Short-term dietary exposure

The 2011 JMPR decided that an acute reference dose is unnecessary for saflufenacil. The Meeting therefore concluded that the short-term dietary exposure to residues of saflufenacil resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

5.34 SPINETORAM (233)

RESIDUE AND ANALYTICAL ASPECTS

Spinetoram is in the class of spinosyn insecticides obtained from chemical modification of 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. It also established the following residue definition for plant and animal commodities and recommended a number of MRLs:

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.

Spinetoram was subsequently reviewed by the 2012 Meeting for additional MRLs. The 2008 and 2012 Meetings estimated maximum residue levels for beans, except broad bean and soya bean (green pods and immature seeds); blueberries; Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead brassicas; celery; lettuce, head; eggs; grapes; lettuce, leaf; nectarine; Onion, bulb; onion, Welsh; oranges, sweet, sour; peach; pome fruits; raspberries, red, black; spinach; spring onion; sugar beet; tomato; tree nuts; edible offal, mammalian; meat (from mammals other than marine mammals); milk fats; milks; poultry fats; poultry meat; and poultry, edible offal of.

The current Meeting received information on analytical methods and 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, i.e., GRM 05.03 and GRM 05.04, were already reviewed by the 2008 JMPR to be satisfactorily validated. These methods determine 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).

The Meeting received more recent information on validation of analytical method GRM 05.03 for representative crops was provided to the current Meeting.

The mean recovery ranges from 70% to 110% and relative standard deviation was all < 20%.

Stability of residues in stored analytical samples

The 2008 JMPR over 12 months and concluded that spinetoram and its N-demethyl and N-formyl metabolites were stable for at least about 12 months (372 days) in orange, sugar beet, soya bean and wheat samples stored in deep freezer at -20 °C.

The results of a new study on frozen storage stability was provided to the current Meeting. The Meeting concluded that spinetoram and its N-demethyl and N-formyl metabolites were stable for at least about 2 years (744 days) in apple, melon and maize samples stored frozen at -20 °C.

Results of supervised residue trials on crops

The Meeting received information on supervised trials of spinetoram on citrus fruits, pome fruits, stone fruits, berry fruits and other small fruits, Assorted tropical fruits, bulb vegetables, Fruiting vegetables - Cucurbits, Fruiting vegetables-other than Cucurbits, pulses, root and tuber vegetables, cereal grains and oilseeds.

For all analytes and matrices, the LOQ was 0.01 mg/kg, except that for rice the LOQ was 0.02 mg/kg.

Spinetoram residues for estimation of maximum residues, and total residues of spinetoram, N-demethyl-J and N-formyl-J (hereafter, abbreviated as "total residues") for estimation of STMRs were calculated in the same manner as done by the 2008 and 2012 JMPR.

Where only spinetoram residues were analysed and reported, to estimate dietary exposure and animal dietary burden, conversion factors were used. Based on the available metabolism studies, appropriate conversion factors (CF=[N-demethyl-J]/[XDE-175-J] and CF=[N-formyl-J]/[XDE-175-J]) for N-demethyl-J and for N-formyl-J are: avocado, feijoa and tamarillo 0.091 and 0.03; kiwifruit and passionfruit 0.05 and 0.017; and sweet corn 0.072 and 0.148.

Where only XDE-175-J of spinetoram was analysed and reported, the following conversion factor was used to estimate XDE-175-L: 0.33.

Citrus fruits

Tangerine

Eight supervised trials on tangerines were carried out in Brazil in 2006 which were reviewed by the 2012 JMPR. Each site received 3 applications of a 250 WG formulation of spinetoram at the rate of 70 g ai/ha for a total of 210 g ai/ha per season. The GAP in Brazil is 3 applications at 25–100 g ai/ha spinetoram. The PHI is 1 day.

As no trials exactly matched the critical GAP with deviations in application rate, the Meeting decided to apply the scaling factor of 100/70 to the trial results to estimate the residue levels at the critical GAP rate of 100 g ai/ha (n=6).

Scaled spinetoram residues were (6): 0.026, 0.026, 0.037, 0.040, 0.054 and 0.064 mg/kg.

Corresponding total residues were (6): 0.40, 0.40, 0.052, 0.069, 0.076 and 0.079 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and STMR of 0.0605 mg/kg for the subgroup of mandarins, according to the Codex classification.

Pome fruits

Persimmon

Two residue trials on persimmon were conducted in New Zealand during 2012 (SFF11-053/200-01). Each treated plot received 4 applications of 120 SC spinetoram at a concentration of 2.4 g ai/hL and RTI of 14 days. The GAP in Australia consists of 4 applications at 4.8 g ai/hL, RTI of 14 days and a PHI of 0 day.

The spinetoram residues from trials after scaling to the critical GAP were in rank order (n=2): 0.020×4.8/2.4=0.040 and 0.022×4.8/2.4=0.044 mg/kg.

