambda-cyhalothrin on citrus fruits (mandarins and oranges), pome fruits (apples and pears), stone fruits (cherries, peaches and plums), grapes, small berries (currants, gooseberries, raspberries and strawberries), olives, mangoes, onions, brassica vegetables (broccoli, cauliflower and cabbage), spinach, fruiting vegetables cucurbits (cucumbers, courgettes and melons), fruiting vegetables other than cucurbits (bell peppers, tomatoes and sweet corn), legume vegetables (beans, peas and immature soya beans), pulses (beans, peas, soya beans), root and tuber vegetables (carrots and potatoes), stem vegetables (asparagus and leek), cereals (wheat, oats, barley, maize, rice, rye, triticale and sorghum), sugarcane, tree nuts (almonds and pecan) and oilseeds (oilseed rape, sunflowers, cotton and peanuts).

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the sample with the higher residue was taken as the best estimate of the residue from the plot. All residue data refers to lambda-cyhalothrin residues as measured.

Labels (or translation of labels) were available from Australia, France, Italy, Portugal, Spain, Thailand and the United States describing the registered uses of lambda-cyhalothrin.

Citrus fruits

Lambda-cyhalothrin is registered in Portugal and Spain for use on citrus fruits at 0.001 and 0.002 kg ai/hL respectively with a PHI of 7 days. Supervised residue trials conducted in Southern Europe on mandarins and oranges according to the Spanish GAP were submitted. For whole mandarin fruits residues were (n = 10): 0.02, 0.03, 0.04, 0.05, 0.05, 0.06, 0.06, 0.07, 0.11 and 0.16 mg/kg. The corresponding residues in mandarin pulp were < 0.01(10) mg/kg. For whole orange fruits residues were (n = 5): 0.04(4) and 0.05 mg/kg and in the orange pulp < 0.01(6) and 0.01 mg/kg.

The Meeting decided to combine the trials in the mandarins and oranges for the purposes of estimating a maximum residue level, an HR and a STMR. Residues for whole citrus fruit in rank order were: (*n* = 15): 0.02, 0.03, 0.04(5), 0.05(3), 0.06, 0.06, 0.07, 0.11 and 0.16 mg/kg. Residues in citrus pulp in rank order were: < 0.01(16) and 0.01 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in citrus fruit of 0.2 (whole fruit), 0.01(pulp) and 0.01 mg/kg (pulp) respectively.

Pome fruit

Lambda-cyhalothrin is registered in France for use on apple, pear, nashi pear and quinces and in Spain for the use on fruit trees at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe on apples according to the French GAP were submitted. The apple fruit residues were (*n* = 8): < 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.04 and 0.04 mg/kg.

In the USA lambda-cyhalothrin is registered on apples, pears and quinces at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US on apples and pears according to the US GAP were submitted. In apples fruits a residue level of 0.09 mg/kg was found. The pear fruit residues were (*n* = 7): 0.05, 0.05, 0.06, 0.07, 0.09, 0.1 and 0.1mg/kg.

The Meeting decided to combine the trials for apples and pears conducted according to the comparable US GAP for the purpose of estimation a maximum residue level, an HR and an STMR for pome fruits. Residues for fruits in rank order were (*n* = 8) 0.05, 0.05, 0.06, 0.07, 0.09, 0.09, 0.1 and 0.1 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in pome fruits of 0.2, 0.08 and 0.1 mg/kg respectively.

Stone fruit

Lambda-cyhalothrin is registered in the US for use on cherries at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to the US GAP were submitted. In cherry fruits residues were (*n* = 10): 0.05, 0.07, 0.07, 0.09, 0.11, 0.14, 0.15, 0.16, 0.18 and 0.18 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in cherries of 0.3, 0.125 and 0.18 mg/kg respectively.

In France lambda-cyhalothrin is registered on peaches, apricots and nectarines at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in France according to the French GAP were submitted. In peaches residues were (*n* = 3): 0.02, 0.02 and 0.03 mg/kg.

In Italy the registration on peaches, apricots and nectarines is for 0.004 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to the Italian GAP were submitted. In peaches residues were (*n* = 6): 0.01, 0.02, 0.03(3) and 0.05 mg/kg.

Lambda-cyhalothrin is registered in the US for use on peaches, apricots and nectarines at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to the US GAP were submitted. In peach fruits residues were (*n* = 14): 0.02, 0.04, 0.05, 0.06, 0.08, 0.09, 0.09, 0.11, 0.11, 0.13, 0.14, 0.14, 0.2 and 0.33 mg/kg.

The Meeting decided to extrapolate the residue data for peaches to apricots and nectarines. Based on the GAP from the US the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in peaches, apricots and nectarines of 0.5, 0.1 and 0.33 mg/kg respectively.

In France lambda-cyhalothrin is registered on plums at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in France according to the French GAP were submitted. In plums residues were (*n* = 2): < 0.01 and 0.01 mg/kg.

Lambda-cyhalothrin is registered in the US for use on plums at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to the US GAP were submitted. In plums residues were (*n* = 12): < 0.01, < 0.01, 0.01, 0.01, 0.02(3), 0.03, 0.04, 0.06, 0.07, 0.1 mg/kg.

Based on the GAP from the US the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in plums, except prunes of 0.2, 0.02 and 0.1 mg/kg respectively.

Berries and other small fruits

Lambda-cyhalothrin is registered in France for use on currants at 0.002 kg ai/hL with a PHI of 21 days. Supervised residue trials conducted in Northern Europe according to the French GAP were submitted. In currants residues were (*n* = 4): 0.02, 0.02, 0.06 and 0.07 mg/kg.

In Spain lambda-cyhalothrin is registered on currants at 0.02 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in Southern Europe according to the Spanish GAP were submitted. In currants residues were (*n* = 9): < 0.01, < 0.01, 0.02, 0.03(3), 0.04, 0.06 and 0.07 mg/kg.

For gooseberries supervised residue trial data was submitted, but the only available GAP from Italy for small berries and other fruits is registered at a 50% higher application rate.

