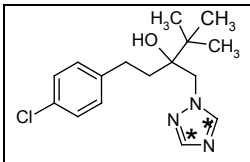
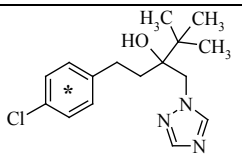
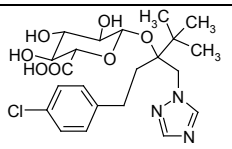
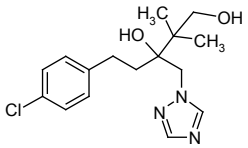
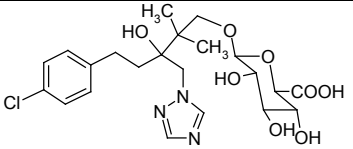
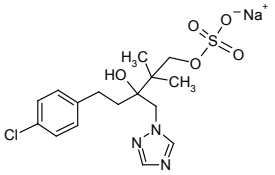
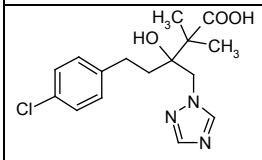
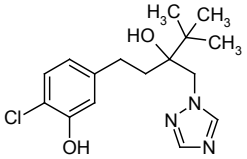
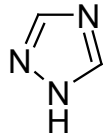
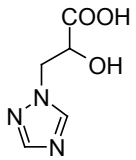
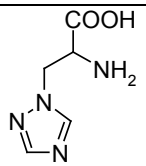
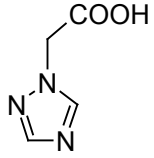
5.25 TEBUCONAZOLE (189)

RESIDUE AND ANALYTICAL ASPECTS

Tebuconazole was last evaluated for residues in 2008. In 2010, the compound was evaluated for toxicology within the periodic review program, when an ADI of 0–0.03 mg/kg bw and a ARfD of 0.3 mg/kg bw were established. The compound was scheduled for periodic review for residues at the present Meeting. Data on metabolism in livestock animals and plant, field rotational crops studies, environmental fate, methods of residue analysis, storage stability studies, GAP information, residue data on various crops, processing studies, and animal feeding studies were submitted.

Animal metabolism

Metabolism studies were conducted in rats, goats and hens. The positions of the radiolabel compounds used in the studies and the structures of the main metabolites found in animals and plants are shown below:

 [triazolyl-3,5-^{14}C]tebuconazole	 [Phenyl-UL-^{14}C]tebuconazole	 tebuconazole glucuronide
 tebuconazole-1-hydroxy	 tebuconazole-1-OH-glucuronide	 Tebuconazole-1-hydroxysulfate
 tebuconazole-carboxylic acid	 Tebuconazole-m-hydroxy	 1,2,4-Triazole (M26)
 Triazole lactic acid	 Triazole alanine	 Triazole acetic acid

The metabolism of tebuconazole in rats was evaluated by the WHO panel of the JMPR at the 2010 Meeting. In summary, the main metabolites of tebuconazole in rats were the oxidation products of one of the methyl groups of the tertiary butyl moiety (alcohol and the carboxylic acid), further conjugation with glucuronide and/or sulfate, and oxidation to triol and keto acid derivatives and cleavage of the triazole moiety (mostly in males).

In a study conducted in 1987, a lactating goat was treated orally with [phenyl-UL-^{14}C]tebuconazole at 15.0 mg/kg bw on three consecutive days. Milk was collected twice a day. The highest tebuconazole equivalents levels were found in liver (5.18 mg/kg) and kidney (3.96 mg/kg), where tebuconazole accounted for 12.4 and 2.5% TRR, respectively. Fat, muscle and milk contained 0.15, 0.05 and 0.04 mg/kg tebuconazole equiv., respectively. Over 85% of the

radioactivity in milk and tissues were recovered in the organosoluble extract. Tebuconazole was not detected in muscle and milk (< 0.01 mg/kg) and accounted for 0.01 mg/kg in fat. The predominant residues in all cases were the conjugates of tebuconazole-1-hydroxy, representing 92.8% TRR in kidney, 67.9% TRR in liver, 68.1% TRR in fat, 67.6% TRR in muscle and 49.4% TRR in milk. Tebuconazole-1-hydroxy levels corresponded to 15.3% TRR in liver, 2.3% TRR in kidney, 12.5% TRR in fat, 21.4% TRR in muscle 22.2% TRR in milk.

In a more recent goat study (2002), two animals were orally dosed with [triazolyl-3,5-^{14}C]tebuconazole at a rate of 3.0 mg/kg bw for 3 consecutive days. The highest tebuconazole equivalents levels were found in liver (1.9 mg/kg) and kidney (2.0 mg/kg). Fat, muscle and milk contained 0.095, 0.027 and 0.011 mg/kg tebuconazole equiv., respectively. Residues of unchanged parent were highest in fat and liver (18 and 15% of the total radioactive residues, TRR, respectively), and accounted for 3, 5 and 7% TRR in kidney, muscle and milk. The main metabolites were tebuconazole-1-OH-glucuronide, found in all tissues at 46 to 77% TRR, and tebuconazole-glucuronide, only found in liver and kidney (17 and 36% TRR, respectively). Milk contained also a polar component (12% TRR), which has chromatographic properties similar to 1,2,4-triazole.

In a study conducted in 1988, laying hens were orally dosed with 10 mg/kg bw [phenyl-UL-^{14}C]tebuconazole for three consecutive days. Quantification of metabolites was based on the recovered radioactivity only. The mean TRR were higher in liver and kidney (8.29 and 6.42 mg/kg tebuconazole equiv.), followed by gizzard (2.09 mg/kg), heart (1.77 mg/kg), fat (1.27 mg/kg), skin (0.5 mg/kg), muscle (0.44 mg/kg) and eggs (0.15 mg/kg). Tebuconazole amounted from 28.3 to 42.3% TRR in eggs, liver and kidney, and from 61.4 to 87.3% TRR in muscle, heart, skin, fat, and gizzard. Tebuconazole-1-hydroxy was detected in all tissues (8.4 to 29.4% TRR) and eggs (56.5% TRR). Tebuconazole-carboxylic acid and tebuconazole-1-hydroxysulfate were detected in liver and kidney (12.6 to 23.1% of the TRR).

In another study (1991), 10 mg/kg bw [phenyl-UL-^{14}C]tebuconazole (approx. 100 mg/kg feed) was administered orally to laying hens on three consecutive days. A total of 84.2% of the administered dose was recovered during the experiment, from which 80.3% in the excreta. The highest TRR were found in liver (10.86 mg/kg tebuconazole equiv.), kidney (9.05 mg/kg) and fat (5.25 mg/kg); muscle and eggs accounted for 0.9 mg/kg each and skin for 1.61 mg/kg. In liver and kidney, tebuconazole accounted for 4 and 2% TRR, respectively, with tebuconazole 1-hydroxysulfate being the main metabolite found (67 and 45.2% TRR, respectively), and tebuconazole-1-hydroxy accounting for less than 10% TRR. In muscle, tebuconazole represented 19 to 38% TRR and tebuconazole-1-hydroxy 22 to 27% TRR. In eggs, those levels were 52.9 and 31.6% TRR, respectively. Tebuconazole-carboxylic acid was present in kidney at 23.5% TRR.

In a more recent study (2002), laying hens were dosed orally for 3 days with [triazolyl-3,5-^{14}C]tebuconazole at 2.0 mg/kg bw (30 mg/kg in the feed). TRR was 3.72 mg/kg tebuconazole equ., in liver, 0.295 mg/kg in fat, 0.179 mg/kg in muscle and ranged from 0.037 to 0.162 mg/kg in eggs. Tebuconazole was the major radioactive residue in fat and muscle (65.4 and 53.4% TRR, respectively) and accounted for 16.5% TRR in liver and from 31.4 to 42.7% in eggs. Tebuconazole-1-hydroxy was present in all tissues (19 to 24.9% TRR) and in eggs (about 30% TRR). Tebuconazole-carboxylic acid and tebuconazole-1-hydroxysulfate were found in liver at 22.7 and 26.4% TRR, respectively. 1,2,4-triazole was detected only in muscle and eggs (11 to 14% of the TRR).

In summary, the metabolism of tebuconazole was extensive in goats, where the main metabolites were tebuconazole-1-hydroxy (up to 22% TRR) and its conjugates (up to 93% TRR). In hens, tebuconazole was a major component in fat and skin. Tebuconazole-1-hydroxy or its conjugates were found in all tissues (over 20% TRR in liver and muscle) and corresponded to over 50% TRR in eggs. Tebuconazole-carboxylic acid was also detected in hen liver and kidney and 1,2,4-triazole in hen muscle and eggs. The metabolic pathway of tebuconazole in livestock animals is similar to that

observed in rats, which involves mainly hydroxylation and carboxylation of the tertiary butyl moiety, followed by conjugation. Cleavage of the triazole was only observed in hens.

Plant metabolism

The metabolism of tebuconazole was investigated from 1985 to 1991 in wheat, peanuts, and grapes under simulated field conditions. In the first study conducted in wheat, [triazole-3,5-^{14}C]tebuconazole was applied to the seeds at approx. 11 g/100 kg, the seeds planted in a sandy loam soil (70 kg seed/ha) and the wheat grown in a greenhouse. Samples of green forage were taken at the boot stage and grain and straw at maturity. Straw contained the highest percentage of the applied radioactivity (17.1%). About 11% of the radioactivity was translocated to green forage and 24% to mature wheat plant. Grains contained 2.4% of the applied radioactivity. Tebuconazole accounted for 25.0% of radioactivity in straw and 76.0% in roots. Tebuconazole-1-hydroxy and its glucuronide conjugate were identified in straw (29% of the radioactivity).

