5.8 Cyclaniliprole (296)

RESIDUE AND ANALYTICAL ASPECTS

Cyclaniliprole is an insecticide belonging to the chemical class of diamide insecticides which act at the ryanodine receptor, which is critical for muscle contraction.

Cyclaniliprole was first evaluated by the 2017 JMPR where an ADI of 0–0.04 mg/kg bw was established. An ARfD was determined to be unnecessary.

A residue definition of *cyclaniliprole* was determined for compliance with the MRL for plant and animal commodities and for dietary risk assessment for animal commodities.

For dietary risk assessment for plant commodities, the residue definition was determined to be *cyclaniliprole + 3-bromo-2-((2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b]-[1,4]oxazin-4-ylidene)amino)-5-chloro-N(1-cyclopropylethyl)benzamide (NK-1375)*, expressed as cyclaniliprole equivalents.

The residue is fat-soluble.

Cyclaniliprole was scheduled by the Fiftieth Session of the CCPR for the reassessment of the trials reviewed in 2017 and the evaluation of additional new uses. The current Meeting received revised GAP information for several of the uses evaluated by the 2017 JMPR as well as new GAP information, supervised field trials on citrus fruits, berries and tuberous and corm vegetables, and orange and potato processing studies.

Methods of analysis

The LC-MS/MS analytical method (Report JSM 0269) used for analysis of residues of cyclaniliprole and NK-1375 in plant commodities, with LOQs of 0.01 mg/kg for each analyte, was reviewed by the 2017 JMPR. All samples collected from the supervised residue trials submitted to the current Meeting were analysed using the same method.

Stability of residues in stored analytical samples

The stability of residues of cyclaniliprole and NK-1375 during frozen storage was evaluated by the 2017 JMPR. Cyclaniliprole and NK-1375 were determined to be stable when stored frozen for at least 18 months at -20 ºC in commodities representative of the high water, high acid, high starch, high protein and high oil commodity groups.

The periods of demonstrated stability adequately covered the frozen storage intervals of the samples in the supervised residue trials on crops considered by the current Meeting.

Results of supervised residue trials on crops

The current Meeting received supervised trial data for cyclaniliprole on lemons, oranges, grapefruits, raspberries, blueberries, strawberries, kiwifruit and potato. The Meeting also received revised use pattern information for pome fruits, stone fruits, *Brassica* head and stem vegetables, fruiting vegetables except cucurbits, fruiting vegetables, leafy vegetables, tree nuts and tea, previously assessed at the 2017 Meeting. Therefore, the supervised residue trials for these crops were reassessed in the framework of the revised use patterns.

Residues for maximum residue estimation are expressed in mg cyclaniliprole/kg. Residues for dietary risk assessment include parent cyclaniliprole and metabolite NK1375. The totals (sum of the mean of parent and NK-1375) are expressed as parent equivalents by applying a conversion factor of 1.064 to NK-1375.

For all crops, with the exception of tea, the number of applications, re-treatment interval and PHI approximated the critical GAPs from USA (citrus fruits only) or Canada, however, individual application rates were all greater than those of the critical GAPs. Therefore, the current Meeting agreed

to utilize the proportionality approach to estimate residues matching the critical GAP for estimation of the maximum residue levels and dietary exposures. For tea, all trials were conducted within 25% of the critical GAP in Japan.

Citrus fruits

The critical GAP for citrus fruits is from the USA; 3×80 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from the USA on citrus fruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 7-day RTI and 1-day PHI.

Lemons

Cyclaniliprole residues in lemons in ranked order were (n = 5): 0.018, 0.048, 0.13, 0.14 and 0.17 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): 0.015, 0.038, 0.11 (2) and 0.14 mg/kg.

Total cyclaniliprole residues in lemons in ranked order were (n = 5): 0.029, 0.059, 0.14, 0.15 and 0.18 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): 0.023, 0.047, 0.12 (2) and 0.15 mg/kg.

Orange

Cyclaniliprole residues in oranges in ranked order were (n = 12): 0.033, 0.092, 0.093, 0.098, 0.11, 0.12 (2), 0.13, 0.14, 0.16, 0.19 and 0.36 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 12): 0.026, 0.074, 0.075, 0.078, 0.090, 0.094, 0.095, 0.10, 0.11, 0.13, 0.15 and 0.28 mg/kg.

Total cyclaniliprole residues in oranges in ranked order were (n = 12): 0.044, 0.10 (2), 0.11, 0.12, 0.13 (2), 0.14, 0.15, 0.17, 0.20 and 0.39 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 12): 0.035, 0.083 (2), 0.087, 0.099, 0.10 (2), 0.11, 0.12, 0.14, 0.16 and 0.31 mg/kg.

Grapefruit

Cyclaniliprole residues in grapefruits in ranked order were (n = 6): 0.024, 0.042, 0.059, 0.078, 0.082 and 0.096 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 6): 0.019, 0.034, 0.047, 0.061, 0.066 and 0.077 mg/kg.

Total cyclaniliprole residues in grapefruits in ranked order were (n = 6): 0.035, 0.053, 0.07, 0.089, 0.093 and 0.11 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 6): 0.028, 0.042, 0.056, 0.069, 0.075 and 0.085 mg/kg.

The Meeting noted that the GAP covers the group of citrus fruits and that median residues of lemons, oranges and grapefruits are within a 5-fold difference. Although trials were not provided for mandarins, the Meeting noted that residues in lemons/limes have been shown to be similar to or greater than residues in mandarins. The Kruskal-Wallis H-test also determined that the datasets were from the same population. Therefore, the Meeting decided to combine the three datasets of lemons, oranges and grapefruits.

Combined scaled cyclaniliprole residues in lemons, oranges and grapefruits were (n = 23): 0.015, 0.019, 0.026, 0.034, 0.038, 0.047, 0.061, 0.066, 0.074, 0.075, 0.077, 0.078, 0.090, 0.094, 0.095, 0.096, 0.11 (3), 0.13, 0.14, 0.15 and 0.28 mg/kg.

Total scaled cyclaniliprole residues in lemons, oranges and grapefruits in ranked order were (n = 23): 0.023, 0.028, 0.035, 0.042, 0.047, 0.056, 0.069, 0.075, 0.083 (2), 0.085, 0.087, 0.099, 0.10 (2), 0.11, 0.12 (3), 0.14, 0.15, 0.16 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.087 mg/kg for the Group of citrus fruits.

