5.5 CYPERMETHRINS (INCLUDING ALPHA- AND ZETA-CYPERMETHRIN) (118)

RESIDUE AND ANALYTICAL ASPECTS

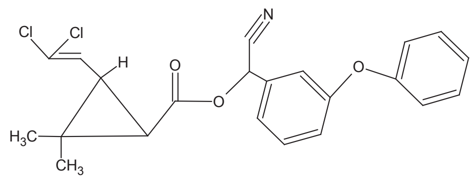
Cypermethrins was evaluated by JMPR 1979 (T, R), 1981 (T, R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R) and 2009 (R). The last periodic review for toxicology was in 2006 and for residues in 2008 and included cypermethrin, alpha-cypermethrin and zeta-cypermethrin. The 2006 Meeting estimated the acceptable daily intake (ADI) as 0–0.02 mg/kg bw and estimated the acute reference dose (ARfD) as 0.04 mg/kg bw. The 2008 Meeting defined the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities as cypermethrin (sum of isomers). The residue is fat soluble. In 2009 additional information on the use of cypermethrin was submitted and evaluated. Cypermethrin was listed by the Forty-second Session of the CCPR[14] for the evaluation of 2011 JMPR for additional maximum residue levels.

The Meeting received information on zeta-cypermethrin from the manufacturer on storage stability, residue analysis, use patterns, residues resulting from supervised trials on citrus fruits and tree nuts, and fates of residue during processing. In addition, the Meeting received information on cypermethrin on residue analysis, use patterns, and residues resulting from supervised trials on asparagus and pomelo from Thailand. China and India submitted information on cypermethrin about storage stability, residue analysis, use patterns, residues resulting from supervised trials on teas, and on fates of residue during processing (China). Furthermore, the Meeting received information from Japan on use patterns of cypermethrin.

Chemical name

(Zeta)-Cypermethrin or (*RS*)-α-cyano-3-phenoxybenzyl-(1*RS*,3*RS*;1*RS*,3*RS*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (*RS*)-α-cyano-3-phenoxybenzyl-(1*RS*)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

Structural formula:



Cypermethrin and zeta-cypermethrin are similar pyrethroid insecticides with the same basic chemical formula and molecular weight. Both products are mixtures of eight individual isomers that only differ in the structural orientation of their chemical bonds.

Analytical methods

The Meeting received description and validation data for analytical methods of cypermethrin and zeta-cypermethrin.

The extended revision of GC-ECD/GC-MS method DFG S19 was submitted to the Meeting as multiresidue enforcement method. This method was already shown to be valid for the

[14] ALINORM 10/33/24

determination of cypermethrin in various plant matrices. The method is now shown to be valid for the determination of zeta-cypermethrin in plant material with high water content and/or high acid content (LOQ = 0.01 mg/kg).

In addition, seven GC-ECD analytical methods were received for use in the supervised residue trials, processing studies and storage stability studies for the determination of cypermethrin or zeta-cypermethrin in plant material (LOQ varied between 0.01, 0.025 and 0.05 mg/kg). The Meeting noted that for two of the methods recoveries were acceptable, but there were only a limited number of samples (1–2 per concentration level).

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of cypermethrin in plant commodities stored frozen. The 2008 Meeting considered storage stability studies of cypermethrin and zeta-cypermethrin mutually supportive.

In additional studies provided for the present Meeting, cypermethrin was shown to be stable when stored at -18 °C for at least 18 months in crops with high water content (apple, lettuce and tomatoes) and high oil content (soya beans). Storage at +25 and +4 °C showed no degradation of cypermethrin residues in tea samples (dried tea leaves as traded) for a period of at least 4 months. Since the cypermethrins do not dissociate in water, storage stability on crops with high water content can be extrapolated to crops with high acid content.

Samples from supervised residue trials on citrus fruits, asparagus and tea were either analysed directly after harvest or were analysed within the storage stability periods indicated above.

Results of supervised trials on crops

The Meeting received supervised trials data for zeta-cypermethrin on oranges, lemons, grapefruit, almonds and pecans, and for cypermethrin on pomelo, asparagus and tea.

