5.29 SPINETORAM (233)

RESIDUE AND ANALYTICAL ASPECTS

Spinetoram belongs to the class of spinosyn insecticides obtained from chemical modification of the fermentation product of *Saccharopolyspora spinosa.* It consists of two closely related active ingredients (XDE-175-J and XDE-175-L) present approximately in a three to one ratio.

It was first evaluated by the 2008 JMPR which established an ADI of 0–0.05 mg/kg bw and decided that an ARfD is unnecessary. The 2008 Meeting estimated 11 maximum residue levels on a basis of the following residue definition.

Definition of the residue (for compliance with the MRL): *Spinetoram*.

Definition of the residue (for estimation of dietary intake): *Spinetoram and N-demethyl and N-formyl metabolites of the major spinetoram component*.

The residue is fat-soluble.

Note: Spinetoram consists of two related components.

At the Forty-third Session, the CCPR included spinetoram in the Priority List for additional MRLs. The current Meeting received information on supervised trials on additional crops in support of additional maximum residue levels.

Methods of analysis

The analytical methods used in the supervised trials provided to the current Meeting were already reviewed by the 2008 JMPR to be satisfactorily validated. These methods had been developed for the determination of residues of XDE-175-J and XDE-175-L and their metabolites N-demethyl-175-J and -L, N-formyl-175-J and -L in plant matrices using HPLC with positive-ion electron-spray (ESI) tandem mass spectrometry (LC-MS/MS).

Procedural recoveries in the analysis of commodities for which supervised trial data were submitted to the current Meeting were available. The mean recovery ranged from 73% to 111% except that the mean recovery of N-formyl-J in blueberry which was 64%. The relative standard deviations were all < 20%, where it could be calculated.

Stability of pesticide residues in stored analytical samples

The 2008 JMPR concluded that at -20 ºC, spinetoram and its N-demethyl and N-formyl metabolites were stable for about 12 months (372 days) in orange, sugar beet, soya bean and wheat. The storage periods of samples in the supervised trial studies were mostly within 372 days or only slightly longer.

Results of supervised residue trials on crops

The Meeting received information on supervised field trials of spinetoram on citrus fruits, stone fruits, berries and other small fruits, bulb vegetables, Brassica vegetables, common beans, spinach and celery.

For all analytes and matrices, the LOQ was 0.01 mg/kg. The LOD was reported to be 0.003 mg/kg for trials conducted in the USA and 0.005 mg/kg for trials conducted in Australia.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive 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, a brief explanation of the derivation was supplied.

Citrus fruits

There is an existing CXL of 0.07 mg/kg for oranges (sweet, sour) estimated by the 2008 JMPR on the basis of supervised trials in the USA conducted according to US GAP (3 applications of a maximum rate of 103 g ai/ha for a total seasonal rate of 210 g ai/ha and a PHI of 1 day). Additional trials conducted on oranges and tangerines in Brazil were submitted in support of a group MRL on citrus fruits.

Orange

Twelve supervised trials on oranges were conducted in the USA between 2004 and 2007 following the US GAP for citrus fruits (maximum rate of 103 g ai/ha, three applications, maximum seasonal rate of 210 g ai/ha, PHI one day). They were reviewed by the 2008 JMPR and regarded as six valid trials. While there were six valid trial results, the 2008 Meeting concluded that since each of the trials was conducted using low (approximately 700 L/ha) and high (approximately 3300 L/ha) spray volume and resulting in similar residue situation, two data sets from the two different spray volume applications were considered mutually supportive.

Residues of spinetoram in oranges from trials in the USA conducted following US GAP for citrus fruits were re-evaluated by the current Meeting. In rank order they were: < 0.01, 0.011, 0.018, 0.021, 0.027 and 0.029 mg/kg.

Corresponding total residues of spinetoram and the two metabolites for estimation of STMR in ranked order were: 0.022, 0.038, 0.039, 0.046, 0.061 and 0.062 mg/kg.