In a second study, [triazole-3,5-^{14}C]tebuconazole was sprayed to wheat during the boot stage at 0.5 kg ai/ha, and plants grown in a greenhouse. In green forage, total radioactive residues (TRR) amounted 28.0 mg/kg tebuconazole equiv. at the day of the application, decreasing to 9.8 mg/kg after 21 days and increasing to 20 mg/kg at day 28; unchanged tebuconazole was the predominant residue (87.3 to 123% TRR throughout the study). At plant maturity, most of the radioactivity was found in straw (37 mg/kg), 95.1% of unchanged tebuconazole. Grain contained 0.5 mg/kg (1.2% of radioactivity in the whole plant), from which 6% was tebuconazole, 80% tebuconazole alanine and 13% triazole acetic acid. The majority of the radioactivity recovered from wheat grain was in starch (74.0%).

The metabolism of [triazole-3,5-^{14}C]tebuconazole and [phenyl-UL-^{14}C]tebuconazole were investigated in peanuts after 3 spray applications at 0.25 kg ai/ha. The plants were grown in a greenhouse and harvested at 7 weeks PHI. Foliage had the highest residue level (29.2 and 22.6 mg/kg tebuconazole equiv. in the triazole and phenyl labels, respectively), followed by the nuts (1.19 and 0.09 mg/kg) and shells (0.16 and 0.27 mg/kg). Most of the residues in foliage was tebuconazole (62% TRR) and about 15% was tebuconazole-1-hydroxy. No tebuconazole was detected in nuts, which contained mostly the cleavage product triazole alanine (54.1% TRR), triazole lactic acid and 1,2,4 triazole (10% TRR each). Peanut shells contained tebuconazole (about 15% TRR), tebuconazole-1-hydroxy and its conjugates.

In another study conducted in peanuts, [Phenyl-UL-^{14}C]tebuconazole was applied seven times to peanut plants at 0.6 kg ai/ha, the plants grown under field conditions, moved into a greenhouse in the last phase of the study and harvested 14 weeks after the last application. TRR in foliage/forage were 110 mg/kg (98% of the residues in the plant), 70% of which corresponding to tebuconazole residues; tebuconazole-1-hydroxy and tebuconazole-m-hydroxy represented < 10% TRR each. In nuts, TRR was 0.55 mg/kg and tebuconazole was the only residue identified (19% TRR); about 64% TRR remained in the lipid and aqueous fractions. Residues in the shell amounted 17.7 mg/kg, mostly as tebuconazole (58% TRR).

[Phenyl-UL-^{14}C]tebuconazole was applied once to grapes at 0.28 kg ai/ha and samples taken at 0 to 28 days PHI. TRR declined from 7.86 mg/kg at 3 days to 2.1 mg/kg at 28 days PHI, and the majority of the recovered residue (> 90% TRR) was identified as tebuconazole at any sampling time. There was evidence of small amounts of cellulose conjugation, but no metabolites were detected.

In summary, metabolism studies conducted in wheat, peanut and grapes have shown that tebuconazole was the main compound found in most samples. The main metabolite in wheat grain and peanut nut is triazole alanine. Hydroxylation of the tertiary butyl moiety of tebuconazole and conjugation also occurred. The compound was able to translocate from the treated wheat seeds to the forage and mature plant, and from foliar application to peanut plants to the peanut kernel. Although metabolism studies were not conducted in vegetables, metabolism studies showing that tebuconazole

is the main residue in cereal and peanut forage support the conclusion that the same occurs in leafy vegetables.

Environmental fate in soil

[Phenyl-UL-^{14}C]tebuconazole showed a half-life longer than 1 year in sandy loam soil treated at 10 mg/kg (13 kg ai/ha), when about 30% of the radioactivity was found bound to the organic components of the soil. In another study, [phenyl-UL-^{14}C]tebuconazole and [triazole-UL-^{14}C]tebuconazole were shown to be more stable in silt soil (Höfchen) (40% of the applied radioactivity as unchanged parent after 433 days) compared with silt loam (Nisse, manure-treated) (60%). 1,2,4-Triazole was found at higher levels in the silt soil (3.8% of the applied radioactivity). Other possible metabolites found in both soils are a mixture of tebuconazole-5-keto (or its tautomer tebuconazole-5-enol) and tebuconazole-4-hydroxy.

Soil dissipation studies with tebuconazole were carried out under field conditions in Europe (6 trials, 1989, 1997 and 2001) and North America (20 trials, 1988 to 1999) at various application rates and soil types. DT_{50} ranged from 8 to 912 days, and in most cases was over 100 days.

Thirteen long-term field studies (3 to 6 years) were conducted in various locations in Europe between 1991 to 1997 plus one in Canada (2003). In all cases, tebuconazole was shown to be stable in soil, but there is no indication of accumulation. In two trials conducted in Germany, residues in the upper 10 cm soil layer decreased from 0.16 mg/kg in the first and second year to 0.12 mg/kg in the third year. In bare soil plots, residues peaked after each application, followed by an initial rapid decline reaching a plateau, where additional decline was significantly slower.

Rotational crops

The metabolism of tebuconazole was investigated in rotational crops under confined conditions in kale, red beet, and spring wheat. [Triazole-3,5-^{14}C]tebuconazole or [phenyl-UL-^{14}C]tebuconazole were applied to the target crop (wheat) at a rate of 0.50 or 0.56 kg ai/ha at the boot stage of growth, the wheat harvested, the soil re-treated at the same rate, and after ageing for 29/30 days, the first set of rotational crops were planted (immediate planting), followed by an intermediate (122/135 days after treatment, DAT) and a final planting (273 days DAT). In soil, radioactivity was mostly due to tebuconazole at day 29/30 DAT (minimum of 83.2%); at 122 DAT, it corresponded to 31.9% TRR. At intermediate and final planting, most of the radioactivity was found in soil as bound residues (52.9 to 88% TRR). There was a significant uptake of ^{14}C-activity by the plants from the treated soil. Residues in wheat from the [triazole-3,5-^{14}C]tebuconazole treatment were mostly concentrated at in crops from the intermediate planting, mainly on wheat grain (35.4 mg/kg; 64.8% TRR of wheat plant at harvest) and from 0.8 to 2.7 mg/kg in kale, beet tops and roots. Wheat grain from the final planting period had 7.6 mg/kg. The major metabolites detected in the crops were triazole alanine (> 50% TRR in wheat grain, beet root and kale at 29 to 273 days after planting), triazole lactic acid (mainly in wheat straw and beet top; 20.5 to 52% TRR), and triazole acetic acid (wheat grain and straw, 16.2 to 42% TRR). In general, residues from the [phenyl-UL-^{14}C] tebuconazole treatment declined during the study period, and were most concentrated in wheat straw from the initial planting (0.548 mg/kg; 78.6% TRR in wheat plant at harvest). The highest residues in wheat grain and beet roots were found in plants from the intermediate planting (0.110 and 0.049 mg/kg, respectively). Tebuconazole was extensively metabolised in both studies, with low amounts detected in wheat straw, beet and kale from the initial planting (4.3 to 15% of TRR at harvest).

In another study conducted, [phenyl-UL-^{14}C]tebuconazole was incorporated into a sandy loam topsoil layer at a rate of 2.5 kg ai/ha (10x the recommended rate), spring wheat planted after 32 and 152 days, sampled for forage after 7 - 8 weeks and harvested at maturity. Residues in soil did not change significantly during the whole experiment period (around 0.8–1.2 mg/kg equ.). Wheat grain contained < 3% TRR present in the wheat plant at harvest (0.26 and 0.075 mg/kg), and most of the residues were present in straw (6.29 and 3.9 mg/kg). In grain, only the parent compound was detected,

but at very low concentration (< 0.01 mg/kg). In wheat straw, tebuconazole was the major residue (2.27 mg/kg equ., 36% TRR) and tebuconazole-1-hydroxy and its conjugates represented 7.1% TRR. Tebuconazole accounted for over 50% TRR in wheat forage.

Four field rotational crop studies were conducted with tebuconazole in winter wheat in Germany. In three trials, tebuconazole was sprayed once onto the bare soil at 0.5 kg ai/ha and wheat was sown approximately 30 days after application as a rotation crop. In the fourth trial, the product was applied at the same rate and after harvest; the field was re-planted with winter wheat. Tebuconazole residues were only detected in the upper soil layers (0–10 cm), at levels ranging from 0.09 to 0.47 mg/kg (0 to 63 days after planting). With the exception of one sample of green material (0.14 mg/kg; 240 days after planting), residues in all other samples were below the LOQ (0.05 mg/kg).

Eleven field rotational studies were conducted in the USA in 1997/1998 with spinach, wheat, sorghum and turnip planted 30 and 120 days after treatment of the soil with seven applications (7 days interval) of EC tebuconazole at 0.25 kg ai/ha. Tebuconazole residues ranged between < 0.01 and 0.05 mg/kg in plant matrices.

In twenty field trials conducted in USA in 1997/1998, wheat was treated once with tebuconazole at 0.126 kg, the wheat was destroyed after 35 days and soya beans were planted-back into the same plots. Tebuconazole residues were only detected in one hay sample (0.04 mg/kg). Residues were < 0.01 mg/kg in soya bean seed and forage and < 0.02 mg/kg in hay.

In summary, tebuconazole was the major residues in rotational crops, being metabolised to three major metabolites, triazole alanine, triazole lactic acid and triazole acetic acid. The metabolite distribution pattern showed little variation between the planting intervals, an indication that metabolite formation is influenced by the plants more than the soil. Field studies have shown that tebuconazole was generally present at levels < 0.05 mg/kg in succeeding crops.

Analytical methods

Tebuconazole can be analysed in plant commodities using the multi-residue enforcement method DFG S19. This method involves extraction with acetone/water, partition in ethyl acetate/cyclohexane and sodium chloride, clean-up by gel permeation chromatography (GPC) and analysis by GC/MSD. LOQ is 0.02 mg/kg. Various specialized methods were used in the supervised residue trials. In the methods developed in the 1980´s and early 1990´s, the plant material is extracted with organic solvent (dichloromethane, acetonitrile, acetone/water), cleaned up with SPE (C18, silica gel, aluminium oxide, diatomaceous earth) and analysed by gas chromatography using either TID, NPD or MSD. LOQ is 0.02 or 0.05 mg/kg. In all methods, inclusion of hexane extraction step for lipid removal is required for high fat content matrices. In the more recent methods, the sample is extracted with acetonitrile:water, submitted to SPE clean up or injected directly to the LC/MS/MS for quantification. LOQ ranged from 0.01 to 0.05 mg/kg. Some methods used matrix-matched standards or internal stable labelled standards for quantification.