In 2008 trials were available for alpha-cypermethrin on citrus fruits, almonds and tea but no suitable GAP was available to evaluate them. Since no suitable GAP is available in 2011, these trials cannot be used here and they will not be mentioned in the text below.

The recommendations proposed by the Meeting were verified using the OECD MRL calculator. For all trials the outcome of the OECD MRL calculator agreed with the recommendation made by the Meeting.

Citrus fruits

Field trials for zeta-cypermethrin or cypermethrin treatment on shaddocks and pomelos were conducted in the Thailand (pomelo) and the USA (grapefruit).

Critical GAP for cypermethrin on pomelos in Thailand is for four foliar spray applications at 12 g ai/hl at a 7-day interval and PHI 14 days. In trials from Thailand (4 × 9.4 g hL, PHI 14 days) matching this GAP cypermethrin (sum of isomers) residues in pomelo whole fruit were 0.11, 0.11, 0.14, 0.16, 0.18 and 0.25 mg/kg (n = 6).

Critical GAP for zeta-cypermethrin on citrus fruits in the USA is for an unspecified number of ground or aerial applications to foliage at 56 g ai/ha (max 224 g ai/ha per season) with an interval of at least 14 days and PHI 1 day. In trials from the USA (4 × 56 g ai/ha, PHI 1 day, interval 14 days) matching this GAP cypermethrin (sum of isomers) residues in grapefruit whole fruit were 0.05, 0.06, 0.12, 0.12, 0.16 and 0.20 mg/kg (n = 6). In two of the trials residues were also measured in the pulp and showed that cypermethrin (sum of isomers) residues were < 0.05 (2) mg/kg.

Since the GAPs for Thailand and the USA are different, the data on grapefruit and pomelo cannot be combined. Since the highest residue is found in the Thai dataset, the Meeting agreed to use the Thai dataset for pomelo. The Meeting estimated a maximum residue level of 0.5 mg/kg for shaddocks and pomelos and an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg based on the residues in the pulp from trials in the USA.

Field trials with zeta-cypermethrin treatment on oranges were conducted in the USA and Italy.

Critical GAP for zeta-cypermethrin on citrus fruits in the USA is for an unspecified number of ground or aerial applications to foliage at 56 g ai/ha (maximum of 224 g ai/ha per season) with an interval of at least 14 days and PHI 1 day. In trials from the USA (4 × 56 g ai/ha, PHI 1 day, interval 14 days) matching this GAP cypermethrin (sum of isomers) residues in orange whole fruit were < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, 0.13, 0.14, 0.14, 0.14, 0.14, 0.15 and 0.16 mg/kg (n = 12). Where residues were higher at longer PHIs these were selected instead. In four of the trials residues were also measured in the pulp and showed that cypermethrin (sum of isomers) residues were < 0.05 (4) mg/kg.

No GAP matched the field trial conducted in Italy.

Field trials with zeta-cypermethrin treatment on lemons were conducted in the USA and Italy.

Critical GAP for zeta-cypermethrin on citrus fruits in the USA is for an unspecified number of ground or aerial applications to foliage at 56 g ai/ha (maximum 224 g ai/ha per season) with an interval of at least 14 days and PHI 1 day. In trials from the USA (4 × 56 g ai/ha, PHI 1 day, interval 14 days) matching this GAP cypermethrin (sum or isomers) residues in lemon whole fruit were 0.06, 0.07, 0.08, 0.08 and 0.08 mg/kg (n = 5). In two of the trials residues were also measured in the pulp and showed that cypermethrin (sum of isomers) residues were < 0.05 (2) mg/kg.

No GAP matched the field trial conducted in Italy.

The Meeting noted that the datasets for oranges and lemons matching USA GAP for citrus fruit were from similar populations (Mann-Whitney U test). Since residue behaviour within the citrus fruit group is expected to be similar, the Meeting agreed that the datasets for oranges and lemons could be combined to estimate a maximum residue level for citrus fruits, except shaddocks and pomelos. Cypermethrin residues in oranges and lemons (whole fruit) were: < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, 0.06, 0.07, 0.08, 0.08, 0.08, 0.13, 0.14, 0.14, 0.14, 0.14, 0.15 and 0.16 mg/kg (n = 17).