The Meeting considered that the existing Codex MRL for pome fruits (0.05 mg/kg) covers the residues of persimmon.

Stone fruits

Cherries

Twelve supervised trials were carried out in France (6), Spain (2), Italy (2), Germany (1) and Poland (1) during 2013 and 2014. Each treated plot received 2 applications of 250 WG spinetoram at a nominal rate of 75 g ai/ha and RTI of 28 days. The GAP in Italy allows 1 application at 100 g ai/ha, and a PHI of 7 days.

The decline trials indicate that residues arising from the first application will be well below the LOQ at the time of last application and therefore, the impact of the first application on the final residues was negligible.

Spinetoram residues from the trials approximating the GAP in Greece (only one application) were (12): < 0.01 (6), 0.011, 0.013, 0.015, 0.027, 0.028 and 0.069 mg/kg.

Corresponding total residues were (12): < 0.02 (6), 0.021, 0.034, 0.037, 0.038, 0.038 and 0.079 mg/kg.

The Meeting estimated a maximum residue level of 0.09 mg/kg and STMR of 0.0205 mg/kg for a subgroup of cherries.

Plums

Ten supervised trials were carried out in France (5), Spain (3) and Italy (2) during 2011. Each treated plot received 2 applications of 250 WG spinetoram at a nominal rate of 100 g ai/ha and RTI of 27-29 days. The critical GAP in Italy allows 1 application at 100 g ai/ha with a PHI of 7 days.

The decline trials indicate that residues arising from the first application will be well below the LOQ at the time of last application and therefore, the impact of the first application on the final residues was negligible.

Spinetoram residues from the trials approximating the GAP in Italy (only one application) were (10): < 0.01 (9) and 0.014 mg/kg. In addition, the 11 trials conducted in Europe in 2007 and 2008 and submitted to the 2012 JMPR in which 3 to 4 applications were made at a rate of around 100 g ai/ha can be evaluated against the GAP in Italy as the earlier applications do not have significant impact on the final residue. Residues were (11): < 0.01 (4), 0.012, 0.012, 0.013, 0.016, 0.016, 0.016 and 0.082 mg/kg. As these populations were not significantly different (Kruskal-Wallis H test), the Meeting evaluated the combined residue set (21): < 0.01 (13), 0.012, 0.012, 0.013, 0.014, 0.016, 0.016, 0.016 and 0.082 mg/kg.

Corresponding total residues were: < 0.02 (13), 0.022, 0.023, 0.024, 0.026, 0.026, 0.028, 0.036 and 0.118 mg/kg.

The Meeting estimated a maximum residue level of 0.09 mg/kg and STMR of 0.02 mg/kg for the subgroup of plums.

Apricot

Six supervised trials were carried out in Southern France (3), Spain (1), Greece (1) and Italy (1) during 2014. Each treated plot received 2 applications of 250 WG spinetoram at a nominal rate 100 g ai/ha and RTI of 22-32 days. The GAP in Italy consists of 1 application at 100 g ai/ha and a PHI of 7 days.

For the same reason as for cherries and plums, the Meeting utilized the results of trials using 2 applications.

Spinetoram residues from those trials were (6): < 0.01, 0.024, 0.035, 0.053, 0.069 and 0.078 mg/kg.

Corresponding total residues were: < 0.02, 0.045, 0.034, 0.063, 0.080 and 0.088 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and STMR of 0.0485 mg/kg for apricot.

Berries and other small fruits

Currants, Black, Red, White

Twelve supervised trials were carried out in France (6), the UK (3), Germany (2) and Italy (1) during 2013-2015 (Reports 130177, 140137 and 150595). Each treated plot received 2 applications of 25 SC

spinetoram at a nominal rate of 60 g ai/ha and RTI of 28 days. The GAP in the USA for bush berry (including currant and blue berry among others) allows 6 applications at 105 g ai/ha (seasonal maximum rate of 342 g ai/ha), RTI of 6 days and a PHI of 3 days. Decline trials indicate that residues 7 days after the first application were mostly less than 20% of those of the day of the first application and therefore, the Meeting used the results of these trials with 2 applications for estimating a maximum residue level after scaling to the GAP rate in the USA.

Scaling up to the GAP rate in the USA, spinetoram residues were (12): 0.017, 0.020, 0.061, 0.065, 0.13, 0.13, 0.13, 0.15, 0.17, 0.19, 0.20 and 0.31 mg/kg.

Corresponding total residues were (12): 0.043, 0.070, 0.11, 0.15, 0.17, 0.18, 0.18, 0.20, 0.22, 0.26, 0.27 and 0.35 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and STMR of 0.18 mg/kg for currants, black, red, white.

Strawberry

Eight outdoor supervised trials were carried out in Brazil during 2006/2007. Each treated plot received 4 applications of 250 WG spinetoram at a nominal rate of 50 g ai/ha. The GAP in Brazil consists of 4 applications at 50 g ai/ha (5 g ai/hL) and a PHI of 3 days.

