5.23 TEBUCONAZOLE (189)

RESIDUE AND ANALYTICAL ASPECTS

Tebuconazole was evaluated in 1994 for residues and toxicology, when an ADI of 0–0.03 mg/kg body weight was established, and was re-evaluated in 1997 for residues. The present Meeting received data on analytical methods, Good Agriculture Practice (GAP) and supervised residue trial data for oranges, pome fruit, plum, elderberry, mango, papaya, leek, onion, garlic, head cabbage, Brussels sprouts, broccoli, melon, watermelon, tomato, lettuce, bean, soya, carrot, artichoke, celery, barley, rice, maize, oilseed rape, coffee, and hops. Processing studies were also provided.

The definition of the residue for compliance with MRLs and for estimations of dietary intake is tebuconazole.

Methods of analysis

In addition to the analytical methods submitted to previous meetings, new methods for analysis of tebuconazole in plant materials were reported. After extraction with organic solvents and clean-up on Florisil, C-18 or silica columns, and/or gel permeation chromatography, tebuconazole was determined by gas chromatography with a NPD, ECD or MS detectors or LC-MS/MS. In some LC methods, no clean-up step was required. In general, the LOQ ranged from 0.01 to 0.05 mg/kg.

Results of supervised residue trials on crops

Residue trial data provided to this and previous Meetings have shown that residues of tebuconazole in most treated crops decrease rapidly after the day of application, after what the levels seems to plateau. Therefore, the Meeting agreed that whenever possible, similar residue population coming from different PHI will be combined for the final estimation. In some cases, residues coming from different GAP rate also gave the same residue population and the data was combined.

Orange

Data was available from fourteen trials on oranges, of which 10 trials were from Brazil (critical GAP is 2×0.018 kg ai/hL, 20 days PHI) and four from South Africa (GAP is 2×0.02 kg ai/hL, 175 days PHI).

Two Brazilian trials conducted with 3 applications at 0.015 kg ai/hL, gave residues of 1.3 (2) mg/kg. Trials conducted at shorter PHI or a higher rate gave residues ranging from < 0.1 to 2.2 mg/kg.

In two trials conducted in South Africa, complying with that countries GAP, resulted in residues of < 0.01 and 0.02 mg/kg in the fruit and < 0.01 (2) in the pulp. Two trials conducted at double rate gave residues within the same range.

The Meeting agreed that there was insufficient data available, conducted according to GAP, to estimate a maximum residue level for tebuconazole in oranges.

Pome fruits

Ten supervised residue trials with tebuconazole in apples and pears from Southern Europe were submitted. In Italy tebuconazole is approved for use on apples with a maximum of four foliar sprays at 0.225 kg ai/ha (0.0125 kg ai/hL), with a PHI of 30 days. For pears, maximum GAP is 0.30 kg ai/ha and a 15 day PHI. GAP in Spain for apples and pears is 0.15 kg ai/ha (0.01 kg ai/hL) with a 14 day PHI. In Brazil maximum GAP for apples is 0.0125 kg ai/hL with 20 day PHI.

In four trials conducted in apples in France, Greece and Italy complying with the Italian GAP, residues within the 30 day PHI were 0.13, 0.19, 0.34 and 0.47 mg/kg. In four trials conducted in pears in Italy and Portugal according to Italian GAP, residues within a 15 day PHI were: < 0.05, 0.07, 0.28 and 0.38 mg/kg. Two other Italian trials were conducted at lower rate and PHI.

Two trials conducted on apples in Brazil (GAP of 0.0125 kg ai/hL, 20 days PHI) submitted to the 1997 JMPR gave residues of < 0.1 and 0.20 mg/kg; also submitted were two trials from Italy and Spain, conducted according to GAP, giving residues of 0.12, 0.13 and 0.24 mg/kg.

The Meeting agreed that residues from the 13 trials, conducted according to GAP, in apples and pears in Brazil and Europe submitted to both Meetings gave residues in the same range and could be combined for the purpose of estimating a STMR, HR and maximum residue levels, and with which to base a recommendation for pome fruit. Residues in rank order, median underlined, were: < 0.05, 0.07, < 0.1, 0.12, 0.13 (2), <u>0.19</u>, 0.20, 0.24, 0.28, 0.34, 0.38 and 0.47 mg/kg

The Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.47 mg/kg and an STMR of 0.19 mg/kg for tebuconazole in pome fruit.

The Meeting also agreed to withdraw its previous recommendation of 0.5 mg/kg for tebuconazole in pome fruit.

Plums

GAP for plums in France is 3×0.015 kg ai/hL with a PHI of 7 days. A total of 16 trials were conducted with tebuconazole on plums in Europe from 1992 to 2005 matching the French GAP. Residues found in whole fruit, 7 days after the final application in rank order, median underlined, were: 0.03 (2), < 0.05 (4), 0.05, 0.06, 0.07 (2), 0.08 (2), 0.10 (2), 0.12 (2) mg/kg.

Six trials conducted in France and Italy, also matching the French GAP, and previously submitted to the 1997 JMPR gave residues in whole fruit of < 0.02, 0.03 (3), 0.09 and 0.11 mg/kg.