Based on the dataset matching the GAP of the USA, the Meeting estimated a maximum residue level of 0.3 mg/kg for citrus fruits, except shaddocks and pomelos. The Meeting estimated an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg based on residues in the pulp from trials in the USA.

Stem vegetables

The JMPR 2008 Meeting estimated an STMR value and an HR value of 0.01 and 0.01 mg/kg, respectively, for cypermethrin residues in asparagus. The estimated maximum residue level was 0.01* mg/kg for asparagus. These estimations were based on seven alpha-cypermethrin trials on asparagus in France with conditions in line with German GAP for asparagus (0.0125 kg ai/ha) and no specified PHI). In addition, Thailand provided data in 2008 on two asparagus trials with cypermethrin treatments. However, these trials were considered insufficient for estimating a maximum residue level.

Additional field trials for cypermethrin treatments to asparagus were conducted in Thailand with the same GAP as the trials provided to the 2008 JMPR Meeting.

Critical GAP for asparagus in Thailand is for an unspecified number of foliar spray applications at 25 g ai/hL and a PHI of 3 days. In trials from Thailand (2–3 × 25 g ai/hL, PHI 3 days) matching this GAP from both the 2008 and the 2011 datasets cypermethrin (sum of isomers) residues in green asparagus were: 0.01, 0.03, 0.06, 0.09, 0.09, 0.18 and 0.20 mg/kg (n = 7).

Since the GAP from Thailand resulted in higher residues than the GAP of Germany, the Meeting decided to withdraw the previous maximum residue level recommendation. Based on the dataset matching the Thai GAP, the Meeting estimated a maximum residue level of 0.4 mg/kg for asparagus to replace the previous recommendation of 0.01* mg/kg. The Meeting estimated an STMR of 0.09 mg/kg and an HR of 0.20 mg/kg.

Tree nuts

Field trials for zeta-cypermethrin treatment on almonds were conducted in the USA.

Critical GAP for zeta-cypermethrin on tree nuts in the USA is for an unspecified number of ground or aerial foliar applications at 56 g ai/ha (maximum of 280 g ai/ha per season) with a treatment interval of 7 days and a PHI of 7 days. In trials from the USA (5 × 56 g ai/ha, PHI 7 days, interval 7 days) matching this GAP cypermethrin (sum of isomers) residues in almond nutmeat were: < 0.05, < 0.05, < 0.05, < 0.05 and < 0.05 mg/kg (n = 5).

Field trials for zeta-cypermethrin treatment on pecans were conducted in the USA.

Critical GAP for zeta-cypermethrin on tree nuts in the USA is for an unspecified number of ground or aerial foliar applications at 56 g ai/ha (maximum of 280 g ai/ha per season) with an interval of 7 days and a PHI of 7 days. In trials from the USA (5 × 56 g ai/ha, PHI 7 days, interval 7 days) matching this GAP cypermethrin (sum of isomers) residues in pecan nutmeat were: < 0.05, < 0.05, < 0.05, < 0.05 and < 0.05 mg/kg (n = 5).

The Meeting agreed that the USA data sets for almonds and pecans are similar and could be combined to estimate a maximum residue level for tree nuts. The combined dataset resulted in the following residues: < 0.05 (10) mg/kg.

Based on the dataset for almonds and pecans. matching USA GAP, the Meeting estimated a maximum residue level of 0.05* mg/kg for tree nuts and an STMR value of 0.05 mg/kg and an HR value of 0.05 mg/kg for tree nuts.

Miscellaneous fodder and forage crops

Field trials for zeta-cypermethrin treatment on almond hulls were conducted in the USA.

