in Germany matched GAP in Belgium, with levels of propineb residues of < 0.10 and 0.10 mg/kg, respectively. The levels of propylenethiourea residues were: < 0.01 mg/kg.

The Meeting considered that the number of trials on apples and pears was inadequate for the purpose of estimating maximum residue levels and agreed to withdraw its previous recommendation for propineb of 2 mg/kg as CS_2 for apples and pears.

Cherry

Six trials on cherry were conducted in Germany (GAP, 0.105 kg ai/hl, 28-day PHI) which approximated German GAP. Two trials were conducted at two locations, which differed only in the formulation used; one trial at each location was selected for estimating maximum residue levels. The residue levels in the six trials were < 0.05 (two), 0.05, 0.06, 0.13 and 0.15 mg/kg for CS_2 and < 0.01 (four) and 0.02 (two) mg/kg for propylenethiourea.

The residue levels of propineb (1.9 × CS_2) and propylenethiourea, combined as explained above (residue = propineb + 2.3 × propylenethiourea), used for estimating the STMR were < 0.12 (three), 0.14, 0.29 and 0.33 mg/kg. The highest reside level for dietary intake was estimated to be 0.35 mg/kg (residue = propineb + 3.3 × propylenethiourea). The Meeting estimated a maximum residue level for propineb in cherries of 0.2 mg/kg as CS_2, an STMR of 0.13 mg/kg as propineb and a highest reside level of 0.35 mg/kg as propineb.

Grape

Trials on wine grapes were conducted in France (GAP, 0.68 kg ai/ha, 21-day PHI) and Germany (GAP, 2.8 kg ai/ha, 0.14 kg ai/hl, 56-day PHI) after pre-blossom application. None of the trials approximated GAP in the respective countries. Trials were also conducted on table and wine grapes after pre- and post-blossom applications in France (GAP, 0.68 kg ai/ha, 21-day PHI), Greece (GAP, 0.14 kg ai/hl, 7-day PHI for table grapes, 21-day PHI for wine grapes), Italy (GAP, 0.14 kg ai/hl, 28-day PHI) and Spain (GAP, 0.28 kg ai/hl, 15-day PHI). None of the trials matched GAP. The Meeting agreed to withdraw the previous recommendations for propineb in grapes of 2 mg/kg as CS_2.

Olive

Trials on olives were conducted in Spain (GAP, 0.21 kg ai/hl, 15-day PHI), but none matched GAP.

Onion

Trials on onion were conducted in Australia (GAP, 1.4 kg ai/ha, 0.14 kg ai/hl, 14-day PHI) and Brazil (GAP 2.1 kg ai/ha, 7-day PHI), but the latter was available only in the form of a summary. The residue levels of propineb (measured as propylene diamine and not CS_2) in the Australian trials approximating GAP were < 0.2 and 1.2 mg/kg. The number of trials was considered by the Meeting to be inadequate for estimating a maximum residue level, and the Meeting agreed to withdraw its previous recommendation for propineb in onion, bulb, of 0.2 (*) mg/kg as CS_2.

Garlic

Trials on garlic were conducted in Brazil; however, the data were supplied only in summary form and were therefore not suitable for estimating a maximum residue level.

Lettuce

Trials on lettuce were conducted in Australia (GAP, 1.4 kg ai/ha, 0.14 kg ai/hl, 3-day PHI) and Brazil (no information on GAP). The latter was available only in the form of a summary. The residue levels of propineb (measured as propylene diamine and not CS_2) in the Australian trials approximating GAP were 0.3 and 2.5 mg/kg. The number of trials was considered by the Meeting to be inadequate for the purposes of estimating a maximum residue level.

Brassica vegetables

Trials on head cabbage were available from Brazil (no GAP) and on Chinese cabbage from Thailand (no GAP). As no relevant GAP was available and as the data were provided only in summary form, the Meeting was unable to estimate a maximum residue level for these vegetables.

Cucumber

Trials on cucumbers grown in greenhouses in Greece (GAP for vegetables, 0.18 kg ai/ha, 3-day PHI), Italy (no GAP) and Spain (GAP, 0.21 kg ai/ha, 3-day PHI) were made available to the Meeting. The trials in Italy and Spain did not match GAP for those countries and were assessed against the GAP of Greece. The levels of propineb residues (measured as CS_2) in three trials in Greece approximating GAP in Greece were 0.60, 0.90 and 1.1 mg/kg (propylenethiourea, 0.01, < 0.01 and 0.02 mg/kg). The levels of propineb residues in one trial in Italy and three in Spain matching GAP ± 25% in Greece were 0.20, 0.20, 0.43 and 0.47 mg/kg (propylenethiourea, < 0.01 (four) mg/kg). Conversion of the residue levels expressed in terms of propineb to CS_2 gives values of 0.10 (two), 0.22, 0.24, 0.31, 0.47 and 0.57 mg/kg. The Meeting estimated a maximum residue level for propineb in cucumbers of 1 mg/kg as CS_2.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea for estimating the STMR were: 0.22 (two), 0.45, 0.49, 0.62, 0.92 and 1.1 mg/kg. The highest reside level was estimated to be 1.1 mg/kg. For estimation of dietary intake, the Meeting estimated STMR and highest reside levels for propineb in cucumbers of 0.49 and 1.1 mg/kg, respectively.

Melon (except watermelon)

Trials on melons (except watermelon) were reported from Greece (GAP for vegetables, 0.18 kg ai/ha, 3-day PHI) and Spain (GAP, 0.21 kg ai/hl, 15-day PHI; GAP for cucurbits, 0.21 kg ai/hl, 3-day PHI). The levels of propineb residues (measured as propylene diamine) in two trials in Spain matching Spanish GAP ± 25% were 0.52 and 1.5 mg/kg (propylenethiourea, 0.05 and 0.06 mg/kg). One field trial in Greece, in which 0.43 mg/kg were found (propylenethiourea, < 0.01 mg/kg) also matched GAP in that country. Data were not available for propineb measured as CS_2 in any of the trials at the relevant PHI. The Meeting considered three trials inadequate for the purposes of estimating a maximum residue level for melon (except watermelon) and agreed to withdraw its previous recommendation of 0.1 (*) mg/kg as CS_2.

Watermelon

Trials on watermelon were reported from Greece (GAP for vegetables, 0.18 kg ai/hl, 3-day PHI) and Italy (no GAP). The levels of propineb residues in two trials in Greece matching Greek GAP ± 25% were 0.17 and 0.31 mg/kg (propylenethiourea, < 0.01 and 0.02 mg/kg). Two field trials in Italy approximating GAP in Greece showed residue levels of 0.17 and 0.29 mg/kg (propylenethiourea, 0.01 and 0.02 mg/kg). Data were not available for propineb determined as CS_2 at the relevant PHI in any of the trials. The Meeting considered the number of trials inadequate for the purposes of estimating a maximum residue level for watermelon.

Tomato

Trials on field tomatoes were reported from France (GAP, 0.21 kg ai/hl, 7-day PHI), Germany (GAP, 0.84 kg ai/ha at crop height < 0.5 m; 1.26 kg ai/ha at crop height 0.5–1.25 m; 1.68 kg ai/ha at crop height > 1.25 m; 7-day PHI) and Spain (GAP, 0.21 kg ai/hl, 3-day PHI). The CS_2 residue levels in four trials in Germany matching GAP were 0.11, 0.14, 0.40 and 0.55 mg/kg, equivalent to 0.21, 0.27, 0.76 and 1.0 mg/kg as propineb (propylenethiourea, < 0.02 (three) and 0.02 mg/kg).

Four trials were available from France and four from Spain which were conducted according to GAP in the respective countries. As GAP in France and Spain differs only with respect to the PHI, the Meeting decided to evaluate the French and Spanish trials against the GAP of Spain to obtain a representative data set. The residue levels of propineb in these trials were 0.14, 0.22, 0.26, 0.35, 0.49, 0.94, 1.0 and 1.1 mg/kg (propylenethiourea, < 0.01, 0.02 (two), 0.04, 0.05 (two) and 0.06 (two) mg/kg).

Additional trials on tomatoes grown under protected cover (greenhouse) were reported from France, Germany and Spain and evaluated against the GAP of Spain, which is the same for tomatoes grown in the field and protected under cover. The residue levels of CS_2 reported in terms of propineb ≥ 3 days after the last application were 0.82, 1.1, 1.3, 1.5, 2.3 and 2.4 mg/kg. The levels of propylenethiourea residues were 0.04, 0.05, 0.06, 0.08, 0.09 and 0.16 mg/kg.

The Meeting considered that the residue levels in field trials conducted in Germany according to German GAP and the trials under cover and in the field conducted according to GAP in Spain represent similar residue populations and could be combined for the purposes of estimating a maximum residue level. The residue levels expressed in terms of CS_2, were: 0.07, 0.11 (two), 0.14 (two), 0.18, 0.25, 0.40, 0.42, 0.49, 0.52, 0.54, 0.57 (two), 0.68, 0.78 and 1.2 (two) mg/kg.

The Meeting estimated a maximum residue level for propineb in tomatoes of 2 mg/kg as CS_2 to replace the previous recommendation for tomatoes of 1 mg/kg as CS_2.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea in the 18 trials used for estimating the STMR were: 0.16, 0.26, 0.27, 0.31 (two), 0.44, 0.61, 0.81, 0.89, 1.1 (three), 1.2 (two), 1.3, 1.7, 2.5 and 2.8 mg/kg. The Meeting estimated the STMR for propineb in tomatoes at 1.0 mg/kg and the highest reside level at 2.9 mg/kg.

Peppers (sweet)

Trials on field-grown peppers in France (no GAP) and Spain (GAP, 0.21 kg ai/hl, 3-day PHI) were made available to the Meeting. The French trials were evaluated against GAP of Spain. In two trials in France matching GAP in Spain, the residue levels of propineb were 0.22 and 0.83 mg/kg (propylenethiourea, 0.02 and 0.07 mg/kg). Four trials in Spain that matched GAP for peppers showed propineb residue levels of 0.60, 1.4 (two) and 1.7 mg/kg (propylenethiourea, 0.09, 0.12, 0.17 and 0.18 mg/kg). The levels of propineb residues in field-grown peppers were thus: 0.22, 0.60, 0.83, 1.4 (two) and 1.7 mg/kg. The corresponding levels of propylenethiourea residues were: 0.02, 0.07, 0.09, 0.12, 0.17 and 0.18 mg/kg.

Trials on peppers grown in greenhouses in France (no GAP), Germany (no GAP) and Spain (GAP, 0.21 kg ai/hl, 3-day PHI) were made available to the Meeting. The trials in France and Germany were evaluated against GAP in Spain. Residues of propineb in sweet peppers grown indoors were 1.3, 2.1 and 11 mg/kg (propylenethiourea, 0.05, 0.23 and 0.71 mg/kg) in three trials in Spain; and 0.75, 1.4, 1.5 and 1.7 mg/kg (propylenethiourea, 0.06, 0.07, 0.10 and 0.11 mg/kg) in four trials in France. Thus, the levels of propineb in sweet peppers grown in greenhouses were: 0.75, 1.3, 1.4, 1.5, 1.7, 2.1 and 11 mg/kg (propylenethiourea: 0.05, 0.06, 0.07, 0.10, 0.11, 0.23 and 0.71 mg/kg). Conversion of the levels of CS_2 residues reported in terms of propineb back to CS_2 gave levels of 0.11, 0.31, 0.39, 0.43, 0.68, 0.73 (three), 0.78, 0.88 (two), 1.1 and 5.7 mg/kg. The Meeting estimated a maximum residue level for propineb in peppers, sweet, of 7 mg/kg as CS_2.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea in the 13 trials used for estimating the STMR were: 0.27, 0.89, 0.99, 1.0, 1.4, 1.6 (two), 1.7 (two), 2.0, 2.1, 2.6 and 13 mg/kg as propineb. The STMR was 1.6 mg/kg and the highest reside level was estimated to be 13 mg/kg.

Potato

Field trials on potatoes were made available to the Meeting from France (GAP, 0.21 kg ai/hl, PHI not specified), Germany (GAP, 1.3 kg ai/ha, 7-day PHI), Spain (GAP, 0.21 kg ai/hl, 15-day PHI) and the United Kingdom (no GAP). The trials in Germany and the United Kingdom did not comply with the relevant GAP. The trials in France were evaluated against GAP in Spain.

In three trials in France approximating Spanish GAP, the levels of propineb residues on potatoes were < 0.10 (two) and 0.14 mg/kg (propylenethiourea, < 0.01 (three) mg/kg). Three trials in Spain approximating GAP in that country showed propineb residue levels of < 0.10 (three) mg/kg (propylenethiourea, < 0.01 (three) mg/kg). Conversion of the residue levels determined as CS_2 but reported in terms of propineb to CS_2 gave levels of < 0.05 (five) and 0.073 mg/kg. The Meeting estimated a maximum

residue level for propineb in potatoes of 0.1 mg/kg as CS_2, which replaces the previous recommendation of 0.1 (*) mg/kg.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea in six trials used for estimating the STMR were: 0.12 (five) and 0.16 mg/kg. The Meeting estimated an STMR for propineb in potatoes of < 0.12 mg/kg and a highest reside level of 0.16 mg/kg.

Celery

Two trials on celery were reported from Australia (GAP, 1.4 kg ai/ha, 0.14 kg ai/hl, 7-day PHI), which showed propineb residue levels of < 0.2 and 0.4 mg/kg (propylenethiourea not analysed). The Meeting considered the number of trials inadequate for the purpose of estimating a maximum residue level for celery.

Asparagus

In a single trial on asparagus in Peru (GAP, 2.1 kg ai/ha, 0.21 kg ai/hl, 30-day PHI) that matched GAP in that country, the residue levels of propineb were < 0.01 mg/kg (propylenethiourea not measured).

The Meeting considered the number of trials inadequate for the purpose of estimating a maximum residue level for asparagus.

Fate of residues during processing

The Meeting received the results of studies on incurred residues of propineb and propylenethiourea in apples, pears, cherries, tomatoes, grapes and olives after washing and further processing in a range of fractions. Only the studies relevant to commodities for which maximum residue levels have been estimated are reported below.

It would not usually be appropriate to derive processing factors for propylenethiourea, as these would reflect both the effect of processing and also the formation of propylenethiourea from propineb, especially after boiling steps. In the present case, the use of processing factors would result in overestimates of the residue levels of propylenethiourea in processed commodities, and the Meeting decided to continue to use this approach. Nevertheless, if concern about dietary intake were identified, the Meeting would consider refining the approach to estimate propylenethiourea residues in processed commodities.

In trials in Germany, cherries were processed according to simulated household and commercial practices into washed fruit, juice, jam and preserves. The processing factors for juice and jam prepared by household procedures in two trials each were 0.5–0.6 (mean, 0.55) for juice and 0.3–0.4 (mean, 0.35) for jam. Propylenethiourea residues did not concentrate in juice or jam, with mean processing factors of < 0.68 for juice and < 0.78 for jam. After simulated commercial preparation, the mean processing factors for propineb in three trials each were 0.63 (range, 0.6–0.7) for washed fruit and 0.15 (range, 0.13–0.16) for preserves. The corresponding mean values for propylenethiourea were 1 for washed fruit and < 0.5 for preserves.

The Meeting considered that it would be appropriate to use the mean processing factors from the various studies, to reflect different commercial practices. For cherries, it estimated processing factors for propineb of 0.63 in washed fruit, 0.55 in juice, 0.15 in preserves and 0.35 in jam. The processing factors for propylenethiourea were 1 in washed fruit, < 0.68 in juice, < 0.5 in preserves and < 0.78 in jam.

Processing studies for tomatoes with respect to washed fruit, juice, ketchup, paste and preserves were reported. For washed fruit, the mean processing factors in four studies were 0.45 (range, 0.3–0.6) for propineb and 0.4 (range, 0.3–0.5) for propylenethiourea. In the case of juice, the mean processing factor for propineb in 10 studies was < 0.12 (range, < 0.06–0.2), while that for propylenethiourea in nine studies was 0.91 (range, 0.3–2.3). The levels of residues of propineb were significantly reduced during the preparation of preserves and ketchup, with mean processing factors of 0.15 in four studies on preserves (range, 0.1–0.2) and < 0.12 in six studies on ketchup (range, < 0.06–< 0.25). Residues were concentrated during preparation of paste, with a mean processing factor in four studies of 1.1 (range, 0.4–2.0). The mean processing factors for

propylenethiourea were 0.75 (n = 4; range, 0.5–1) for preserves, 0.54 (n = 5; range, 0.3–0.7) for ketchup and 11 (n = 4; range, 6.8–17) for paste.

The Meeting considered that it would be appropriate to use the mean processing factors from the various studies to reflect different commercial practices. For tomato, it estimated processing factors for propineb of 0.45 in washed fruit, < 0.12 in juice, 0.15 in preserves, < 0.12 in ketchup and 1.1 in paste. For propylenethiourea, processing factors of 0.4 in washed fruit, 0.91 in tomato juice, 0.75 in preserves, 0.54 in ketchup and 11 in paste were established.

Commodity	Processing factor$_{propineb}$	Propineb residues (mg/kg)		Processing factor$_{propylenethiourea}$	Propylenethiourea residues (mg/kg)		Adjusted values (mg/kg)	
		For STMR/ STMR-P	For HR/ HR-P		For STMR/ STMR-P	For HR/ HR-P	STMR[1]	HR[2]
Cherry		0.128	0.351		0.01	0.02		
Washed	0.63	0.0803	0.221	1	0.01	0.02	0.103	0.287
Juice	0.55	0.0701		0.68	0.0068		0.0858	
Preserves	0.15	0.0191		0.5	0.005		0.0306	
Jam	0.35	0.0446		0.78	0.0078		0.0626	
Tomato		1.0	2.93		0.03	0.16		
Washed	0.45	0.45	1.32	0.4	0.012	0.064	0.478	1.53
Juice	0.12	0.12		0.91	0.0273		0.183	
Preserves	0.15	0.15		0.75	0.0225		0.202	
Ketchup	0.12	0.12		0.54	0.0162		0.157	
Paste	1.1	1.1		11	0.33		1.86	

[1] Adjusted STMR-P = STMR-P$_{propineb}$ + 2.3 × STMR-P$_{propylenethiourea}$
[2] adjusted HR-P = HR-P$_{propineb}$ + 3.3 × HR-P$_{propylenethiourea}$

Residues in animals commodities

Dietary burden of farm animals

The Meeting estimated the dietary burden of propineb residues of farm animals on the basis of the diets described in Appendix IX of the *FAO Manual*. As no relevant items were identified, the dietary burdens for estimating MRLs and STMRs for animal commodities (residue levels in animal feeds expressed in dry weight) are zero for all the relevant animal diets.

Maximum residue levels

The Meeting estimated maximum residue levels of 0.05 (*) mg/kg for meat (from mammals other than marine mammals), 0.05 (*) mg/kg for edible offal (mammalian) and 0.01 (*) mg/kg for milks.

The Meeting estimated maximum residue levels of 0.05 (*) mg/kg for poultry meat, 0.05 (*) for poultry offal and 0.01 (*) mg/kg for eggs. The STMRs for animal commodities are zero.

DIETARY RISK ASSESSMENT

The Meeting considered how best to approach the dietary risk assessment of mixed residues of propineb and propylenethiourea and decided that an appropriately conservative approach would be to calculate the sum of the residues after scaling the propylenethiourea residues to account for the difference in toxicity. The relevant factors for long-term and short-term intake were derived from the ratios of the ADI and ARfD values for propineb and propylenethiourea, which are 2.3 and 3.3, respectively. Dietary intake

estimates for the residues, adjusted for potency and combined, were compared with the ADI and interim ARfD for propineb (See general item 2.2, Interim acute reference dose).

Long-term intake

The evaluation of propineb resulted in recommendations for MRLs and STMRs for raw and processed commodities. Data were available on the consumption of 15 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3.

The IEDIs in the five GEMS/Food regional diets, based on estimated STMRs, were 4–30% of the ADI of 0–0.007 mg/kg bw for propineb (Annex 3). The Meeting concluded that the long-term intake of residues of propineb and propylenethiourea from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The IESTI for propineb was calculated for the food commodities (and their processing fractions) for which maximum and highest reside levels had been estimated and for which data on consumption were available. The results are shown in Annex 4.

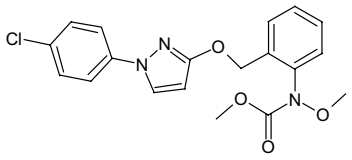
The IESTI was 0–110 % of the interim ARfD (0.1 mg/kg bw) for the general population and 0–120% of the interim ARfD for children ≤ 6 years. The values 110% and 120% represent the estimated short-term intake of sweet peppers by the general population and children, respectively.

The Meeting concluded that the short-term intake of residues of propineb from uses other than on sweet peppers that have been considered by the JMPR is unlikely to present a public health concern.

4.26 PYRACLOSTROBIN (210)

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of pyraclostrobin were considered for the first time by the present Meeting.



Pyraclostrobin, chemical name (IUPAC) methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]-oxymethyl}phenyl)-*N*-methoxycarbamate, is a new fungicidal active ingredient. It represents a modification of the structural pattern of natural fungicides called strobilurins.

The Meeting received information on the metabolism and environmental fate of pyraclostrobin, methods of residue analysis, freezer storage stability, national registered use patterns, the results of supervised residue trials, farm animal feeding studies, fate of residues in processing and national MRLs.

Metabolism

Animals

The Meeting received the results of metabolism studies in rats, lactating goats and laying hens. The metabolism and distribution of pyraclostrobin in plants and livestock was investigated with [chlorophenyl-^{14}C]pyraclostrobin and [tolyl-^{14}C]pyraclostrobin

The main metabolite are methyl-*N*-(2{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) carbamate (500M07) and 1-(4-chlorophenyl)-1*H*-pyrazol-3-yl hydrogen sulfate.

Metabolism in laboratory rats was evaluated by the WHO panel of the 2003 JMPR, which concluded that the metabolism proceeds through three main pathways. The methoxy group on the tolyl-methoxycarbamate moiety is readily lost, with few main metabolites retaining this group. Hydroxylation of the benzene or pyrazole ring is followed by conjugation with glucuronide. Many metabolites are derived from the chlorophenol pyrrazole or tolyl-methoxycarbamate moieties of pyraclostrobine. The metabolites were similar in both sexes and at all doses. No unchanged parent compound was found in bile or urine, and only small amounts were found in faeces.

Studies of the metabolism of pyraclostrobin in *goats* showed that residues in products of animal origin derive from the parent compound as well as from its *N*-desmethoxylation product. The metabolism and distribution of pyraclostrobin were investigated in lactating goats given material labelled in the chlorophenyl or in the tolyl ring. After five consecutive daily oral administrations of ^{14}C-pyraclostrobin at a nominal dosage of 12 or 50 mg/kg of feed, there was rapid absorption from the gastrointestinal tract. Radioactivity was excreted mainly via the faeces. The radiolabel in milk accounted for only 0.1–0.5% of the total applied radioactivity. There was no indication of accumulation of ^{14}C-pyraclostrobin in tissues. The parent compound was found in fat, muscle and, at lower amounts, in liver. Metabolites are formed in liver and kidney by hydroxylation of the chlorophenyl and tolyl rings and by cleavage of the molecule. Little extraction was seen in liver.

^{14}C-Pyraclostrobin is thus metabolized in goats by three key steps: (1) desmethoxylation at the oxime ether bond, (2) hydroxylation of the chlorophenyl, the pyrazole or the tolyl ring system and (3) cleavage of the two ring systems with subsequent oxidation of the two resulting molecules.

Pyraclostrobin was present in all tissues and in milk and was the main residue component in muscle and in fat (log P_{ow} = 3.99).

Tissues and eggs from *hens* that received an exaggerated dose of 12 mg/kg feed of [chlorophenyl-^{14}C]pyraclostrobin or 13 mg/kg [tolyl-^{14}C]pyraclostrobin contained low residue levels consisting of three main metabolites. The parent compound was found in fat and eggs but not in liver. The main metabolite in liver was the glucuronic acid conjugate, which was bound to the tolyl ring of the demethoxylated parent structure. The desmethoxy metabolite 500M07 was also present in fat and eggs,

Five routes of biotransformation were detected. The predominant transformation was the demethoxylation step. Second, the demethoxylated metabolite was oxygenated at the tolyl ring, followed by conjugation with glucuronic acid. Third, the demethoxylated metabolite was hydroxylated at the chlorophenyl or the pyrazole ring, again followed by a conjugation reaction with glucuronic acid. Fourth, the parent compound was hydroxylated at the chlorophenyl ring in the *para* position, whereby the C-l was shifted to the *meta* position (NIH shift). Fifth, the parent compound was cleaved at the methylene ether bridge. A specific variation was substitution of C-l by glucuronic acid.

The main metabolite in fat and eggs was 500M07, and that in liver was the glucuronic acid conjugate. The metabolism in rats, goats and hens were comparable.

Plants

The Meeting received the results of studies of the metabolism of pyraclostrobin in grapes, potatoes and wheat.

The metabolism of pyraclostrobin in *grapes* was investigated with material labelled in the tolyl or the chlorophenyl ring. Applications were made six times at a rate of 0.25 kg ai/ha, and the grapes were harvested

40 days after the last application. The relevant residue in grapes consists of the parent compound and its desmethoxy metabolite 500M07. Some other compounds were identified as products formed by cleavage of the molecule. *O*-Glucosylation and methoxylation were of minor importance, representing much less than 10% of the TRR.

Studies of metabolism in *potato* were conducted with material labelled in the tolyl or the chlorophenyl ring. Six post-emergence applications were made at the intended use rate of 300 g/ha. The relevant residue in potato green matter and tuber consisted of the parent compound (65% and 2.5% of the TRR, respectively) and its desmethoxy metabolite 500M07 (6.2% and 0.6% of the TRR, respectively) at growth stage 70.

Some other compounds were identified as products formed by cleavage of the molecule. *O*-Glucosylation and methoxylation were of minor importance, representing far less than 10% of the TRR. The total residue levels in the edible portion (potato tubers) were low. One derivative found in larger amounts in tubers was identified as the naturally occurring amino acid L-tryptophan. This compound represented 10% of the TRR in tuber at growth stage 70, but its contribution increased to 29.2% of the TRR at growth stage 85–89. It should not therefore be regarded as a relevant residue that must be covered by the analytical method.

Wheat received two application at 0.3 kg ai/ha, and samples were collected 0, 31 and 41 days after the last treatment. The relevant residue of ^{14}C-pyraclostrobin in wheat consists of unchanged parent compound and its desmethoxy metabolite 500M07. Tryptophan, which is formed in considerable amounts from pyraclostrobin in grain, is a natural ingredient and is therefore of no toxicological concern. All the other metabolites identified represented < 10% TRR and are thus of minor importance. The low levels of unextractable residues in forage and straw indicate that pyraclostrobin and its metabolites are not firmly associated with cell wall polymers. Somewhat larger amounts of unextractable were found in grain, as some of the radioactivity was incorporated into or associated with grain protein and starch.

The metabolic pathways in grapes, potatoes and wheat were qualitatively similar. Pyraclostrobin and its desmethoxy metabolite 500M07 constituted the main part of the residue. In addition, hydroxylation in the tolyl and the chlorophenyl rings and cleavage reactions between the two ring systems were observed. The hydroxylation reaction is followed by glucosylation or methylation, whereas the intermediates of the cleavage reaction are further transformed by conjugation or the shikimate pathway. Transformation via the shikimate pathway resulted in the formation of the natural amino acid L-tryptophan in potato tubers and wheat grain.

Environmental fate

Soil

The Meeting received the results of studies on the fate and behaviour in soil of [tolyl-U-^{14}C]pyraclostrobin and [chlorophenyl-U-^{14}C]pyraclostrobin.

Pyraclostrobin was investigated for aerobic metabolism in a number of soils. The degradation of pyraclostrobin in aerobic soil studies is characterized by a relatively low mineralization rate (about 5% of the total applied radioactivity within 100 days) and formation of large amounts of bound residues (about 55% of the total). The same metabolites, the *trans*-azooxy and the *trans*-azo dimers (or *N*,*N*′-bis-[2-(1*H*-pyrazol-3-yloxymethyl)phenyl]diazene) of pyraclostrobin, were found in all soil types. The amount of the *trans*-azooxy dimer generally exceeded 10% the total applied radioactivity (maximum, 31%), whereas that of the *trans*-azo dimer slightly exceeded 10% of the total applied in only one of the investigated soils. The amount of bound residue increased with time, and the most of the radiolabel was associated with insoluble humins and high-molecular-mass humic acids. No release of pyraclostrobin or its metabolites was observed, even with harsh extraction methods (NaOH) or with intensive activity of soil-eating animals (earthworms). Photolytic degradation leads to the same degradation products; however, all the metabolites were formed in amounts less than 10% of the total applied radioactivity.

Pyraclostrobin is degraded in soil under laboratory conditions, with DT_{50} values ranging from 12 to 101 days in five microbially active soils. Higher soil moisture contents generally accelerated the degradation. Photolysis did not significantly influence the degradation rate; however, it reduced the amounts of the *trans*-azooxy and the *trans*-azo dimers of pyraclostrobin. In field studies, the DT_{50} values of pyraclostrobin were much lower, ranging from 2 to 37 days. The DT_{90} values in the field were 83–230 days. The DT_{50} values of the soil metabolites in the laboratory were 60–166 days for the *trans*-azooxy dimer and 38–159 days for the *trans*-azo dimer. (The high values for the latter were calculated for soils in which the metabolite was formed in amounts < 10% total applied radioactivity.) Under field conditions, however, the metabolites 500M07 and *trans*-azo dimer were not detected. Only the *trans*-azooxy dimer was found sporadically in trace amounts close to the LOQ.

With regard to mobility, no radiolabel was found in leaching studies, and pyraclostrobin remained in the first layer of soil (< 12 cm). Thus, pyraclostrobin and its metabolites are not mobile in soil.

The results indicate that pyraclostrobin and its metabolites are not stable in soil. They were degraded quickly and were not mobile.

Succeeding crops

The residue levels and the nature of the residues of pyraclostrobin were investigated in three succeeding crops, radish, lettuce and wheat, after application at a rate of 900 g ai/ha. The total residues in the edible parts of the succeeding crops were low at all plant-back intervals. There was no accumulation of pyraclostrobin or its degradation products in the parts of plants used for human or animal consumption.

Methods of analysis

Methods for the determination of pyraclostrobin in plant and animal matrices are based on HPLC with ultraviolet, mass spectrometry or tandem mass spectrometry detection. The LOQ is 0.02 mg/kg in plant matrices, 0.01 mg/kg in milk and 0.05 mg/kg in others animal matrices.

Plant matrices are extracted with methanol:water and purified on a micro-C_{18} column with a micro silica gel column step. Independent laboratory validation showed good performance of the methods.

Animal matrices can be extracted with acetone or acetonitrile and purified by liquid–liquid partition. Further clean-up is necessary before determination.

For enforcement, HPLC with ultraviolet detection was used, but some difficulties were found for crops like hops and oilseed crops.

Stability of residues in stored analytical samples

The stability of pyraclostrobin in plant matrices was shown to be 19 months. Untreated samples were fortified with 1.0 mg/kg pyraclostrobin and its metabolite 500M07. The residues in peanut meat, peanut oil, wheat grain, wheat straw, sugar beet tops, sugar beet roots, tomatoes and grape juice were stable during storage (range, 88–106% for the parent and 84–120% for the metabolite 500 M07).

Untreated samples of muscle, liver and milk from a cow were fortified with pyraclostrobin at 0.5 mg/kg (0.1 mg/kg in milk) or a mixture of 0.5 mg/kg (0.1 mg/kg for milk) pyraclostrobin and the same amount of a hydroxylated metabolite. Other potential metabolites also form these analytes on cleavage of the methylene ether bridge. After about 0, 30, 60, 90, 120 and 240 days, samples were analysed by BASF methods Nos 439 and 446. The results used to calculate stability were corrected for individual procedural recoveries. The average results of analysis for the parent compound with method 446 show degradation in muscle and milk. The model hydroxylated metabolite appeared to be less stable after 240 days' storage (68–86% in liver, milk and muscle). Nevertheless, this result does not affect the validity of the cow feeding study,

as milk samples, in which degradation of the metabolite was fastest, were analysed within 91 days of sampling.

Definition of the residue

Three studies were performed on metabolism in three crop categories: grape for fruits, potato for root and tuber vegetables and wheat for cereals. Pyraclostrobin (grape fruits, potato green matter, wheat forage, wheat straw) and the desmethoxy metabolite 500M07 (grape fruits, potato green matter, wheat forage, wheat straw) accounted for most of the residue in most plant samples investigated. As the desmethoxy metabolite occurred in much smaller amounts than parent pyraclostrobin, the metabolite was not included in the definition of the relevant residue.

Studies of metabolism in goats and hens showed that the residues in products of animal origin derive from the parent compound and from its *N*-desmethoxylation product. Oxidation of the aromatic rings to several hydroxylated compounds and cleavage of the molecule led to further metabolites. As these transformations occur in matrices with small amounts of parent or little extractability, residue data obtained by this method represent reasonable worst-case estimates for risk assessment in all matrices. Furthermore, a method for parent only was developed to monitor residues of pyraclostrobin.

The Meeting agreed that the parent compound is suitable for enforcement in plant and animal commodities and is also the compound of interest for dietary risk assessment.

Definition of the residue for compliance with MRL and for estimation of dietary intake: pyraclostrobin.

The residue is fat-soluble.

Results of supervised trials on crops

The Meeting received data from supervised trials on citrus, nuts, apple, stone fruit, grape, strawberry, raspberry, blueberry, banana, mango, papaya, carrot, radish, sugar beet, garlic, onion, tomato, red pepper, summer squash, cucumber, lettuce, bean, lentil, pea dry, peanut, soya bean, oat, wheat, barley, maize and coffee. Most of the trials were carried out in the USA. All of the information from Europe and the USA was acceptable. The trials were conducted according to GLP.

Citrus fruit

GAP trials was reported from the Republic of Korea (citrus), South Africa (grapefruit and orange) and the USA (grapefruit, lemon, lime, orange, tangelo and tangerine).

Orange

Trials were conducted in Argentina (one) at 0.075 kg ai/ha, with four applications, including a study on the decline of residues, and in the USA (13) at GAP (0.274 kg ai/ha, four applications, 14-day PHI). The residue levels in orange were: 0.12, 0.13, 0.17 (two), 0.18, 0.19, 0.23, 0.24, 0.25, 0.26, 0.34, 0.35, 0.37 and 0.51 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.24 mg/kg and a highest reside level of 0.51 mg/kg for orange.

No residue was detected in pulp in five trials (< 0.02 mg/kg).

Grapefruit

Six trials were carried out in the USA at GAP (0.27 kg ai/ha, four applications,14-day PHI). The pyraclostrobin residue levels were: 0.07, 0.08, 0.11, 0.12, 0.19 and 0.24 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.12 mg/kg and a highest reside level of 0.24 mg/kg for grapefruit.

The residue in pulp was below the LOQ in one trial.

Lemon

Trials were conducted in Argentina (two trials at 0.075 kg ai/ha, four applications with two decay curves), Brazil (four trials with one decay curve) and the USA (five trials at GAP: 0.27 kg ai/ha, four applications, 14-day PHI). The trials in Brazil could not be evaluated (no GAP), and no results were available from the trial in Argentina at 14 days.

Pyraclostrobin residue levels in lemons in the five US trials were 0.15, 0.19, 0.20, 0.28 and 0.32 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.20 mg/kg and a highest reside level of 0.32 mg/kg for lemon.

The Meeting agreed to combine the above results in order to estimate a maximum residue level for citrus fruit. The combined results from the trials in Argentina and the USA, in ranked order, were: 0.07, 0.08, 0.11, 0.12 (two), 0.13, 0.15, 0.17 (two), 0.18, 0.19 (three), 0.20, 0.23, 0.24 (two), 0.25, 0.26, 0.28, 0.32, 0.34, 0.35, 0.37 and 0.51 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, with an STMR of 0.19 mg/kg and a highest reside level of 0.51 mg/kg for citrus.

Apple

GAP in Brazil was reported to be a rate of 0.1 kg ai/ha, with four applications and a 14-day PHI. Eight trials were conducted in Brazil at 0.15 kg ai/ha with two decay curves and six trials at 0.3 kg ai/ha. The Meeting agreed that no maximum residue level for apple could be established.

Stone fruit

GAP was reported from Canada (stone fruit) and the USA (peach, nectarine, apricot, plum, prune and cherry). The rate of application in the two countries is the same, 0.13 kg ai/ha with five applications. The waiting period is 10 days in Canada and 0 day in the USA.

Peach

Eighteen trials were carried out in the USA according to GAP. Two trials with decay curves were available. Pyraclostrobin residue levels in peaches were 0.07, 0.08 (two), 0.10 (two), 0.11, 0.13, 0.14, 0.15 (two), 0.16 (two), 0.20, 0.21, 0.23, 0.26, 0.28 and 0.31 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.15 mg/kg and a highest reside level of 0.31 mg/kg for peaches.

Cherry

Twelve trials on sour cherries were conducted in the USA according to GAP. Pyraclostrobin residue levels were 0.25 (two), 0.27, 0.34, 0.38, 0.42, 0.43, 0.48, 0.50 (two), 0.51 and 0.63 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.43 mg/kg and a highest reside level of 0.63 mg/kg for cherry.

Plum: Twelve trials were carried out in the USA according to GAP, including two with decay curves. Pyraclostrobin residue levels were 0.02 (two), 0.03, 0.04 (two), 0.05, 0.06 (three), 0.12, 0.13 and 0.19 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.06 mg/kg and a highest reside level of 0.19 mg/kg for plums.