Four supervised trials on oranges were carried out in Brazil in 2004 with three applications at the spray concentration of 2.3–14 g ai/hL, corresponding to the application rate of 70 g ai/ha or 140 g ai/ha for a total seasonal rate of 210 g ai/ha. The registered use in Brazil for citrus fruits allows the maximum of three applications of 20–40 hL/ha at 1.25–2.5 g ai/hL with a PHI of 1 day.

Residues of spinetoram in oranges from one trial in Brazil conducted following GAP in Brazil were < 0.01 mg/kg and corresponding total residues were < 0.02 mg/kg.

Tangerine

A total of eight supervised trials on tangerines were carried out in Brazil in 2006 with 3 applications at the spray concentration of 3.5–7 g ai/hL, corresponding to the application rate of 70 g ai/ha for a total of 210 g ai/ha per season.

No trials conducted in Brazil matched the GAP of Brazil.

As for the trials conducted on oranges in Brazil, only one trial matched the GAP in Brazil. The Meeting decided to maintain the previous recommendation of 0.07 mg/kg for oranges, sweet, sour.

Stone Fruits

The 2008 JMPR reviewed information on the supervised field trial data on apricot, cherries, nectarine and peach conducted in Australia and New Zealand and decided that since no approved GAP was available, no maximum residue level could be recommended for spinetoram in stone fruits. The GAPs in Australia and New Zealand have since been approved.

In addition, supervised trials on stone fruits were also available from Chile, Argentina, Japan and Europe.

A total of 23 supervised trials were conducted in Australia during the 2005–2006 season (four on apricot, eight on cherry, four on nectarine and seven on peaches). Each plot was treated with 4 or 7 applications at a spray concentration of 5 g or 7.5 g ai/hL. The registered use of spinetoram in Australia for stone fruits allows a maximum of four applications at a spray concentration of 2.5–5 g ai/hL with a PHI of 3 days. However, in all of the trials conducted, samples were not taken 3 days

after the last application (taken 0 day, 7 days and later after the last application). Therefore, the results of these trials could not be used for estimating maximum residue levels.

A total of 28 supervised trials were conducted in New Zealand during the 2005-2006 season (eight on apricot, 12 on cherry and eight on peach). Four applications were made to each plot at rates of 2.5 g ai/hL, 3.7 g ai/hL, 5 g ai/hL or 7.6 g ai/ha.

Apricot

Residues of spinetoram in apricot from trials in New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.078 and 0.11 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.11 and 0.14 mg/kg.

One trial was conducted in Chile in which two applications were made to apricot trees at the spray concentration of 3.6 g ai/hL corresponding to the application rate of 75–79 g ai/ha. There was no GAP available for apricot in Chile or Argentina.

Cherries

Residues of spinetoram in cherries from trials in New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.036, 0.055 and 0.067 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were: 0.062, 0.078 and 0.10 mg/kg.

One trial was conducted in Chile during 2007. In this trial, cherry trees were treated with two applications at the spray concentration of 3.6 g ai/hL corresponding to the rate of 78 g ai/ha. There is no GAP in Chile or in Argentina for cherries.

Nectarine

Two supervised trials were conducted in Argentina during 2008, and one trial in Chile in 2007. The trials in Argentina used 3 applications at a spray concentration of 4 g ai/hL resulting in a rate of 71–75 g ai/ha and a PHI of 1 day. The registered use in Argentina for nectarine allows a maximum of 3 applications at a spray concentration of 3.75–5 g ai/hL with the minimum application rate of 60 g ai/ha and a PHI of 1 day.

The trial in Chile used two applications at a spray concentration of 4 g ai/hL corresponding to a rate of 72 g ai/ha. There is no current GAP for nectarine in Chile. However, the trial was conducted at the same rate as the trials in Argentina with 2 applications instead of three applications. As the decline studies on stone fruits indicate that the contribution of earlier applications (interval of 14 days between applications) to the residues of spinetoram in harvested fruits was insignificant (on average no more than 20%), the Meeting decided to use the residue result from this trial.