The Meeting decided to combine all the data to increase the dataset for the purposes of estimating a maximum residue level, STMR and HR and to make a recommendation for plums. Residues from the 22 trials in rank order, median underlined, were: < 0.02, 0.03 (5), < 0.05 (4), <u>0.05, 0.06</u>, 0.07 (2), 0.08 (2), 0.09, 0.10 (2), 0.11, 0.12 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an HR of 0.12 mg/kg and an STMR of 0.055 mg/kg for tebuconazole in plums.

Elderberries

Six trials were conducted in Austria according to GAP (3× 0.038 kg ai/hL. Residues within the 24 day PHI in rank order, median underlined were: 0.26, <u>0.30, 0.39</u> and 0.70 mg/kg. In two trials, samples where harvested 14 days after the last application.

The Meeting estimated a maximum residue level of 2 mg/kg, an HR of 0.73 mg/kg and an STMR of 0.345 mg/kg for tebuconazole in elderberries.

Mango

Data was available from 18 trials on mangoes in Brazil, where the GAP is 3 × 0.02 kg ai/hL with a 20 day PHI. In eight trials conducted according to GAP residues in rank order, median underlined, were: < 0.05 (3), <u>0.02</u> (2) and < 0.1 (3) mg/kg. The trials conducted at double rate gave residues at 20 days PHI from < 0.05 to 0.09 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.1 mg/kg and an STMR of 0.02 mg/kg for tebuconazole in mango.

Papaya

Tebuconazole is registered in Brazil (GAP of 6× 0.2 kg ai/ha, 7 day PHI) and Australia (GAP of 6× 0.125 kg/ha, 3 day PHI). In six trials conducted in Brazil according to GAP, residues in rank order, median underlined, were: 0.06, 0.15, 0.17, 0.19, 0.32 and 1.2 mg/kg. Residues in six trials conducted at double rate ranged from 0.18 to 2.4 mg/kg at a PHI of 7 days.

One trial conducted in Australia at GAP gave residues of 0.07 mg/kg; one trial at double rate gave a residue of < 0.01 mg/kg.

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

Leek

Tebuconazole is registered in Europe at 3× 0.25 or 0.30 kg ai/ha (the Netherlands) with a 14 day PHI. In 12 field trials conducted in Belgium, France and Germany in 1995/1996, complying with the Dutch GAP, residues in rank order, median underlined, 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 1 mg/kg, an HR of 0.44 mg/kg and an STMR of 0.195 mg/kg for tebuconazole in leek.

Garlic

Two trials conducted in Brazil according to GAP (4× 0.20 kg ai/ha, 14 day PHI) gave residues in the garlic bulb of 0.02 (2) mg/kg; two other trials conducted at double rate gave residues of 0.03 and 0.04 mg/kg.

Two trials conducted in France according to GAP (2× 0.25 kg ai/ha, 21 day PHI) gave residues of 0.03 and 0.06 mg/kg. Three trials conducted in 1995/1995 in Europe at the same rate and submitted to the 1997 JMPR had residues of < 0.02 (2) and 0.02 mg/kg

Residues from the seven trials according to GAP submitted to both Meetings were: < 0.02 (4), 0.02, 0.03 and 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.06 mg/kg and an STMR of 0.02 mg/kg for tebuconazole in garlic.

Onions

Six trials conducted in Brazil from 1993 to 2004 within the GAP rate (0.20 or 0.25 kg ai/ha) gave residues at 14 days PHI of < 0.02 (3), 0.02, 0.03 and 0.06 mg/kg. In six other trials, conducted at higher or lower rates, residues found were in the range of < 0.02 to 0.10 mg/kg.

Tebuconazole is registered in Germany and in the United Kingdom at 2× 0.25 kg ai/ha with a 21 day PHI. Seven trials were conducted in France (no GAP provided), Germany and the UK according to GAP. In five trials, residues in the bulb were < 0.05 (5) mg/kg. In two trials the whole plant or the washed bulb was analysed (which had been incorrectly described by 1997 Meeting).

The 11 trials conducted in Brazil and Europe complying with GAP gave residues of: < 0.02 (3) 0.02, 0.03, < 0.05 (5) and 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.06 mg/kg and an STMR of 0.05 mg/kg for tebuconazole in onion.

Brassica (cole or cabbage) vegetables

Critical GAP for tebuconazole in head cabbage in Europe is 3× 0.250 kg ai/ha, 21 day PHI (Austria, Germany and the Netherlands). In the UK, a maximum of 0.56 kg ai/ha per season is recommended. From ten trials conducted in France, Germany and UK matching European critical GAP residues in rank order, median underlined, were: < 0.05 (6), 0.32 (2), 0.37 and 0.56 mg/kg. In three other trials conducted at higher rates gave residues within the same range.

Reported GAP for tebuconazole in Brussels sprouts is 3 applications of 0.25 kg ai/ha in Germany and 0.30 kg ai/ha in the Netherlands with a, PHI of 21 days. Nine trials were conducted in France, Germany, the Netherlands and the UK from 1990 to 2000. In eight trials matching the German GAP, residues were < 0.05 (2), 0.05, 0.07, 0.11, 0.12, 0.15 and 0.19 mg/kg. In one trial matching the Netherlands GAP, residues were 0.49 mg/kg.