In Portugal lambda-cyhalothrin is registered on grapes at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to the Portuguese GAP were submitted. In grapes residues were (*n* = 11): < 0.01(4), 0.02(4), 0.03, 0.04 and 0.06 mg/kg.

In Italy and Spain lambda-cyhalothrin is registered on grapes at 0.003 kg ai/hL with a PHI of 7 days. One supervised residue trial conducted in Southern France according to these GAPs was submitted. In grapes residues were: 0.01 mg/kg.

Lambda-cyhalothrin is registered in France for use on raspberries at 0.002 kg ai/hL with a PHI of 14 days. Supervised residue trials conducted in France and the UK according to the French GAP were submitted. In raspberries residues were (*n* = 4): < 0.01, 0.01, 0.02 and 0.04 mg/kg.

In France lambda-cyhalothrin is registered on strawberries at 0.013 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in France (North and South), Italy and the UK according to the French GAP were submitted. In strawberries residues were (*n* = 14): < 0.01(6), 0.01, 0.02(3), 0.03, 0.03, 0.04 and 0.06 mg/kg.

In Spain lambda-cyhalothrin is registered on strawberries at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Southern Europe according to the Spanish GAP were submitted. In strawberries residues were (*n* = 16): 0.01(3), 0.02(6), 0.03(3), 0.05, 0.07, 0.08 and 0.09 mg/kg.

The Meeting noted that residues in berries and other small fruits are of the same magnitude and decided to extrapolate the data population based on the use of lambda-cyhalothrin in strawberries according to Spanish GAP to a group maximum residue recommendation. The estimated maximum residue level, STMR value and HR value for lambda-cyhalothrin in berries and other small fruits were 0.2, 0.02 and 0.09 mg/kg respectively.

Olives

Lambda-cyhalothrin is registered in France for use on olive trees at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to the French GAP were submitted. In olives residues were (*n* = 12): 0.03, 0.05, 0.06, 0.06, 0.09, 0.12, 0.13, 0.18, 0.25, 0.25, 0.41 and 0.42 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in olives of 1, 0.125 and 0.42 mg/kg respectively.

Mangoes

Lambda-cyhalothrin is registered in Thailand for use on mango trees at 1.25 g ai/hL with a PHI of 8 days. Supervised residue trials conducted in Thailand according to this GAP were submitted. In mango fruits residues were (n = 5): 0.01, 0.02, 0.03, 0.04 and 0.07 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in mango of 0.2, 0.03 and 0.07 mg/kg respectively.

Bulb vegetables

Lambda-cyhalothrin is registered in France for use on leek at 0.008 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in Northern France and the United Kingdom according to this GAP were submitted. In leek plants residues were (n = 8): 0.02, 0.03, 0.04, 0.05, 0.05, 0.1, 0.1 and 0.11 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on bulb onions at 0.034 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In dry onions residues were (n = 9): < 0.01(4), 0.01, 0.04, 0.05, 0.06 and 0.06 mg/kg.

The Meeting decided to extrapolate the data for leek to support a group maximum residue level for the group of bulb vegetables. The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in bulb vegetables of 0.2, 0.05 and 0.11 mg/kg, respectively.

Flowerhead brassica

Lambda-cyhalothrin is registered in the United States for use on broccoli at 0.034 kg ai/ha with a PHI of 1 day. Supervised residue trials conducted in the US according to this GAP were submitted. In broccoli residues were (n = 10): 0.04, 0.05, 0.09, 0.18, 0.2, 0.23, 0.27, 0.28, 0.3 and 0.3 mg/kg.

In Spain lambda-cyhalothrin is registered on broccoli at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Spain according to the GAP were submitted. In broccoli residues were (n = 4): 0.06, 0.08, 0.08 and 0.09 mg/kg.

Lambda-cyhalothrin is registered in Spain for use on cauliflower at 0.02 kg ai/ha with a PHI of 7 days. One supervised residue trial conducted in Spain according to the GAP was submitted. In cauliflower residues were (n = 1): 0.02 mg/kg.

The Meeting noted that the data for flowerhead brassica from Spain is not sufficient for a proposal. Based on the US GAP for broccoli the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in flowerhead brassicas of 0.5, 0.215 and 0.3 mg/kg, respectively.

Head cabbages

Lambda-cyhalothrin is registered in the United States for use on head cabbage at 0.034 kg ai/ha with a PHI of 1 day. Supervised residue trials conducted in the US according to this GAP were submitted. In cabbage residues were (n = 6): 0.36, 0.41, 0.46, 0.52, 0.55 and 0.67 mg/kg.

In Spain lambda-cyhalothrin is registered on cabbage at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Southern Europe according to the GAP were submitted. In cabbage residues were (n = 6): 0.01, 0.02, 0.08, 0.08, 0.13 and 0.17 mg/kg.

Based on the more critical US GAP the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in head cabbages of 1, 0.49 and 0.67 mg/kg, respectively. The IESTI calculation indicates that the consumption of head cabbage at the HR level of 0.67 mg/kg coming from trials according this GAP would lead to an exceedance of the ARfD by

160%. Consequently, the Meeting used the prospective alternative GAP approach and selected residue data according to the Spanish GAP for the maximum residue level estimation.

Based on the Spanish GAP the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in head cabbages of 0.3, 0.08 and 0.17 mg/kg, respectively.

Spinach

Lambda-cyhalothrin is registered in France for use on spinach at 0.006 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in France according to this GAP were submitted. In spinach residues were (n = 2): 0.04 and 0.08 mg/kg.

The Meeting decided that the residue data submitted for spinach is not sufficient to recommend a maximum residue level, an STMR and an HR value for spinach.

Fruiting vegetables – Cucurbits

Lambda-cyhalothrin is registered in Spain for use on cucurbits (outdoor and protected) at 0.02 kg ai/ha with a PHI of 3 days. Supervised residue trials conducted in Spain and Italy according to this GAP were submitted.

