5.20 PROTHIOCONAZOLE (232)

RESIDUE AND ANALYTICAL ASPECTS

Prothioconazole was evaluated for the first time by the 2008 JMPR which recommended maximum residue limits for barley, oats, rye, triticale and wheat grain and straw, peanut, rape seed and for meat, mammalian fats, edible offal and milks based on a residue definition of 'prothioconazole-desthio'.

At the Forty-first Session of the CCPR, the Delegation of the USA expressed a concern that because JMPR had adopted the above residue definition, all US field trial data which reported only 'total residue' (i.e., the sum of prothioconazole and desthio-prothioconazole) had been discarded, even though residues of the parent compound, prothioconazole were a very small part of the total residue.

The CCPR noted this concern and requested JMPR to review the existing US data (together with any additional residue information) on pulses, sugar beet, cereal grains (wheat and barley), canola (rape seed), soya bean, and cereal forages/straws.

The current Meeting was provided with information on residues of the sulfonic acid and desthio metabolites of prothioconazole that were analysed seperately in the above US/Canadian field trials (but initially summed and reported as 'total prothioconazole' residues).

Results of supervised trials on crops

The NAFTA statistical calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Pulses (beans (dry), peas (dry) and soya bean)

The 2008 JMPR reported that a total of 22 trials on peas (dry) and beans (dry) were carried out with 3 foliar application of a SC480 formulation at a target rate of 200 g/ha in Canada (9) and USA (13), but that the results of these trials could not be used to estimate residue levels as only total prothioconazole residues had been reported. The 2008 JMPR also reported that although 19 trials in USA on soya beans had been provided, these did not comply with the US GAP and also only reported total prothioconazole residues.

Additional information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in these trials were provided to the meeting.

In trials on beans conducted in the USA and Canada, matching the USA GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in beans (dry) were < 0.05 (7), 0.08, 0.12 and 0.22 mg/kg (n=10).

In trials conducted on field peas in USA and Canada, matching the North American GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in peas (dry) were < 0.05 (7), 0.06, 0.1, 0.11, 0.36, 0.49 and 0.57 mg/kg (n=13)

The Meeting considered that these results for peas (dry) and beans (dry) were from similar populations and based on the combined residue data set (< 0.05 (13), ≤ 0.05, 0.06, 0.08, 0.1, 0.11,

0.12, 0.22, 0.36, 0.49 and 0.57 mg/kg (n=23), estimated a maximum residue level of 1 mg/kg for prothioconazole in pulses (except soya beans, dry) and estimated an STMR of 0.05 mg/kg.

The value derived from use of the NAFTA calculator was 0.83 mg/kg, which differed from the estimate of 1 mg/kg made by the Meeting. With 60% of the values < LOQ, a higher level is required to accommodate the range of commodities in this commodity group.

While information on residues of desthio-proconazole in soya beans (dry) were provided from trials conducted on soya beans in USA, the Meeting confirmed that these trials, involving three foliar applications of about 0.15 kg ai/ha, were not supported by any matching GAP.

Sugar beet

The 2008 JMPR received reports of 12 residue trials on sugar beet from USA, complying with US GAP, but where only total residues were reported.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in sugar beet roots from these trials were provided to the meeting.

In trials on sugar beet conducted in the USA and Canada, matching the North American GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in sugar beet roots were < 0.05 (8), < 0.05, 0.11, 0.17 and 0.19 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.3 mg/kg for prothioconazole in sugar beet and estimated an STMR of 0.05 mg/kg.

The value derived from use of the NAFTA calculator was 0.18 mg/kg, which differed from the estimate of 0.3 mg/kg made by the Meeting. With 75% of the values < LOQ, the Meeting considered the calculator derived value may not be a reliable estimate of maximum expected residues in sugar beet.

Cereal grains

The 2008 JMPR reported that a total of 123 trials had been carried out on cereals (wheat, triticale and barley) with SC 480, EC250 and FS200 formulations in Canada, Europe and USA but that only 'total residues' had been reported from US and Canadian trials.

