5.23 SPIROTETRAMAT (234)

RESIDUE AND ANALYTICAL ASPECTS

Spirotetramat was first evaluated by the JMPR in 2008. An ADI of 0-0.05 mg/kg bw and an acute reference dose of 1.0 mg/kg bw were established. Maximum residue levels were recommended for many crops and animal commodities.

The manufacturer has submitted additional data for mangoes, kiwifruit, papaya, litchi, avocado, guava, onions, edible beans and peas with pods, succulent shelled beans and peas, pulses including soya beans and cotton. Animal feed residues data have been provided for legumes and pulses. Cotton and soya bean processing studies have also been submitted.

Analytical methods

Suitable analytical methods were available for quantifying spirotetramat residues including the metabolites spirotetramat -enol, spirotetramat -ketohydroxy, spirotetramat -mono-hydroxy and spirotetramat enol-Glc in plant matrices by HPLC-MS/MS. The limits of quantification (LOQ) for plant commodities are generally 0.01 to 0.02 mg/kg (as parent equivalents) for each analyte.

Stability of pesticide residues in stored analytical samples

Samples from the residue trials were stored for periods less than the period of stability demonstrated in studies submitted to JMPR 2008. Since the storage stability data from JMPR 2008 cover a diverse range of crops and demonstrated stability of all analytes for up to 2 years, it is considered that these data should be sufficient to cover the storage stability of all the samples.

Results of supervised trials on crops

The Meeting received supervised trials data from the foliar application of spirotetramat as an oil dispersion (OD) or suspension concentrate formulation (SC) to a variety of tropical fruit crops, legume vegetables, pulses and cotton. Brussels sprouts data which were submitted for the 2008 JMPR are also re-evaluated here as revised GAP has become available.

The 2008 JMPR established the following residue definitions for spirotetramat.

Residue for enforcement plant commodities: spirotetramat plus spirotetramat enol, expressed as spirotetramat.

Residue for dietary intake plant commodities: spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat.

Residue for enforcement and dietary intake animal commodities: spirotetramat enol, expressed as spirotetramat

Consequently, in the discussions below residues of spirotetramat plus enol are considered first for estimation of maximum residue levels followed by total residues (spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat) for estimation of STMR and HR values for dietary risk assessment.

Assorted tropical and sub-tropical fruits – inedible peel

Residue trials were conducted in avocado at five sites in the USA (2), Mexico (1) and Chile (2). Residues of spirotetramat plus enol in two trials from Chile, matching GAP of that country (3 × 300 g ai/ha, PHI 3 days) were 0.18 and 0.35 mg/kg. In three trials from Mexico and the USA that matched the GAP of Mexico (3 applications at 288 g ai/ ha with a 14-day retreatment interval, 1-day PHI)

residues of spirotetramat plus enol were 0.069, 0.13, and 0.20 mg/kg. There are insufficient data to estimate a maximum residue level for avocado.

Residue trials were conducted in guava at two sites in Mexico according to the GAP for USA for various tropical fruits (3 applications at 175 g ai/ ha with a 14-day retreatment interval, 1-day PHI). The ranked order of residues of spirotetramat plus enol from supervised trials collected 1 day after the last application is 0.54 and 0.92 mg/kg.

The Meeting considered the number of trials insufficient to estimate a maximum residue level.

Residue trials were conducted in litchi at three sites in Mexico according to the GAP for USA for various tropical fruits (3 applications at 175 g ai/ ha with a 14-day retreatment interval, 1-day PHI). The ranked order of residues of spirotetramat plus enol from supervised trials collected 1 day after the last application was 0.76, 0.85 and 5.2 mg/kg. The Meeting estimated a maximum residue level of 15 mg/kg for litchi.

The ranked order of total residues of spirotetramat from supervised trials collected 1 day after the last application was 1.3, 1.6 and 6.0 mg/kg. The Meeting estimated an STMR of 1.6 mg/kg and an HR of 6.0 mg/kg for total residues of spirotetramat for use in dietary intake calculations.

Residue trials were conducted in papaya at four sites in Mexico according to Mexican GAP (3 applications at 288 g ai/ha with a 14-day retreatment interval, 1-day PHI). The ranked order of residues of spirotetramat plus enol from supervised trials collected 1 day after the last application was 0.09, 0.096, 0.17 and 0.18 mg/kg. The Meeting estimated a maximum residue level of 0.4 mg/kg for papaya.