Eight outdoor supervised trials were carried out in France (2), Spain (2), Italy (2), Bulgaria (1), and Greece (1) during 2012 and 2013. Each treated plot received 2 or 3 applications of 25 SC spinetoram at a nominal rate of 50 g ai/ha and RTI of 14–29. The GAP in Brazil consists of 4 applications at 50 g ai/ha and a PHI of 3 days. Decline trials demonstrate that only the final application significantly contributes to the final residue. No GAP is available from Europe.

Eight indoor trials were carried out in Netherlands (1), Germany (2), France (2), Greece (1), Spain (1), and Italy (1) during 2012 and 2013. Each treated plot received 3 applications of 25 SC spinetoram at a nominal rate of 50 g ai/ha and RTI of 12–14 days. The GAP in Brazil consists of 4 applications at 50 g ai/ha and a PHI of 3 days. Decline trials demonstrate that only the final application significantly contributes to the harvest residue.

Spinetoram residues in the trials following the GAP in Brazil were in mg/kg:

Outdoor trials in Brazil: < 0.01 (2), 0.011, 0.015, 0.017, 0.022, 0.024, 0.063.

Outdoor trials in Europe: < 0.01 (2), 0.012, 0.013, 0.015, 0.016 (2), 0.025.

Indoor trials in Europe: 0.014, 0.015, 0.016, 0.022, 0.026, 0.035, 0.065, 0.113.

These data populations were not significantly different (Kruskal-Wallis H test) and could be combined to estimate a maximum residue level. The Meeting estimated a maximum residue level of 0.15 mg/kg.

Corresponding total residues were: < 0.02 (4), 0.021, 0.022, 0.023, 0.024, 0.025, 0.025, 0.026, 0.026, 0.026, 0.027, 0.032, 0.032, 0.034(2), 0.035, 0.036, 0.045, 0.075, 0.11 and 0.14 mg/kg.

The Meeting estimated an STMR of 0.026 mg/kg.

Assorted tropical and sub-tropical fruits – edible peel

Olive

Eight supervised trials were carried out in Spain (4), Italy (4), during 2008, 2009 and 2011. Each treated plot received 2 applications of 250 WG spinetoram at a nominal rate of 25 g ai/ha and RTI of 21 days. The GAP in Greece consists of 2 applications at 25 g ai/ha, RTI of 28 days and a PHI of 21 days.

Spinetoram residues from those trials were (8): < 0.01 (7) and 0.045 mg/kg.

Corresponding total residue were: < 0.02 (7) and 0.055mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg and STMR of 0.02 mg/kg.

Assorted tropical and sub-tropical fruits – inedible peel

Litchi

Six supervised trials were carried out in Thailand during 2015. Each treated plot received 3 applications of 120 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 7 days. The GAP in Thailand for litchi consists of 3 applications at 60 g ai/ha and a PHI of 14 days.

Spinetoram residues from the trials matching the GAP in Thailand were (5): < 0.01 (4) and 0.011 mg/kg.

Corresponding total residues were: < 0.02 (4) and 0.061 mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg and STMR of 0.02 mg/kg for litchi.

Avocado

Three supervised trials were carried out in New Zealand during 2012 and 2013. Each treated plot received 4 applications of 120 SC spinetoram at 2.4 or 4.8 g ai/hL and RTI of 13–15 days.

Six supervised trials were carried out in Colombia during 2014. Each treated plot received 3 applications of 60 SC spinetoram at 60 g ai/ha and RTI 6–8 days.

The GAP in Australia allows up to 4 applications at 4.8 g ai/hL with an RTI of 7–14 days and a PHI of 0 days. Although samples were taken and analysed one DALA in most of the Colombian trials, a decline study indicates that there is no significant decline from 0 DALA to 1 DALA, the data from these trials were used for estimating a maximum residue level.

Spinetoram residues from the trials in New Zealand and Colombia matching the GAP in Australia after scaling to the GAP rate of 4.8 g ai/hL were (n=9) 0.020, 0.027, 0.030, 0.041, 0.052, 0.076, 0.090, 0.096 and 0.13 mg/kg.

Total residues in flesh were < 0.02 mg/kg (3). When the total residues in whole fruit was 0.217 mg/kg, those in flesh were < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and STMR of 0.02 mg/kg for avocado.

Feijoa

Three supervised trial was carried out in New Zealand in 2013. The treated plots received 3 or 4 applications of 120 SC spinetoram at 2.4 or 4.8 g ai/hL and RTI of 13–14 days. The GAP in New Zealand for feijoa (included in tropical and sub-tropical fruit with inedible peel) consists of 4 applications at 96 g ai/ha, 4.8 g ai/hL, RTI of 7-14 days and a PHI of 14 days.