Based on the European data and GAP, the 2008 JMPR recommended a maximum residue of 0.05 mg/kg for barley, oat, rye, triticale and wheat, based on the combined data for barley and wheat following a seed treatment and 2–3 applications of 0.2 kg ai/ha, PHI 35–64 days. Results from these European trials were < 0.01 (10), 0.01, 0.01, 0.02 (4) mg/kg for barley grain and < 0.01 (16) for wheat grain.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in wheat and barley from the North American trials were provided to the present meeting.

Wheat

In trials on wheat conducted in the USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 30 days), residues of desthio-prothioconazole in wheat grain were < 0.02 (8), < 0.02, 0.02, 0.03, 0.04 and 0.05 mg/kg (n=13).

The Meeting estimated a maximum residue level of 0.1 mg/kg for prothioconazole in wheat (to replace the previous recommendation of 0.05 mg/kg) and estimated an STMR value of 0.02 mg/kg (to replace the previous estimate of 0.01 mg/kg).

The value derived from use of the NAFTA calculator was 0.07 mg/kg, which differed from the estimate of 0.1 mg/kg made by the Meeting. With 70% of the values < LOQ, the Meeting

considered the calculator derived value may not be a reliable estimate of maximum expected residues in wheat grain.

Barley

In trials on barley conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 32 days), residues of desthio-prothioconazole in barley grain were < 0.02, < 0.02, < 0.02, 0.03, 0.03, 0.04, 0.05, 0.07, 0.07 and 0.09 mg/kg (n=10).

The Meeting estimated a maximum residue level of 0.2 mg/kg for prothioconazole for barley (to replace the previous recommendation of 0.05 mg/kg) and estimated an STMR value of 0.035 mg/kg (to replace the previous estimate of 0.01 mg/kg).

The value derived from use of the NAFTA calculator of 0.2 mg/kg was in agreement with the estimate of 0.2 mg/kg made by the Meeting.

The Meeting also confirmed the 2008 JMPR recommendations for oat, rye and triticale, where maximum residue levels of 0.05 mg/kg and STMRs of 0.01 mg/kg were estimated, based on extrapolation from the European data on wheat and barley matching the European GAP for these cereal crops.

Oil seeds

The 2008 JMPR received a total of 34 trials on oil seed rape/canola carried out with either EC250 or SC 480 formulations. The trials were performed in Canada (16), France (7), Germany (2), the UK (2), Sweden (1) and the USA (6). In the 22 Canadian and USA trials only the total residue was reported.

Based on data from the European trials matching the UK GAP (2 × 0.175 kg ai/ha, PHI 56 days), with reported prothioconazole-desthio residues of < 0.01 (7), 0.01 (3) and 0.02 mg/kg, the 2008 JMPR recommended a maximum residue level of 0.05 mg/kg for rape seed.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in the North American trials were provided to the meeting. GAP in USA is for two applications during early-mid flowering, prior to significant petal fall and at least 36 days before harvest.

In trials on oil seed rape (canola) conducted in USA and Canada, matching the USA GAP (2 × 0.2 kg ai/ha, 14 days apart, early-mid flowering, minimum 30 day PHI) residues of desthio-prothioconazole in rape seed sampled at earliest maturity, i.e., 36 to 71 days after a mid-late flowering treatment, and consistent with the US GAP) were < 0.02 (8), < 0.02, 0.03, 0.04 and 0.08 mg/kg (n=12)

The Meeting estimated a maximum residue level of 0.1 mg/kg for prothioconazole in rape seed based on the US GAP and data (to replace the previous recommendation of 0.05 mg/kg) and estimated an STMR of 0.02 mg/kg (to replace the previous value of 0.01 mg/kg).

The value derived from use of the NAFTA calculator of 0.08 mg/kg differed from the estimate of 0.1 mg/kg made by the Meeting. With 75% of the values < LOQ, the calculator value may not be a reliable estimate of maximum expected residues in wheat grain.

Peanut

Information on the residues of desthio-prothioconazole in peanut meat from the trials on peanuts conducted in the USA (and initally summarised by the 2008 JMPR) was provided to the meeting.