The Meeting estimated a median residue of 0.078 mg/kg (parent only) for animal dietary burden calculations.

Pome fruits

The critical GAP for pome fruit is from Canada; 3×80 g ai/ha, 14-day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on pome fruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha/application, 14-day RTI and 1-day PHI.

Apple

Cyclaniliprole residues in apples in ranked order were (n = 16): 0.013, 0.023, 0.027, 0.035, 0.037, 0.046, 0.049, 0.054 (2), 0.055, 0.058, 0.068 (2), 0.10 (2) and 0.13 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 16): 0.01, 0.018, 0.021, 0.027, 0.030, 0.037, 0.039, 0.042, 0.043 (2), 0.046, 0.053, 0.054, 0.079 (2) and 0.10 mg/kg.

Total cyclaniliprole residues in apples in ranked order were (n = 16): 0.023, 0.033, 0.038, 0.046, 0.053, 0.056, 0.059, 0.065 (2), 0.067, 0.073, 0.079, 0.084, 0.12, 0.13 and 0.17 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 16): 0.018, 0.026, 0.030, 0.036, 0.043, 0.045, 0.047, 0.051, 0.052, 0.053, 0.058, 0.063, 0.065, 0.095, 0.10 and 0.14 mg/kg.

Pear

Cyclaniliprole residues in pears in ranked order were (n = 8): 0.037, 0.060, 0.069, 0.097, 0.11, 0.13 and 0.14 (2) mg/kg. Using scaling factors of 0.7–0.8, scaled residues in ranked order were (n = 8): 0.029, 0.048, 0.055, 0.078, 0.079, 0.10, 0.11 (2) mg/kg.

Total cyclaniliprole residues in pears in ranked order were (n = 8): 0.051, 0.070, 0.081, 0.12 (2), 0.14 and 0.16 (2) mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 8): 0.040, 0.056, 0.065, 0.085, 0.097, 0.11 and 0.13 (2) mg/kg.

The Meeting noted that the scaled median residues of cyclaniliprole in apples and pears were within five-fold and that the datasets were from the same population (Mann-Whitney U-test). The Meeting decided to combine the data to estimate a maximum residue level for pome fruits. The combined cyclaniliprole scaled residues in apples and pears were (n = 24): 0.01, 0.018, 0.021, 0.027, 0.029, 0.030, 0.037, 0.039, 0.042, 0.043 (2), 0.046, 0.048, 0.053, 0.054, 0.055, 0.078, 0.079 (3), 0.10 (2) and 0.11 (2) mg/kg.

Scaled total cyclaniliprole residues in apples and pears in ranked order were (n = 24): 0.018, 0.026, 0.030, 0.036, 0.040, 0.043, 0.045, 0.047, 0.051, 0.052, 0.053, 0.056, 0.058, 0.063, 0.065 (2), 0.085, 0.095, 0.097, 0.10, 0.11, 0.13 (2) and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.057 mg/kg for pome fruits, except Japanese persimmons, and withdraws its previous recommended maximum residue level of 0.3 mg/kg for the Group of pome fruits.

The Meeting estimated a median residue of 0.047 mg/kg (parent only) for animal dietary burden calculations.

Stone fruit

The critical GAP for stone fruit is from Canada; 3×80 g ai/ha, 7-day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on stone fruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 7-day RTI and 7-day PHI.

Cherries

Cyclaniliprole residues in cherries in ranked order were (n = 15): 0.010, 0.016, 0.082, 0.097, 0.13 (2), 0.14 (2), 0.18, 0.24, 0.28, 0.30, 0.33, 0.44 and 0.56 mg/kg. Using scaling factors of 0.7–0.8, scaled residues in ranked order were (n = 15): 0.008, 0.013, 0.063, 0.075, 0.10, 0.11 (3), 0.14, 0.19 (2), 0.24,

0.26, 0.36 and 0.45 mg/kg.

Residue levels in the field trials from Canada and the USA were reported as flesh without stone. At the 2017 Meeting, it was concluded that, based on the Japanese trials on cherries, the contribution of the pit to the weight of the whole fruit is approximately 10%. Correcting the residue levels using this weight/weight ratio would lead to the same maximum residue level.

Total cyclaniliprole residues in flesh in ranked order were (n = 15): 0.021, 0.027, 0.10, 0.11, 0.14 (2), 0.16, 0.17, 0.19, 0.26, 0.32, 0.34 (2), 0.48 and 0.61 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 15): 0.017, 0.022, 0.077, 0.085, 0.11 (2), 0.12, 0.14, 0.15, 0.21, 0.23, 0.26, 0.27, 0.40 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.14 mg/kg for the Subgroup of cherries, to replace its previous recommended maximum residue level of 0.9 mg/kg.

Plums

Cyclaniliprole residues in plums in ranked order were (n = 8): 0.019 (2), 0.024, 0.027, 0.056, 0.062, 0.065 and 0.091 mg/kg. Using scaling factors of 0.8–1.2, scaled residues in ranked order were (n = 8): 0.015 (2), 0.019, 0.033, 0.044, 0.049, 0.052 and 0.073 mg/kg.

Residue levels in the field trials from Canada and the USA were reported as flesh without stone. At the 2017 Meeting, it was concluded that, based on the ratio of the residue levels in flesh versus whole fruit which ranged between 0.86 and 0.97, an overestimation of residues of approximately 10% was anticipated. Correcting for this factor would lead to the same maximum residue level.

Total cyclaniliprole residues in plums in ranked order were (n = 8): 0.030 (2), 0.035, 0.042, 0.067, 0.075, 0.076 and 0.11 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 8): 0.024 (2), 0.028, 0.051, 0.053, 0.060, 0.061 and 0.089 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR value of 0.052 mg/kg for the Subgroup of plums, to replace its previous recommended maximum residue level of 0.2 mg/kg.