Spinetoram residues from the independent trials matching the GAP in New Zealand were: < 0.01 mg/kg (1).

The Meeting concluded that the data were insufficient for estimating a maximum residue level.

Mango

Six supervised trials were carried out in six provinces in Thailand during 2013. Each treated plot received 3 applications of 250 WG spinetoram at a nominal rate of 60 g ai/ha and RTI of 7 days. The GAP in Thailand consists of 3 applications at 60 g ai/ha, RTI of 7 days and a PHI of 14 days.

Spinetoram residues from the trials matching the GAP in Thailand were: < 0.01 mg/kg (5). In another trial, residues of spinetoram were analysed on 0 DALA but were below the LOQ of 0.01 mg/kg in whole fruits.

Corresponding total residues were: < 0.02 mg/kg (5).

The Meeting estimated a maximum residue level of 0.01* mg/kg and STMR of 0.02 mg/kg.

Tamarillo

Three supervised trials on tamarillo were conducted in New Zealand during 2012 and 2013. Each treated plot received 4 applications of 120 SC spinetoram at a nominal rate of 24–50 g ai/ha and RTI of 14 days. The GAP in New Zealand consists of 4 applications at 96 g ai/ha, 4.8 g ai/hL, 14 days and a PHI of 14 days.

Spinetoram residues from the trials matching the GAP in New Zealand were: < 0.01 mg/kg (1).

The Meeting concluded that the data were insufficient for estimating a maximum residue level.

Kiwifruit

Two supervised trials were carried out in New Zealand in 2012. The treated plot received 4 applications of 120 SC spinetoram at 2.4 g ai/hL and RTI of 14 days. The GAP in Australia consists of 4 applications at 4.8 g ai/hL, RTI of 7–14 days and a PHI of 7 days. In New Zealand, spinetoram is not allowed for use on kiwifruit.

Spinetoram residues from the trials matching the GAP in Australia (after scaling) were: 0.096 (0.048×4.8/2.4) and 0.11 (0.053×4.8/2.4) mg/kg.

The Meeting concluded that the data were insufficient for estimating a maximum residue level.

Passion fruit

Three supervised trials were carried out in New Zealand in 2012 and 2013. The treated plot received 4 applications of 120 SC spinetoram at 2.4 or 4.8 g ai/hL and RTI of 13 or 14 days. The GAP in Australia consists of 4 applications at 4.8 g ai/hL, RTI 7-14 days and a PHI of 0 days.

Spinetoram residues from the trials matching the GAP in Australia (after scaling) were: 0.051, 0.098 (0.049×4.8/2.4) and 0.17 (0.087×4.8/2.4) mg/kg.

Corresponding total residues were: 0.061, 0.12 (0.059×4.8/2.4) and 0.19 (0.097×4.8/2.4) mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and STMR of 0.12 mg/kg for passionfruit.

Bulb vegetables

Leek

Eight supervised trials were carried out in Denmark (2), Germany (4) and Poland (2) during 2014 and 2015 (Reports 150016 and 140141). Each treated plot received 2 applications of 25 SC spinetoram at a nominal rate 60 g ai/ha and RTI of 28 days. The GAP in the Netherlands consists of 2 applications at 60 g ai/ha, RTI of 28 days and a PHI of 7 days.

Spinetoram residues from the trials matching the GAP were (8): < 0.01 (3), 0.014, 0.018, 0.018, 0.021 and 0.028 mg/kg.

Corresponding total residues were: < 0.02 (3), 0.024, 0.028, 0.028, 0.031, 0.053 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and STMR of 0.026 mg/kg for leek.

Fruiting vegetables, Cucurbits

Cucumber

Eight indoor trials were carried out in Brazil during 2006 and 2007. Each treated plot received 4 applications of 250 WG spinetoram at a nominal rate of 50 g ai/ha. The GAP in Brazil consists of 4 applications at 50 g ai/ha and a PHI of 3 days.

Six supervised outdoor trials were carried out in France (2), Spain (2), Greece (1) and Italy (1) during 2012 and 2013. Each treated plot received 2 applications of 25 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 27–29 days. These trials were evaluated against the GAP in Brazil.

Six indoor trials were carried out in France (1), Spain (1), Italy (1), Greece (1) and Germany (2), during 2012 and 2013. Each treated plot received 3 applications of 25 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 12–14 days.

Spinetoram residues from the trials matching the GAP in Brazil were in mg/kg:

Indoor trials in Brazil: < 0.01 (7), 0.012

Outdoor trials in Europe: < 0.01 (6)

Indoor trials in Europe: < 0.01 (2), 0.010, 0.011, 0.012, 0.021

These trials were not significantly different.

The corresponding total residues were: < 0.02 (15), 0.020, 0.021, 0.022, 0.022 and 0.031 mg/kg.