Residues of spinetoram in nectarine from trials in Argentina and Chile conducted in accordance with GAP in Argentina in rank order were: 0.012, 0.013 and 0.072 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.022, 0.023 and 0.082 mg/kg.

Peach

Four trials were conducted in Argentina and two in Japan. Trials were also conducted on peaches in Spain (4), France (6), but no registration has yet been granted in Europe.

Residues of spinetoram in peach from trials in New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.026 and 0.084 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.041 and 0.12 mg/kg.

In four supervised trials conducted in Argentina during 2007 and 2008, 3 applications were made at a spray concentration of 3.75 g ai/ hL resulting in the rate of 75 g ai/ha. The registered use in Argentina for peach is identical to that for nectarine, i.e., a maximum of 3 applications at a spray concentration of 3.75–5 g ai/ha with the minimum application rate of 60 g ai/ha and a PHI of 1 day.

The trial in Chile used 3 applications at the spray concentration of 6 g ai/hL resulting in a rate of 108 g ai/ha. There is no current GAP for peach in Chile but this trial was matching GAP in Argentina.

Residues of spinetoram in peach from trials in Argentina and Chile conducted in accordance with GAP in Argentina in ranked order were: 0.021, 0.039, 0.050, 0.068 and 0.14 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.031, 0.049, 0.060, 0.078 and 0.17 mg/kg.

Two supervised trials were conducted in Japan during 2006 with 2 applications at the spray concentration of 5 g ai/ha. The registered use in Japan for peach allows two applications at 2.5–5 g ai/hL and 20–70 hL/ha and a PHI of 1 day.

Residues of spinetoram in peach from trials in Japan conducted in accordance with GAP in Japan in ranked order were: 0.20 and 0.27 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.27 and 0.35 mg/kg.

A total of ten supervised trials were conducted in Southern Europe on different varieties of peaches during 2006 and 2007 with 3 or 4 applications at the spray concentration of 8–11 g ai/hL corresponding to 97–102 g ai/ha. Spinetoram is yet to be registered in Europe.

Plum

Eleven supervised trials were carried out in France (6), Germany (4) and Italy (1) during 2007 and 2008. Each treated plot received 3 or 4 applications at the spray concentrations of 10–13 g ai/hL resulting in rates of 98–109 g ai/ha. Spinetoram is yet to be registered in Europe.

One trial was conducted in Chile. Two applications at spray concentration of 4 g ai/hL corresponding to 72 g ai/ha were made. There is no GAP in Chile or in Argentina for plum.

Summary for stone fruits

Data sets for individual stone fruits from trials matching GAP were not sufficient for estimating individual maximum residue levels for them as shown below.

Commodity	Trials conducted in	Residues, mg/kg
Trials matching GAP of Australia		
Apricot	New Zealand	0.078, 0.11
Cherries	New Zealand	0.036, 0.055, 0.067
Peach	New Zealand	0.026, 0.084
Trials matching GAP of Argentina		
Nectarine	Argentina/Chile	0.012, 0.013, 0.072
Peach	Argentina/Chile	0.021, 0.039, 0.050, 0.068, 0.14
Trials matching GAP of Japan		
Peach	Japan	0.20, 0.27

Among these data sets from four different countries, residues in the Japanese trials on peach were significantly higher than those from the trials conducted in other countries. However, the data from Japanese trials were considered insufficient to estimate a maximum level.

While GAP in Australia was for stone fruits, the number of trials on each crop matching Australian GAP was not sufficient to estimate a maximum residue level for individual commodities or for the stone fruit group.

The Meeting decided to use the results of trials conducted on nectarine and peach in Argentina and Chile matching GAP of Argentina to estimate maximum residue levels for nectarine and peach.

Combined residues, in rank order, were (n=8): 0.012, 0.013, 0.021, 0.039, 0.050, 0.068, 0.072 and 0.14 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.022, 0.023, 0.031, 0.049, 0.060, 0.078, 0.082 and 0.17 mg/kg.

The Meeting estimated a maximum level of 0.3 mg/kg and an STMR of 0.055 mg/kg for both nectarine and peach.