Two methods to analyse tebuconazole and its metabolite tebuconazole-1-hydroxy in animal commodities were reported. In the Mobay method 97468, the samples are extracted with methanol, methanol/hexane or methanol/acetonitrile, the extract partitioned in dichloromethane/water or directly hydrolysed with HCl, purified by GPC and a combination of silica and florisil column or HPLC clean up. Tebuconazole is measured directly by GC/NPD and tebuconazole-1-hydroxy is derivatised to a monosilyl ether before quantitation. GC-MSD is used for confirmation. LOQ for tebuconazole and the metabolite was 0.1 mg/kg in cattle kidney, 0.05 mg/kg in cattle liver and fat, and milk. In poultry commodities, the method was satisfactory validated for tebuconazole in muscle, liver, fat and skin at 0.05 mg/kg and in eggs at 0.01 mg/kg. In Method 101316, the matrices are extracted with methanol and acetonitrile, the extract hydrolysed overnight under acidic reflux, residues separated by GPC, hexane/acetonitrile partitioning and HPLC. Tebuconazole and the t-butyldimethylsilane derivative of the 1-hydroxy metabolite were analysed by GC/NPD, and GC-MSD used for confirmation. LOQ for

tebuconazole and the metabolite was 0.1 mg/kg in cattle and poultry tissues and eggs, and 0.05 mg/kg in milk.

Stability of residues in stored analytical samples

Tebuconazole residues showed to be stable in various crops fortified at 1.0 mg/kg under frozen storage (-10 °C to -24 °C) for at least 30 months (at least 86% of the residues remained). Residues in wheat straw and forage and peanut meat showed stability for at least 63 months of storage.

Stability studies conducted with ^{14}C tebuconazole and ^{14}C tebuconazole-1-hydroxy showed that the compounds were stable for at least 5.6 months (169 days) at -24 °C in chickens and cattle tissues (from 94 to 119% remaining) and for at least 12 months in eggs and milk. The concentration of the compounds did not show a profile of decline during the period of the studies.

The periods of sample storage in the supervised trials and the feeding studies conducted with tebuconazole are considered acceptable.

Definition of the residue

Metabolism studies conducted in goat and hens show that tebuconazole was present in all animal commodities. The main metabolite was tebuconazole-1-hydroxy, free and/or in its conjugated form, represented at over 20% TRR in liver and muscle of cattle and poultry, about 50% TRR and milk and eggs and over 90% TRR in hen kidney. Tebuconazole-carboxylic acid was present in hen liver and kidney at about 20% TRR and 1,2,4-triazole at > 10% TRR in hen muscle and eggs. 1,2,4 triazole is not as specific marker for tebuconazole use as it can be formed in plants treated with other triazole compounds. Animal feeding studies have shown that residues of tebuconazole-1-hydroxy are not found in cattle and poultry meat, milk and eggs from animals exposed to tebuconazole residues at up to 4–5 times the estimated livestock dietary burden and was only found in poultry liver (0.11–0.2 mg/kg) at 2.3 times the maximum dietary burden. The metabolite is only found at the estimated dietary burden in cattle liver and kidney (< 0.2 mg/kg), two minor commodities in trade and with a low impact in the total human diet. Tebuconazole residues do not accumulate in fat.

Residue definition for animal commodities for enforcement and risk assessment purposes:

Tebuconazole

Residues of tebuconazole are not fat soluble

Tebuconazole was the major compound found in plant commodities samples, with only two exceptions. Triazole alanine, a common triazole metabolite, was the main residue in wheat grain and peanut nut (> 50% TRR) and tebuconazole-1-hydroxy and its conjugates represented about 30% TRR in wheat straw. Triazole alanine is not as specific marker for tebuconazole use as it can be formed in plants treated with other triazole compounds. The presence of tebuconazole-1-hydroxy is only found in a feed item, not relevant for human exposure.

Residue definition for plant commodities for enforcement and risk assessment purposes:

Tebuconazole

Results of supervised trials on crops

The OECD MRL calculator was used to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. The Meeting reviewed the trial conditions and other relevant factors related to each dataset to arrive at a best estimate of the maximum residue level using expert judgment. When the OECD calculator suggested a different value, an explanation on the discrepancy was included in the text.

Citrus fruits

In Brazil, critical GAP for tebuconazole in citrus is 2 × 0.015 kg ai/hL, 20 days PHI. Two trials conducted with 3 applications at the GAP rate gave residues of 1.3 (2) mg/kg. These trials are considered to be at GAP as the first application is unlikely to affect residues at 20 days PHI. Ten other trials did not match GAP.

In two trials conducted in oranges in South Africa at GAP (2 × 0.02 kg ai/hL), residues at 175 days PHI were < 0.01 and 0.01 mg/kg in the fruit and < 0.01 (2) in the pulp. Two trials conducted at double rate gave residues within the same range.

Data was received for eight post-harvest trials conducted in Germany in oranges and mandarins at 0.1 kg ai/hL, however there is no GAP that match these trials.

The Meeting agreed that there were an insufficient number of trials conducted according to GAP to estimate a maximum residue level for tebuconazole in citrus or any commodity within the group.

Apples and pears

In Spain, maximum GAP rate in apple and pears is 4 × 0.019 kg ai/hL, with PHI of 14 days. In six trials conducted in apples in France, Italy and Greece matching this GAP, residues were: 0.17, 0.21, 0.27, 0.39, 0.47 and 0.50 mg/kg. In four trials conducted in pears in Italy and Portugal at the same GAP, residues were: < 0.05, 0.07, 0.28 and 0.38 mg/kg.

Residues in apples and pears conducted at the same GAP belong to the same population and can be combined as < 0.05, 0.07, 0.17, 0.21, 0.27, 0.28, 0.38, 0.39, 0.47 and 0.50 mg/kg

The Meeting estimates a maximum residue level of 1 mg/kg, a HR of 0.50 mg/kg and a STMR of 0.275 mg/kg for tebuconazole in apple and pears.

The Meeting withdraws its previous recommendation of maximum residues level of 0.5 mg/kg for tebuconazole in apples and pears.

Cherries

Tebuconazole is registered in cherry in France and Italy at maximum of 2 × 0.02 kg ai/hL and 7 days PHI. In Spain, up to 3 applications of the same rate can be used. In thirteen trials conducted in France, Italy, Spain and Portugal with 2-3 applications of the GAP rate, residues at 7 days PHI were 0.06, 0.10 (2), 0.12, 0.13, 0.17, 0.18, 0.20, 0.26, 0.29, 0.30, 0.33 and 0.40 mg/kg.

In the Czech Republic, GAP consists of 2 × 0.25 kg ai/ha with a 7 day PHI. In seven trials conducted in Germany complying with this GAP, residues were: 0.32, 0.38, 0.45, 0.46, 0.48, 0.51 and 0.74 mg/kg.

In ten trials conducted in USA according to GAP (up to 6 × 0.25 kg ai/ha, 0 days PHI), residues were 0.41, 0.61, 0.64, 0.79, 0.86 (2), 0.92, 0.97, 1.4, and 3.1 mg/kg.

Using the residue data coming from the most critical GAP (USA), the Meeting estimates a maximum residue level of 4 mg/kg, a HR of 3.1 mg/kg and a STMR of 0.86 mg/kg for tebuconazole in cherries.

The Meeting withdraws its previous recommendation of maximum residues level of 5 mg/kg for tebuconazole in cherry.

Apricot, peach and nectarines

In three trials conducted in peaches in Brazil according to GAP (3 × 0.2 kg ai/ha and 7 days PHI), residues in whole fruit were 0.01, 0.02 and < 0.1 mg/kg.

Tebuconazole is registered in Italy and Spain in apricot, peach and nectarine at a maximum of 2 × 0.28 kg ai/ha and 7 days PHI. In nine trials conducted in peaches in Italy, France, Greece and Spain matching this GAP, residues were 0.09, 0.11, 0.21, 0.22 and 0.35 mg/kg in whole fruit and 0.06, 0.10, 0.11, 0.13, 0.17, 0.19, 0.23 (2) and 0.37 mg/kg in peach without stone. In the five trials, the residue ratio in whole fruit/fruit without stone was calculated (0.91, 0.94, 0.96, 0.9 and 1; mean of 0.94). When the mean ratio was applied to residues in fruit without stone, the residue population in whole fruit is 0.06, 0.09, 0.11, 0.12, 0.16, 0.18, 0.21, 0.22 and 0.35 mg/kg

In two trials conducted in nectarines in Italy according to GAP, residues were 0.06 and 0.14 mg/kg in fruit without stone and 0.05 and 0.12 (by applying a ratio of 0.83 to 0.14 mg/kg) mg/kg in whole fruit. In two trials conducted in apricots in Italy according to GAP, residues at 7 days PHI were 0.30 and 0.32 mg/kg in fruit without stone and 0.27 (by applying a ratio of 0.9 to 0.30 mg/kg) and 0.29 mg/kg in whole fruit.

In seven trials conducted in peaches in the USA according to GAP (0.25 kg ai/ha, 0 day PHI), residues in fruit without stone were 0.20, 0.21, 0.44, 0.46, 0.66, 0.97 and 1.0 mg/kg. By applying the whole fruit/fruit without stone ratio estimated previously for peaches (0.94), the estimated residues in whole fruit were 0.19, 0.20, 0.41, 0.43, 0.62, 0.91 and 0.94 mg/kg.

Based on the most critical GAP and highest residue population (USA), the Meeting estimated a maximum residue level of 2 mg/kg, a HR of 1.0 mg/kg and a STMR of 0.46 mg/kg for tebuconazole in apricot, peaches and nectarine.

The Meeting withdraws its previous recommendation of maximum residues level of 1 mg/kg for tebuconazole in peaches.

Plums

GAP for tebuconazole in plums is 3 × 0.013 kg ai/hL in the Netherlands and 3 × 0.019 kg ai/hL in Spain, with a 7 day PHI.