The ranked order of total residues of spirotetramat from supervised trials collected 1 day after the last application was 0.13, 0.13, 0.21 and 0.22 mg/kg. The Meeting estimated an STMR of 0.17 mg/kg and an HR of 0.22 mg/kg for total residues of spirotetramat in papaya for use in dietary intake calculations.

Four supervised trials on mango conducted in Australia that complied with GAP in that country (2 × 9.6 g ai/hL, 21-day intervals with a 14-day PHI) were made available to the Meeting. The ranked order of residues of spirotetramat-plus-enol, on a whole fruit basis, from trials matching Australian GAP is 0.05, 0.06, 0.07 and 0.16 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg for mango.

The ranked order of total residues of spirotetramat on a pulp and skin basis from trials matching Australian GAP was 0.12 0.14, 0.18 and 0.25 mg/kg. The Meeting estimated an STMR of 0.16 mg/kg and an HR of 0.25 mg/kg for total residues of spirotetramat in mango for use in dietary intake calculations.

Five supervised trials were conducted in kiwifruit in New Zealand in which 2 applications of spirotetramat were made at 4.8 g ai/hL. The GAP in New Zealand consists of 3 applications of spirotetramat at 4.8 g ai/hL. The first application should be pre-flowering, the 2nd at fruit set and the 3rd application at 21 days after fruit set. The trials can be considered as matching this GAP.

No residues of either spirotetramat or -enol were detected at harvest (129–156 days after last application); individual compound LOQs were both 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02* mg/kg for residues of spirotetramat in kiwifruit.

The ranked order of total residues of spirotetramat from supervised trials collected at harvest (129–156 days) after the last application was < 0.054, 0.054, < 0.055, < 0.055 and 0.066 mg/kg. The Meeting estimated an STMR of 0.055 mg/kg and an HR of 0.066 mg/kg for total residues of spirotetramat in kiwifruit for use in dietary intake calculations.

Onions, bulb

Trials were conducted on onions in Australia according to GAP (2 applications at 48g ai/ha with a PHI of 7 days). The ranked order of residues of spirotetramat plus enol from supervised trials according to Australian GAP were: < 0.04 (3), 0.04, 0.08, 0.10 and 0.21 mg/kg. The Meeting estimated a maximum residue level of 0.4 mg/kg for residues of spirotetramat in bulb onions.

The ranked order of total residues of spirotetramat from supervised trials according to GAP was < 0.11 (3), 0.11, 0.15 and 0.16 and 0.27 mg/kg (STMR = 0.11 mg/kg). For onions, bulb the HR is 0.27 mg/kg and the STMR is 0.11 mg/kg.

Brussels sprouts

Eight supervised trials (seven locations) were conducted in Europe (Germany, France and the United Kingdom) during 2004–2005, in which 3 applications of spirotetramat were made to Brussels sprouts at 72g ai/ha. The GAP for the United Kingdom, Belgium, Ireland and Austria allows 2 applications at 75 g ai/ha with a PHI of 3 days.

The Meeting considered the influence of two sprays compared to three sprays on the final residue in determining whether or not the trials matched GAP and noted only a slow decline in residues. As three foliar applications were used in the trials and the additional application would affect the final residue, none of the trials are considered to approximate GAP.

Trials were also conducted at two sites in Australia in which 3 applications of spirotetramat were made to Brussels sprouts according to Australian GAP (3 applications at 96 g ai/ha with a PHI of 3 days). The ranked order of residues of spirotetramat plus enol from supervised trials according to Australian GAP was 0.07 and 0.15 mg/kg. The Meeting considered the number of trials inadequate to estimate a maximum residue level.

Legume vegetables

Residue trials were conducted in peas with pods at three different sites in the USA and in beans with pods (snap beans, podded) at six different sites in the USA according to the critical US GAP (application at 88 g ai/ha – maximum of 175 g ai/ha per season with a 1-day PHI).

The ranked order of residues of spirotetramat plus enol in beans with pods at a 1-day PHI from supervised trials was 0.059, 0.17, 0.37, 0.43, 0.53 and 0.67 mg/kg.

The ranked order of total residues of spirotetramat in beans with pods at a 1-day PHI from supervised trials was 0.15, 0.26, 0.47, 0.54, 0.80 and 0.84 mg/kg.

