5.17 SPIROTETRAMAT (234)

RESIDUE AND ANALYTICAL ASPECTS

Spirotetramat is a systemic insecticide for the control of a broad spectrum of sucking insects. It was first evaluated by JMPR in 2008 (T,R). The latest residue evaluation was conducted in 2015 (R).

The 2008 JMPR established an ADI for spirotetramat of 0–0.05 mg/kg bw and an ARfD of 1 mg/kg bw.

The residue definition for compliance with the MRL for plant commodities is *spirotetramat plus spirotetramat enol, expressed as spirotetramat*.

The residue definition for estimation of dietary exposure for plant commodities is *spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat*.

The residue definition for compliance with the MRL and dietary exposure for animal commodities is *spirotetramat enol, expressed as spirotetramat*.

The residue is not fat soluble.

It was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 Extra JMPR. New supervised trial data in three commodities (strawberries, carrot and sugar beet), new data on storage stability and processing studies in sugar beets were provided to the present meeting.

Methods of analysis

Analytical methods used in raw agricultural commodities from field trials were suitable for quantifying spirotetramat residues including the metabolites spirotetramat enol, spirotetramat ketohydroxy, spirotetramat monohydroxy and spirotetramat enol glucoside in the various plant commodities. The methods were based on LC-MS/MS and the reference method used was evaluated by the Meeting in 2008 and 2013. The limits of quantitation (LOQ) for the raw commodities are 0.01 mg/kg (expressed as parent equivalents) for each analyte and 0.05 mg/kg for total spirotetramat equivalents.

For the determination of residues in dry beans and kiwi fruit a modification M005 of the analytical method 00857 was applied. The limit of quantification was 0.01 mg/kg for individual residues. The residues of individual analytes were expressed as spirotetramat equivalents and summed up to yield the total residue of spirotetramat plus enol (LOQ 0.02 mg/kg) and spirotetramat plus 4 metabolites (LOQ 0.05 mg/kg). The recoveries for individual residue components were tested at 0.01 and 0.1 mg/kg for dry beans and kiwi fruit, and their relative standard deviations were within an acceptable range.

In addition, the analytical method FN-007- P08-01 which is a modification 00857, was applied to determination of residues in sugar beet leaves and roots. The residues of individual analytes were expressed as spirotetramat equivalents and summed up to yield the total residue of spirotetramat plus enol (LOQ 0.02 mg/kg) and spirotetramat plus 4 metabolites (LOQ 0.05 mg/kg). The recoveries for individual residue components were tested at 0.01, 0.1 and 2 mg/kg for both leaves and roots and their relative standard deviations were within an acceptable range.

Stability of pesticides in stored analytical samples

Individual data on storage stability of spirotetramat and its metabolites were evaluated by the JMPR in 2008. The Meeting concluded that spirotetramat including its enol metabolite was stable (≥80% remaining) for up to 2 years in tomato, lettuce, climbing French beans, tomato paste (*high water*), potato (*high starch*) and almond nutmeat (*high oil*) stored frozen for intervals typical of storage prior to analysis.

An additional storage stability study on dry beans (*high protein*) and kiwi fruit (*high acid*) was submitted (M-610814-01-1). Spirotetramat and its metabolites STM-enol, STM-ketohydroxy, STM-

mono-hydroxy and STM-enol-Glc are stable for at least 18 months (kiwi fruit 545 days, bean dry 548 days) when stored at ≤ -18 °C.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for the foliar application of spirotetramat as a suspension concentrate (SC) or oil dispersion (OD) formulation to carrots, sugar beets and strawberries.

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

All residues presented for the metabolites are expressed as parent equivalents. Where a component is reported as <'value', the <'value' is added into the calculation of the total equivalents.

Strawberry

In Spain, spirotetramat is registered for indoor use on strawberries at a rate of 2×0.1 kg ai/ha, with a 14-day retreatment interval. No explicit PHI was indicated as the last application is growth stage specific, i.e., up to BBCH 56 (inflorescence elongating). Eight residue trials were conducted in the EU approximating the Spanish GAP.

Residues of the *sum of spirotetramat and spirotetramat -enol* from the trials were (n=8): 0.02, 0.03, 0.04, 0.05(3) and 0.15(2) mg/kg.

Total residues of spirotetramat from the trials were (n=8): 0.05, 0.06, 0.07, 0.08(2), 0.09 and 0.19(2) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.08 mg/kg and an HR of 0.19 mg/kg for strawberries.

Carrot

The critical GAP is from the registration in USA on carrots, at a rate of 2×0.09 kg ai/ha, a 7-day retreatment interval and a 1-day PHI. Eight residue trials were conducted in the USA approximating the critical GAP.

Residues of the sum of spirotetramat and spirotetramat -enol from the trials were (n=8): < 0.02(6), 0.029 and 0.030 mg/kg in roots.

Total residues of spirotetramat from the trials were (n=8): < 0.05(4), 0.059, 0.060, 0.07, and 0.1 (highest individual residue of 0.114) mg/kg in roots.

The Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR of 0.0545 mg/kg and an HR of 0.114 mg/kg for carrots.