The present meeting agreed that the information, reporting desthio-prothioconazole residues of < 0.02 mg/kg in 12 trials matching the US GAP, confirmed the 2008 JMPR conclusion (based on the lack of measurable 'total residues' in these trials) that only low residues of desthio-prothioconazole would be expected in peanut meat.

The Meeting confirmed the previous recommendations for a maximum residue level of 0.02(*) mg/kg for prothioconazole in peanut and an STMR of 0.01 mg/kg.

Primary feed commodities

The 2008 JMPR evaluated prothioconazole residue information from North America on a number of primary feed commodities and concluded that the data from these trials could not be used for estimation of residue levels because only the total residue was reported.

The present meeting received information on the the individual residue components measured in these trials from Canada and USA.

Sugar beet leaves and tops

The 2008 JMPR received reports of 12 residue trials on sugar beet from USA, complying with US GAP, but where only total residues were reported. These studies were not evaluated by the 2008 Meeting.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in sugar beet tops from these trials were provided to the present meeting.

In trials on sugar beet conducted in USA and Canada, matching the North American GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in sugar beet tops were 0.45, 0.48, 0.58, 0.61, 1.1, 1.5, 1.5, 1.8, 2.1, 2.2, 2.4 and 3.9 mg/kg (n=12)

The Meeting estimated an STMR of 1.5 mg/kg and a highest residue of 3.9 mg/kg for desthio-prothioconazole in sugar beet tops.

Soya bean forage and hay

While the present meeting received data on residues of desthio-prothioconazole in soya bean forage and hay from trials initially evaluated by the 2008 JMPR, none of these trials matched the US GAP and the meeting was unable to use these data to estimate residue levels.

Peanut hay

The present meeting received data on residues of desthio-prothioconazole in peanut hay from trials in USA, initially evaluated by the 2008 JMPR, but as noted by the 2008 JMPR, peanut hay from prothioconazole-treated peanuts cannot be used as an animal feed in USA, and the Meeting was unable to use these data to estimate residue levels.

Cereal forage, hay and straw

Cereal forage

The 2008 JMPR noted that forage samples in most of the North American trials and many European trials were taken 7 days after last application and since several countries labels do not contain any restriction on grazing, this 7-day sampling interval was considered the shortest under practical conditions, and residues measured in 7 day samples were used for estimation of animal burden. In the North European trials considered by the 2008 JMPR, the prothioconazole-desthio residues (fresh weight) 7 days after ther last application were: 0.11, 0.32, 0.57, 0.65, 0.78, 0.89, 0.92, 1.0, 1.1 and 1.8 mg/kg in wheat forage and 0.6, 0.85, 1.0, 1.2, 1.7, 2.0 and 2.6 mg/kg in barley forage.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in wheat forage from the North American trials were provided to the present meeting.

In trials conducted in the USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year), residues of desthio-prothioconazole in wheat forage sampled 7 days after the last application were 0.05, 0.09, 0.11, 0.23, 0.31, 0.37, 0.46, 0.66, 0.74, 0.89, 1.2, 1.2, 1.2, 1.3, 1.6, 1.6, 1.6, 1.6, 1.8, 1.8, 2.1, 2.4 and 5.4 mg/kg (n=23, fresh weight basis).

The meeting agreed that for purposes of calculating animal dietary burdens, the results of the North American trials on wheat could be used to calculate animal dietary burdens from both wheat and barley forage, and estimated STMRs of 1.2 mg/kg and highest residues of 5.4 mg/kg for wheat and barley forages (to replace the previous STMR estimates of 0.96 mg/kg and highest residue estimates of 2.6 mg/kg).

For other cereal forage commodities, the Meeting confirmed the STMRs of 0.96 mg/kg and highest residues of 2.6 mg/kg for oat, rye, and triticale forage, estimated by the 2008 JMPR based on the combined European data for wheat and barley.

Cereal fodders

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in wheat and barley hay from the North American trials were provided to the present meeting.