The ranked order of residues of spirotetramat plus enol in peas with pods at a 1-day PHI was 0.58, 0.66 and 1.2 mg/kg.

The ranked order of total residues of spirotetramat in peas with pods at a 1-day PHI from supervised trials was 0.63, 0.74 and 1.3 mg/kg.

Residue trials were also conducted in garden peas (succulent seeds of shelled peas) and Lima beans at 6 different sites in the USA according to the critical US GAP (application at 88 g ai/ha – maximum of 175 g ai/ha per season with a 1-day PHI).

The ranked order of residues of spirotetramat plus enol in succulent seeds of shelled peas at a 1-day PHI from supervised trials was 0.36, 0.40, 0.43, 0.52, 0.56 and 0.59 mg/kg.

The ranked order of total residues of spirotetramat in succulent seeds of shelled peas at a 1-day PHI from supervised trials was 0.45, 0.49, 0.55, 0.62, 0.74 and 0.76 mg/kg.

The ranked order of residues of spirotetramat plus enol in succulent seeds of shelled Lima beans at a 1-day PHI from supervised trials was 0.079, 0.10, 0.18, 0.19, 0.23 and 0.33 mg/kg.

The ranked order of total residues of spirotetramat in succulent seeds of shelled beans at a 1-day PHI from supervised trials was 0.11, 0.13, 0.24, 0.25, 0.31 and 0.44 mg/kg.

The Meeting noted residue trial data are available from the USA for peas with pods, beans with pods as well as shelled peas and beans, all members of the legume vegetables crop group. The USA use pattern is for the crop group legume vegetables. The Meeting decided to estimate a maximum residue level for legume vegetables based on spirotetramat residues in beans with pods. The Meeting estimated a maximum residue level of 1.5 mg/kg for residues of spirotetramat in legume vegetables. For the purpose of dietary intake assessment the HR is 0.84 mg/kg and the STMR is 0.505 mg/kg for legume vegetables, also based on residues in common beans.

Soya bean

Residue trials were conducted at nineteen different sites in the USA and Canada, according to the critical US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 21-day PHI).

The ranked order of total spirotetramat plus enol residues found in soya bean seeds according to the critical US GAP was 0.042, 0.045, 0.061, 0.071, 0.13, 0.13, 0.15, 0.27, 0.33, 0.39, 0.41, 0.75, 0.76, 1.0, 1.1, 1.5, 1.5, 2.0 and 2.2 mg/kg. The Meeting estimated a maximum residue level for spirotetramat on soya bean (dry) of 4 mg/kg.

The ranked order of total residues of spirotetramat in soya bean seeds according to the critical US GAP was 0.072, 0.075, 0.091, 0.11, 0.16, 0.16, 0.18, 0.30, 0.36, 0.45, 0.48, 0.82, 0.84, 1.0, 1.2, 1.6, 1.6, 2.2 and 2.7 mg/kg. The HR is 2.7 mg/kg and the STMR is 0.45 mg/kg.

Dried shelled peas and beans

Trials in peas were conducted in USA during 2007–2008 at five different sites, according to US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 7-day PHI).

The ranked order of residues of spirotetramat plus enol in dry shelled pea seeds at a 7-day PHI from supervised trials was 0.039, 0.21, 0.23, 0.72, and 1.0 mg/kg.

The ranked order of total residues of spirotetramat in dry shelled pea seeds at a 7-day PHI from supervised trials was 0.069, 0.24, 0.26, 0.78 and 1.1 mg/kg.

Trials in beans (cowpeas) were conducted in USA during 2007–2008 at eight different sites, according to US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 7-day PHI).

The ranked order of residues of spirotetramat plus enol in dry shelled bean seeds at USA GAP (7-day PHI) from supervised trials was < 0.02, < 0.02, 0.026, 0.063, 0.067, 0.11, 0.48, 0.54 and 0.73 mg/kg.

The ranked order of total residues of spirotetramat in dry shelled bean seeds at USA GAP (7-day PHI) from supervised trials was < 0.05, 0.05, 0.056, 0.14, 0.17, 0.18, 0.52, 0.80 and 1.2 mg/kg.

The Meeting considered the residue data for beans (dry) and peas (dry) can be combined (Mann-Whitney test) to recommend a maximum residue level for the group pulses (except soya bean).