GAP for tebuconazole for flower head brassicas in Germany is 2× 0.25 kg ai/ha with a 21 day PHI. In Spain, GAP in broccoli consists of up to 2 applications at 0.025 kg ai/hL with a 14 day PHI. Two trials conducted in broccoli in Germany in 2003 according to GAP gave residues of < 0.02 (2) mg/kg. Four trials conducted in Italy and Spain in 2001/2002 matching Spanish GAP gave residues of < 0.05, 0.06, 0.08 and 0.15 mg/kg.

The Meeting agreed that the residue populations found in the trials in head cabbage and Brussels sprouts, conducted according to GAP, belonged to the same population and could be combined. Residues of tebuconazole in rank order, median underlined, were: (n = 19) < 0.05 (8), 0.05, 0.07, 0.11, 0.12, 0.15, 0.19, 0.32(2), 0.37, 0.49 and 0.56 mg/kg. Based on this data set, the Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.56 mg/kg and an STMR of 0.05 mg/kg for tebuconazole in brassica (cole or cabbage) vegetables.

Melons

The recommended PHI for tebuconazole in melons in Brazil is 14 days with the application rate varying according to the formulation (4× 0.15 kg ai/ha, 3× 0.20 kg ai/ha or 0.25 kg ai/ha). In seven trials conducted in Brazil using 3 to 5 applications at 0.20 to 0.30 kg ai/ha residues in the fruit 14 days after the last application were: < 0.01, < 0.05 (4), 0.03 and < 0.1 mg/kg. Three trials using 5× 0.15 kg ai/ha gave residues of < 0.05 (2) and 0.1 mg/kg. Four trials conducted at higher rates or a shorter PHI gave residues within the same range. The Meeting agreed that trials conducted in Brazil according to GAP could be combined resulting in residues of tebuconazole of: < 0.01, < 0.05 (6), 0.03, < 0.1 and 0.1 mg/kg

In Italy, tebuconazole can be applied up to 4 times at 0.125 kg ai/ha (0.0125 kg ai/hL), with a PHI of 7 days. Twenty trials conducted from 1991 to 2005 in France, Italy, Greece and Spain were submitted. In ten trials conducted according to Italian GAP residues at a PHI of 7 days in the fruit were: 0.02, 0.03 (3), 0.04, 0.05 (2), 0.06, 0.07 and 0.09 mg/kg. In three trials residues found in the pulp were: < 0.02 (3) mg/kg. In 10 trials conducted at higher rates or a shorter PHI, residues in fruit and pulp were in the same range.

The 20 trials conducted in Brazil and Europe according to GAP gave residues in the fruit of < 0.01, 0.02, 0.03 (4); 0.04, < 0.05 (6), 0.05 (2), 0.06, 0.07, 0.09, < 0.1 and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an HR of 0.02 mg/kg (in the pulp) and an STMR of 0.02 mg/kg (in the pulp) for tebuconazole in melon, except watermelon.

Watermelon

The recommended rate for tebuconazole in watermelon in Brazil is 4× 0.20 kg ai/ha with 14 day PHI. In two trials conducted according to GAP in 2004 residues in fruit were < 0.01 and 0.01mg/kg. Two additional trials conducted at double rate gave residues up to 0.02 mg/kg.

In Italy, tebuconazole can be applied up to 4 times at 0.125 kg ai/ha (0.0125 kg ai/hL), with a PHI of 7 days. In three trials conducted in Italy from 1992 to 1993 according to GAP, residues in fruit were < 0.02, 0.03 and 0.04 mg/kg. Residues in pulp were < 0.02 (3) mg/kg. In one trial conducted at a lower rate the residue found was 0.05 mg/kg.

The Meeting agreed residues from the five trials conducted in Brazil and Italy that complied with GAP could be combined giving residues of: < 0.01, 0.01, < 0.02, 0.03 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.02 mg/kg (in the pulp) and an STMR of 0.02 mg/kg (in the pulp) for tebuconazole in watermelon.

Sweet corn

Seven trials were conducted in Brazil, where the GAP for sweet corn is 3× 0.20 kg ai/ha with a 15 day PHI. In four trials conducted according to GAP, residues found were: < 0.1 mg/kg (4). Four trials at double rate gave the same results.

The Meeting agreed that the trials conducted at higher GAP supports a conclusion that it is unlikely that residues in the sweet corn, from trials conducted at GAP, will exceed 0.1 mg/kg. Hence, the Meeting estimates a maximum residue level, an HR and an STMR of 0.1 mg/kg for tebuconazole in sweet corn (corn-on-the-cob).

Tomato

In Brazil tebuconazole is approved for use on tomatoes with an application rate of 4×0.25 kg ai/ha (0.025 kg ai/hL) and a PHI of 7 days. Five trials were conducted according to this GAP, resulted in residues of tebuconazole of: < 0.05 (2), 0.05, 0.06 and 0.10 mg/kg. Five other trials conducted at a lower rate gave residues in the same range.

In Italy, GAP consists of 4×0.125 kg ai/ha (0.0125 kg ai/hL) and in Spain 0.025 kg ai/hL. In both countries the PHI is 3 days. The previous Spanish GAP, which supported the current Codex MRL, had a PHI of 7 days.

Six trials conducted in Spain complying with Spanish GAP, gave residues of 0.03, 0.09, 0.13, 0.15, 0.23 and 0.28 mg/kg. In six indoor or field trials conducted in Spain and Greece at the same rate but a 7 day PHI gave residues of: 0.10, 0.13, 0.24, 0.33, 0.45 and 0.46 mg/kg.