In cucumbers grown indoors residues were (n = 4): < 0.01(4) mg/kg.

For courgettes grown in field residues were (n = 7): < 0.01, < 0.01, 0.01(5) mg/kg.

In France lambda-cyhalothrin is registered on melons (outdoor and protected) at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Northern France according to the GAP were submitted for the indoor and outdoor application.

In whole melon fruits grown in field residues were (n = 6): < 0.01(6) mg/kg. The corresponding residue values in melon pulp (outdoor melons) were (n = 6): < 0.01(6) mg/kg.

In whole melon fruits grown under protection residues were (n = 5): < 0.01(4) and 0.02 mg/kg. The corresponding residue values in melon pulp (protected melons) were (n = 5): < 0.01(5) mg/kg.

The Meeting decided to combine the trials for cucumbers, courgettes and melons for mutual support for the purpose of estimating a maximum residue level, an HR and a STMR. Residues for fruiting vegetables, cucurbits in rank order were (n = 22) < 0.01(16), 0.01(5) and 0.02 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in fruiting vegetables, cucurbits of 0.05, 0.01 and 0.02 mg/kg, respectively.

Fruiting vegetables other than cucurbits, except mushrooms

Lambda-cyhalothrin is registered in the United States for use on sweet peppers at 0.034 kg ai/ha with a PHI of 5 days. Supervised residue trials on bell pepper conducted in the US according to this GAP were submitted. In bell pepper residues were (n = 8): 0.01, 0.02(3), 0.05, 0.05, 0.12 and 0.15 mg/kg.

For the purpose to extrapolate to dry Chilli pepper the Meeting estimated an STMR value and an HR value for lambda-cyhalothrin in sweet peppers of 0.035 and 0.15 mg/kg, respectively.

For tomatoes lambda-cyhalothrin is registered in the United States at 0.034 kg ai/ha with a PHI of 5 days. Supervised residue trials conducted in the US according to this GAP were submitted. In tomatoes residues were (n = 23): < 0.01(4), 0.01, 0.01, 0.02(4), 0.03(3), 0.04(5), 0.06, 0.08, 0.09, 0.13 and 0.15 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on sweet corn at 0.034 kg ai/ha with a PHI of 1 days. Supervised residue trials conducted in the US according to this GAP were submitted. In sweet corn (on the cob) residues were (n = 6): < 0.01(4), 0.14 and 0.18 mg/kg.

The Meeting decided to combine all data for mutual support to recommend a group MRL for fruiting vegetables other than cucurbits, except fungi. The corresponding reside data was (*n* = 37): < 0.01(8), 0.01(3), 0.02(7), 0.03(3), 0.04(5), 0.05, 0.05, 0.06, 0.08, 0.09, 0.12, 0.13, 0.14, 0.15, 0.15 and 0.18 mg/kg. Based on the combined data for lambda-cyhalothrin the Meeting estimated a maximum residue level, an STMR value and an HR value of 0.3, 0.03 and 0.18 mg/kg, respectively.

Applying the default concentration factor of 10 for sweet pepper to dried chilli pepper and an HR value of 0.15 mg/kg for sweet pepper the Meeting estimated a maximum residue level, an STMR and an HR value of 3, 0.35 and 1.5 mg/kg for lambda-cyhalothrin in dried chilli pepper, respectively.

Legume vegetables

Lambda-cyhalothrin is registered in the United States for use on green beans as legume vegetables at 0.034 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In beans with pods (fresh) residues were (*n* = 6): 0.02(4), 0.03 and 0.03 mg/kg.

For green beans lambda-cyhalothrin is registered in Spain at 0.02 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to this GAP were submitted. In beans with pods (fresh) residues were (*n* = 5): 0.01, 0.02, 0.02, 0.03 and 0.04 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on peas as legume vegetables at 0.034 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In peas without pods (fresh) residues were (*n* = 3): 0.01, 0.05 and 0.11 mg/kg.

For fresh peas lambda-cyhalothrin is registered in Spain at 0.02 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to this GAP were submitted. In peas without pods (fresh) residues were (*n* = 5): < 0.01(5) mg/kg.

For immature soya beans lambda-cyhalothrin is registered in Thailand at 0.016 kg ai/ha with a PHI of 8 days. Supervised residue trials conducted in Thailand according to this GAP were submitted. In whole pods with immature soya bean seeds residues were (*n* = 4): 0.05, 0.06, 0.07 and 0.08 mg/kg.

The Meeting decided to combine the trials for beans with pods and peas without pods according to US GAP for the purpose of estimating a maximum residue level, an HR and an STMR for the group of legume vegetables. Residues in rank order were (*n* = 9): 0.01, 0.02(4), 0.03, 0.03, 0.05 and 0.11 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in legume vegetables of 0.2, 0.02 and 0.11 mg/kg, respectively.

Pulses

Lambda-cyhalothrin is registered in the United States for use on beans and peas as pulses at 0.034 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted on beans and peas in the US according to this GAP were submitted. In bean seeds (dry) residues were (*n* = 9): < 0.01(9) mg/kg. In pea seeds (dry) residues were (*n* = 5): < 0.01(4) and 0.05mg/kg.

For soya beans lambda-cyhalothrin is registered in the US at 0.034 kg ai/ha with a PHI of 30 days for ground and aerial application. Supervised residue trials conducted in the US according to this GAP were submitted. In soya bean seeds (dry) residues were (*n* = 19): < 0.01(19) mg/kg.

The Meeting decided to combine the trials for beans, peas and soya beans as pulses according to US GAP for the purpose of estimation a maximum residue level, an HR and a STMR. Residues for pulses in rank order are (*n* = 33): < 0.01(32) and 0.05 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in pulses of 0.05 and 0.01 mg/kg, respectively.

Root and tuber vegetables

Lambda-cyhalothrin is registered in Italy for use on carrots at 0.013 kg ai/ha with a PHI of 3 days. Supervised residue trials conducted in Southern Europe with exaggerated rates of 0.025 kg ai/ha were submitted. In carrot roots residues were (*n* = 7): < 0.01(7) mg/kg.