Critical GAP for zeta-cypermethrin on tree nuts in the USA is for an unspecified number of ground or aerial foliar applications at 56 g ai/ha (maximum of 280 g ai/ha per season) with an interval of 7 days and PHI 7 days. In trials from the USA (5 × 56 g ai/ha, PHI 7 days, interval 7 days) matching this GAP cypermethrin (sum of isomers) residues in almond hulls were: 0.90, 0.95, 2.3, 2.4 and 2.7 mg/kg, as received (n = 5).

Based on these data, the Meeting estimated a median value of 2.3 mg/kg.

Teas

Field trials for cypermethrin treatment on tea were conducted in China and India. Directly after picking the fresh tea leaves, the tea was processed into dried tea leaves as traded. Residues listed here are for the processed tea.

Critical GAP for cypermethrin on tea in China is for one spray application at 45 g ai/ha and a PHI of 7 days. In trials from China (45 g ai/ha, PHI 7 days) matching this GAP cypermethrin (sum of isomers) residues in green processed tea were: 1.6, 3.9, 4.9 and 5.6 mg/kg (n = 4). In trials from China matching this GAP, cypermethrin (sum of isomers) residues in black processed tea were 1.6 and 3.6 mg/kg (n = 2). The Meeting agreed that the data sets for green and black processed tea are similar and could be combined to form the following dataset for green and black processed tea: 1.6, 1.6, 3.6, 3.9, 4.9 and 5.6 mg/kg (n = 6).

Critical GAP for cypermethrin on tea in India is for one foliar spray application at 63 g ai/ha and a PHI of 7 days. In trials from India (63 g ai/ha, PHI 7 days) matching this GAP cypermethrin residues in black processed tea were 1.1 and 2.0 mg/kg (n = 2).

Since the highest residue is found in the Chinese dataset, the Meeting decided to use the tea data corresponding to the GAP of China. Residues for green and black processed tea were: 1.6, 1.6, 3.6, 3.9, 4.9 and 5.6 mg/kg (n = 6).

Based on the dataset for green and black processed tea matching Chinese GAP, the Meeting estimated a maximum residue level of 15 mg/kg for tea, green, black (black, fermented and dried) and an STMR value of 3.75 mg/kg.

Fate of residues in storage

The effect of storage on cypermethrin residues in processed tea (dried tea leaves as traded) at +4 °C and +25 °C on cypermethrin residues was investigated by determination of degradation rates. After 4 months of storage the degradation rates were 3.3–5.6% for storage at +25 °C and 2.1–3.5% for storage at +4 °C.

The Meeting, therefore, concluded that storage for 4 months at room temperature or under cold storage did not influence the fate of cypermethrin residues in processed tea.

Fate of residues during processing

In the 2008 Report of the JMPR it was shown that alpha-cypermethrin and cypermethrin residues were stable during hydrolysis conditions simulating pasteurization, baking, brewing and boiling. The 2008 JMPR Meeting calculated processing factors for a number of food processes. Additional processing studies with (zeta-) cypermethrin were submitted for oranges and tea in the 2011 Meeting.

Cypermethrin (sum of isomers) residue levels in dried orange pomace (0.22 and 0.32 mg/kg) and orange oil (0.50 and 0.63 mg/kg) were higher than in the corresponding RAC (< 0.05 mg/kg). Processing factors could not be derived for the processing of oranges in orange juice, orange oil or dried pulp (pomace) as cypermethrin (sum of isomers) residues in the RAC were below the LOQ (< 0.05 mg/kg).

For the processing of tea (dried tea leaves as traded) into tea infusion, processing factors could be derived. In the table below relevant processing factors for tea infusion are summarized. The STMR-P is calculated as $STMR_{RAC}$ × processing factor.

Commodity	Processed fraction	Processing factors (n = 4)	Best estimate
Tea (black)	Tea infusion (3 g/450 mL, 20 min)	0.0083, 0.0085, 0.0088, 0.011	0.0099
Tea (green)	Tea infusion (3 g/450 mL, 20 min)	0.0086, 0.010, 0.011, 0.013	
Tea (black)	Tea infusion (3 g/150 mL, 5 min)	< 0.089, < 0.13	

Livestock dietary burden

For estimating the livestock dietary burden, relevant trials were received by the present Meeting involving almond hulls. These feed commodities are additional to the feed commodities already taken into account at the 2008 and 2009 JMPR Meetings. The present Meeting estimated the dietary burden of cypermethrin residues on the basis of the 2009 livestock diets as listed in the FAO manual appendix IX (OECD feedstuff table). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values from feed is suitable for estimating STMR values for animal commodities.