Berries and other small fruits

Raspberries

Six supervised trials were conducted in the USA during 2010. Each treated plot received 4 applications at 25–105 g ai/ha of a 250 WG formulation of spinetoram. The total treatment for the season was 324–330 g ai/ha. The registered use in the USA for caneberries including raspberry allows up to 6 applications at 53–105 g ai/ha for a seasonal maximum of 342 g ai/ha and PHI of 1 day. Although the number of applications in the trials was four while the GAP allows up to six applications, the decline data show that contribution of the two earlier applications to the residues in harvested fruits was negligible.

Residues of spinetoram in raspberry from trials in the USA conducted in accordance with US GAP, in ranked order, were: 0.034, 0.17, 0.18, 0.26, 0.32 and 0.42 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.057, 0.21, 0.32, 0.51, 0.55 and 0.78 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg and STMR of 0.42 mg/kg for raspberries, red, black.

Blueberries

Six supervised trials were conducted on blueberries during 2010 in the USA. Each treated plot received 4 applications at 25–104 g ai/ha of a 250 WG formulation of spinetoram. The total treatment for the season was 327–330 g ai/ha. The registered use in the USA for blueberry allows up to 6 applications at 53–105 g ai/ha for a seasonal maximum of 342 g ai/ha and PHI of 3 days. Although the number of applications in the trials was four while the GAP allows up to six applications, the decline data show that contribution of the two extra earlier applications to the residues in harvested fruits was insignificant.

Residues of spinetoram in blueberry from trials in the USA conducted in accordance with US GAP, in ranked order, were: 0.049, 0.050, 0.053, 0.056, 0.069 and 0.080 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.10, 0.11, 0.11, 0.13, 0.16, and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and STMR of 0.12 mg/kg for blueberries.

Grapes

Eight supervised trials, four in France and four in Italy, were conducted during 2007 and 2008. The trials in Italy used 3 applications at 6–7 g ai/hL while those in France 4 applications from 4.5 to 5 g ai/hL. While registration of spinetoram is yet to be granted in these countries, the registered use in Turkey for grapes allows spray concentration of 4–6 g ai/hL with a PHI of 7 days. There was no description of maximum number of applications on the label.

One trial was conducted in Chile during 2008, in which 2 applications of 250 WG spinetoram were made at 60 g ai/ha. There is no GAP for grapes in Chile.

Residues of spinetoram in grapes from trials in France and Italy conducted in accordance with the GAP in Turkey, in ranked order, were: < 0.01, 0.018, 0.029, 0.039, 0.081, 0.096, 0.097 and 0.17 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: < 0.02, 0.028, 0.039, 0.049, 0.098, 0.11, 0.14 and 0.23 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and STMR of 0.074 mg/kg for grapes.

Bulb vegetables

Onion, bulb

Eight trials were conducted on bulb onions during 2007 in Brazil. Onion plants were treated 4 times with spinetoram at the rate of 62.5 g ai/ha for a seasonal total of 250 g ai/ha. The trials were carried out according to the US GAP as the proposed label for Brazil had not yet been approved. The US GAP for bulb vegetables allows up to five applications at 44–88 g ai/ha for a maximum seasonal rate of 263 g ai/ha with a PHI of 1 day. As there was no residue expected to be found in onion bulb and there was no significant translocation of spinetoram occurring in plant, the Meeting agreed to evaluate the residue data of onion bulb from trials in Brazil against US GAP.

Residues of spinetoram in onion bulb from trials in Brazil conducted in accordance with US GAP in ranked order were: < 0.01 (8) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: < 0.02 (8) mg/kg. However, as residues of the four components were below the limit of detection except that the major component of spinetoram (XDE-175-J) was found < 0.01 mg/kg on 1 day after the last application in two trials only, the Meeting concluded that in the case of onion, bulb, it was more appropriate to use < 0.01 mg/kg rather than < 0.02 mg/kg for total residue concentrations.

The Meeting therefore estimated a maximum residue level of 0.01* mg/kg and STMR of 0.01 mg/kg for onion, bulb.