A total of 22 trials were conducted with tebuconazole on plums in Europe. In trials conducted in Germany matching the GAP of the Netherlands, residues in fruit were 0.06, 0.08 and 0.12 mg/kg. Trials conducted in France, Italy and Spain matching Spanish GAP were: 0.03 (3), < 0.05 (4), 0.05, 0.07, 0.07, 0.08, 0.10 (2), 0.11, 0.12, 0.24, 0.28, 0.38 and 0.40 mg/kg.

Nine trials were conducted in plums in USA at the maximum GAP rate (6 × 0.25 kg ai/ha; 0 day PHI), giving residues at in fruit of 0.02, 0.03 (2), 0.06, 0.08, 0.12, 0.13, 0.37 and 0.47 mg/kg.

Based on the most critical GAP and highest residue population (USA), the Meeting estimated a maximum residue level of 1 mg/kg, a HR of 0.47 mg/kg and a STMR of 0.08 mg/kg for tebuconazole in plums (including prunes).

The Meeting withdraws its previous recommendation of maximum residues level of 0.2 mg/kg for tebuconazole in plums (including prunes).

Elderberrries

Six trials were conducted in Austria according to the GAP rate of 3 × 0.038 kg ai/hL. Residues within the 24 days PHI were: 0.26, 0.30, 0.39, 0.70 mg/kg. In two trials, samples were harvested 14 days after the last application.

The Meeting estimated a maximum residue level of 1.5 mg/kg, a HR of 0.70 mg/kg and a STMR of 0.345 mg/kg for tebuconazole in elderberries.

The Meeting withdraws its previous recommendation of maximum residues level of 2 mg/kg for tebuconazole in elderberries

Grapes

In Brazil, the critical GAP for tebuconazole in grapes is for a maximum application rate of 0.025 kg ai/hL, maximum number of applications unspecified and a 14 day PHI. Five trials were conducted in the country with 4-6 applications of the GAP rate, with residues of 0.30 (2), 0.52, 0.60 and 0.63 mg/kg. Four trials did not match the GAP.

In France, tebuconazole can be used up to 3 times at 0.1 kg ai/ha with a PHI of 14 days. In two trials conducted in France and Germany matching this GAP, residues were 0.20 and 0.51 mg/kg.

In Italy, the GAP is 3 × 0.1 kg ai/ha with a PHI of 14 days. In five trials conducted in Italy, Portugal and Spain matching this GAP, residues were 0.03, 0.04 (2), < 0.1 and 0.14 mg/kg.

In Portugal, the GAP is 3 × 0.1 kg ai/ha with a PHI of 7 days. In eight trials conducted in Italy, Portugal and Spain matching this GAP, residues were: < 0.02, 0.08, 0.09, 0.11, 0.13, 0.14, 0.38 and 0.41 mg/kg.

Seventeen trials were conducted in the USA according to GAP (8 × 0.126 kg ai/ha). Residues at 14 days PHI were 0.09, 0.10, 0.20, 0.27, 0.33, 0.43, 0.56, 0.67, 0.72, 0.78, 0.94, 0.99, 1.0, 1.5 (2), 1.8 and 4.6 mg/kg.

Based on the most critical GAP and highest residue population (USA), the Meeting estimated a maximum residue level of 6 mg/kg, a HR of 4.6 mg/kg and a STMR of 0.72 mg/kg for tebuconazole in grapes.

The Meeting withdraws its previous recommendation of maximum residues level of 2 mg/kg for tebuconazole in grapes.

Olives

In six trials conducted with tebuconazole in olives in Greece, Italy, Spain and Portugal matching Spanish GAP (one application at 0.015 kg ai/hL before flowering), residues were: < 0.01 (2) and < 0.05 (4) mg/kg. As the application is done before flowering, no residues are expected in the olive fruit.

The Meeting estimated a maximum residue level of 0.05* mg/kg and a STMR of 0 mg/kg for tebuconazole in olives.

Bananas

Tebuconazole is registered to be used in bananas in Australia at up to 6 × 0.1 kg ai/ha with a 1 day PHI. Three trials were conducted in the country according to GAP, giving residues of 0.04, 0.16 and 0.19 mg/kg in whole fruit and 0.03, 0.10 and 0.14 mg/kg in pulp. In three trials conducted with bagged banana, residues in whole fruit and in the pulp were: < 0.01, 0.01 and < 0.02. Six other trials conducted at double rate gave residues within the same range (maximum of 0.16 mg/kg).

Thirteen trials were conducted in Brazil. In one trial conducted according to GAP (5 × 0.1 kg ai/ha, 5 days PHI), residues in the fruit were 0.02 mg/kg. Twelve trials did not match GAP.

Tebuconazole is registered in Mexico and the USA at a rate of 0.1 kg ai/ha with a 0 day PHI. In the USA, the maximum number of application is five. In three trials conducted in Puerto Rico and in four trials conducted in the USA (Hawaii) according to the US GAP rate, residues at 0 day PHI were: < 0.01 (6) and 0.03 mg/kg in fruit and < 0.01 (4) mg/kg in the pulp.

As the number of trials conducted at the most critical GAP giving rise to the highest residues (Australia) was not considered sufficient to make an estimation, the Meeting used the data from trials conducted in the USA.

The Meeting estimated a maximum residue level of 0.05 mg/kg, a HR of 0.03 mg/kg and a STMR of 0.01 mg/kg for tebuconazole in bananas.

The Meeting confirms its previous recommendation of maximum residues level of 0.05 mg/kg for tebuconazole in bananas.

Mango

A total of 18 trials were conducted with tebuconazole in mangoes in Brazil, where the critical GAP is 3 × 0.02 kg ai/hL with a 20 days PHI. In five trials matching GAP, residues in the fruit were 0.02 (2) and < 0.05 (3) mg/kg. The trials conducted at double rate or 4–6 applications gave residues at 20 days PHI from < 0.05 to < 0.1 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg, a HR of 0.05 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in mango.

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in mango.

Papaya

Tebuconazole is registered for papaya in Australia (6 × 0.125 kg/ha, 3 days PHI). One trial conducted in at the country at this GAP gave residues of 0.07 mg/kg; one trial at double rate gave residues < 0.01 mg/kg.

In six trials conducted in Brazil according to GAP (up to 6 × 0.2 kg ai/ha, 7 days PHI), residues in the fruit were: 0.06, 0.15, 0.17, 0.19, 0.32 and 1.2 mg/kg. Six trials were conducted at double rate.

Based on the trials conducted in Brazil, the Meeting estimated a maximum residue level of 2 mg/kg, a HR of 1.2 mg/kg and a STMR of 0.18 mg/kg for tebuconazole in papaya.

The Meeting confirms its previous recommendation of maximum residues level of 2 mg/kg for tebuconazole in papaya.

Passion fruit

Tebuconazole is registered to be used in passion fruit in Brazil at a maximum rate of 4 × 0.024 kg ai/hL and 7 days PHI. In five trials conducted in the country according to GAP, residues in the fruit were 0.02 (2) and < 0.1 (3) mg/kg. Three trials conducted at double rate gave residues < 0.1 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a HR of 0.1 mg/kg and a STMR of 0.1 mg/kg for tebuconazole in passion fruit.

Garlic

In Brazil, the critical GAP rate for tebuconazole in garlic is 4 × 0.25 kg ai/ha; PHI is 14 days. Three trials according to GAP gave residues in the bulb of 0.02 (2) and < 0.05, mg/kg. Three trials conducted at double rate gave residues up to 0.04 mg/kg.

In five trials conducted in France according to GAP (2 × 0.25 kg ai/ha, 21 days PHI), residues were: < 0.02 (2), 0.02, 0.03 and 0.06 mg/kg.

Based on the highest residue population (France), the Meeting estimated a maximum residue level of 0.1 mg/kg, a HR of 0.06 mg/kg and a STMR of 0.02 mg/kg for tebuconazole in garlic.

The Meeting confirms its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in garlic.

Leek

Tebuconazole is registered in leek in Northern Europe, with a critical GAP in the Netherlands (3 × 0.30 kg ai/ha, 14 days PHI). In 12 field trials conducted in Belgium, France and Germany according to this GAP, residues were: 0.03, 0.14, 0.15 (2), 0.19 (2), 0.20, 0.22, 0.24, 0.28, 0.31 and 0.44 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, a HR of 0.44 mg/kg and a STMR of 0.195 mg/kg for tebuconazole in leek.

The Meeting withdraw its previous recommendation of maximum residues level of 1 mg/kg for tebuconazole in leek.

Onion, bulb

Twelve trials were conducted with onions in Brazil, where the critical GAP is 4 × 0.25 kg ai/ha and 14 days PHI. In six trials conducted according to GAP, residues in bulb were: < 0.02 (3), 0.02, 0.03 and 0.06 mg/kg. Six other trials conducted at higher rate gave residues up to 0.10 mg/kg.

Tebuconazole is registered in Germany and Austria at 2 × 0.25 kg ai/ha and 21 days PHI. Seventeen trials were conducted in Germany, France, Belgium, the Netherlands and the UK according to German/Austrian GAP, giving residues of < 0.01 (7), 0.01, 0.02, 0.03 and < 0.05 (7) mg/kg.

GAP in Spain is 1 application at 0.50 kg ai/ha after seeding. Seven trials conducted in Spain, Greece and Portugal did not match this GAP.

Based on the most critical GAP and the highest residue population (Brazil), the Meeting estimates a maximum residue level of 0.1 mg/kg, a HR of 0.06 mg/kg and a STMR of 0.02 mg/kg for tebuconazole in onion, bulb.

The Meeting confirms its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in onion, bulb.

Broccoli

Tebuconazole is registered in Germany in broccoli at 2 × 0.25 kg ai/ha with a 21 day PHI. Six trials conducted in France, Germany and the Netherlands according to this GAP gave residues of < 0.01 (3), < 0.02 (2) and 0.11 mg/kg. Nine trials conducted in Greece, Italy and Spain did not match any GAP from Southern Europe.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a HR of 0.11 mg/kg and a STMR of 0.015 mg/kg for tebuconazole in broccoli.

