5.27 SPIROTETRAMAT (234)

RESIDUE AND ANALYTICAL ASPECTS

The compound was evaluated by the JMPR for the first time in 2008. The Meeting established an ADI of 0–0.05 mg/kg bw per day and an ARfD of 1 mg/kg/bw and defined the residues as follow:

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*.

The residue is not fat soluble.

Additional residue data were evaluated by the 2011 JMPR.

Siprotetramat was listed by the Forty-sixth Session of CCPR (2014) for the evaluation by the 2015 JMPR for additional MRLs. Supervised trials data were submitted for evaluation on avocado, guava and sweet corn for the evaluation by the 2015 JMPR.

Analytical methods

Analytical methods were evaluated by the 2008 and 2011 Meetings. Recovery data obtained from the analysis of avocado, guava and sweet corn and sweet corn fodder. The limit of quantification was 0.01 mg/kg for individual residues. The residues of individual analyte 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 in the matrices tested 0.01 and 0.1 mg/kg or 1.0 and 10 mg/kg spike level and their relative standard deviations were within acceptable range.

Stability of analytes

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 about 2 years in tomato, potato, lettuce, almond nutmeat, climbing French beans and tomato paste. No new information was provided.

Residues resulting from supervised trials in crops

Results of new trials and some of the previously submitted ones on guava, avocado and sweet corn were evaluated by the present meeting. The sum of respective residues was expressed in spirotetramat equivalent.

Assorted tropical and sub-tropical fruits – edible peel

Guava

In 2008 and 2011, four residue trials in guava were conducted (including 13 plots) in Mexico. The trials were performed either with the OD 150 or the SC 240 formulation. The trials were conducted at two different application rates: 3x 0.288 kg a.i./ha or 3x 150 kg a.i./ha at spray intervals of 14 days. The US GAP permits 3 applications at 0.179 kg a.i./ha rate at 14 days intervals with a PHI of 1 day. The results of supervised trials conducted in Mexico are evaluated against the US GAP.

The results indicate that the type of formulation and concentration of the spray solution did not affect the residue level. Therefore, the highest residues were selected from each set of trials.

The sum of residues of spirotetramat and its enol metabolite deriving from the 3 times 0.288 kg ai/ha nominal application rates at 1-3 days after last application were: 0.429, 0.660, 0.906 and 1.30 mg/kg.

Taking into account the nominal application rate of 288 g a.i./ha and the USA GAP rate of 179 g a.i./ha, the scaling factor is 179/228=0.6215. The residues scaled to match US GAP are in rank order: 0.27, 0.41, 0.56, and 0.81 mg/kg.

The sum of residues of spirotetramat and 4 metabolites are: 0.474, 0.79, 0.965 and 1.37 mg/kg.

The residues scaled to US GAP are: 0.29, 0.49, 0.60, and 0.85 mg/kg.

The Meeting estimated maximum residue level of 2 mg/kg, an HR of 0.85 mg/kg and an STMR residue of 0.55 mg/kg.

Assorted tropical and sub-tropical fruits – inedible peel

Avocado

The uses on avocado and the corresponding residue trials were previously submitted in 2010, but no recommendation could be made at that time. Subsequently, the GAPs of Chile and Mexico have been changed.

The use of spirotetramat in/on avocado is registered in the USA (3 applications of maximum 0.179 kg ai/ha at 14 days interval with a maximum seasonal rate of 0.44 kg ai/ha and PHI of 1 day), Chile (2 applications with a maximum seasonal rate of 0.8 kg ai/ha and PHI of 3 days) and Mexico (1 applications at maximum rate of 0.168 kg ai/ha and PHI of 1 day.

Five trials were conducted in USA, Chile and Mexico with nominal application rates of 0.288 kg ai/ha.

The critical GAP is from USA. The results of trials were evaluated based on the US GAP.

The highest sum of spirotetramat and enol from each replicate plots corresponding to this GAP are: 0.045, 0.11, 0.17, 0.20, 0.29 mg/kg.

Taking into account the targeted application rates of 0.288 and the maximum authorised rate of 0.179, the scaling factor is 0.179/0.288=0.6215.

The scaled residues in avocado fruits were in rank order: 0.028, 0.067, 0.106, 0.125, and 0.183 mg/kg.

For dietary intake assessment the sum of residues of spirotetramat and 4 metabolites was considered. They are in rank order: 0.055, 0.13, 0.20, 0.24, and 0.31 mg/kg.

