5.22 SPINOSAD (203)

RESIDUE AND ANALYTICAL ASPECTS

Spinosad was first evaluated by the JMPR in 2001 for toxicology and residues and then in 2004 and 2008 for residues. An ADI of 0–0.02 mg/kg bw was estimated and an acute reference dose was determined to be unnecessary.

The 2011 Meeting received residues studies from the manufacturer to support additional maximum residue levels for various berries, bulb vegetables, tree nuts and hops. Residues data were also submitted by COLEACP-PIP to support maximum residue levels for papaya, passionfruit, okra and French beans.

Analytical methods

The analytical methods provided with the supervised trials are generally based on the two methods previously reviewed by JMPR in 2001, namely HPLC and immunoassay.

The HPLC methods, after an extraction specific to the matrix, follow a reasonably standard clean-up, with determination based on UV or MS detection. These methods allow measurement of the individual spinosyns and provide data on spinosyns A, D, K, B and B of D in residue trials. Spinosyn A usually contributes most of the residue, and some HPLC methods concentrate on spinosyns A and D. The LOQ for most substrates is 0.01 mg/kg.

Immunoassay methods, after an extraction designed for the matrix, may or may not require clean-up before the final colorimetric determination. The methods are specific and measure the sum of the spinosyns and their metabolites. When the HPLC and immunoassay methods were tested side-by-side, the agreement was usually good. The LOQ for most substrates is 0.01 mg/kg.

Results of supervised trials on crops

The OECD 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 OECD 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 provided.

Blueberries

The Meeting received data for blueberries from supervised trials conducted in the USA and Australia. The Australian trial did not conform to Australian GAP (1-day PHI) and was not considered further.

The GAP in the USA consists of up to 6 applications at 105 g ai/ha (for a total seasonal maximum of 504 g ai/ha) and a PHI of 3 days. The residues that correspond to USA GAP are in ranked order (n = 5): 0.041, 0.084, 0.11, 0.16, and 0.18 mg/kg. The Meeting estimated a maximum residue level of 0.4 mg/kg for spinosad on blueberries. The STMR is 0.11 mg/kg.

Cranberry

Data on cranberries were reviewed by the JMPR in 2008. However, the Meeting decided that since none of the trials matched any GAP available at that time, no estimate could be made for a maximum residue level for spinosad in cranberries. The GAP in the USA has since changed and the same trials are now re-evaluated against the new GAP.

Six supervised trials were conducted in the USA and Canada in 1999, according to maximum GAP of the USA (three foliar applications at 175 g ai/ha with a PHI of 21 days).

All residue values were < 0.01 mg/kg. The Meeting estimated an MRL for spinosad on cranberry of 0.02 mg/kg. The STMR is 0.01 mg/kg.

Raspberries

The Meeting received data from supervised trials on raspberries, conducted in the USA, Switzerland and the UK.

The GAP in the USA is up to 6 applications at a rate of 105g ai/ha (or a seasonal maximum of 504 g ai/ha) and a PHI of 1 day. Spinosad residues in raspberries in US trials conducted according to USA GAP were 0.07 and 0.42 mg/kg and in one trial on boysenberries residues were 1.8 mg/kg.

Four supervised trials on raspberries (two in Switzerland and two in the UK) were conducted during 2007 according to the GAP in Belgium, which is up to 2 applications at 9.6 g ai/hL and a PHI of 3 days.

The ranked order of residues from supervised trials in Switzerland and the UK according to GAP was: < 0.01, 0.14, 0.14 and 0.42 mg/kg.

Although residues were higher in trials from the USA, the Meeting considered that there were an insufficient number of trials to recommend a maximum residue level for raspberries. Using the trials from Europe matching the GAP of Belgium the Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.14 mg/kg and agreed to extrapolate these estimates to dewberries and blackberries.

Papaya

As part of the Pesticide Initiative Project field trials from Côte d'Ivoire and Ghana were conducted where spinosad was applied as foliar sprays to papaya (3 × 96g ai/ha with intervals of 56 and 77 days).

Residues observed in rank order at a 3 day PHI were;

- after the first application: <0.01, 0.012, 0.085, 0.12, 0.15, 0.23 mg/kg,
- after the second application: 0.023, 0.029, 0.13, 0.14, 0.15, 0.17 mg/kg
- and after the last application: 0.012, 0.019 mg/kg.

While the application conditions for the trials were based on the requirement for appropriate control of pests, they were not supported by an official label or an official declaration of approved use. In the absence of evidence for an approved GAP, the Meeting could not estimate a maximum residue level for spinosad in papaya.

Passionfruit

Three supervised trials were conducted in Kenya during 2005/2006 and two in 2007 matching the Kenyan GAP (96g ai/ha with a 1-day PHI and with the number of applications not specified).

The ranked order of residues from supervised trials complying with GAP was: 0.080, 0.11, 0.23, 0.33 and 0.33 mg/kg. The Meeting estimated a MRL for spinosad on passionfruit of 0.7 mg/kg. The STMR is 0.23 mg/kg.

Onions, bulb

The Meeting received a total of twenty supervised trials on bulb onions from France (9), Italy (4), the UK (2), Brazil (3) and New Zealand (2) and eleven on spring onions from France (5), Germany (2),

Italy (1) and the USA (3). As there is no GAP for onions in New Zealand, the data from that country was not considered further. For the other countries the GAP for onions is applicable to both bulb and spring (green) onions.