In Poland, the GAP is 4×0.3 kg ai/ha (0.020 kg ai/hL) with a 7 day PHI. Five indoor trials conducted in Belgium, Germany and the Netherlands at 3×0.4 to 0.5 kg ai/ha (0.025 kg ai/hL) gave residues 7 days after the final application of 0.12 to 0.43 mg/kg. These trials did not match the GAP in northern Europe (Poland).

Three trials conducted according to the current Spanish GAP submitted to the 1994 JMPR gave residues of 0.04, 0.19 and 0.28 mg/kg. Two trials conducted according to GAP in South Africa (5×0.019 kg ai/hL, 7 days PHI) submitted to the 1994 JMPR gave residues of 0.02 and 0.04 mg/kg.

Sixteen trials were conducted in Mexico and USA using 6×0.23 to 0.30 kg ai/ha, giving residues of 7 days after the last application that ranged from 0.05 to 0.97 mg/kg. There is no GAP for tebuconazole in tomato in these countries.

The Meeting agreed that the trials conducted according to GAP in Brazil, South Africa and Spain belonged to different data populations and could not be combined.

The Meeting agreed that the data complying with the Spanish GAP submitted to the 1994 and the present Meeting could be used for estimating a maximum residue level, STMR and HR. The Meeting also agreed that residues from European trials conducted at 7 days PHI did not significantly differ from residues from the 3 day PHI and could be combined. Residue of tebuconazole in tomatoes in rank order, median underlined, were: (n = 15) is 0.03, 0.04, 0.09, 0.10, 0.13 (2), 0.15, 0.19, 0.23, 0.24, 0.28 (2), 0.33, 0.45 and 0.46 mg/kg

The Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.46 mg/kg and an STMR of 0.15 mg/kg for tebuconazole in tomato

The Meeting agreed to withdraw its previous recommendation of a maximum residue level of 0.2 mg/kg for tebuconazole in tomato.

Lettuce, Head

Data was available from eight supervised trials conducted in head lettuce in France, Greece, Italy, Portugal and Spain in 1998–1999 complying with the Spanish GAP (0.025 kg ai/hL with a 7 day PHI), residues within 7 days of the final treatment were: 0.18, 0.23, 0.44, 0.65, 1.3, 1.4, 2.3 and 3.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, an HR of 3.2 mg/kg and an STMR of 0.98 mg/kg for tebuconazole in head lettuce.

Beans

In Spain tebuconazole is registered for use on beans at 3× 0.025 kg ai/hL with a 3 day PHI. Eight indoor trials were conducted in French beans in France, Germany and Spain complying with Spanish GAP, giving residues in beans (with pods) of: 0.12, 0.25, 0.41, 0.43, 0.54, 0.55, 0.58 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an HR of 1.2 mg/kg and an STMR of 0.49 mg/kg for tebuconazole in common bean (pods and/or immature seeds).

Soya bean, dry

In Brazil, GAP for tebuconazole in soya beans is a maximum of 3 applications at 0.15 kg ai/ha with a PHI of 30 days. In eight trials conducted complying with this GAP, residues were: 0.02, 0.03 (3), < 0.05 (3) and < 0.10 mg/kg. In six trials conducted at double rate residues up to 0.10 mg/kg were found.

In the USA, GAP is for 3 applications at 0.126 kg ai/ha and a 21 day PHI. In 20 trials conducted in the USA in 2003 according to the GAP rate, residues within the 21 day PHI were: < 0.01 (3), 0.01 (6), 0.02 (5), 0.03, 0.04 (2), 0.05 and 0.06 (2) mg/kg.

The Meeting agreed to combine the data from Brazil and the USA to increase the database for the purposes of estimating a maximum residue level, STMR and highest residue. Twenty eight trials conducted according to the GAP of Brazil and the USA gave residues of: < 0.01 (3), 0.01 (6), 0.02 (6), 0.03 (4), 0.04 (2), < 0.05 (3), 0.05, 0.06 (2) and < 0.10, mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.02 mg/kg for tebuconazole in soya bean (dry).

Carrot

The GAP for tebuconazole in Brazil for carrots is 4 applications at 0.20 kg ai/ha with a 14 day PHI. In five trials complying with GAP, residues found were: < 0.1 (3), 0.17 and 0.19 mg/kg. Seven additional trials conducted at higher than GAP rates gave residues ranging from < 0.10 to 0.27 mg/kg.

In Europe (Austria, German, Belgium, Ireland and the UK), tebuconazole can be applied up to 3 times at 0.25 kg ai/ha with a PHI of 21 days. In eight trials conducted in France, Germany and the UK complying with the European GAP, residues found were: 0.09, 0.10, 0.11 (2), 0.13, 0.18, 0.19 and 0.22 mg/kg.

The 13 Trials conducted according to GAP in Brazil and Europe residues found in rank order, median underlined, were: 0.07, 0.09, < 0.1 (3), 0.11 (2), 0.13, 0.17, 0.18, 0.19 (2) and 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an HR of 0.22 mg/kg and an STMR of 0.11 mg/kg for tebuconazole in carrot.