Squash, Summer

Six outdoor supervised trials were carried out in France (2), Spain (1), Greece (1) and Italy (2) during 2012 and 2013. Each treated plot received 2 applications of 25 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 27–29 days. Since there is no GAP is available for summer squash in Europe or Brazil, the Meeting used the GAP in Australia for cucurbits (including cucumber and summer squash) which allows four applications at 48 g ai/ha, RTI of 7-14 days and PHI of 3 days. This GAP is similar to the GAP in Brazil.

Six indoor trials were carried out in France (2), Spain (1), Italy (1), Netherlands (1) and Greece (1), during 2012 and 2013. Each treated plot received 3 applications of 25 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 12–16 days.

Spinetoram residues from the trials matching the GAP in Australia were in mg/kg:

Outdoor: < 0.01 (4), 0.012 (2);

Indoor: < 0.01 (5), 0.035;

These residues were not significantly different.

The data populations of indoor and outdoor trials on cucumber and summer squash evaluated against the comparable GAP were not significantly different. The Meeting considered the combined dataset for estimating a maximum residue level for the Subgroup of Fruiting vegetables, Cucurbits - Cucumbers and Summer squashes.

Combined spinetoram residues were: < 0.01 (24), 0.010, 0.011, 0.012, 0.012, 0.012, 0.012, 0.021 and 0.035 mg/kg.

The corresponding total residues were: < 0.02 (24), 0.020, 0.020, 0.021, 0.022, 0.022, 0.022, 0.031 and 0.045 mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg and STMR of 0.02 mg/kg for the Subgroup of Fruiting vegetables, Cucurbits - Cucumbers and Summer squashes.

Melons

Eight supervised trials were carried out in Brazil during 2005, 2006 and 2007 Each treated plot received 4 applications of spinetoram at a nominal rate of 50 g ai/ha. The GAP in Brazil for melon consists of 4 applications at 40 g ai/ha and a PHI of 3 days.

Eight supervised trials were carried out in France (2), Spain (3) and Italy (3) during 2012 and 2013. Each treated plot received 2 applications of 25 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 27 or 28 days.

Spinetoram residues from the Brazilian trials matching the GAP were (8): < 0.01 mg/kg (8).

In the outdoor trials in Europe, the application rates were 50% higher than the maximum rate in the GAP in Brazil. However, spinetoram residues from these trials were (8): < 0.01 mg/kg (8).

In the indoor trials in Europe, the application rates were about 50% higher than the maximum rate in the GAP in Brazil. Spinetoram residues from these trials were: < 0.01 (7) and 0.011×40 / 57 = 0.0077 mg/kg.

Utilizing all the trial data, the Meeting estimated a maximum residue level of 0.01* mg/kg for melons, except watermelon.

Corresponding total residues in flesh (if flesh was not analysed, then the value of whole fruit) were all < 0.02 mg/kg (24). Some residues were detected in peel.

The Meeting estimated an STMR of 0.02 mg/kg for melons, except watermelon.

Fruiting vegetables, other than Cucurbits

Peppers

Eight indoor trials were carried out in Brazil on non-bell peppers during 2006 and 2007. Each treated plot received 4 applications of spinetoram at a nominal rate of 50 g ai/ha. The GAP in Brazil consists of 4 applications at 50 g ai/ha and a PHI of 3 days.

Eight outdoor trials were carried out in France (2), Spain (2), Italy (2) and Greece (2) during 2012 and 2013 on both bell and non-bell peppers. Each treated plot received 2 applications of 25 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 28 or 29 days.

Eight indoor trials were carried out in France (2), Netherlands (1), Denmark (1), Germany (1), Spain (1), Italy (1) and Greece (1) during 2012 and 2013 on bell and non-bell peppers. Each treated plot received 3 applications of 25 SC spinetoram at a nominal rate of 60 g ai/ha and RTI of 13–14 days.

Spinetoram residues from the trials matching the GAP in Brazil were in mg/kg:

Indoor in Brazil: < 0.01 (4), 0.012, 0.016, 0.023, 0.38;

Indoor in Europe: < 0.01, 0.012, 0.015, 0.018, 0.023, 0.029, 0.043, 0.059;

Outdoor in Europe: < 0.01 (3), 0.016, 0.017, 0.019, 0.081, 0.082.

Since the data population from these trials were not significantly different according the Kruskal-Wallis H test, the Meeting combined the data sets for estimating a maximum residue level for peppers. Combined data were (24): < 0.01 (8), 0.012, 0.012, 0.015, 0.016, 0.016, 0.017, 0.018, 0.019, 0.023, 0.023, 0.029, 0.043, 0.059, 0.081, 0.082 and 0.38 mg/kg.

The corresponding total residues were: < 0.02 (8), 0.022, 0.022, 0.025, 0.026, 0.026, 0.027, 0.028, 0.029, 0.033, 0.039, 0.041, 0.053, 0.081, 0.092, 0.103 and 0.45 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and STMR of 0.026 mg/kg for a subgroup of peppers (except martynia, okra and roselle).