Welsh onions and spring onion

Two supervised trials on Welsh onions were conducted in Japan during 2006. Each treated plot received 2 applications of spinetoram of 20 hL/ha at the spray concentration of 4.8 g ai/hL resulting in the application rate of 96 g ai/ha. The registered use in Japan for Welsh onion allows 2 applications of 10–30 hL/ha at the spray concentration of 4.8 g ai/hL with a PHI of 1 day.

Residues of spinetoram in Welsh onion from trials in Japan complying with GAP in Japan, in ranked order were: 0.10 and 0.13 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.12 and 0.20 mg/kg.

Six field trials were conducted in the USA on green onion during 2010 and 2011. Each treated plot received three applications of spinetoram at the rate of 87–92 g ai/ha (total seasonal rate of 262–268 g ai/ha). The registered use in the USA for bulb vegetables allows up to 5 applications at 44–87 g ai/ha with the maximum seasonal rate of 262 g ai/ha with a PHI of 1 day.

Residues of spinetoram in green onion from trials in the USA conducted in accordance with US GAP, in ranked order were: 0.029, 0.042, 0.066, 0.094, 0.10 and 0.43 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.13, 0.18, 0.22, 0.40, 0.42 and 0.86 mg/kg.

Based on the results of trials conducted in the USA, the Meeting estimated a maximum residue level of 0.8 mg/kg and STMR of 0.33 mg/kg for spring onion and Welsh onion.

Brassica vegetables

Numerous trials on Brassica vegetables were conducted during 2009 in Australia (10 on broccoli, 10 on cabbage, and one each on cauliflower and Brussels sprouts). One trial each for broccoli, cauliflower, cabbage, and Brussels sprouts were conducted in New Zealand. In one set of trials, spinetoram was applied once at a target rate of 35 g ai/ha, followed by three applications at 7 day intervals at a target rate of 88 g ai/ha, for a seasonal total of about 300 g ai/ha. The other set of trials used 4 applications at target rates of 18, 24, and 36 g ai/ha. The GAP in Australia allows 4 applications of spinetoram at the rate of 24–48 g ai/ha and a PHI of 3 days.

In the trials conducted in Australia and New Zealand, concentrations of spinetoram and total concentrations of spinetoram and the two metabolites were reported. As for the latter, the calculation method was clearly different from that of JMPR as the value of 0.01 mg/kg was reported.

Broccoli

In three trials the actual application rates were up to on average 77% of the maximum GAP rate. In other trials the application rates of last three applications were on average 1.9 times the maximum GAP rate. As the number of trials conducted with the application rate within ± 25% of the maximum GAP rate was three, the Meeting decided to use proportionality approach for estimating residues at the maximum GAP rate; i.e., multiplying the highest residue at PHI in each trial by a relevant scaling factor.

Scaled residues of spinetoram in broccoli from trials in Australia and New Zealand, in ranked order were (n=7)(residues found in the trials and scaling factor in parentheses): 0.022 (0.04 × 48/86), 0.026 (0.02 × 48/37) , 0.031 (0.06 × 48/92), 0.045 (0.09 × 48/91), 0.052 (0.10 × 48/92), 0.16 (0.08 × 48/24) and 0.17 (0.09 × 48/26) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.033 (0.06 × 48/86), 0.052 (0.10 × 48/92), 0.058 (0.03 × 48/25), 0.063 (0.12 × 48/91), 0.073 (0.14 × 48/92), 0.16 (0.08 × 48/24) and 0.18 (0.10 × 48/26) mg/kg.

Cauliflower

Residues of spinetoram in cauliflower from trials in Australia and New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.01 and 0.10 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.01 and 0.11 mg/kg.

Cabbages, Head

In three trials the application rates were on average 81% of the maximum GAP rate. In other trials the application rates of last three applications were on average 1.9 times the maximum GAP rate. As the number of trials conducted with the application rate within ± 25% of the maximum GAP rate was three, the Meeting decided to use proportionality approach for estimating residues at the maximum GAP rate; i.e., multiplying the highest residue at PHI in each trial by a relevant scaling factor.