Artichoke

Tebuconazole is registered for use on artichoke in Italy (GAP 4 applications at 0.125 kg ai/ha (0.0125 kg ai/hL) and a 7 day PHI). Data was available from six trials performed in Italy and Spain, from, 1991 to 2002, that complied with Italian GAP, residues found were: < 0.05, 0.12 (2), 0.17, 0.29 and 0.32 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an HR of 0.32 mg/kg and an STMR of 0.15 mg/kg for tebuconazole in artichoke.

Celery

The use of tebuconazole in/on (stalk, bleached) celery is registered in France at 3 applications at 0.25 kg ai/ha with a PHI of 21 days. Three trials were conducted in France 2000–2001 that complied with French GAP, giving residues of 0.11, 0.19 and 0.21 mg/kg;

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

Barley

Tebuconazole is registered in a number of European countries, e.g., Germany (GAP 2 applications at 0.31 kg ai/ha with a PHI of 35 days), in Denmark (GAP 0.25 kg ai/ha, PHI 42 days) and France (28 days PHI). Residues from 19 trials conducted in Europe at 0.25–0.38 kg ai/ha and a PHI of 28 to 35 days were: < 0.05 (8), 0.06 (3), 0.08, 0.10, 0.13, 0.21, 0.38, 0.85, 0.93 and 0.96 mg/kg. Eighteen trials conducted at the same rate range but with a harvest interval of from 36 to 50 days resulted in residues of: < 0.05 (9), 0.06, 0.07 (3), 0.08 (2), 0.10, 0.65 and 1.1 mg/kg. The Meeting agreed that the residues from the thirty seven trials conducted in Europe could be combined resulting residues of: < 0.05 (17), 0.06 (4), 0.07 (3), 0.08 (3), 0.10 (2), 0.13, 0.21, 0.38, 0.65, 0.85, 0.93, 0.96 and 1.1 mg/kg. In three trials conducted at double rate, residues were within the same range.

The Meeting estimated a maximum residue level of 2 mg/kg and ad STMR of 0.06 mg/kg for tebuconazole in barley.

The Meeting withdraws its previous recommendation of 0.2 mg/kg for tebuconazole in barely, which had been based on a seed treatment.

Rice

Two trials were conducted with tebuconazole in rice in Brazil according to GAP (2 applications at 0.15 kg ai/ha) with residues at 35 days PHI of 0.01 and 0.02 mg/kg. In two trials conducted at double rate gave residues of 0.03 mg/kg.

In Spain, the compound is registered to be used at 0.25 kg ai/ha with a 35 day PHI. In eight trials conducted in Italy and Spain, complying with Spanish GAP, residues found in rank order, median underlined, were: 0.11, 0.12, 0.24, 0.26, 0.29, 0.33, 0.53 and 0.97 mg/kg.

The Meeting agreed that the trials conducted in Brazil and in Europe belonged to different populations and could not be combined. Hence the estimations were made based on trials conducted according to the more critical GAP of Spain

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.275 mg/kg for tebuconazole in rice.

Maize

Eight trials were conducted in Brazil, where the GAP for maize is 3 applications at 0.20 kg ai/ha with a 15 day PHI. In four trials conducted according to GAP, residues were 0.01, 0.02 and < 0.1 (2) mg/kg. Four trials at the double rate gave similar results.

The Meeting agreed that the trials conducted at higher GAP supported a conclusion that residues in harvested maize from trials conducted at GAP were unlikely would exceed 0.1 mg/kg. The Meeting estimated a maximum residue level and an STMR of 0.1 mg/kg for tebuconazole in maize.

Peanut

The GAP for tebuconazole in the USA in peanuts is 4 applications at 0.23 kg ai/ha with a 14 day PHI. No new trials were submitted to the present Meeting. The current Codex MRL of 0.05 mg/kg was estimated in 1994, based on trials conducted in the USA using 7 applications at GAP rate and in South Africa according to GAP (0.02, 0.04 and < 0.05 (4) mg/kg). Trials conducted at double GAP rate in South Africa (PHI of 42 days) resulted in no detectable residues (< 0.05 mg/kg), which indicated that residues in peanut kernels would be ≤ 0.04 mg/kg.

In 1997, thirteen new trials conducted in USA using 7 applications at the GAP rate were submitted and considered, giving residues of < 0.01 (4), 0.01, 0.03 (3), < 0.05 (4) and 0.08 mg/kg..

The current Meeting considered the residue data from trials according to GAP submitted to both the 1994 and 1997 Meetings, grouped as < 0.01 (4), 0.01, 0.02, <u>0.03</u> (3), 0.04, < 0.05 (8) and 0.08 mg/kg (n = 19). The Meeting agreed that a MRL of 0.05 mg/kg might not cover all the residue situations when trials are conducted according to GAP.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.03 mg/kg for tebuconazole in peanut kernels.

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

Rape seed

In Germany, tebuconazole is registered for 2 applications at 0.375 kg ai/ha with a 56 day PHI. In Denmark, the rate is 2× 0.25 kg ai/ha with no PHI specified, i.e., last application no later than BBCH 69.