The ranked order of residues of spirotetramat plus enol in dry shelled bean and pea seeds at USA GAP from supervised trials were: < 0.02, < 0.02, 0.026, 0.039, 0.063, 0.067, 0.11, 0.21, 0.23, 0.48, 0.54, 0.72, 0.73 and 1.0 mg/kg. The Meeting estimated a maximum residue level for spirotetramat in pulses (except soya beans) of 2 mg/kg. The ranked order of total residues of spirotetramat in dry shelled bean and pea seeds at USA GAP from supervised trials was < 0.05, 0.05, 0.056, 0.069, 0.14, 0.17, 0.18, 0.24, 0.26, 0.52, 0.78, 0.80, 1.1 and 1.2 mg/kg. The HR is 1.2 mg/kg and the STMR is 0.21 mg/kg.

Cotton seed

Residue trials were conducted at eleven different sites in the USA, ten according to the critical US GAP (application at 88 g ai/ha – maximum of 175 g ai/ha per season with a 21-day PHI).

The ranked order of total spirotetramat plus enol residues found in cotton seeds according to the critical US GAP was (n = 10): < 0.02, < 0.02, 0.02, 0.030, 0.033, 0.049, 0.052, 0.092, 0.094 and 0.26 mg/kg. The Meeting estimated a maximum residue level for spirotetramat on cotton seed of 0.4 mg/kg.

The ranked order of total residues of spirotetramat in cotton seeds according to the critical US GAP was < 0.05, 0.055, 0.057, 0.077, 0.079, 0.11, 0.12, 0.13, 0.13 and 0.29 mg/kg. The STMR is 0.095 mg/kg.

Animal feeds

The Meeting received supervised trials data for a variety of animal feeds (soya bean forage and hay, various legume animal feeds and cotton gin by-products).

Legume animal feeds (bean hay and forage, pea hay and vines)

Residue trials on soya beans were conducted at nineteen different sites in the USA and Canada, according to the critical US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 3-day PHI for forage and hay). The ranked order of total residues of spirotetramat found in soya bean forage (wet weight) according to the critical US GAP were: 0.66, 1.2, 1.7, 2.2, 2.3, 2.7, 2.7, 2.9, 3.3, 3.3, 3.6, 3.7, 3.9, 4.6, 4.7, 4.8, 5.1, 6.6 and 6.6 mg/kg. Correcting the data for dry matter contents the ranked order of total residues of spirotetramat found in soya bean forage (dry weight) according to the critical US GAP was 3.0, 7.4, 11,13, 14, 14, 16, 16, 17, 19, 19, 20, 20, 24, 25, 28, 29, 33 and 40 mg/kg. The highest and median residues for calculating livestock dietary burden are 40 and 19 mg/kg respectively (dry weight basis).

The ranked order of total residues of spirotetramat found in soya bean hay (wet weight) according to the critical US GAP was 1.7, 1.7, 1.9, 4.3, 4.9, 5.0, 5.4, 5.8, 6.5, 8.2, 8.5, 8.9, 9.0, 9.6, 10, 10, 10, 12 and 12 mg/kg. Correcting the data for reported dry matter contents results in total residues of spirotetramat found in soya bean hay (dry weight) of 2.5, 2.9, 3.6, 7.0, 7.6, 9.1, 9.1, 9.8, 11, 12, 12, 13, 13, 14, 14, 15, 15, 15 and 17 mg/kg.

The ranked order of total residues of spirotetramat found in cowpea forage (wet weight) according to the critical US GAP was 2.0, 2.2, 2.7, 2.7, 3.4 and 4.1 mg/kg. When corrected for dry matter, total residues of spirotetramat found in cowpea forage (dry weight) were 5.1, 5.3, 6.9, 7.9, 10 and 12 mg/kg.

The ranked order of total residues of spirotetramat found in cowpea hay (wet weight) matching the critical US GAP were: 0.28, 1.0, 1.1, 1.1, 2.1 and 2.6 mg/kg. On correcting for dry matter, total residues of spirotetramat were 0.39, 1.3, 1.6, 1.9, 2.6 and 3.9 mg/kg.

The ranked order of total residues of spirotetramat found in pea hay (wet weight) according to the critical US GAP *mg/kg* was 0.49, 0.61, 1.4, 5.2 and 5.7 mg/kg and when converted to a dry matter basis 0.88, 1.1, 1.8, 8.0 and 9.7 mg/kg.