In trials conducted in USA and Canada, matching the GAP of the USA (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year), residues of desthio-prothioconazole in wheat hay sampled 12–14 days after the last application were 0.21, 0.29, 0.32, 0.33, 0.41, 0.42, 0.45, 0.55, 0.61, 0.77, 0.83, 0.87, 0.87, 0.97, 1.1, 1.4, 1.4, 1.5, 1.6, 1.6, 1.6, 1.9, 1.9, 2.0, 2.0, 2.2, 2.3, 2.4, 2.6, 3.0 and 3.3 mg/kg (n=31, fresh weight basis).

In trials conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year) residues of desthio-prothioconazole in barley hay sampled 12–14 days after the last application were 0.3, 0.39, 0.53, 0.61, 0.63, 0.64, 0.69, 0.69, 0.71, 0.81, 1.1, 1.1, 1.3, 1.4, 1.4, 1.6, 1.9, 2.0, 2.3, 2.4, 2.8, 3.0, 3.3 and 4.2 mg/kg (n=24, fresh weight basis).

The Meeting agreed that because of the similarity of the data sets for wheat and barley hay the data sets for wheat and barley hays could be combined to recommend a maximum residue level for cereal hays.

Based on the combined data set of: 0.21, 0.29, 0.3, 0.32, 0.33, 0.39, 0.41, 0.42, 0.45, 0.53, 0.55, 0.61, 0.61, 0.63, 0.64, 0.69, 0.69, 0.71, 0.77, 0.81, 0.83, 0.87, 0.87, 0.97, 1.1, 1.1, 1.1, 1.3, 1.4, 1.4, 1.4, 1.4, 1.5, 1.6, 1.6, 1.6, 1.6, 1.9, 1.9, 1.9, 2.0, 2.0, 2.0, 2.2, 2.3, 2.3, 2.4, 2.4, 2.6, 2.8, 3.0, 3.0, 3.3, 3.3 and 4.2 mg/kg (n=55) and allowing for the common 88% dry matter content for most cereal hays, the meeting estimated a maximum residue level of 5 mg/kg, an STMR of 1.5 mg/kg and a highest residue of 4.8 mg/kg for desthio-prothioconazole for fodder (dry) of cereal grains

The value derived from use of the NAFTA calculator of 6 mg/kg, after adjusting for dry matter content and rounding, differed from the estimate of 5 mg/kg made by the Meeting. The Meeting considered the value derived from the NAFTA calculator to have been shaped by the lowest values in the dataset.

The 2008 JMPR evaluated data from European cereal trials and estimated an STMR of 0.3 mg/kg, a highest residue of 1.36 mg/kg and a maximum residue level of 2 mg/kg, for barley, oat, rye, triticale and wheat straw (dry weight), based on a combined data set for wheat and barley straw (fresh weight) of: 0.08, 0.08, 0.09, 0.1, 0.1, 0.11, 0.13, 0.13, 0.14, 0.14, 0.14, 0.15, 0.16, 0.19, 0.19, 0.2, 0.24, 0.25, 0.27, 0.3, 0.31, 0.38, 0.42, 0.47, 0.52, 0.53, 0.53, 0.72, 0.72, 0.72, 0.75, 0.77, 1.0, 1.1, 1.1, and 1.2 mg/kg.

In trials on wheat conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 30 days) residues of desthio-prothioconazole in wheat straw from 13 of these trials, sampled at grain harvest, close to 30 days after the last treatment,

residues (fresh weight basis) were 0.12, 0.15, 0.21, 0.23, 0.36, 0.41, 0.57, 0.67, 0.89, 0.89, 1.4, 1.4 and 1.7 mg/kg (n=13).

In trials on barley conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 32 days) residues of desthio-prothioconazole in barley straw from 10 of these trials, sampled at grain harvest, close to 32 days after the last treatment, residues (fresh weight basis) were: < 0.05, 0.17, 0.19, 0.22, 0.27, 0.61, 0.85, 0.92, 1.3 and 1.6 mg/kg (n=10).

The Meeting agreed that because of the similarity of the data sets for wheat and barley straw, the data sets for wheat and barley straws could be combined to recommend a maximum residue level for cereal straws.