Berries and small fruit

Grape

A total of 48 trials were performed in representative growing areas in Brazil, Europe and the USA. GAP was 0.1 kg ai/ha with two applications and a 7-day PHI in Brazil (four trials), 0.16 kg ai/ha with eight and three applications and a 35-day PHI in Europe (30 trials) and 0.168 kg ai/ha with three applications and a 14-day PHI in the USA (14 trials).

The pyraclostrobin residue levels in grapes in trials conducted according to GAP in Brazil were 0.36, 0.79, 1.1 and 1.4. The levels in trials conducted according to GAP in Europe (France, Germany, Italy and Spain) were 0.13, 0.16, 0.17 (two), 0.20, 0.23, 0.25, 0.26, 0.36, 0.40, 0.44 (two), 0.47, 0.56, 0.59 (two), 0.64, 0.67, 0.74, 0.75, 0.76, 0.78 (two), 1.2 and 1.3 mg/kg. The levels in trials conducted according to GAP in the USA were 0.09, 0.10 (two), 0.12 (two), 0.22, 0.24, 0.35, 0.43, 0.49 (two), 0.55, 0.67 and 1.2 mg/kg.

The Meeting agreed to combine the results in order to estimate a maximum residue level for grapes. The levels, in ranked order, were: 0.09, 0.10 (two), 0.12 (two), 0.13, 0.16, 0.17 (two), 0.20, 0.22, 0.23, 0.24, 0.25, 0.26, 0.35, 0.36 (two), 0.40, 0.43, 0.44 (two), 0.47, 0.49 (two), 0.55, 0.56, 0.59 (two), 0.64, 0.67 (two), 0.74, 0.75, 0.76, 0.78 (two), 0.79, 1.1, 1.2 (two), 1.3 and 1.4. The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.44 mg/kg and a highest reside level of 1.4 mg/kg for grapes.

Strawberry

GAP was reported for Canada and the USA. Eight trials were carried out in the USA at GAP (0.2 kg ai/ha, five applications, 0-day PHI), one with a decay curve.

The levels of pyraclostrobin residues in strawberries in trials conducted according to GAP in the USA were: 0.06, 0.10, 0.13, 0.15, 0.16, 0.19, 0.24 and 0.26 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.16 mg/kg and a highest reside level of 0.26 mg/kg for strawberry on the basis outdoor uses of pyraclostrobin.

Raspberry

GAP is reported for the USA only, with four applications at 0.2 kg ai/ha and 0-day PHI. The results of three trials were provided.

The Meeting agreed that no maximum residue level for raspberries could be established.

Blueberry

GAP was available in Canada and the USA. The rate of application (0.2 kg ai/ha) and the number of applications (four) were the same, but the PHI in the USA is 0 days. Six trials were performed in the USA, but one included 50% ripe fruit.

The levels of pyraclostrobin residues in blueberries in trials conducted according to GAP in the USA were, in ranked order: 0.19, 0.30, 0.33, 0.35, 0.48 and 0.57 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.34 mg/kg and a highest reside level of 0.57 mg/kg for blueberry.

Assorted tropical fruit minus inedible peel

Banana

Twelve trials were conducted in the main banana-growing regions of Central and South America. In all the trials, the formulation BAS 500 00F was applied eight times at a rate of 0.1 kg ai/ha. According to regional agricultural practice, the bananas were treated both bagged and unbagged and collected separately. Samples of whole bananas with peel were taken directly after the last application. No levels > 0.02 mg/kg were found in any sample.

The levels of pyraclostrobin residues in bananas in trials conducted according to GAP in Colombia (two), Costa Rica (three), Ecuador (three), France, Guatemala and Mexico were < 0.02.mg/kg. The Meeting estimated a maximum residue level of 0.02* mg/kg, an STMR of 0.02 mg/kg and a highest reside level of 0.02 mg/kg for bananas.

Mango

GAP in Brazil requires a maximum rate of 0.1 kg ai/ha, with two applications and a 7-day PHI. Four trials were conducted in Brazil at a rate of 0.225 kg ai/ha with three applications, and three trials were conducted at a rate of 0.45 kg ai/ha. No residues were detected at 0 or 7 days (< 0.05 mg/kg).

The Meeting agreed to propose a maximum residue level of 0.05* mg/kg and STMR and highest reside values of 0.05 mg/kg.

Papaya

GAP in Brazil requires a maximum rate of 0.1 kg ai/ha, four applications and a 7-day PHI. Four trials were reported from Brazil at a rate of 0.125 kg ai/ha and three trials at 0.25 kg ai/ha. No residues were detected at 7 days (< 0.05 mg/kg)

The Meeting estimated a maximum residue level of 0.05* mg/kg and STMR and highest reside values of 0.05 mg/kg for papaya.

Bulb vegetables

GAP was reported for Brazil (onions), Canada (bulb vegetable) and the USA (garlic and onions). The maximum rate of application is 0.1 kg ai/ha in Brazil and 0.17 kg ai/ha in Canada and the USA. The PHI is 3 days for onions and 7 days for garlic in Brazil and 7 days in Canada and the USA.

Seven trials were conducted on garlic in Brazil, but only four in accordance with GAP, and seven trials were conducted on onions, none of which conformed to GAP. Nine trials on onions were conducted in the USA.

Garlic

In the four trials in Brazil conforming to GAP, all the residue levels were < 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg and STMR and highest reside values of 0.05 mg/kg for garlic.

Onion

Four trials in Brazil conducted at a rate of 0.15 kg ai/ha and a PHI of 7 days and three trials at a rate of 0.30 kg ai/ha and 7-day PHI could not be used to evaluate the residue levels.

Bulb onion

In six trials carried out in the USA according to GAP, the levels of pyraclostrobin residues in dry onions were: 0.02 (five) and 0.09 mg/kg. The Meeting estimated a maximum residue level of 0.20 mg/kg, an STMR of 0.02 mg/kg and a highest reside level of 0.09 mg/kg for onions, dry.

Spring onion

In three trials conducted according to GAP in the USA, the levels of pyraclostrobin residues in spring onions were 0.05, 0.42 and 0.53 mg/kg.

The Meeting agreed that no maximum residue level for spring onions could be established

Fruiting vegetables

Tomato

GAP was reported for Brazil, Canada (fruiting vegetables), Chile and the USA. The critical GAP was a maximum rate of 0.224 kg ai/ha, six applications and a 0-day PHI. Three outdoor trials were conducted in Brazil and 21 in the USA, which included two with decay curves.

The levels of pyraclostrobin residues in tomatoes in trials conducted according to GAP in Brazil were, in ranked order: 0.02, 0.03 and 0.12 mg/kg. The levels in the trials in the USA were, in ranked order: 0.06, 0.07 (two), 0.08, 0.10, 0.11 (four), 0.12 (three), 0.13 (two), 0.15, 0.16, 0.17 (three), 019 and 0.21 mg/kg.

The Meeting combined the data from Brazil and the USA, giving levels, in ranked order, of: 0.02, 0.03, 0.06, 0.07 (two), 0.08, 0.10, 0.11 (four), 0.12 (four), 0.13 (two), 0.15, 0.16, 0.17 (three), 019 and 0.21 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.12 mg/kg and a highest reside level of 0.21 mg/kg for tomato.

Chili pepper

GAP was reported for Brazil (maximum rate of 0.1 kg ai/ha and 3-day PHI), Canada (fruiting vegetable), the Republic of Korea and the USA (maximum rate of 0.224 kg ai/ha, six applications and 0-day GAP).

Four trials were reported from Brazil at 0.15 kg ai/ha and three at 0.3 kg ai/ha, which did not correspond to GAP.

The levels of pyraclostrobin residues in chili peppers in trials conforming to GAP in the USA were 0.14, 0.22 and 0.82 mg/kg.

The Meeting agreed that no maximum residue level for chili pepper could be established.

Fruiting vegetables

GAP was reported for Canada (fruiting vegetable, cucurbits) and the USA (squash summer), at a rate of application of 0.22 kg ai/ha, four applications and a 0-day PHI.

Summer squash

In six trials conducted according to GAP on summer squash in the USA, the levels of residues, in ranked order, were: 0.03, 0.07, 0.14, 0.17 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.15 mg/kg and a highest reside level of 0.18 mg/kg for summer squash.

Cucumber

Four trials were carried out on cucumber in Brazil at 0.1 kg ai/ha and three trials at 0.2 kg ai/ha, in accordance with GAP in Brazil (0.1 kg ai/ha, 3-day PHI). The pyraclostrobin residue levels were < 0.02 mg/kg.

The Meeting agreed that the data were insufficient, and no maximum residue level could be recommended.

Lettuce

No GAP was provided. Five trials in the USA were conducted at 0.22 kg ai/ha. The Meeting agreed that no maximum residue level for lettuce could be recommended.

Legume vegetables and pulses

Beans

GAP for beans in Brazil is a maximum rate of 0.075 kg ai/ha, three applications and a 14-day PHI; that in Canada is a maximum rate of 0.1kg ai/ha, two applications and a 30-day PHI; and that in the USA is a maximum rate of 0.2 kg ai/ha, two applications and a 30-day PHI.

In 10 trials conducted at 0.224 kg ai/ha, the residue levels 21 days after application were < 0.02 (eight), 0.04 and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.02 mg/kg and a highest reside level of 0.10 mg/kg for dry beans.

The results of nine trials on snap beans were presented, but no GAP was available. The Meeting agreed that no maximum residue level for snap beans could be established.

Lentils

GAP was reported for Canada at a maximum rate of 0.1 kg ai/ha, two applications and a 30-day PHI. GAP in the USA is a maximum rate of 0.22 kg ai/ha with two applications.

Three trials were carried out in Canada, and three were conducted in the USA at a rate of 0.224 kg ai/ha. Pyraclostrobin residue levels in lentils in trials conforming to GAP in the USA were, in ranked order: 0.03, 0.08, 0.11, 0.15, 0.17 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.13 mg/kg and a highest reside level of 0.39 mg/kg for lentils.

Peas, dry

GAP in Canada for dry field peas is a maximum rate of 0.1 kg ai/ha, two applications and a 30-day PHI. That in the USA is a maximum rate of application of 0.224 kg ai/ha and a 30-day PHI. Six trials were conducted in Canada and two in the USA at the rate of 0.224 kg ai/ha.

The levels of pyraclostrobin residues in peas (dry) in trials conducted according to GAP in the USA, in ranked order, were: < 0.02 (two), 0.04, 0.05, 0.09, 0.13, 0.14, and 0.20 mg/kg.

The Meeting estimated a maximum residue level for peas, dry, of 0.3 mg/kg, an STMR of 0.07 mg/kg and a highest reside level of 0.20 mg/kg.

Peanut

GAP was reported for Argentina, Brazil and the USA. The critical GAP was that of the USA, which requires a maximum rate of 0.274 kg ai/ha, five applications and a 14-day PHI.

In four trials conducted in Brazil and 12 in the USA, no residues were detected in nutmeat (< 0.02 mg/kg).

The pyraclostrobin residue levels in peanut in trials conforming to GAP in Brazil and the USA were < 0.02 mg/kg or < 0.025 mg/kg (one). The Meeting estimated a maximum residue level of 0.05* mg/kg, an STMR of 0.02 mg/kg and a highest reside level of 0.025 mg/kg for peanut.

Soya bean

GAP was reported for Argentina, Brazil and Paraguay. GAP in Brazil is a maximum rate of 0.08 kg ai/ha with two applications and a 14-day PHI. One trial was conducted in Argentina and eight in Brazil (only four at GAP). In Argentina, the residue level was 0.03 mg/kg. In Brazil, results were presented only for grain. No residues were detected (< 0.02 mg/kg), even after application at 0.1 kg ai/ha.

The Meeting agreed that no maximum residue level for soya bean could be established.

Root and tuber vegetables

Carrot

GAP was reported for Brazil, Canada and the USA. The rate and number of applications are the same in Canada and the USA (0.22 kg ai/ha, three applications), but the PHI is 3 days in Canada and 0 days in the USA. In Brazil, the rate of application is lower (0.1 kg ai/ha) and the PHI is 7 days. One trial was conducted in Brazil and eight in the USA, only six of which were at GAP.

The levels of pyraclostrobin residues in carrots in trials conducted according to GAP in Brazil and the USA, in ranked order, were: 0.03 (two), 0.04, 0.12 (two), 0.15 and 0.24.mg/kg. The Meeting estimated a maximum residue level of 0.50 mg/kg, an STMR of 0.12 mg/kg and a highest reside level of 0.24 mg/kg for carrots.

Radish

GAP in the USA is a maximum application rate of 0.224 kg ai/ha, three applications and a 0-day PHI).The same GAP is applicable to horseradish. Five trials were carried out in the USA, and the values for radish tops and root were reported.

The levels of pyraclostrobin residues in radishes were 0.05, 0.07, 0.08, 0.23 and 0.30 mg/kg. The Meeting estimated a maximum residue level of 0.50 mg/kg, an STMR of 0.08 mg/kg and a highest reside level of 0.30 mg/kg for radish.

The residue levels in radish tops were 7.5, 9.6, 9.9, 12 and 15 mg/kg The Meeting estimated a maximum residue level of 20 mg/kg, an STMR of 9.9 mg/kg and a highest reside level of 15 mg/kg for radish tops.

Sugar beet

GAP in Canada and the USA is the same, with a maximum rate of 0.22 kg ai/ha, four applications and a 7-day PHI. In 12 trials conducted in USA according to GAP, the pyraclostrobin residue levels in sugar beet were: < 0.02 (two), 0.02, 0.03 (two), 0.04 (two), 0.06, 0.08 (two), 0.11 and 0.13 mg/kg. The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.04 mg/kg and a highest reside level of 0.13 mg/kg for sugar beet.

Potato

GAP was reported for Brazil, Canada and the USA. GAP in Brazil is a maximum rate of 0.1 kg ai/ha with five applications and a 3-day PHI, and GAP in the USA is a maximum rate of application of 0.219 kg ai/ha with six applications and a 3-day PHI.

In trials conducted according to GAP in Brazil, Canada and the USA, no residues were detected (< 0.02 mg/kg).

The Meeting estimated a maximum residue level for potatoes of 0.02* mg/kg and STMR and highest reside values of 0.02 mg/kg.

Cereal grains

Oats

GAP was reported for Brazil, Denmark, Estonia, France, Ireland, Latvia, Lithuania and the United Kingdom. The maximum rate of application was around 0.2 kg ai/ha with one to two applications and a PHI of 30 days.

Eight trials were conducted according to GAP in Brazil at 0.166, 0.2, 0.333 or 0.4 kg ai/ha. The levels of pyraclostrobin residues in oat grain were, in ranked order: 0.04, 0.05, 0.06, 0.14, 0.20, 0.23, 0.25 and 0.42 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.17 mg/kg and a highest reside level of 0.42 mg/kg for oat grain.

Wheat

GAP was reported from Argentina, Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Lithuania, The Netherlands, Switzerland and the United Kingdom. The rate of application was 0.20–0.25 kg ai/ha with two applications and a 35-day PHI. GAP in the USA is a maximum of 0.22 kg ai/ha and a 40-day PHI.

In Brazil, eight trials were conducted according to GAP, four at 0.167 kg ai/ha and four at 0.2 kg ai/ha; 13 trials exceeded GAP: four at 0.3 kg ai/ha, three at 0.335 kg ai/ha, three at 0.4 kg ai/ha and three at 0.6 kg ai/ha. Thirty trials were conducted in Europe: one in Denmark, eight in France, five in Germany, two in The Netherlands, nine in Spain, one in Sweden and four in the United Kingdom. In North America, 11 trials were conducted in Canada and 23 in the USA according to US GAP.

The levels of pyraclostrobin residues in wheat grain in the trials conducted according to GAP in Brazil were: 0.02, 0.03 and 0.04 (two) mg/kg.

In all the European trials, samples of whole plant without roots were taken directly after the last application. On the third sampling day, at the proposed PHI of 35 days, various samples were taken, depending on ripening, with ears taken in 30 trials and grain in 27 trials. The pyraclostrobin residue levels in wheat grain in trials that conformed to GAP were: < 0.02 (22), 0.03, 0.04 (two), 0.05 and 0.09 mg/kg.

The residue levels in wheat grain in 11 trials in Canada and 23 trials in the USA that conformed to GAP were < 0.02 mg/kg.

The levels of pyraclostrobin residues in wheat grain in GAP trials in Brazil, Europe, Canada and the USA were of the same order of magnitude, and the Meeting decided that the data could be pooled. The residue levels, in ranked order, were: < 0.02 (56), 0.02, 0.03 (two), 0.04 (four), 0.05 and 0.09 mg/kg. The Meeting estimated a maximum residue level for wheat grain of 0.2 mg/kg, an STMR of 0.02 mg/kg and a highest reside level of 0.09 mg/kg.

Barley

GAP was reported for Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Luxembourg, Macedonia, Switzerland, the United Kingdom and the USA. GAP in Europe is a rate of application of 0.20–0.25 kg ai/ha, two applications and a 30–35-day PHI. Two trials were conducted according to GAP in Belgium, seven in France, four in Germany, three in Spain, five in Sweden and four in the United Kingdom, for a total of 25 trials.

The pyraclostrobin residue levels in barley grain in trials corresponding to GAP in Europe were, in ranked order: < 0.02 (six), 0.02 (two), 0.03 (six), 0.04 (four), 0.05 (two), 0.06, 0.07, 0.08, 0.09, 0.10, 0.29 and 0.32 mg/kg.

A total of 14 trials were carried out in Brazil, but only eight conformed to GAP. The residue levels in barley grain in the latter trials were, in ranked order: 0.04, 0.05, 0.06, 0.07, 0.08 (three) and 0.09 mg/kg.

In the 26 trials conducted in the USA on barley grain according to GAP (0.22 kg ai/ha), the pyraclostrobin residue levels, in ranked order, were: < 0.02 (19), 0.03 (three), 0.05 (two), 0.07 and 0.14 mg/kg.

As GAP in Brazil, Europe and the USA is similar and the residue levels were in the same range, the results were combined. The levels, in ranked order, were: < 0.02 (25), 0.02 (two), 0.03 (nine), 0.04 (five), 0.05 (five), 0.06 (two), 0.07 (three), 0.08 (four), 0.09 (two), 0.10, 0.14, 0.29 and 0.32 mg/kg.

The Meeting estimated a maximum residue level for barley grain of 0.5 mg/kg, an STMR of 0.03 mg/kg and a highest reside level of 0.32 mg/kg.

Maize

GAP in Brazil allows two applications of 0.15 kg ai/ha or 0.1 kg ai/ha with a 45-day PHI on maize.

Four trials were conducted at 0.2 kg ai/ha and four at 0.133 kg ai/ha. The residue levels in trials conforming to GAP were < 0.02 mg/kg.

The Meeting estimated a maximum residue level for maize of 0.02* mg/kg and STMR and highest reside values of 0.02 mg/kg.

Rye

GAP in the USA allows two applications of 0.22 kg ai/ha with a 40-day on rye. In five trials conducted at 0.22 kg ai/ha but with a PHI of about 60 days, the pyraclostrobin residue levels in rye were < 0.02 mg/kg at 60 days.

The Meeting agreed that no maximum residue level for rye could be estimated.

Tree nuts

GAP was reported from the USA for beechnut, Brazil nut, butter nut, cashew, macadamia nut, pecan, walnut and pistachio. The rate of application was 0.13 kg ai/ha, with four applications and a waiting period of 14 days (pecan and pistachio). For almond, the new GAP was 0.13 kg ai/ha, with four applications and a waiting period of > 100 days.

Almond: Ten trials were carried out in the USA with a 120-day PHI. The results for nutmeat were < 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02*mg/kg, an STMR of 0.02 mg/kg and a highest reside level of 0.02 mg/kg.

Pecan: Ten trials were conducted in the USA according to GAP. Pyraclostrobin residue levels in pecan were < 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02*mg/kg, an STMR of 0.02 mg/kg and a highest reside level of 0.02 mg/kg for pecan.

Pistachio: Six trials were carried out in the USA according to GAP. The pyraclostrobin residue levels were: 0.02 (two), 0.16, 0.27, 0.44 and 0.45 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.22 mg/kg and a highest reside level of 0.45 mg/kg for pistachio.

Coffee

GAP in Brazil is a maximum rate of 0.2 kg ai/ha with two applications and a 45-day PHI. Four trials were conducted at 0.175 kg ai/ha and three at 0.35 kg ai/ha. The pyraclostrobin residue levels were < 0.02 (two), 0.03 and 0.15 mg/kg.

The Meeting agreed that no maximum residue level for coffee could be estimated

Animal feedstuffs

Fodder beet leaves and tops

GAP is the same for Canada and the USA, with a maximum rate of 0.22 kg ai/ha, four applications and a 7-day PHI. In 12 trials conducted in the USA according to GAP, the levels of pyraclostrobin residues, in ranked order, were: 0.28, 1.3, 1.4, 1.5 (two), 1.6, 1.7, 2.0, 2.6, 2.8, 3.9 and 5.3 mg/kg.

Eight trials were conducted in Europe and reported, but the registration is pending.

The Meeting estimated a maximum residue level of 10 mg/kg, an STMR of 1.64 mg/kg and a highest reside level of 5.3 mg/kg for sugar beet tops. On a dry basis, the maximum residue level was 50 mg/kg, the STMR was 7.1 mg/kg and the highest reside level was 23 mg/kg.

Peanut hay

GAP was reported for Argentina, Brazil and the USA. The critical GAP is 0.274 kg ai/ha with five applications and a 14-day PHI. In 12 trials conducted according to GAP in the USA, the pyraclostrobin residue levels in peanut hay, in ranked order, were: 1.5, 3.3, 4.0, 4.8, 4.9, 9.0, 15, 18, 19 (two) and 24 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg, an STMR of 9.0 mg/kg and a highest reside level of 24 mg/kg for peanut hay.

On the basis of the dry matter, which is listed as 85% in the *FAO Manual*, the STMR is equivalent to 11 mg/kg and the highest reside level to 29 mg/kg. These values were used to calculate the animal burden.

Pea hays and vines

GAP was reported for Canada (dried field peas, 0.1 kg ai/ha with two applications and a 30-day PHI) and the USA (0.22 kg ai/ha and a 30-day PHI). Six trials were conducted in Canada and two in the USA at an application rate of 0.224 kg ai/ha.

The levels of pyraclostrobin residues in pea vines in trials conforming to GAP in the USA were: 3.3, 3.8, 4.2, 5.0, 5.1, 5.5 (two) and 7.0 mg/kg.

The Meeting estimated a maximum residue level for pea vines of 10 mg/kg, an STMR of 5.1 mg/kg and a highest reside level of 7.0 mg/kg.

On the basis of the dry matter, which is listed as 25% in the *FAO Manual*, the maximum residue level was estimated at 40 mg/kg, the STMR at 20 mg/kg and the highest reside level at 28 mg/kg in pea vine. These values were used to calculate the animal burden.

The levels of pyraclostrobin residues in pea hay in trials conforming to GAP in the USA were: 4.9, 5.3, 6.4, 7.2, 7.5, 9.2, 12 and 18 mg/kg.

The Meeting estimated a maximum residue level for pea hay of 20 mg/kg, an STMR of 6.8 mg/kg and a highest reside level of 18 mg/kg.

On the basis of the dry matter, which is listed as 88% in the *FAO Manual*, the maximum residue level was estimated at 30 mg/kg, the STMR at 7.8 mg/kg and the highest reside level at 20 mg/kg in pea hay.

Barley straw, hay (fodder) and haulms

GAP was reported for Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Luxembourg, Macedonia, Switzerland, the United Kingdom and the USA. The maximum rate of application is 0.2–0.25 kg ai/ha with two applications and a 30–35-day PHI. In Europe, 25 trials were conducted, with two in Belgium, seven in France, four in Germany, three in Spain, five in Sweden and four in the United Kingdom.

The levels of pyraclostrobin residues in barley straw in trials that complied with GAP in Europe were: 0.48, 0.66, 0.78 (two), 0.72, 0.84, 0.99, 1.0, 1.7 (two), 1.8, 2.0, 2.6 (two), 2.8 (three), 3.9, 4.4 (two), 4.8, 4.9, 5.7, 5.8 and 6.9 mg/kg.

The levels of pyraclostrobin residues in barley straw in trials that complied with GAP in Canada and the USA were: 0.09, 0.12 (two), 0.26, 0.30 (two), 0.31, 0.32 (two), 0.39, 0.45, 0.52, 0.57, 0.82, 1.1, 1.3, 1.4, 1.5 (two), 1.9, 2.4, 2.8 and 4.0 mg/kg.

The Meeting agreed to combine the above results for estimating a maximum residue level for barley straw. The residue levels, in ranked order, were: 0.09, 0.12 (two), 0.26, 0.30 (two), 0.31, 0.32 (two), 0.39, 0.45, 0.48, 0.52, 0.57, 0.66, 0.72, 0.78 (two), 0.82, 0.84, 0.99, 1.0, 1.1, 1.3, 1.4, 1.5 (two), 1.7 (two), 1.8, 1.9, 2.0, 2.4, 2.6 (two), 2.8 (four), 3.9, 4.0, 4.4 (two), 4.8, 4.9, 5.7, 5.8 and 6.9 mg/kg.

The levels of pyraclostrobin residues in barley haulms in trials that complied with GAP in Europe were: 0.41, 0.53, 0.54, 0.58, 0.72, 0.73, 0.74, 0.87, 0.88, 0.98, 1.2, 1.3, 1.4 (two), 1.5, 1.6, 1.7, 1.8, 2.5, 3.2, 3.4, 4.1, 4.3, 6.6 and 7.6 mg/kg.

The levels of pyraclostrobin residues in barley hay in trials that complied with GAP in Canada and the USA were: 0.93, 0.96, 1.0 (two), 1.1, 1.2, 1.3, 1.5, 1.6 (three), 1.9, 2.1, 2.2 (two), 2.5, 2.8, 3.2 (two), 3.6, 3.7, 12 (two), 17 and 19 mg/kg.

Wheat straw, hay (fodder) and haulms

GAP was reported for Argentina, Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Lithuania, The Netherlands, Switzerland, the United Kingdom and the USA. The rate of application is 0.20–0.25 kg ai/ha with two applications and a 35-day PHI.

In 27 trials in Europe, samples of whole plant without roots were taken directly after the last application, and samples of haulms and straw were taken about 3 weeks after the last application. On the third sampling day, which was at the proposed 35-day PHI, various samples were taken, depending on ripening; in 27 trials, haulms and straw were taken.

The levels of pyraclostrobin residues in wheat straw in trials that conformed to GAP in Europe were: 0.67, 0.75, 0.87, 1.2, 1.4, 1.5, 1.6, 1.7, 1.7 (two), 1.8, 1.9 (two), 2.0 (two), 2.1, 2.2, (five), 2.3, 2.5, 3.2, 5.0, 5.5 and 5.7 mg/kg.

The levels of pyraclostrobin residues in wheat straw in trials that conformed to GAP in Canada and the USA were: 0.03, 0.06, 0.07, 0.09, 0.10 (two), 0.11, 0.12, 0.13 (two), 0.15, 0.20, 0.21, 0.23, 0.24, 0.32, 0.34, 0.37, 0.52, 0.56, 0.74, 0.85, 0.90, 0.95, 1.1, 1.6, 1.7, 2.2, 3.5, 3.8 and 4.1 mg/kg.

The Meeting agreed to combine the above results for estimating a maximum residue level for wheat straw. The residue levels, in ranked order, were: 0.03, 0.06, 0.07, 0.09, 0.10 (two), 0.11, 0.12, 0.13 (two), 0.15, 0.20, 0.21, 0.23, 0.24, 0.32, 0.34, 0.37, 0.52, 0.56, 0.67, 0.74, 0.75, 0.85, 0.87, 0.90, 0.95, 1.1, 1.2, 1.4, 1.5, 1.6 (two), 1.7 (four), 1.9 (three), 2.0 (two), 2.1, 2.2 (six), 2.3, 2.5, 3.1, 3.5, 3.8, 4.1, 5.0, 5.5 and 5.7 mg/kg.

The levels of pyraclostrobin residues in wheat haulms in trials that conformed to GAP in Europe were: 0.50, 0.52, 0.56, 0.62, 0.74, 0.75, 0.79, 0.81, 0.84, 0.85, 0.89, 0.92, 0.94, 0.96, 0.98, 0.99, 1.0 (two), 1.1, 1.2, 1.3 (two), 1.4 (two), 1.5, 1.6, 1.9, 2.7 (two) and 3.2 mg/kg.

The levels of pyraclostrobin residues in wheat hay in trials that conformed to GAP in Canada and the USA were: 0.21, 0.24, 0.27, 0.43, 0.46, 0.49, 0.54, 0.72, 0.75, 0.83, 0.89, 0.91, 0.93, 0.95, 1.0 (two), 1.1, 1.2, 1.4 (two), 1.5 (two), 1.6, 1.8 (two), 1.9, 2.0, 2.2 (two), 2.3, 3.0, 3.1 and 4.6 mg/kg.

Rye straw

GAP was reported from the USA at a rate of application of 0.2–0.25 kg ai/ha with two applications and a 40-day PHI. Five trials were conducted but with a longer PHI. The levels of pyraclostrobin residues were 0.11, 0.14, 0.17, 0.27 and 0.30 mg/kg.

The Meeting agreed that no maximum residue level for rye straw could be estimated.

The Meeting agreed to combine the results for barley and wheat straw (106 trials) in estimating a maximum residue level for cereal straw. The residue levels, in ranked order, were: 0.03, 0.06, 0.07, 0.09 (two), 0.10 (two), 0.11, 0.12 (three), 0.13 (two), 0.15, 0.20, 0.21, 0.23, 0.24, 0.26, 0.30 (two), 0.31, 0.32 (three), 0.34, 0.37, 0.39, 0.45, 0.48, 0.52 (two), 0.56, 0.57, 0.66, 0.67, 0.72, 0.74, 0.75, 0.78 (two), 0.82, 0.84, 0.85, 0.87, 0.90, 0.95, 0.99, 1.03, 1.1 (two), 1.2, 1.3, 1.4 (two), 1.5 (three), 1.6 (two), 1.7 (six), 1.8 (two), 1.9 (three), 2.0 (two), 2.1 (two), 2.2 (six), 2.3, 2.4, 2.5, 2.6 (two), 2.8 (four), 3.1, 3.5, 3.8, 3.9, 4.0, 4.10, 4.4 (two), 4.8, 4.9, 5.0, 5.5, 5.7 (two), 5.8 and 6.9 mg/kg.

The Meeting agreed to combine the results for barley and wheat fodder (59 trials) in estimating a maximum residue level for cereal fodder. The residue levels, in ranked order, were: 0.21, 0.24, 0.27, 0.43, 0.46, 0.49, 0.54, 0.72, 0.75, 0.83, 0.89, 0.91, 0.93 (two), 0.95, 0.96, 1.0 (four), 1.1 (two), 1.2 (two), 1.3, 1.4 (two), 1.5 (three), 1.6 (four), 1.8 (two), 1.9 (two), 2.0, 2.1, 2.2 (four), 2.3, 2.5, 2.8, 3.0, 3.1, 3.2 (two), 3.6, 3.7, 4.6, 11, 12, 17 and 19 mg/kg.

Allowing for the standard 88% dry matter for cereal straw and fodder (*FAO Manual* p. 49), the Meeting estimated a maximum residue level of 30 mg/kg, an STMR of 1.69 mg/kg and a highest reside level of 21.7 mg/kg. The highest reside level was taken into account in calculating the animal dietary burden.

Almond hulls

GAP was reported from the USA with 10 trials conducted according to GAP. The levels of pyraclostrobin residues in almond hulls were: < 0.02 (two), 0.11, 0.16, 0.19, 0.21, 0.47, 0.55, 0.87 and 1.3 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.20 mg/kg and a highest reside level of 1.34 mg/kg for almond hulls. The highest reside level was taken into account in calculating the animal dietary burden.

Fate of residues during processing

Studies were conducted on grapes, barley and wheat, and the respective intermediate end- and waste products were analysed. For grapes, the data covered whole grapes, cold must, heated must, wet pomace, wine from cold must, wine from heated must, juice and raisins. For barley, the data covered pearling dust, pot barley, malt, malt germs, spent grain, trub (flocks), beer yeast and beer. For wheat, flour, bran, middlings, shorts and germ were analysed.

The processing factors for total residues in the transformation from *grape* to must, wine and juice were < 1 (0.08–0.013), indicating that the residues did not concentrate. Concentration factors of 2.4–5.6 were calculated for residues in processing from whole grape to pomace; the concentration factor for total residues in processing from whole grapes to raisins was 3.1, which may be due to loss of water during processing.

In the processed fractions obtained for pot *barley* and beer production, such as pearling dust, malt, malt germs, spent grain, trub (flocks) and beer yeast, none of which are meant for consumption, the residues of pyraclostrobin showed some concentration, with factors ranging from 1.29 to 7.86. In the final products to be consumed, such as pot barley and beer, however, no concentration of pyraclostrobin residues was observed, as expressed by processing factors of < 1 (< 0.6). The processing factor from barley to beer cannot be calculated owing to the low contamination of barley, but the transfer factor can be assumed to be low.

The processing factors for total residues in the transformation from *wheat* grain to all processed fractions were < 1 (< 0.6), indicating that the residues did not concentrate. The transfer factor for wheat germ was 0.8. The processing factors and STMR-P values for all the commodities investigated were:

Commodity	Processing factor	STMR-P (mg/kg)
Grape juice	0.013	0.005
Wine	< 0.1	< 0.044
Must	0.15	0.07
Wet pomace	2.4–5.6	2.46
Raisin	3.1	1.36
Malt	1	0.03
Beer	< 0.6	< 0.025
Wheat flour	< 0.6	< 0.01
Wheat bran	< 0.6	< 0.01
Wheat germ	0.8	0.016

Residues in animals commodities

Dietary burden of farm animals

The Meeting estimated the dietary burden of pyraclostrobin residues in farm animals on the basis of the diets listed in Appendix IX of the *FAO Manual*. The percentage of dry matter is taken as 100% when MRLs and STMR values are expressed as dry weight.

Estimated maximum dietary burden of farm animals

Commodity	Group	Residue (mg/kg highest residue)	Residue (mg/kg on dry matter basis)[a]	Dietary content (%)			Residue contribution (mg/kg)		
				Beef cattle	Dairy cattle	Poultry	Beef cattle	Dairy cattle	Poultry
Almond hulls	AM	1.34	1.34						
Barley grain	GC	0.36	0.36	50	40	75	0.18		0.27
Cereal fodder	AS	21.7	21.7	25	60/50		5.4	10.8	
Sugar beet	AB	0.15	0.15						
Peanut hay	AL	28.8	28.8	25	50		7.28	14.4	
Pea hay	AL	20.5	20.5						
Pea vines	AL	28	28	25	50				
Fodder beet leaves	AV	23	23						
Total				100	100	75	12.9	25.2	0.27

[a] 100% dry matter for all commodities

Estimated median dietary burden of farm animals

Commodity	Group	Residue (mg/kg on STMR basis)	Residue (mg/kg on dry matter basis)[a]	Dietary content (%)			Residue contribution (mg/kg)		
				Beef cattle	Dairy cattle	Poultry	Beef cattle	Dairy cattle	Poultry
Almonds hulls	AM	0.2	0.22	10	10				
Barley grain	GC	0.034	0.034	50	40	75	0.017	0.014	0.025
Cereal fodder	AS	1.69	1.69	10	60				
Fodder beet tops	AV	7.1	7.1	20	10		1.42	0.71	
Sugar beet	AB	0.045	0.045	20	20				
Peanut hay	AL	10.6	10.6	25	50				
Pea hay	AL	7.75	7.75	25	50				
Pea vines	AL	20.2	20.2	25	50		5.06	10.1	
Total				95	100	75	6.5	10.8	0.025

[a] 100% dry matter for all commodities

The dietary burdens of pyraclostrobin for estimates of STMR and highest reside level values in animal commodities (residue levels in animal feeds expressed as dry weight) are, respectively, 6.5 mg/kg and 12.9 mg/kg for beef cattle, 10.8 mg/kg and 25.2 mg/kg for dairy cattle and 0.025 mg/kg and 0.27 mg/kg for poultry.

Feeding studies

In one feeding study, dairy cows were given feed containing pyraclostrobin at 0, 8.8, 27.2 or 89.6 mg/kg for 28 days. No residues of pyraclostrobin were detected in milk, meat, fat, kidney or tissues from the group given the concentration relevant to normal agricultural conditions (27.2 mg/kg) or at the other two concentrations. Low levels of pyraclostrobin metabolites might occur in liver.

The Meeting decided not consider these studies, as pyraclostrobin is fat-soluble and no residues were detected. The study of metabolism in goats, summarized below, was used to estimate residues in animal products.

Tissue	Residue (mg/kg)						
	At 12 ppm		At 50 ppm		Value taken into account	Dietary burden estimate (ppm)	
	Chlorophenyl label	Tolyl label	Chlorophenyl label	Tolyl label		25.2	10.8
Milk[a]	0.012	0.01	0.067	0.027	0.047	0.0236	0.01
Muscle	0.01	0.01	0.089	0.048	0.089	0.044	0.009
Fat	0.069	0.061	0.82	0.32	0.82	0.41	0.063
Liver	0.008[b]	0.006[b]	0.021	0.07	0.07	0.035	0.007
Kidney	0.01[b]	0.007[b]	0.074[b]	0.073[b]	0.074	0.037	0.009

[a] Mean values; comprises pyraclostrobin and metabolite 500M07
[b] Comprises pyraclostrobin and metabolite 500M07 at the lower dose for liver and at both doses for kidney

Maximum residue levels

On the basis of the estimated residue levels at the calculated dietary burdens, the Meeting recommended a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for milk.