Peaches (including nectarines and apricots)

Cyclaniliprole residues in peaches in ranked order were (n = 13): 0.019, 0.023, 0.041, 0.045, 0.050, 0.051, 0.054, 0.064, 0.081, 0.094, 0.11, 0.16 and 0.19 mg/kg. Using scaling factors of 0.8–1.1, scaled residues in ranked order were (n = 13): 0.018, 0.021, 0.033, 0.036, 0.040, 0.041, 0.044, 0.051, 0.065, 0.073, 0.087, 0.13 and 0.15 mg/kg.

Residue levels in the field trials from Canada and the USA were reported as flesh without stone. At the 2017 Meeting, it was concluded that, based on the ratio of the residue levels in flesh versus whole fruit which ranged between 0.85 and 0.96, an overestimation of residues of approximately 10% was anticipated. Correcting for this factor would lead to the same maximum residue level.

Total cyclaniliprole residues in peaches in ranked order were (n = 13): 0.030, 0.034, 0.056, 0.058, 0.061, 0.062, 0.065, 0.078, 0.092, 0.10, 0.12, 0.17 and 0.20 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues were (n = 13): 0.027, 0.034, 0.045, 0.047, 0.049, 0.050, 0.053, 0.063, 0.074, 0.078, 0.095, 0.14 and 0.16 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.053 mg/kg for the Subgroup of peaches, and confirms its previous recommended maximum residue level of 0.3 mg/kg.

Cane berries

The critical GAP for caneberries is from Canada; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on raspberries where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 5–6 day RTI and 1-day PHI.

Raspberries

Cyclaniliprole residues in raspberries in ranked order were (n = 5): 0.14, 0.24, 0.30, 0.31 and 0.53 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): 0.11, 0.18, 0.24, 0.25 and 0.42 mg/kg.

Total cyclaniliprole residues in raspberries in ranked order were (n = 5): 0.16, 0.27, 0.34, 0.36 and 0.58 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): 0.13, 0.21, 0.27, 0.30 and 0.47 mg/kg.

Noting that raspberries are the representative crop of the subgroup cane berries, the Meeting estimated a maximum residue level of 0.8 mg/kg and an STMR of 0.27 mg/kg for the Subgroup of cane berries.

Bush berries

The critical GAP for bushberries is from Canada; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on blueberries where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 5-day RTI and 1-day PHI.

Blueberries

Cyclaniliprole residues in blueberries in ranked order were (n = 10): 0.10, 0.14, 0.15, 0.20, 0.23, 0.29 (2), 0.42, 0.43 and 1.0 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 10): 0.079, 0.12 (2), 0.16, 0.19, 0.23 (2), 0.32, 0.34 and 0.81 mg/kg.

Total cyclaniliprole residues in blueberries in ranked order were (n = 10): 0.12, 0.20, 0.22, 0.24, 0.32, 0.37, 0.38, 0.50, 0.58 and 1.1 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): 0.092, 0.16, 0.19, 0.20, 0.25, 0.30(2), 0.39, 0.45, 0.89 mg/kg.

Noting that blueberries is the representative crop of the subgroup bush berries, the Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.275 mg/kg for the Subgroup of bush berries and extrapolated these values to elderberries and Guelder rose.

Grapes

The critical GAP for grapes is from Canada; 3×80 g ai/ha, 7-day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on grapes where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 6-day RTI and 6–7-day PHI.

Cyclaniliprole residues in grapes in ranked order were (n = 15): 0.025, 0.044, 0.048, 0.076, 0.11, 0.12 (2), 0.14 (2), 0.17, 0.21, 0.24, 0.33, 0.39 and 0.51 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 15): 0.020, 0.035, 0.038, 0.061, 0.088, 0.094, 0.096, 0.11(2), 0.14, 0.17, 0.19, 0.26, 0.31 and 0.41 mg/kg.

Total cyclaniliprole residues in grapes in ranked order were (n = 15): 0.036, 0.055, 0.059, 0.092, 0.13 (2), 0.15 (2), 0.17, 0.22, 0.25, 0.28, 0.44, 0.48 and 0.59 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 15): 0.029, 0.044, 0.047, 0.074, 0.10 (2), 0.12 (2), 0.14, 0.18, 0.20, 0.22, 0.34, 0.38 and 0.47 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.12 mg/kg for grapes to replace its previous recommended maximum residue level of 0.8 mg/kg.

The Meeting estimated a median residue of 0.11 mg/kg (parent only) for animal dietary burden calculations.

Low growing berries

The critical GAP for low growing berries is from Canada; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on grapes where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 4–6 day RTI and 1-day PHI.

Strawberries

Cyclaniliprole residues in strawberries in ranked order were (n = 9): 0.054, 0.091, 0.10, 0.23, 0.14, 0.15, 0.16, 0.21 and 0.34 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 9): 0.043, 0.074, 0.079, 0.099, 0.11, 0.12, 0.13, 0.17 and 0.28 mg/kg.

Total cyclaniliprole residues in strawberries in ranked order were (n = 9): 0.065, 0.10, 0.11, 0.14, 0.16 (2), 0.18, 0.25 and 0.36 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 9): 0.051, 0.083, 0.088, 0.12 (2), 0.13, 0.14, 0.20 and 0.29 mg/kg.

Noting that strawberries is the representative crop of the subgroup low growing berries but that the cultural practices for cranberries are significantly different from those of the other berries within the same crop subgroup, the Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.12 mg/kg for the Subgroup of low growing berries, except cranberries.

Kiwifruit

The critical GAP is from Canada for "small fruits vine climbing, except grapes" including kiwifruit; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from the USA on kiwifruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 5-day RTI and 1-day PHI.

Cyclaniliprole residues in kiwifruit in ranked order were (n = 3): 0.013, 0.24 and 0.49 mg/kg.

Total cyclaniliprole residues in kiwifruit in ranked order were (n = 3): 0.024, 0.25 and 0.50 mg/kg.

The Meeting noted that three trials are insufficient to estimate a maximum residue level and STMR for kiwifruit.

Brassica vegetables (except Brassica leafy vegetables)

The critical GAP for flowerhead brassicas is from Canada for "Brassica head and stem vegetables"; 3 × 60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on Brassica vegetables where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha/application, 6–8 day RTI and 1-day PHI.