In twenty five trials conducted from 2000 to 2007 in Belgium, France, Germany, Netherlands and the UK using 2 applications at 0.20–0.375 kg ai/ha, according to GAP in Germany or Denmark, residues found were: 0.02 (2), 0.03 (2), 0.04 (2), < 0.05 (2), 0.06, 0.07, <u>0.08</u> (2), 0.09, 0.11 (3), 0.12 (4), 0.13, 0.16, 0.17, 0.19 and 0.28 mg/kg. Six trials conducted at a lower rate gave residues of up to 0.15 mg/kg.

One trial conducted in France according to German GAP submitted to the 1994 JMPR gave residues of < 0.05 mg/kg.

Considering the 26 trials submitted to the current Meeting and to the 1994 JMPR, the residues found in rank order, median underlined, were: 0.02 (2), 0.03 (2), 0.04 (2), < 0.05 (3), 0.06, 0.07, <u>0.08</u> (2), 0.09, 0.11 (3), 0.12 (4), 0.13, 0.16, 0.17, 0.19 and 0.28 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a highest residue of 0.28 mg/kg and an STMR of 0.09 mg/kg for tebuconazole in rape seed.

The Meeting agreed to withdraw its previous recommendation of 0.05 mg/kg for tebuconazole in rape seed.

Coffee

Tebuconazole can be used in coffee in Brazil at 3 applications at 0.25 kg ai/ha with a 30 day PHI. In five trials from Brazil conducted from 1990 to 2004 complying with GAP residues found were: 0.02 (2) and < 0.10 (3) mg/kg. Eleven trials conducted at a higher GAP gave residues that ranged from < 0.01 to 0.07 mg/kg.

Four trials conducted in Guatemala (no GAP) using 3 applications at 0.25 kg ai/ha, gave residues of: < 0.01 to 0.03 mg/kg 30 days after the last application.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.1 mg/kg for tebuconazole in coffee. This estimation is supported by the trials conducted in Brazil at double GAP rate.

Hops

In the Czech Republic, tebuconazole can be applied twice at 0.56 kg ai/ha (0.02 kg ai/hL) with a 21 day PHI. In eight trials conducted in Germany complying with this GAP, residues in the cone, kiln dried, were: 5.8, 6.0, 6.3, 8.3, 11, 12, 18 and 21 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg, an HR of 21 mg/kg and an STMR of 9.65 mg/kg for tebuconazole in hops.

Animal feed commodities

Straw and/or fodder

In 36 barley trials conducted in France, Germany, Greece, Italy, Portugal, Spain and the UK using 2 applications at 0.19–0.38 kg ai/ha, complying with GAP rate in German and Denmark, residues in straw 27 to 50 days after the last application (PHI for grain) were: 0.14, 0.29, 0.38, 0.45, 0.49, 0.50, 0.71, 0.72, 0.77, 0.80, 0.86, 0.88, 1.3, 1.4, 1.7 (3), 2.0, 2.2 (2), 2.4, 2.5, 2.8 (2), 3.1, 3.3, 3.8, 3.9, 4.3, 4.9, 5.6, 5.8, 6.7, 7.9, 13, and 17 mg/kg. When the STMR and the highest residues are corrected for dry matter content (88%, according to the OECD feed table), the values derived are 2.4 and 19 mg/kg, respectively

The Meeting estimated a maximum residue level of 30 mg/kg, a highest residue of 19 mg/kg and an STMR of 2.4 mg/kg for tebuconazole in barley straw and fodder (dry).

The Meeting withdraws its previous recommendation of 10 mg/kg for barley straw and fodder (dry).

No soya bean trials were conducted where fodder samples were harvested at the grain PHI.

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

The Meeting agreed that there were insufficient trials conducted according to GAP to estimate a maximum residue level for tebuconazole in soya bean fodder or rice straw and fodder, dry.

Forage

Forage samples, described as forage, green material or rest of the plant were harvested in a number of trials at different PHIs. Whenever data was available, either the 7 days PHI residue value or any later harvest date that gave higher residues was chosen to represent the level of residues to which animals could be exposed. In cases where such data was not available, the highest value from any PHI available (up to the grain PHI) was taken, including those from a 0 day PHI.

The residues in barley forage from trials conducted according to GAP rate in Europe in rank order were (n = 39): 0.29, 0.35, 0.37, 0.78, 1.0, 1.2 (2), 1.4 (2), 2.0, 2.3, 2.8, 3.2, 3.4, 3.8, 4.3 (2), 4.7, 5.2, 5.8, 6.0, 6.1, 6.2, 6.4, 6.5, 6.7, 7.4, 7.6, 8.6, 8.9, 9.0, 9.2, 9.5, 9.6, 10, 12, 14 (2) and 18 mg/kg.

Available PHI for rape forage were 0 or 14 days; residues in rape forage were (n = 25): 2.5 (3), 2.6, 2.7, 3.1, 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, 5.7, 6.3, 7.2, 7.5 and 11 mg/kg.

Residues in rice forage from seven trials conducted at GAP rate at 0 or 7 day PHI were: 1.7, 1.8, 4.5, 5.3, 5.5, 6.2 and 8.3 mg/kg.

In 20 soya bean trials conducted in USA according to GAP rate, residues in forage at 0 or 7 day PHI were: 2.1, 3.6, 4.8, 4.9, 5.0, 5.7 (2), 7.7, 8.5 (2), 8.6, 9.1, 12, 13 (2), 14 (3), 15 and 18 mg/kg.