All plant commodities used in the dietary burden calculation are listed below. Dietary burden for livestock might be underestimated, since residue data are not available for several feedstuff derived from crops treated with cypermethrin.

Codex Group	CROP	FEED STUFF	Highest residue	STMR	DM (%)
AL	Alfalfa	forage	11	3.65	35
AL	Alfalfa	hay	20	11.5	100
AF/AS	Barley	forage	1.4	0.39	30
AF/AS	Barley	straw	6.9	3.6	100
AL	Bean	vines	2.1	0.71	35
AM/AV	Beet, sugar	tops	8.3	1.5	100
AM/AV	Cabbage	heads, leaves	0.65	0.02	15
AF/AS	Corn, field	forage/silage	0.1	0.05	40
AF/AS	Corn, field	stover	6.9	3.6	100
AF/AS	Corn, pop	stover	6.9	3.6	100
AF/AS	Corn, sweet	forage	0.1	0.05	48
AF/AS	Corn, sweet	stover	6.9	3.6	100
AL	Cow pea	forage	0.86	0.45	30
AL	Cow pea	hay	1.1	0.42	100
AM/AV	Kale	leaves	0.52	0.07	15
AF/AS	Millet	straw	6.9	3.6	100
AF/AS	Oat	straw	6.9	3.6	100
AL	Pea	vines	0.86	0.45	25
AL	Pea	hay	1.1	0.42	100
AM/AV	Rape	forage	0.24	0.05	30
AF/AS	Rice	straw	6.9	3.6	100
AF/AS	Rye	straw	6.9	3.6	100
AF/AS	Sorghum, grain	stover	6.9	3.6	100
AF/AS	Triticale	straw	6.9	3.6	100
AF/AS	Wheat	forage	1.4	0.38	25
AF/AS	Wheat	straw	6.9	3.6	100
VR	Carrot	culls	0.01	0.01	12
VR	Cassava/tapioca	roots	0.01	0.01	37
VR	Potato	culls	0.01	0.01	20
VR	Swede	roots	0.01	0.01	10
VR	Turnip	roots	0.01	0.01	15
GC	Barley	grain	–	1.38	88
VD	Bean	seed	–	0.05	88
GC	Corn, field	grain	–	0.035	88
GC	Corn, pop	grain	–	0.035	88
VD	Cowpea	seed	–	0.05	88
VD	Lupin	seed	–	0.05	88
GC	Millet	grain	–	0.035	88
GC	Oat	grain	–	1.38	89
VD	Pea	seed	–	0.05	90
GC	Rice	grain	–	0.57	88
GC	Rye	grain	–	1.38	88
GC	Sorghum, grain	grain	–	0.035	86
VD	Soya bean	seed	–	0.05	89
GC	Triticale	grain	–	0035	89
VD	Vetch	seed	–	0.05	89
GC	Wheat	grain	–	1.38	89
AM/AV	Almond	hulls	–	2.3	90
SO	Cotton	undelinted seed		0.05	88
AM/AV	Cotton	gin by-products	0.55	0.36	90
AB	Grape	pomace, wet	–	0.032	15
CM/CF	Wheat	milled by-products	–	3.45	88

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. A mean and maximum dietary burden for livestock, based on cypermethrin use, is shown in the table below.

Animal dietary burden for cypermethrin, expressed as ppm of dry matter diet

	US	EU	AU	JPN	Overall	
	max	max	max	max	max	
beef cattle	6.07	24.4	31.4	4.71	31.4 (AU)	a
dairy cattle	9.35	17.1	21.6	7.23	21.6 (AU)	b
poultry broiler	2.74	1.89	2.03	1.96	2.74 (US)	
poultry layer	2.74	3.10	2.03	1.20	3.10 (EU)	c,d
	mean	mean	mean	mean	mean	
beef cattle	4.30	8.48	11.3	3.86	11.3 (AU)	a
dairy cattle	4.66	6.86	8.47	5.11	8.47 (AU)	b
poultry broiler	2.74	1.89	2.03	0.91	2.74 (US)	
poultry layer	2.74	2.26	2.03	1.20	2.74 (US)	c,d

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

[b] Highest mean and maximum dairy cattle dietary burden suitable for maximum residue level and STMR estimates for milk.