Flowerhead Brassicas

Cyclaniliprole residues in broccoli in ranked order were (n = 10): 0.11, 0.12, 0.18, 0.20, 0.34, 0.37, 0.41, 0.42, 0.47, and 0.66 mg/kg. Using scaling factors of 0.72–0.98, scaled residues in ranked order were (n = 10): 0.08, 0.12, 0.15, 0.18, 0.25, 0.28, 0.31, 0.32, 0.35 and 0.48 mg/kg.

Total cyclaniliprole residues in broccoli in ranked order were (n = 10): 0.12, 0.13, 0.19, 0.23, 0.38 (2), 0.42, 0.49, 0.54, and 0.71 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): 0.088, 0.13, 0.17, 0.19, 0.28 (2), 0.32, 0.38, 0.41 and 0.51 mg/kg.

Noting that broccoli is the representative crop of the flowerhead brassicas subgroup, the Meeting estimated a maximum residue level of 0.8 mg/kg and an STMR of 0.28 mg/kg for the Subgroup of flowerhead brassicas to replace its previous recommended maximum residue level of 1 mg/kg.

Brussels sprouts

Residue trials performed on Brussels sprouts in Europe, reviewed by the 2017 JMPR, did not match the critical GAP from Canada nor could the proportionality approach be used. Therefore, the Meeting could not estimate a maximum residue level for Brussels sprouts.

Cabbages, head

Cyclaniliprole residues in cabbage heads with wrapper leaves in ranked order were (n = 10): < 0.01 (2), 0.014, 0.025, 0.027, 0.040, 0.082, 0.15, 0.32 and 0.39 mg/kg. Using scaling factors of 0.60–0.98, scaled

residues in ranked order were (n = 10): < 0.01 (2), 0.01, 0.017, 0.024 (2), 0.063, 0.11, 0.31 and 0.38 mg/kg.

Total cyclaniliprole residues in cabbage heads with wrapper leaves in ranked order were (n = 10): < 0.01 (2), 0.025, 0.035, 0.038, 0.051, 0.094, 0.17, 0.34, and 0.42 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): < 0.01 (2), 0.018, 0.024, 0.031, 0.034, 0.072, 0.13, 0.33 and 0.41 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.0325 mg/kg for cabbage heads and withdraws its previous recommendation of 0.7 mg/kg for the Subgroup of head Brassicas.

The Meeting estimated a median residue of 0.024 mg/kg and a highest residue of 0.38 mg/kg (parent only) for animal dietary burden calculations.

Fruiting vegetables – Cucurbits

The critical GAP for fruiting vegetables-cucurbits is from Canada for "cucurbit vegetables"; 3×60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on fruiting vegetables - cucurbits where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 7-day RTI and 1-day PHI.

Subgroup of cucumbers and summer squashes

Cucumbers

Cyclaniliprole residues in cucumbers in ranked order were (n = 9): < 0.01 (2), 0.011, 0.013, 0.014, 0.018, 0.019, 0.024, and 0.025 mg/kg. Using scaling factors of approximately 0.74, scaled residues in ranked order were (n = 9): < 0.01 (3), 0.010, 0.011, 0.013, 0.014 and 0.018 (2) mg/kg.

Total cyclaniliprole residues in cucumbers in ranked order were (n = 9): < 0.01 (2), 0.022, 0.024, 0.025, 0.029, 0.030, 0.035 and 0.036 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 9): < 0.01 (2), 0.016, 0.018, 0.019, 0.021, 0.022 and 0.026 (2) mg/kg.

Summer squashes

Cyclaniliprole residues in summer squashes in ranked order were (n = 9): < 0.01(2), 0.014, 0.016, 0.026, 0.028(2), 0.033 and 0.046 mg/kg. Using scaling factors of approximately 0.75, scaled residues in ranked order were (n = 9): < 0.01 (2), 0.011, 0.012, 0.020, 0.021 (2), 0.024 and 0.034 mg/kg.

Total cyclaniliprole residues in summer squashes in ranked order were (n = 9): < 0.01 (2), 0.025, 0.027, 0.037, 0.039, 0.040, 0.043 and 0.057 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 9): < 0.01 (2), 0.019, 0.021, 0.028, 0.029, 0.030, 0.032 and 0.042 mg/kg.

The Meeting noted that the median residues of cucumbers and summer squashes were within 5-fold, and that the Mann-Whitney U-test determined the datasets of cucumbers and summer squashes were from the same population. Therefore, the Meeting decided to combine the two datasets of cucumbers and summer squashes.

The ranked order of the combined cyclaniliprole scaled residues in cucumbers and summer squashes were (n = 18): < 0.01(5), 0.010, 0.011 (2), 0.012, 0.013, 0.014, 0.018 (2), 0.020, 0.021 (2), 0.024 and 0.034 mg/kg.

The ranked order of total cyclaniliprole scaled residues in cucumbers and summer squashes were (n = 18): < 0.01 (4), 0.016, 0.018, 0.019 (2), 0.021 (2), 0.022, 0.026 (2), 0.028, 0.029, 0.030, 0.032 and 0.042 mg/kg.

Noting that cucumbers and summer squashes are the representative crops for the crop subgroup cucumbers and summer squashes, the Meeting estimated a maximum residue level of 0.05 mg/kg and

an STMR of 0.021 mg/kg for the Subgroup of cucumbers and summer squashes to replace its previous recommended maximum residue level of 0.06 mg/kg.

Melons, pumpkins and winter squashes

Melons

The critical GAP for melons is from Canada for "cucurbit vegetables": 3 × 60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on melons where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 6–8 day RTI and 1-day PHI.

Cyclaniliprole residues in melons in ranked order were (n = 10): 0.014, 0.017, 0.023, 0.039, 0.040, 0.042, 0.044, 0.051, 0.071 and 0.087 mg/kg. Using scaling factors of approximately 0.75, the scaled residues in ranked order were (n = 10): 0.010, 0.013, 0.017, 0.029, 0.030, 0.031, 0.033, 0.038, 0.052 and 0.064 mg/kg.

In the absence of data on melons without peel, residues used for the estimation of the STMR are based on whole fruit. Total cyclaniliprole residues in whole melon in ranked order were (n = 10): 0.024, 0.028, 0.033, 0.050, 0.055 (2), 0.058, 0.063, 0.081, and 0.099 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): 0.018, 0.021, 0.025, 0.037, 0.041 (2), 0.043, 0.047, 0.060 and 0.073 mg/kg for whole melon.