Brussels sprout

Tebuconazole is registered in northern Europe, with the critical GAP from the Netherlands, with a maximum GAP of 3 × 0.30 kg ai/ha and 21 days PHI. In Germany, GAP is 3 × 0.25 kg ai/ha with a 21 day PHI. In four trials conducted in France, Germany, Netherlands and the UK, matching the GAP of the Netherlands, residues were: < 0.05 (2), 0.07 and 0.19 mg/kg. In 12 trials conducted in France, Germany and the UK, according to German GAP, residues were: < 0.02, 0.02, 0.05, 0.06, 0.07, 0.09, 0.10, 0.11, 0.12 (2), 0.15 and 0.17 mg/kg.

Based on the largest residue population, the Meeting estimated a maximum residue level of 0.3 mg/kg, a HR of 0.19 mg/kg and a STMR of 0.095 mg/kg for tebuconazole in Brussels sprout.

Cabbages, head

The critical GAP for tebuconazole in head cabbage in Northern Europe is 3 × 0.256 kg ai/ha, with a 21 day PHI (the Netherlands). In ten trials conducted in France, Germany and the UK matching this GAP residues were: < 0.05 (6), 0.32 (2), 0.37 and 0.56 mg/kg. Three other trials were not at GAP.

The Meeting estimated a maximum residue level of 1 mg/kg, a HR of 0.56 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in head cabbage.

The Meeting withdraw its previous recommendation of maximum residues level of 1 mg/kg for tebuconazole in brassica (Cole or Cabbage) vegetables; head cabbage, flowered brassicas.

Cauliflower

Tebuconazole is registered for use in cauliflower in France and the Netherlands at a maximum GAP of 3 × 0.25-0.26 kg ai/ha, PHI is 21 days. In 21 trials conducted according to GAP in France, Germany, the Netherlands and the UK, residues in cauliflower head were: < 0.01 (6), < 0.02 (2) and < 0.05 (13) mg/kg. Three trials conducted in Italy and Spain did not match GAP.

The Meeting estimated a maximum residue level of 0.05* mg/kg, a HR of 0.05 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in cauliflower

Cucumber

Tebuconazole is registered in Brazil in cucumber at a maximum of 4 × 0.2 kg ai/ha and a 5 day PHI. Three trials were conducted in the country according to GAP, giving residues of < 0.01 (2) and 0.06 mg/kg. Three other trials did not match GAP.

In Italy, the compound is registered in cucumber at a maximum rate of 4 × 0.125 kg ai/ha and a 3 day PHI. Seven trials conducted in cucumber in Italy, Greece and Spain according to this GAP gave residues of < 0.02, 0.03, 0.04, < 0.05 (2), 0.08 and 0.09 mg/kg. Six trials conducted in Spain and Greece were not at GAP. Four trials were conducted in Germany, Belgium and the Netherlands (no GAP).

Using the more extensive European data, the Meeting estimated a maximum residue level of 0.15 mg/kg, a HR of 0.09 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in cucumber.

The Meeting withdraws its previous recommendation of maximum residue level of 0.2 mg/kg for tebuconazole in cucumber.

Squash, summer

In Italy, the compound is registered in zucchini at a maximum rate of 4 × 0.125 kg ai/ha and a 3 day PHI. Five trials conducted in zucchini in Italy according to GAP gave residues of < 0.05 (3), 0.08 and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a HR of 0.10 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in squash, summer.

The Meeting withdraws its previous recommendation of maximum residues level of 0.02 mg/kg for tebuconazole in squash, summer.

Melons

The critical GAP for tebuconazole in melons in Brazil is 0.25 kg ai/ha (number of applications not specified) and a 14 day PHI. Seven trials were conducted in Brazil according to GAP, giving residues in the fruit of < 0.01, 0.03, < 0.05 (4) and 0.10 mg/kg. When applying the ratio pulp/whole fruit of 0.36 (see below) to this data, estimated residues in the pulp were: < 0.01, 0.02, < 0.02 and 0.036 mg/kg. Seven trials were not according to GAP.

In Italy, tebuconazole is registered to be used at a maximum of 4 × 0.125 kg ai/ha, with a 7 day PHI. In eight field trials conducted in France and Italy according to Italian GAP, residues in the fruit were: 0.03 (2), 0.04 (2), 0.05, 0.07 (2) and 0.09 mg/kg. In five trials residues in the pulp were: < 0.01 (2) and < 0.02 (3) mg/kg. The mean ratio of residues in pulp/fruit was < 0.36 (n = 4). In four

greenhouse trials conducted in Italy and Spain at the same GAP, residues in fruit were: < 0.02, 0.03, 0.05 and 0.06 mg/kg. When applying the ratio of 0.36 to this data, estimated residues in the pulp were: 0.007, 0.01, 0.02 and 0.02 mg/kg.

Trials conducted in Italy and France gave a higher residue population (all detectable residues) and were used for the estimations. The combined residues of tebuconazole were: < 0.02, 0.03 (2), 0.04 (2), 0.05 (3), 0.06, 0.07 (2) and 0.09 mg/kg in whole fruit and 0.007, < 0.01 (2), < 0.02 (3), 0.01, and 0.02 (2) mg/kg in the pulp

The Meeting estimates a maximum residue level of 0.15 mg/kg, a HR of 0.02 mg/kg (in the pulp) and a STMR of 0.02 mg/kg (in the pulp) for tebuconazole in melons, except watermelon.

The Meeting withdraw its previous recommendation of maximum residues level of 0.2 mg/kg for tebuconazole in melons, except watermelon.

Watermelon

The maximum rate for tebuconazole in watermelon in Brazil is 4 × 0.20 kg ai/ha with 14 days PHI. In two trials conducted according to GAP, residues in fruit were: < 0.01 and 0.01mg/kg. Two trials were conducted at double rate.

In Italy, the compound can be applied up to 4 × 0.125 kg ai/ha and 7 days PHI. In three trials conducted according to Italian GAP, residues in fruit were: < 0.02, 0.03 and 0.04 mg/kg. Residues in pulp were: < 0.02 (3) mg/kg. One trial conducted at a lower rate gave residues of 0.05 mg/kg.

The Meeting agree that three trials conducted at the same GAP were not sufficient to estimate a maximum residue level for watermelon.

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in watermelon.

Eggplant

Tebuconazole is registered in Brazil in eggplant (aubergine) at a maximum rate of 4 × 0.2 kg ai/ha and 7 days PHI. In six trials conducted in that country according to GAP, residues were 0.02, 0.03, 0.04 (2) and < 0.10 (2) mg/kg. Two other trials did not match GAP.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a HR of 0.10 mg/kg and a STMR of 0.04 mg/kg for tebuconazole in eggplant.

Peppers, sweet

Tebuconazole is registered in Brazil at a maximum rate of 4 × 0.2 kg ai/ha and 7 days PHI. In three field trials conducted in that country according to GAP, residues were: < 0.10 (3) mg/kg. Three trials were conducted at double rate.

In Italy, the compound can be applied at a maximum of 4 × 0.0125 kg ai/hL and 3 days PHI. Twelve indoor trials conducted in Italy, Germany, the Netherlands, France, and Spain according to this GAP gave residues of 0.06 (2), 0.13, 0.15, 0.16, 0.20, 0.23, 0.25, 0.27, 0.33 (2) and 0.40 mg/kg.

In Spain, the maximum GAP is 3 × 0.025 kg ai/hL and 7 days PHI. Eight indoor trials conducted in the Netherlands, Germany and Spain according to this GAP gave residues of 0.10 (2), 0.15 (2), 0.24, 0.30, 0.35 and 0.62 mg/kg.

Based on the most critical GAP (Spain) and highest residue population, the Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.62 mg/kg and a STMR of 0.185 mg/kg for tebuconazole in sweet peppers.

The Meeting withdraws its previous recommendation of maximum residues level of 0.5 mg/kg for tebuconazole in sweet peppers.

By applying a concentration factor of 10, the Meeting also estimates a maximum residue level of 10 mg/kg, a HR of 6.2 mg/kg and a STMR of 1.85 mg/kg for tebuconazole in peppers, chili (dry).

The Meeting withdraws its previous recommendation of maximum residues level of 5 mg/kg for tebuconazole in peppers, chili (dry).

Sweet corn

Tebuconazole is registered in maize Brazil at a maximum rate of 3 × 0.20 kg ai/ha and 15 days PHI. In three trials conducted in Brazil with 4 applications, residues were: < 0.1 mg/kg.

Tebuconazole is registered in USA in sweet corn at a total maximum application rate of 0.756 kg ai/ha per season with a 7 day PHI. In twelve trials conducted in that country according to GAP, residues were: < 0.01 (2), 0.03, 0.04 (2), 0.05, 0.07, 0.08 (2), 0.10, 0.32 and 0.36 mg/kg.

Based on the highest residue population (USA), the Meeting estimated a maximum residue level of 0.6 mg/kg, an HR of 0.36 and a STMR of 0.06 mg/kg for tebuconazole in sweet corn (corn-on-the-cob).

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in sweet corn (corn-on-the-cob).

Tomato

Tebuconazole is registered in tomato in Brazil at 4 × 0.25 kg ai/ha with a 7 day PHI. Six trials were conducted in that country complying with this GAP, residues found were: < 0.05 (2), 0.05, 0.06, 0.10 and 0.11 mg/kg. Five trials did not match GAP.

In Spain the GAP is 3 × 0.025 kg ai/hL, 3 days PHI. Seven indoor trials conducted in Germany and Spain according to this GAP gave residues of 0.03, 0.13, 0.15, 0.19, 0.23 and 0.46 mg/kg. In two trials conducted at the same GAP in the field, residues were 0.09 and 0.15 mg/kg. Residues conducted in Europe at the Spanish GAP were: 0.03, 0.09, 0.13, 0.15 (2), 0.19, 0.23 and 0.46 mg/kg.

Based on the trials giving the highest residue levels (Europe), the Meeting estimated a maximum residue level of 0.7 mg/kg, a HR of 0.46 and a STMR of 0.15 mg/kg for tebuconazole in tomato.

The Meeting withdraws its previous maximum residue level recommendation of 0.5 mg/kg for tebuconazole in tomato.