The Meeting recommended a maximum residue level of 0.5 mg/kg for meat (fat) of mammals other than marine mammals and for edible offal, an STMR of 0.008 mg/kg and a highest reside level of 0.037 mg/kg for edible offal, an STMR of 0.009 mg/kg and a highest reside level of 0.044 mg/kg for muscle, and an STMR of 0.063 mg/kg and a highest reside level of 0.41 mg/kg for fat.

No feeding study was performed in chickens. The Meeting noted that in the study of metabolism in laying hens, pyraclostrobin was not detected in tissues (< 0.002 mg/kg) or eggs (< 0.002 mg/kg) at a feeding level of 12 mg/kg, which was 30 times higher than the calculated dietary burden (0.27 ppm).

The Meeting agreed that it is unlikely that pyraclostrobin residues will be detected in the products of poultry fed commodities treated with this compound. The Meeting estimated a maximum residue level of 0.05* mg/kg and STMR and highest reside level values of 0 for pyraclostrobin in eggs, meat (fat) and edible offal of poultry.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of pyraclostrobin calculated on the basis of the recommendations made at th present Meeting for the five GEMS/Food regional diets represented 0–3% of the ADI (0–0.03 mg/kg per day in a 2-year study in rats).

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

Short-term intake

The IESTI of pyraclostrobin calculated on the basis of the recommendations made at the present Meeting represented 0–90% of the ARfD (0–0.05 mg/kg per day in a study on developmental toxicity in rabbits) for children and 0–40% of the ARfD for the general population.

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

4.27 SPICES

RESIDUE AND ANALYTICAL ASPECTS

The issue of setting maximum residue levels for spices on the basis of the results of monitoring was discussed by the CCPR on several occasions. The 2002 JMPR prepared guidelines for the format of submission of monitoring data for evaluation (ALINORM 02/24). At its Thirty-sixth Session, the CCPR proposed to divide the commodity group 028 into subgroups on the basis of the part of the plant from which they are obtained (seeds, fruits or berries, roots or rhizomes, bark, buds, arils and flower stigmas) and proposed that maximum residue levels for pesticides that had been evaluated within the Codex system should be set for the subgroups instead of for each pesticide–spice combination (ALINORM 04/24, para 236). Furthermore, the maximum residue levels for dry chili peppers should be set on the basis of the existing maximum residue levels for peppers, taking into account the processing and dehydration factors as appropriate (ALINORM 04/24, para 242).

The Government of India, through the Indian Spice Board, the American Spice Trade Association, the European Spice Association and the Government of Egypt provided data resulting from pesticide monitoring programmes on spices during the period 1996–2003. The Delegation of South Africa coordinated the compilation of data for submission to the JMPR.

The JMPR reviewed the residue monitoring data provided and estimated maximum residue levels for the spice subgroups. The residue data on cumin from Egypt indicated that several pesticides might be applied post-harvest. Similarly, the residue levels of malathion and profenofos on anise seed were much higher than those of other pesticides, indicating possible post-harvest use of malathion and profenofos. The Meeting concluded that post-harvest use of pesticides on spices should be regulated by national governments, and monitoring data should not be used for estimating maximum residue levels reflecting post-harvest use. Consequently, the results of residue trials that suggested post-harvest use were not included in the 2004 evaluation.

The Meeting emphasized that the fact that it has estimated maximum, median and high residue values does not mean that it has approved use of the compounds on spices and chili peppers.

The Meeting noted that poppy seed (SO 698), mustard seed (SO 90) and sesame seed (SO700) are used as major food ingredients in several countries. It therefore considered it more appropriate to keep them in the oil seeds group (A023) and to remove them from group A028. The recommended maximum residue levels for the seed subgroup of spices does not include these seeds.

The large number of residue values for some pesticide–commodity combination allowed proper statistical treatment of the monitoring data. The principles applied are discussed in detail under section 2.6 of the General Considerations.

In addition, the following major principles were followed in evaluating the residue data for estimation of maximum, median and high residue values:

- All the residue data were considered; no data point was excluded as an outlier.
- Residue values reported as '0' were replaced by 'below the limit of quantification' (LOQ).
- Maximum, median and high residue levels were recommended when the database allowed estimation of > 95th percentile of the residue population at a 95% confidence (probability) level. That required a minimum of 58–59 samples. Use of the 95% confidence interval is recommended, as it is used for estimating the variability factor in short-term exposure assessment and is generally applied in biometry.
- As very few data were available for commodities derived from bark, buds, arils and flower stigmas, these spices are summarized together in the tables. Maximum residue levels could be estimated in only a few cases
- When residues were detectable, estimation of the maximum residue level for the subgroup also took into account the number of residue data and residue levels for the particular pesticide–commodity combination.
- A maximum residue level was proposed at the limit of determination when no residues were detectable, even if the minimum sample requirements (59) was not met for satisfying the specified probability (> 95th percentile) and confidence (95%) interval for any subgroup.
- When residues were undetectable and different LOQ values were reported for a particular pesticide from the different data sources, the maximum residue level was proposed at the highest LOQ provided for the pesticide. As there was no evidence for nil residues, the median was calculated from the values corresponding to the reported LOQs. The high residue level was considered to be equal to the highest reported LOQ. Addition of * after a residue value does not necessarily indicate that residues will not occur in detectable amounts if a more sensitive method is used.
- The estimated median and high residue values can be used in the same way as the STMR and highest residue values obtained from supervised trials for estimating long-term and short-term intake of residues.
- A substantial proportion of random samples did not contain detectable residues, indicating that the sampled lots had probably not been treated with or exposed to the given pesticide. Therefore, the median residue values were derived from the detected residue levels. Long-term intake was calculated from the residue data for that commodity that made the largest contribution to intake and the percentage of the treated proportion of that crop.
- When no residues were detected, the median level of residues was taken as equivalent to the median LOQ, as a conservative estimate.
- The short-term intake calculations were performed with the highest residue value for the pesticide measured in any spice sample, after the necessary adjustments for consumption figures described in the evaluation.

Sampling and analytical methods

The samples were taken from randomly selected lots either before export or upon arrival in the importing country. No information was provided on the sampling procedures, the size or the mass of samples.

The samples were analysed by multi-residue procedures, resulting in average recoveries of 70–120%, with the exception of ethion, with a recovery of 150%. The LOQs ranged from 0.01 mg/kg to 0.5 mg/kg. The difference in the LOQ values reported by different laboratories was sometimes 10-fold. Data on the reproducibility of methods and other performance parameters were provided in only a few cases.

Results of monitoring studies

Acephate

The 225 samples analysed comprised seeds (79), fruits or berries (77), roots or rhizomes (42) and bark, buds and arils (27). All the results were below the LOQ: 0.2 mg/kg for data from the American Spice Trade Association and India and 0.02 mg/kg for data from the European Spice Association, regardless of the subgroup in which the spices were classified.

The Meeting estimated a maximum residue limit of 0.2 (*) mg/kg and median and high residue values of 0.2 mg/kg for spices.

As none of the samples contained detectable residues, no factor can be introduced into calculations of long-term intake to take into account the proportion of samples containing detectable residues.

Azinphos-methyl

The 260 samples analysed comprised seeds (86), fruits or berries (92), roots or rhizomes (46) and bark, buds and arils (36).

All the results were below the limit of determination: 0.5 mg/kg for data from the American Spice Trade Association and India and 0.1 mg/kg for data from the European Spice Association.

The Meeting estimated a maximum residue level of 0.5 (*) mg/kg, a median residue level of 0.1 mg/kg and a high residue level of 0.5 mg/kg for spices.

As none of the samples contained detectable residues, no factor can be introduced into calculations of long-term intake to take into account the proportion of samples containing detectable residues.

Chlorpyrifos

The 2632 samples analysed comprised seeds (2165), fruits or berries (155), roots or rhizomes (270) and bark, buds and arils (42). The LOQ was 0.05 mg/kg in all data sources.

Detectable residues were found in celery seed, coriander and cumin. The levels, in ranked order, were: 0.12, 0.15, 0.16, 0.18, 0.25, 0.26, 0.41, 0.44, 0.54 and 0.54 mg/kg. Detectable residues were found in one of 18 samples of anise seeds in Canada and 78 of 744 samples in Egypt. The levels found were, in ranked order: 0.01 (two), 0.05 (12), 0.06 (seven), 0.07 (eight), 0.08 (nine), 0.09 (four), 0.1 (two), 0.11 (three), 0.13 (six), 0.14 (six), 0.15, 0.17 (two), 0.18, 0.21 (three), 0.22, 0.23, 0.32, 0.33, 0.36, 0.5 (two), 0.54, 0.9, 1.8, 2, 3 and 3.6 mg/kg. For fennel, 1228 samples were analysed, and 18 contained detectable residues. The levels, in ranked order, were: 0.05 (two), 0.06, 0.07, 0.08, 0.1 (two), 0.11 (five), 0.13, 0.14, 0.15, 0.22 (two) and 1.4 mg/kg.

The Meeting concluded that the levels of residues in seeds are comparable and estimated a maximum residue level of 5 mg/kg, a median residue level of 0.09 mg/kg and a high residue level of 3.6 mg/kg (based on residue data for anise seed) for the seed subgroup of spices.

Detectable residues were measured in cardamom and pepper in the fruit subgroup, at levels, in ranked order, of: 0.05 (two), 0.06, 0.07, 0.08, 0.11, 0.20, 0.54 and 0.71 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a median residue level of 0.05 mg/kg and a high residue level of 0.71 mg/kg for the fruit subgroup.

Detectable residues were found in ginger and turmeric in the roots subgroup, at levels, in ranked order, of: 0.05, 0.13, 0.24, 0.28, 0.31, 0.37 and 0.72 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a median residue level of 0.05 mg/kg and a high residue level of 0.72 mg/kg for the roots subgroup.

Detectable residues were found (> 0.05 mg/kg) in the subgroups of bark, buds and arils in three studies. As only 42 measurements were available, however, maximum residue levels could not be estimated for these subgroups.

The Meeting recommended use of a high residue level of 3.6 mg/kg for calculation of short-term intake, and a median residue level of 0.09 mg/kg and a factor of 0.1 to take into account the proportion of samples containing detectable residues for calculating long-term intake.

Chlorpyrifos-methyl

The 1822 samples analysed comprised seeds (1432), fruits or berries (80), roots or rhizomes (142) and bark, buds and arils (25). The LOQ was 0.05 mg/kg in all data sources.

Detectable levels of residues were found in 68 of 983 samples of anise seed, one of 49 samples of celery seed (0.01 mg/kg), one of 19 samples of coriander (0.01 mg/kg) and four of 345 samples of fennel (0.07, 0.08, 0.12 and 0.16 mg/kg). The combined residue levels were, in ranked order: 0.02 (two), 0.05 (two), 0.06 (four), 0.07 (three), 0.08 (seven), 0.09 (eight), 0.1 (five), 0.11, 0.12 (three), 0.13 (three), 0.14, 0.15 (two), 0.16 (five), 0.17, 0.18 (two), 0.19, 0.2 (two), 0.22 (three), 0.24 (two), 0.25, 0.28, 0.3, 0.31, 0.32, 0.38 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.39 mg/kg and a median residue level of 0.05 mg/kg for the seed subgroup of spices.

Three of 156 samples of caraway contained detectable residues, at: 0.06, 0.1 and 0.12 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, a high residue level of 0.12 mg/kg and a median residue level of 0.1 mg/kg for the fruits subgroup of spices.

Detectable residues were found in ginger and turmeric in the roots subgroup, at levels, in ranked order, of: 0.013 (12), 0.017, 0.03 (two), 0.031, 0.034 (two), 0.037, 0.038, 0.05, 0.06, 0.07, 0.071, 0.073, 0.082, 0.089, 0.091, 0.098, 0.14 (three), 0.16, 0.29, 0.39 and 2.9 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 2.9 mg/kg and a median residue level (on the basis of data for ginger) of 0.77 mg/kg for the roots subgroup.

Lack of sufficient data prevented estimation of maximum residue levels for the bark, buds and arils subgroups.

The Meeting recommended use of a high residue level of 2.9 mg/kg for calculating short-term intake, and a median residue level of 0.77 mg/kg and a factor of 1 to take into account the proportion of samples containing detectable residues for calculating long-term intake.

Cypermethrin

The 174 samples analysed comprised seeds (38), fruits or berries (65), roots or rhizomes (58) and bark, buds and arils (13). The LOQ was 0.05 mg/kg in all data sources.

Commodities in the seed subgroup contained detectable residues at levels of 0.076–0.93 mg/kg.

One of 57 samples of pepper contained detectable residues (0.065 mg/kg), but none were found in eight samples of other commodities in the fruits subgroup. The Meeting estimated a maximum residue level of 0.1 mg/kg, a high residue level of 0.05 mg/kg and a median residue level of 0.05 mg/kg for the fruits or berries subgroup of spices.

Three of 58 samples of commodities in the subgroup of roots or rhizomes contained detectable residues, at levels of: 0.05, 0.11 and 0.12 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a high residue level of 0.12 mg/kg and a median residue level of 0.11 mg/kg for roots or rhizomes.

The limited database was considered insufficient for estimating maximum residue levels for the other subgroups.

The Meeting recommended use of a high residue level of 0.12 mg/kg for calculating short-term intake, and a median residue level of 0.11 mg/kg and a factor of 0.04 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Diazinon

The 1948 samples analysed comprised seeds (1559), fruits or berries (115), roots or rhizomes (234) and bark, buds and arils (40). The LOQ was 0.1 mg/kg for the data from the American Spice Trade Association and India and 0.05 mg/kg for those from Egypt and Europe.

The residue levels in spices from fruits and from bark, buds and arils were below the LOQ (0.1 mg/kg).

Detectable residues were found in 69 of 667 samples of anise, at levels, in ranked order, of: 0.05, 0.06 (four), 0.07, 0.08 (two), 0.09 (three), 0.1 (two), 0.11, 0.12 (two), 0.13, 0.14 (four), 0.15 (three), 0.16 (two), 0.17 (four), 0.18 (two), 0.19 (three), 0.21, 0.22, 0.24, 0.28, 0.3, 0.32 (two), 0.33 (two), 0.35, 0.37, 0.39, 0.41, 0.42 (two), 0.47, 0.473, 0.48, 0.51, 0.59, 0.6, 0.82, 0.88, 0.9, 1.1 (two), 1.2, 1.3, 1.8 (two), 2.1, 2.7, 3.5 and 3.6 mg/kg. Detectable residues were found in 31 of 734 samples of fennel seed, at levels, in ranked order, of: 0.05 (two), 0.06 (three), 0.07 (three), 0.08 (two), 0.1 (three) 0.12, 0.17 (two), 0.19, 0.2, 0.21, 0.23, 0.24 (two), 0.26, 0.45, 0.59, 0.65, 0.72, 0.76, 0.77, 1.2 and 1.7 mg/kg. Detectable residues were measured in celery and cumin seeds at levels of 0.1 (two), 0.14 and 0.29 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.6 mg/kg and a median residue level (on the basis of data on anise seed) of 0.19 mg/kg for the seed subgroup.

Detectable residues were measured in two samples of turmeric, at levels of 0.23 and 0.26 mg/kg. No residues were measured in fruit and rhizome spices.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.26 mg/kg and a median residue level of 0.05 mg/kg for the roots or rhizomes subgroup of spices, and a maximum residue level of 0.1 (*) mg/kg, a high residue level of 0.1 mg/kg and a median residue level of 0.05 mg/kg for fruits. No recommendation could be made for the bark, buds and arils subgroups.

The Meeting recommended use of a high residue level of 3.6 mg/kg for calculating short-term intake, and a median residue level of 0.19 mg/kg and a factor of 0.1 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Dichlorvos

The 277 samples analysed comprised seeds (100), fruits or berries (93), roots or rhizomes (48) and bark, buds and arils (36).

The residue levels in all samples were below the LOQ (0.1 mg/kg). The Meeting estimated a maximum residue level of 0.1 (*) mg/kg and high and median residue levels of 0.1 mg/kg for residues of dichlorvos on all spices.

As none of the samples contained detectable residues, no factor can be used in long-term intake calculations to take into account the proportion of samples containing detectable residues.

Dicofol

The 416 samples analysed comprised seeds (67), fruits or berries (85), roots or rhizomes (230) and bark, buds and arils (34). The LOQ was 0.05 mg/kg for all data sources.

No residues were detected in the seeds subgroup. One of 42 pepper samples contained residue at the LOQ.

Detectable residues were found in ginger and turmeric in the roots subgroup, at levels, in ranked order, of: 0.02. 0.035, 0.036 and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.05 (*) mg/kg and high and median residue levels of 0.05 mg/kg for the seed subgroup, and a maximum residue level of 0.1 mg/kg and high and median residue levels of 0.05 mg/kg for the fruit, rhizomes and roots subgroups.

Four samples of spices in the bark, buds and arils subgroups contained residues at the LOQ (0.05 mg/kg). The data did not allow estimation of maximum residue levels for these subgroups.

The Meeting recommended use of a high residue level of 0.05 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.03 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Dimethoate

The 2613 samples analysed comprised seeds (2121), fruits or berries (381), roots or rhizomes (75) and bark, buds and arils (36).

Detectable residues were found in 61 of 744 samples of anise seeds at levels, in ranked order, of: 0.05 (three), 0.06 (five), 0.07 (three), 0.08 (two), 0.09 (two), 0.1 (two), 0.12 (three), 0.13 (three), 0.14, 0.15 (five), 0.17 (two), 0.18, 0.24 (two), 0.25 (four), 0.27 (two), 0.28 (two), 0.29, 0.29, 0.32, 0.35, 0.36, 0.39, 0.41, 0.42, 0.43, 0.44, 0.46, 0.53 (two), 0.57, 0.62, 0.9, 1.4, 2.5 and 3 mg/kg.

Detectable residues were found in 69 of 1284 samples of fennel at levels, in ranked order, of: 0.03, 0.05 (four), 0.06 (four), 0.07 (six), 0.08 (four), 0.09 (four), 0.1 (three), 0.11, 0.12, 0.13, 0.14 (three), 0.15 (four), 0.16, 0.18 (two), 0.2 (two), 0.21, 0.25 (two), 0.3, 0.32 (three), 0.33 (two), 0.34, 0.35, 0.37, 0.38 (two), 0.43 (two), 0.51 (four), 0.53 (two), 0.54, 0.94, 1.1 and 1.4 (two) mg/kg. Residues were not detected in the other seed samples (0.05–0.1 mg/kg).

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3 mg/kg and a median residue level of 0.17 mg/kg (on the basis of data on anise seed) for the seeds subgroup.

Five of 277 samples of caraway samples from Egypt contained residues, at levels of: 0.08, 0.17 (two) and 0.22 (two) mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.22 mg/kg and a median residue level of 0.05 mg/kg for the fruits subgroup.

No residue was detected in 75 samples of root and rhizome spices. The Meeting estimated a maximum residue level of 0.1 (*) mg/kg and high and median residue levels of 0.1 mg/kg for the roots and rhizomes subgroup.

No limits could be estimated for the bark, buds and arils subgroups.

The Meeting recommended use of a high residue level of 3 mg/kg for calculating short-term intake, and a median residue level of 0.17 mg/kg and a factor of 0.08 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Disulfoton

The 223 samples analysed comprised seeds (67), fruits or berries (66), roots or rhizomes (69) and bark, buds and arils (21).

As all the residue levels were below the LOQ (0.05 mg/kg), the Meeting estimated a maximum residue level of 0.05 (*) mg/kg and high and median residue levels of 0.05 mg/kg for disulfoton on spices. As none of the samples contained detectable residues, no factor could be used in calculating long-term intake to take into account the proportion of samples containing detectable residues.

Endosulfan

The 981 samples analysed comprised seeds (331), fruits or berries (208), roots or rhizomes (401) and bark, buds and arils (41). The LOQ was 0.03 mg/kg for the trials reported by the American Spice Trade Association and India and 0.1 mg/kg for data from Europe.

Data were provided for α-endosulfan, β-endosulfan, endosulfan sulfate, as well as for total endosulfan residues. The maximum residue levels were estimated on the basis of the results of monitoring for total endosulfan residues.

In the seeds subgroup, detectable residues were measured in celery seed, coriander and dill seed, at levels in ranked order of: 0.035 (two), 0.04, 0.1 (11), 0.12, 0.14, 0.20, 0.34, 0.45 and 0.63 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.63 mg/kg and a median residue level of 0.03 mg/kg for the seeds subgroup of spices.

In the fruits subgroup, detectable residues were measured in cardamom and pepper, at levels in ranked order of: 0.03, 0.04, 0.075, 0.08, 0.09 (four), 0.10, 0.11, 0.12 (three), 3.1 and 3.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.2 mg/kg and a median residue level of 0.12 mg/kg (on the basis of data for pepper) for the fruits subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric at levels, in ranked order, of: 0.04 (two), 0.06, 0.08, 0.1 and 0.24 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.24 mg/kg and a median residue level of 0.1 mg/kg for the subgroup roots or rhizomes.

The 41 samples in the bark, buds and arils subgroups did not contain detectable residues (< 0.1 mg/kg).

The Meeting recommended use of a high residue level of 3.2 mg/kg for calculating short-term intake, and a median residue level of 0.12 mg/kg and a factor of 0.05 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Ethion

The 754 analysed comprised seeds (190), fruits or berries (155), roots or rhizomes (367) and bark, buds and arils (42). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India and 0.05 mg/kg for data from the European Spice Association.

In the seeds subgroup, detectable residues were measured in anise, coriander and cumin at levels, in ranked order, of 0.11, 0.13, 0.21 and 1.8 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.8 mg/kg and a median residue level of 0.1 mg/kg for the seeds subgroup of spices.

In the fruits subgroup, detectable residues were measured in cardamom and pepper (black, white and pink) at levels, in ranked order, of 0.12, 0.33 and 3.1 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.1 mg/kg and a median residue level of 1.7 mg/kg (on the basis of data on pepper) for the fruits subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger, at levels of 0.11 and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, a high residue level of 0.15 mg/kg and a median residue level of 0.05 mg/kg for the roots or rhizomes subgroup of spices.

The 42 samples in the bark, buds and arils subgroups did not contain detectable residues (< 0.05–< 0.1 mg/kg)

The Meeting recommended use of a high residue level of 3.1 mg/kg for calculating short-term intake, and a median residue level of 1.7 mg/kg and a factor of 0.02 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Fenitrothion

The 2424 samples analysed comprised seeds (1920), fruits or berries (230), roots or rhizomes (234) and bark, buds and arils (40). The limit of determination was 0.1 mg/kg for data from the American Spice Trade Association and India, and 0.05 mg/kg for data from Egypt and the European Spice Association.

Detectable residues were found in 22 of 756 samples of anise seeds in Egypt, at levels of: 0.05, 0.08 (two), 0.1, 0.12 (two), 0.13, 0.15, 0.25, 0.4 (two), 0.41 (two), 0.87, 0.88, 1 (three), 1.4 (two), 2 and 5.4 mg/kg. No residues was detected in 18 samples from other sources (< 0.1 mg/kg). Detectable residues were measured in celery seed, cumin and coriander at levels of 0.17, 0.19 and 1.5 mg/kg, respectively.

The Meeting estimated a maximum residue level of 7 mg/kg, a high residue level of 5.4 mg/kg and and a median residue level of 0.4 mg/kg (on the basis of data for anise seed) for the seed subgroup of spices.

Detectable residues were measured in caraway in the fruit subgroup, at levels of: 0.05, 0.1, 0.12, 0.22 and 0.4 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.4 mg/kg and a median residue level of 0.05 mg/kg for the fruit subgroup of spices.

All the samples in the root subgroup of spices contained residues at levels below the LOQ. The Meeting estimated a maximum residue level of 0.1 (*) mg/kg, a high residue level of 0.1 mg/kg and a median residue level of 0.05 mg/kg for the root subgroup of spices.

All samples in the bark, buds and arils subgroups contained residues at levels below the LOQ. The database did not allow estimation of a maximum residue level.

The Meeting recommended use of a high residue level of 5.4 mg/kg for calculating short-term intake, and a median residue level of 0.4 mg/kg and a factor of 0.03 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Iprodion

The 339 samples analysed comprised seeds (93), fruits or berries (38), roots or rhizomes (192) and bark, buds and arils (16). The LOQ was 0.05 mg/kg in all the data sources.

No residues were detectable in seeds. The Meeting estimated a maximum residue level of 0.05 (*) mg/kg and high and median residue levels of 0.05 mg/kg for the seed subgroup of spices.

One of 92 samples of ginger contained residue at the LOQ level (0.05 mg/kg). The Meeting estimated a maximum residue level of 0.1 mg/kg and high and median residue levels of 0.05 mg/kg for the root subgroup of spices.

Detectable residues were also found in the other subgroups, but the database was insufficient for estimating maximum residue levels.

The Meeting recommended use of a high residue level of 0.05 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.01 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Malathion

The total number of samples analysed (581) included seeds (185), fruits or berries (115), roots or rhizomes (234) and bark, buds and arils (47). The limit of determination was 0.1 mg/kg for data from American Spice Trade Association and India, and 0.05 mg/kg for data from Egypt and the European Spice Association.

In the seed subgroup, detectable residues were measured in anise, celery seed, cumin, fennel seed and nutmeg. The levels, in ranked order, were: 0.16 (four), 0.18, 0.22, 0.32, 0.38, 0.48, 0.58 and 0.86 mg/kg. As the data from Egypt indicated post-harvest use, they were not taken into consideration.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 0.86 mg/kg and a median residue level of 0.48 mg/kg (on the basis of data on celery seed) for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured in three of 66 samples of pepper, at levels of 0.1, 0.42 and 0.48 mg/kg, and in 17 of 307 samples of caraway at levels of: 0.1, 0.3, 0.05 (two), 0.06 (two), 0.07 (four), 0.09 (two), 0.19, 0.26, 0.31, 0.33 and 0.46 mg/kg. The combined residue levels, in ranked order, were: 0.1, 0.3, 0.05 (two), 0.06 (two), 0.07 (four), 0.09 (two), 0.1, 0.19, 0.26, 0.31, 0.33, 0.42, 0.46 and 0.48 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.48 mg/kg and a median residue level of 0.05 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric, at levels of 0.1, 0.12 and 0.16 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.16 mg/kg and a median residue level of 0.05 mg/kg for the root or rhizome subgroup of spices.

The ranked order of the detectable residue levels in 47 samples from the bark, buds and arils subgroups was: 0.1 (four), 0.12, 0.14, 0.3, 0.48, 0.96, 1.02, 1.04, 1.88, 1.96 and 2 mg/kg.

The Meeting considered that the database was insufficient for estimating maximum residue levels.

The Meeting recommended use of a high residue level of 0.86 mg/kg for calculating short-term intake, and a median residue level of 0.48 mg/kg and a factor of 0.06 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Metalaxyl

The 1306 samples analysed in Egypt comprised anise seeds (411) and fennel seeds (895). The LOQ was 0.05 mg/kg.

Six of 411 samples of anise seeds contained detectable residues, at levels of: 0.2, 0.22, 0.4, 0.47, 0.64 and 0.65 mg/kg. Four of 895 samples of fennel contained detectable residues, at levels of: 0.17, 0.29, 0.4 and

3.2 mg/kg. The combined residue levels, in ranked order, were: 0.17, 0.2, 0.22, 0.29, 0.4 (two), 0.47, 0.64, 0.65 and 3.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.2 mg/kg and a median residue level of 0.43 mg/kg for the seed subgroup of spices.

For calculation of long-term intake, the Meeting recommended use of a correction factor of 0.015 to take into account the proportion of samples containing detectable residues.

Methamidophos

The 260 samples analysed comprised seeds (96), fruits or berries (92), roots or rhizomes (46) and bark, buds and arils (36). All the residue levels were below the limit of determination (0.1mg/kg for data from the American Spice Trade Association and India and 0.01 mg/kg for data from the European Spice Association). The data on cumin from Egypt, which indicated post-harvest use, were not taken into consideration.

The Meeting estimated a maximum residue level of 0.1 (*) mg/kg, a high residue level of 0.1 mg/kg and a median residue level of 0.01 mg/kg for spices.

Mevinphos

The 554 samples analysed comprised seeds (158), fruits or berries (114), roots or rhizomes (232) and bark, buds and arils (40). The LOQ was 0.2 mg/kg for data from the American Spice Trade Association and India, and 0.05 mg/kg for data from the European Spice Association.

In the seed subgroup, detectable residues were measured in celery seed at 2.9 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 2.9 mg/kg and a median residue level of 0.05 mg/kg (on the basis of data on celery seed) for the seed subgroup of spices.

In the fruit subgroup, no detectable residues were measured. The Meeting estimated a maximum residue level of 0.2 (*) mg/kg, a high residue level of 0.2 mg/kg and a median residue level of 0.05 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric. The levels, in ranked order, were: 0.2, 0.21, 0.22, 0.24, 0.27, 0.3, 0.31, 0.34, 0.37, 0.39, 0.4, 0.41 and 0.47 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.47 mg/kg and a median residue level of 0.31 mg/kg for the root or rhizome subgroup of spices.

The 40 samples from bark, buds and arils did not contain detectable residues (< 0.2 mg/kg). The database did not allow estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 2.9 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.02 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Parathion

The 329 samples analysed comprised seeds (114), fruits or berries (105), roots or rhizomes (74) and bark, buds and arils (36). The LOQ was 0.1 mg/kg for all data sources.

Seed spices did not contain detectable residues. The Meeting estimated a maximum residue level of 0.1 (*) mg/kg and high and median residue levels of 0.1 mg/kg for the seed subgroup of spices.

One sample of pepper and one sample in the root and rhizome subgroup contained residues at the LOQ. The Meeting estimated a maximum residue level of 0.2 mg/kg and high and median residue levels of 0.1 mg/kg for the fruit and the root and rhizome subgroups of spices.

Three samples in the bark subgroup contained residues at the LOQ, indicating that detectable residues might occur in these commodities. The database was insufficient for estimating maximum residue levels.

The Meeting recommended use of a high residue level of 0.1 mg/kg for calculating short-term intake, and a median residue level of 0.1 mg/kg and a factor of 1 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Parathion-methyl

The 821 samples analysed comprised seeds (359), fruits or berries (155), roots or rhizomes (265) and bark, buds and arils (42). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India and 0.05 mg/kg for data from Egypt and the European Spice Association.

In the seed subgroup, detectable residues were measured in anise, celery seed, coriander, cumin and fennel seed. The levels, in ranked order, were: 0.1, 0.13, 0.14, 0.16, 0.2, 0.21, 0.23, 0.24 (two), 0.31, 0.33, 0.36, 0.37, 0.38, 0.43, 0.51, 0.86, 0.97, 1.1, 1.2 and 2.4 (two) mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 2.4 mg/kg and a median residue levels of 0.43 mg/kg (on the basis of data on cumin seed) for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured in pepper at levels of 0.1 and 3.4 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.4 mg/kg and a median residue level of 0.1 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric. The levels, in ranked order, were: 0.1, 0.13, 0.14 (two), 0.17, 0.24, 0.3, 1.2 (two), 1.5 and 1.7 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.7 mg/kg and a median residue level of 0.24 mg/kg for the root or rhizome subgroup of spices.

Three of the 42 samples from the bark, buds and arils subgroups contain detectable residues at the LOQ (< 0.1 mg/kg) The database did not allow estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 3.4 mg/kg for calculating short-term intake, and a median residue level of 0.43 mg/kg and a factor of 0.25 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Permethrin

A total of 160 samples of various spices, including 68 seeds, were analysed for residues of permethrin. No residues were detected. The Meeting estimated a maximum residue level of 0.05 (*) mg/kg and high and median residue levels of 0.05 mg/kg.

As none of the samples contained detectable residues, no factor can be used in calculating long-term intake to take into account the proportion of samples containing detectable residues.

Phenthoate

Ten of 415 samples of anise seed contained detectable residues, at levels of: 0.05, 0.19, 0.49, 1.1 (two), 1.3, 1.4 (two), 5 and 5.2. The LOQ was 0.05 mg/kg.

The Meeting estimated a maximum residue level of 7 mg/kg, a high residue level of 5.2 mg/kg and a median residue level of 1.2 mg/kg for the seed subgroup of spices.

For the calculation of long-term intake, the Meeting recommended use of a correction factor of 0.024 to take into account the proportion of samples containing detectable residues.

Phorate

The 336 samples analysed comprised seeds (115), fruits or berries (117), roots or rhizomes (75) and bark, buds and arils (29). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India, and 0.05 mg/kg for data from the European Spice Association.

Of the samples analysed, only two of cumin showed detectable residues of phorate, at 0.12 and 0.3 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.3 mg/kg and a median residue level of 0.21 mg/kg for the seed subgroup of spices, and a maximum residue level of 0.1 (*) mg/kg and high and median residue levels of 0.1 mg/kg for the fruit and the root and rhizome subgroups. The data were insufficient for estimating maximum residue levels for the other subgroups.

The Meeting recommended use of a high residue level of 0.3 mg/kg for calculating short-term intake, and a median residue level of 0.21 mg/kg and a factor of 0.06 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Phosalone

The 607 samples analysed comprised seeds (176), fruits or berries (80), roots or rhizomes (226) and bark, buds and arils (25). The origin of the samples was not given in several cases. The LOQ was 0.05 mg/kg for all data sources.

Samples of anise, celery and cumin contained detectable residues at levels of 0.1, 0.95 and 0.25 mg/kg, respectively.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 0.95 mg/kg and a median residue level of 0.25 mg/kg for the seed subgroup of spices.

Three of 44 samples of pepper contained detectable residues, at levels of 0.05, 0.85 and 0.89 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 0.89 mg/kg and a median residue level of 0.85 mg/kg for the fruit subgroup of spices.

Detectable residues were found in ginger and turmeric in the root subgroup. The levels, in ranked order, were: 0.05, 0.14, 0.22, 0.27, 0.31, 0.4, 0.49, 0.5 and 1.49 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.49 mg/kg and a median residue level of 0.31 mg/kg for the root and rhizome subgroup.

Residues were also detected in spices in the bark, buds and arils subgroups. The data available were, however, insufficient to allow estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 1.5 mg/kg for calculating short-term intake, and a median residue level of 0.85 mg/kg and a factor of 0.07 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Pirimicarb

In Egypt, 129 of 484 samples of anise seed and 54 of 824 samples of fennel seed contained detectable residues, at levels of: 0.05 (11), 0.06 (22), 0.07 (nine), 0.08 (nine), 0.09 (14), 0.1 (11), 0.12 (six), 0.13 (seven), 0.14 (eight), 0.15 (seven), 0.16 (six), 0.17 (four), 0.18 (three), 0.19 (two), 0.2 (three), 0.22 (five), 0.23, 0.24, 0.26, 0.27 (three), 0.28 (four), 0.29 (two), 0.31, 0.33 (three), 0.34 (two), 0.35, 0.37 (two), 0.38, 0.39, 0.41, 0.42 (two), 0.43, 0.44, 0.45, 0.47 (two), 0.53 (two), 0.54 (two), 0.58 (two), 0.59 (two), 0.6 (two), 0.64, 0.67, 0.69, 0.7 (two), 0.8, 0.84, 0.93, 0.94, 1.2, 1.4 (two), 1.5 and 3 mg/kg. The LOQ was 0.05 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3 mg/kg and a median residue level of 0.14 mg/kg for the seed subgroup of spices.

For the calculation of long-term intake, the Meeting recommended use of a correction factor of 0.27 to take into account the proportion of samples containing detectable residues.

Pirimiphos-methyl

The 1314 samples analysed comprised seeds (1137), fruits or berries (94), roots or rhizomes (47) and bark, buds and arils (36). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India and 0.05 mg/kg for those from Egypt and Europe.

In the seed subgroup, detectable residues were measured in 16 of 492 samples of anise, at levels of: 0.05, 0.06, 0.07, 0.08, 0.12, 0.17, 0.18, 0.19, 0.27, 0.32, 0.47, 0.58, 0.6, 0.61, 0.63 and 1.8 mg/kg); in five of 556 samples of fennel, at levels of: 0.05, 0.07, 0.08, 0.1 and 0.11 mg/kg) and in one sample of nutmeg at 0.1 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.8 mg/kg and a median residue level of 0.23 mg/kg (on the basis of data for anise) for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured at the LOQ in cardamon (0.18 mg/kg) and pepper (0.1 mg/kg, two samples).

The Meeting estimated a maximum residue level of 0.5 mg/kg and high and median residue levels of 0.1 mg/kg for the fruit subgroup of spices.

Residues were also detected at the LOQ in one sample in the root subgroup and in the bark, buds and arils subgroups. The data were insufficient for estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 1.8 mg/kg for calculating short-term intake, and a median residue level of 0.23 mg/kg and a factor of 0.03 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Quintozene

The 550 samples analysed comprised seeds (163), fruits or berries (111), roots or rhizomes (236) and bark, buds and arils (40). The LOQ was 0.01 mg/kg for all data sources.

In the seed subgroup, detectable residues were measured in coriander, cumin, and fennel seed. The levels, in ranked order, were: 0.01 (two), 0.02 (two) and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a high residue level of 0.05 mg/kg and a median residue level of 0.01 mg/kg for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured at the LOQ in one sample of pepper and one of vanilla.

The Meeting estimated a maximum residue level of 0.02 mg/kg and high and median residue levels of 0.01 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric. The levels, in ranked order, were: 0.01, 0.04, 0.05 (two), 0.08 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 1.2 mg/kg and a median residue level of 0.05 mg/kg (on the basis of data on turmeric) for the root and rhizome subgroup of spices.

In the subgroup of bark, buds and arils, detectable residues were measured at the LOQ in cloves, cassia and cinnamon.