Noting that melons is the representative crop of the melons, pumpkins and winter squashes crop subgroup, the Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.041 mg/kg for the Subgroup of melons, pumpkins and winter squashes to replace its previous recommended maximum residue level of 0.15 mg/kg.

Fruiting vegetables, other than Cucurbits

The critical GAP for fruiting vegetables, other than cucurbits is from Canada for "fruiting vegetables"; 3 × 60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on cherry tomatoes, tomatoes, sweet bell peppers and non-bell peppers where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 6–8 day RTI and 1-day PHI.

Tomatoes

Cyclaniliprole residues in field tomatoes (including cherry tomatoes) in ranked order were (n = 22): 0.011, 0.013, 0.017, 0.018, 0.019, 0.025 (2), 0.026 (2), 0.029, 0.030, 0.032 (2), 0.033, 0.034, 0.037, 0.038, 0.040, 0.042, 0.043, 0.070 and 0.076 mg/kg. Using scaling factors of 0.72–0.99, scaled residues in ranked order were (n = 22): 0.008, 0.010, 0.015, 0.017, 0.018, 0.019, 0.020, 0.021, 0.023, 0.024 (3), 0.025 (3), 0.027, 0.028, 0.029, 0.031, 0.032, 0.053, and 0.058 mg/kg.

Total cyclaniliprole residues in tomatoes (including cherry tomatoes) in ranked order were (n = 22): 0.019, 0.022, 0.028, 0.029 (2), 0.036 (3), 0.037, 0.040, 0.041, 0.042, 0.043, 0.045, 0.047, 0.048, 0.049, 0.051, 0.053 (2), 0.08 and 0.1 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 22): 0.014, 0.017, 0.022, 0.027 (2), 0.028, 0.029, 0.030, 0.031 (2), 0.032, 0.034, 0.035 (2), 0.036 (3), 0.037, 0.039 (2), 0.060 and 0.076 mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.033 mg/kg for the Subgroup of tomatoes and withdraws its previous recommendations of 0.1 mg/kg for tomato and cherry tomato.

The Meeting estimated a median residue of 0.024 mg/kg (parent only) for animal dietary burden calculations.

Peppers

Cyclaniliprole residues in bell peppers and non-bell peppers [NB] in ranked order were (n = 12): 0.014,

0.019, 0.025, 0.041[NB], 0.046, 0.048, 0.057[NB], 0.068, 0.072, 0.077[NB], 0.098, and 0.10 mg/kg. Using scaling factors of 0.74–0.99, scaled residues in ranked order were (n = 12): 0.011, 0.014, 0.018, 0.031[NB], 0.036, 0.043[NB], 0.045, 0.050, 0.054, 0.058[NB], 0.073 and 0.099 mg/kg.

Total cyclaniliprole residues in sweet bell and non-bell peppers in ranked order were (n = 12): 0.025, 0.029, 0.035, 0.051[NB], 0.056, 0.059, 0.067[NB], 0.083, 0.094[NB], 0.096, 0.11, and 0.12 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues were (n = 12): 0.020, 0.022, 0.026, 0.039[NB], 0.044, 0.050[NB], 0.055, 0.063, 0.071, 0.071[NB], 0.082 and 0.119 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR of 0.0525 mg/kg for the Subgroup of peppers (excluding martynia, okra and roselle), to replace its previous recommended maximum residue level of 0.2 mg/kg.

The Canadian critical GAP for fruiting vegetables, other than cucurbits, also covers eggplants. The Meeting decided the pepper data could be used to extrapolate the maximum residue level of 0.15 mg/kg and the STMR of 0.0525 mg/kg for peppers to the Subgroup of eggplants to replace its previous recommended maximum residue level of 0.1 mg/kg.

Chili peppers, dried

Based on the estimated maximum residue level of 0.15 mg/kg for the Subgroup of peppers (excluding Martynia, okra and Roselle) and applying a default processing factor of 10, the Meeting estimated a maximum residue level of 1.5 mg/kg for peppers, chili, dried, together with an STMR of 0.525 mg/kg parent equivalents (0.0525 mg/kg ×10), to replace its previous recommended maximum residue level of 2.0 mg/kg.

Leafy vegetables (including Brassica leafy vegetables)

The critical GAP for leafy vegetables (including Brassica leafy vegetables) is from Canada for "leafy vegetables"; 3 × 60 g ai/ha, 7 day-RTI, 1-day PHI. The Meeting received trials from Canada and the USA on leafy vegetables where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 6–9 day RTI and 1-day PHI.

Head lettuce

Cyclaniliprole residues in head lettuce with wrapper leaves, in ranked order were (n = 7): 0.067, 0.26, 0.32, 0.56, 1.2, 1.4 and 2.2 mg/kg. Using scaling factors of 0.74–0.97, scaled residues in head lettuce with wrapper leaves in ranked order were (n = 7): 0.051, 0.19, 0.28, 0.54, 0.87, 1.04 and 2.14 mg/kg.

Total cyclaniliprole residues in head lettuce with wrapper leaves were in ranked order (n = 7): 0.096, 0.31, 0.36, 0.61, 1.4, 1.6 and 2.3 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in head lettuce with wrapper leaves were in ranked order (n = 7): 0.074, 0.23, 0.32, 0.59, 1.02, 1.19 and 2.24 mg/kg.

Leaf lettuce

Cyclaniliprole residues in leaf lettuce in ranked order were (n = 10): 0.094, 0.25, 0.77, 0.86, 1.2, 1.3, 2.0, 2.2, 2.4 and 3.0 mg/kg. Using scaling factors of 0.73–0.98, scaled residues in ranked order were (n = 10): 0.072, 0.18, 0.57, 0.63, 0.97, 1.18, 1.82, 1.68, 1.97 and 2.27 mg/kg.

Total cyclaniliprole residues in leaf lettuce in ranked order were (n = 10): 0.11, 0.27, 0.79, 1.0, 1.3, 1.4, 2.2, 2.6 (2) and 3.3 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues were in ranked order (n = 10): 0.084, 0.20, 0.58, 0.73, 1.05, 1.28, 1.98 (2), 2.16 and 2.50 mg/kg.