Beans, dry

Tebuconazole is registered in Brazil in beans at up to 3 × 0.20 kg ai/ha with a 14 days PHI. In ten trials conducted in that country at this GAP, residues were: < 0.05 (5), 0.05 (2), < 0.10, 0.10 and 0.16 mg/kg. Eight trials conducted at lower or higher GAP gave residues in the same range.

In the USA, the compound can be used at a maximum of 3 × 0.189 kg ai/ha with a 14 days PHI. None of the 14 trials conducted in that country were at GAP.

Based on the Brazilian results, the Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in beans, dry.

Soya bean, dry

In Brazil, tebuconazole can be applied up to 3 × 0.15 kg ai/ha with a 30 days PHI. In eight trials conducted in that country within GAP, residues were: 0.02, 0.03 (3), < 0.05 (3), < 0.10 mg/kg. Six trials were conducted at double rate.

In the USA, GAP is up to 3 × 0.126 kg ai/ha and 21 days PHI. In 20 trials conducted in that country according to GAP, residues were: < 0.01 (3), 0.01 (7), 0.02 (4), 0.03 (2), 0.04 (2) and 0.05 (2) mg/kg.

Based on the largest residue data population (USA), the Meeting estimated a maximum residue level of 0.15 mg/kg, a highest residue of 0.05mg/kg and a STMR of 0.02 mg/kg for tebuconazole in soya bean, dry.

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in soya bean, dry.

Carrot

The GAP for tebuconazole in carrots in Brazil is up to 4 × 0.20 kg ai/ha and a 14 day PHI. In five trials conducted according to GAP, residues were: < 0.1 (3), 0.17 and 0.19 mg/kg. Seven other trials conducted at higher GAP gave residues up to 0.27 mg/kg.

In the Netherlands and Germany, tebuconazole can be used up to 3 × 0.258 kg ai/ha with a PHI of 21 days. In eight trials conducted in France, Germany and the UK according to this GAP, residues were 0.09, 0.10, 0.11 (2), 0.13, 0.18, 0.19 and 0.22 mg/kg.

Based on the most critical GAP and highest residue population from Europe, the Meeting estimated a maximum residue level of 0.4 mg/kg, a HR of 0.22 mg/kg and a STMR of 0.11 mg/kg for tebuconazole in carrot. The Meeting withdraws its previous of maximum residue level recommendation of 0.5 mg/kg for tebuconazole in carrots.

Artichoke, globe

The use of tebuconazole in/on artichoke is registered in Italy, with up to 4 applications at 0.12 kg ai/ha (0.0125 kg ai/hL) and 7 days PHI. Six trials were performed in Italy and Spain according to Italian GAP, with residues of < 0.05, 0.12 (2), 0.17, 0.29 and 0.32 mg/kg.

In Peru, critical GAP is 0.10 kg ai/ha with a 3 day PHI (number of applications not specified). Two trials conducted in the country did not match GAP. One trial was conducted in Mexico, where there is no GAP.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a HR of 0.32 mg/kg and a STMR of 0.145 mg/kg for tebuconazole in artichoke, globe.

The Meeting withdraws its previous recommendation of 0.5 mg/kg for tebuconazole in globe artichoke.

Barley

Tebuconazole is registered in Germany at 2 × 0.31 kg ai/ha (PHI of 35 days). In 18 trials conducted in Germany, France and the UK according to this GAP, residues were: < 0.05 (11), 0.06 (2), 0.08 (2), 0.10, 0.13 and 0.21 mg/kg.

In France, GAP is 2 × 0.25 kg ai/ha and 28 days PHI. In 14 trials conducted in France, Germany, Greece, Italy, Portugal and Spain according to this GAP, residues were: < 0.05 (5), 0.07 (2), 0.10, 0.38, 0.65, 0.85, 0.93, 0.96 and 1.1 mg/kg

Based on the trials with the most critical GAP (France) and highest residue population, the Meeting estimated a maximum residue level of 2 mg/kg and a STMR of 0.085 mg/kg for tebuconazole in barley. The Meeting agrees to expand these estimations to oats

The Meeting confirms its previous recommendation for tebuconazole in barley, and withdraw its previous recommendation of 0.05* mg/kg in oats.

Maize

Tebuconazole is registered in maize Brazil at a maximum of 3 × 0.20 kg ai/ha and a 15 day PHI. In four trials conducted in Brazil according to GAP, residues were: 0.01, 0.02 and < 0.1 (2) mg/kg Three trials conducted at double rate gave similar results.

In USA, the rate is 0.189 kg ai/ha (maximum 0.757 kg ai/ha per season) with a 36 day PHI. In three trials conducted in USA according to GAP, residues were < 0.01 (3) mg/kg. Fourteen trials conducted at higher PHIs gave the same results.

The Meeting decided that four trials according to GAP were insufficient to estimate a maximum residue level for tebuconazole in maize and withdraw its previous recommendation of 0.1 mg/kg.

Rice

Tebuconazole is registered in rice in Brazil at a maximum of 2 × 0.15 kg ai/ha, and a 35 day PHI. Four trials were conducted in Brazil according to GAP, residues found were: 0.01(2), 0.02 and 0.03 mg/kg. Two trials conducted at double rate.

In Spain, GAP is 0.15 kg ai/ha (number of applications not specified) and a 35 day PHI. In eight trials conducted in Italy and Spain according to this GAP, residues in rice (with husk) were 0.11, 0.12, 0.24, 0.26, 0.29, 0.33, 0.53 and 0.97 mg/kg.

Based on trials with the highest residue population (Europe), the Meeting estimated a maximum residue level of 1.5 mg/kg and a STMR of 0.275 mg/kg for tebuconazole in rice.

The Meeting withdraws its previous recommendation of 2 mg/kg for tebuconazole in rice.

Wheat and Rye

The GAP rate for tebuconazole in wheat in Brazil is 0.187 kg ai/ha (number of applications not specified); PHI is 35 days. In eight trials conducted in that country according to GAP, residues were: 0.02 (4), 0.03 and < 0.05 (3) mg/kg

In Canada and the USA, the GAP rate for wheat a single application at 0.126 kg ai/ha, with a PHI of 36 and 30 days, respectively. In 21 trials conducted in Canada and four in USA according to GAP, residues were: < 0.01 (2), 0.01 (4), < 0.02 (8), 0.02 (4), 0.04, < 0.05 (4), 0.06 and 0.08 mg/kg.

In France, the GAP rate for wheat and rye is 2 × 0.25 kg ai/ha, with a PHI of 28 days. In ten trials conducted in France, Greece, Italy and Spain according to this GAP, residues were 0.02 mg/kg in triticale and < 0.01, 0.01 (2) and < 0.05 (4), 0.06 and 0.09 mg/kg in wheat.

In Ireland and the UK, the GAP rate is 2 × 0.25 kg ai/ha and the last application should be done before the watery ripe stage (up to BBCH 71). In 27 trials conducted in Germany, France and the UK according to this GAP residues in wheat were: < 0.01 (3), 0.02 (3), 0.03 (2), < 0.05 (18) and 0.06 mg/kg. Six trials conducted in Germany and Sweden in rye gave residues of < 0.01, < 0.05 (5) mg/kg.

In Portugal, GAP for wheat is 2 × 0.25 kg ai/ha, with a PHI of 35 days. One trial conducted in Italy according to this GAP gave residues of 0.02 mg/kg.

Based on the trials with the most critical GAP (France) and highest residue population, the Meeting estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in wheat. The Meeting also agreed to expand these estimations to rye and triticale.

The Meeting withdraws its previous recommendation of 0.05 mg/kg for tebuconazole in wheat.

The Meeting withdraws its previous recommendation of 0.05* mg/kg for tebuconazole in rye.

Tree nuts

In Italy, tebuconazole is registered for use on walnuts and other tree nuts (not specified) at 2 × 0.226 kg ai/ha, applied until the end of flowering. Four trials were conducted in that country in walnut according to GAP, with residues of < 0.05 (4) mg/kg

In the USA, the GAP for tree nuts is up to 4 × 0.252 kg ai/ha and a 35 day PHI. In six trials conducted in almonds, according to GAP, residues were < 0.05 (6) mg/kg. In four trials conducted in pecans at the GAP rate, samples collected 12 to 25 days after the last application gave residues of < 0.05 mg/kg.

Based on the trials with the most critical GAP (USA), the Meeting estimated a maximum residue level of 0.05* mg/kg, an HR of 0 mg/kg and a STMR of 0 mg/kg for tebuconazole in tree nuts.

Cotton seed

The GAP rate for tebuconazole in cotton in Brazil is 0.15 kg ai/ha (normally, 3 applications is enough) and 21 days PHI. Seven trials were conducted in the country with 4 or 5 applications of the GAP rate, giving residues at 21 days PHI of 0.01, 0.02 (2), 0.03 and < 0.1 (3) mg/kg.

In the USA, maximum GAP rate is 0.252 kg ai/ha (maximum of 0.756 kg ai/ha/season) and a 30 day PHI. In 17 trials conducted in that country according to GAP, residues in fuzzy (undelinted) seeds were: < 0.05 (8), 0.05, 0.10 (2), 0.12, 0.22, 0.42, 0.43, 0.69 and 1.6 mg/kg.

Based on the trials with the most critical GAP (USA) and highest residue population, the Meeting estimated a maximum residue level of 2 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in cotton seed.

Peanut

In Brazil, the critical GAP for tebuconazole in peanuts is 0.125 kg ai/ha (number of applications not specified) with a 30 day PHI. In seven trials conducted according to GAP, residues were 0.01, 0.02 (2), 0.03, < 0.05 (2) and < 0.1 mg/kg. Five trials conducted at a higher rate gave residues in the same range.

In the USA, the critical GAP rate is 4 × 0.23 kg ai/ha, and a PHI of 14 days. The Meeting agreed that residues from the first 3 applications are unlikely to affect the final residues at the PHI. In 12 trials conducted with 7 applications, residues at 14 days PHI were: < 0.01 (3), 0.01, < 0.02, 0.03, 0.04, < 0.05 (4) and 0.08 mg/kg

Based on the data from the most critical GAP (USA) with the highest detected residue, the Meeting estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.035 mg/kg for tebuconazole in peanut kernels.