Lambda-cyhalothrin is registered in Italy for use on potatoes at 0.013 kg ai/ha with a PHI of 15 days. Supervised residue trials conducted in Southern Europe with exaggerated rates of 0.025 kg ai/ha were submitted. In potato tubers residues were (*n* = 8): < 0.01(8) mg/kg.

The Meeting decided to combine the data available for the group of root and tuber vegetables based on the residue data for carrots and potatoes. The combined residues derived from supervised residue trials at exaggerated rates were (*n* = 15): < 0.01(15) mg/kg. The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in root and tuber vegetables of 0.01*, 0 and 0 mg/kg, respectively.

Asparagus

Lambda-cyhalothrin is registered in Thailand for use on asparagus at 0.018 kg ai/ha with a PHI of 3 days. Supervised residue trials conducted in Thailand according to this GAP were submitted. In asparagus sticks residues were (*n* = 6): 0.01(6) mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in asparagus of 0.02, 0.01 and 0.01 mg/kg, respectively.

Barley grain

In France lambda-cyhalothrin is registered on barley at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on barley conducted in Southern Europe according this GAP were submitted. In barley grain residues were (*n* = 29): < 0.01(3), 0.01(8), 0.02(5), 0.03(4), 0.04(4), 0.05, 0.06, 0.07, 0.08 and 0.33 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in barley grain of 0.5 and 0.02 mg/kg, respectively.

Maize grain

Lambda-cyhalothrin is registered in the United States for use on maize at 0.034 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In maize grain residues were (*n* = 19): < 0.01(18) and 0.01 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in maize grain of 0.02 and 0.01 mg/kg, respectively.

Oats, rye, triticale and wheat grain

Lambda-cyhalothrin is registered in the France for use on oats at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on oats conducted in Germany according to this GAP were submitted. In oats grain residues were (*n* = 5): < 0.01(4) and 0.02 mg/kg.

In France lambda-cyhalothrin is registered on rye at 0.008 kg ai/ha with a PHI of 28 days. One supervised residues trials on rye conducted in Germany according to this GAP was submitted. In rye grain residues were (*n* = 1): 0.01 mg/kg.

In France lambda-cyhalothrin is registered on triticale at 0.008 kg ai/ha with a PHI of 28 days. One supervised residues trials on triticale conducted in Germany according to this GAP was submitted. In triticale grain residues were (*n* = 1): < 0.01 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on wheat at 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials conducted in the US according to this GAP were submitted. In wheat grain residues were (*n* = 24): < 0.01(19), 0.01, 0.01, 0.02, 0.02 and 0.03 mg/kg.

In France lambda-cyhalothrin is registered on wheat at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on wheat conducted in Germany according to this GAP were submitted. In wheat grain residues were (*n* = 2): < 0.01 and 0.01 mg/kg.

The Meeting decided to extrapolate the data for wheat grain according to US GAP to make recommendation for oats, rye and triticale grain. The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in oats, rye, triticale and wheat grain of 0.05 and 0.01 mg/kg, respectively.

Rice grain

In the US lambda-cyhalothrin is registered on rice at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In rice grain residues were (*n* = 16): 0.06, 0.14, 0.15, 0.19, 0.2, 0.2, 0.24, 0.27, 0.32, 0.35, 0.42, 0.47, 0.48, 0.51, 0.66 and 0.79 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in rice grain of 1 and 0.295 mg/kg respectively.

Sorghum grain

Lambda-cyhalothrin is registered in the United States for use on sorghum at a maximum of 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials from the US were conducted at lower application rates of 0.022 kg ai/ha using ground and aerial application as well as furrow irrigation. None of these residue trials matched the maximum GAP submitted for sorghum.

The Meeting decided that the data submitted was not sufficient for an evaluation for the use of lambda-cyhalothrin in sorghum grain.

Sugar cane

Lambda-cyhalothrin is registered in the United States for use on sugar cane at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In sugar cane residues were (*n* = 9): < 0.01, < 0.01, 0.01, 0.02(5) and 0.03 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in sugar cane of 0.05, 0.02 and 0.03 mg/kg, respectively.

Tree nuts

Lambda-cyhalothrin is registered in the United States for use on almonds at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In almond nutmeat residues were (*n* = 5): < 0.01(5) mg/kg.

For pecans lambda-cyhalothrin is also registered in the US at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In pecan nutmeat residues were (*n* = 8): < 0.01(8) mg/kg.

Due to the fact that lambda-cyhalothrin is non-systemic and is mainly located on the surface of the commodities the Meeting decided to combine the data for almond and pecan nutmeat for mutual support to extrapolate to the whole group of tree nuts. The combined residues are: < 0.01(13) mg/kg

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in tree nuts of 0.01*, 0.01 and 0.01 mg/kg, respectively.

Oilseeds

Lambda-cyhalothrin is registered in the United States for use on oilseed rape at 0.034 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In rape seeds residues were (n = 7): < 0.01(3), 0.01, 0.02, 0.05 and 0.05 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on sunflowers at 0.034 kg ai/ha with a PHI of 45 days either with ground or with aerial application. Supervised residue trials conducted in the US according to these GAPs were submitted. In sunflower seeds residues following ground application were (n = 11): < 0.01(6), 0.01, 0.01, 0.03, 0.04 and 0.15 mg/kg. After aerial application residues in the seeds were (n = 5): < 0.01(4) and 0.03 mg/kg.