The database was insufficient for estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 1.2 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.035 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

Vinclozolin

The 442 samples analysed comprised seeds (110), fruits or berries (80), roots or rhizomes (227) and bark, buds and arils (25). The LOQ was 0.05 mg/kg for all data sources.

None of the sample contained detectable residues.

The Meeting estimated a maximum residue level of 0.05 (*) mg/kg and high and median residue levels of 0.05 mg/kg for spices.

As none of the samples contained detectable residues, no factor can be used in calculating long-term intakes to take into account the proportion of samples containing detectable residues.

Other pesticides

The results of monitoring were submitted for aldicarb, amitraz, bendiocarb, bifenthrin, captan, carbaryl, carbofuran, chlorothalonil, chlorpropham, cyfluthrin, demeton, dicloran, dicrotophos, diphenylamine, esfenvalerate, ethoprop, ethoxyquin, fenamiphos, fenarimol, fenpropathrin, fenthion, fenvalerate, folpet, imazalil, isophenphos, methoicarb, methomyl, myclobutanil, monocrotophos, *ortho*-phenylphenol, oxamyl, phosmet, phosphamidon, propiconazole, propoxur, pyrethrins, terbufos, thiabendazole, triadimefon, trichlorfon and triforin. The amount of data on residues did not, however, meet the minimum requirements for estimating maximum residue levels.

Estimation of maximum residue levels for pesticide residues in and on dry chili peppers

The database of the US Department of Agriculture indicates that the water content of various fresh peppers ranges from 88% to 94%. The average dehydration factor, derived on the basis of the assumption of complete loss of water, is 11.6. A similar approximate value (11.3) can be obtained by taking into account the water content of dried peppers. As dried peppers always contain 5–10% water, the rounded value of 10 used by the spice trade industry can be considered realistic for estimating the concentration of pesticide residues when it is assumed that all the residues present in fresh peppers remain in the dried peppers. As no processing studies were available, in accord with the request of the CCPR, the Meeting used the default value of 10 for estimating maximum residue levels for pesticide residues in dried chili peppers.

Further work or information

Before maximum residue levels can be estimated, additional data are required on residues in subgroups of spices for which insufficient data were available for evaluation by the present Meeting.

DIETARY RISK ASSESSMENT

The Meeting evaluated data on residues of 28 pesticides based on monitoring and estimated maximum reside levels for 47 pesticides in or on dried chili peppers on the basis of MRLs established for fresh sweet and chili peppers. The intakes of the pesticides from spices and chili were compared to existing ADI and ARfD values only; intakes arising from other uses of the compounds were not considered.

Details of the intake estimations are given in Annex 5 to this report.

4.28 SPINOSAD (203)

RESIDUE AND ANALYTICAL ASPECTS

Spinosad was first evaluated by the 2001 JMPR, which established an ADI of 0–0.02 mg/kg bw. An ARfD was judged to be unnecessary. MRLs were recommended for fruits, vegetables, nuts, oil seeds, cereal grains, animal feeds and animal commodities. Questions about the MRL for milk were raised by the CCPR at its Thirty-fifth and Thirty-sixth Sessions, and the JMPR was requested to consider further how MRLs for milk and milk fat should be expressed.

The Meeting received information on registered uses and data from supervised residue trials on grapes and stored grain. Information on direct uses of spinosad on sheep for control of blowfly and lice and supporting residue data were also received.

Methods of analysis

An immunoassay method previously evaluated by the 2001 JMPR was used in the supervised trials on grapes.

The analytical method used for analysis of spinosad residues in cereal grains and processed products was based on previously evaluated methods. Samples were extracted with acetonitrile and water and the extracts cleaned up on a strong cation-exchange column. Spinosyns A, D, K, B and *N*-demethyl D were eluted with dilute ammonium acetate in acetonitrile and methanol, ready for analysis by HPLC with mass selective detection. The LOQ was 0.01 mg/kg.

The analytical methods used for fat, muscle, liver, kidney and bovine milk were similar in principle to the above method, but with variations in clean-up depending on the substrate. The LOQ for milk was 0.005 mg/kg, and that for the other substrates was 0.01 mg/kg.

Results of supervised trials on crops

Grape

The Meeting received the results of supervised trials for use of spinosad on grapes in the USA. The samples were analysed by immunoassay method GRM 96.11, which was evaluated by the JMPR previously.

In the USA, spinosad may be applied to grapes at 0.14 kg ai/ha with a maximum seasonal application of 0.49 kg ai/ha and harvesting 7 days after the final application. In 12 trials in the USA that conformed

substantially to the registered use, the residue levels were: < 0.01, 0.02, 0.03, 0.05, 0.077, 0.082, 0.086, 0.13, 0.17, 0.22, 0.23 and 0.39 mg/kg.

The residue levels of spinosad in grapes in supervised trials in France, Italy and Spain are recorded in Table 39 (p. 761) of the JMPR Residue Evaluations for 2001. Spinosad may be used on grapes in Cyprus at 0.072 kg ai/ha with a PHI of 7 days. The conditions used in trials in France, Italy and Spain, where the application rate was 0.060 kg with a PHI of 5 days, were considered sufficiently similar to those of Cyprus GAP. The residue levels, determined by an HPLC method, in grapes in two trials in France (0.01 and 0.03 mg/kg), one trial in Italy (0.09 mg/kg) and one trial in Spain (0.19 mg/kg) were, in ranked order: 0.01, 0.03, 0.09 and 0.19 mg/kg. The levels in the same samples determined by the immunoassay method were: 0.02, 0.04, 0.15 and 0.24 mg/kg.

The Meeting combined the data from Europe and the USA obtained by the immunoassay method. The residue levels in the 16 trials, in ranked order, median underlined, were: < 0.01, 0.02 (two), 0.03, 0.04, 0.05, 0.077, <u>0.082</u>, <u>0.086</u>, 0.13, 0.15, 0.17, 0.22, 0.23, 0.24 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR value for spinosad in grapes of 0.084 mg/kg.

Fate of residues during storage

In a series of trials with cereal grain (barley, maize, oats, rice and wheat) in the USA, spinosad was applied to grain at a target rate of 1 g ai/t. Most of the trials were small-scale, only 18–23 kg grain being treated; in two larger trials, 9.9 t of maize and 30.9 t of wheat were treated. The duration of storage was 3–11 months at ambient temperatures. Samples were analysed by HPLC with mass spectromtery detection.

The residue levels in grain immediately after treatment represented 43–91% of the target application rate, reflecting the efficiency of application in the experiments. In the two larger trials, the initial residue levels were 77% and 87% of the target rates. The residue levels declined very slowly, if at all. The highest residue level in each trial was taken, whether at day 0 or after 11 months' storage. The trial in which a dose rate of 1.6 g ai/t was used was excluded as being outside GAP. The residue levels in the 20 trials were: 0.43, 0.45, 0.47, 0.58, 0.59, 0.63, 0.67, 0.69 (three), 0.70, 0.75, 0.79, 0.81, 0.86, 0.90, 0.91 (two), 0.93 and 0.95 mg/kg.

In three further trials in the USA in which wheat in storage batches of 135–225 t was treated at 1 g ai/t for storage and processing, the spinosad residue levels after 6 months' storage were 0.52, 0.73 and 0.79 mg/kg.

The residue levels in the 23 trials, in ranked order, were: 0.43, 0.45, 0.47, 0.52, 0.58, 0.59, 0.63, 0.67, 0.69 (three), <u>0.70</u>, 0.73, 0.75, 0.79 (two), 0.81, 0.86, 0.90, 0.91 (two), 0.93 and 0.95 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR for spinosad on cereal grains of 0.70 mg/kg on the basis of post-harvest use. The Meeting withdrew its previous recommendations for maize (0.01* mg/kg) and sorghum (1 mg/kg), to be replaced by the recommendation for cereal grains.

Fate of residues during processing

Three trials in France and one in Italy on processing of grapes to pomace and wine are summarized on pp. 823–824 of the JMPR Residue Evaluations of 2001.

In these trials, the levels of spinosad residues were below the LOQ (0.01 mg/kg) in all wine samples. As the residue levels in grapes were low (< 0.01–0.03 mg/kg), the best estimate of the processing factor for wine is < 0.33. Processing factors of 3.3 and 1.4 for juice and 1.6 for raisins produced from grapes were calculated in two trials in the USA. Juice was produced on a very small scale, with manual crushing, pressing and straining of about 1 kg of grapes, and this was not considered representative of a commercial process.

Processing studies on cereals were provided from the USA, comprising milling of maize (two trials), rice (two trials) and wheat (one trial) and three trials of wheat milling and baking. Spinosad residues were found essentially on the outside of the grain and were strongly concentrated in the aspirated grain fraction from the milling of maize and wheat. The residue levels in grits and flour were much lower than those in the grain. Most of the residues on rice remained with the husk and bran, with little occurring on white rice.

The following processing factors were calculated from the results of the trials. The factors are mean values, excluding those calculated from undetectable results, except for wine in which no residues were detected.

Commodity	Product	Processing factor	No. of trials
Grapes	Wine	< 0.33	4
	Raisins	1.6	1
Maize	Grits	0.082	2
	Flour	0.19	2
	Oil, dry milling	0.28	2
	Oil, wet milling	1.1	2
Rice	Hulls	2.8	2
	Bran	0.79	2
	Brown rice	0.11	2
	White rice	0.022	2
Wheat	Bran	2.0	4
	Shorts	1.2	4
	Flour	0.26	4
	Baked bread	0.14	3

The Meeting used the processing factors for wine, raisins and cereals to estimate STMR-Ps for processed commodities.

The processing factor for wine (< 0.33) was applied to the STMR for grape (0.084 mg/kg) to calculate an STMR-P of 0.028 mg/kg for wine.

The processing factor for raisins (1.6) was applied to the highest residue level in grapes (0.39 mg/kg) and the STMR for grape (0.084 mg/kg) to calculate a highest residue level of 0.62 mg/kg and an STMR-P of 0.13 mg/kg for raisins.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR-P value of 0.13 mg/kg for spinosad on dried grapes (currants, raisins and sultanas).

The processing factors for processed cereal fractions were applied to the STMR for cereal grains (0.70 mg/kg) to calculate the following STMR-P values: grits, 0.057 mg/kg; maize flour, 0.13 mg/kg; maize oil, 0.77 mg/kg; rice hulls, 2.0 mg/kg; rice bran, 0.55 mg/kg; brown rice, 0.077 mg/kg; white rice, 0.015 mg/kg; wheat bran, 1.4 mg/kg; wheat flour, 0.18 mg/kg; and white bread, 0.098 mg/kg.

The processing factor for wheat bran (2.0) was applied to the highest residue level in cereals grain (0.95 mg/kg) to calculate a highest residue level of 1.9 mg/kg for wheat bran.

The Meeting estimated a maximum residue level for spinosad on wheat bran of 2 mg/kg.

Residues in animal commodities

Direct treatment of animals

The Meeting received information on residue levels occurring in the tissues of sheep treated with spinosad in a plunge dip, by application of a pour-on formulation and by application of an aerosol to fly-strike wounds.

Sheep (25) were treated in a plunge dip containing 20 mg ai/l spinosad prepared from a 25 g/l suspension concentrate in a supervised trial in line with Australian guidelines and registered uses in Australia in 2000. Groups of animals were slaughtered for tissue collection on days 5, 15, 35, 49 and 63 after treatment. Samples were analysed by HPLC-MS after a conventional extraction and clean-up procedure evaluated by the 2001 JMPR. The highest levels of residues of spinosad in tissues 5 or 15 days after treatment were: 0.014 mg/kg in liver, 0.011 mg/kg in kidney, 0.011 mg/kg in muscle, 0.032 mg/kg in back fat and 0.094 mg/kg in peri-renal fat.

Two plunge dip trials on sheep in Australia were reported by the 2001 JMPR (Residue Evaluations, Table 73, pp. 813–814). The dip concentration was 10 mg ai/l. The highest tissue concentrations of spinosad residues were: < 0.01 mg/kg in liver, 0.014 mg/kg in kidney, < 0.01 mg/kg in muscle, 0.033 mg/kg in back fat and 0.042 mg/kg in peri-renal fat.

The data on residues from pour-on trials on sheep could not be evaluated because spinosad pour-on uses on sheep are not registered.

A spinosad aerosol spray is registered in Australia for treating fly-strike wounds on sheep. A typical wound of 200 cm^2 should take 6 s to treat. In a trial of the aerosol formulation in Australia in 2002, 14 sheep with fly-strike lesions measuring 108–1600 cm^2 were treated with spinosad according to the proposed label instructions and were slaughtered 2 and 7 days after treatment for tissue collection. The aerosol product contained 4 mg/g spinosad and 0.8 mg/g chlorhexidine digluconate (The registered product has 2.8 mg/g spinosad and 0.39 mg/g chlorhexidine digluconate.) and was delivered at a rate of 1.54 g of formulation per second. The animals were clipped around the fly-strike area, the area was measured and the dose was calculated at a rate of 1 s of aerosol spray per 40 cm^2 of affected area. The highest residue levels were: 0.04 mg/kg in liver, 0.03 mg/kg in kidney, 0.03 mg/kg in muscle, 0.14 mg/kg in back fat and 0.20 mg/kg in peri-renal fat.

The Meeting noted that the aerosol treatment resulted in higher residue levels in tissues than the plunge dip or the previously evaluated jetting treatment.

The Meeting estimated maximum residue levels for spinosad of 0.3 (fat) mg/kg in sheep meat and 0.1 mg/kg in edible offal of sheep.

Maximum residue levels

Spinosad residues can occur in meat and milk after direct use on animals or from residues in animal feeds.

The 2001 JMPR evaluated a feeding study with dairy cows, compiled a dietary burden for farm animals and estimated maximum residue levels of 2 mg/kg in cattle meat (fat), 0.5 mg/kg in cattle kidneyand 0.5 mg/kg in cattle liver It estimated STMRs of 0.32 mg/kg in cattle fat, 0.010 mg/kg in cattle meat, 0.032 mg/kg in cattle kidney and 0.064 mg/kg in cattle liver. These estimates for cattle commodities were superseded by estimates derived from direct treatment of cattle, which resulted in higher residue levels. The MRL recommendations associated with direct treatment of cattle were: 3 mg/kg (fat) in cattle meat, 1 mg/kg in cattle kidney and 2 mg/kg in cattle liver.

The 2002 JMPR[1] introduced a policy of recommending maximum residue levels for mammalian meat and offal rather than MRLs for cattle meat and offal when residues occurred in feed and a suitable study of cattle feeding was available. In the light of this policy, the Meeting recommended that the 2001 recommendations be reviewed.

The current Meeting proposed maximum residue levels for mammalian meat and offal based on the results of the feeding study in dairy cows and the corresponding dietary burden. None of the recommendations for MRLs by the current Meeting change the previously estimated dietary burden of spinosad residue in cattle. The MRLs for cattle meat, liver and kidney were retained because they are related to direct treatment, which produces higher residue levels than occur from feed. Therefore, the MRLs for mammalian meat and offal should have the qualification 'except cattle'.

The Meeting estimated a maximum residue level of 2 (fat) mg/kg for 'Meat (from mammals other than marine mammals) [except cattle]' and associated STMRs of 0.01 mg/kg for meat and 0.32 mg/kg for fat.

The Meeting estimated a maximum residue level of 0.5 mg/kg for 'Edible offal (mammalian) [except cattle]' and associated STMRs of 0.064 mg/kg for liver and 0.032 mg/kg for kidney.

The Meeting withdrew the current recommendations for sheep meat (0.01* (fat) mg/kg) and edible offal of sheep (0.01* mg/kg), which are superseded by the recommendations for mammalian meat and offal. The Meeting also noted that residue levels resulting from direct treatment of sheep by jetting, plunge dipping and aerosol treatment of wounds did not exceed the maximum residue levels resulting from feed residues. There is no separate MRL recommendation for sheep related to these direct uses.

The CCPR expressed concern about the MRL for spinosad in milk, the levels of spinosad in milk fat and how MRLs might best be expressed for partially fat-soluble compounds in milk. (See also general report item 2.7 on fat-soluble pesticide residues in milk.)

The 2001 JMPR reported that, after direct treatment of dairy cows with spinosad, residues were measured in 119 samples of milk and cream and that the mean quotient of the concentration in cream divided by the concentration in milk was 4.2. A plot of the same residue levels in whole milk against those in cream showed that the residue level in milk was approximately 24% of that in cream (line of best fit through the origin). (See figure in section 2.7.)

The levels of spinosad residues in milk and cream from a feeding study in dairy cows are summarized in Table 79 of the JMPR Residue Evaluations of 2001. The mean quotient of the concentration in cream divided by the concentration in milk from cows at feeding levels of 1, 3 and 10 ppm was 4.0, in good agreement with the results for direct treatment.

The MRL for milk (1 mg/kg) was estimated on the basis of the highest residue level in milk, 0.65 mg/kg, after direct treatment. The calculated concentration in cream would then be $0.65 \times 4.2 = 2.7$ mg/kg. On the assumption that cream is approximately 50% fat, the concentration in fat would be about 5 mg/kg.

The Meeting estimated a maximum residue level for spinosad residues in cattle milk fat of 5 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of spinosad resulted in recommendations for new MRLs and STMR values for raw and processed commodities. Data on consumption were available for 42 food commodities from this and previous evaluations and were used to calculate dietary intake. The results are shown in Annex 3.

[1] JMPR Report. 2002. 2.11. Maximum residue levels for animal commodities—group MRLs.

The IEDIs in the five GEMS/Food regional diets, based on estimated STMRs were 9-30% of the ADI (0-0.02 mg/kg bw). The Meeting concluded that long-term intake of residues of spinosad from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2001 JMPR concluded that it was unnecessary to establish an ARfD for spinosad. The Meeting therefore concluded that short-term dietary intake of spinosad residues is unlikely to present a risk to consumers.

4.29 TRIADIMENOL (168) AND TRIADIMEFON (133)

TOXICOLOGY

The toxicity of triadimenol ((1RS,2RS;1RS,2SR)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-ol), a triazole fungicide, was evaluated by the 1989 JMPR, when an ADI of 0–0.05 mg/kg bw was established based on a NOAEL of 5 mg/kg bw per day in a two-generation study in rats. As currently manufactured, triadimenol is an 80:20 mixture of the diastereoisomers A (1RS,2SR) and B (1RS,2RS). Older studies of toxicity in the database were performed with 60:40 mixtures.

Triadimefon is closely chemically related to triadimenol, with which it shares some similar metabolic pathways in animals. The toxicity of triadimefon ((RS)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-one) was evaluated by the JMPR in 1981, 1983 and 1985. An ADI of 0–0.03 mg/kg bw was established based on a NOAEL of 50 ppm, equivalent to 2.5 mg/kg bw per day, in a 2-year study in rats.

Although triadimenol and triadimefon are independent active ingredients, on the basis of their close chemical and toxicological relationship they were re-evaluated together by the present Meeting within the periodic review programme of the CCPR. Triadimenol and triadimefon act as fungicides by blocking fungal ergosterol biosynthesis. The mechanism of action of these fungicides is inhibition of demethylation.

Triadimenol

In rats, radiolabelled triadimenol is rapidly absorbed from the gastrointestinal tract, with radioactivity reaching peak concentrations in most tissues between 1 and 4 h after dosing. Up to 90% of the administered dose was excreted, with an elimination half-life for the radiolabel of between 6 and 15 h. Excretion was essentially complete within 96 h. After 5–6 days, radioactivity in most organs was below the limits of quantification.

Renal excretion accounted for up to 21% of the orally administered dose in males and up to 48% in females. The remainder was found in the faeces. In bile-duct cannulated males 93% of the administered dose was recovered in the bile and only 6% in the urine. Thus a substantial amount of the administered dose undergoes enterohepatic recycling. Radioactivity in expired air was negligible.

Triadimenol was extensively metabolized, predominantly by oxidation of one of the *t*-butyl methyl groups to give hydroxy or carboxy derivatives. The putative intermediate triadimefon has not been isolated. Cleavage of the chloro-phenyl and the triazole group was of minor significance. In the urine and faeces most of the metabolites were not conjugated, but in bile the metabolites were found to be extensively glucuronidated.

Triadimenol has low to moderate acute toxicity. The acute oral LD_{50} both in mice and rats was in the range of 700 to 1500 mg/kg bw, with increasing toxicity for increasing isomer ratios A (1RS,2SR):B (1RS,2RS). This finding was supported by an oral LD_{50} of 579 mg/kg bw for isomer A and 5000 mg/kg bw for isomer B tested separately. In rats, the dermal LD_{50} was > 5000 mg/kg bw and the LC_{50} upon inhalation was > 0.954 mg/l of air (after an exposure of 4 h).

Triadimenol is not an eye or skin irritant in rabbits and is not a sensitizer in the maximization test in guinea-pigs.

In short-term studies in mice, rats and dogs, the main effect of triadimenol was on the liver.

In a study comparing the 80:20 and 60:40 isomer mixtures, rats were treated for 28 days by gavage. Both isomer compositions slightly increased motor activity at ≥ 45 mg/kg bw per day and induced mixed function oxidase activity and reversibly increased liver weight at 100 mg/kg bw per day. In mice fed diets containing triadimenol at a concentration of 160 to 4500 ppm for 13 weeks, one out of ten males at 4500 ppm died. In both sexes at ≥ 1500 ppm, there were increased liver weights accompanied by increased alanine aminotransferase and aspartate aminotransferase activities. Reduced erythrocyte volume fraction and increased mean corpuscular haemoglobin concentration were observed in females at the highest dose. The NOAEL was 500 ppm, equal to 76.8 mg/kg bw per day.

In two 3-month feeding studies in rats, liver weights were increased at ≥ 600 ppm (< 10% at 600 ppm), with cellular hypertrophy at 3000 ppm. Liver enzyme activities in serum were not increased. In one study, at the highest dose of 2400 ppm, kidney and ovary weights were also increased. At the highest doses in both studies, there were slight changes in some haematology parameters. The lowest NOAEL after oral administration in the short-term studies in rats was 600 ppm, equal to 39.6 mg/kg bw per day. In a 3-week study in rats treated by inhalation, no effects were observed at up to the highest dose of 2.2 mg/l of air.

In a 3-week study in rabbits, dermal application of triadimenol did not cause any dermal or systemic reactions at the highest dose tested, 250 mg/kg bw per day.

In a 3-month, a 6-month and a 2-year study, dogs were given diets containing triadimenol at concentrations of up to 2400 ppm. The only significant findings were decreased body-weight gain at 2400 ppm, liver and kidney weight increases at the highest doses and increased P450 levels. The overall NOAEL was 600 ppm, equal to 21.1 mg/kg bw per day.

In two long-term studies, mice were given diets containing triadimenol at a concentration of up to 2000 ppm. In one study, Crl:CD-1(ICR)BR mice were kept for 80 weeks and in the other study CF_1/WF 74 mice were kept for 2 years. At 2000 ppm, reduced body-weight gains were recorded and liver weights were increased, as were testes weights in one study. Additionally, liver enzyme activity was higher. In one study, histopathological examination of the liver showed more basophilic foci at ≥ 80 ppm, predominantly in males, but there was a poor dose–response relationship and similar values have been reported in control groups in other studies. Hepatocellular hypertrophy and single cell necrosis were found at ≥ 400 ppm. At 2000 ppm, additional histopathological changes to the liver were reported. At the intermediate dose, 400 ppm, but not at the highest dose, males had slightly more liver adenomas and carcinomas. There was no clear dose–response relationship, and values were within the historical control range of 6–17%. In females at the highest dose, two out of 50 animals had luteomas; this was within the range for historical controls of 0.9–10%. In the other study, females at the intermediate and highest dose had more liver adenomas and in both sexes at the highest dose, the incidences of liver hyperplastic nodules and thyroid cystic alterations were increased. The increase in liver adenomas is a common finding in mice, which is considered to be of questionable relevance for humans. The overall NOAEL was 500 ppm, equal to 140 mg/kg bw per day.

In a long-term feeding study in rats, at the highest concentration of 2000 ppm reduced body-weight gain was found in both sexes, as were changes in the weights of a number of organs, including spleen, lung and testes. However, there was a poor relationship with dose. In females, kidney, liver and ovarian weights were higher at the highest dose. In both sexes at 2000 ppm, the activities of liver enzymes (alanine aminotransferase and aspartate aminotransferase in both sexes and glutamate dehydrogenase in males) were slightly increased. At the highest dose, minor changes in haematology parameters were at the borderline of the physiological range at some time-points. There was no histopathological evidence for any non-neoplastic or neoplastic changes. The NOAEL was 500 ppm, equal to 25 mg/kg bw per day.

In a series of studies of genotoxicity in vitro and in vivo, triadimenol consistently gave negative results. The Meeting concluded that triadimenol is unlikely to be genotoxic.

In view of the lack of genotoxicity observed and the finding of liver tumours only in female mice and only at concentrations at which liver toxicity was observed, the Meeting concluded that triadimenol is not likely to pose a carcinogenic risk to humans.

To study reproductive performance during exposure to triadimenol, two- and three-generation feeding studies were performed in rats given diets containing triadimenol at concentrations of up to 500 ppm and up to 2000 ppm, respectively. In the study in which the higher doses were administered, matings in all three generations consistently showed reduced fertility at ≥ 500 ppm; in F_0 matings, this finding was observed at 125 ppm. Reduced viability was observed in F_1 pups of both matings at 2000 ppm, F_2 pups from the first mating at ≥ 500 ppm and F_2 pups of the second mating at 2000 ppm. All F_3 pups from the first mating died at ≥ 500 ppm, but not those from the second mating. At 500 ppm, increased testicular and ovarian weights were observed in F_{1b} parents in the study in which lower doses were administered and increased testicular weights in the F_{2b} parents at 2000 ppm. The lowest NOAEL in these studies was 100 ppm, equal to 8.6 mg/kg bw per day

Several studies of developmental toxicity were performed in rats, over a dose range of 5 to 120 mg/kg bw per day. In one study, an increase in supernumerary lumbar ribs was found at ≥ 25 mg/kg bw per day, and in another study there was an increase in postimplantation losses at 120 mg/kg bw per day. In three out of the four studies, increased placental weights were noted at doses of 30 to 100 mg/kg bw per day. Such effects have been reported with other azoles. Triadimenol did not induce malformations in studies of developmental toxicity and clear NOAELs for developmental toxicity could be established; the lowest NOAEL was 15 mg/kg bw per day.

The NOAEL for offspring toxicity in rabbits was 4 mg/kg bw per day, on the basis of slightly increased postimplantation losses at the maternally toxic dose of 200 mg/kg bw per day.

Clinical signs (general restlessness, alternating phases of increased and reduced motility, aggressivity) observed during tests for acute toxicity suggested possible effects on the central nervous system.

The Meeting concluded that the existing database on triadimenol was adequate to characterize the potential hazards to fetuses, infants and children.

A medical survey of personnel working in the production of triadimenol gave no indication of any substance-related effects.

Toxicological evaluation

Although a series of tests for acute neurotoxicity in mice were available, a NOAEL for triadimenol for neurotoxicity could not be identified because of technical shortcomings in these studies. As triadimenol is closely related to triadimefon in terms of chemical structure and toxicological effects, and in the view of the lack of sound studies of neurotoxicity with triadimenol, the Meeting concluded that studies of neurotoxicity performed with triadimefon could serve as a basis for derivating an ADI and an ARfD for triadimenol. This was supported by evidence for similar neurotoxic potential in a published study of acute toxicity with triadimenol and triadimefon.

The Meeting established an ADI of 0–0.03 mg/kg based on the NOAEL of 3.4 mg/kg bw per day for hyperactivity in a study of neurotoxicity with triadimefon in a 13-week feeding study in rats, and with a safety factor of 100.

The Meeting established an ARfD of 0.08 mg/kg bw on the basis of the NOAEL of 2 mg/kg bw for hyperactivity in a study of acute neurotoxicity in rats treated with triadimefon by gavage. A safety factor of 25 was applied because the effects were C_{max}-dependent and reversible (see comments on triadimefon).

A toxicological monograph was prepared for triadimenol and triadimefon.

Triadimefon

In a study on the absorption, distribution, metabolism and excretion of triadimefon in rats, the dose given and pretreatment with non-labelled triadimefon did not significantly affect excretion and metabolism patterns. In males about one-third and in females about two-thirds of the administered dose was excreted in the urine and vice versa in the faeces. After 96 h, 2% of the radioactivity remained in females and 9% in males, with the highest residue levels found in liver and kidneys.

The metabolism of triadimefon starts either by direct oxidation of a *t*-butyl methyl group to the hydroxy or the carboxy compound with subsequent glucuronidation, or these steps are preceded by reduction of the keto group of triadimefon to the putative intermediate, triadimenol. Therefore, many of the metabolites found in triadimenol metabolism studies are also found with triadimefon. Nevertheless, the metabolism of triadimefon in rats provides a pathway for demethylation of the *t*-butyl group, which is not seen with triadimenol. This might be owing to very low biotransformation of triadimenol via triadimefon as intermediate.

The acute oral LD_{50} in mice and rats was in the range of 363 to 1855 mg/kg bw. The dermal LD_{50} was > 5000 mg/kg bw and the LC_{50} on inhalation was > 3.27 mg/l of air.

In rabbits, a few treatment-related effects including skin and eye irritation were recorded, but the irritation potential of triadimefon was very low. In guinea-pigs, technical-grade triadimefon of low purity was a sensitizer in the Büehler test for skin sensitization. However, purified triadimefon did not have any sensitizing potential in guinea-pigs in the Magnusson & Kligman maximization test, even after induction with technical-grade triadimefon of low purity.

In short-term studies in rats and dogs, the main effects of triadimefon were on the liver.

In three short-term studies in rats (treated by gavage at doses of up to 30 mg/kg bw per day for 30 days, by gavage at doses of up to 25 mg/kg bw per day for 4 weeks and given diets containing triadimefon at concentrations of up to 2000 ppm for 12 weeks) the overall NOAEL was 150 mg/kg bw per day, the highest dose tested.

In two studies in dogs fed diets containing triadimefon for 13 weeks and 2 years, the highest concentrations administered were 2400 ppm and 2000 ppm, respectively. Body-weight decreases, relative liver weight increases and liver enzyme induction were observed predominantly in the group receiving the highest dose, and, in the short-term study only, there were also effects on haematology parameters. The overall NOAEL in these studies was 600 ppm, equal to 17.3 mg/kg bw per day, in the 2-year study.

The dermal application of triadimefon at 1000 mg/kg bw per day to rats for 3 weeks (6 h per day for 5 days per week) caused diffuse acanthosis at the application site and increased activity and reactivity. The NOAEL was 300 mg/kg bw per day. The dermal application of triadimefon at 50 and 250 mg/kg bw per day to rabbits for 4 weeks (5 days per week) caused mild erythema at the application sites. Rats exposed by inhalation to triadimefon at 0.3 mg/l of air had reduced body-weight gain and increased liver weights.

In two 2-year feeding studies in mice, severely decreased body-weight gains, changes in several haematology parameters and increased liver weights and increased enzyme activity were observed at the highest dietary concentration of 1800 ppm. Starting at 300 ppm, histopathological changes, including nodular changes, hypertrophy and single cell necrosis, were found in the liver. These effects were more pronounced at the highest dose, and in one study an increase in hepatocellular adenomas was also reported. In the other study, a re-examination of histopathology slides led to re-classification of findings for adenomas and carcinomas. Owing to incomplete re-examination, a final conclusion on whether the incidences were increased or not was not possible. However, liver adenomas in the presence of liver toxicity in mice are generally not believed to be of toxicological concern for humans.

The lowest NOAEL was 50 ppm in the feed, equal to 13.5 mg/kg bw per day, on the basis of nodular changes and single cell necrosis in the liver at 300 ppm.

With the exception of behavioural changes and severe histopathological lesions in several organs observed in one study at the highest dose of 5000 ppm, the toxicological profile in two 2-year feeding studies in rats was very similar to that of the studies in mice. After 23 weeks of exposure to the highest dose at 5000 ppm, animals showed violent activity and refused the feed and became moribund. The surviving animals in this group were terminated at week 39. They showed haemorrhagic lesions in the stomach mucosa, blood-filled and dilated alveolar vessels, degenerative processes in proximal kidney tubules of females, atrophied spleens with signs of decreased haematopoesis, some giant spermatids in testes and decreased haematopoesis in the bone marrow of males. At the lower dietary concentrations of 1800 and 500 ppm, reduced body-weight gains, increased liver weights and mildly increased liver enzyme activities were recorded. In one study, ovary weights were higher and adrenal weights lower. Mild effects on haematology were found in both studies. In one study at the highest dietary concentration of 1800 ppm, a marginal increase in thyroid cystic hyperplasias and more thyroid follicular adenomas (five versus zero for both sexes taken together) were found. When compared with historical controls, this effect was not significant. The overall NOAEL was 300 ppm, equal to 16.4 mg/kg bw per day.

In a series of studies of genotoxicity in vitro and in vivo, all results were consistently negative. The Meeting concluded that triadimefon is unlikely to be genotoxic

In view of the lack of genotoxicity and the finding only of liver adenomas in mice and equivocal changes in thyroid follicular adenomas in rats at concentrations at which organ toxicity was observed, the Meeting concluded that triadimefon is not likely to pose a carcinogenic risk to humans.

In two related multigeneration studies, rats received diets containing triadimefon at concentrations of up to 1800 ppm. Maternal and pup weight development was reduced at doses of ≥ 300 ppm and, in the first generation at the highest dose, the viability of the pups was reduced. At the highest dose, two matings of the F_1 animals to give F_2 generation pups resulted in one female becoming pregnant in the first mating and none in the second. In the second study, again at 1800 ppm, the fertility of the F_0 generation was not affected, but that of the F_1 generation was, albeit not to the same extent as in the first study. Viability and pup weights were reduced. In a cross mating in which only one sex was exposed to triadimefon, only the matings with exposed males gave significantly reduced fertility, correlating with reduced insemination indices. Therefore, reduced fertility seemed to have resulted mainly from impaired mounting willingness of exposed males. In males at the highest dose, the concentration of testosterone was double that in control males, and testes weights were increased. However, no correlation between individual testosterone levels and spermiograms and mating willingness was observed, although reduced mating willingness did appear to correlate with reduced body weight. It appears that prenatal, but not postnatal, exposure of males affected mating willingness. The lowest NOAEL was 50 ppm, equivalent to 3.75 mg/kg bw per day, based on a LOAEL of 1800 ppm for reproductive effects.

In studies of developmental toxicity in rats treated by inhalation (one study) and by gavage (two studies), inhalation exposure at air concentrations of up to 0.114 mg/l of air on days 6–15 of gestation did not result in any findings indicative of developmental toxicity. In the studies of rats treated by gavage, however, supernumerary ribs in one study at 90 mg/kg bw per day, increased placental weights at 100 mg/kg bw per day, and cleft palates at doses of ≥ 75 mg/kg bw per day were found. These doses also reduced the body-weight gains of dams by up to 50% over the exposure period, but not when averaged over the whole gestation period. In four studies in rabbits, body-weight loss in dams was observed at a dose of ≥ 30 mg/kg bw per day. Over the dose range of 60 to 120 mg/kg bw per day, increased litter losses, and caudal vertebrae malformations and cleft palates were found either in one or the other study and delayed ossification and scapula malformations were observed in both studies. Additionally, in one study, the uncommon finding of umbilical hernia was recorded in pups at 60 and 80 mg/kg bw per day. Scapula deformations were also found

at 40 mg/kg bw per day, the lowest dose tested in the study. Overall, the lowest NOAEL for offspring toxicity was 20 mg/kg bw on the basis of scapula deformations at 40 mg/kg bw in rabbits.

Several studies provide evidence that triadimefon has neurotoxic potential. In a study in which single doses of triadimefon were administered by gavage and in a 13-week feeding study, several signs of hyperactivity, increased motility and stereotypic behaviour were found. The NOAEL in the former study was 2 mg/kg bw on the basis of reversible neurotoxic effects at 35 mg/kg bw. These were considered to be C_{max}-dependent effects in view of the fact that a dose of 54.6 mg/kg bw per day in the short-term feeding study caused similar effects only after several days. The NOAEL for this study was 50 ppm, equivalent to 3.4 mg/kg bw. In a comparative study of acute neurotoxicity in Long Evans rats treated by gavage with a group of 14 triazoles or structurally related compounds, hyperactivity at 100 mg/kg bw, but not at 50 mg/kg bw, was recorded for both triadimenol and triadimefon. In this study, the dose–response curves for triadimenol and triadimefon were very similar, suggesting a common mechanism of neurotoxicity.

The Meeting concluded that the existing database on triadimefon was adequate to characterize the potential hazards to fetuses, infants and children.

A medical survey of the personnel working in the production of triadimefon gave no indication of any substance-related effects.

Toxicological evaluation

The Meeting established an ADI of 0–0.03 mg/kg bw on the basis of the NOAEL of 3.4 mg/kg bw per day for hyperactivity in a study of neurotoxicity in rats fed with triadimefon and a safety factor of 100.

The Meeting established an ARfD of 0.08 mg/kg bw based on the NOAEL of 2 mg/kg bw for hyperactivity in a study of acute neurotoxicity in rats given triadimefon by gavage. A safety factor of 25 was used since the effects were C_{max}-dependent and reversible.

A toxicological monograph was prepared for triadimenol and triadimefon.

Plant metabolites of triadimefon, triadimenol and other triazole fungicides

Triazole, triazolylalanine and triazole acetic acid are plant metabolites of several triazole fungicides, including triadimenol and triadimefon.

After oral administration of triazole, triazolylalanine and triazole acetic acid to rats, these compounds are rapidly and completely absorbed. Urinary excretion is the main excretion pathway for 90% or more of the administered dose, and only a few percent are found in the faeces. Except for triazolylalanine, which is metabolized to a minor extent to *N*-acetyltriazolylalanine, these compounds are virtually not metabolized and are excreted unchanged. Owing to rapid and complete excretion, there is no potential for accumulation in the body for any of these plant metabolites.