The Meeting noted that the barley, rape and rice forage residue data represent similar populations and could be combined as follows: (n = 91) 0.29, 0.35, 0.37, 0.78, 1.0, 1.2 (2), 1.4 (2), 1.7, 1.8, 2.0, 2.1, 2.3, 2.5 (3), 2.6, 2.7 (2), 2.8, 3.1, 3.2, 3.4, 3.6 (2), 3.7, 3.8 (2), 3.9, 4.0, 4.2 (2), 4.3 (3), 4.5, 4.6, 4.7, 4.8 (2), 4.9 (2), 5.0, 5.1, 5.2 (2), 5.3, 5.5, 5.7 (3), 5.8, 6.0, 6.1, 6.2 (2), 6.3, 6.4, 6.5, 6.7, 7.2, 7.4, 7.5, 7.6, 7.7, 8.3, 8.5 (2), 8.6 (2), 8.9, 9.0, 9.1, 9.2, 9.5, 9.6, 10, 11, 12 (2), 13 (2), 14 (5), 15 and 18 (2) mg/kg.

The Meeting estimated an STMR of 5.2 mg/kg and a highest residue of 18 mg/kg for tebuconazole in the forages of barley, rape, rice and soya bean.

Fate of residues during processing

In two processing studies conducted in Germany, treated oranges, with residues ranging from 0.20 to 0.27 mg/kg, were processed to pulp, juice and marmalade. No residues were found in the pulp (< 0.05 mg/kg), with a mean PF=< 0.22. Residues concentrated in the peel (mean PF=4), and decreased in juice (mean PF=< 0.2) and marmalade (mean PF=0.4).

Two apple processing studies were conducted in the USA (1990/2004). Treated samples contained < 0.01 and 0.03 mg/kg. Residues concentrated in wet and dry pomace, with PF of 3.3 and > 5, respectively. Washing and drying the fruit did not alter residue concentration. The PF for sauce and juice was < 0.33 and for juice concentrate 0.33. In one study submitted to the 1994 JMPR, residues in treated apple were 0.37 mg/kg. It increased slightly in washed fruit (PF=1.1) and considerably in dry pomace (PF=18). The processing factor in sauce and apple dried was 0.5 and in juice, 0.14.

Based on the estimated PFs and an STMR of 0.19 mg/kg for pome fruits, the Meeting estimated an STMR-P of 0.08 mg/kg for apple sauce, 0.08 mg/kg for apple juice (mean PF of 0.42). The Meeting also estimated an STMR-P of 0.63 mg/kg for wet apple pomace (PF=3.3) and of 2.2 mg/kg for dry apple pomace (mean PF=11.5).

One processing study was conducted in plums in the USA (2001). Residues in treated plums ranged from 0.17 to 0.19 mg/kg, concentrated in prunes with a mean PF of 1.2. In one processing study submitted to the 1997 JMPR, washed and plum preserve had a PF of 0.7, residues remained unchanged in jam and increased in prunes with a PF of 4.7.

Based on an STMR of 0.06 mg/kg, an HR of 0.12 mg/kg estimated for plums and a mean PF of 3, the Meeting estimate a maximum residue level of 0.5 mg/kg (based on a highest residue of 0.36 mg/kg) and an STMR-P of 0.18 mg/kg for prunes.

Three studies were conducted in Europe and one in the USA to determine the fate of tebuconazole residues in treated tomato (0.12 to 1.2 mg/kg) after processing. Residues were reduced in all steps, with a mean PF of 0.95 after washing; 0.25 after peeling, 0.55 for tomato juice, 0.3 in tomato preserve; 0.33 in tomato puree and 0.87 in tomato paste.

Based on the estimated PFs and an STMR of 0.19 mg/kg estimated for tomato, the Meeting estimated an STMR-P of 0.10 mg/kg for tebuconazole in tomato juice, 0.057 mg/kg in preserve, 0.06 mg/kg in purée, 0.16 mg/kg in tomato paste and 0.054 mg/kg in peeled tomato. The Meeting also estimated an HR-P of 0.115 mg/kg for peeled tomato based on an HR of 0.46 mg/kg on tomato.

In two studies conducted in Germany (2003), beans (with pods) treated in a green house with residues of 0.43 and 0.55 mg/kg were processed. Mean PFs in washed beans and cooked beans were 0.28 and 0.2, respectively. Based on an STMR of 0.48 mg/kg in the raw commodity, the Meeting estimated an STMR-P of 0.096 mg/kg for beans (with pods), cooked.

In one processing study conducted in treated soya bean in 2004, residues in the seed (0.14 mg/kg) concentrated in aspired grain fractions and hulls, with PF of 276 and 1.1, respectively. The PF was 0.2 in soya bean meal, 0.3 in protein isolate, 0.2 in defatted flour, 0.4 in full fat flour and 0.07 in refined oil.

Based on an STMR of 0.02 mg/kg in soya bean, dry, and the estimated PFs, the Meeting estimated an STMR-P of 5.5 mg/kg for aspired soya bean grain fractions, 0.022 mg/kg for soya bean hulls, 0.004 mg/kg for soya bean meal, and 0.001 mg/kg in refined oil.