The scaled residues in rank order are: 0.034, 0.080, 0.126, 0.147, and 0.193 mg/kg.

The highest residue observed in any single sample was 0.23 mg/kg.

The Meeting estimated a maximum residue level an STMR and HR of 0.4 mg/kg, 0.126 mg/kg and 0.23 mg/kg, respectively.

Sweet corn

Seven trials were conducted in Australia between 2008 and 2010 with applications close to Australian maximum GAP (2 times 0.072 kg a.i./ha at 7 day intervals with a PHI of 7 days). One sample was taken from each plot.

In Australian trials the sum of spirotetramat and enol in ear without husk were: 0.056, 0.056, 0.1, 0.12, 0.12, 0.24 and 0.40 mg/kg.

For dietary intake assessment the sum of residues of spirotetramat and 4 metabolites was considered. They were in rank order: 0.12, 0.12, 0.18, 0.18, 0.18, 0.3 and 0.62.

Eight trials were conducted in Canada approximating maximum GAP which permits treatments with 3 × 0.088 kg ai/ha at 7 days intervals and a PHI of 7 days. Duplicate samples were taken in each trial.

Some Canadian trials were carried out at the same location, timing, dosage and equipment. The highest sum of spirotetramat and enol in ear without husk from the independent trials were: 0.040, 0.061, 0.235, 0.48 and 0.545 mg/kg.

For dietary intake assessment the sum of residues of spirotetramat and 4 metabolites was considered. They were in rank order: 0.071, 0.125, 0.31, 0.60 and 0.695 mg/kg.

The maximum residue in a single sample was 0.75 mg/kg.

Based on the Canadian trials reflecting maximum GAP, the Meeting estimated a maximum residue level of 1.5 mg/kg, and for dietary risk assessment an STMR residue of 0.31 mg/kg and an HR of 0.75 mg/kg.

Animal feed

Residue data on sweet corn forage and stover derived from supervised trials conducted in Australia and Canada were made available for evaluation. The trial conditions, reflecting maximum GAP are described under sweet corn.

The independent Canadian trials resulted in the following highest average residues:

Sum of spirotetramat and enol:

Sweet corn forage 7 days after last application: 0.027, 0.18, 0.18, 0.25 and 1.8 mg/kg.

Sum of residues of spirotetramat and 4 metabolites:

Sweet corn forage 7 days after last application: 0.06, 0.29, 0.32, 0.35 and 1.9 mg/kg.

The meeting estimated 0.32 mg/kg median and 1.9 mg/kg high residue for animal burden calculation.

In the independent Canadian trials 47–85 days after last application the residues in sweet corn stover were:

Sum of spirotetramat and enol: < 0.02, 0.023, 0.046, 0.11 and 0.41 mg/kg

Sum of residues of spirotetramat and 4 metabolites: < 0.05, 0.078, 0.10, 0.11, and 0.58 mg/kg.

In Australian trials 7 days after last application the sum of residues in/on sweet corn fodder was:

Spirotetramat and enol: 0.18, 0.2, 0.31, 0.28, 0.33, 0.5, 0.58 mg/kg.

Spirotetramat and 4 metabolites: 0.39, 0.47, 0.54, 0.57, 0.63, 1.0, and 1.36 mg/kg,

The Australian trials resulted in higher residues in sweet corn stover and fodder. Based on the Australian trials the Meeting estimated highest and median residues of 1.36 mg/kg and 0.57 mg/kg for sweet corn stover and fodder.

Farm animal feeding studies

Based on a dairy cattle feeding study and poultry metabolism study the 2008 JMPR estimated residue levels in animal commodities. No new information was provided.

Residues in animal commodities

The residues in sweet corn forage and stover do not increase the maximum animal burden that would affect the maximum, HR and median residue values estimated by the 2008 Meeting.

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 dietary intake assessment.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI is 0–0.05 mg/kgbw. The long-term intake calculated for the commodities considered by the present meeting is 0% of maximum ADI and did not affect the previously made long-term dietary estimates. Hence, a new risk assessment was not necessary.

Short-term intake

The ARfD is 1 mg/kgbw. The estimated short-term intakes of avocado, guava and sweet corn are up to 1% 2% of ARfD for the general population and children.

The Meeting concluded that the short-term intake of residues of spirotetramat from the uses