The acute oral toxicity of all three compounds is low, with LD_{50}s of > 5000 mg/kg bw, except for triazole, with an LD_{50} of 1649 mg/kg bw.

Only a few tests for genotoxicity have been performed on triazole and triazole acetic acid and all gave negative results. Triazolylalanine was more extensively tested; only one test for cell transformation in vitro gave a positive result, while the results of another similar test and all other tests were negative.

In a 3-month feeding study in rats, triazole induced fat deposition in the liver and changes in haematological parameters at the highest dose of 2500 ppm. In 3-month feeding studies in rats and, the only effect of triazolylalanine was to reduce body-weight gain at the highest dose of 20 000 ppm. No effects were recorded in a 2-week study in rats fed with triazole acetic acid at the highest dose of 8000 ppm.

In a study of developmental toxicity with triazole in rats, at ≥ 100 mg/kg bw per day fetuses showed increased incidence of undescended testicles and at 200 mg/kg bw per day malformations of the hind legs were found. In studies of reproductive and developmental toxicity with triazolylalanine in rats, only very minor effects on pups, indicative of general toxicity, such as reduced birth weights and retarded ossification processes were found at high doses. There were no studies of reproductive and developmental toxicity with triazole acetic acid.

Since triazolylalanine and triazole acetic acid were of low systemic toxicity and developmental effects with triazole occur at doses of ◘ 100 mg/kg bw per day, these metabolites were judged not to pose an additional risk to humans.

*Levels relevant to risk assessment of triadimenol**

Species	Study	Effect	NOAEL	LOAEL
Mouse	80-week study of toxicity and carcinogenicity[a]	Toxicity	500 ppm, equal to 140 mg/kg bw per day	2000 ppm, equal to 620 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 140 mg/kg bw per day	2000 ppm, equal to 620 mg/kg bw per day
Rat	2-year study of toxicity and carcinogenicity[a]	Toxicity	500 ppm, equal to 25 mg/kg bw per day	2000 ppm, equal to 105 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 105 mg/kg bw per day[c]	—
	Two-generation study of reproductive toxicity[a]	Parental toxicity	100 ppm, equal to 8.6 mg/kg bw per day	500 ppm, equal to 43.0 mg/kg bw per day
		Pup toxicity	100 ppm, equal to 8.6 mg/kg bw per day	500 ppm, equal to 43.0 mg/kg bw per day
	Developmental toxicity[b]	Maternal toxicity	25 mg/kg bw per day	60 mg/kg bw per day
		Embryo- and fetotoxicity	15 mg/kg bw per day	25 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	40 mg/kg bw per day	200 mg/kg bw per day
		Embryo- and fetotoxicity	40 mg/kg bw per day	200 mg/kg bw per day
Dog	13-week study of toxicity[a]	Toxicity	600 ppm equal to 21.1 mg/kg bw per day	2400 ppm equal to 85.9 mg/kg bw per day

* See comments on triadimefon
[a] Diet
[b] Gavage
[c] Highest dose tested

Estimate of acceptable daily intake for humans

0–0.03 mg/kg bw

Estimate of acute reference dose

0.08 mg/kg bw

Studies that would provide information useful for the continued evaluation of the compound

Further observations in humans

Critical end-points for establishing guidance values for exposure to triadimenol

Absorption, distribution, metabolism and excretion in animals	
Rate and extent of oral absorption	Rapid (peak within 1.5 h); > 90%
Distribution	Widely distributed
Potential for accumulation	Low, half lives of 6–15 h
Rate and extent of excretion	79–90% within 24 h
Metabolism	Very extensive; predominantly oxidation of *t*-butyl methyl group
Toxicologically significant compounds (animals, plants and the environment)	Triadimenol, triadimefon, triazole
Acute toxicity	
Rat, LD_{50}, oral	579–5000 mg/kg bw (varies with isomer composition)
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 0.95 mg/l
Rabbit, dermal irritation	Not irritating
Rabbit, eye irritation	Not irritating
Skin sensitization	Not sensitizing (Magnusson & Kligman maximization test)
Short-term studies of toxicity	
Critical effects	Liver toxicity (2-year study in dogs)
Lowest NOAEL	21.1 mg/kg bw
Genotoxicity	Negative results in vitro and in vivo
Long-term studies of toxicity and carcinogenicity	
Critical effects	Body and organ weight changes (2-year study in rats)
Lowest NOAEL	25 mg/kg bw
Carcinogenicity	Liver adenomas in female mice; unlikely to pose a carcinogenic risk to humans
Reproductive toxicity	
Critical effects	Increased ovary and testes weights (rat)
Lowest reproductive NOAEL	8.6 mg/kg bw
Critical effects	Increased supernumerary lumbar ribs; not teratogenic (rat)
Lowest developmental NOAEL	15 mg/kg bw
Neurotoxicity/delayed neurotoxicity	
Critical effects at LOAEL	See triadimefon
Lowest NOAEL	See triadimefon
Other toxicological studies	Metabolites are of no greater toxicological concern than the parent
Medical data	No effects on health in manufacturing personnel

Summary	*Value*	*Study*	*Safety factor*
ADI	0–0.03 mg/kg bw	Rat, short-term study of neurotoxicity with triadimefon (see triadimefon)	100
ARfD	0.08 mg/kg bw	Rat, study of acute neurotoxicity with triadimefon (see triadimefon)	25

Levels relevant to risk assessment of triadimefon

Species	Study	Effect	NOAEL	LOAEL
Mouse	21-month study of toxicity and carcinogenicity[a]	Toxicity	50 ppm, equal to 13.5 mg/kg bw per day	300 ppm, equal to 76 mg/kg bw per day
		Carcinogenicity	300 ppm, equal to 76 mg/kg bw per day	1800 ppm, equal to 550 mg/kg bw per day
Rat	105-week study of toxicity and carcinogenicity[a]	Toxicity	300 ppm, equal to 16.4 mg/kg bw per day	1800 ppm, equal to 114 mg/kg bw per day
		Carcinogenicity	1800 ppm, equal to 114 mg/kg bw per day[c]	—
	Two-generation study of reproductive toxicity[a]	Parental toxicity	300 ppm, equal to 22.8 mg/kg bw per day	1800 ppm, equal to 136.8 mg/kg bw per day
		Pup toxicity	300 ppm, equal to 22.8 mg/kg bw per day	1800 ppm, equal to 136.8 mg/kg bw per day
	Developmental toxicity[b]	Maternal toxicity	10 mg/kg bw per day	30 mg/kg bw per day
		Embryo- and fetotoxicity	30 mg/kg bw per day	90 mg/kg bw per day
	Acute neurotoxicity[b]	Neurotoxicity	2 mg/kg bw	35 mg/kg bw
	13-week study of neurotoxicity[a]	Neurotoxicity	50 ppm, equivalent to 3.4 mg/kg bw per day	800 ppm, equivalent to 54.6 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	10 mg/kg bw per day	30 mg/kg bw per day
		Embryo- and fetotoxicity	20 mg/kg bw per day	50 mg/kg bw per day
Dog	2-year study of toxicity[a]	Toxicity	300 ppm equal to 11.7 mg/kg bw per day	200 ppm equal to 48.8 mg/kg bw per day

[a] Diet
[b] Gavage
[c] Highest dose tested

Estimate of acceptable daily intake for humans

0–0.03 mg/kg bw

Estimate of acute reference dose

0.08 mg/kg bw

Studies that would provide information useful for the continued evaluation of the compound

Further observations in humans

Critical end-points for setting guidance values for exposure to triadimenol

Absorption, distribution, metabolism and excretion in animals	
Rate and extent of oral absorption	≥ 28% in females, ≥ 67% in males as urinary excretion
Distribution	Widely distributed in kidneys and liver
Potential for accumulation	Low
Rate and extent of excretion	90–98% excretion within 96 h
Metabolism	Very extensive; predominantly oxidation of tert-butyl methyl group
Toxicologically significant compounds (plants, animals and the environment)	Triadimenol, triadimefon, triazole
Acute toxicity	
Rat, LD_{50}, oral	363–1855 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 3.27 mg/l
Rabbit, dermal irritation	Not irritating
Rabbit, eye irritation	Not irritating
Skin sensitization	Technical-grade triadimefon is sensitizing, purified triadimefon is not sensitizing (Büehler, and Magnusson & Kligman maximization tests)
Short-term studies of toxicity	
Critical effects	Liver effects (dog)
Lowest NOAEL	17.3 mg/kg bw
Genotoxicity	Negative in vitro and in vivo
Long-term studies of toxicity and carcinogenicity	
Critical effects	Liver nodular changes, hypertrophy and single cell necrosis
Lowest NOAEL	13.5 mg/kg bw per day
Carcinogenicity	Liver adenomas in mice; unlikely to pose a carcinogenic risk to humans
Reproductive toxicity	
Critical effects	Impaired reproductive performance (rat)
Lowest reproductive NOAEL	22.8 mg/kg bw per day
Critical effects	Scapula malformations at maternal toxic doses (rabbit)
Lowest developmental NOAEL	20 mg/kg bw per day
Neurotoxicity/delayed neurotoxicity	
Critical effects	Increased activity in study of acute neurotoxicity after gavage administration (rat)
Lowest NOAEL	2 mg/kg bw
Critical effects	Increased activity in short-term feeding study (rat)
Lowest NOAEL	3.4 mg/kg bw
Other toxicological studies	Metabolites are of no greater toxicological concern than the parent
Medical data	No effects on health in manufacturing personnel

Summary	Value	Study	Safety factor
ADI	0–0.03 mg/kg	Rat, short-term study of neurotoxicity	100
ARfD	0.08 mg/kg	Rat, study of acute neurotoxicity	25

DIETARY RISK ASSESSMENT

Triadimenol

Long-term intake

Theoretical maximum daily intakes were calculated for the commodities of human consumption for which Codex MRLs existed (Annex 3). The theoretical maximum daily intakes in the five GEMS/Food regional diets represented 1–20% of the maximum ADI (0.03 mg/kg bw per day). The Meeting concluded

that the long-term intake of residues of triadimenol resulting from uses of triadimenol and triadimefon considered by the JMPR is unlikely to present a public heath concern.

Short-term intake

An ARfD of 0.08 mg/kg bw was established for triadimenol by the present Meeting. IESTIs could not, however, be calculated, as the residues of the compound were evaluated by the Meeting before the procedures for estimation of STMR and highest residue values were established. Triadimenol was scheduled for periodic evaluation of residues in 2006, when the risk assessment would be finalized.

Triadimefon

Long-term intake

Theoretical maximum daily intakes were calculated for the commodities of human consumption for which Codex MRLs existed (Annex 3). The theoretical maximum daily intakes in the five GEMS/Food regional diets represented 1–6% of the maximum ADI (0.03 mg/kg bw per day). The Meeting concluded that the long-term intake of residues of triadimefon considered by the JMPR is unlikely to present a public heath concern.

Short-term intake

An ARfD of 0.08 mg/kg bw was established for triadimefon by the present Meeting. IESTIs could not, however, be calculated, as the residues of the compound were evaluated by the Meeting before the procedures for estimation of STMR and highest residue values were established. Triadimefon was scheduled for periodic evaluation of residues in 2006, when the risk assessment would be finalized.

4.30 TRIFLOXYSTROBIN (213)

TOXICOLOGY

Trifloxystrobin (methyl(*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α,-trifluoro-*meta*-tolyl)ethylideneamino-oxy]-*ortho*-tolyl}acetate) is a new broad-spectrum foliar fungicide, which is a synthetic analogue of the naturally occurring strobilurins. Trifloxystrobin has not been evaluated previously by the JMPR.

After oral administration, radiolabelled trifloxystrobin was rapidly and appreciably absorbed (66% of the administered dose) in rats of both sexes. The main route of elimination (63–84%) was in the faeces; some of the fecal elimination was via bile (30–45%) while only one-third or less of the administered dose was excreted in the urine, and none through expired air. There was almost complete degradation of trifloxystrobin after single low dose, at 0.5 mg/kg bw, but up to 45% was eliminated unchanged in the faeces after a high dose, at 100 mg/kg bw. The metabolite pattern in rats is very complex; about 35 metabolites were identified in the urine, faeces and bile. The main steps in the metabolic pathway include hydrolysis of the methyl ester to the corresponding acid, *O*-demethylation of the methoxyimino group yielding a hydroxyimino compound and oxidation of the ethylideneamino methyl group to a primary alcohol and then to the corresponding carboxylic acid. These steps are followed by a complex pattern of further, minor reactions. Cleavage between the glyoxylphenyl and trifluormethylphenyl moieties accounted for about 10% of the administered dose.

The metabolism of trifloxystrobin in plants is similar to that in animals and occurs primarily via cleavage of the methyl ester group to form CGA 321113 (*E*,*E*)-methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid. In the rat, this metabolite undergoes further hydroxylation and conjugation (glucuronide and sulfate) at the trifluoromethyl phenyl ring. In goat liver, taurine and glycine conjugates of CGA 321113 were the principal residue components (up to 28% of the total

radioactive residues). Conjugated metabolites are generally less toxic and more rapidly excreted than an unconjugated parent compound. Being biotransformation products in the rat, CGA 321113 and its metabolites are assumed to have been adequately tested and accounted for in rats given trifloxystrobin. Also, CGA 321113 is not likely to be more toxic than trifloxystrobin.

Dermal absorption of trifloxystrobin in rats was low and slightly decreased with increasing dose. Compared with human epidermis, rat epidermis was 9 and 19 times more permeable in a test in vitro at a dose of 0.24 and 10.27 mg/cm^2, respectively. In a study of absorption in vivo, in which a low or a high dose of radiolabelled trifloxystrobin was applied to the shaved backs of male rats, the amount of recovered radioactivity in the blood was low, but the overall absorption was moderate, ranging from 5 to 10% in 24 h and increasing to 16% at 48 h.

Trifloxystrobin has low acute oral toxicity in rats and mice (LD_{50}, > 5000 mg/kg), low acute dermal toxicity in rats and rabbits (LD_{50}, > 2000 mg/kg), low acute inhalation toxicity in rats (LC_{50}, > 4.65 mg/l), is not a skin irritant in rabbits, is a moderate eye irritant in unwashed rabbit eyes but is not irritating in washed rabbit eyes. It is a skin sensitizer in guinea-pigs, according to the Magnusson & Kligman maximization test, but is not a skin sensitizer in guinea-pigs according to the Buehler test.

In studies of toxicity with repeated doses, slight decreases (5–10%) in body weight and/or body-weight gain were regarded as non-adverse in the absence of other effects.

In studies of repeated doses in mice, the liver and spleen were the principal target organs at the same or higher doses than those affecting body weight and food efficiency. In the 90-day study in male and female mice, liver weight was increased and there were findings on microscopy, including hepatocyte hypertrophy and focal or single cell necrosis. There were also increased incidences of extramedullary haematopoiesis in the spleen at doses of ≥ 315 mg/kg bw per day. The NOAEL for these effects was 77 mg/kg bw per day.

In a 90-day dietary study in rats, the NOAEL was 31 mg/kg bw per day on the basis of statistically significantly decreased body-weight gain of 20% and 40% in males and females, respectively, increased relative liver weights, changes in clinical chemistry and liver histopathology findings (mainly hepatocellular hypertrophy), in addition to atrophy of the pancreas at the next higher dose of 127 mg/kg bw per day.

At or above a daily dose of trifloxystrobin at 150 mg/kg bw per day for 3 months or 50 mg/kg bw per day for 1 year, dogs had episodes of diarrhoea, vomiting, reduced food intake, increased relative liver weight and hepatocyte hypertrophy, in addition to changes in clinical chemistry parameters indicative of liver toxicity and/or perturbed metabolism, dehydration, poor nutrition and possible starvation. Body weights were also affected. In the 3-month study, animals of both sexes had body-weight loss of about 0.4 kg and 2.8 kg at 150 and 500 mg/kg bw per day, respectively. In the 1-year study, body-weight gain in females at 50 and 200 mg/kg bw per day were decreased throughout the study, and at week 52 body-weight gain was about 20% below control values. The NOAELs were 30 and 5 mg/kg bw per day in the 3-month and 1-year studies, respectively.

The long-term study of toxicity and carcinogenicity with trifloxystrobin was evaluated in bioassays in mice and rats. In the 18-month dietary feeding study in mice, the NOAEL was 36 mg/kg bw per day on the basis of liver effects, including increased liver weight (both sexes) and increased single cell necrosis (males), in addition to impaired body-weight gain (females). There was no evidence of carcinogenicity in mice tested at adequate doses.

In the 2-year study in rats, the NOAEL was 30 mg/kg bw per day on the basis of statistically significantly retarded body-weight gain in males (11–17%) and females (17–27%) and decreased food consumption (by 4% and 8%, respectively) and increased relative weights of heart, liver and kidneys (each by about 20%) in females at the highest dose of 62 mg/kg bw per day. The overall incidence of tumours was lower in the treated animals. Benign adrenal medullary tumours (10% versus 0% in controls) and haemangioma in the mesenteric lymph nodes (10.2% versus 0% in controls) were increased in male rats at the highest dose tested. Incidences of the adrenal medullary tumours were within the range of incidences for historical controls. The incidence of haemangioma in the mesenteric lymph nodes in males of the high dose

group was outside the range of historical control incidences. There was markedly reduced mortality in the group receiving the highest dose tested, and this may have contributed to the higher incidence of tumours in this group compared to controls. In ageing male rats of this strain, degenerative lesions associated with the mesenteric lymph nodes are common and are hard to distinguish from neoplastic lesions (haemangiomas). Some age-associated non-neoplastic findings, such as angiomatous hyperplasia of the mesenteric lymph nodes, were increased in males at the highest dose and the increases were correlated with decreased food intake and a lower body-weight development.

The Meeting concluded that there was no treatment-related carcinogenicity of any toxicological concern.

A wide range of assays for genotoxic potential with trifloxystrobin were conducted in vitro and in vivo, including testing for gene mutation, chromosomal damage and DNA repair. At or near cytotoxic doses and in the presence of metabolic activation, trifloxystrobin was weakly mutagenic at cytotoxic doses in the test for forward gene mutation in Chinese hamster V79 cells. Results were equivocal in the absence of metabolic activation. Metabolites of trifloxystrobin [CGA 357261 (*Z*, *E*-isomer), CGA 373466 and NOA 414412] were not mutagenic in the Ames test. The Meeting concluded that trifloxystrobin and its metabolites are not genotoxic.

Because of the absence of findings indicative of genotoxicity or carcinogenicity, the Meeting concluded that trifloxystrobin is unlikely to pose a carcinogenic risk to humans.

In the two-generation study in rats given trifloxystrobin at a dose of 55 or 111 mg/kg bw per day, pups in the $F_1$and F_2 litters had retarded body-weight development during lactation. The NOAEL for parental toxicity was 3.8 mg/kg bw per day on the basis of findings at 55 mg/kg bw per day, i.e. reduced body weight and food consumption, in addition to histopathology findings in the liver and kidneys. The NOAEL for offspring toxicity was 3.8 mg/kg bw per day on the basis of retarded body-weight development during lactation. The NOAEL for reproductive toxicity was 111 mg/kg bw per day.

Trifloxystrobin was not teratogenic in rats and rabbits when tested at doses of up to 1000 and 500 mg/kg bw per day, respectively. In rats, the NOAEL for developmental toxicity was 100 mg/kg bw per day on the basis of increased incidences of enlarged thymus. In rabbits, the NOAEL for developmental toxicity was 250 mg/kg bw per day on the basis of increased incidences of skeletal anomalies in the form of fused sternebrae 3 and 4. Maternal toxicity in rats and rabbits was limited to reduced food consumption and body-weight loss at 100 and 250 mg/kg bw per day with NOAELs of 10 and 50 mg/kg bw per day, respectively. The developmental effects were considered to be a consequence of overall maternal toxicity.

The Meeting concluded that the existing database on trifloxystrobin was adequate to characterize the potential hazards to fetuses, infants and children.

In a study of acute oral neurotoxicity in rats given a single dose of trifloxystrobin at 2000 mg/kg bw, the functional observational battery revealed no indications for potential neurological or behavioural effects.

Toxicological evaluation

The Meeting established an ADI of 0–0.04 mg/kg bw based on the parental NOAEL of 3.8 mg/kg bw per day in a multigeneration study of reproductive toxicity in rats and a 100-fold safety factor. The LOAEL was 55 mg/kg bw per day on the basis of effects on body weight and food consumption, in addition to liver and kidney histopathology findings. This value is supported by the NOAEL of 5 mg/kg bw per day in the 1-year study in dogs.

The Meeting concluded that it was unnecessary to establish an ARfD for trifloxystrobin on the basis of its low acute toxicity and the fact that developmental effects were considered to be a result of severe

maternal toxicity, which is related to decreased food intake rather than systemic toxicity. Also, the vomiting and diarrhoea observed in dogs were clearly related to local irritation, rather than systemic acute toxicity.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month study of toxicity and carcinogenicity[a]	Toxicity	300 ppm, equal to 36 mg/kg bw per day	1000 ppm, equal to 124 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 246 mg/kg bw per day[b]	—
Rat	2-year studies of toxicity and carcinogenicity[a]	Toxicity	750 ppm, equal to 30 mg/kg bw per day	1500 ppm, equal to 62 mg/kg bw per day[b]
		Carcinogenicity	1500 ppm, equal to 62 mg/kg bw per day[b]	—
	Two-generation reproductive toxicity[a]	Parental toxicity	50 ppm, equal to 3.8 mg/kg bw per day	750 ppm, equal to 55 mg/kg bw per day
		Offspring toxicity	50 ppm, equal to 3.8 mg/kg bw per day	750 ppm, equal to 55 mg/kg bw per day
	Developmental toxicity[c]	Maternal toxicity	10 mg/kg bw per day	100 mg/kg bw per day
		Embryo- and fetotoxicity	100 mg/kg bw per day	1000 mg/kg bw per day
Rabbit	Developmental toxicity[c]	Maternal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
		Embryo- and fetotoxicity	250 mg/kg bw per day	500 mg/kg bw per day
Dog	3-month study of toxicity[d,e]	Toxicity	30 mg/kg bw per day	150 mg/kg bw per day
	12-month study of toxicity[d]	Toxicity	5 mg/kg bw per day	50 mg/kg bw per day

[a] Diet
[b] Highest dose tested
[c] Gavage
[d] Gelatine capsule
[e] Two or more studies combined

Estimate of acceptable daily intake for humans

0–0.04 mg/kg bw

Estimate of acute reference dose

Unnecessary

Studies that would provide information useful for continued evaluation of the compound

Further observations in humans

Critical end-points for setting guidance values for exposure to trifloxystrobin

Absorption, distribution, excretion and metabolism in animals	
Rate and extent of absorption	66% in 48 h
Distribution	Widely distributed; highest concentrations in blood, liver and kidneys
Potential for accumulation	No potential for accumulation.
Rate and extent of excretion	Within 48 h, 72–96% of the administered dose is eliminated in the urine and faeces
Metabolism in animals	Extensive: hydrolysis, *O*-demethylation, oxidation, conjugation, chain shortening and cleavage between glyoxylphenyl and trifluoromethyl moieties
Toxicologically significant compounds (plants, animals and the environment)	Parent compound, main acid metabolite is CGA 321113

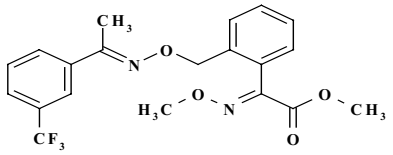
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation:	> 4.6 mg/l
Rabbit, skin irritation:	Not irritating
Rabbit, eye irritation:	Not irritating
Skin sensitization	Sensitizer (Magnusson & Kligman test)
Short-term studies of toxicity	
Target/critical effect	Body weight, food consumption, clinical signs, liver (pathology), kidney (weight), pancreas (atrophy), spleen (weight and pathology)
Lowest relevant oral NOAEL	5 mg/kg bw per day (1-year study in dogs)
Lowest relevant dermal NOAEL	≥ 1000 mg/kg bw per day (28-day study in rats)
Lowest relevant inhalation NOAEC	No relevant study
Genotoxicity	No genotoxic potential, negative results in vivo, one positive result in study in vitro at cytotoxic doses.
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight (mouse, rat), food consumption (rat), liver (mouse, rat)
Lowest relevant NOAEL	30 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans
Reproductive toxicity	
Target/critical effect	Decreased body-weight gain of pups accompanied by delayed eye opening at parental toxic doses
Lowest relevant reproductive NOAEL	50 ppm (3.8 mg/kg bw per day)s
Developmental target/critical effect	Enlarged thymus (rat) and skeletal effects (rabbit) at maternally toxic doses
Lowest relevant developmental NOAEL	100 mg/kg bw per day (rat)
Neurotoxicity	No evidence of acute neurotoxicity in rats
Other toxicological studies	No evidence of replicative DNA synthesis in rat or mouse heptocytes after 3-months administration in diet
	A range of metabolites had low acute oral toxicity and there was no evidence of genotoxic activity
Medical data	New active substance; limited data; some evidence of skin and eye irritation in three people during field trials (but 120 people without effects)

Summary	***Value***	***Study***	***Safety factor***
ADI	0–0.04 mg/kg bw	Rat, reproduction study, reduced body weight, liver and kidney effects	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

The residue and analytical aspects of trifloxystrobin were considered for the first time by the present Meeting.

Trifloxystrobin, a member of the strobilurin group, is a broad-spectrum contact fungicide for foliar use; it has mesosystemic properties. The mode of action of strobilurins involves inhibition of mitochondrial respiration by blockage of the electron transfer chain. The fungicidal properties of trifloxystrobin are derived from the parent ester, and the acid (the main metabolite) is essentially inactive. Trifloxystrobin has registered uses on horticultural crops, vegetables and cereals in many countries.



IUPAC name:	methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*meta*-tolyl)ethylidene-aminooxy]-*ortho*-tolyl}acetate
Chemical Abstracts name:	methyl (α*E*)-α-(methoxyimino)-2-[[[(*E*)-[1-[3-(trifluoromethyl)phenyl]-ethylidene]amino]oxy]methyl]benzeneacetate

The Meeting received information on the metabolism and environmental fate of trifloxystrobin, methods of residue analysis, stability in freezer storage, national registered use patterns, the results of supervised residue trials, the results of farm animal feeding studies, fate of residues in processing and national MRLs.

Trifloxystrobin is a white powder which melts at 73 °C. It is not highly volatile (vapour pressure, 3×10^{-6} Pa). It does not dissociate and is only slightly water-soluble (0.6 mg/l). The log P_{OW} is 4.5, suggesting that bioaccumulation may occur. Trifloxystrobin is hydrolytically stable at environmental pHs, but photochemical degradation was shown to occur. The active technical substance is not considered to be explosive or inflammable.

Metabolism

Animals

The metabolism of trifloxystrobin was investigated in rats, goats and poultry, and the metabolic pathways were comparable in the three species. The studies were performed with ^{14}C-trifloxystrobin labelled uniformly in one of the two phenyl rings, [glyoxylphenyl-U^{14}C]trifloxystrobin and [trifluoromethylphenyl-U^{14}C]trifloxystrobin, each compound being administered separately. The name [glyoxylphenyl-U^{14}C]trifloxystrobin was introduced during the development of trifloxystrobin to reflect the route of synthesis of radiolabelled material.

After oral administration to *rats* of each sex, rabiolabelled trifloxystrobin was rapidly and appreciably absorbed (35–65% of dose). Faeces was the main route of elimination (63–84%), some of which was through bile (30–45%) while only one-third or less of the administered dose was excreted in urine and none in expired air. There was near-complete degradation of trifloxystrobin after a single low dose of 0.5 mg/kg bw;

however, after a dose of 100 mg/kg bw, up to 45% was eliminated unchanged in faeces. The pattern of metabolites in rats is complex: about 35 metabolites were isolated from urine, faeces and bile and identified. The main steps in the metabolic pathway include hydrolysis of the methyl ester to the corresponding acid, *O*-demethylation of the methoxyimino group, yielding a hydroxyimino compound, and oxidation of the ethylideneamino methyl group to a primary alcohol and then to the corresponding carboxylic acid. These stepa are followed by a complex pattern of further, minor reactions. Cleavage between the two phenyl rings accounted for about 10% of the dose.

Lactating *goats* were given diets containing [glyoxylphenyl-U^{14}C]trifloxystrobin or [trifluoromethylylphenyl-U^{14}C]trifloxystrobin at an equivalent of 100 ppm for 4 days and were slaughtered 6 h after the last dose. Up to 20% of the applied dose was excreted in urine and 45% in faeces, while 0.05–0.08% of the total dose was eliminated in milk, corresponding to about 0.1 mg/kg trifloxystrobin equivalents, and a plateau was reached after 48 h.

Most tissue residues were found in liver, bile and kidney, accounting for 0.28–0.57%, 0.07–0.24% and 0.026–0.052% of the applied dose, respectively. These values correspond to 2.6–5.2 mg/kg, 29–77 mg/kg and 1.7–2.9 mg/kg as trifloxystrobin equivalents. Lower levels were found in fat, muscle and blood. The main components of the residue were the parent compound, its carboxylic acid, CGA 321113 (chemical name: *(E,E)*-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)ethylideneaminooxymethyl]phenyl}acetic acid) and taurine and glycine conjugates of CGA 321113. The amino acid conjugates were the main residue components in the liver (up to 28% TRR). These metabolites were not considered to be of toxicological concern. CGA 321113 was the main radioactive residue in muscle (up to 57% TRR) and kidney (up to 74% TRR), and trifloxystrobin was the principal component in milk (up to 74% TRR) and fat (up to 82% TRR).

Hens were given diets containing trifloxystrobin at an equivalent of 100 ppm in the diet for 4 days and were killed 6 h after the last dose. Up to 0.16% and 87% of the applied dose were eliminated in eggs and excreta, respectively. A plateau was not reached in egg yolk. The residue levels appeared to be increasing rapidly at the end of the study.

Eggs contained 0.1–0.2% of the applied dose. The maximum concentration in egg white was 0.56 mg/kg, and that in egg yolk was 2.3 mg/kg as trifloxystrobin equivalents. Lean meat contained 0.11–0.22% of the dose (0.13–0.35 mg/kg trifloxystrobin equivalents); skin and attached fat 0.14–0.39% (0.8–1.8 mg/kg); peritoneal fat, 0.07–0.21% (1.9–2.7 mg/kg); kidney, 0.11–0.25% (6–13 mg/kg); and liver, 0.28–0.68% (3.8–8.6 mg/kg). The TRR (including that in intestine and gizzard) was 78–91%.

Characterization of the radioactive tissue residues revealed that parent trifloxystrobin was a major residue in muscle (up to 28% TRR), fat and skin (up to 55% TRR) and egg yolk (up to 9% TRR) of laying hens. The carboxylic acid derivative (CGA 321113) was the main residue in egg white (up to 26% TRR) and liver (up to 5.1% TRR).

Plants

The metabolism of trifloxystrobin in plants was investigated in wheat, apples, cucumbers, sugar beet and peanuts with ^{14}C-trifloxystrobin applied by spray. Although the number of metabolite fractions differed in the different plants, the metabolic pathways in these the crops were comparable.

In mature *wheat*, the highest TRRs were found in straw (3.85 mg/kg trifloxystrobin equivalents), followed by husks (0.14 mg/kg) and grain (0.02 mg/kg). The composition of the TRRs was complex; trifloxystrobin and its isomers constituted less than 5%.

Studies on wheat showed that the absorption of trifloxystrobin by plants was relatively rapid, with about 15% of the TRR appearing within the first 24 h, 29% within 3 days and 44% within 14 days. Characterization of the surface radioactivity in wheat revealed that trifloxystrobin is relatively stable to photodegradation, accounting for up to about 80% of the surface radioactivity after 14 days. In contrast, absorbed residue appeared to undergo rapid degradation: the trifloxystrobin concentration declined

exponentially, with an apparent half-life of 12 h. Up to 35 metabolite fractions were found in wheat, most of which constituted less than 1% TRR.

In *apple*, 14 days after treatment, the main residue component was the parent compound trifloxystrobin (*E*,*E* isomer), which, together with its *Z,Z*, *Z,E* and *E,Z* isomers, constituted about 92% of the residue.

In the leaves and fruits of *cucumber*, the residue consisted of trifloxystrobin (80–93% TRR), isomers of trifloxystrobin (2.3–3.8% TRR) and CGA 321113 (0.9–4.2% TRR).

In *sugar-beet*, the main compounds found, with both labels, in the tops and roots were trifloxystrobin and its *E,Z* and *Z,Z* isomers. They accounted for up to 69% TRR in tops (1.1 mg/kg trifloxystrobin) and 52% in roots (0.02 mg/kg trifloxystrobin). CGA 321113 represented up to 5.2% (0.073 mg/kg) and up to 11% (0.012 mg/kg) of the TRR in tops and roots, respectively.

In *peanut*, many metabolite fractions containing only one moiety of the parent molecule were detected, generally similar to those found in wheat. Extensive formation of sugar and malonyl sugar conjugates was found in most metabolite fractions. In vines, the percentage of extractable radioactive residues (acetonitrile:water) amounted to 91% TRR. Extractable residues represented up to 74% in mature hay and up to 53% in nutmeat. The unextracted residues were solubilized by hot extraction and sequential hydrolyses with cellulase, protease, HCl and NaOH. The radioactive residues that remained unextracted under these exhaustive conditions represented < 10% TRR.

In general, the metabolism of trifloxystrobin in crops is complex, owing to isomerization of the parent compound and its metabolites. Overall, the metabolism of trifloxystrobin is similar in all crops and involves the following steps:

- *cis–trans* isomerization of trifloxystrobin (*E,E*- isomer) to its *E,Z*-, *Z,Z* and *Z,E*- isomers
- hydrolysis of the methyl esters of the parent and its isomers to carboxylic acids
- *cis–trans* isomerization of the *E,E*-carboxylic acid CGA 321113
- hydroxylation of the trifluoromethylphenyl ring, followed by sugar conjugation
- oxidation of the methyl of the 2-ethylideneamino group with subsequent sugar conjugation
- cleavage of the N–O bridge, followed by oxidation of the trifluoromethylphenyl moiety to form the acetophenone derivative, with subsequent sugar conjugation
- cleavage of the N–O bridge, followed by oxidation of the glyoxylphenyl moiety, with eventual formation of phthalic acid
- formation of unextracted residues.

Environmental fate

Water–sediment systems

Because trifloxystrobin is used for foliar spray treatment and on paddy rice, only studies of hydrolysis and degradation in water–sediment systems were considered.

Trifloxystrobin is relatively stable hydrolytically under sterile neutral and weakly acid conditions, whereas under alkaline conditions hydrolytic degradation increases with increasing pH. The acid CGA 321113 formed under alkaline conditions is not degraded hydrolytically. No ring cleavage is observed at pH ≥ 5.

In biologically active aquatic systems such as a paddy rice plot, trifloxystrobin was rapidly degraded in both flooding water and paddy soil, with a maximum half-life of 2–5 days. As in sterile hydrolysis, the main product in a paddy rice field was the acid CGA 321113. While this metabolite is stable to sterile

hydrolysis, it was rapidly degraded in the rice plot, with degradation half-lives of 7–8 days in flooding water and paddy soil. Besides CGA 321113, formed by biotic hydrolysis, isomerization of the parent compound and CGA 321113 occurred, resulting in formation of the parent *Z,E*- isomer CGA 357261 in small amounts and the acid *Z,E*- isomer CGA 373466 in large amounts. CGA 373466 degraded rapidly in the water layer, with a half-life of 4.2 days. A half-life with reasonable significance could not be estimated for CGA 357261 owing to the very low concentrations in the range of the LOQ.

The photolytic half-lives of trifloxystrobin in sterile aqueous buffered solutions at 25 °C under a xenon arc light (12 h light–12 h dark cycle) were 20.4 h at pH 5 and 31.5 h at pH 7. The corresponding predicted environmental half-lives in summer sunlight at a geographical latitude of 40° N were 1.1 and 1.7 days at pH 5 and pH 7, respectively.

Rotational crops

The Meeting received the results of confined crop rotation studies with ^{14}C-trifloxystrobin with both labels and from crop rotation trials with unlabelled trifloxystrobin. In some trials, a first crop was treated with trifloxystrobin, while in others bare ground was treated directly with trifloxystrobin as an extreme case for residues in soil from the first crop. The normal rotation was a first crop followed in rotation by a root crop (radish, turnip), a vegetable (lettuce, spinach) and a cereal (wheat). The rotation crops were sown or planted from 30 days to 1 year after the final treatment of the first crop or bare ground.

In a study with an exaggerated application rate of 2.2 kg ai/ha to bare soil, turnips, spinach and wheat were planted and components of each were analysed 30 and 120 days after application. The residue levels of trifloxystrobin equivalent were higher with the trifluoromethylphenyl label than the glyoxylphenyl label. The levels of trifluoromethylphenyl label (as trifloxystrobin equivalents) after 30/120 days were: 0.06/0.04 mg/kg in turnip leaves, 0.02/0.02 mg/kg in turnip roots, 0.25/0.26 mg/kg in spinach, 0.28/0.19 mg/kg in 25% mature wheat fodder, 0.14/0.10 mg/kg in mature wheat fodder, 0.17/0.20 mg/kg in wheat straw and 0.07/0.06 mg/kg in wheat grain. With the other label, only a small proportion of the TRR were usually identified or characterized; trifloxystrobin represented < 2%. CGA 321113 represented up to 8.5% of the TRR in turnip leaves and 17.5% in turnip roots (0.003 mg/kg). With the trifluoromethyl-^{14}C label, 37–100% of the TRR was identified or characterized. Trifloxystrobin, its conformational isomers and the acid CGA 321113 and its isomers were reported, all at < 0.01 mg/kg. Trifluoroacetic acid was found as a major degradation product in all crops, especially in wheat (up to 0.23 mg/kg in immature fodder and 0.12 mg/kg in straw), indicating breakdown of the trifluoromethylphenyl ring. As trifluoroacetic acid was observed only rarely as a plant metabolite in target crops after foliar application, it is likely that its precursor is formed in the soil or rhizosphere of the plants.