Cos lettuce

In trials from the USA matching the critical GAP, cyclaniliprole residues in cos lettuce were (n = 3): 0.74, 0.76 and 0.94 mg/kg. Using scaling factors of 0.8–0.9, scaled residues were (n = 3): 0.57, 0.67 and 0.70 mg/kg.

Total cyclaniliprole residues in cos lettuce in ranked order were (n = 3): 0.84, 0.85 and 1.0 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues were (n = 3): 0.63, 0.75 and 0.77 mg/kg.

Spinach

Cyclaniliprole residues in spinach in ranked order were (n = 8): 1.4, 2.0, 2.3, 2.4, 2.8, 2.9, 3.4 and 4.6 mg/kg. Using scaling factors of 0.73–0.99, scaled residues in ranked order were (n = 8): 1.4, 1.8, 1.9, 2.1, 2.2, 2.5, 2.9 and 3.5 mg/kg.

Total cyclaniliprole residues in spinach in ranked order were (n = 8): 1.5, 2.1, 2.5, 2.7, 3.3 (2), 4.1 and 5.5 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 8): 1.5, 2.0 (2), 2.4 (2), 3.0, 3.3 and 4.2 mg/kg.

The Meeting noted that the scaled median residues of cyclaniliprole in head lettuce (with wrapper leaves), leaf lettuce, cos lettuce and spinach were within a 5-fold range. From the Kruskal-Wallis H-test, the datasets of head lettuce (with wrapper leaves), leaf lettuce, cos lettuce and spinach were not from the same population. Therefore, using the spinach dataset, the Meeting estimated a maximum residue level of 7 mg/kg and an STMR of 2.4 mg/kg for the Subgroup of Leafy greens.

Subgroup of Leaves of Brassicaceae

Mustard greens

Cyclaniliprole residues in mustard greens in ranked order were (n = 5): 1.4, 3.0, 4.0, 4.1, and 5.9 mg/kg. Using scaling factors of 0.75–0.98, scaled residues in ranked order were (n = 5): 1.4, 3.0 (2), 4.0 and 4.4 mg/kg.

Total cyclaniliprole residues in mustard greens in ranked order were (n = 5): 1.5, 3.5, 4.3, 4.4 and 6.2 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): 1.5, 3.2, 3.5, 4.3 and 4.6 mg/kg.

Noting that mustard greens is the representative crop of the leaves of brassicaceae subgroup, the Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 3.5 mg/kg for the Subgroup of leaves of brassicaceae to replace its previous recommended maximum residue level of 15 mg/kg.

The Meeting estimated a median residue value of 3.0 mg /kg and a highest residue of 4.4 mg/kg, both for parent only, for the Subgroup of leaves of brassicaceae for livestock dietary burden calculations.

Tuberous and Corm Vegetables

The critical GAP for tuberous and corm vegetables is from Canada; 3×60 g ai/ha, 5 day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on potatoes where 3 foliar spray applications were made at a 100 g ai/ha per application, 4–6-day RTI and 6–7-day PHI.

Cyclaniliprole residues in potatoes were all < 0.01 mg/kg (n = 25) when treated at seasonal application rates of 214-308 g ai/ha, equivalent to 1.2–1.7-fold the critical GAP in Canada. Therefore, when treated in accordance with the critical GAP from Canada, residues of cyclaniliprole in potatoes are not expected to be quantifiable.

Total cyclaniliprole residues in potatoes were all < 0.01 mg/kg (n = 25) following treatment at exaggerated rates (1.2–1.7-fold the critical GAP in Canada). Therefore, when treated in accordance with the critical GAP from Canada, total residues of cyclaniliprole in potatoes are not expected to be quantifiable.

The Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR of 0 mg/kg parent equivalents for the Subgroup of Tuberous and corm vegetables.

The Meeting estimated a median residue value of 0 mg/kg (parent only) for potatoes for livestock dietary burden calculations.

Tree nuts

The critical GAP for tree nuts is from Canada: 3 × 80 g ai/ha, 14 day-RTI, 30-day PHI. The Meeting received trials from the USA on tree nuts where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 12–15 day RTI and 30-day PHI for almonds and 14–30 days for pecans.

Almonds

Cyclaniliprole residues in almond nutmeats in ranked order were (n = 5): < 0.01 (2), 0.013 (2) and 0.015 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): < 0.01 (2), 0.010 (2) and 0.012 mg/kg.

Total cyclaniliprole residues in almond nutmeats in ranked order were (n = 5): < 0.01 (2), 0.024 (2) and 0.026 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): < 0.01 (2), 0.019 (2) and 0.021 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.019 mg/kg for almonds.

Pecans

Two of the five pecan field trials from the USA differed from the critical GAP with regard to the pre-harvest interval. Therefore, due to the insufficient number of trials, conducted in accordance with the critical GAP, the Meeting did not estimate a maximum residue level and STMR for pecans.

Tea

The critical GAP for tea is from Japan: 1 × 4.5 g ai/hL and a 3-day PHI.

In trials from Japan matching the critical GAP, cyclaniliprole residues in dried tea leaves in ranked order were (n = 6): 4.8, 6.8, 8.4, 13, 16 and 28 mg/kg.

The total cyclaniliprole residues in dried tea leaves in ranked order were (n = 6): 4.9, 7.5, 11, 14, 17 and 30 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 12.5 mg/kg for tea, green, black (black, fermented and dried).

Miscellaneous fodder and forage

Almond hulls

The critical GAP for tree nuts is from Canada: 3×80 g ai/ha, 14 day-RTI, 30-day PHI. The Meeting received trials from the USA on almonds where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha/application, 13–15 day RTI and 30–31 day PHI.

Cyclaniliprole residues in almond hulls, on a dry weight basis, in ranked order were (n = 5): 1.8, 2.0, 2.1, 2.5 and 3.3 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): 1.4, 1.6, 1.7, 2.0 and 2.6 mg/kg.

The Meeting estimated a maximum residue level of 6 mg/kg and median residue of 1.7 mg/kg for almond hulls.