The Meeting decided that the data for sunflower seeds from ground and aerial application were from the same data population and can be combined. The combined residues were (n = 16): < 0.01(10), 0.01, 0.01, 0.03, 0.03, 0.04 and 0.15 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on cotton at 0.045 kg ai/ha with a PHI of 21 days either with ground or with aerial application. Supervised residue trials conducted in the US according to the GAP for aerial application were submitted. In cottonseeds residues following aerial application were (n = 4): < 0.01(4) mg/kg

Lambda-cyhalothrin is registered in the United States for use on peanuts at 0.034 kg ai/ha with a PHI of 14 days either with ground or with aerial application. Supervised residue trials conducted in the US according to the GAP for both application techniques were submitted. In peanut nutmeat residues following ground application were (n = 6): < 0.02(6) mg/kg. After aerial application residues in the nutmeat were (n = 2): < 0.02 and < 0.02 mg/kg.

The Meeting decided that the data for peanut nutmeat from ground and aerial application were from the same data population and can be combined. The combined residues are (n = 8): < 0.02(8) mg/kg.

Based on the use on sunflowers the Meeting decided to recommend a group maximum residue level for lambda-cyhalothrin in oilseeds. The estimated maximum residue level and STMR value for lambda-cyhalothrin in oilseeds were 0.2 and 0.01 mg/kg, respectively.

Peanut hay

Lambda-cyhalothrin is registered in the United States for use on peanuts at 0.034 kg ai/ha with a PHI of 14 days either with ground or with aerial application. Supervised residue trials conducted in the US according to the GAP for both application techniques were submitted, but only data after ground treatment is available for peanut hay. In peanut hay residues following ground application were (n = 5): 0.35, 0.65, 1.3, 1.3 and 2.2 mg/kg.

The Meeting estimated an STMR value and a highest residue value for lambda-cyhalothrin in peanut hay of 1.3 and 2.2 mg/kg respectively.

Soya bean fodder

For soya beans lambda-cyhalothrin is registered in the US at 0.034 kg ai/ha with a PHI of 30 days for ground and aerial application. One supervised residue trial conducted in the US according to the GAP for ground treatment was submitted. In soya bean fodder residues were: 0.3 mg/kg.

The Meeting concluded that the data submitted on soya bean fodder is not sufficient for an estimation of STMR and highest residue values.

Barley, oats, rye, sorghum and wheat forage

Due to the low degradation rate of lambda-cyhalothrin in plant metabolism studies no significant decline related to the dry matter content was anticipated by the Meeting. Therefore, the highest residue up to the PHI specified for grain harvesting was used for forage commodities unless specific limitations for grazing and/or forage were given on the label.

Lambda-cyhalothrin is registered in the United States for use on wheat at 0.034 kg ai/ha with a PHI for grazing and forage of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In wheat forage residues were (*n* = 23): < 0.01, < 0.01, 0.19, 0.26, 0.27, 0.29, 0.3, 0.3, 0.31, 0.33, 0.35, 0.35, 0.37, 0.38, 0.43, 0.43, 0.51, 0.59, 0.65, 0.71, 0.75. 0.91 and 1.2 mg/kg.

In France lambda-cyhalothrin is registered on wheat at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on wheat conducted in Germany according to this GAP were submitted. In wheat forage residues were (*n* = 4): 0.04, 0.04, 0.05 and 0.06 mg/kg.

In Italy lambda-cyhalothrin is registered on barley at a rate of 0.015 kg ai/ha without a specified PHI for forage or grazing. Supervised residues trials conducted in Southern Europe according to this GAP were submitted. In barley forage residues after 0 to 18 days were (*n* = 12): 0.18, 0.24, 0.24, 0.28, 0.42, 0.42, 0.55, 0.72, 0.86, 0.92, 1.1 and 1.4 mg/kg.

In France lambda-cyhalothrin is registered on barley at 0.008 kg ai/ha without a specified PHI for forage or grazing. Supervised residues trials on barley conducted in Germany according to this GAP were submitted. In barley forage residues were (*n* = 5): 0.07, 0.15, 0.46, 0.52 and 0.88 mg/kg.

Lambda-cyhalothrin is registered in the France for use on oats at 0.008 kg ai/ha without a specified PHI for forage or grazing. Supervised residues trials on oats conducted in Germany according to this GAP were submitted. In oats forage after 0 days residues were (*n* = 5): 0.08, 0.17, 0.24, 0.24 and 0.3 mg/kg.

In France lambda-cyhalothrin is registered on rye at 0.008 kg ai/ha without a specified PHI for forage or grazing. One supervised residues trials on rye conducted in Germany according to this GAP was submitted. In rye forage after 0 days residues were (*n* = 1): 0.15 mg/kg.

In France lambda-cyhalothrin is registered on triticale at 0.008 kg ai/ha without a specified PHI for forage or grazing. One supervised residues trials on triticale conducted in Germany according to this GAP was submitted. In triticale forage after 0 days residues were (*n* = 1): 0.16 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on sorghum at 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials conducted in the US according to this GAP were submitted. In sorghum forage residues after 30 days within 30% of the GAP were (*n* = 10): 0.06, 0.08, 0.09, 0.09, 0.1, 0.11, 0.14, 0.16, 0.18 and 0.22 mg/kg.

The Meeting decided to estimate STMR and highest residue values for barley, oats, rye, sorghum and wheat forage on basis of the highest data population for barley according to the GAP from Italy. The corresponding STMR and highest residue values for lambda-cyhalothrin in barley, oats, rye, sorghum and wheat forage were 0.49 and 1.4 mg/kg (fresh-weight basis), respectively.

Maize forage

Lambda-cyhalothrin is registered in the United States for use on maize and sweet corn at 0.034 kg ai/ha with a PHI of 1 day for grazing. Supervised residue trials conducted in the US according to this GAP were submitted. In maize forage residues were (*n* = 6): 1.2, 1.4, 1.7, 2.0, 2.3 and 2.8 mg/kg.

The Meeting estimated an STMR value and a highest residue value for lambda-cyhalothrin in maize forage of 1.85 and 2.8 mg/kg (fresh-weight basis) respectively.