In unconfined rotational studies with unlabelled trifloxystrobin, no residues of trifloxystrobin (< 0.02 mg/kg) or CGA 321113 (< 0.02 mg/kg) were detected in any of the rotational crops at 30-day plant-back intervals, except in wheat straw and grain in one trial,.

The rotational crop studies suggest that trifloxystrobin itself and the acid CGA 321113 do not occur in rotational crops at levels ≥ 0.01 mg/kg.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of trifloxystrobin and the metabolite CGA 321113 in crops and animal commodities. The methods rely on gas–liquid chromatography, HPLC and liquid chromatography with tandem mass spectrometry detection and generally achieve LOQs of 0.01–0.02 mg/kg in crop and animal matrices, except dry matrices such as hay, straw (LOQ, 0.05 mg/kg) and hops (LOQ, 0.1 mg/kg). The recoveries were in the range of 70–120% for both analytes.

In most of the field studies, the determination of trifloxystrobin and CGA 321113 in plant and animal commodities was based on extraction of the samples with acetonitrile and water (80:20, v/v), filtration,

liquid–liquid partitioning with a three-solvent system (sodium chloride-saturated water, toluene and hexane), clean-up on a C18 solid extraction column, partitioning into methyl *tert*-butyl ether:hexane, concentration to dryness and dissolution in 0.1% polyethylene glycol in acetone for gas chromatographic analysis with nitrogen–phosphorus detection. The LOQ was 0.02 mg/kg in all matrices except peanut hay and cereal straw (0.05 mg/kg) and milk (0.01 mg/kg). This method (or with electron capture detection) was used in the rotational crop, storage stability and field trial studies. The nitrogen–phosphorus detection method is proposed as a monitoring method.

The standard multi-method DFG S 19 can be used for enforcement purposes for the determination of trifloxystrobin in all plant materials except hops.

Data on the extraction efficiency of the methods with weathered radiolabelled samples from the studies of metabolism in apples, cucumbers, peanuts, wheat grain and straw, and matrices from the animal metabolism studies were submitted. The amount of residue extracted was similar to that in the metabolism studies.

Stability of residues in stored analytical samples

The Meeting received information on the stability of trifloxystrobin and CGA 321113 in crops, farm animal commodities and processed commodities at freezer temperatures for 1–2 years. Trifloxystrobin and CGA 321113 were generally stable for the duration of testing, i.e. a decline in residue levels was not evident or was < 30%.

Definition of the residue

The metabolism of trifloxystrobin in animals is similar to that in plants and occurs primarily via cleavage of the methyl ester group to form CGA 321113. In plants, the main component of the residue is trifloxystrobin. CGA 321113 is the principal residue component in animal tissues (except fat). Trifloxystrobin is the principal residue in milk and fat.

The metabolite CGA 321113 accounts for about 30% of the terminal residue in some raw plant commodities (strawberries, leeks, Brussels sprouts, flowerhead brassicas, carrots, barley, wheat, maize, rice, hops, peanut fodder, barley straw, maize fodder and rice straw). Furthermore, trifloxystrobin can be hydrolysed to CGA 321113 during processing. In these cases, the nature of the residue in the processed product may differ somewhat from that in the raw agricultural commodity. Therefore, CGA 321113 should be included in the residue definition for risk assessment for plant commodities.

The Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*, and that for animal commodities should be the parent compound plus CGA 321113 (expressed as trifloxystrobin equivalents).

The Meeting agreed that the residue definition for consideration of dietary intake should consist of the parent compound plus CGA 321113 (expressed as trifloxystrobin equivalents), to cover the occurrence of residues in both plant and animal commodities as well as in processed products.

The log P_{OW} for trifloxystrobin is 4.5, which suggests that the compound is fat-soluble. As the levels of trifloxystrobin were higher in fat than in muscle, residues in fat are appropriate for controlling residues in meat. The Meeting agreed that the residues of trifloxystrobin are fat-soluble.

Definition of the residue in plant commodities for compliance with MRLs: trifloxystrobin.

Definition of the residue in plant commodities for estimation of dietary intake: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin.

Definition of the residue in animal commodities for compliance with MRLs and estimation of dietary intake: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin.

The residue is fat-soluble.

Results of supervised trials on crops

The Meeting received the results of supervised trials on citrus fruit, pome fruit, stone fruit, grapes, strawberries, bananas, leeks, head cabbage, Brussels sprouts, cauliflower and broccoli, cucumbers, melons, summer squash, tomatoes, peppers, Chinese cabbage, beans, soya beans, carrots, celeriac, potatoes, sugar-beet, celery, chicory, cereals (wheat, barley, maize, rice), almonds, tree nuts, cotton-seed, peanuts, coffee beans and hops; and on animal feed items such as almond hulls, cereal straws, peanut hay and sugar-beet tops. In most cases, the acid metabolite CGA 321113 was determined as well as the parent compound.

The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA 321113 as trifloxystrobin. As CGA 321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated as in the examples below.

Trifloxystrobin (mg/kg)	CGA 321113 (mg/kg)	Total (expressed as trifloxystrobin) (mg/kg)
< 0.02	< 0.02	< 0.02
< 0.02	0.03	0.05
0.10	< 0.02	0.10
0.92	0.16	1.1

Two sets of data are reported: trifloxystrobin *per se* for estimation of maximum residue levels and the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin for estimation of STMRs.

Treatment with trifloxystrobin is limited to up to four applications per season, but in some trials on fruits (pome fruit, grapes, banana) and vegetables (cucurbits, sweet pepper, tomato) up to 10 treatments were made. To investigate the influence of the number of applications on the residue levels, two trials were conducted in apples. Trifloxystrobin was applied four times to apple trees at a rate of 0.12 or 0.15 kg ai/ha with spray intervals of 12–17 days. Samples of fruit were taken before and after each application. The average carry-over of residue (ratio of residue concentration before and after pesticide application) was approximately 40% and at the same level, suggesting that two applications are likely to result in higher residue levels than one application, but three or more applications should not produce residue levels significantly different from those resulting from two. The Meeting agreed that the residue at harvest is influenced only by the final three or four applications, and trials with more than four treatments were used to estimate maximum residue levels and STMRs.

Citrus fruit

The results of supervised trials for residues in orange, grapefruit and lemon were received from South Africa and the USA.

Use of trifloxystrobin as a foliar spray is registered in South Africa with two applications of 0.005 kg ai/hl and a PHI of 76 days. The six trials on orange that were submitted did not reflect GAP.

In the USA, trifloxystrobin may be used as a foliar spray on citrus fruit at three to four applications of 0.07–0.14 kg ai/ha with a 30-day PHI. As the level of CGA 321113 was below the LOQ in all samples, the data populations for enforcement and risk assessment purposes are identical. The levels of trifloxystrobin residues in whole fruit in trials approximating these conditions at the highest rate were: 0.05, 0.07, 0.08, 0.09, 0.10, 0.11, 0.12, 0.15 (two), 0.16, 0.17, 0.19, 0.21 and 0.23 mg/kg in orange; < 0.02, 0.03 (two), 0.04, 0.06, 0.08 (two) and 0.10 mg/kg in grapefruit; and < 0.02, 0.02, 0.09, 0.11, 0.13 and 0.22 mg/kg in lemon.

The Meeting agreed to combine these results in estimating a maximum residue level for citrus fruit. As no data were available on residues in the edible portion, the STMR was also estimated from the data for whole fruit. The combined concentrations in the 28 trials in the USA, in ranked order, were: < 0.02 (two), 0.02, 0.03 (two), 0.04, 0.05, 0.06, 0.07, 0.08 (three), 0.09 (two), 0.10 (two), 0.11 (two), 0.12, 0.13, 0.15 (two), 0.16, 0.17, 0.19, 0.21, 0.22 and 0.23 mg/kg for trifloxystrobin as well as for the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR value of 0.095 mg/kg for residues of trifloxystrobin in whole citrus fruits.

Pome fruit

Trials were conducted on apple and pear in Australia, Canada, Europe, South Africa and the USA.

In Australia, trifloxystrobin may be applied to *apples* in three applications of 0.005 kg ai/hl with a 35-day PHI. Because the number of treatments had little influence on the residue concentration, two trials with six applications of 0.0038 kg ai/hl were considered close enough to GAP to allow evaluation. The trifloxystrobin residue level in apples was < 0.04 mg/kg, and the level for the sum of trifloxystrobin and CGA 321113 (< 0.04 mg/kg) expressed as trifloxystrobin was 0.08 mg/kg.

GAP for use of trifloxystrobin on apples and pears is similar in many countries in Europe. In France and Italy, trifloxystrobin is registered for use on apples and pears up to a total of three applications at 0.0075 kg ai/hl with a PHI of 14 days. The trifloxystrobin residue levels in apples in four trials in France, one in Germany, one in Greece, six in Italy, three in Spain and nine in Switzerland, conducted according to appropriate GAP, were: 0.04 (two), 0.05 (four), 0.06, 0.07 (two), 0.08, 0.09 (two), 0.10 (two), 0.12, 0.13, 0.15, 0.17, 0.19 (two), 0.20, 0.21, 0.30 and 0.44 mg/kg. The residue levels of CGA 321113 were all below the LOQ.

One trial in Greece, one in Italy and two in Spain on *pears* were reported. The residue concentrations of both trifloxystrobin and the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.06, 0.07, 0.11 and 0.12 mg/kg.

In Spain, four treatments at 0.0075–0.015 kg ai/hl with a PHI of 14 days are allowed on apples and pears. The residue concentration of both trifloxystrobin and the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin in one Spanish trial on apples was 0.19 mg/kg.

In Germany, four treatments at 0.025 kg ai/ha per metre height of crown (0.075 kg ai/ha for a tree with a 3-m crown) and 0.005 kg ai/hl with a PHI of 14 days on apples and pears are allowed. The residue levels of trifloxystrobin and of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin in one trial on apples were both 0.11 mg/kg. The residue level of trifloxystrobin in one trial on pears was 0.17 mg/kg, and the level of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin was 0.19 mg/kg.

In Belgium and Luxembourg, four treatments with 0.085 kg ai/ha and a PHI of 14 days are allowed on apples and pears. The trifloxystrobin residue levels in apples in five trials in France, two in Germany and three in The Netherlands were: 0.03, 0.04, 0.05, 0.07 (four), 0.13 (two), 0.14 and 0.37 mg/kg. The levels of

the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.03, 0.04, 0.05, 0.07 (four), 0.13, 0.14, 0.15 and 0.41 mg/kg.

In South Africa, trifloxystrobin is registered for use on apples at up to three applications of 0.0038–0.005 kg ai/hl with a PHI of 7 days, and it is registered for use on pears at three applications of 0.0038 kg ai/hl with a PHI of 14 days. In two trials each on apples and pears, the residue levels of trifloxystrobin were 0.03, 0.04, 0.05 and 0.06 mg/kg, and the levels of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.03, 0.04 and 0.06 (two) mg/kg.

The use pattern in the USA allows spraying of trifloxystrobin in four applications of 0.105 kg ai/ha on apples and pears with a PHI of 14 days. The concentrations of trifloxystrobin residues in trials in Canada and the USA in apples were: 0.04, 0.09, 0.10, 0.12, 0.13, 0.14, 0.16 (two), 0.18 (three), 0.21, 0.24, 0.26, 0.31 and 0.37 mg/kg, and those in pears were: 0.07, 0.08, 0.09, 0.10 (two), 0.14, 0.15, 0.17, 0.22 and 0.23 mg/kg. The residue levels of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin in apples were: 0.04, 0.09, 0.10, 0.12, 0.13, 0.14, 0.16 (two), 0.18 (two), 0.21 (two), 0.24, 0.26, 0.31 and 0.37 mg/kg, and those in pears were: 0.07, 0.08, 0.09, 0.10, 0.14, 0.15, 0.17, 0.20, 0.22 and 0.23 mg/kg.

The Meeting agreed to combine the data sets on apples and pears from two trials in Australia 42 trials in Europe, four trials in South Africa and 26 trials in Canada and the USA. The residue concentrations of trifloxystrobin *per se*, in ranked order, were: 0.03 (two), < 0.04, 0.04 (five), 0.05 (six), 0.06 (three), 0.07 (eight), 0.08 (three), 0.09 (four), 0.10 (five), 0.11 (two), 0.12 (three), 0.13 (four), 0.14 (three), 0.15 (two), 0.16 (two), 0.17 (three), 0.18 (three), 0.19 (three), 0.20, 0.21 (two), 0.22, 0.23, 0.24, 0.26, 0.30, 0.31, 0.37 (two) and 0.44 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin, in ranked order, were: 0.03 (two), < 0.04, 0.04 (five), 0.05 (five), 0.06 (four), 0.07 (eight), 0.08 (three), 0.09 (four), 0.10 (four), 0.11 (two), 0.12 (three), 0.13 (three), 0.14 (three), 0.15 (three), 0.16 (two), 0.17 (two), 0.18 (two), 0.19 (four), 0.20 (two), 0.21 (three), 0.22, 0.23, 0.24, 0.26, 0.30, 0.31, 0.37, 0.41 and 0.44 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR value of 0.11 mg/kg for residues of trifloxystrobin in pome fruit.

Stone fruit

The results of supervised trials on residues of trifloxystrobin in apricots, cherries, peaches and plums were received from Europe and the USA. Trifloxystrobin is registered for use on apricots, nectarines, peaches, cherries and plums in Switzerland (three applications of 0.2 kg ai/ha, 0.013 kg ai/hl, 21-day PHI) and the USA (four applications of 0.14 kg ai/ha, 1-day PHI). In Spain, trifloxystrobin may be used on peaches and nectarines four times at 0.015 kg ai/hl with a 7-day PHI.

In 14 trials on *cherry* in six states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues were: 0.26, 0.33, 0.34, 0.37, 0.38, 0.39, 0.53, 0.54, 0.55, 0.56, 0.58, 0.63, 0.66 and 0.84 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.28, 0.37, 0.38 (two), 0.41, 0.42, 0.58, 0.59 (two), 0.61, 0.62, 0.69, 0.73 and 0.90 mg/kg

In two trials on *apricot* in Switzerland, which matched GAP, the trifloxystrobin residue levels were 0.14 and 0.28 mg/kg, and the total residue levels were 0.14 and 0.30 mg/kg.

Three trials conducted in southern Europe (France, Italy and Spain) on *peach* were evaluated against Spanish GAP. The trifloxystrobin residue levels were 0.14, 0.18 and 0.48 mg/kg, and the total residue levels were 0.15, 0.18 and 0.52 mg/kg. In 14 trials on peach in six states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues were: 0.06, 0.18, 0.21, 0.25, 0.32, 0.34, 0.39, 0.41, 0.65, 0.82 (two), 0.89, 1.8 and 1.9 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.06, 0.21 (two), 0.25, 0.32, 0.34, 0.39, 0.41, 0.70, 0.86, 0.88, 0.94, 1.9 and 2.0 mg/kg.

In nine trials on *plum* in four states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues and of total residues were: 0.02, 0.06 (two), 0.09, 0.15, 0.19, 0.21 (two) and 0.53 mg/kg.

The Meeting agreed to combine the data from all the trials on residues in stone fruit. The combined results for trifloxystrobin were: 0.02, 0.06 (three), 0.09, 0.14 (two), 0.15, 0.18 (two), 0.19, 0.21 (three), 0.25, 0.26, 0.28, 0.32, 0.33, 0.34 (two), 0.37, 0.38, 0.39 (two), 0.41, 0.48, 0.53 (two), 0.54, 0.55, 0.56, 0.58, 0.63, 0.65, 0.66, 0.82 (two), 0.84, 0.89, 1.8 and 1.9 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.02, 0.06 (three), 0.09, 0.14, 0.15 (two), 0.18, 0.19, 0.21 (four), 0.25, 0.28, 0.30, 0.32, 0.34, 0.37, 0.38 (two), 0.39, 0.41 (two), 0.42, 0.52, 0.53, 0.58, 0.59 (two), 0.61, 0.62, 0.69, 0.70, 0.73, 0.86, 0.88, 0.90, 0.94, 1.9 and 2.0 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.38 mg/kg for residues in stone fruit.

Berries and small fruit

Trials on *grape* were conducted in Australia, Canada, France, Germany, Greece, Italy, South Africa, Spain, Switzerland and the USA.

In Australia, trifloxystrobin may be used on grapes at 0.0075 kg ai/hl with a 35-day PHI after three applications. In trials in Australia matching GAP conditions, the trifloxystrobin residue levels were: < 0.02, 0.04, 0.08 and 0.09 (two) mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: < 0.02, 0.04, 0.09 (two) and 0.11 mg/kg.

In Canada, trifloxystrobin may be used up to four times at 0.07 kg ai/ha and in the USA up to 0.14 kg ai/ha with a 14-day PHI. In two Canadian and 12 US trials matching GAP conditions, the trifloxystrobin residue levels were: 0.04, 0.06, 0.09, 0.16, 0.17, 0.21, 0.26, 0.28, 0.29, 0.33, 0.61, 0.62, 1.1 and 2.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.04, 0.06, 0.09, 0.16, 0.17, 0.21, 0.26, 0.28, 0.33, 0.36, 0.63, 0.64, 1.2 and 2.2 mg/kg.

In Germany, registered use is three applications of 0.12 kg ai/ha with harvesting 35 days after the last treatment. Two trials in France, four in Germany and four in Switzerland with three applications of 0.13 kg ai/ha and a 35–36-day PHI matched this GAP. The trifloxystrobin residue levels were 0.03, 0.04 (three), 0.06 (two), 0.13, 0.14, 0.27 and 0.29 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.04 (two), 0.05 (two), 0.06, 0.07, 0.16 (two), 0.29 and 0.30 mg/kg.

Trifloxystrobin is registered for use in South Africa at up to 0.011 kg ai/hl with a 14-day PHI. Residues in grapes in three trials with this use pattern were 0.11, 0.18 and 0.24 mg/kg for trifloxystrobin and 0.15, 0.22 and 0.38 mg/kg for total residues.

Trifloxystrobin is registered for use in Spain at four applications of 0.075 kg ai/ha with a 30-day PHI. In one trial in Greece, two in Italy and four in Spain approximating these conditions, the trifloxystrobin residue levels were 0.05, 0.08, 0.11, 0.13, 0.14, 0.28 and 0.36 mg/kg. The total residue levels were 0.05, 0.08, 0.11, 0.13, 0.14, 0.28 and 0.38 mg/kg.

In summary, the residue levels of trifloxystrobin *per se* in 39 trials in Australia, Europe, South Africa, Canada and the USA, in ranked order, were: < 0.02, 0.03, 0.04 (five), 0.05, 0.06 (three), 0.08 (two), 0.09 (three), 0.11 (two), 0.13 (two), 0.14 (two), 0.16, 0.17, 0.18, 0.21, 0.24, 0.26, 0.27, 0.28 (two), 0.29 (two), 0.33, 0.36, 0.61, 0.62, 1.1 and 2.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: < 0.02, 0.04 (four), 0.05 (three), 0.06 (two), 0.07, 0.08, 0.09 (three), 0.11 (two), 0.13, 0.14, 0.15, 0.16 (three), 0.17, 0.21, 0.22, 0.26, 0.28 (two), 0.29, 0.30, 0.33, 0.36, 0.38 (two), 0.63, 0.64, 1.2 and 2.2 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.15 mg/kg for residues in grapes.

The Swiss pattern of use of trifloxystrobin on *strawberry* allows three spray applications at 0.25 kg ai/ha with a PHI of 14 days. In five trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were: 0.04, 0.05, 0.06, 0.10 and 0.13 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.08, 0.09, 0.10, 0.14 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.10 mg/kg for residues in strawberries.

Banana

Trifloxystrobin may be used in Latin America on bananas at four applications of 0.09 kg ai/ha with a 0-day PHI. The results of supervised trials on residues in bagged and unbagged banana after up to 11 treatments at 0.01–0.16 kg ai/ha by aerial application were received from Colombia (four), Costa Rica (six), Ecuador (six), Guatemala (four), Honduras (two) and Mexico (two). The treatment was typical of that performed by commercial aerial sprayers from a fixed-winged airplane or a helicopter. In four trials in Martinique, bananas were treated six times at 0.09 kg ai/ha by a foliar backpack sprayer with aerial boom. In two trials in Puerto Rico, plants were treated 10 times at 0.1–0.13 kg ai/ha by spraying over the top, simulating aerial application. Although the actual treatment rate in some trials exceeded GAP by more than 30%, these trials were included in the evaluation because of the very low residue levels ($\leq$ LOQ). In whole bagged and unbagged fruit, the trifloxystrobin residue concentrations for estimation of the maximum residue level were: < 0.01 (four), < 0.02 (23), 0.02 and 0.03 (two) mg/kg. In the edible portion, the residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: < 0.01 (four) and < 0.02 (26) mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.02 mg/kg for residues in bananas.

Leek

The Swiss pattern of use of trifloxystrobin on leeks allows three spray applications at 0.19 kg ai/ha with a PHI of 7 days. The levels of trifloxystrobin residues in leek in one trial in France, one in Germany, one in The Netherlands and two in Switzerland that met these conditions were: 0.08, 0.14, 0.15 and 0.40 (two) mg/kg. The corresponding total residues were: 0.13, 0.26, 0.31, 0.47 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.31 mg/kg for residues in leeks.

Brassica vegetables

The Swiss pattern of use of trifloxystrobin on broccoli, cauliflower, Brussels sprouts and head cabbage allows three spray applications at 0.13–0.25 kg ai/ha with a PHI of 7 days. The trials on head cabbage, Brussels sprouts, broccoli and cauliflower were evaluated together for mutual support.

One trial on *head cabbage* in Germany, one in The Netherlands and two in Switzerland matching maximum GAP, with a rate of 0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: 0.02 (two), 0.03 and 0.07 mg/kg, and those of total residues were 0.03, 0.04 (two) and 0.11 mg/kg.

Two trials on *Brussels sprouts* in France, one in Germany, two in Switzerland and one in the United Kingdom matching maximum GAP, with a rate of 0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: 0.10, 0.16, 0.18, 0.19, 0.20 and 0.35 mg/kg, and those of total residues were: 0.18, 0.22, 0.26, 0.27, 0.28 and 0.39 mg/kg.

One trial on *cauliflower* in Germany and two in Switzerland and two trials on broccoli in Germany and one in the United Kingdom, which matched GAP with a rate of 0.2–0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: < 0.01, < 0.02, 0.09, 0.13 (two) and 0.26 mg/kg, and those of total residues were: < 0.02, 0.04, 0.13, 0.16, 0.23 and 0.26 mg/kg.

The combined levels of trifloxystrobin residues in broccoli, cauliflower, Brussels sprouts and head cabbage were, in ranked order: < 0.01, < 0.02, 0.02 (two), 0.03, 0.07, 0.09, 0.10, 0.13 (two), 0.16, 0.18, 0.19, 0.20, 0.26 and 0.35 mg/kg. Those of total residues were: < 0.02, 0.03, 0.04 (three), 0.11, 0.13, 0.16, 0.18, 0.22, 0.23, 0.26 (two), 0.27, 0.28 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.17 mg/kg for residues in flowerhead brassica, Brussels sprouts and head cabbage.

Chinese cabbage

Trifloxystrobin is registered in Switzerland for use on Chinese cabbage up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin residues in Chinese cabbage in two Swiss trials were 0.01 and 0.33 mg/kg. The corresponding total residue levels were 0.01 and 0.35 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in Chinese cabbage.

Fruiting vegetables

Cucurbits

Trifloxystrobin is registered in Switzerland for use on *cucumber* up to three times at 0.25 kg ai/ha and a 3-day PHI for indoor use. Eight trials conducted in glasshouses in Italy (one), The Netherlands (two), Spain (four) and Switzerland (one) approximated Swiss GAP. The trifloxystrobin residue levels were: 0.02, 0.03 (two), 0.04, 0.06, 0.07 and 0.14 (two) mg/kg. The total residue levels were 0.02, 0.03 (two), 0.04, 0.10, 0.12 and 0.17 (two) mg/kg.

Trifloxystrobin is registered in the USA for use on cucurbit vegetables such as chayote, Chinese waxgourd, citron melon, cucumber, gherkin, edible gourds, muskmelon, pumpkin, summer squash, winter squash and watermelon, as up to four applications of 0.14 kg ai/ha and a 0-day PHI for outdoor use. Eight outdoor trials on *cucumber* in seven states in accord with GAP conditions were reported. The trifloxystrobin residue levels were: 0.03, 0.04 (three), 0.05, 0.06, 0.17 and 0.22 mg/kg. The total residue levels were 0.03, 0.04 (three), 0.05, 0.06, 0.17 and 0.24 mg/kg.

The data from the indoor and outdoor trials on cucumbers could be combined as they were apparently for similar data populations. The residue levels of trifloxystrobin *per se* in the European and North American trials were, in ranked order: 0.02, 0.03 (three), 0.04 (four), 0.05, 0.06 (two), 0.07, 0.14 (two), 0.17 and 0.22 mg/kg. The corresponding total residue levels were 0.02, 0.03 (three), 0.04 (four), 0.05, 0.06, 0.10, 0.12, 0.17 (three) and 0.24 mg/kg.

In Italy, trifloxystrobin may be used on *melon* up to three times at 0.13 kg ai/ha with a 3-day PHI. Three trials in Italy and four in Spain complied with this use pattern. Both the trifloxystrobin and the total residue levels were: < 0.02 (two), 0.04, 0.07, 0.10, 0.11 and 0.19 mg/kg. Six trials in the USA on melons matching GAP for cucurbits resulted in trifloxystrobin and total residue levels of: 0.07, 0.10 (two), 0.11, 0.18 and 0.24 mg/kg.

In five trials in the USA on *summer squash* matching GAP for cucurbits, the trifloxystrobin and the total residue levels were: < 0.02, 0.09, 0.11, 0.15 and 0.23 mg/kg.

The Meeting decided to pool the data on cucumbers (16 trials), melons (13 trials) and summer squash (five trials) to estimate a maximum residue level for cucurbits. The trifloxystrobin residue levels were < 0.02 (three), 0.02, 0.03 (three), 0.04 (five), 0.05, 0.06 (two), 0.07 (three), 0.09, 0.10 (three), 0.11 (three), 0.14 (two), 0.15, 0.17, 0.18, 0.19, 0.22, 0.23 and 0.24 mg/kg. The corresponding total residue levels, in ranked order, were: < 0.02 (three), 0.02, 0.03 (three), 0.04 (five), 0.05, 0.06, 0.07 (two), 0.09, 0.10 (four), 0.11 (three), 0.12, 0.15, 0.17 (three), 0.18, 0.19, 0.23 and 0.24 (two) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.095 mg/kg for residues in cucurbits.

Sweet peppers

In the USA, trifloxystrobin may be used on sweet peppers four times at 0.14 kg ai/ha with a 3-day PHI. The levels of both trifloxystrobin and total residues in 12 outdoor trials in five states conducted according to GAP were: 0.03, 0.04 (two), 0.05 (two), 0.08, 0.12 (three), 0.14 and 0.16 (two) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, and an STMR of 0.1 mg/kg.

Tomato

In the USA, trifloxystrobin may be used on tomatoes four times at 0.14 kg ai/ha with a 3-day PHI. The trifloxystrobin and the total residue levels in 18 outdoor trials in five states conducted according to GAP were: < 0.02 (two), 0.03, 0.06, 0.07 (five), 0.09 (three), 0.10, 0.13, 0.20, 0.29, 0.43 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for residues in tomatoes.

Legume vegetables and pulses

Beans (dry)

Trifloxystrobin may be used on beans in Brazil three times at 0.1–0.13 kg ai/ha with a 15-day PHI. Five trials with four applications at 0.15 kg ai/ha and a further five trials with three to four applications of 0.094 kg ai/ha and a 15-day PHI in Brazil approximately matched GAP. The trifloxystrobin residue levels were < 0.02 (four) and ≤ 0.05 (six) mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in beans (dry).

Soya beans (dry)

Trifloxystrobin may be used on soya beans in Brazil twice at 0.056–0.075 kg ai/ha with a 30-day PHI and once at 0.056 kg ai/ha with a 20-day PHI in Argentina. Three trials with two applications at 0.063 kg ai/ha, three trials with two applications at 0.094 kg ai/ha and a further three trials with two applications at 0.13 kg ai/ha and a 21–30-day PHI in Brazil were reported. The trifloxystrobin residue levels were all < 0.05 mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in soya bean (dry).

Root and tuber vegetables

Carrot

Trifloxystrobin is registered in Switzerland for use on carrots up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin residues in carrots in one trial in Belgium, one in Germany, two in The Netherlands and two in Switzerland conducted according to the Swiss use pattern were: < 0.02, 0.02 (two), 0.03 (two) and 0.04 mg/kg. The corresponding total residue levels were < 0.02, 0.02, 0.03, 0.04 (two) and 0.08 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.035 mg/kg for residues in carrot.

Celeriac

Trifloxystrobin is registered in Switzerland for use on celeriac up to three times at 0.25 kg ai/ha with a 14-day PHI. The concentrations of trifloxystrobin residues in celeriac in two Swiss trials were 0.02 and 0.03 mg/kg. The corresponding total residue levels were 0.03 and 0.04 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and STMR for residues in celeriac.

Potato

In the USA, trifloxystrobin may be used on potatoes six times at 0.14 kg ai/ha with a 7-day PHI. In 15 trials in 13 states conducted according to GAP, all the levels of trifloxystrobin and CGA 321113 residues in tubers were below the LOQ (0.02 mg/kg).

The Meeting estimated a maximum residue level of 0.02* mg/kg and an STMR of 0.02 mg/kg for residues in potato.

Sugar-beet

Italian GAP allows three treatments with an emulsifiable concentrate at rates of 0.11–0.15 kg ai/ha, and Swiss GAP allows one application at 0.15 kg ai/ha, both with a PHI of 21 days, for sugar-beet. In nine trials in France, two in Italy, two in Spain and one in Switzerland that matched GAP, the residue levels of trifloxystrobin *per se* and of total residues in the roots were: < 0.02 (13) and 0.02 mg/kg.

Trifloxystrobin is registered in the USA for use on sugar-beet up to three times at 0.12 kg ai/ha with a 21-day PHI. The trifloxystrobin residue levels in sugar-beet roots in 19 trials in seven states conducted in line with these conditions were: < 0.02 (11), 0.02 (three), 0.03 (three) and 0.04 (two) mg/kg. The corresponding total residue levels were < 0.02 (11), 0.02 (three), 0.03 (two), 0.04 (two) and 0.06 mg/kg.

In summary, the trifloxystrobin residue levels in the 14 trials in Europe and 19 in the USA were: < 0.02 (24), 0.02 (four), 0.03 (three) and 0.04 (two) mg/kg. The corresponding total residue levels were $\underline{< 0.02}$ (24), 0.02 (four), 0.03 (two), 0.04 (two) and 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.02 mg/kg for residues in sugar-beet.

Celery

Trifloxystrobin is registered in Switzerland for use on celery up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin and total residues in whole celery plants without roots in three Swiss trials conducted according to GAP were: 0.12, $\underline{0.18}$ and 0.21 mg/kg.

The Meeting concluded that there were sufficient data and estimated a maximum residue level of 1 mg/kg and an STMR of 0.18 mg/kg for residues in celery as a minor crop.

Witloof chicory

Trifloxystrobin is registered in Switzerland for use on chicory up to three times at 0.25 kg ai/ha with a 21-day PHI. The concentrations of trifloxystrobin residues in chicory leaves in two Swiss trials were 0.34 and 0.86 mg/kg. The corresponding total residue levels were 0.37 and 0.94 mg/kg. The trifloxystrobin and the total residue levels in the roots were both 0.02 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and STMR for residues in witloof chicory.

Cereal grains

Barley

In some countries of Europe, trifloxystrobin is used twice at 0.25 kg ai/ha (France, Germany, United Kingdom) or 0.19 kg ai/ha (Belgium) or once at 0.15 kg ai/ha (Austria). The PHI is 35 days in Austria, Germany and the United Kingdom and 42 days in Belgium and France. In one trial in Denmark, 30 in France, six in Germany and two in the United Kingdom matching the appropriate European GAP, the trifloxystrobin residue levels in barley grain were < 0.02 (10), 0.02 (four), 0.03 (five), 0.04 (two), 0.05 (four), 0.06, 0.07 (three), 0.11 (four), 0.12 (two), 0.13 (two), 0.18 and 0.40 mg/kg. The corresponding total residue levels were < 0.02 (10), 0.02 (four), 0.03 (four), 0.04 (three), 0.05 (two), 0.07 (four), 0.09 (two), 0.11 (three), 0.13, 0.14, 0.15, 0.16, 0.17, 0.18 and 0.46 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.04 mg/kg for residues in barley. A highest residue level of 0.46 mg/kg was estimated for calculating the dietary burden of farm animals.

Wheat

Brazilian GAP allows two treatments at 0.075 kg ai/ha with a 30-day PHI. Six Brazilian trials were conducted with three applications at 0.15 kg ai/ha. In all these trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

Trifloxystrobin may be used twice at 0.25 kg ai/ha in France Germany, Ireland and the United Kingdom; at 0.19 kg ai/ha in Austria, Belgium, Hungary, Italy, Luxembourg, Poland and Switzerland; and at 0.13 kg ai/ha in Slovakia, with PHIs of 35–45 days. In 26 trials in France, 10 in Germany, one in Sweden and two in Switzerland matching the appropriate European GAP, the trifloxystrobin residue levels in wheat grain were: < 0.02 (32), 0.02 (three), 0.03 (two), 0.05 and 0.14 mg/kg. The corresponding total residue levels were: < 0.02 (32), 0.02 (three), 0.03 (two), 0.07 and 0.20 mg/kg.

Trifloxystrobin is registered in the USA for use on wheat up to two times at 0.09 kg ai/ha with a 35-day PHI. In 33 trials in 11 states where these conditions were approximated, the trifloxystrobin and the total residue levels in wheat grain were: < 0.02 (30), 0.02 and 0.03 (two) mg/kg.

In summary, the trifloxystrobin residue levels in the 39 European and the 33 US trials were: < 0.02 (62), 0.02 (four), 0.03 (four), 0.05 and 0.14 mg/kg. The corresponding total residue levels were: ≤ 0.02 (62), 0.02 (four), 0.03 (four), 0.07 and 0.20 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.02 mg/kg for residues in wheat. A highest residue level of 0.2 mg/kg was estimated for calculating the dietary burden of farm animals.

Maize

Brazilian GAP allows two treatments at 0.075–0.1 kg ai/ha with a 30-day PHI. Three Brazilian trials at three times 0.1 kg ai/ha were conducted. In all the trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

Trifloxystrobin is registered in the USA for use on maize up to three times at 0.11 kg ai/ha. The PHI for maize grain is not specified, but the product should not be applied after silking. In 24 field trials in 14 states where these conditions were approximated, the levels of trifloxystrobin residues in maize grain were < 0.02 (24) mg/kg, and the total residue levels were < 0.02 (23) and 0.05 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.02 mg/kg for residues in maize. A highest residue level of 0.05 mg/kg was estimated for calculating the dietary burden of farm animals.

Rice

Brazilian GAP allows two foliar treatments at 0.10–0.13 kg ai/ha with a 15-day PHI. Five Brazilian trials with three applications at 0.15 kg ai/ha and a 14–18-day PHI were conducted. The levels of trifloxystrobin residues in rice grain with husk were: < 0.05, 0.05, 0.10, 0.13 and 0.22 mg/kg. As CGA 321113 was not determined, these trials were not included in the evaluation.

Trifloxystrobin is registered in the USA for use on rice up to two times at 0.17 kg ai/ha with a 35-day PHI. In 19 trials in five states where these conditions were approximated, the trifloxystrobin residue levels in rice grain with husk before processing were: < 0.02 (five), 0.03, 0.04 (two), 0.10, 0.11 (two), 0.12, 0.25, 0.30, 0.34, 0.56, 0.68, 2.4 and 3.4 mg/kg. The corresponding total residue levels were < 0.02 (five), 0.04, 0.06, 0.07, 0.13, 0.16, 0.20, 0.21, 0.33, 0.41, 0.46, 0.63, 0.75, 2.5 and 3.4 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.16 mg/kg for residues in rice. A highest residue level of 3.4 mg/kg was estimated for calculating the dietary burden of farm animals.

Tree nuts

Trifloxystrobin is registered in the USA for use on beechnuts, brazil nuts, butternuts, cashew nuts, chestnuts, chinquapins, filberts, macadamia nuts and walnuts up to four times, and almonds up to three times at 0.14 kg ai/ha with a 60-day PHI. Three treatments at 0.091 kg ai/ha with a PHI of 30 days may be used on pecans.

In six trials on *almonds* in California in which these conditions were approximated, the trifloxystrobin and the total residue levels in almond nuts without shells were < 0.02 mg/kg.

In 11 trials on *pecans* in five states, with eight treatments at 0.14 kg ai/ha and a 30-day PHI, the trifloxystrobin and the total residue levels in pecan nuts without shells were < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.02* mg/kg and an STMR of 0 mg/kg for residues in tree nuts.