The ranked order of total residues of spirotetramat found in pea vines (wet weight) according to the critical US GAP was 0.19, 0.31, 0.85, 1.9 and 3.1 mg/kg. On correction for dry mater content, the ranked order of total residues of spirotetramat were: 0.66, 1.1, 2.7, 5.3 and 11 mg/kg.

The Meeting considered the legume animal feed residue data could support a maximum residue level for the group legume animal feeds based on the commodity with the highest residues, i.e., soya bean hay. The ranked order of total residues of spirotetramat in soya bean hay (dry weight) were 2.5, 2.9, 3.6, 7.0, 7.6, 9.1, 9.1, 9.8, 11, 12, 12, 13, 13, 14, 14, 15, 15, 15 and 17 mg/kg. The

Meeting estimated a maximum residue level for spirotetramat on legume animal feed of 30 mg/kg (dry weight). The highest residue is 17 mg/kg and the median is 12 mg/kg.

Cotton gin by-products (gin trash)

The ranked order of total residues of spirotetramat in cotton gin by-products (wet weight) according to the critical US GAP was 0.16, 0.51, 0.67, 1.2 and 4.9 mg/kg and when corrected for dry matter content were: 0.20, 0.60, 0.79, 1.5 and 5.9 mg/kg. The highest residue is 5.9 mg/kg and the median is 0.79 mg/kg.

Fate of residues during processing

The Meeting received processing studies for cottonseed and soya beans.

The processing factors derived from the processing studies and the resulting STMR-Ps and HR-Ps are summarized in the table below. The processing factors are the ratio of the residue in the processed commodity divided by the residue in the raw agricultural commodity (RAC). Processing factors were calculated for total spirotetramat residues, required for estimating residues in processed commodities for dietary risk assessment and also for spirotetramat +enol required for estimating residues for compliance. For most commodities the two processing factors were comparable.

Of the traded commodities, the only commodity for which there was significant increase in residues measured using the compliance definition was cottonseed meal. Based on the maximum residue level of 0.4 mg/kg (spirotetramat + enol) in cottonseed and a processing factor of 2.28 for cottonseed meal, (0.4 × 2.3 = 0.92 mg/kg) the Meeting estimated a maximum residue level for spirotetramat in cotton seed meal of 1 mg/kg.

Processing factors (PF) from the processing of cottonseed and soya beans

	Processed Commodity	PF Total residue [a]	STMR/ STMR-P or median	HR/ HR-P or highest	PF spirotetramat + enol[b]
Cottonseed	Cottonseed	-	0.095	0.29	-
	Meal	1.25	0.12	0.36	2.28
	Hull	1.05	0.10	0.30	0.55
	Oil, refined	< 1	0	0	< 1
Soya bean	Soya bean	-	0.45	2.7	-
	Aspirated Grain Fractions	4.12	1.9	11.1	3.0
	Meal	1.37	0.62	3.7	1.33
	Hull	< 1	0.40	2.4	< 1
	Oil, refined	< 1	0	0	< 1
	Defatted flour	1.01	0.46	2.7	< 1
	Soya milk	< 1	0.06	0.34	< 1

[a] The factor is the ratio of the total residue (parent spirotetramat plus four metabolites, calculated as spirotetramat) in the processed item divided by the total residue in the RAC

[b] The factor is the ratio of the spirotetramat + enol in the processed item divided by spirotetramat + enol in the RAC

Processed commodity STMR-Ps and HR-Ps were calculated on the basis of the total parent residue PF.

Residues in animal commodities

Farm animal dietary burden

Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

Potential cattle feed items include: almond hulls, apple pomace, citrus pulp, grape pomace, potato culls and dried pulp, cabbage heads, cotton seed, cotton seed meal and hulls, cotton gin by-products, soya bean forage and fodder (hay), soya beans, soya bean meal and hulls, soya bean aspirated grain fractions, bean and pea seed, bean vines and pea vines and hay.

Potential poultry feed items include: potato culls and dried pulp, cabbage heads, cotton seed meal, soya bean forage and hay, soya beans, soya bean meal and hulls, bean and pea seed, pea vines and hay.