Using the concentration factor of 10, the Meeting also estimated a maximum residue level of 4 mg/kg and STMR of 0.26 mg/kg for dried chili peppers.

Pulses

Soya bean, dry

Four supervised trials were carried out in Brazil during 2006 and 200). Each treated plot received 2 applications of 120 SC spinetoram at a nominal rate of 24 g ai/ha. The GAP in Brazil consists of 2 applications at 18 g ai/ha and a PHI of 7 days.

The application rate was slightly higher than 125% of the maximum rate of the GAP in Brazil. However, the spinetoram residues were all < 0.01 mg/kg (4). In addition, residues were < 0.01 mg/kg on day 0 in two decline studies. Based on these results, the Meeting estimated a maximum residue level of 0.01* mg/kg for soya bean, dry.

Corresponding total residues were all < 0.02 mg/kg (4). Total residues were also < 0.02 mg/kg on the day of application (0 day).

The Meeting estimated an STMR of 0.02 mg/kg for soya bean, dry.

Root and tuber vegetables

Potato

Four supervised trials were carried out in Brazil during 2006 and 2007. Each treated plot received 3 applications of 250 WG spinetoram at a nominal rate of 60 g ai/ha. The GAP in Brazil consists of 3 applications at 50 g ai/ha and a PHI of 1 day.

Two supervised trials were carried out in New Zealand during 2010. Each treated plot received 4 applications of 120 SC spinetoram at a nominal rate of 60 g ai/ha. The GAP in New Zealand consists of 4 applications at 60 g ai/ha, RTI of 7 days and a PHI of 7 days. However, as the number of trials in Brazil was not sufficient for estimating a maximum residue level for potato and the GAP in Brazil is more critical, data were evaluated against the GAP in Brazil.

Spinetoram residues were all < 0.01 mg/kg (6). In addition, residues were < 0.01 mg/kg on day 0 in six decline studies. Based on these results, the Meeting estimated a maximum residue level of 0.01* mg/kg.

Corresponding total residues were all < 0.02 mg/kg (6). Total residues were also < 0.02 mg/kg on the day of application (0 day).

The Meeting estimated STMR of 0.02 mg/kg for potato.

Cereal grains

Rice

Six supervised trials were carried out in China during 2009 and 2010. Each treated plot received 2 applications of 60 SC spinetoram at a nominal rate 28 g ai/ha and RTI of 7 days. The GAP in China consists of 2 applications at 27 g ai/ha, RTI of 7-10 days and a PHI of 21 days. Residues of spinetoram and the main metabolites were analysed by modified method GRM 05.03 for rice, with a validated LOQ of 0.02 mg/kg (grain) and 0.04 mg/kg (hulls and plant).

Spinetoram residues in husked rice from the trials matching the GAP in China were: < 0.02 mg/kg (6). Since in all the trials residues are below the LOQ, and residues of husked rice from 14 days after the last application, were < 0.02 mg/kg (shorter than the PHI of 21 days), the Meeting estimated a maximum residue level of 0.02* mg/kg for husked rice.

Corresponding total residues were all < 0.04 mg/kg (6). The Meeting estimated an STMR of 0.04 mg/kg for husked rice.

Maize

Four supervised trials were carried out in Brazil during 2006 and 2007. Each treated plot received 3 applications of 120 SC spinetoram at a nominal rate 24 g ai/ha. The GAP in Brazil consists of 3 applications at 12 g ai/ha and a PHI of 7 days.

Despite that there were only four trials, as they used the double rate resulting in residues below the LOQ. At the double rate, spinetoram residues were all < 0.01 mg/kg (4). In addition, residues at 0 day were < 0.01 mg/kg in two decline trials.

The Meeting estimated a maximum residue level of 0.01* mg/kg.

Corresponding total residues were all < 0.02 mg/kg (4).

The Meeting estimated an STMR of 0.02 mg/kg for maize.

Forage or fodder samples were not analysed.

Sweet Corn (Corn-on-the-cob)

Four supervised trials were carried out in Brazil during 2006 and 2007. Each treated plot received 4 applications of 120 SC spinetoram at a nominal rate 24 g ai/ha. The GAP in Australia consists of 4 applications at 48 g ai/ha and a PHI of 3 days.

Spinetoram residues from trials matching the GAP in Australia were: < 0.01 mg/kg (4). Residues were also < 0.01 mg/kg (4) at 0 days after the last application.

Corresponding total residues were: < 0.02 mg/kg (4).

The Meeting estimated a maximum residue level of 0.01* mg/kg and STMR of 0.02 mg/kg for sweet corn (corn-on-the-cob)(kernels plus cob with husk removed).