Cotton-seed

Brazilian GAP allows up to three foliar treatments at 0.063–0.075 kg ai/ha with a 21-day PHI. Three Brazilian trials with three applications at 0.1 kg ai/ha and a 21-day PHI were conducted. The samples were not analysed for CGA 321113. In all three trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for cotton-seed.

Peanuts

Brazilian GAP allows three foliar treatments at 0.075 kg ai/ha with a 15-day PHI for peanuts. Three Brazilian trials with three applications at 0.10 kg ai/ha and a 15-day PHI were conducted. The trifloxystrobin residue levels in peanuts without shells were < 0.05 mg/kg. As CGA 321113 was not determined, these trials were not included in the evaluation.

Trifloxystrobin is registered in the USA for use on peanuts twice at an application rate of 0.13 kg ai/ha or six times at 0.064 kg ai/ha with a PHI of 14 days. In 22 trials with eight applications at 0.07 kg ai/ha and 12 trials with eight applications at 0.14 kg ai/ha were in seven states in 1996–98, the trifloxystrobin and total residue levels in kernels were all < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.02* mg/kg and an STMR of 0 mg/kg for residues in peanuts.

Coffee beans

Brazilian GAP allows three treatments at 0.075–0.11 kg ai/ha with a 30-day PHI. Four Brazilian trials with three applications at 0.11 kg ai/ha were conducted. In all four trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA 321113 was not determined, these trials were not included in the evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level or an STMR for coffee beans.

Hops

German and Austrian GAP allows two treatments of hops at a spray concentration of 0.013 kg ai/hl and a PHI of 14 days. Five German trials with four to six applications of trifloxystrobin at a spray concentration of 0.013 kg ai/ha were reported. In cones harvested 14 days after the last treatment and dried, the trifloxystrobin residue levels were: 4.7, 5.4, 8.8, 16 and 26 mg/kg. The corresponding total residue levels were: 6.2, 6.7, 10, 18 and 29 mg/kg.

In the USA, trifloxystrobin may be used on hops four times at 0.14 kg ai/ha with a 14-day PHI. In three trials in two states with six treatments at 0.14 kg ai/ha and a 13–14-day PHI, the trifloxystrobin residue levels in dried cones were 4.5, 9.3 and 10 mg/kg. The corresponding total residue levels were 4.9, 9.9 and 11 mg/kg.

In summary, the trifloxystrobin residue levels in the three trials in Germany and the three in the USA were: 4.5, 4.7, 5.4, 8.8, 9.3, 10, 16 and 26 mg/kg, and the corresponding total residue levels were: 4.9, 6.2, 6.7, 9.9, 10, 11, 18 and 29 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg and an STMR of 9.95 mg/kg for residues in hops, dry.

Animal feedstuffs

Almond hulls

Trifloxystrobin is registered in the USA for use on almonds up to three times at 0.14 kg ai/ha and a 60-day PHI. Six trials on almonds in California approximating these conditions were reported. The trifloxystrobin residue levels in hulls were: 0.25, 0.42, 0.72, 1.2, 1.6 and 1.8 mg/kg, and the total residue levels were: 0.25, 0.42, 0.75, 1.2, 1.6 and 1.9 mg/kg (fresh weight).

Allowing for the standard 90% dry matter for almond hulls (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 1.08 mg/kg for almond hulls (dry weight). A highest residue level of 2.1 mg/kg was estimated for calculating the dietary burden of farm animals.

Peanut fodder

Trifloxystrobin is registered in the USA for use on peanuts with a maximum GAP of two applications at 0.13 kg ai/ha and a PHI of 14 days. In 12 trials with eight applications at 0.14 kg ai/ha in six states in 1996, the trifloxystrobin residue levels in peanut hay were: 0.19 (two), 0.25, 0.27, 0.29, 0.34, 0.46, 0.71, 0.84, 1.4, 3.4 and 3.7 mg/kg. The corresponding total residue levels were: 0.37, 0.40, 0.42, 0.47, 0.50, 0.63, 0.82, 1.1, 1.4, 2.1, 4.1 and 4.2 mg/kg (fresh weight).

Allowing for the standard 85% dry matter for peanut hay (*FAO Manua*l, p. 148), the Meeting estimated a maximum residue level of 5 mg/kg and an STMR (dry weight) of 0.85 mg/kg for residues in peanut fodder. A highest residue level of 4.94 mg/kg was estimated for calculating the dietary burden of farm animals.

Barley straw and fodder, dry

Trifloxystrobin may be used twice at 0.25 kg ai/ha in France, Germany and the United Kingdom; twice at 0.19 kg ai/ha in Belgium; and once at 0.15 kg ai/ha in Austria. The PHI is 35 days in Austria,

Germany and the United Kingdom and 42 days in Belgium and France. The trifloxystrobin residue levels in barley straw in one trial in Denmark, 23 in France, six in Germany and two in the United Kingdom, matching appropriate European GAP were: 0.09, 0.15, 0.23, 0.31, 0.32, 0.33, 0.38 (two), 0.43, 0.49, 0.50, 0.53, 0.61, 0.64, 0.66, 0.68, 0.69, 0.72, 0.78, 0.81 (two), 0.91 (two), 0.93, 1.0, 1.1, 1.3, 1.5, 1.6, 1.8, 2.4 and 4.2 mg/kg. The corresponding total residue levels were: 0.09, 0.15, 0.30, 0.33, 0.38 (three), 0.48, 0.58, 0.64, 0.67, 0.68, 0.75, 0.77, 0.79, 0.80 (two), 0.86, 0.93, 0.94 (two), 1.1 (four), 1.5 (two), 1.7, 1.8, 1.9, 2.6 and 4.4 mg/kg (fresh weight).

Allowing for the standard 89% dry matter for barley straw (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 7 mg/kg and an STMR value (dry weight) of 0.9 mg/kg for residues in barley straw and fodder, dry. A highest residue level of 4.9 mg/kg was estimated for calculating the dietary burden of farm animals.

Wheat straw and fodder, dry

Trifloxystrobin may be used on wheat at 0.25 kg ai/ha in France, Germany, Ireland and the United Kingdom; at 0.19 kg ai/ha in Austria, Belgium, Hungary, Italy, Luxembourg, Poland and Switzerland; and at at 0.13 kg ai/ha in Slovakia. The PHIs are 35–45 days. In 26 trials in France, 10 in Germany, one in Sweden and two in Switzerland that matched appropriate European GAP, the trifloxystrobin residue levels in wheat straw were: < 0.05, 0.07, 0.09 (two), 0.13, 0.16 (two), 0.17, 0.19 (two), 0.30, 0.31, 0.33, 0.34, 0.35, 0.38, 0.40, 0.50, 0.57, 0.59, 0.62, 0.70, 0.73, 0.76, 0.77, 0.81, 0.83, 0.85, 0.94, 0.99, 1.1, 1.3 (two), 1.4, 1.6, 1.8, 1.9, 2.3 and 2.5 mg/kg. The corresponding total residue levels were < 0.05, 0.07, 0.09, 0.13, 0.15, 0.16 (two), 0.24, 0.25, 0.26, 0.38 (three), 0.41, 0.42, 0.43, 0.51, 0.57, 0.77, 0.78 (two), 0.87, 0.89, 0.94, 0.95 (two), 1.0, 1.1, 1.2 (two), 1.3, 1.5, 1.6, 1.7, 1.8, 2.1, 2.6 (two) and 2.7 mg/kg (fresh weight).

Trifloxystrobin is registered in the USA for use on wheat up to two times at 0.09 kg ai/ha with a 35-day PHI. In 23 trials in eight states where these conditions were approximated, the trifloxystrobin residue levels in wheat straw were: 0.08 (two), 0.11 (two), 0.12 (two), 0.13, 0.14, 0.15, 0.17, 0.19 (two), 0.26, 0.27, 0.29, 0.31, 0.34, 0.51, 0.61, 0.96, 0.97, 1.4 and 1.9 mg/kg. The corresponding total residue levels were 0.08, 0.11 (three), 0.12 (two), 0.14, 0.15 (two), 0.19, 0.21, 0.22, 0.26, 0.29, 0.31, 0.36, 0.44, 0.51, 0.64, 1.0, 1.1, 1.6 and 2.4 mg/kg (fresh weight).

In summary, the trifloxystrobin residue levels in the 39 European and the 23 US trials, in ranked order, were: < 0.05, 0.07, 0.08 (two), 0.09 (two), 0.11 (two), 0.12 (two), 0.13 (two), 0.14, 0.15, 0.16 (two), 0.17 (two), 0.19 (four), 0.26, 0.27, 0.29, 0.30, 0.31 (two), 0.33, 0.34 (two), 0.35, 0.38, 0.40, 0.50, 0.51, 0.57, 0.59, 0.61, 0.62, 0.70, 0.73, 0.76, 0.77, 0.81, 0.83, 0.85, 0.94, 0.96, 0.97, 0.99, 1.1, 1.3 (two), 1.4 (two), 1.6, 1.8, 1.9 (two), 2.3 and 2.5 mg/kg. The total residue levels were: < 0.05, 0.07, 0.08, 0.09, 0.11 (three), 0.12 (two), 0.13, 0.14, 0.15 (three), 0.16 (two), 0.19, 0.21, 0.22, 0.24, 0.25, 0.26 (two), 0.29, 0.31, 0.36, 0.38 (two), 0.38, 0.41, 0.42, 0.43, 0.44, 0.51 (two), 0.57, 0.64, 0.77, 0.78 (two), 0.87, 0.89, 0.94, 0.95 (two), 1.0 (two), 1.1 (two), 1.2 (two), 1.3, 1.5, 1.6 (two), 1.7, 1.8, 2.1, 2.4, 2.6 (two) and 2.7 mg/kg (fresh weight).

Allowing for the standard 88% dry matter for wheat straw (*FAO Manual*, p. 149), the Meeting estimated a maximum residue level of 5 mg/kg and an STMR (dry weight) of 0.48 mg/kg for residues in wheat straw and fodder, dry. A highest residue level of 3.07 mg/kg was estimated for calculating the dietary burden of farm animals.

Maize fodder

Trifloxystrobin is registered in the USA for use on maize up to three times at 0.11 kg ai/ha. In 24 field trials in 14 states where these conditions were approximated and with a PHI of 30 days, the trifloxystrobin residue levels in maize stover were: 0.04, 0.32, 0.37, 0.42, 0.43, 0.53, 0.56, 0.64, 0.88, 0.96 (two), 1.0, 1.2, 1.5, 2.0, 2.1, 2.2 (two), 2.7, 2.9, 3.2, 3.9, 4.0 and 5.4 mg/kg. The corresponding total residue

levels were 0.09, 0.37, 0.41, 0.47, 0.56, 0.65, 0.74, 0.80, 1.3, 1.4 (three), 1.5, 1.9, 2.4, 2.5, 2.6, 2.8, 3.5, 3.9, 4.4 (two), 4.5 and 7.1 mg/kg.

Allowing for the standard 83% dry matter for maize stover (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 10 mg/kg and an STMR (dry weight) of 1.75 mg/kg for residues in maize fodder. A highest residue level of 8.55 mg/kg was estimated for calculating the dietary burden of farm animals.

Rice straw and fodder, dry

Trifloxystrobin is registered in the USA for use on rice up to two times at 0.17 kg ai/ha with a 35-day PHI. In 19 trials in five states where these conditions were approximated, the trifloxystrobin residue levels in rice straw were: 0.07, 0.25, 0.37, 0.42, 0.44, 0.50, 0.54, 0.57, 0.78, 1.0, 1.1, 1.3, 2.0, 2.4, 2.5, 2.6 (two), 5.3 and 6.1 mg/kg. The corresponding total residue levels were 0.07, 0.32, 0.45, 0.54, 0.60, 0.74, 0.83, 0.84, 1.0, 1.3, 1.6, 2.1, 2.6, 3.2 (three), 3.7, 5.5 and 7.3 mg/kg (fresh weight).

Allowing for the standard 90% dry matter for rice straw (*FAO Manual*, p. 149), the Meeting estimated a maximum residue level of 10 mg/kg and an STMR (dry weight) of 1.4 mg/kg for residues in rice straw and fodder, dry. A highest residue level of 8.1 mg/kg was estimated for calculating the dietary burden of farm animals.

Sugar-beet leaves or tops

Italian GAP allows three treatments at rates of 0.11–0.15 kg ai/ha, and Swiss GAP allows once at 0.15 kg ai/ha, both with a PHI of 21 days, for sugar-beets. The residue levels of trifloxystrobin *per se* in sugar-beet tops in nine trials in France, two in Italy, two in Spain and one in Switzerland matching GAP were: < 0.02 (three), < 0.05 (five), 0.05, 0.07, 0.09, 0.14, 0.33 and 0.44 mg/kg. The corresponding total residue levels were: < 0.02 (three), < 0.05 (five), 0.05, 0.09 (two), 0.17, 0.41 and 0.44 mg/kg (fresh weight).

Trifloxystrobin is registered in the USA for use on sugar-beet up to three times at 0.12 kg ai/ha with a 21-day PHI. In 19 trials in seven states where these conditions were matched, the trifloxystrobin residues in sugar-beet tops were 0.08 (two), 0.14, 0.17, 0.21, 0.23, 0.24, 0.26, 0.35, 0.54, 0.56, 0.61, 0.64, 0.72, 0.98, 1.6, 2.3 and 2.4 (two) mg/kg. The corresponding total residue levels were 0.08 (two), 0.14, 0.17, 0.23 (two), 0.24, 0.26, 0.39, 0.54, 0.61 (two), 0.66, 0.72, 0.98, 1.6, 2.4 and 2.5 (two) mg/kg (fresh weight).

The data sets from Europe and the USA appeared to be from different populations and were not combined. The Meeting agreed to estimate a maximum residue level and an STMR on the basis of the results of the trials in the USA.

Allowing for the standard 23% dry matter for sugar beet tops (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 15 mg/kg and an STMR (dry weight) of 2.3 mg/kg for residues in sugar-beet leaves or tops. A highest residue level of 10.9 mg/kg was estimated for calculating the dietary burden of farm animals.

Fate of residues during processing

The Meeting received information on the fate and nature of trifloxystrobin residues under various conditions of hydrolysis. Trifloxystrobin is partially hydrolysed to CGA 321113 under conditions representative of baking, brewing and boiling (2.6%) and sterilization (22.5%). It was stable under conditions representative of pasteurization. Any possible effects of hydrolysis on the nature of the residue during processing are covered by the fact that the only relevant metabolite (CGA 321113) was determined in all the residue and processing trials.

The effect of processing on the level of residues of trifloxystrobin has been studied for barley, cabbage, cotton, grapes, hops, maize, oranges, peanuts, pome fruit, potatoes, rice, stone fruit, strawberries, sugar-beet, tomatoes and wheat. The processing factors shown below were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin).

Raw agricultural commodity	Processed product	No. of samples	Mean processing factor
Orange	Juice	5	< 0.19
	Oil	5	130
	Pulp, dry	5	3.4
Apple, pear	Juice	7	0.16
	Sauce and preserve	4	0.48
	Fruit, dried	2	0.39
	Pomace, wet	6	9.4
	Pomace, dried	1	25.6
Plum	Dried prune	4	1.5
Peach	Preserve	1	< 0.05
Grapes	Juice	14	0.24
	Must	27	0.46
	Wine	35	0.15
	Fruit, dried	4	2.3
	Pomace, wet	1	2.25
Strawberry	Preserve	2	0.29
	Jam	2	0.62
Tomato	Paste	5	1.6
	Puree	5	0.56
Potato	Flakes	2	< 0.42
	Chips	2	< 0.42
	Wet peel	2	2.3
Sugar-beet	White sugar	2	< 0.18
	Dried pulp	2	3.4
	Molasses	2	1.5
Barley	Beer	1	0.04
Wheat	Bran	2	2.7
	Germ	1	< 0.67
	Meal and flour	2	0.4
	Wholemeal	1	0.5
	Wholemeal bread	1	0.25
Rice	Polished grain	4	0.18
	Hull	4	3.2
	Bran	4	1.4
Hops	Spent hops	1	0.04
	Yeast	1	0.007
	Beer	1	< 0.001

Oranges were processed into juice, oil and dried pulp with processing factors of < 0.19, 130 and 3.4, respectively. On the basis of the STMR value of 0.095 mg/kg for whole citrus fruits, the STMR-Ps were 0.018 mg/kg for citrus juice and 12 mg/kg for oil. Allowing for the standard 91% dry matter, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR-P of 0.35 mg/kg (0.095 × 3.4 × 1.0989) for residues in dried citrus pulp (dry weight).

Apples and *pears* were processed into juice, sauce or preserve, wet pomace, dry pomace and dried fruit, with processing factors of 0.16, 0.48, 9.4, 25.6 and 0.39, respectively. On the basis of the STMR value of 0.11 mg/kg for pome fruit, the STMR-P was 0.018 mg/kg for juice, 0.053 mg/kg for sauce, 0.053 mg/kg for preserve and 0.043 mg/kg for dried fruit of apple and pear. In the *FAO Manual* (Appendix IX), wet apple pomace is listed as animal feed. Allowing for the standard 40% dry matter, the Meeting estimated an STMR-P of 2.6 mg/kg (0.11 × 9.4 × 2.5) for residues in wet apple pomace (dry weight).

Peaches were processed into preserve (canned fruits) with a processing factor of 0.05. On the basis of the STMR value of 0.38 mg/kg for stone fruit, the STMR-P was 0.019 mg/kg for residues in canned fruits of peaches, nectarines and apricots.

Plums were processed into dried prunes with a processing factor of 1.5. On the basis of the STMR value of 0.38 mg/kg for stone fruit, the STMR-P was 0.57 mg/kg for dried prunes.

Grapes were processed into juice, must, wine and dried fruit (raisins) with processing factors of 0.24, 0.46, 0.15 and 2.3, respectively. On the basis of the STMR value of 0.15 mg/kg for grapes, the STMR-P was 0.036 mg/kg for juice, 0.07 mg/kg for must, 0.023 mg/kg for wine and 0.345 mg/kg for raisins (dried grapes). On the basis of the highest trifloxystrobin residue level of 2.2 mg/kg, the Meeting estimated a maximum residue level of 5 mg/kg for residues in raisins (dried grapes).

Strawberries were processed into preserve (canned fruits) and jam with processing factors of 0.29 and 0.62, respectively. On the basis of the STMR value of 0.10 mg/kg for strawberries, the STMR-P values were 0.029 mg/kg for residues in canned strawberries and 0.062 mg/kg for those in jam.

Head cabbage was cooked. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the levels of residues in the processed commodity could not be estimated.

Tomatoes were processed into paste and puree with processing factors of 1.6 and 0.56, respectively. On the basis of the STMR value of 0.08 mg/kg for tomato, the STMR-Ps were 0.13 mg/kg for residues in tomato paste and 0.045 mg/kg for residues in puree.

Potatoes were processed into flakes, chips and wet peel with processing factors of 0.42, 0.42 and 2.3, respectively. On the basis of the STMR value of 0.02 mg/kg for residues in potatoes, the STMR-Ps were 0.008 mg/kg for residues in potato flakes and chips. In the *FAO Manual* (Appendix IX), wet peel (processed potato waste) is listed as animal feed. Allowing for the standard 15% dry matter, an STMR-P of 0.307 mg/kg (0.02 × 2.3 × 6.67) was estimated for potato wet peel (dry weight).

Sugar-beet was processed into white sugar, dried pulp and molasses with processing factors of 0.18, 3.4 and 1.5, respectively. On the basis of the STMR value of 0.02 mg/kg, the STMR-P for white sugar was 0.0036 mg/kg. In the *FAO Manual* (Appendix IX), sugar-beet dried pulp (88% dry matter) and molasses (75% dry matter) are listed as animal feeds. On the basis of the highest trifloxystrobin residue level of 0.04 mg/kg, the Meeting estimated maximum residue levels of 0.2 mg/kg (0.04 × 3.4 × 1.14) for sugar-beet dried pulp and 0.1 mg/kg (0.04 × 1.5 × 1.33) for sugar-beet molasses (dry weight). The estimated STMR-P values were 0.077 mg/kg (0.02 × 3.4 × 1.14) for sugar-beet dried pulp and 0.04 mg/kg (0.02 × 1.5 × 1.33) for sugar beet molasses (dry weight).

Wheat was processed into the milled by-products bran, flour, wholemeal, wholemeal bread and germ, with processing factors of 2.7, 0.4, 0.67, 0.33 and 0.67, respectively. On the basis of the STMR value of 0.02 mg/kg for wheat grain, the STMR-Ps were 0.008 for wheat flour, 0.01 for wholemeal, 0.005 for wholemeal bread and 0.013 for germ. In the *FAO Manual* (Appendix IX), bran is listed as an animal feed.

Allowing for the standard 88% dry matter for wheat milled by-products, the Meeting estimated an STMR-P of 0.062 mg/kg (0.02 × 2.7 × 1.14) for wheat bran, unprocessed (dry weight). On the basis of the highest trifloxystrobin residue level of 0.14 mg/kg, the Meeting estimated a maximum residue level of 0.5 mg/kg (0.14 × 2.7 × 1.14 = 0.43) for wheat bran, unprocessed (dry weight).

Maize was processed to meal, grits, flour and oil. Because residues were not detected in the raw commodity, processing factors could not be calculated and the residue levels in the processed commodities could not be estimated.

Rice with husk was processed into polished rice, bran and hulls with processing factors of 0.18, 1.4 and 3.2, respectively. On the basis of the STMR of 0.16 mg/kg for rice with husks, an STMR-P of 0.029 mg/kg was calculated for polished rice. In the *FAO Manual* (Appendix IX), rice bran and hulls are listed as animal feed. Allowing for the standard 90% dry matter, the Meeting estimated STMR-P values of 0.57 mg/kg (0.16 × 3.2 × 1.1) for rice hulls and 0.25 mg/kg (0.16 × 1.4 × 1.1) for rice bran, unprocessed (dry weight). On the basis of the highest trifloxystrobin residue level of 3.4 mg/kg in rice with husks, the Meeting estimated a maximum residue level of 7 mg/kg for residues in rice bran, unprocessed (dry weight).

Cotton was processed to refined oil. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the residue levels in the processed commodities could not be estimated.

Peanuts were processed to meal and refined oil. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the residue levels in the processed commodities could not be estimated.

Hops were processed for use in beer, with a processing factor of 0.001. On the basis of the STMR value of 9.95 mg/kg for dry hops, an STMR-P of 0.01 mg/kg was calculated for beer. Barley was processed into beer with a processing factor of 0.04. On the basis of the STMR value of 0.04 mg/kg, the STMR-P for beer was 0.0016 mg/kg. Because the STMR-P arising from residues in barley was lower, the Meeting estimated an STMR-P of 0.01 mg/kg for residues in beer, on the basis of residues in hops.

Residues in animal commodities

Dietary burden of farm animals

The Meeting estimated the dietary burden of trifloxystrobin residues in farm animals on the basis of the diets listed in Appendix IX of the *FAO Manual*. Calculation from highest residue and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed as dry weight.

Estimated maximum dietary burden of farm animals

Commodity	CC	Residue (mg/kg)	Basis	Dry matter (%)	Residue, dry weight (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						Beef cattle	Dairy cattle	Poultry	Beef cattle	Dairy cattle	Poultry
Almond hulls	AM	2.1	HR	100	2.1						
Apple pomace, wet	AB	2.6	STMR-P	100	2.6	15			0.39		
Barley grain	GC	0.46	HR	88	0.528			40			0.211
Barley straw	AS	4.9	HR	100	4.9		60			2.94	
Citrus pulp, dried	AB	0.35	STMR-P	100	0.35						
Maize grain	GC	0.05	HR	88	0.057						

Commodity	CC	Residue (mg/kg)	Basis	Dry matter (%)	Residue, dry weight (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						Beef cattle	Dairy cattle	Poultry	Beef cattle	Dairy cattle	Poultry
Maize fodder	AS	8.55	HR	100	8.55	25			2.14		
Peanut fodder (hay)	AL	4.94	HR	100	4.94						
Potato wet peel	AB	0.307	STMR-P	100	0.307						
Rice	GC	3.4	HR	88	3.86	40	30	60	1.54	1.16	2.32
Rice bran	CM	0.25	STMR-P	100	0.25						
Rice hulls	CM	0.57	STMR-P	100	0.57						
Rice straw and fodder, dry	AS	8.1	HR	100	8.1						
Sugar-beet leaves and tops	AV	10.9	HR	100	10.9	20	10		2.18	1.09	
Sugar-beet, dried pulp	AB	0.077	STMR-P	100	0.077						
Sugar-beet molasses	DM	0.04	STMR-P	100	0.04						
Wheat grain	GC	0.2	HR	89	0.225						
Wheat straw	AS	3.07	HR	100	3.07						
Wheat milled by-products (bran)	CM	0.062	STMR-P	100	0.062						
Total						**100**	**100**	**100**	**6.3**	**5.2**	**2.5**

Estimated mean dietary burden of farm animals

Commodity	CC	Residue (mg/kg)	Basis	Dry matter (%)	Residue/ dry weight (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						Beef cattle	Dairy cattle	Poultry	Beef cattle	Dairy cattle	Poultry
Almond hulls	AM	1.08	STMR	100	1.08		10			0.108	
Apple pomace, wet	AB	2.6	STMR-P	100	2.6	40	20		1.04	0.52	
Barley grain	GC	0.04	STMR	88	0.045						
Barley straw	AS	0.9	STMR	100	0.9		60			0.54	
Citrus pulp, dried	AB	0.35	STMR-P	100	0.35						
Maize grain	GC	0.02	STMR	88	0.023						
Maize fodder	AS	1.75	STMR	100	1.75	25			0.4375		
Peanut fodder (hay)	AL	0.85	STMR	100	0.85	15			0.1275		
Potato, wet peel	AB	0.307	STMR-P	100	0.307						
Rice	GC	0.16	STMR	88	0.182			60			0.1092
Rice bran	CM	0.25	STMR-P	100	0.25			25			0.0625
Rice hulls	CM	0.57	STMR-P	100	0.57			15			0.086
Rice straw and fodder, dry	AS	1.4	STMR	100	1.4						
Sugar-beet leaves and tops	AV	2.3	STMR	100	2.3	20	10		0.46	0.23	
Sugar-beet dried pulp	AB	0.077	STMR-P	100	0.077						
Sugar-beet molasses	DM	0.04	STMR-P	100	0.04						
Wheat grain	GC	0.02	STMR	89	0.0225						

Commodity	CC	Residue (mg/kg)	Basis	Dry matter (%)	Residue/ dry weight (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						Beef cattle	Dairy cattle	Poultry	Beef cattle	Dairy cattle	Poultry
Wheat straw	AS	0.48	STMR	100	0.48						
Wheat milled by-products (bran)	CM	0.062	STMR-P	100	0.062						
Total						**100**	**100**	**100**	**2.1**	**1.4**	**0.26**

The dietary burdens of trifloxystrobin for estimating maximum residue levels and STMRs for animal commodities (residue concentrations in animal feeds expressed as dry weight) are 6.3 and 2.1 mg/kg for beef cattle, 5.2 and 1.4 mg/kg for dairy cattle, 2.5 and 0.26 mg/kg for poultry.

Feeding studies

The Meeting received information on residues arising in tissues and milk of *dairy cows* dosed with trifloxystrobin in capsules at the equivalent of 2, 5.9 or 21 ppm in the diet for 28–30 days.

The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of relative molecular masses. A conversion factor of 1.036 is required to express the CGA 321113 residues as trifloxystrobin equivalents. As this metabolite constitutes a significant proportion of the residue in animal products, when the level of trifloxystrobin or CGA 321113 was below its LOQ, the sum of trifloxystrobin and CGA 321113 was calculated, as in the examples below, and expressed as trifloxystrobin.

Trifloxystrobin (mg/kg)	CGA 321113 (mg/kg)	Total expressed as trifloxystrobin (mg/kg)
< 0.02	< 0.02	< 0.04
< 0.02	0.03	0.05
0.09	< 0.02	0.11

No residues (sum of trifloxystrobin and CGA 321113) were detectable in milk (< 0.02 mg/kg), round muscle (< 0.04 mg/kg) or tenderloin (< 0.04 mg/kg) from cattle given the highly exaggerated feeding level of 21 ppm. No residues of either parent or metabolite were found in liver, kidney or fat samples from animals at 2 or 5.9 ppm (total residue, < 0.04 mg/kg). Maximum residue levels of 0.09 mg/kg (total residue, 0.11 mg/kg) and 0.02 mg/kg (total residue, 0.04 mg/kg), detected as the metabolite CGA 321113 and expressed as trifloxystrobin, were found in liver and kidney, respectively, from cattle at 21 ppm; and maximum residue levels of 0.06 mg/kg (total residue, 0.08 mg/kg) and 0.05 mg/kg (total residue, 0.07 mg/kg), detected as intact trifloxystrobin, were found in perirenal fat and omental fat, respectively, from these animals.

The Meeting received information on the concentrations of residues in tissues and eggs from *laying hens* dosed with trifloxystrobin at the equivalent of 1.5, 4.5 or 15 ppm in the diet for 28 days. The hens were killed on day 29, and composite tissue samples of breast plus thigh, skin plus attached fat, peritoneal fat, and liver were taken. Eggs and tissues were analysed for trifloxystrobin and CGA 321113. No residues (total residues, < 0.04 mg/kg) were detected in any of the eggs, tissues or organs taken from hens at the highest dietary level of 15 ppm.

Maximum residue levels

The Meeting noted that no trifloxystrobin or CGA 321113 residues were detected in milk (total, < 0.02 mg/kg), muscle (< 0.04 mg/kg), kidney (< 0.04 mg/kg), liver (< 0.04 mg/kg) or fat (< 0.04 mg/kg) from animals dosed for 28 days at 5.9 ppm, which was close to the maximum dietary burdens of beef and dairy cattle (8.2 and 7.4 ppm). The highest residue level of trifloxystrobin was found in perirenal fat at

0.06 mg/kg (total residue, 0.08 mg/kg), and the highest level of CGA 321113 was found in liver at 0.09 mg/kg (total residue, 0.11 mg/kg) from animals given 21 ppm.

Dietary burden (ppm)	Trifloxystrobin total residue (mg/kg)								
Feeding level [ppm]	Milk	Muscle		Liver		Kidney		Fat	
	(mean)	Highest	Mean	Highest	Mean	Highest	Mean	Highest	Mean
MRL beef cattle									
(6.3)		*(< 0.012)*		*(0.033)*		*(0.012)*		*(0.024)*	
[21]		< 0.04		0.11		0.04		0.08	
MRL dairy cattle									
(5.2)	*(< 0.005)*								
[21]	< 0.02								
STMR beef cattle									
(2.1)			*(< 0.004)*		*(0.008)*		*(0.004)*		*(0.006)*
[21]			< 0.04		0.08		0.04		0.06
STMR dairy cattle									
(1.4)	*(< 0.001)*								
[21]	< 0.02								

The maximum concentrations of residues expected in tissues are < 0.012 mg/kg in muscle, 0.033 mg/kg in liver, 0.012 mg/kg in kidney, 0.024 mg/kg in fat and < 0.005 mg/kg in milk. The mean extrapolated concentrations are < 0.004 mg/kg in muscle, 0.008 mg/kg in liver, 0.004 mg/kg in kidney, 0.006 mg/kg in fat and < 0.001 mg/kg in milk.

Taking into account the fat solubility of trifloxystrobin (the acid metabolite CGA 321113 is poorly soluble in fat), the Meeting estimated a maximum residue level of 0.05 mg/kg for the sum of trifloxystrobin and CGA 321113 in meat (fat) from mammals other than marine mammals on the basis of residue levels in trimmable fat, and a maximum residue level of 0.02* mg/kg for residues in milks. The estimated maximum residue levels are 0.05 mg/kg for liver and 0.04* mg/kg for kidney of cattle, goats, pigs and sheep.

The estimated STMR values are 0.006 mg/kg in fat, 0 mg/kg in muscle, 0.008 mg/kg in liver, 0.004 mg/kg in kidney and 0 in milks.

The Meeting noted that in the feeding study in laying hens, no trifloxystrobin or CGA 321113 residues (total residue, < 0.04 mg/kg) were detected in eggs, tissues or organs from hens at the highest feeding level of 15 ppm. As the maximum dietary burden of 2.5 mg/kg was much lower, the Meeting agreed that the expected level of trifloxystrobin and CGA 321113 residues in poultry tissues and eggs would be essentially 0.

The Meeting estimated maximum residue levels of 0.04* mg/kg for residues in eggs, poultry meat (fat) and edible offal. The Meeting recommended that the STMR values should be 0 in eggs, poultry meat, edible offal and fat.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDIs of trifloxystrobin, on the basis of the STMRs estimated for 37 commodities, for the five GEMS/Food regional diets represented 1–2% of the ADI (Annex 3). The Meeting concluded that the long-term intake of residues of trifloxystrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2004 JMPR decided that it was unnecessary to establish an ArfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health concern.

5. RECOMMENDATIONS

5.1 The Meeting developed a guidance document for deriving acute reference doses (ARfDs) (section 2.1). This document includes general considerations, summarizing all previous considerations of the Meeting on this topic, including a stepwise process for setting ARfDs and for selecting appropriate end-points and safety factors, as well as specific guidance for assessing particular toxicologic end-points of relevance for setting ARfDs. This document should be updated regularly, as further experience in establishing ARfDs is gained. The introduction of a specific test protocol for single-dose, oral toxicity studies will aid in establishing ARfDs when relevant.

5.2 The WHO Core Assessment Group occasionally establishes ARfDs for compounds that were not scheduled for toxicological evaluation, on the basis of data from previous evaluations, to facilitate acute dietary risk assessment. The Meeting decided to call these values 'interim ARfDs'. These interim ARfDs can be used in dietary risk assessments until they are replaced by a full evaluation, if this is considered necessary.

5.3 The pilot work-sharing project concluded and recommended the following:

- The availability of several national or regional evaluations was found to be useful by the WHO and FAO evaluators. Although problems were encountered, consideration of national or regional evaluations in the development of JMPR monographs had several benefits. FAO, WHO and OECD should consider means to facilitate the provision of national and regional evaluations for JMPR evaluators.
- Consideration of multiple national and regional evaluations should promote international harmonization of dossiers and evaluations.
- The evaluation process, including standardization of formats and development of guidelines, should be further harmonized at the international level. Good progress has been reached in toxicological evaluations, and more basic work is necessary to improve work-sharing for residue evaluations.

- A further JMPR pilot work-sharing project should have a more flexible procedure, which should be reviewed when there is greater harmonization of formats and evaluation procedures (harmonization of guidance documents).

5.4 The JMPR considered that extensive use of the interim MRL process might create a serious problem. As interim MRLs are limited to a period of four years, pesticides nominated under the process must be scheduled for and reviewed by the JMPR within this period. If there are many interim MRL pesticide nominations, evaluations might not be completed for some within the four-year period or other priorities, such as periodic review of pesticides and evaluations, might have to be severely curtailed, owing to the current limited resources of the JMPR.

5.5 For spices, the Meeting recommended that CCPR accept the principle of setting MRLs on the basis of monitoring data covering the 95th percentile of the residue population with 95% confidence. That decision would facilitate use of statistically based procedures for estimating maximum residue levels and acceptance of recommended limits. It should be noted, however, that when MRLs are set at the 95th percentile with 95% confidence, the residue levels might exceed the MRL in 5% of cases.

Monitoring data should not be used for estimating maximum residue levels reflecting post-harvest use, which results in significantly higher residue levels than foliar application or exposure to spray drift.

5.6 The Meeting decided that two maximum residue levels will be estimated for fat-soluble pesticides from now on, if the data permit: one for whole milk and one for milk fat. For enforcement purposes, the residue level in milk fat can be compared with the MRL for milk (fat), or the residue level in whole milk can be compared with the MRL for milk. When needed, maximum residue levels in milk products can be calculated from these two numbers, by taking into account both the fat content of the milk product and the contribution from the non-fat fraction.

5.7 For animal feed commodities, the Meeting agreed that the assumption of the 1986 JMPR used in developing guidance in this area, that "it was unrealistic to assume that the theoretical maximum residue level would be achieved and maintained in the rations of food-producing animals receiving feeds produced on the farm", should no longer apply. Hence, the concept of time for residues to reach a plateau level, rapid or slow, is also no longer required, and the process of estimating dietary burdens is simplified. The Meeting recognized that it is unlikely that the individual ingredients in mixed feeds produced from commercially available ingredients would all contain residues at the theoretical maximum level; in these cases, the STMR should be applied for each component.

A revision of the relevant text in the *FAO Manual*, taking into account the above, will appear on the FAO website.

5.8 The Meeting expressed interest in receiving spreadsheets and documentation for evaluating the statistical method for MRL estimation. Such systems might aid the evaluators but could never replace professional judgement, when available. Further developments are awaited.

5.9 Some of the recommendations of the York workshop on minimum data requirements and the global zoning report have been used by the JMPR and will continue to be considered as auxiliary advice. The Meeting concluded, however, that substantial additional work is required to make the recommendations generally applicable as guidance. Areas that require additional effort include: (1) defining significance in trade, perhaps with a table of commodities and their classification; (2) determining the criteria for zones and the number of zones for each commodity; (3) extending the list of commodity translations, for the purpose of recommending maximum residue levels for one commodity on the basis of data from field trials for another commodity; and (4) completing the list of representative crops for the purpose of recommending maximum residue levels for crop groups.

6. FUTURE WORK

The items listed below should be considered by the Meeting in 2006 and 2007. The compounds listed include those recommended as priorities by the CCPR at its Thirty-sixth and earlier sesssions and compunds scheduled for re-evaluation within the CCPR periodic review programme.