Scaled residues of spinetoram in broccoli from trials in Australia and New Zealand in ranked order were (n=7)(residues found in the trials and scaling factor in parentheses): < 0.013 (< 0.01 × 48/37), 0.011 (0.02 × 48/90), 0.011 (0.01 × 48/43), 0.016 (0.03 × 48/88), 0.026 (0.02 × 48/37), 0.034 (0.06 × 48/84) and 0.063 (0.12 × 48/92) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.011 (0.02 × 48/90), 0.022 (0.04 × 48/88), 0.026 (0.02 × 48/37), 0.033 (0.03 × 48/43), 0.051 (0.09 × 48/84), 0.052 (0.04 × 48/37) and 0.10 (0.20 × 48/92) mg/kg.

Two supervised trials on cabbage were conducted in Japan during 2006. Each treated plot received 2 applications of 20 hL/ha at the spray concentration of 4.8 g ai/hL resulting in the rate of 96 g ai/ha.

Residues of spinetoram in cabbage from trials in Japan conducted in accordance with GAP in Japan in ranked order were: 0.03 and 0.14 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.05 and 0.15 mg/kg.

Brussels sprouts

Residues of spinetoram in Brussels sprout from trials in Australia and New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.02 (2) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.02 and 0.03 mg/kg.

Summary for Brassica vegetables

Data sets for individual brassica vegetable commodities from trials matching GAP were not sufficient for estimating individual maximum residue levels for them.

Residues in these commodities from trials conducted in Australia and New Zealand matching GAP of Australia, and scaled residues are as follows for these commodities.

Commodity	Trials conducted in	Residues, mg/kg
Broccoli	Australia, New Zealand (scaled)	0.022, 0.026, 0.031, 0.045, 0.052, 0.16, 0.17
Cauliflower	Australia, New Zealand	0.01, 0.10
Cabbage	Australia, New Zealand (scaled)	< 0.013, 0.011, 0.011, 0.016, 0.026, 0.034, 0.063
Brussels sprout	Australia, New Zealand	0.02, 0.02

As the residue concentrations in broccoli, cauliflower, cabbage and Brussels sprout from trials in Australia and New Zealand were not significantly different, and the GAP in Australia is for Brassica vegetables, the Meeting considered estimating a maximum residue level for Brassica vegetables.

The residues in broccoli, cauliflower, cabbage and Brussels sprout from trials in Australia and New Zealand were considered together.

The combined residues of spinetoram in broccoli, cauliflower, cabbage and Brussels sprout from trials in Australia and New Zealand in ranked order were (n=18): < 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.022, 0.03, 0.03, 0.03, 0.03, 0.04, 0.05, 0.06, 0.10, 0.16 and 0.17 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were (n=18): 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.03, 0.03, 0.05, 0.05, 0.05, 0.06, 0.06, 0.07, 0.10, 0.11, 0.16 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and STMR of 0.05 mg/kg for Brassica vegetables.

For the purpose of calculating animal dietary burden on a basis of spinetoram residues in cabbage leaves, the Meeting estimated a highest residue of 0.063 mg/kg and median residue of 0.016 mg/kg.

Spinach

Six supervised field trials were conducted during 2010 in the USA. Each treated plot received four applications of spinetoram at the target rate of 35 g ai/ha for the first application and 87 g ai/ha for the second through fourth applications. The registered use in the USA for leafy vegetables allows up to 6

applications at the rate of 43–87 g ai/ha with the maximum seasonal rate of 300 g ai/ha and a PHI of 1 day.

Residues of spinetoram in spinach from trials in the USA conducted in accordance with US GAP, in ranked order were: 0.28, 0.36, 0.75, 0.80, 3.6 and 3.7 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.52, 0.82, 1.5, 1.7, 6.6 and 7.3 mg/kg.

The Meeting estimated a maximum residue level of 8 mg/kg and STMR of 1.6 mg/kg for spinach.