Oilseeds

Cotton seed

Ten supervised residue trials were carried out in Brazil during 2013 and 2014. Each treated plot received 3 or 4 applications of 60 SC or 120 SC spinetoram at a nominal rate of 24 or 36 g ai/ha. The GAP in Colombia allows applications (number not specified) at 18 g ai/ha and a PHI of 1 day. However, there were not sufficient numbers of trials matching this GAP. The GAP in Brazil consists of 4 applications at 18 g ai/ha and a PHI of 7 days.

Nine supervised trials were carried out in Greece during 2014 and 2015. Each treated plot received 2 applications of 120 SC spinetoram at a nominal rate 60 g ai/ha and RTI of 28/29 days. These trials were evaluated against the GAP in Brazil.

In many trials in Brazil and Europe, spinetoram was applied 3 times or 2 times. As the decline trials indicate that at the time of the last application, residues are negligible and any previous applications do not have an impact on the final residues. Therefore, the Meeting considered the trials where application numbers do not match the GAP in Brazil. In the trials in Brazil, the application rates were either slightly higher than 125% or double the maximum GAP rate. The spinetoram residues were all < 0.01 mg/kg (10). In the trials in Europe, the application rates were about 3 times the maximum GAP rates. The spinetoram residues were all < 0.01 mg/kg (9).

In these trials, total residues were: < 0.02 mg/kg (19).

The Meeting estimated a maximum residue level of 0.01 * mg/kg and STMR of 0 mg/kg for cotton seed.

Animal feedstuffs

Rice straw and hulls

Spinetoram residues in rice straw from the trials matching the GAP in China were (6): < 0.04 (3), 0.21, 0.31 and 0.50 mg/kg, which are converted to < 0.044 (3), 0.23, 0.34 and 0.56 mg/kg on a dry weight basis (90% DM).

The Meeting estimated a maximum residue level of 1.5 mg/kg for rice straw and fodder, dry, on a dry weight basis.

Corresponding total residues were (6): < 0.08 (3), 0.24, 0.35 and 0.54 mg/kg.

The Meeting estimated a median residue of 0.16 mg/kg and highest residue of 0.54 mg/kg for rice straw (as received).

Total residues in rice hulls from the trials matching the GAP in China were (6): < 0.08 (4), 0.25 and 0.30 mg/kg.

The Meeting estimated a median residue of 0.08 mg/kg for rice hulls (on an as received basis).

Sweet corn forage and stover

Total residues in forage from the trials matching the GAP in Australia were (4): 0.12, 0.14, 0.17 and 3.3 mg/kg.

The Meeting estimated a median residue of 0.155 mg/kg and highest residue of 3.3 mg/kg for sweet corn forage (as received).

Spinetoram residues in stover from the trials matching the GAP in Australia were (4): < 0.01, 0.021, 0.029 and 0.048 mg/kg, which are converted to < 0.012, 0.025, 0.035 and 0.058 mg/kg on a dry weight basis (83% DM).

The Meeting estimated a maximum residue level of 0.15 mg/kg on a dry weight basis for sweet corn fodder.

Total residues in stover from the trials matching the GAP in Australia were (4): < 0.02, 0.029, 0.039 and 0.058 mg/kg

The Meeting estimated a median residue of 0.034 mg/kg and highest residue of 0.058 mg/kg for sweet corn stover (on an as received basis).

Residues in processed commodities

Processing studies on olives, soya beans and maize were provided to the current Meeting. However, in all the studies residues in raw agricultural commodities were below the LOQ. Therefore, it was not possible to calculate processing factors for these RACs. In processed commodities, residues were also below the LOQ, except in one trial, residue in maize oil was at the LOQ.

Farm animal dietary burden

The current Meeting calculated animal burden using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual and those commodities which were evaluated by the 2008, 2012 and the current Meeting that can be fed to animals.

	US-Canada		EU		Australia		Japan	
	Max	mean	max	Mean	max	Mean	Max	mean
Beef cattle	0.032	0.032	0.286	0.187	5.541 [a]	0.299 [b]	0.318	0.108
Dairy cattle	3.129 [c]	0.180	0.327	0.221 [d]	2.802	0.181	0.167	0.062
Broilers	0.026	0.026	0.020	0.020	0.026	0.026	0.016	0.016
Layers	0.026	0.026	0.063 [e]	0.049 [f]	0.026	0.026	0.018	0.018

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

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

[c] Suitable for estimating maximum residue level for milk.

[d] Suitable for estimating STMR for milk

[e] Suitable for estimating maximum residue level for meat, fat and edible offal of poultry.

[f] Suitable for estimating STMR for eggs.

Residues in milk and cattle tissues

The 2008 JMPR evaluated one animal feeding study on lactating cows dosed daily for 29 consecutive days with a mixture of spinetoram and N-demethyl and N-formyl metabolites of XDE-175-J (1.2, 3.7, 11.5 and 38.6 ppm in the diet) or spinetoram only (37.6 ppm).