Based on the combined data set of: < 0.05, 0.12, 0.15, 0.17, 0.19, 0.21, 0.22, 0.23, 0.27, 0.36, 0.41, 0.57, 0.61, 0.67, 0.85, 0.89, 0.89, 0.92, 1.3, 1.4, 1.4, 1.6 and 1.7 mg/kg (n=23) and allowing for the common 88% dry matter content for most cereal straws, the meeting estimated a maximum residue level of 4 mg/kg, an STMR of 0.65 mg/kg and a highest residue of 1.9 mg/kg for desthio-prothioconazole (dry weight basis) in straw and fodder (dry) of cereal grains and to withdraw the previous recommendations for maximum residue levels, STMRs and highest residues for barley straw, oat straw, rye straw, triticale straw and wheat straw.

The value derived from use of the NAFTA calculator of 5 mg/kg, after adjusting for dry matter content and rounding, differed from the estimate of 4 mg/kg made by the Meeting. The NAFTA calculator derived value appeared to be influenced by the lowest values in the dataset.

Fate of residues during processing

The 2008 JMPR evaluated a number of studies on the effects of processing on the fate of prothioconazole residues in wheat, rape seed, peanut and soya bean. Processing factors derived from these studies included:

raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors.
peanut	meal	1.8
peanut	peanut butter	0.6
peanut	peanut, roasted	0.5
peanut	refined oil	< 0.1
rape seed	meal	< 0.7
rape seed	refined oil	< 0.7
wheat	aspirated grain fraction	250
wheat	bran	2.4
wheat	flour	< 0.4
wheat	middling	0.6
wheat	shorts	1
wheat	wheat germ	2

The processing factor for peanut meal (1.8) was applied to the estimated STMR for peanut (0.01 mg/kg) to produce a STMR-P value of 0.018 mg/kg for peanut meal (for the purposes of livestock dietary burden estimation).

The processing factor for refined rape seed oil (< 0.7) was applied to the estimated STMR for rape seed (0.02 mg/kg) to produce a STMR-P value of 0.014 mg/kg for refined rape seed oil. This concentration falls below the estimated maximum residue level for rape seed, and the Meeting agreed that a maximum residue level for rape seed oils need not be recommended.

The processing factor for rape seed meal (< 0.7) was applied to the estimated STMR for rape seed (0.02 mg/kg) to produce a STMR-P value of 0.014 mg/kg for rape seed meal (for the purposes of livestock dietary burden estimation).

The processing factors for wheat bran (2.4), flour (< 0.4) and wheat germ (2) were applied to the estimated STMR for wheat (0.02 mg/kg) to produce STMR-P values for wheat bran (0.048 mg/kg), flour (0.008 mg/kg) and wheat germ (0.04 mg/kg). For the purposes of estimating livestock dietary burdens, the processing factor of 250 for aspirated grain fraction from wheat was applied to the wheat grain STMR (0.02 mg/kg) to produce a STMR-P of 5 mg/kg.

The Meeting agreed that it was not necessary to recommend a maximum residue level for wheat flour as residues did not concentrate during processing of wheat and also agreed to withdraw its previous maximum residue level recommendation of 0.05 mg/kg for wheat flour.

Residues in animal commodities

Farm animal dietary burden

The Meeting confirmed the conclusion of the 2008 JMPR that the feeding study conducted with parent prothioconazole does not represent the practical residue situations where the feed items contain the parent compound only up to 5% of the TRR and the major part of the residue was the prothioconazole-desthio and that the dietary burden should be calculated from the prothioconazole-desthio residues measured in feed commodities and compared to the residues found in animal commodities after the administration of prothioconazole-desthio.

Some processed and forage commodities do not appear in the Annex 1 Table as no maximum residue level estimate was required, but were used in estimating livestock dietary burdens. Those commodities are listed below.