Common beans

Eight greenhouse trials were conducted in Brazil during 2006. For each of the sites, four applications of a 250 WG formulation of spinetoram were made to French beans at the rate of 50 g ai/ha for a seasonal total of 200 g ai/ha.

The GAP has not yet been approved in Brazil. The closest GAP that matched these trials is the GAP in USA (total seasonal rate of 245 g ai/ha and a PHI of 3 days). Since the label in the USA does not preclude greenhouse use, the Meeting decided to evaluate the results of greenhouse trials conducted in Brazil against the US GAP.

Residues of spinetoram in French beans from trials in Brazil matching US GAP, in ranked order were: < 0.01 (2), 0.014, 0.014, 0.016, 0.017 and 0.030 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: < 0.02 (2), 0.024, 0.024, 0.026, 0.027 and 0.040 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and STMR of 0.024 mg/kg for common bean (pods and/or immature seeds). The Meeting agreed to extend the maximum residue level and STMR to beans, except broad bean and soya bean (green pods and immature seeds).

Celery

Eight supervised field trials on celery were conducted in the USA. Each treated plot received four applications of spinetoram at the target rate of 35 g ai/ha for the first application and 87 g ai/ha for the second through fourth applications. The registered use in the USA for celery allows up to six applications at the rate of 44–88 g ai/ha with the maximum total seasonal application of 300 g ai/ha and a PHI of 1 day. In trials the number of application was four, different from six specified as the maximum in GAP. The decline data indicate that only the last application contributes significantly to residues in harvested celery.

Residues of spinetoram in celery from trials in the USA conducted in accordance with US GAP in ranked order were: 0.024, 0.086, 0.10, 0.16, 0.18, 0.19, 2.6 and 3.0 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.097, 0.17, 0.22, 0.29, 0.31, 0.73, 5.0 and 5.3 mg/kg.

The Meeting estimated a maximum residue level of 6 mg/kg and STMR of 0.30 mg/kg for celery.

Residues in animal commodities

Farm animal dietary burden

The commodities for which maximum residues were estimated by the current Meeting include cabbage which can be used as feed. Since the contribution of cabbage in feed of cattle or other mammals is insignificant, the Meeting did not re-calculate dietary burden for cattle.

Calculated dietary burdens for layer are shown below.

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

	US-Canada		EU		Australia		Japan	
	max	mean	max	Mean	max	mean	Max	mean
Layers	0	0	0.043 [a]	0.029 [b]	0	0	0	0

[a] Suitable for estimating maximum residue levels for meat, fat and edible offal of poultry and eggs.

[b] Suitable for estimating STMRs for meat, fat and edible offal of poultry and eggs.

Residues in poultry tissues and eggs

No information was available on a poultry feeding study.

The maximum burden for layers was calculated to be 0.043 ppm and mean burden was 0.029 ppm. The dose level used in the metabolism study on laying hens was 10 ppm in the diet. The concentration of spinetoram found was the highest in abdominal fat at 1.37 mg/kg, followed by 0.78 mg/kg in skin with fat, 0.11 mg/kg in eggs, 0.11 mg/kg in liver and 0.048 mg/kg in muscle. The metabolites included in the residue definition were not identified or found at lower concentrations than the parent.

At 0.043 ppm dietary burden, the concentration of spinetoram was calculated to be 0.005 mg/kg in abdominal fat and significantly lower in muscle, liver and eggs. The Meeting estimated a maximum residue level of 0.01* mg/kg for poultry meat, poultry fats, edible offal of poultry, and eggs; and an STMR of 0.01 mg/kg for poultry fats, poultry meat, edible offal of poultry and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of spinetoram were calculated for the 13 GEMS/Food cluster diets using STMRs estimated by the Meeting in 2009 and 2012 (Annex 3). The ADI is 0–0.05 mg/kg bw and the calculated IEDIs were 0–1 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of spinetoram resulting from the uses considered by the 2009 and current JMPR is unlikely to present a public health concern.

Short-term intake

The 2008 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of spinetoram is unlikely to present a public health concern.