The Meeting withdraws its previous recommendation of 0.1 mg/kg for tebuconazole in peanuts.

Rape seed

In Germany, tebuconazole is registered to be applied up to 2 × 0.375 kg ai/ha with a PHI of 56 days. In twelve trials conducted in Belgium, France, Germany, the Netherlands and the UK matching this GAP, residues were: < 0.05 (2), 0.03, 0.04, 0.06, 0.09, 0.11, 0.12 (2), 0.13, 0.17, 0.19 mg/kg.

Nineteen trials conducted in Europe did not match any GAP in the region.

The Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR of 0.10 mg/kg for tebuconazole in rape seed.

The Meeting withdraws its previous recommendation of 0.5 mg/kg for tebuconazole in rape seed.

Coffee beans

The critical GAP for tebuconazole in coffee in Brazil is for 3 × 0.25 kg ai/ha, with a 30 days PHI. The Meeting agreed that residues from the first two applications are unlike to affect the final residues at the GAP PHI, as the second application was done more than 100 days before harvest. In nine trials conducted in the country in which 3 or 5 applications were made at the GAP rate, residues were: < 0.01 (2), 0.02 (2), 0.06 and < 0.10 (4) mg/kg. Six trials conducted at double GAP rate gave residues in a same range.

Four trials were conducted in Guatemala (no GAP).

The Meeting estimated a maximum residue level of 0.1 mg/kg and a STMR of 0.04 mg/kg for tebuconazole in coffee beans.

The Meeting confirms its previous recommendation of 0.1 mg/kg for tebuconazole in coffee beans.

Hops, dry

In the Czech Republic, tebuconazole can be applied to hops at up to 2 × 0.56 kg ai/ha with a 21 day PHI. In eight trials conducted in Germany within this GAP, residues in cones, kiln dried were: 5.8, 6.0, 6.3, 8.3, 11, 12, 18 and 21 mg/kg.

In the USA, the GAP rate is 0.252 kg ai/ha (maximum of 1 kg ai/ha/season) and a 14 day PHI. In three trials conducted in the country according to GAP, residues were: 0.73, 1.1 and 3.2 mg/kg.

Based on the trials with the most critical GAP (the Czech Republic) and highest residue population, the Meeting estimated a maximum residue level of 40 mg/kg and a STMR of 9.65 mg/kg for tebuconazole in hops, dry

The Meeting withdraw its previous recommendation of 30 mg/kg for tebuconazole in hops.

Animal feed commodities

Feed commodities were analysed in the studies described previously for the edible commodities. Only the trials conducted according to GAP as described before were discussed here. Maximum residue levels were not estimated for forage. Highest and/or medium residues were estimated for commodities listed in the OECD feeding table for dietary burden calculation purposes.

Barley, wheat, rye and triticale straw and/or fodder

In 16 trials conducted in barley in Germany and the UK according to German GAP (2 × 0.31 kg ai/ha 35 days PHI), residues in barley straw were: 0.14, 0.45 0.50, 0.72, 0.77, 0.86, 0.88, 1.3, 1.7 (2), 2.2, 2.5, 2.8, 3.1, 3.9 and 4.3 mg/kg.

In ten trials conducted in France, Germany, Greece, Italy, Portugal and Spain according to French GAP (2 × 0.25 kg ai/ha, 42 days PHI), residues in barley straw were: 0.29, 0.80, 1.4, 3.3, 3.8, 4.9, 5.8, 7.9, 13 and 17 mg/kg

Residues of tebuconazole in wheat straw from 25 trials conducted in Canada and USA according to GAP were: < 0.10 (3), 0.11, 0.12, 0.13, 0.14, 0.20, 0.26, 0.30, 0.34, 0.35, 0.36, 0.50, 0.52, 0.58, 0.64, 0.68, 0.87, 0.94, 1.0, 1.1, 1.4 (2) and 2.1 mg/kg.

Residues of tebuconazole in wheat and rye straw from 27 trials conducted in France, Germany, Sweden and the UK according to the GAP of the UK (2 × 0.25 kg ai/ha and the last

application up to BBCH 71) were: 0.29, 0.47, 0.68, 0.86, 0.92, 0.98, 1.1, 1.3 (3), 1.4, 1.5, 1.6, 1.8, 1.9, 2.7, 3.0, 3.3, 3.6 (2), 3.9, 4.8, 5.2, 6.0, 7.1 (2), and 7.8 mg/kg.

In 12 trials conducted in Spain, Italy and France according to French GAP (2 × 0.25 kg ai/ha, 28 day PHI) residues in wheat and rye straw were: 1.1, 1.8, 2.2, 2.3 (2), 3.2, 3.4, 3.5 (2), 4.2, 5.6 and 12 mg/kg.

Residues in 25 trials conducted in Canada and the U.S. according to GAP gave residues in wheat hay of: 0.49, 0.67, 0.71, 0.78, 0.93, 0.99, 1.0 (2), 1.1 (3), 1.4, 1.6 (3), 1.8, 2.1, 2.2 (3), 2.5 (2), 2.6, 3.5 and 4.4 mg/kg.

Based on the trials with the highest residue population (barley according to French GAP), the Meeting estimated a maximum residue level of 40 mg/kg for barley straw and fodder, dry; rye straw and fodder, dry; and wheat straw and fodder, dry (residues corrected for 88% dry matter).

The Meeting estimated a median and a highest residue of 4.35 and 17 mg/kg, respectively, for tebuconazole in barley straw and fodder.

The Meeting estimated a median and highest residues, of 3.3 and 12 mg/kg, respectively for tebuconazole in wheat and rye straw and fodder.

The Meeting estimated a median and a highest residue of 1.6 and 4.4 mg/kg, respectively, for tebuconazole in wheat hay.

The Meeting withdraws its previous recommendation of 30 mg/kg for barley straw and fodder, of 10 mg/kg for wheat straw and fodder, dry and of 5 mg/kg for rye straw and fodder, dry.

Maize fodder

The residues in maize fodder from five trials conducted in USA according to GAP were: 0.20, 0.28, 0.61, 0.83, and 2.4 mg/kg.

The Meeting estimated a median and a highest residue of 0.61 and 2.4 mg/kg, respectively, for tebuconazole in maize fodder.

The Meeting also estimated a maximum residue level of 6 mg/kg for tebuconazole in maize fodder, dry (residues corrected for 83% dry matter).

Rice straw

Four rice trials conducted in Spain and Italy according to Spanish GAP, residues found in straw 33 or 35 days after the last application (grain PHI) were: 1.1 (2), 1.6, and 1.7 mg/kg.

The Meeting agreed that there were insufficient trials according to GAP to estimate a maximum residue level for tebuconazole in rice straw.

Peanut fodder/hay/vine

In 16 trials conducted in USA considered to be at GAP, residues in hay/vine were: 1.8, 3.7, 5.0, 5.1, 5.6, 6.8, 8.6, 9.1, 9.4, 11, 13, 15, 17, 18, 20 and 23 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg, a median residue of 9.25 mg/kg and a highest residue of 23 mg/kg for tebuconazole in peanut fodder. The Meeting withdraws its previous recommendation of 30 mg/kg.

Forage

In the trials, the forage samples (described as forage, green material or rest of the plant) were harvested at different PHIs. Whenever data was available, the 7 days PHI residue (or any day later that gave a higher residue) was chosen to represent the level of residues to which animals would be

exposed. In cases where this data point was not available, the highest value from any PHI available (up to the grain PHI) would be taken, including from 0 day PHI.

Barley forage

The residues in barley forage from 37 trials conducted according to GAP rate in Europe were: 0.29, 0.35, 0.37, 0.78, 1.0, 1.2 (2), 1.4 (2), 2.0, 3.4, 3.8, 4.3 (2), 4.7, 5.2, 5.6, 5.7, 5.8, 6.0, 6.1, 6.2, 6.5, 7.2, 7.4, 8.9, 9.0, 9.2 (2), 9.6, 10 (2), 12, 14 (2) and 18 mg/kg.

The Meeting estimates a median and highest residue of 5.8 and 18 mg/kg, respectively, for tebuconazole in barley forage.

Maize forage

The residues in maize forage from 20 trials conducted according to GAP rate in USA were: 0.09, 0.10, 0.12, 0.13, 0.19, 0.22, 0.25, 0.28, 0.30, 0.37, 0.44, 0.47 (2), 0.49 (2), 0.75 (2), 0.98 and 2.9 (2) mg/kg

The Meeting estimated a median and highest residue of 0.405 and 2.9 mg/kg, respectively, for tebuconazole in maize forage.

Wheat, rye and triticale forage

Residues of tebuconazole in wheat, rye and triticale forage from 43 trials conducted in Europe according to GAP were: 0.40, 0.49, 0.92, 1.3, 1.5, 2.2 (2), 2.3, 2.4, 2.6 (3), 2.7, 2.9, 3.3, 3.4, 3.5, 3.7 (2), 3.9, 4.1, 4.3, 4.6, 4.7, 4.8, 5.1, 5.2, 5.7 (2), 5.8 (2), 5.9, 6.1, 6.2, 6.4, 6.6 (3), 6.7, 6.8, 7.8, 8.7, 9.4, 9.5 and 12 mg/kg.

Residues in 25 trials conducted in Canada and USA according to GAP in wheat forage were: 0.01, 0.02 (3), 0.07 (2), 0.10, 0.11, 0.18 (2), 0.19, 0.20 (2), 0.22, 0.28, 0.32, 0.34, 0.47, 0.53 (2), 0.61, 0.62, 0.65, 1.0 and 1.8 mg/kg

Based on the highest residue population (Europe), the Meeting estimated a median and a highest residue of 4.6 and 12 mg/kg, respectively, for tebuconazole in wheat, rye and triticale forage.

Rape forage

From 25 trials conducted in rape in Europe according to GAP residues in forage were: 2.5 (2), 2.6, 2.7, 3.1, 3.4, 3.6, 3.7, 3.8, 3.9, 4.0, 4.2 (2), 4.3, 4.6, 4.8, 4.9, 5.1, 5.2, 5.6, 5.7, 6.3, 7.3, 7.5 and 11 mg/kg.