Summary of livestock dietary burden (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	Max	mean	max	Mean	max	Mean
Beef cattle	1.2	0.43	6.3	3.3	40[a]	19[c]	0.51	0.51
Dairy cattle	9.00	4.6	6.2	3.2	22[b]	11[d]	0.45	0.45
Poultry Broiler	1.02	0.27	0.59	0.43	0.39	0.39	0.24	0.24
Poultry Layer	1.02	0.27	4.8[e]	2.3[f]	0.39	0.39	0.20	0.20

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

[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 meat.

[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 meat and eggs.

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

Animal commodity maximum residue levels

A lactating dairy cow feeding study was reported by the 2008 JMPR where cows were dosed orally for 29 consecutive days with spirotetramat at target dose rates (based on feed dry weight) of 3, 9 or 30 ppm. The maximum dietary burden for beef cattle is 40 ppm and is higher than the highest dose level in the feeding study of 30 ppm. Residues in kidney (the tissue with highest residues) in the cattle feeding study show a linear relationship (R^2 = 0.9998) with dose. The Meeting considered it acceptable to assume proportionality of dose *vs.* residues for the tissues and milk and extrapolate the results from the 30 pm feed level to estimate residues in tissues at a dietary burden of 40 ppm.

	Feed level	Residues	Feed level	Residues (mg/kg) in			
	(ppm) for milk residues	(mg/kg) in milk	(ppm) for tissue residues	Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study [a]	30	0.005	30	0.014	0.038	0.41	0.032
Dietary burden and residue estimate	22	< 0.005	40	0.019	0.051	0.55	0.043
STMR beef or dairy cattle							
Feeding study [b]	9 30	< 0.005 < 0.005	9 30	0.0034 0.0088	0.012 0.030	0.072 0.26	0.008 0.016
Dietary burden and residue estimate	11	< 0.005	19	0.006	0.021	0.16	0.012

[a] highest residues for tissues and mean residues for milk

[b] mean residues for tissues and mean residues for milk

The Meeting estimated the following STMR values: milk 0.005 mg/kg; muscle 0.006 mg/kg; edible offal (based on kidney) 0.16 mg/kg and fat 0.012 mg/kg.

The Meeting estimated the following HR values: milk 0.005 mg/kg; muscle 0.019 mg/kg; edible offal (based on kidney) 0.55 mg/kg and fat 0.043 mg/kg.

The Meeting estimated the following maximum residue levels: milk – 0.01 mg/kg; meat (mammalian except marine) – 0.05 mg/kg and edible offal – 1 mg/kg to replace its previous recommendations of: milk – 0.005* mg/kg; meat (mammalian except marine) – 0.01* mg/kg and edible offal – 0.03 mg/kg.

A poultry feeding study was not available however, in the poultry metabolism study evaluated by the 2008 JMPR where laying hens were dosed at 1.01 mg/kg bw day (12.9 ppm in the diet), residues of spirotetramat-enol in muscle (0.001 mg/kg), fat (0.001 mg/kg) and liver (0.009 mg/kg) were all < 0.01 mg/kg. Residues in eggs were 0.013 mg/kg.

The maximum dietary burden of poultry is 4.8 ppm. Scaling the results of the metabolism study for the poultry dietary burden the Meeting estimated the following HR values: muscle 0.00037 mg/kg, fat 0.00037 mg/kg, liver 0.0033 mg/kg and eggs 0.0048 mg/kg.

The Meeting estimated the following maximum residue levels for poultry commodities: poultry meat 0.01 (*) mg/kg; poultry edible offal 0.01 mg/kg and eggs 0.01 mg/kg.

The mean dietary burden of poultry is 2.3 ppm. The Meeting estimated the following STMR values: poultry meat 0 mg/kg; poultry fat 0 mg/kg; poultry edible offal (based on liver) 0.0016 mg/kg and eggs 0.0023 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of spirotetramat has resulted in recommendations for MRLs and STMRs for raw and processed commodities. Consumption data were available for 37 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3. The International Estimated Daily Intakes for the 13 GEMS/Food regional diets, based on estimated STMRs were in the range 2–20% of the maximum ADI of 0.05 mg/kg bw (Annex 3).

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

Short-term intake

The International Estimated Short-term Intake (IESTI) for spirotetramat was calculated for the food commodities (and their processing fractions) for which maximum residue levels and HRs were estimated and for which consumption data were available. The results are shown in Annex 4. The IESTI was a maximum of 40% of the ARfD (1.0 mg/kg bw).

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