In two studies conducted in barley, treated samples containing 0.65 and 0.93 mg/kg were processed into beer at a pilot plant in Germany (2002). Residues concentrated in pearl barley rub-off (mean PF=2.5) and did not change in malt sprouts. Mean PF was 0.51 in brewer's malt, 0.45 in brewer's grain, 0.30 in hops draft, 0.19 in brewer's yeast and < 0.025 in beer. Based on an estimated STMR of 0.05 mg/kg in barley, the Meeting estimated an STMR-P of 0.001 mg/kg in beer.

In two studies conducted in France (2002), treated rape seed samples containing 0.12 mg/kg were processed to oil. Residue levels did not changed in solvent-extracted oil, crude oil and extracted press cake meal, but reduced in screw-pressed oil (PF=0.1), pomace (PF=0.85) and refined oil (PF=0.8). Based on the PFs and on an STMR of 0.08 mg/kg estimated for rape seed, the Meeting estimated an STMR-P of 0.08 mg/kg for rape seed oil, crude and 0.064 mg/kg for rape seed oil, edible.

In a processing study conducted in Guatemala (1999), residues of tebuconazole in treated coffee beans (dried) were 0.04 mg/kg. PF for roasted coffee and instant coffee were 2 and 0.8 mg/kg, respectively.

Based on an STMR of 0.1 mg/kg in coffee and the estimated PFs, the Meeting estimated an STMR-P of 0.2 mg/kg for roasted coffee and of 0.08 mg/kg for instant coffee. Based on a highest residue of 0.1 mg/kg, the Meeting also recommends a maximum residue level of 0.5 mg/kg for roasted coffee.

In one study conducted in Germany (2001), treated kiln-dried hops (8.3 mg/kg) were processed to beer, with a PF of 0.01 mg/kg. Spent hops and brewer's yeast had PF of 0.01 and 0.02, respectively.

Based on an STMR of 9.65 mg/kg in hops, the estimated PF and applying a dilution factor of 10 (hops in beer, 2002 JMPR) the Meeting estimated an STMR-P of 0.009 mg/kg for beer (coming from hops).

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 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops), the STMR or highest residue levels estimated at the present Meeting and the current MRLs for some feed items. Dietary burden calculations are provided in Annex 6.

		Animal dietary burden, tebuconazole, ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	27.5	24.1	60[a]
	mean	14.67	7.5	17.3[c]
Dairy cattle	max	33.1	23.7	47.6[b]
	mean	15.9	7.5	26.3[d]
Poultry - broiler	max	0.12	0.08	0.19
	mean	0.11	0.06	0.19
Poultry - layer	max	0.12	7.2[e]	0.19
	mean	0.12	3.9[f]	0.19

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

[b] Highest maximum dairy cattle dietary burden suitable for MRL 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 MRL 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 MRL and STMR estimation (residue levels in animal feeds expressed on dry weight) reached a maximum of 60 ppm for cattle and 7.2 ppm for poultry.

Farm animal feeding studies

Two dairy cattle feeding studies were submitted to the 1994 JMPR. The animals were fed for 28 days at 25/75/250 ppm or 30/90/300 ppm. No residues were detected in kidney (< 0.05 or < 0.1 mg/kg) or milk (< 0.01 or < 0.05 mg/kg) at any dose in both studies. Meat was only analysed from the higher dose groups, with no residues detected (< 0.05 or < 0.1 mg/kg). Residues in liver were < 0.05, 0.06, 0.07 mg/kg at 25 ppm and 0.06, 0.07 and 0.12 mg/kg at 75 ppm. From the second study, residues were < 0.1 (3) mg/kg at 30 mg/kg and 0.1 and 0.2 (2) mg/kg at 90 ppm.

Two poultry studies were also submitted, with laying hens fed at 2, 6 and 20 ppm tebuconazole for 28 days. Tissues and eggs were analysed for tebuconazole and residues were only found in liver at the highest dose in both studies.

Animal commodity maximum residue levels

The animal feeding studies have shown that, with the exception of cattle liver, no residues are expected in commodities following the feeding of animals at the expected dietary burden.

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

The Meeting also estimated an STMR of 0 in meat (from mammalian other than marine mammals), poultry meat, poultry edible offal, eggs and milks, an HR of 0 mg/kg in meat (from mammalian other than marine mammals), poultry meat and eggs, and 0.05 mg/kg in poultry edible offal.

Estimations for mammalian edible offal will be done based on the residues found in cattle liver at the two lower doses in the second study (interpolation). The Meeting estimated a maximum residue level of 0.5 mg/kg, and an HR and STMR of 0.2 mg/kg.

The Meeting withdraws its previous recommendations for tebuconazole in cattle meat, milk and edible offal and chicken eggs, meat and edible offal at the LOQ (0.05 mg/kg or 0.01 mg/kg for milk).

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 and the 1997 JMPR and MRLs recommended by the 1994 JMPR. The results are shown in Annex 3. The IEDI ranged from 1 to 9% 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 were unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for tebuconazole was calculated for the plant commodities for which STMRs, HRs and MRLs were estimated by the current and previous Meetings and for which consumption data were available. The results are shown in Annex 4. The IESTI ranged from 0 to 31.4 µg/kg bw for the general population and from 0 to 65.6 µg/kg bw for children. An ARfD for tebuconazole has not yet been considered by the Meeting; therefore, the risk assessment for this compound could not be finalized.