The maximum and mean dietary burdens in cattle were 5.54 and 0.30 ppm of dry matter diet respectively for estimating a maximum residue level and STMR for edible tissues, and 3.13 and 0.22 mg/kg for milk. The maximum residue levels, STMRs and HRs for relevant commodities of mammal origin were estimated using the residue levels identified by the 2008 JMPR in tissues and in milk.

Maximum residue level beef or dairy cattle	Feed level (ppm) for milk residues	Spinetoram (mg/kg) in milk	Feed level (ppm) for tissue residues	Spinetoram (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Feeding study[a]	1.2 3.7	< 0.01 0.0187	3.7 11.5	0.043 0.086	0.057 0.11	0.040 0.074	0.69 1.41
Dietary burden and highest residue for spinetoram only	3.13	0.017	5.54	0.053	0.070	0.048	0.86

STMR beef or dairy cattle	Feed level (ppm) for milk residues	Total residue (mg/kg) in milk	Feed level (ppm) for tissue residues	Total residue (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Feeding study[c]	0 1.2	< 0.02 < 0.02	0 1.2	< 0.02 < 0.02	< 0.02 < 0.02	< 0.02 < 0.02	< 0.02 0.10
Dietary burden and mean residue	0.22	< 0.003	0.30	< 0.005	< 0.005	< 0.005	0.025

The level <LOQ at 0 ppm dose is assumed to be 0 mg/kg residue for calculation.

The Meeting estimated STMRs of 0.003 mg/kg for milk, 0.005 mg/kg for muscle, liver and kidney, and 0.025 mg/kg for fat. The mean ratio of the total residues in cream to those in whole milk was calculated to be 5.7. An STMR for milk fat was estimated to be 0.017 mg/kg.

On the basis of the calculations shown above, the Meeting estimated maximum residue levels of 0.02 mg/kg for milks, 1 mg/kg (fat) for meat (from mammals other than marine mammals) and 0.1 mg/kg for edible offal, mammalian to replace the corresponding previous recommendations. The Meeting estimated a new maximum residue level of 1 mg/kg for mammalian fats. Using the mean ratio of spinetoram residues in cream to those in whole milk of 6.6, the Meeting estimated a maximum residue level of 0.15 mg/kg for milk fats to replace the previous recommendation.

Residues in egg and poultry tissues

The current Meeting calculated dietary burdens for poultry. The maximum and mean dietary burdens in cattle were 0.063 and 0.049 ppm of dry matter diet respectively for estimating a maximum residue level and STMR for edible tissues and eggs.

The 2008 JMPR reviewed a metabolism study on laying hens, in which either XDE-175-J or XDE-175-L (components of spinetoram) was administered for 7 consecutive days at a dose equivalent to 10 ppm in the diet. In the eggs or tissues, the major residue was unchanged administered compound (49–70% TRR) except in liver (12–13% TRR). Using the results of the metabolism study and a

typical ratio in the active ingredients of 3 to 1 between XDE-175-J and XDE-175-L, the residues of spinetoram were calculated to be 0.89 mg/kg in abdominal fat, 0.59 mg/kg in skin with fat, 0.037 mg/kg in muscle, 0.078 mg/kg in liver and 0.078 mg/kg for day 4 egg. N-Demethyl metabolite was detected only in liver and the N-formyl metabolite was not detected in any of the samples. The total residues in liver were calculated to be 0.081 mg/kg.

Maximum residue level Broilers and layers	Feed level (ppm) for tissue residues	Spinetoram (mg/kg) in			
		Muscle	Liver	Fat	Eggs
Metabolism study	10	0.037	0.078	0.886	0.078
Dietary burden and highest residue	0.063	< 0.01	< 0.01	< 0.01	< 0.01

STMR Broilers and layers	Feed level (ppm) for tissue residues	Total residue (mg/kg) in			
		Muscle	Liver	Fat	Eggs
Metabolism study	10	0.037	0.081	0.886	0.078
Dietary burden and highest residue	0.049	0.00018	0.00040	0.0043	0.00038

The Meeting estimated a maximum residue level of 0.01 * mg/kg for poultry meat (fat), poultry edible offal, poultry fats and eggs. The Meeting estimated STMR of 0.0002 mg/kg for muscle, 0.0004 mg/kg for liver, 0.004 mg/kg for fat, and 0.0004 mg/kg for eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment for plant and animal commodities.

Definition of the residue (for compliance with the MRL) for plant and animal commodities: *Spinetoram*.

Definition of the residue (for estimation of dietary risk assessment) for plant and animal commodities: *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.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDIs) of spinetoram were calculated for the 17 GEMS/Food cluster diets using STMRs estimated by the Meeting in 2008, 2012 and 2017. The ADI is 0–0.05 mg/kg bw and the calculated IEDIs were 0.3–2 % of the maximum ADI. The Meeting concluded that the long-term dietary exposure to residues of spinetoram resulting from the uses considered by the 2009 and current JMPR is unlikely to present a public health concern.

Short-term dietary exposure

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