Commodity	STMR or STMR-P (mg/kg)	High residue (mg/kg)
Barley forage (fresh)	1.2	5.4
Peanut meal	0.018	
Rape seed meal	0.014	
Sugar beet leaves or tops	1.5	3.9
Wheat aspirated fraction	5	
Wheat forage (fresh)	1.2	5.4

The 2008 JMPR reported the results of a 28 day prothioconazole-desthio feeding study in cattle where milk and tissue samples were analysed for residues of total prothioconazole-desthio (prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio and prothioconazole-desthio). Residues were observed in liver and kidney at all feeding levels, increasing in a linear fashion.

Total prothioconazole-desthio residues (mg/kg) in the edible tissues of dairy cattle after 28 days of dosing with prothioconazole-desthio.

Tissue	4 ppm dose		25 ppm dose		100 ppm dose	
	range	mean	range	mean	range	Mean
Liver	0.02–0.05	0.04	0.18–0.26	0.22	0.61–1.6	0.95
Kidney	0.01–0.04	0.02	0.11–0.17	0.14	0.41–1.1	0.65
Muscle	< 0.01	< 0.01	< 0.01	< 0.01	0.01–0.03	0.02
Fat	< 0.01	< 0.01	0.01–0.02	0.01	0.03–0.14	0.07

For poultry, the Meeting noted that the 2008 JMPR had concluded that the poultry feeding study designs did not reflect the residue composition in feed and that the results could not be used for estimating maximum residue limits or STMR values, and therefore the present Meeting did not estimate a dietary burden for poultry.

The Meeting revised the 2008 JMPR estimation of the dietary burden in farm animals on the basis of the above residue estimates in animal feeds and the animal diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR for some bulk commodities and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle are provided in Annex 6.

	Livestock dietary burden, prothioconazole-desthio, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	7.81	1.72	6.21	2.68	21.6 [a]	4.8 [b]
Dairy cattle	10.57	2.16	7.1	3.33	12.97 [c]	3.84 [d]

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

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat

[c] Highest maximum dairy cattle dietary burden suitable for MRL estimates for milk.

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

Estimation of maximum residue and STMR values in animal commodities

For MRL estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden (21.6 ppm) between the relevant feeding levels (4 and 25 ppm) from the prothioconazole-desthio dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups and the STMR values were calculated by interpolating the STMR dietary burden (4.8 ppm) between the relevant feeding levels (4 and 25 ppm) and using the mean tissue concentrations from those feeding groups.

Dietary burden (ppm) Feeding level [ppm]	Muscle	Liver	Kidney	Fat
MRL	highest	highest	highest	Highest
MRL cattle (21.6) [4, 25]	< 0.01 [< 0.01, < 0.01]	0.23 [0.05, 026]	015 [0.04, 0.17]	0.02 [< 0.01, 0.02]
STMR	mean	mean	mean	Mean
STMR cattle (4.8) [4, 25]	< 0.01 [< 0.01, < 0.01]	0.05 [0.04, 0.22]	0.025 [0.02, 0.14]	0.01 [< 0.01, 0.01]

The data from the cattle feeding studies were used to support the estimation of maximum residue levels for mammalian meat and milk.

In milk the highest feeding dose (100 ppm) resulted in a maximum of 0.02 mg/kg residue, and no residue (< 0.004 mg/kg) could be detected at lower dose levels. Consequently no residue is expected in milk where the feed contains residues up to 13 ppm.

The Meeting estimated a maximum residue level of 0.5 mg/kg for edible offal (Mammalian) to replace the previous recommendations of 0.02 mg/kg and confirmed the previous recommended maximum residue levels for meat (0.01 mg/kg) and milk (0.004 (*) mg/kg).

The Meeting also agreed to recommend withdrawal of the 2008 JMPR recommendation for a maximum residue level of 0.02 mg/kg in mammalian fat.

The STMR values of 0.01 mg/kg for meat and fat, and the STMR value of 0.004 mg/kg for milk estimated by the 2008 JMPR were confirmed and the Meeting established STMRs of 0.05 mg/kg for liver, 0.025 mg/kg for kidney and established HRs of 0.23 mg/kg for liver, 0.15 mg/kg for kidney and 0.02 mg/kg in fat.