Residues in processed commodities

At the current Meeting, processing studies were reviewed for oranges and potatoes, while at the 2017 Meeting processing studies were reviewed for apples, peaches, tomatoes, plums, grapes, and tea. Maximum residue levels in processed commodities are only proposed where they are higher than the maximum residue levels in the raw commodity. For maximum residue level derivation the processing factors are based on parent only. For estimation of the dietary exposure, STMR-P's were based on the processing factors for parent + metabolite NK-1375 (separate table).

Table 1 Maximum Residue Level Derivation for Processed Commodities

Raw Agricultural Commodity (RAC)	Processed Commodity	PF (parent only)	PF (best estimate)	MRL × PF (mg/kg)
Citrus fruit [MRL = 0.4 mg/kg]	Citrus, oil	116[a]	116 (n = 1)	50
Plum [MRL = 0.15]	Prunes	3.7	3.7 (n = 1)	0.6
Tomato [MRL = 0.08]	Tomato, dried	3.33, 3.75, 3.8, 4, 5.5	3.8 (median, n = 5)	0.35

[a] Noting that the Meeting is recommending a maximum residue level for the Group of citrus fruits, the processing factor for orange was extrapolated to the entire citrus fruit crop group.

Cyclaniliprole residues were shown to concentrate in citrus oil, prunes, and tomato, dried.

The Meeting estimated a maximum residue level of 50 mg/kg (0.4 mg/kg x 116 = 46.4 mg/kg) for citrus oil. The Meeting also estimated maximum residue levels of 0.6 mg/kg (0.15 mg/kg × 3.7 = 0.56 mg/kg) for prunes and 0.35 mg/kg (0.08 mg/kg × 3.8 = 0.30 mg/kg) for tomato, dried to replace its previous recommended maximum residue levels of 0.8 mg/kg and 0.4 mg/kg, respectively, for these processed commodities.

Table 2 Derivation of STMR-Ps for dietary exposure estimation

Commodity	PF (parent + NK-1375)	PF (best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)
Citrus fruit			0.087	
- juice	0.12	0.12 (n = 1)		0.01
- oil	116	116 (n = 1)		10.1
Apples			0.057	
- juice, pasteurised	0.13, < 0.33, < 0.5	< 0.33 (median, n = 3)		0.019
Plums			0.052	
- dried	3.7 [a]	3.7 (n = 1)		0.19
Grapes			0.12	
- must	0.63, 0.63, 0.71, 0.86	0.67 (median n = 4)		0.08
- juice, pasteurised	0.20, 0.12, 0.33, 0.38, 0.50, 0.71	0.36 (median, n = 6)		0.04
- wine, stored	0.14, 0.20, < 0.33, 0.38, 0.040, 0.50	0.355 (median, n = 6)		0.04
Tomatoes			0.033	
- canned	< 0.14, < 0.17, < 0.2, < 0.5, < 0.5	0.14 (median, n = 5)		0.005
- paste	0.49, 0.50, 0.67, 1.57, 1.8, 2.5	1.12 (median, n = 6)		0.04
- juice, pasteurised	< 0.5, 0.17, 0.8, 1.14, 1.5	0.8 (median, n = 6)		0.03
- dried	3, 3.2, 3.3, 5, 6	3.3 (median, n = 5)		0.11
Potatoes			0	
-crisps	< 0.26	< 0.26 (n = 1)		0
-flakes/granules	< 0.26	< 0.26 (n = 1)		0

Commodity	PF (parent + NK-1375)	PF (best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)
Tea			13	
-infusion	0.09 (3), 0.13 (2), 0.14, 0.17 (3), 0.19	0.14 (median)		1.8

PF based on total cyclaniliprole; cyclaniliprole + NK-1375 expressed as parent equivalents

STMR-P is used for the dietary exposure estimates and is based on the residue definition for dietary risk assessment: cyclaniliprole + NK-1375 expressed as parent equivalents

Livestock dietary burden

The Meeting estimated the livestock dietary burden for cyclaniliprole on the basis of the diets (USA/Canada, EU, Australia and Japan) using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual[9]. Calculation from highest residue and median values (some bulk commodities) provide the levels in feed suitable for estimating maximum and highest residue levels while calculation from median values for feed is suitable for estimating STMR values for animal commodities.

The commodities used in estimating livestock dietary burdens are included in the table below and capture both the feed items assesssed at the 2017 Meeting together with the new feed items assessed by the current Meeting. In the rotational crop studies, reviewed by the 2017 Meeting, residues of cyclaniliprole were detected in wheat straw and forage. For the dietary burden calculation, these levels were extrapolated to the straw/hay (dry feed commodities) and forage (wet feed commodities) of the whole group of cereal grain crops. The input was based on the intake of parent only.

Table 3 Commodities for consideration in dietary burden calculations

Codex Classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
AB 0001	Citrus pulp, dry (median 0.078 mg/kg x PF 1.27)	0.099	
AB 0226	Apple pomace, wet (median 0.047 mg/kg ×PF 3.2)	0.15	-
AB 0269	Grape pomace, wet (median 0.11 mg/kg ×PF 1.7)	0.19	-
VL 0054	Leaves of Brassicaceae, (based on mustard greens dataset)	3.0	4.4
VB 0041	Cabbages, head	0.024	0.38
AB – no code	Tomato pomace, wet (median of 0.024×PF 0.67)	0.02	-
	Potato, wet peels (median of 0 x PF 4.25)	0	
AF – no code	Barley, forage (30% DM)	0.01	0.026
AS 0640	Barley, hay (88% DM)	0.0475	0.18
AS 0641	Barley, straw (89% DM)	0.0475	0.18
AF/AS – no code	Corn, field, forage/silage (40% DM)	0.01	0.026
AS 0645	Corn, field, stover (83% DM)	0.0475	0.18
AF – no code	Corn, pop, stover (83% DM)	0.0475	0.18
AF – no code	Corn, sweet, forage (48% DM)	0.01	0.026
AF – no code	Corn, sweet, stover (83% DM)	0.0475	0.18
AF – no code	Millet, forage (30% DM)	0.01	0.026
AF – no code	Millet, hay (85% DM)	0.0475	0.18
AF 0646	Millet, straw (90% DM)	0.0475	0.18
AF 0647	Oat, forage (30% DM)	0.01	0.026