The GAP in Brazil for bulb onions is up to 3 applications at 96 g ai/ha with a PHI of 1 day. Residues from trials according to the GAP were below the LOQ of 0.01 mg/kg (n = 3).

The GAP in France is 2 applications at 96 g ai/ha and a PHI of 7 days.

Residues in bulb onions from trials from the UK, France and Italy, approximating GAP from France (n = 15) are: < 0.01(10), 0.02, 0.03, < 0.05(3) mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg for spinosad in bulb onions. The STMR is 0.01 mg/kg.

Spring onions

The Meeting received data from eleven supervised trials conducted on spring onions in USA and France, Germany and Italy.

In France GAP for onions is 2 applications of spinosad at 96 g ai/ha and a PHI of 7 days. Residues in spring onions from trials from France, Germany and Italy approximating GAP of France in ranked order (n = 8) were: < 0.01 (3), 0.01, 0.01, 0.02, 0.03 and 0.11 mg/kg.

The GAP in the USA is up to 5 applications at a maximum rate of 140 g ai/ha (maximum seasonal rate of 504 g ai/ha) and a PHI of 1 day. The residues from the USA trials in ranked order were: 0.11, 0.2 and 1.5 mg/kg.

As residues in trials matching the GAP of the USA would lead to the higher maximum residue level the Meeting used the data from the USA trials to estimate a maximum residue level of 4 mg/kg for spinosad in spring onions. The STMR is 0.2 mg/kg.

Okra

Field trials on okra from Côte d'Ivoire were conducted within the Pesticide Initiative Project aiming to provide data for establishing import MRLs in the European Union. Spinosad was applied as foliar sprays to okra (1 or 2 applications of spinosad at 160 g ai/ha at a 14-day interval and a PHI of 2 days). The residues at two days after the last application were 0.05, 0.35, and 0.61 mg/kg.

While the application conditions for the trials were based on the requirement for appropriate control of pests, they were not supported by an official label or an official declaration of approved use. In the absence of evidence of an approved GAP, the Meeting could not estimate a maximum residue level for spinosad in okra.

Green beans

Three supervised trials were conducted in Kenya and Senegal, but did not match the GAP of Kenya (96 g ai/ ha and a PHI of 1 day). Consequently, the Meeting was unable to estimate a maximum residue level, HR or STMR.

Tree nuts

Almonds

Data from supervised trials on almonds conducted in the USA (GAP of 180 g ai/ha with a PHI of 14 days) were reviewed by the 2001 JMPR and Codex MRLs of 0.01* mg/kg for nutmeat and 2 mg/kg for almond hulls have been established. The GAP has since changed and new trials were evaluated by the Meeting.

The new GAP for almonds in the USA is up to 3 applications at a maximum rate of 175 g ai/ha with a PHI of 1 day. Supervised trials on almonds were conducted in the USA that matched the revised GAP. Residues of spinosad in almond nutmeat were in rank order: < 0.01, < 0.02, < 0.02, 0.032, 0.044, and 0.047 mg/kg.

Pecans

The Meeting received data from four trials conducted on pecans in the USA, however the trials did not match the new US GAP.

Walnuts

Data were received from two supervised trials conducted in Italy. The GAP for tree nuts in Italy is up to 3 applications at a rate of 216 g ai/ha with a PHI of 7 days. Residues corresponding to GAP were below the LOQ of 0.005 (2) mg/kg. The Meeting considered two trials to insufficient to estimate a maximum residue level for walnuts.

The Meeting agreed to use the data on almonds from the USA to estimate a maximum residue level of 0.07 mg/kg for tree nuts and an STMR of 0.026 mg/kg. The recommendation replaces the previous recommendation of 0.01* mg/kg for almonds.

Hops, dry

Two supervised trials were conducted on basil in the USA. The data were provided to support a maximum residue level for hops. The Meeting agreed that data for basil were not relevant for hops.

Animal feed commodities

Almond hulls

Residues of spinosad in almond hulls from trials conducted according to the GAP of the USA in ranked order were: 0.62, 0.76, 0.95, 3.5, 4.5 and 5.1 mg/kg. The median residue is 2.23 mg/kg. The Meeting considered that almond hulls are not traded and agreed to withdraw its previous recommendation of 2 mg/kg for almond hulls.

Residues in animal commodities

Almond hulls are the only commodity in the present evaluation which can be considered as a beef and dairy cattle feed item and are not consumed by poultry. Maximum and mean dietary burdens for beef and dairy cattle were recalculated to determine if the resulting higher residues on almond hulls from the updated USA GAP would change the dietary burdens previously estimated by JMPR. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

The increased residue levels for almond hulls do not change the previously estimated maximum dietary burden of spinosad in cattle and the corresponding previous recommendations on animal commodities will remain the same.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of spinosad resulted in recommendations for new MRLs and STMR values for raw and processed commodities. Data on consumption were available for 71 food commodities from this and previous evaluations and were used to calculate dietary intake. The results are shown in Annex 3.

The IEDIs in the five GEMS/Food regional diets, based on estimated STMRs were 10–40% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that long-term intake of residues of spinosad from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2001 JMPR concluded that it was unnecessary to establish an ARfD for spinosad. The Meeting therefore concluded that short-term dietary intake of spinosad residues is unlikely to present a risk to consumers.