Straw and fodder of cereal grains

In Italy lambda-cyhalothrin is registered on barley at a rate of 0.015 kg ai/ha with a PHI of 30 days. Supervised residues trials conducted in Southern Europe according to this GAP were submitted. In barley straw residues were (*n* = 34): 0.06, 0.08, 0.09(3), 0.11, 0.11, 0.12, 0.13, 0.14, 0.14, 0.15, 0.15, 0.16, 0.16, 0.18, 0.19, 0.21, 0.23, 0.25, 0.28, 0.3, 0.3, 0.31, 0.32, 0.35, 0.4, 0.44, 0.48, 0.51, 0.65, 0.7, 0.82 and 1.2 mg/kg (fresh-weight basis). On a dry weight basis (DM 89%) residues were: 0.07, 0.09, 0.1(3), 0.12, 0.12, 0.13, 0.15, 0.16, 0.16, 0.17, 0.17, 0.18, 0.18, 0.2, 0.21, 0.24, 0.26, 0.28, 0.31, 0.34, 0.34, 0.35, 0.36, 0.39, 0.45, 0.49, 0.54, 0.57, 0.73, 0.79, 0.92 and 1.4 mg/kg.

In France lambda-cyhalothrin is registered on barley at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on barley conducted in Germany according to this GAP were submitted. In barley straw residues were (*n* = 5): 0.15, 0.25, 0.34, 0.41 and 0.43 mg/kg (fresh-weight basis). On a dry weight basis (DM 89%) residues were: 0.17, 0.28, 0.38, 0.46 and 0.48 mg/kg.

For the use on maize and sweet corn as fodder lambda-cyhalothrin is registered in the United States at 0.034 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In maize fodder residues were (*n* = 20): < 0.01, < 0.01, 0.05, 0.1, 0.12, 0.13(3), 0.15, 0.18, 0.19, 0.19, 0.2, 0.22, 0.23, 0.23, 0.24, 0.28, 0.34 and 0.4 mg/kg (fresh-weight basis). On a dry weight basis (DM 83%) residues were: < 0.01, < 0.01, 0.06, 0.12, 0.14, 0.16(3), 0.18, 0.22, 0.23, 0.23, 0.24, 0.26, 0.28, 0.28, 029, 0.34, 0.41 and 0.48 mg/kg.

Lambda-cyhalothrin is registered in France for use on oats at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on oats conducted in Germany according to this GAP were submitted. In oat straw residues were (*n* = 4): 0.04, 0.06, 0.06 and 0.25 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.04, 0.07, 0.07 and 0.28 mg/kg.

In the USA lambda-cyhalothrin is registered on rice at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In rice straw residues were (*n* = 16): 0.15, 0.22, 0.23, 0.23, 0.42, 0.43, 0.45, 0.49, 0.49, 0.52, 0.65, 0.85, 0.87, 1.2, 1.4 and 1.4 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.17, 0.24, 0.26, 0.26, 0.47, 0.48, 0.5, 0.54, 0.54, 0.58, 0.72, 0.94, 0.97, 1.3, 1.6 and 1.6 mg/kg.

In France lambda-cyhalothrin is registered on rye at 0.008 kg ai/ha with a PHI of 28 days. One supervised residue trial on rye conducted in Germany according to this GAP was submitted. In rye straw residues were (*n* = 1): 0.1 mg/kg (fresh-weight basis). On a dry weight basis (DM 88%) residues were: 0.11 mg/kg.

In France lambda-cyhalothrin is registered on triticale at 0.008 kg ai/ha with a PHI of 28 days. One supervised residue trial on triticale conducted in Germany according to this GAP was submitted. In triticale straw residues were (*n* = 1): 0.06 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.07 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on wheat at 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials conducted in the US according to this GAP were submitted. In wheat straw residues were (*n* = 24): 0.19, 0.21, 0.23, 0.24, 0.26, 0.27, 0.28, 0.29, 0.3, 0.31, 0.33, 0.35, 0.35, 0.36, 0.44, 0.47, 0.5, 0.52, 0.53, 0.7, 0.7, 0.84, 0.92 and 1.3 mg/kg (fresh-weight basis). On a dry weight basis (DM 88%) residues were: 0.21, 0.24, 0.26, 0.27, 0.29, 0.3, 0.31, 0.33, 0.34, 0.35, 0.37, 0.39, 0.39, 0.4, 0.49, 0.53, 0.56, 0.58, 0.6, 0.79, 0.79, 0.94, 1.0 and 1.5 mg/kg.

In France lambda-cyhalothrin is registered on wheat at 0.008 kg ai/ha with a PHI of at least 28 days. Supervised residues trials on wheat conducted in Germany according to this GAP were submitted. In wheat straw residues were (*n* = 9): 0.1, 0.11, 0.16, 0.2, 0.26, 0.34, 0.41, 0.42 and 0.61 mg/kg (fresh-weight basis). On a dry weight basis (DM 88%) residues were: 0.11, 0.12, 0.18, 0.22, 0.29, 0.38, 0.46, 0.47 and 0.69 mg/kg.

The Meeting noted that residues in cereal straw and fodder crops were of the same magnitude and decided to make recommendations for the whole group of straw and fodder of cereal grains. From the data population for rice straw according to US GAP that resulted in the highest residues, the

Meeting estimated a maximum residue level, an STMR value and a highest residue value for lambda-cyhalothrin in straw and fodder of cereal grains (dry-weight bases) of 2, 0.54 and 1.6 mg/kg respectively.

Almond hulls

Lambda-cyhalothrin is registered in the United States for use on almonds at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In almond hulls residues were (*n* = 5): 0.29, 0.34, 0.38, 0.49 and 1.0 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.32, 0.38, 0.42, 0.54 and 1.1 mg/kg.

The Meeting estimated a maximum residue level and a STMR value for lambda-cyhalothrin in almond hulls (dry-weight bases) of 2 and 0.42 mg/kg respectively.

Fate of residues during processing

The Meeting received information on the fate of lambda-cyhalothrin residues during processing of oranges, apples, peaches, plums, strawberries, currants, grapes, olives, tomatoes, spinach, beans, wheat, sorghum, rice sugarcane, soya beans and cotton seeds. Also information was provided on hydrolysis studies of lambda-cyhalothrin to assist with identification of the nature of the residue during processing. Processing factors presented below have been calculated for lambda-cyhalothrin for all commodities relevant to trade and/or the dietary intake estimation. Further data on processed commodities are presented in the evaluation for this active substance.