[9] http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/

Codex Classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
AS 0647	Oat, hay (90% DM)	0.0475	0.18
AF – no code	Oat, straw (90% DM)	0.0475	0.18
AS0469	Rice, straw (90% DM)	0.0475	0.18
AF0650	Rye, forage (30% DM)	0.01	0.026
AS0650	Rye, straw (88% DM)	0.0475	0.18
AF0651	Sorghum, grain, forage (35% DM)	0.01	0.026
AS – no code	Sorghum, grain, stover (88% DM)	0.0475	0.18
AF – no code	Triticale, forage (30% DM)	0.01	0.026
AF – no code	Triticale, hay (88% DM)	0.0475	0.18
AF – no code	Triticale, straw (90% DM)	0.0475	0.18
AF 0654	Wheat forage (25% DM)	0.01	0.026
AS 0654	Wheat, hay (88% DM)	0.0475	0.18
AS 0654	Wheat, straw (88% DM	0.0475	0.18
AM 0660	Almond hulls	1.7	-

Note: levels for cereal straw, hay, and forage are presented on as received basis.

The dietary burden calculations for cyclaniliprole for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6 of the 2019 JMPR Report and summarized below.

Table 4 Livestock dietary burden for cyclaniliprole

		Livestock dietary burden for cyclaniliprole (based on cyclaniliprole parent only) ppm of dry matter diet			
		USA/Canada	EU	Australia	Japan
Max	**beef cattle**	0.06	9.0	14.7[a]	0.11
	dairy cattle	4.52	6.0	12.1[b]	0.07
	poultry – broiler	-	0.005	-	-
	poultry – layer	-	1.49[c]	-	-
Mean	**beef cattle**	0.021	6.10	10.0[d]	0.03
	dairy cattle	3.06	4.07	8.3[e]	0.02
	poultry – broiler	-	-	-	-
	poultry – layer	-	1.00[f]	-	-

[a] Highest maximum beef cattle dietary burden suitable for maximum residue level estimates for mammalian meat.
[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk.
[c] Highest maximum poultry-layer dietary burden suitable for maximum residue level estimates for poultry meat and eggs.
[d] Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian meat.
[e] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
[f] Highest mean poultry-layer dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodity maximum residue levels

Table 5 Animal commodity residue levels for mammalian matrices

	Feeding level (ppm) for milk residues	Residues (mg/kg) in milk cream [a]	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study [b]	3.5	0.02	3.5	< 0.01	0.040	0.045	0.045
	11.6	0.078	11.6	0.032	0.141	0.114	0.199
Dietary burden and high residue estimate	12.1	0.078	14.7	0.032	0.141	0.114	0.199
STMR beef or dairy cattle							
Feeding study [c]	3.5	0.02	3.5	< 0.01	0.021	0.022	0.023
	11.6	0.078	11.6	0.018	0.071	0.059	0.074
Dietary burden and mean residue estimate	8.3	0.054	10.0	0.016	0.061	0.052	0.064

[a] No residues were found in skimmed milk, all residues were detected in milk cream which contains 50% milk fat, therefore residues in milk fat are 0.156 mg/kg (0.078 mg/kg ÷ 0.50). Based on the default milk fat content of 4% for whole milk, the maximum residue level and STMR for mammalian milk were estimated at 0.01 mg/kg (0.156 x 0.04 = 0.006) and 0.004 mg/kg ((0.054 ÷ 0.5) x 0.04 = 0.004), respectively.

[b] Highest residue for tissues and milk cream

[c] Mean residues for tissues and milk cream

The Meeting estimated maximum residue levels of 0.01 mg/kg for milks, 0.2 mg/kg for milk fats, 0.25 mg/kg for meat, based on fat (from mammals other than marine mammals) and mammalian fats (except milk fats) and 0.2 mg/kg for edible offal (mammalian). The Meeting estimated STMRs of 0.004 mg/kg for milks, 0.108 mg/kg for milk fats, 0.016 mg/kg for meat (muscle), 0.061 mg/kg for liver, 0.052 mg/kg for kidney and 0.064 mg/kg for mammalian fat. These recommendations are intended to replace all previous recommendations for all ruminant matrices.

Poultry

In the absence of a poultry feeding study, the Meeting relied on the laying hen metabolism study to determine the maximum residue levels and STMRs in poultry commodities.

Table 6 Animal commodity residue levels for poultry matrices

	Dose level (ppm) for egg TRRs	Cyclaniliprole TRRs in eggs (mg eq/kg)	Dose level (ppm) for tissue TRRs	TRRs (mg eq/kg) in			
				Fat	Skin	Muscle	Liver
Dose level from metabolism study	10.8	0.156	10.8	0.158	0.09	0.006	0.17
Dietary burden and high residue estimate	1.49	0.0004	1.49	0.0004	0.0002	0.00001	0.0004
Dietary burden and mean residue estimate	1.0	0.00027	1.0	0.00027	0.00013	0.000007	0.00027

The Meeting estimated maximum residue levels of 0.01(*) mg/kg for eggs and poultry fats, meat and edible offal and STMRs of 0 for these poultry commodities.

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 and IESTI assessment.

Definition of the residue for compliance with the MRL for plant and animal commodities: *cyclaniliprole.*

Definition of the residue for dietary risk assessment for plant commodities: *cyclaniliprole + 3-bromo-2-((2-bromo-4H- pyrazolo[1,5-d]pyrido[3,2-b]-[1,4]oxazin-4-ylidene)amino)-5-chloro-N-(1-cyclopropylethyl)benzamide (NK-1375), expressed as cyclaniliprole equivalents.* The molecular weight conversion factor to express NK-1375 in cyclaniliprole equivalents = 1.064.

Definition of the residue for dietary risk assessment for animal commodities: *cyclaniliprole*

The residue is fat-soluble.

The Meeting maintained its previous recommendation for the maximum residue level of 0.45 mg/kg (dw) in straw and fodder, dry of cereal grains (AS 0081).

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for cyclaniliprole is 0–0.04 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for cyclaniliprole 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 JMPR Report.

The IEDIs ranged from 1–10% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of cyclaniliprole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2017 JMPR decided that an ARfD for cyclaniliprole was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of cyclaniliprole from the uses considered is unlikely to present a public health concern.