[c] Highest mean and maximum poultry broiler or poultry layer dietary burden suitable for maximum residue level and STMR estimates for poultry meat.

[d] Highest mean and maximum poultry layer suitable for maximum residue level and STMR estimates for eggs.

Livestock feeding studies

Livestock feeding studies with alpha-cypermethrin, zeta-cypermethrin and cypermethrin for cattle and poultry have been submitted and evaluated by JMPR 2008.

Residues in animal commodities

Cattle

The estimated mean and maximum dietary burden for beef and dairy cattle remained the same compared with estimates from JMPR 2009, so there is no change in estimated maximum residue levels, STMRs and HRs for mammalian meat, fat, offal and milk.

Poultry

The estimated mean dietary burden for broiler and layer poultry (2.74 ppm) remained the same compared with estimates from JMPR 2009, so there is no change in estimated STMR values for poultry meat, fats, edible offal and eggs.

The estimated maximum dietary burden for broiler and laying poultry (3.10 ppm) was lower than estimated at JMPR 2009 (3.89 ppm). This lower value was due only to the 2009 change in livestock diets. For maximum residue level estimation, the high residues in eggs, muscle, liver and fat were calculated by interpolating the maximum dietary burden (3.10 ppm) between the relevant feeding levels (0, 1.6 and 7.2 ppm) from the alpha-cypermethrin laying hen feeding study and using the highest meat and egg concentrations from those feeding groups (see table below).

				Residues (mg/kg) in:		
	Feed level (ppm) for egg residues	Residues (ng/g) in eggs	Feed level (ppm) for tissue residues	Muscle	Liver	Fat
Maximum residue level - layer and broiler poultry						
Feeding study [a,b]	0 7.2	0 0.011	0 7.2	0 < 0.05	0 < 0.05	0 0.088

Dietary burden and residue estimate	3.10	0.0047	3.10	0.022	0.022	0.038

[a] highest residues for tissues and eggs

[b] residues were interpolated between 0 and 7.2 ppm feed, because the 1.6 ppm level resulted in residues below LOQ for all matrices.

The Meeting estimated an HR value of 0.022 mg/kg in muscle and liver and an HR of 0.038 mg/kg for fat.

The Meeting estimated a maximum residue level of 0.1 mg/kg for poultry meat (fat) and poultry fats and 0.05* mg/kg for edible offal of poultry. These recommendations take into account that cypermethrin is fat-soluble, and that higher residues could be expected in the fat of broilers in line with the decision taken in JMPR 2008.

The Meeting estimated an HR value of 0.0047 mg/kg for eggs and a maximum residue level of 0.01* mg/kg for eggs.

DIETARY RISK ASSESSMENT

Long-term intake

Based on the evaluation of cypermethrin, alpha-cypermethrin and zeta-cypermethrin, maximum residue levels, HRs and STMRs were estimated for raw and processed commodities in JMPR 2008, 2009 and at the present Meeting. When data on consumption were available for the listed food commodities, dietary intakes were calculated for the GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDI of in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 7–30% of the maximum ADI of 0.02 mg/kg bw. The Meeting concluded that the long-term intake of residues of cypermethrins from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for cypermethrin, alpha-cypermethrin and zeta-cypermethrin was calculated for the food commodities (and their processing factors) for which maximum residue levels, STMRs and HRs were estimated at the present Meeting. The results are shown in Annex 4.

The IESTI varied from 0–8% of the ARfD (0.04 mg/kg bw). The Meeting concluded that the short-term intake of residues of cypermethrins from uses considered by the Meeting is unlikely to present a public health concern.