Sugar beet, roots

In Canada and the USA, spirotetramat is registered for the use on sugar beets at a rate of 2×0.16 kg ai/ha, a 14-day retreatment interval with a 28 day PHI. Seventeen residue trials were conducted in Canada (six trials) and the USA (11 trials) approximating the Canadian and US GAPs. From these only fifteen trials were considered independent.

Residues of the sum of spirotetramat and spirotetramat -enol from the trials were (n=15): < 0.02(5), 0.02, 0.021, 0.022, 0.023, 0.024, 0.025, 0.027(2), 0.030 and 0.042 mg/kg.

Total residues of spirotetramat from the trials were (n=15): <0.05(5), 0.05, 0.051, 0.052, 0.053, 0.054, 0.055, 0.057(2), 0.06 and 0.072 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg, an STMR of 0.052 mg/kg and a highest residue of 0.072 mg/kg for sugar beet roots

Animal feedstuffs

Sugar beet, leaves and tops

In the USA and Canada, spirotetramat is registered for the use on sugar beets at a rate of 2×0.16 kg ai/ha, a 14-day retreatment interval with a 28 day PHI. Seventeen residue trials were conducted in Canada (six trials) and the USA (11 trials) approximating the Canadian and US GAPs. From the above only fifteen trials were considered independent.

Residues of sum of spirotetramat and spirotetramat -enol from the trials were (n=15): < 0.02, 0.023, 0.033, 0.057, 0.068, 0.13, 0.14, 0.22 (2), 0.24, 0.37, 0.49, 0.53, 0.64 and 1.45 mg/kg in sugar beet leaves or tops (as received).

Total residues of spirotetramat from the trials were (n=15): 0.072, 0.081, 0.10, 0.13, 0.21, 0.23 (2), 0.25, 0.3, 0.31, 0.48, 0.69, 0.75, 0.8 and 1.7 mg/kg in sugar beet leaves or tops (as received).

The Meeting estimated a maximum residue level of 8 mg/kg [expressed on dry weight basis (23% DM content)] and a median residue of 0.25 mg/kg and an highest residue of 1.7 mg/kg for sugar beet leaves or tops (as received)

Fate of residues during processing

The processing factors derived from the processing studies and the resulting recommendations for STMR-Ps, HR-Ps, and/or maximum residue levels are summarized in the table below.

RAC	Processed Commodity	Processing Factor (mean)	RAC MRL	Processed Commodity MRL	RAC STMR	Processed Commodity STMR-P
Sugar beet (roots)	dried pulp	*Risk assessment:* 0.7, 1.1 (0.9) *Enforcement:* 0.8, 1.3 (1.05)	0.06	-	0.052	0.047
	molasses	*Risk assessment:* 1.3, 2.6 (1.95) *Enforcement:* 2.7, 5 (3.85)	0.06	0.3	0.052	0.1
	refined sugar	*Risk assessment/ Enforcement:* <0.3, <1 (<0.65)	0.06	-	0.052	0.034

Each value represents a separate study. The factor is the ratio of the total residue in the processed item divided by the total residue in the RAC. The total residue is the parent spirotetramat plus four metabolites, calculated as spirotetramat.

In cases were residues in the processing item was <LOQ, the LOQ value (in this case was 0.02 for sum of spirotetramat and spirotetramat -enol and 0.05 mg/kg for total residues of spirotetramat) was used and the PF included the "<" symbol.

Residues in animal commodities

Estimated maximum and mean dietary burdens of livestock

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on the feed items evaluated by the current (carrots, sugar beet tops, pulp, and molasses) and previous Meetings. The calculations were made according to the animal diets listed in Appendix IX of the 2016 edition of the FAO manual.

Animal dietary burden, spirotetramat total residue, mg/kg of dry matter diet					
		US-Canada	EU	Australia	Japan
Beef cattle	max	1.4	6.53	40[a]	0.52
	mean	0.65	3.37	19.0[b]	0.52
Dairy cattle	max	10.2	7.2	22.3	0.47
	mean	5.1	3.37	10.8	0.47
Poultry Broiler	max	0.27	0.63	0.39	0.24
	mean	0.27	0.46	0.39	0.24
Poultry Layer	max	0.27	4.9	0.39	0.24
	mean	0.27	2.3	0.39	0.24

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat and milk.

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

The spirotetramat dietary burden reached a level of 40 ppm for cattle and 4.9 ppm for poultry. These results are similar or only slightly higher than the previous livestock dietary burden calculations performed in the 2011 JMPR (highest maximum beef or dairy cattle dietary burden was 40 ppm of dry matter diet). The meeting confirmed its previous recommendations for animal commodities.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

The residue definition for compliance with the MRL for plant commodities is spirotetramat plus spirotetramat enol, expressed as spirotetramat.

The residue definition for estimation of dietary exposure for plant commodities is spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat.

The residue definition for compliance with the MRL and dietary exposure for animal commodities is spirotetramat enol, expressed as spirotetramat.

The residue is not fat soluble

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for spirotetramat is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for spirotetramat were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 Extra JMPR Report.

The IEDIs ranged from 2–20% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of spirotetramat from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for spirotetramat is 1 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for spirotetramat were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 Extra JMPR Report.

The IESTIs were 0% of the ARfD for children and for the general population. The Meeting concluded that acute dietary exposure to residues of spirotetramat from uses considered by the present Meeting is unlikely to present a public health concern.