2006 JMPR

Toxicological evaluations

New compounds
Bifenazate
Dimethomorph
Quinoxyfen

Periodic re-evaluations
Cyfluthrin and β-cyfluthrin (157)
Cyromazine (169)
α- and ζ-Cypermethrin
Flusilazole (165)
Procymidone (136)
Profenofos (171)

Evaluations
Haloxyfop (194)
Pirimiphos-methyl (086): acute toxicity
Thiabendazole (065): acute toxicity
Thiophanate-methyl (077): acute toxicity

Residue evaluations

New compounds
Bifenazate
Dimethomorph
Quinoxyfen

Periodic re-evaluations
α- and ζ-Cypermethrin
Cypermethrin (118)
Pirimicarb (101)
Propamocarb (148)
Propiconazole (160)
Triadimefon (133) To be evaluated
Triadimenol (168) together

Evaluations
Propargite (113)

2007 JMPR

Toxicological evaluations

New compounds
Pyrimethanil
Zoxamide

Periodic re-evaluations
Azinphos-methyl (002)
λ-Cyhalothrin
Fentin (040)
Vinclozolin (159)

Residue evaluations

New compounds
Pyrimethanil
Zoxamide

Periodic re-evaluations
Clofentezine (156)
Permethrin (120)
Triazophos (143)
Triforine (116)

ANNEX 1

ACCEPTABLE DAILY INTAKES, SHORT-TERM DIETARY INTAKES, ACUTE REFERENCE DOSES, RECOMMENDED MAXIMUM RESIDUE LIMITS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES RECORDED BY THE 2004 MEETING

The following extracts of the results of the annual Joint FAO/WHO Meeting on Pesticide Residues (JMPR) are provided to make them accessible to interested parties at an early date.

The Meeting evaluated 31 pesticides. Three were new compounds, and 11 were re-evaluated within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting allocated acceptable daily intakes (ADIs), acute reference doses (ARfDs) and, for the first time, interim ARfDs. Interm ARfDs were allocated for use in short-term dietary risk assessment of compounds that were not scheduled for toxicological evaluation. These values are derived ad hoc from data used at previous meetings. They can be used in dietary risk assessments until they are replaced by a full evaluation, if this is considered necessary.

The Meeting estimated maximum residue levels, which it recommended for use as maximum residue limits (MRLs) by the CCPR. It also estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimation of the dietary intake of residues of the pesticides reviewed. Application of HR levels is explained in the report of the 1999 Meeting (section 2.4). The allocations and estimates are shown in the Table 1.

The Meeting also estimated, for the first time, maximum residue levels of various pesticides in spice subgroups specified by the CCPR from monitoring data, and in dried chilli peppers taking into account the MRLs for fresh chilli peppers and peppers. The recommended values are listed separately in Tables 2 and 3.

Pesticides for which the estimated dietary intakes might, on the basis of the available information, exceed their ADIs are marked with footnotes, as explained in detail in the report of the 1999 Meeting (section 2.2). Footnotes are also applied to specific commodities when the available information indicated that the ARfD of a pesticide might be exceeded when the commodity was consumed. It should be noted that these distinctions apply only to new compounds and those re-evaluated within the CCPR periodic review programme.

Table 1 includes the Codex reference numbers of the compounds and the Codex classification numbers (CCNs) of the commodities, to facilitate reference to the Codex maximum limits for pesticide residues (*Codex Alimentarius,* Vol. 2B) and other documents and working documents of the Codex Alimentarius Commission. Both compounds and commodities are listed in alphabetical order.

Apart from the abbreviations indicated above, the following qualifications are used in the Table.

* (following name of pesticide)	New compound
** (following name of pesticide)	Compound reviewed within CCPR periodic review programme
* (following recommended MRL)	At or about the limit of quantification
HR-P	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the HR in the raw commodity by the processing factor
Po	The recommendation accommodates post-harvest treatment of the commodity.
PoP (following recommendation for processed foods (classes D and E in the Codex classification)	The recommendation accommodates post-harvest treatment of the primary food commodity.
STMR-P	An STMR for a processed commodity calculated by applying the concentration or reduction factor for the process to the STMR calculated for the raw agricultural commodity.
V (following recommendations for commodities of animal origin)	The recommendation accommodates veterinary uses.
W (in place of a recommended MRL)	The previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

Table 1. Recommended maximum residue levels, STMR and HR values and allocated ADI and ARfD values

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
Bentazone (172)						
ADI: 0–0.1 mg/kg bw						
ARfD: unnecessary						
Captan (007)						
ADI: 0–0.1 mg/kg bw						
ARfD: 0.3 mg/kg bw (for women of child-bearing age)						
Carbofuran (096)	FC 0004	Orange, sweet, sour			0.1	0.05
ADI: 0–0.002 mg/kg bw						
ARfD: 0.009 mg/kg bw						
Residue for estimation of dietary intake in plant and animal commodities: sum of carbofuran, 3-hydroxycarbofuran and conjugated 3-hydroxycarbofuran, expressed as carbofuran						
Chlorpyrifos (017)	SO 0691	Cotton-seed	0.3		0.07	
ADI: 0–0.01 mg/kg bw		Cotton-seed meal		< 0.01		
ARfD: 0.1 mg/kg bw		Cotton-seed hulls			0.05	
	OC 0691	Cotton-seed oil, crude			0.10	
	OR 0691	Cotton-seed oil, refined	0.05		0.01	
	VR 0589	Potato	2		0.51	0.87
	GC 0649	Rice	0.5		0.12	
	CM 1205	Rice, polished			0.008	
	CM 0649	Rice, husked			0.016	
		Rice hulls			0.29	
	CM 1206	Rice bran, unprocessed			0.22	
	VD 0541	Soya bean (dry)	0.1		0.01	
		Soya bean meal			< 0.002	
	OC 0541	Soya bean oil, crude			0.004	
	OR 0541	Soya bean oil, refined	0.03		0.004	
	DT 1114	Tea, green, black (black, fermented and dried)	2		0.34	
Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: chlorpyrifos						
The residue is fat-soluble						
Dimethipin (151)						
ADI: 0–0.02 mg/kg bw						
ARfD: 0.2 mg/kg bw						
Dithiocarbamates	VC 0424	Cucumber	2 c, N, p	2 c, N		
Ferbam	MO 0105	Edible offal (mammalian)	0.1 C, m, p	0.1 C, m		
ADI: 0–0.003 mg/kg bw	PE 0112	Eggs	0.05(*) C, p	0.05(*) C		
Propineb	FB 0269	Grapes	5 C, m, n	5 C, m, n, p		

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
ADI: 0–0.007 mg/kg bw	MM 0095	Meat (from mammals other than marine mammals)	0.05(*) c, m, p	0.05(*) c, m		
Thiram	VC 0046	Melon (except watermelon)	0.5 C	0.5 C, p		
ADI: 0–0.01 mg/kg bw	ML 0106	Milks	0.05(*) c, m, p	0.05(*) c, m		
Ziram	VA 0385	Onion, bulb	0.5 C	0.5 C, p		
ADI: 0–0.003 mg/kg bw	TN 0672	Pecan	0.1(*) Z	0.1(*) T Z		
	VO 0445	Peppers, sweet	7 c, m, P	1 c, m,		
	FP 0009	Pome fruits	5 C, M, H, Z	5 C, M, p, H, Z		
	VR 0587	Potato	0.2 c, m, n, p	0.2 c, m, n		
	PM 0110	Poultry meat	0.1 c, p	0.1 C		
	PO 0111	Poultry, edible offal of	0.1 c, p	0.1 C		
	FS 0012	Stone fruit	7 h, p, Z	7 T h, Z		

Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: total dithiocarbamates, determined as CS_2, evolved during acid digestion and expressed as mg CS_2/kg.

Notes:

1. Recommended MRLs refer to the total residues from the use of any or each of the dithiocarbamates.
2. Recommendations are based on trials with; n, maneb; m, metiram; c, mancozeb; p, propineb; h, thiram; z, ziram. Compounds shown in upper case as those on which the estimates of maximum residue levels are mainly based.
3. The information provided to the JMPR precludes an estimate that the dietary intake would be below the interim ARfD for propineb.

T: the 1996 JMPR recommended that the MRL should be designated as temporary pending review of data on environmental fate.

Ethoprophos** (149)	FI 0327	Banana	0.02	0.02(*)	0.02	0.02
ADI: 0–0.0004 mg/kg bw	VR 0574	Beetroot	W	0.02(*)		
ARfD: 0.05 mg/kg bw	VB 0041	Cabbage, head	W	0.02(*)		
	VC 0424	Cucumber	0.01	0.02(*)	0.01	0.01
	MO 0105	Edible offal (mammalian)	0.01(*)		Liver 0 Kidney 0	Liver 0 Kidney 0
	VC 0425	Gherkin	W	0.02*		
	FB 0269	Grape	W	0.02*		
	VL 0482	Lettuce, head	W	0.02(*)		
	GC 0645	Maize	W	0.02(*)		
	AS 0645	Maize fodder	W	0.02(*)		
	AF 0645	Maize forage	W	0.02(*)		
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)		Muscle 0 Fat 0	Muscle 0 Fat 0
	VC 0046	Melons, except watermelon	0.02	0.02(*)	0.005	0.012
	ML 0106	Milks	0.01(*)		0	
	VA 0385	Onion, bulb	W	0.02(*)		
	SO 0697	Peanut	W	0.02(*)		
	AL 0697	Peanut fodder	W	0.02(*)		
	VP 0063	Peas (pods and succulent = immature seeds)	W	0.02(*)		
	VO 0051	Peppers	W	0.02(*)		
	VO 0445	Peppers, sweet	0.05		0.005	0.044

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
	FI 0353	Pineapple	W	0.02(*)		
	AM 0353	Pineapple fodder	W	0.02(*)		
	AV 0353	Pineapple forage	W	0.02(*)		
	VR 0589	Potato	0.05	0.02(*)	0.01	0.03
	VD 0541	Soya bean (dry)	W	0.02(*)		
	AL 0541	Soya bean fodder	W	0.02(*)		
	GS 0659	Sugar cane	0.02	–	0.02	0.02
	VR 0508	Sweet potato	0.05	–	0.01	0.03
	VO 0448	Tomato	0.01(*)	–	0.005	0.01
Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: ethoprophos						
Fenitrothion (037)[1]	FP 0226	Apple	0.5	W	0.04	0.41
ADI: 0–0.005 mg/kg bw	GC 0080	Cereal grain	10 (Po)[2, 3]	10 (Po)	5	7.6
ARfD: 0.04 mg/kg bw	MO 0105	Edible offal (mammalian)	0.05(*)	–	Liver 0	Liver 0
					Kidney 0	Kidney 0
	PE 0112	Egg	0.05(*)	–	0	0
	MM 0095	Meat (from mammals other than marine mammals)	0.05(*)	W	Muscle 0	Muscle 0
					Fat 0	Fat 0
	ML 0106	Milks	0.01	W	0	
	FP 0230	Pear	W	W		
	PM 0110	Poultry meat	0.05(*)	–	Muscle 0	Muscle 0
					Fat 0	Fat 0
	CM 1206	Rice bran, unprocessed	60	W	36	55
	CM 0649	Rice, husked			3.2	4.9
	CM 1205	Rice, polished	W	W	0.44	1.1
		Cooked husked rice			0.55	0.84
		Cooked polished rice			0.2	0.30
		Washed polished rice			0.23	0.35
		Cooked washed polished rice			0.1	0.15
	CM 0654	Wheat bran, unprocessed	30 (PoP)[1]	20 (PoP)	20	30
	CF 1211	Wheat flour	W	W	1.2	1.8
	CP 1211	White bread	W	W	0.5	0.76
	CP 1212	Wholemeal bread	W		1.9	2.9
Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: Fenitrothion						

[1] The information provided to the JMPR precludes an estimate that the dietary intake would be below the ADI.
[2] Proposal by 2003 JMPR, the recommendation is now considered to also cover pre-harvest use of fenitrothion.
[3]The information provided to the JMPR precludes an estimate that the dietary intake would be below the ARfD.

Fenpropimorph (188)

ADI: 0–0.003 mg/kg bw

ARfD: 0.2 mg/kg bw

Fenpyroximate (193)

ADI: 0–0.01 mg/kg bw

ARfD: 0.01mg/kg bw

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
Fludioxonil* (211)	HH 0722	Basil	10		2.4	
ADI: 0–0.4 mg/kg bw	DH 0722	Basil, dry	50		20	
ARfD: unnecessary	VD 0071	Bean (dry)	0.07		0.02	
	VP 0061	Bean, except broad bean and soya bean (green pods and immature seeds)	0.3		0.04	
	VP 0062	Beans, shelled (succulent = immature seeds)	0.03		0.02	
	FB 0264	Blackberry	5		1.0	
	FB 0020	Blueberry	2		0.60	
	VB 0400	Broccoli	0.7		0.23	
	VB 0041	Cabbage, head	2		0.24	
	VR 0577	Carrot	0.7		0.20	
	GC 0080	Cereal grain	0.05(*)		0.02	
	HH 0727	Chive	10		2.8	
		Chive (dried)	50		22	
	FC 0001	Citrus fruit	7 (Po)		1.1	
	SO 0691	Cotton-seed	0.05(*)		0.05	
	VC 0424	Cucumber	0.3		0.06	
	FB 0266	Dewberry (including boysenberry and loganberry)	5		1.0	
	DF 0269	Dried grape (= currant, raisin and sultana)			0.31	
	MO 0105	Edible offal (mammalian)	0.05(*)		0	
	VO 0440	Egg plant (aubergine)	0.3		0.06	
	PE 0112	Egg	0.05(*)		0	
	FB 0269	Grape	2		0.28	
	JF 0269	Grape juice			0.26	
	FI 0341	Kiwifruit	15 (Po)		7.2	
	VL 0482	Lettuce, head	10		2.7	
	AF 0645	Maize forage (dry)	0.03(*)		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)		0	
	VC 0046	Melon, except watermelon	0.03		0.02	
	ML 0106	Milks	0.01		0	
	VL 0485	Mustard greens	10		1.2	
	VA 0385	Onion, bulb	0.5		0.04	
	VA 0389	Onion, spring	5		0.59	
	FP 0230	Pear	0.7		0.21	
	VD 0072	Pea (dry)	0.07		0.02	
	VP 0063	Pea (pods and succulent = immature seeds)	0.3		0.04	
	VP 0064	Pea, shelled (succulent seeds)	0.03		0.02	
	VO 0455	Peppers, sweet	1		0.18	
	TN 0675	Pistachio nut	0.2		0.05	
		Plum juice			0.08	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
		Plum preserve			0.40	
		Plum puree			0.64	
	VR 0589	Potato	0.02		0.01	
	PM 0110	Poultry meat	0.01(*)		0	
	PO 0111	Poultry, edible offal of	0.05(*)		0	
	DF 0014	Prune (dried plum)			0.96	
	SO 0495	Rape seed	0.02(*)		0.02	
	FB 0272	Raspberry, red, black	5		1.0	
	FS 0012	Stone fruit	5 (Po)		0.80	
	AS 0081	Straw and fodder (dry) of cereal grain	0.06(*)		0	
	FB 0275	Strawberry	3		0.27	
		Strawberry juice			0.06	
		Strawberry preserve			0.24	
		Strawberry jam			0.13	
	VC 0431	Squash, summer	0.3		0.06	
	VO 0447	Sweet corn (corn-on-the-cob)	0.01(*)		0.01	
	VO 0448	Tomato	0.5		0.12	
	JF 0448	Tomato juice			0.026	
		Tomato paste			0.17	
	VL 0473	Watercress	10		1.2	
		Wine (grape)			0.01	

Residue for compliance with MRLs and estimation of dietary intake in plant commodities: fludioxonil

Residue for compliance with MRLs and estimation of dietary intake in animal commodities: sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid, expressed as fludioxonil

Fludioxonil is fat-soluble

Folpet (041)

ADI: 0–0.1 mg/kg bw

ARfD: 0.2 mg/kg bw (for women of childbearing age)

Glyphosate** (158)

ADI: 0–1 mg/kg bw

ARfD: unnecessary

Malathion (049)	FP 0226	Apple	0.5	W	0.11	0.37
ADI: 0–0.3 mg/kg bw	FC 0001	Citrus fruit	7	W	0.02	0.22
ARfD: 2 mg/kg bw	FB 0269	Grape	5	W	0.16	2.6
	FS 0247	Peach	W	W		

Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: malathion

Metalaxyl-M* (212)	FP 0009	Apple	0.02(*)	(Metalaxyl)		
				Pome fruit 1	0	
ADI: 0–0.08 mg/kg bw for metalaxyl-M + metalaxyl	FB 0269	Grape	1	1	0.14	
ARfD: unnecessary	VL 0482	Lettuce, head	0.5	2	0.02	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
	VA 0385	Onion, bulb	0.03	2	0.02	
	VO 0445	Peppers, sweet	0.5	Peppers 1	0.03	
	VO 0448	Tomato	0.2	0.5	0.045	
	VR 0589	Potato	0.02(*)	0.05(*)	0.02	
	VL 0502	Spinach	0.1	2	0.02	
	SO 0702	Sunflower seed	0.02(*)	0.05(*)	0	
	SB 0715	Cacao bean	0.02	0.2	0.02	
		Grape juice			0.050	
		Wine			0.092	

Residue (of metalaxyl including metalaxyl-M) for compliance with MRLs and estimation of dietary intake in plant commodities: metalaxyl

Residue (of metalaxyl including metalaxyl-M) for compliance with MRLs and estimation of dietary intake in animal commodities: sum of metalaxyl and metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl.

Notes

No new MRLs are recommended because all MRLs required for metalaxyl-M are covered by existing MRLs for metalaxyl. The values listed in the 'New' column are the estimated maximum residue levels for metalaxyl-M and, because they do not exceed the existing metalaxyl MRLs, are not intended to replace them.

Metalaxyl is a racemic mixture of (*R*) and (*S*) enantiomers. Metalaxyl-M is the (*R*) enantiomer.

No MRLs are currently recommended for animal commodities.

Methamidophos (100)	VC 0424	Cucumber	W	1		
ADI: 0–0.004 mg/kg bw						
ARfD: 0.01 mg/kg bw						
Methomyl (094)	VO 0051	Peppers	0.7	1	0.105	0.44
ADI: 0–0.02 mg/kg bw	AM 0738	Mint hay	0.5	2	0.08	0.32
ARfD: 0.02 mg/kg bw						

Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: sum of methomyl and thiodicarb, expressed as methomyl

Oxydemeton methyl (166)	FP 0226	Apple[2]		0.05	0.01	0.04
ADI: 0–0.0003 [1] mg/kg bw	JF 0226	Apple juice			0.01	
ARfD: 0.002 mg/kg bw		Apple sauce			0.005	
	GC 0640	Barley[4]	0.02(*)	0.05(*)	0.01	
	AS 0640	Barley straw and fodder, dry[4]	0.1	2		
	VB 0041	Cabbage, head [2,3]		0.05(*)	0.03	0.05
	MF 0812	Cattle fat[3]		0.05(*)	0	0
	VB 0404	Cauliflower[4]	0.01(*)	W	0.01	0.01
	VD 0526	Common bean (dry) [5]		0.1	0.01	
	SO 0691	Cotton-seed[5]		0.05	0.01	
	OR 0691	Cotton-seed oil, edible [5]			0.002	
	PE 0112	Egg[3]		0.05(*)	0	0
	FB 0269	Grape[2]		0.1	0.04	0.06
	VL 0480	Kale[3]		0.01(*)	0.01	0.01
	VB 0405	Kohlrabi[3]		0.05	0.02	0.05
	FC 0204	Lemon[3]		0.2	0.01	0.04
	MM 0097	Meat of cattle, pigs and sheep[3]		0.05(*)	0	0

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
	ML 0106	Milks[3]		0.01(*)	0	
	FC 0004	Orange, sweet, sour [2, 3]		0.2	0.01	0.04
	FP 0230	Pear[3]		0.05	0.01	0.04
	MF 0818	Pig fat[3]		0.05(*)	0	0
	VR 0589	Potato[4]	0.01(*)	0.05(*)	0.01	0.01
	PF 0111	Poultry fat[3]		0.05(*)	0	0
	PM 0110	Poultry meat[3]		0.05(*)	0	0
	GC 0650	Rye[4]	0.02(*)	0.05(*)	0.01	
	AS 0650	Rye straw and fodder, dry[4]	0.1	2		
	MF 0822	Sheep fat[3]		0.05(*)	0	0
	VR 0596	Sugar beet[4]	0.01(*)	0.05(*)	0.01	
	AV 0596	Sugar-beet leaf or top[4]	0.05	0.05(*)		
	GC 0654	Wheat[4]	0.02(*)	0.05(*)	0.01	
	AS 0654	Wheat straw and fodder, dry[4]	0.1	2		

Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: sum of oxydemeton methyl, demeton-S-methyl and demeton-S-methylsulphon, expressed as oxydemeton methyl

Notes The definition of the residue and recommendations for MRLs are based only on use of oxydemeton methyl.

[1] Group ADI for demeton-S-methyl and related compounds

[2] The information provided precluded an estimate that the dietary would be below the ARfD for children aged ≤ 6 years

[3] STMRs/STMRPs or HRs/HRPs were estimated on the basis of the 1998 evaluation.

[4] STMRs/STMRPs or HRs/HRPs were estimated on the basis of new data submitted to the 2004 JMPR.

[5] Case 3 commodities do not require estimation of the HR for short-term intake assessment.

Paraquat** (057)	AM 0660	Almond hulls	0.01 (*)			
ADI: 0–0.005 mg/kg bw	FI 0030	Assorted tropical and subtropical fruits minus inedible peel (except passion fruit)	0.01 (*)		0.01	0.01
ARfD: 0.006 mg/kg bw	FB 0018	Berries and other small fruit	0.01 (*)		0	0
	MO 1280	Cattle kidney	W	0.5		
	FC 0001	Citrus fruit	0.02	–	0.01	0.02
	JF 0004	Orange juice			0	
	SO 0691	Cotton-seed	2	0.2	0.21	
	OC 0691	Cotton-seed oil, crude			0.01	
	OR 0691	Cotton-seed oil, edible	W	0.05 (*)		
	MO 0105	Edible offal (mammalian)	0.05		0.0007	0.033
	MO 0097	Edible offal of cattle, pigs and sheep	W	0.05 (*)		
	PE 0112	Egg	0.005 (*)	0.01 (*)	0	0
	AV 1051	Fodder beet leaves or tops	0.2 (dry wt)			
	VC 0045	Fruiting vegetables, cucurbits	0.02		0	0
	VO 0050	Fruiting vegetables, other than cucurbits	0.05		0.01	0.04
	JF 0448	Tomato juice			0	
		Tomato ketchup			0	
	DH 1100	Hops, dry	0.1	0.2	0.05	0.05
		Beer			0.0001	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
	VL 0053	Leafy vegetables	0.07		0.025	0.05
	GC 0645	Maize	0.03	0.1	0.025	
	CF 1255	Maize flour	0.05		0.038	
		Maize germ			0.0075	
		Maize grits and meal			0.013	
	OC 0645	Maize oil, crude			0.006	
		Corn starch			0.006	
	AS 0645	Maize fodder	10 (dry wt.)			
	AF 0645	Maize forage	5 (dry wt.)			
	MM 0095	Meat (from mammals other than marine mammals)	0.005		0.0001	0.005
	MM 0097	Meat of cattle, pigs and sheep	W	0.05 (*)		
	ML 0106	Milks	0.005(*)	0.01 (*)	0.00008	
	FT 0305	Olive	0.1	1	0.05	0.1
	OC 0305	Olive oil, virgin			0.018	
	FI 0351	Passion fruit	W	0.2		
	MO 1284	Pig kidney	W	0.5		
	FP 0009	Pome fruits	0.01 (*)	–	0	0
	VR 0589	Potato	W	0.2		
		Potato crisps			0.02	
		Potato granules			0.05	
	PO 0111	Poultry, edible offal of	0.005 (*)		0	0
	PM 0110	Poultry meat	0.005 (*)		0	0
	VD 0070	Pulses	0.5		0.1	
	GC 0649	Rice	W	10		
	CM 1205	Rice, polished	W	0.5		
	VR 0075	Root and tuber vegetables	0.05		0.02	0.05
	MO 1288	Sheep kidney	W	0.5		
	GC 0651	Sorghum	0.03	0.5	0.025	
		Sorghum flour			0.004	
		Sorghum germ			0.013	
	AF 0651	Sorghum forage (green)	0.3 (dry wt)			
	AS 0651	Sorghum straw and fodder, dry	0.3 (dry wt)			
	VD 0541	Soya bean (dry)	W	0.1		
	AL 0541	Soya bean fodder	0.5 (dry wt)			
	AL 1265	Soya bean forage (green)	2 (dry wt)			
	OC 0541	Soya bean oil, crude			0.01	
	FS 0012	Stone fruit	0.01 (*)		0	0
	DF 0014	Prune			0	
	SO 0702	Sunflower seed	2	2	0.22	
	OC 0702	Sunflower seed oil, crude	W	0.05 (*)	0	
	OR 0702	Sunflower seed oil, edible	W	0.05 (*)		
	DT 1114	Tea, green, black (black, fermented and dried)	0.2		0.06	
	TN 0085	Tree nuts	0.05		0.01	0.05
	AO1 0002	Vegetables (except those listed)	W	0.05 (*)		

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: paraquat cation						
Phorate** (112) ADI: 0–0.0007 mg/kg bw ARfD: 0.003 mg/kg bw						
Pirimicarb** (101) ADI: 0–0.02 mg/kg bw ARfD: 0.1 mg/kg bw						
Pirimiphos-methyl (086) ADI: 0–0.03 mg/kg bw	MO 0105	Edible offal (mammalian)	0.01(*) [1]		0	0
	PE 0112	Egg	0.01	0.05	0	0.01
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*) (fat) [1]	0.05(*)	Muscle: 0 Fat: 0	Muscle: 0 Fat: 0
	PM 0110	Poultry meat	0.01(*) [1]		Muscle: 0 Fat: 0	Muscle: 0 Fat: 0
	PM 0111	Poultry, edible offal of	0.01(*) [1]		0	0
[1] No residues expected from consumption of feed commodities with pirimiphos-methyl residues, as evaluated by JMPR.						
Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: pirimiphos-methyl. The residue is fat-soluble.						
Prochloraz** (142) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	FI 0326	Avocado	W [1]	5 (Po)		
	FI 0030	Assorted tropical and subtropical fruits minus inedible peel	7 (Po)		0.1	0.7
	FI 0327	Banana	W [1]	5 (Po)		
	GC 0640	Barley	W [1]	0.5		
	AS 0640	Barley straw and fodder, dry	W [1]	15		
		Beer			0.01	
	MF 0812	Cattle fat	W [1]	0.5		
	MM 0812	Cattle meat	W [1]	0.1 (*)		
	MO 0812	Cattle, edible offal of	W [1]	5		
	GC 0080	Cereal grains	2		0.11	1.2
	FC 0001	Citrus fruits	10 (Po)		0.1	0.92
	SB 0716	Coffee beans	W	0.2		
	MO 0105	Edible offal (mammalian)	10		1.2	6.2
	PE 0112	Eggs	0.1		0.012	0.07
	SO 0693	Linseed	0.05 (*)		0.05	0.05
	FI 0345	Mango	W [1]	2 (Po)		
	MM 0095	Meat (from mammals other than marine mammals)	0.5 (fat)		0.02 (muscle) 0.06 (fat)	0.1 (muscle) 0.38 (fat)
	ML 0106	Milks	0.05 *	0.1*	0	0
	VO 0450	Mushroom	40	2	4.9	37
	GC 0647	Oat	W [1]	0.5		
	AS 0647	Oat straw and fodder, dry	W [1]	15		
	FC 0004	Orange, sweet, sour	W [1]	5 Po		

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
	FI 0350	Papaya	W [1]	1 Po		
	HS 0790	Pepper, black, white	10		5.1	5.1
	PM 0110	Poultry meat	0.05*		0.001 (muscle) 0.001 (fat)	0.005 (muscle) 0.007 (fat)
	PO 0111	Poultry, edible offal of	0.2		0.015	0.1
	SO 0495	Rape seed	0.7	0.5	0.1	0.48
		Rape-seed meal			0.06	
	OR 0495	Rape-seed oil, edible			0.06	
	GC 0650	Rye	W [1]	0.5		
	AS 0650	Rye straw and fodder, dry	W [1]	15		
	FS 0012	Stone fruit	W	0.05		
	AS 0081	Straw and fodder (dry) of cereal grain	40			
	SO 0702	Sunflower seed	0.5		0.1	0.32
		Sunflower seed meal			0.05	
	OR 0702	Sunflower seed oil, edible	1		0.06	
	GC 0654	Wheat	W [1]	0.5		
	CM 0654	Wheat bran, unprocessed	7		0.54	
	AS 0654	Wheat straw and fodder, dry	W [1]	15		
	CF 1211	Wheat flour			0.025	
	CP 1212	Wholemeal bread			0.14	

[1] Replaced by recommendation for wider group of commodities

Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz.

The residue is fat-soluble

Propiconazole** (160)

ADI: 0–0.07 mg/kg bw

ARfD: 0.3 mg/kg bw

Propineb**	FP 0226	Apple	W	2		
ADI: 0–0.007mg/kg bw	FS 0013	Cherry	0.2	–	0.13	0.35
Interim[1] ARfD: 0.1 mg/kg bw	VC 0424	Cucumber	1	–	0.49	1.1
	MO 0105	Edible offal (mammalian)	0.05 (*)	–	0	0
	PE 0112	Egg	0.01 (*)	–	0	0
	FB 0269	Grape	W	2		
	MM 0095	Meat (from mammals other than marine mammals)	0.05 (*)	–	0	0
	VC 0046	Melon (except watermelon)	W	0.1 (*)		
	VA 0385	Onion, bulb	W	0.2 (*)		
	FP 0230	Pear	W	2		
	VO 0445	Peppers, sweet	7	–	1.6	13
	VR 0587	Potato	0.1	0.1 (*)	0.12	0.16
	PM 0110	Poultry meat	0.05 (*)	–	0	0
	PO 0111	Poultry, edible offal of	0.05 (*)	–	0	0

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
	VO 0448	Tomato	2	1	1	2.9

Residue for compliance with MRLs in plant and animal commodities: total dithiocarbamates, determined as CS_2, evolved during acid digestion and expressed as mg CS_2/kg

Residue for estimation of dietary intake in plant and animal commodities: sum of propineb and propylenethiourea

Notes All recommended MRLs are covered by the existing or recommended MRLs for dithiocarbamates.

[1] The WHO Core Assessment Group is occasionally asked by the FAO Panel of Experts to establish an ARfD for compounds that were not scheduled for toxicological evaluation, for use in acute dietary risk assessment. This value is derived ad hoc from data from previous meetings and is therefore called an interim ARfD. It can be used in dietary risk assessments until they are replaced by full evaluations, if this is considered necessary.

Pyraclostrobin* (210)	AM 0660	Almond hull	2	0.20	
ADI: 0–0.03 mg/kg bw	TN 0660	Almond	0.02(*)	0.02	0.02
ARfD: 0.05 mg/kg bw	FI 0327	Banana	0.02(*)	0.02	0.02
	GC 0640	Barley	0.5	0.03	
		Malt		0.03	
	VD 0071	Bean (dry)	0.2	0.02	0.10
	FB 0020	Blueberry	1	0.34	0.57
	VR 0577	Carrot	0.5	0.12	0.24
	FS 0013	Cherry	1	0.43	0.63
	FC 0001	Citrus fruit	1	0.19	0.51
	DF 0269	Dried grape (currant, raisin, sultana)	5	1.36	4.27
	MO 0095	Edible offal, mammalian	0.05(*)	0.008	0.037
	PE 0112	Egg	0.05(*)	0	0
	AV 1051	Fodder beet leaf or top	50		
	VA 0381	Garlic	0.05(*)	0.05	0.05
	FB 0269	Grape	2	0.44	1.38
	JF 0269	Grape juice		0.005	
		Wine		0.04	
	VD 0533	Lentil (dry)	0.5	0.13	
	GC 0645	Maize	0.02(*)	0.02	
	FI 0345	Mango	0.05(*)	0.05	0.05
	MM 0095	Meat (from mammals other than marine mammals)	0.5 (fat)	Muscle: 0.009 Fat: 0.063	Muscle: 0.044 Fat: 0.41
	ML 0106	Milks	0.03	0.01	
	GC 0647	Oat	0.5	0.17	
	VA 0385	Onion, bulb	0.2	0.02	0.09
	FI 0350	Papaya	0.05(*)	0.05	0.05
	FS 0247	Peach	0.5	0.15	0.31
	SO 0703	Peanut	0.02(*)	0.02	0.02
	AL 0697	Peanut fodder	50		
	VD 0072	Pea (dry)	0.3	0.07	
		Pea vines	40		
		Pea hay	30		
	TN 0672	Pecan	0.02(*)	0.02	0.02
	TN 0678	Pistachio nut	1	0.22	0.45
	FS 0014	Plum (including prune)	0.3	0.06	0.19

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
	VR 0589	Potato	0.02(*)		0.02	0.02
	PM 0110	Poultry meat	0.05(*) (fat)		Muscle 0 fat 0	Muscle 0 fat 0
	PO 0111	Poultry, edible offal of	0.05(*)		0	0
	VR 0494	Radish	0.5		0.08	0.3
	VL 0494	Radish leaf (including radish top)	20		9.9	15
	VC 0431	Squash, summer	0.3		0.15	0.18
	AS 0081	Straw and fodder (dry) of cereal grain	30		1.69	
	FB 0275	Strawberry	0.5		0.16	0.26
	VR 0596	Sugar beet	0.2		0.04	
	VO 0448	Tomato	0.3		0.12	0.21
	GC 0654	Wheat	0.2		0.02	
	CF 1211	Wheat flour			0.012	
	CF 1210	Wheat germ			0.016	

Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: pyraclostrobin.

The residue is fat-soluble.

Spinosad (203)	FM 0812	Cattle milk fat	5			
ADI: 0–0.02 mg/kg bw	GC 0080	Cereal grain	1 (Po)		0.70	
ARfD: unnecessary	DF 0269	Dried grape (currant, raisin and sultana)	1		0.13	
	MO 0105	Edible offal (mammalian) [except cattle][2]	0.5		Liver: 0.064 Kidney: 0.032	
	FB 0269	Grape	0.5		0.084	
	GC 0645	Maize	W [1]	0.01(*)		
	MM 0095	Meat (from mammals other than marine mammals) [except cattle][2]	2 (fat)		Meat 0.01 Fat: 0.32	
	MM 0822	Sheep meat	W [1]	0.01(*) (fat)		
	MO 0822	Sheep, edible offal of	W [1]	0.01(*)		
	GC 0651	Sorghum	W [1]	1		
	CM 0654	Wheat bran, unprocessed	2		1.4	
		Grits			0.057	
	CF 1255	Maize flour			0.13	
	OC 0645	Maize oil, crude			0.77	
	CM 1206	Rice bran, unprocessed			0.55	
		Rice hull			2.0	
	CM 0649	Rice, husked (brown rice)			0.077	
	CM 1205	Rice, polished (white rice)			0.015	
	CF 1211	Wheat flour			0.18	
	CP 1211	White bread			0.098	
		Wine			0.027	

Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: sum of spinosyn A and spinosyn D

The residue is fat-soluble, but residues in milk should be determined in whole milk.

[1] Replaced by recommendation for wider group of commodities.

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
		[2] The recommendations are derived from a dairy cow feeding study and the corresponding animal dietary burden. They are extended to 'Edible offal (mammalian) [except cattle]' and 'Meat (from mammals other than marine mammals) [except cattle]' following the policy of the 2002 JMPR. The proposed MRLs for cattle meat (3 mg/kg, fat), cattle kidney (1 mg/kg) and cattle liver (2mg/kg), arising from the direct use of spinosad on cattle, should remain. They exceed the recommendations for mammalian meat and offal, and so require the restriction 'except cattle' to the general commodity descriptions.				
Triadimefon** (133) ADI: 0–0.03 mg/kg bw ARfD: 0.08 mg/kg bw						
Triadimenol** (168) ADI: 0–0.03 mg/kg bw ARfD: 0.08 mg/kg bw						
Trifloxystrobin* (213) ADI: 0–0.04 mg/kg bw ARfD: unnecessary	AM 0660	Almond hulls[1]	3			
	DF 0226	Apple, dried			0.043	
	JF 0226	Apple juice			0.018	
		Apple sauce			0.053	
		Apple preserve			0.053	
		Apricot, canned			0.019	
	FI 0327	Banana	0.05		0.02	
	GC 0640	Barley	0.5		0.04	
	AS 0640	Barley straw and fodder (dry)[1]	7			
		Beer (residue arising from hops)			0.01	
	VB 0402	Brussels sprout	0.5		0.17	
	VR 0577	Carrot	0.1		0.035	
	VB 0041	Cabbage, head	0.5		0.17	
	VS 0624	Celery	1		0.18	
	FC 0001	Citrus fruit[2]	0.5		0.095	
	JF 0001	Citrus juice[2]			0.018	
	AB 0001	Citrus pulp, dry[1]	1			
		Citrus oil (orange)			12	
	DF 0269	Dried grape (raisin)	5		0.345	
	PE 0112	Egg	0.04(*)		0	
	VB 0042	Flowerhead brassica	0.5		0.17	
	VC 0045	Fruiting vegetables, cucurbits	0.3		0.095	
	FB 0269	Grape	3		0.15	
	JF 0269	Grape juice			0.036	
		Must			0.07	
		Wine			0.023	
	DH 1100	Hops, dry	40		9.95	
	MO 0098	Kidney of cattle, goats, pigs and sheep	0.04(*)		0.004	
	VA 0384	Leek	0.7		0.31	
	MO 0099	Liver of cattle, goats, pigs and sheep	0.05		0.008	
	GC 0645	Maize	0.02		0.02	