Lambda-cyhalothrin was stable under the hydrolysis condition (pH, temperature, time) representing the food processes pasteurisation, baking, brewing, boiling and sterilisation.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Oranges	juice	< 0.14, < 0.33	< 0.33
	wet pomace	1.6, 2	1.8
	dry pomace	3.9, 6.3	5.2
Apples	juice	< 0.1	<1
	wet pomace	< 1, 8.1	8.1
Grapes	raisins	3, 3	3
	wet pomace (white wine)	3.5	3.5
	wet pomace (red wine)	5.5	5.5
	dry pomace (white wine)	11	11
	dry pomace (red wine)	15	15
	young wine (white & red wine)	< 0.5, < 0.5	< 0.5
	juice (white & red)	< 0.5, < 0.5	< 0.5
Olives	virgin oil	0.46, 1	0.73
Tomatoes	juice	0.06	0.06
	paste	0.31	0.31
Wheat	bran	4.5	4.5
	middlings	1.0	1.0
	shorts & germs	1.5	1.5
	patent flour	0.5	0.5
	grain dust (< 420μ)	98	98
Rice	polished rice	< 0.01	< 0.01
	hulls	6.5	6.5
	bran	0.22	0.22

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Sugarcane	molasses	< 0.05	< 0.05
	refined sugar	< 0.05	< 0.05
Soya beans	hulls	< 1	< 1
	meal	< 1	< 1
	refined oil	< 1	< 1
Cottonseed	delinted seed	0.1	0.1
	hulls	0.1	0.1
	meal	< 0.1	< 0.1
	refined oil	0.1	0.1

Oranges were processed into juice and wet and dry pomace. Processing factors were < 0.33, 1.8 and 5.2 respectively. Based on the median residue of 0.05 mg/kg for whole oranges STMR-P values for lambda-cyhalothrin residues were 0.0165 mg/kg in orange juice, 0.09 mg/kg in wet pomace and 0.26 mg/kg in dry pomace.

Apples were processed into juice and wet pomace. Processing factors were < 0.1 for juice and 8.1 for wet pomace. Based on the STMR value of 0.08 mg/kg for pome fruit STMR-P values for lambda-cyhalothrin residues were 0.008 mg/kg for apple juice and 0.65 mg/kg for wet pomace.

Grapes were processed into wine, juice, raisins and wet and dry pomace. Processing factors were 0.5 for wine and juice (red and white combined), 3 for raisins and 5.5 and 15 for wet and dry pomace (based on red wine) respectively. Based on the STMR value of 0.02 for grapes STMR-P values were 0.01 mg/kg for wine and juice (red and white combined), 0.06 mg/kg for raisins and 0.11 mg/kg and 0.3 mg/kg for wet and dry pomace, respectively.

Based on the HR of 0.09 mg/kg estimated for grapes and the processing factor of 3 for raisins, the Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.06 and an HR of 0.27 mg/kg for lambda-cyhalothrin in dried grapes, respectively.

Olives were processed into virgin oil. The processing factor was 0.73. Based on the STMR value of 0.125 mg/kg for olives STMR-P value was 0.091 mg/kg for virgin oil.

Tomatoes were processed into juice and paste. Processing factors were 0.06 for juice and 0.31 for paste, respectively. Based on the STMR value of 0.03 mg/kg for tomatoes STMR-P values were 0.002 mg/kg for tomato juice and 0.007 mg/kg for paste, respectively.

Wheat was processed into bran, middlings, patent flour and grain dust. Processing factors were 4.5 for bran, 1 for middlings, 0.5 for flour (patent flour) and 98 for grain dust. Based on the STMR value of 0.01 mg/kg for wheat grain STMR-P values were 0.045 mg/kg for bran, 0.01 mg/kg for middlings, 0.005 mg/kg for flour and 0.98 mg/kg for grain dust.

Based on the STMR found in wheat grain of 0.01 mg/kg and a processing factor of 4.5 for wheat bran the Meeting estimated a maximum residue level of 0.1 mg/kg for wheat bran.

Rice was processed into polished rice, hulls and bran. Processing factors were < 0.01, 6.5 and 0.22 respectively. Based on the STMR value of 0.295 mg/kg for rice grain STMR-P values were 0.003 mg/kg for polished rice, 1.9 mg/kg for rice hulls and 0.065 mg/kg for rice bran.

Sugarcane was processed into molasses and refined sugar. Processing factors were < 0.05 and < 0.05, respectively. Based on the STMR value of 0.02 mg/kg for sugar cane STMR-P values were 0.001 mg/kg for molasses and refined sugar.

Soya beans were processed into hulls, meal and refined oil. In all cases the processing factors were < 1. Specific STMR-P values for lambda-cyhalothrin in soya beans can not be estimated.

Cottonseed was processed into delinted seed, hulls, meal and refined oil. Processing factors were 0.1 for delinted seeds, 0.1 for hulls, < 0.1 for meal and 0.1 for refined oil. Based on the STMR value of 0.01 mg/kg for cottonseeds STMR-P values were 0.001 for delinted seeds, 0.001 for hulls, 0.001 for meal and 0.001 for refined oil.

Farm animal dietary burden

The Meeting received lactating dairy cow feeding studies which provided information on likely residues resulting in animal tissues and milk from lambda-cyhalothrin residues in the animal diet.

Lactating dairy cows

Lactating Friesian dairy cows between four and nine years old were fed for up to 30 days on diets containing approximately 1, 5 and 25 ppm lambda-cyhalothrin. The lambda-cyhalothrin was incorporated into molasses, which was added to the concentrate feed at each of the twice-daily milking times. Each feeding group contained at least three cows; the 25 mg/kg group contained five cows. At the lowest dose level of 1 ppm no residues above the LOQ of 0.01 mg/kg were detected in meat. Liver and kidney gave small measurable residues at 0.03 mg/kg and 0.02 mg/kg respectively. Most of the residue was found in fat, ranging up to 0.5 mg/kg.