The Meeting estimated a median and a highest residue of 4.2 and 11 mg/kg, respectively for tebuconazole in rape forage

Almond hulls

Six trials conducted in USA according to GAP gave residues in almond hulls of 1.1, 1.2, 1.4, 2.0, 3.0 and 4.1 mg/kg. The Meeting estimated a median residue of 1.7 mg/kg for tebuconazole in almond hulls.

Cotton gin trash

Six trials conducted in USA according to GAP gave residues in cotton gin trash of 0.10, 1.5, 4.1, 7.1, 12 and 13 mg/kg. The Meeting estimated a median and a highest residue of 5.6 and 13 mg/kg, respectively, for tebuconazole in cotton gin trash.

Fate of residues during processing

A hydrolysis study conducted in buffered water (pH 4 to 6, 90 to 120 °C) simulating processing did not show degradation of tebuconazole.

A variety of processing studies were conducted with crops treated with tebuconazole. Processing factors (PF) in commodities with relevance for dietary exposure assessment and for animal dietary burden calculation are shown in the table below. The estimated PFs were multiplied by the estimated STMR of the raw commodity to estimate the STMR-P for the processed commodity.

Processing factor (PF) and estimations for processed commodities.

Commodity	Mean PF (n)*	STMR-P, mg/kg	HR-P, mg/kg	Maximum residue level, mg/kg
Apple, STMR= 0.275 mg/kg, HR=0.5 mg/kg				
Apple juice	0.23 (4)	0.063		
Apple juice, concentrated	0.33 (2)	0.091		
Apple sauce	0.34 (3)	0.094		
Apple, dried	0.61 (3)	0.168	0.305	
Apple wet pomace	2.6 (2)	0.715		
Apple dried pomace	12.7 (2)	3.5		
Plum, STMR=0.08 mg/kg, HR= 0.47 mg/kg				
Prune	2.9 (2)	0.232	1.36	3
Plum sauce	1 (1)	0.08		
Plum preserve	0.67 (1)	0.054		
Peach, STMR=0.46 mg/kg				
Peach juice	0.2 (1)	0.092		
Peach jam	0.013 (1)	0.006		
Peach preserve	0.013 (1)	0.006		
Grape, STMR=0.72mg/kg; HR= 4.6 mg/kg				
Wine	0.28 (22)	0.20		
Dried grapes	1.2 (4)	0.86	5.5	7
Cabbage, head STMR=0.05 mg/kg, HR=0.56 mg/kg				
Cabbage, cooked	0.38 (4)	0.019	0.23	
Tomato, STMR=0.15 mg/kg				
Tomato juice	0.55 (3)	0.033		
Tomato preserve	0.3 (3)	0.018		
Tomato pure	0.33 (6)	0.02		
Tomato paste	3.2 (6)	0.19		
Soya beans, STMR=0.02 mg/kg				
Soya bean oil, refined	0.07 (1)	0.001		
Soya bean aspired grain fractions	276 (1)	5.52		
Soya bean, hulls	1.1 (1)	0.022		
Soya bean meal	0.2 (1)	0.004		
Barley, STMR=0.085 mg/kg				
Barley beer	0.025 (4)	0.013		
Cotton, STMR=0.05 mg/kg				
Cotton oil, refined	0.01 (1)	0.000		
Cotton meal	0.01 (1)	0.000		
Cotton hulls	0.01 (1)	0.000		
Peanut, STMR=0.035 mg/kg				
Peanut oil, refined	0.01 (1)	0.000		
Peanut meal	0.86 (1)	0.026		

Commodity	Mean PF (n)*	STMR-P, mg/kg	HR-P, mg/kg	Maximum residue level, mg/kg
Rape seed, STMR=0.10 mg/kg				
Rape seed oil, refined	1.1 (6)	0.11		
Rape seed meal	0.83 (6)	0.08		
Coffee, STMR= 0.04 mg/kg				
Coffee, roasted	2 (1)	0.08		
Coffee, instant	0.8 (1)	0.032		
Hops, STMR=9.65 mg/kg				
Hops, beer	< 0.01 (1)	0.0965		

*n is the number of processing studies

The Meeting agreed that one processing study is not sufficient to make a recommendation for coffee, roasted and withdraws its previous recommendation of 0.5 mg/kg for coffee, roasted

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of tebuconazole in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops), the STMR, STMR-Ps, median or highest residue levels estimated at the present Meeting. Dietary burden calculations are provided in Annex 6.

		Animal dietary burden, tebuconazole, ppm of dry matter diet			
		US-Canada	EU	Australia	Japan
Beef cattle	max	2.9	26	54[a]	0.1
	mean	1.0	8.3	18.9[c]	0.1
Dairy cattle	max	19.6	24.2	54[b]	4.0
	mean	7.4	8.1	18.9[d]	0.69
Poultry - broiler	max	0.14	0.1	0.19	0.01
	mean	0.14	0.1	0.19	0.01
Poultry - layer	max	0.14	8.5[e]	0.19	0.00
	mean	0.14	3.3[f]	0.19	0.00

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

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

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry tissues and eggs.

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

The tebuconazole dietary burdens for animal commodity maximum residue level and STMR estimation (residue levels in animal feeds expressed on dry weight) reached a maximum of 54 ppm for cattle and of 8.5 ppm for poultry.

Animal feeding studies

Two dairy cattle feeding studies were submitted. The animals were fed for 28 days at 25/75/250 ppm (study 1) or 30/90/300 ppm (study 2), with 3 cows per group in each dose level. In both studies, meat and fat samples were only analysed for tebuconazole at the higher dose group (250 or 300 ppm feed), but no residues were detected (< 0.05 or < 0.1 mg/kg). Mean residues of tebuconazole at 25 and

30 ppm were 0.15 and < 0.1 mg/kg, respectively, in kidney (maximum of 0.25 and < 0.1 mg/kg) and 0.06 and < 0.1mg/kg, respectively, in liver (maximum of 0.07 and < 0.1 mg/kg). Mean residues at 75 and 90 ppm were 0.05 and < 0.1 mg/kg, respectively, in kidney (maximum of 0.05 and < 0.1 mg/kg) and 0.08 and 0.17 mg/kg, respectively, in liver (maximum of 0.12 and 0.2 mg/kg). Two poultry studies were submitted, with laying hens fed at 2, 6 and 20 ppm tebuconazole for 28 days. Residues of tebuconazole were only found in liver and eggs at the highest dose in both studies (at 0.05 mg/kg).

Animal commodity maximum residue levels

The cattle feeding studies have shown that no residues of tebuconazole are expected in muscle and milk at the maximum estimated animal dietary burden (54 ppm). At 250/300 ppm, residues were < LOQ in muscle and milk.

The Meeting estimated a maximum residue level of 0.05* mg/kg, a STMR of 0 mg/kg and a HR of 0 mg/kg for tebuconazole in meat (from mammalian other than marine mammals).

The Meeting estimated a maximum residue level of 0.01* mg/kg and a STMR of 0 mg/kg for tebuconazole in milks.

The Meeting confirms its previous recommendation of 0.05* and 0.01* for tebuconazole in meat (from mammalian other than marine mammals) and milks, respectively.

Residues in kidney and liver at the expected dietary burden are shown in the Table below. Based on the highest estimated residue in cattle liver (0.15 mg/kg), the Meeting estimates a maximum residue level of 0.2 mg/kg, a HR of 0.15 mg/kg and a STMR of 0.06 mg/kg for tebuconazole in edible offal (mammalian).

The Meeting withdraw its previous recommendation of maximum residues level of 0.5 mg/kg for tebuconazole in edible offal (mammalian).

	Feeding level (ppm) for tissue residue	Residues (mg/kg)			Feeding level (ppm) for tissue residue	Residues (mg/kg)	
		Liver	Kidney			Liver	Kidney
Maximum residue level beef or dairy cattle							
Feeding study [a]	25/75	0.10/0.12	0.25*/0.05	Feeding study [a]	30/90	< 0.1/0.2	< 0.1/< 0.1
Dietary burden and residue estimate	54	0.11	-/0.036	Dietary burden and residue estimate	54	0.15	0.05
STMR beef and dairy cattle							
Feeding study [b]	25	0.06	0.15	Feeding study [b]	30	< 0.1	< 0.1
Dietary burden and residue estimate	18.9	0.04	0.11	Dietary burden and residue estimate	18.9	0.06	

[a] highest residues for tissues;

[b] mean residues for tissue; * this value was not considered as the other 2 animals had residues < 0.05 mg/kg and the levels at 75ppm were at or <LOQ.

Poultry feeding studies have shown that no residues are expected at the dietary burden of 8.5 ppm. With exception of liver, no residues were also found at 20 ppm level.

The Meeting estimated a maximum residue level of 0.05* mg/kg, a STMR of 0 mg/kg and a HR of 0 mg/kg for tebuconazole in poultry meat

The Meeting estimated a maximum residue level of 0.05* mg/kg, a STMR of 0.05 mg/kg and a HR of 0.05 mg/kg for tebuconazole in poultry edible offal.

The Meeting estimated a maximum residue level of 0.05* mg/kg and a STMR of 0 mg/kg for tebuconazole in eggs.

The Meeting confirms its previous recommendations of 0.05* mg/kg for tebuconazole in eggs, poultry edible offal and poultry meat.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for tebuconazole is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDI) for tebuconazole was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting. The results are shown in Annex 3. The IEDI ranged from 3 to 10% of the maximum ADI. The Meeting concluded that the long-term intake of residues of tebuconazole from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for tebuconazole is 0.3 mg/kg bw. The International Estimated Short Term Intake (IESTI) for tebuconazole was calculated for the plant commodities for which STMRs/STMR-P and HRs/HR-P were estimated by the current Meeting and for which consumption data were available. The results are shown in Annex 4. The maximum% ARfD was 70%, from the consumption of grapes by children 0–6 years old. The Meeting concluded that the short-term intake of residues of tebuconazole, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.