In the 5 ppm dose group comparable results were obtained. Residues in muscle, liver and kidney were in the range of 0.01 to 0.07 mg/kg. In fatty tissues lambda-cyhalothrin accumulated to a level up to 1.8 mg/kg. At the highest dose rate of 25 mg/kg residues were relatively high. Meat contained lambda-cyhalothrin resides up to 0.4 mg/kg. In liver lower residues compared to kidney were detected (0.08 mg/kg and 0.4 mg/kg respectively). Most of the residue was found in fat ranging from 1.3 up to 7.2 mg/kg.

Tissues from cows in the 25 mg/kg group that were allowed a recovery period on untreated diet of one week contained significantly lower residues of < 0.01–0.05 mg/kg (meat), < 0.01 mg/kg (liver), 0.10–0.20 mg/kg (kidney) and 0.03–2.6 mg/kg (fat).

In the milk residues reached a plateau after a dosing period of 10 to 12 days in all dose groups. For the feeding levels of 1, 5 and 25 ppm average residues in milk were 0.03, 0.1 and 0.83 mg/kg, respectively. No separation between cream and skim milk was conducted.

In a second study lactating Holstein dairy cows between four and six years old were fed for 28 days on diets containing approximately 8, 25 and 60 ppm lambda-cyhalothrin (administered as gelatine capsules). Each feeding group contained at least four cows. At the lowest dose group of 8 ppm lambda-cyhalothrin in the diet, residues were relatively low (< 0.01–0.09 mg/kg for liver and 0.02–0.08 mg/kg in kidney). Over the whole dosage interval up to 60 mg/kg in the diet, an increase in the residue up to 0.09 mg/kg in liver and 0.3 mg/kg in kidney was observed. Residues levels of compound Ia were comparable to lambda-cyhalothrin.

Estimated maximum and mean dietary burdens of farm animals

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 and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, lambda-cyhalothrin, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Beef cattle	4.07	2.83	5.93	4.03	6.12	4.05
Dairy cattle	4.55	3.1	4.79	3.27	6.12[a]	4.07[b]
Poultry - broiler	0.65	0.65	0.25	0.25	0.40	0.40
Poultry - layer	0.65	0.65	1.09	0.74	0.40	0.40

a Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat and milk

b Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat and milk

Animal commodities, MRL estimation

For MRL estimation, the residues in the animal commodities are lambda-cyhalothrin. The residue is fat-soluble.

Cattle

For MRL estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden (6.12 ppm) between the relevant feeding levels (5 and 25 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups. Only the feeding study conducted at rates of 1, 5 and 25 ppm was used for the estimation, since the second study available has a lowest dose of 8 ppm, which is higher than the maximum dietary burden for beef and dairy cattle.

The STMR values for the tissues were calculated by interpolating the mean dietary burden (4.07 ppm) between the relevant feeding levels (1 and 5 ppm) and using the mean tissue concentration from each feeding group.

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

Dietary burden (ppm) Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
MRL					
	mean	highest	highest	highest	highest
MRL beef or dairy cattle (6.12) [5, 25]	0.12 [0.1, 0.57]	0.1 [0.07, 0.4]	0.02 [0.01, 0.08]	0.09 [0.07, 0.4]	2.2 [1.8, 7.2]
STMR					
	mean	mean	mean	mean	mean
STMR beef or dairy cattle (4.07) [1, 5]	0.08 [0.03, 0.1]	0.04 [0.01, 0.05]	0.008 [0.03, 0.01]	0.03 [0.01, 0.04]	1.0 [0.25, 1.3]

The data from the cattle feeding study were used to support mammalian meat and milk MRLs.

The Meeting estimated a maximum residue level for lambda-cyhalothrin in whole milk of 0.2 mg/kg. No information was available on the distribution of residue between fat and non-fat milk fractions.

The residue arising from a dietary burden of 6.12 ppm was 2.2 mg/kg in the fat. Since the target tissue for lambda-cyhalothrin residues in animal tissues is fat, the Meeting recommended a maximum residue level of 3 mg/kg for meat (on a fat basis) and fat.

For kidney and liver the interpolation between the 5 and 25 ppm dose group lead to estimates of 0.09 mg/kg and 0.02 mg/kg respectively. On basis of the estimates, the Meeting recommended maximum residue levels of 0.2 mg/kg for kidney and 0.05 mg/kg for liver. All maximum residue levels recommended for animal commodities represent higher values as compared to those currently established in the Codex system by JECFA.

For dietary risk assessment, the STMR values are 0.08 mg/kg for whole milk, 1.0 mg/kg for meat/fat, 0.04 mg/kg for muscle, 0.03 mg/kg for kidney and 0.008 mg/kg for liver. The estimated HR values were 2.2 mg/kg for meat/fat, 0.1 mg/kg for muscle, 0.09 mg/kg for kidney and 0.02 mg/kg for liver. For liver residue data did not scale according to the dosing level in the feed. The Meeting decided to use the values for the dose level of 5 ppm as a basis for the estimation instead of the values at 1 ppm, since the residue data from higher dose rates seem to reflect a more realistic transfer into the liver of the animals.

For poultry no livestock feeding studies using lambda-cyhalothrin were submitted to the Meeting. A recommendation for maximum residue levels as well as for STMR and HR values is not possible.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of lambda-cyhalothrin 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 3–10% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that the long-term intake of residues of lambda-cyhalothrin from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for lambda-cyhalothrin was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI calculated on the basis of the recommendations made by the JMPR represented 0–60% of the ARfD (0.02 mg/kg bw) for children and 0–40% for the general population.

For head cabbage the prospective approach of an alternative GAP was used.

The Meeting concluded that the short-term intake of residues of lambda-cyhalothrin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.