5.12 Fluensulfone (265)

RESIDUE AND ANALYTICAL ASPECTS

Fluensulfone is a heterocyclic fluoroalkenyl sulfone nematicide. The mode of action is through feeding inhibition and paralysis of adults and juveniles. The IUPAC name for fluensulfone is 5-chloro-1,3-thiazol-2-yl 3,4,4-trifluorobut-3-en-1-yl sulfone.

Fluensulfone was evaluated for toxicology by JMPR in 2013 and 2014.

An ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established by the 2014 JMPR. Residues were evaluated by the JMPR in 2014 and 2016. The 2016 JMPR established the following residue definitions:

For compliance with MRLs for plant commodities: Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents.

- For estimation of dietary exposure for plant commodities: Fluensulfone.
- For compliance with MRLs and for estimation of dietary exposure for animal commodities: Fluensulfone.

The residue is fat-soluble.

The 2014 JMPR agreed that the exposure risks from the metabolite MeS should be assessed using the Threshold of Toxicological Concern (TTC) approach and the 2016 JMPR confirmed that the TTC approach for this metabolite remained appropriate.

Fluensulfone was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received new supporting data and/or GAP information for citrus, pome fruit, stone fruit, grapes, guava, tree nuts, coffee, sugar cane and black pepper, additional rotational crop studies, frozen storage stability studies, processing studies and a livestock feeding study for the BSA/TSA metabolites.

Methods of analysis

The Meeting received additional validation information on the analytical methods (based on Method MTH-083) evaluated by the 2014 JMPR and used for measuring fluensulfone and metabolite BSA residues in the commodities considered by the current Meeting.

The Meeting concluded that for the commodities considered by the Meeting, the methods used in the new residue trials were sufficiently validated and are suitable to measure fluensulfone and metabolite BSA in plant commodities.

Stability of pesticide residues in stored analytical samples

The Meeting received additional information on storage stability of fluensulfone and metabolite BSA in orange, tomato, soya bean, dry beans, cereal grains and sugar cane (raw and processed).

Storage stability studies evaluated by the current and previous Meetings showed that in analytical samples stored at or below -18 °C, fluensulfone and metabolite BSA residues were stable for at least the following intervals:

High water matrices - Fruiting vegetables for 15–16 months, sugar cane for 6 months;

High acid matrices - orange for 18 months

High starch matrices - cereal grains for 10 months; Potato for 23 months; carrot for 17.5 months

High protein matrices - dry beans for 10 months

High oil matrices - peanut for 13 months

Low moisture matrices - cereal straws for 10 months

The Meeting agreed that the demonstrated storage stability in these representative plant commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

Residues in rotational crops

Field rotational crop studies

The 2014 JMPR evaluated confined rotational crop studies (radish, lettuce and wheat as follow crops) and concluded that overall, fluensulfone can be expected to dissipate rather rapidly in the environment, with a concomitant increase in residues of BSA, TSA, and to a much lesser extent, MeS. BSA residues should then decline but TSA appears to be stable for an extended period; may accumulate in soils following repeated uses of fluensulfone.

The 2016 JMPR evaluated a field rotational cropping study involving a single bare soil application of fluensulfone (4.0 kg ai/ha) and to accommodate residues arising in rotational crops, recommended maximum residue levels for root and tuber vegetables, leafy vegetables and legume vegetables not elsewhere specified.

The current Meeting received a new field crop rotation study involving 56 field trials where rotational cereal crops were planted after a bare soil application of fluensulfone at rates of 3.6–4.2 kg ai/ha (approximating the GAP seasonal rate). The plant-back intervals were 3 months (winter wheat) and 10 months (maize, rice, sorghum and spring wheat).

Samples of forage, grain, hay and straw were stored frozen (<-10 °C) for up to 19 months before LC-MS/MS analysis (Method MTH-083) for fluensulfone and metabolite BSA. Mean procedural recoveries ranged from 72–111% and the LOQs for both analytes were 0.01 mg/kg.

Fluensulfone residues were only detected in the 3-month PBI winter wheat hay (0.02 mg/kg), but BSA residues were present up to 0.07 mg/kg in grain, 2.4 mg/kg in forage, 4.0 mg/kg in hay and up to 2.4 mg/kg in straws and stovers. Highest total residues (fluensulfone plus BSA, expressed as fluensulfone) were 0.12 mg/kg (maize grain), 3.7 mg/kg (forages) and 6.2 mg/kg (hays and straws).

The US fluensulfone label includes a requirement to observe a plant-back interval of 90 days for wheat, barley, buckwheat and oats, and 10 month plant-back interval for all other cereal grain crops.

Cereal forages

In 11 trials where wheat was grown as a rotational crop and in 20 trials where maize was grown as a rotational crop, residues of fluensulfone in forage were all < 0.01 mg/kg (n = 35).

For the purposes of estimating the livestock dietary burden, the Meeting agreed to extrapolate these data to cereal forages in general and established a median and highest residue of 0.01 mg/kg for fluensulfone in cereals forages (as received).

Cereal grains

In 15 trials where wheat was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 15) and total residues were < 0.025 (10), 0.03 (2), 0.04 (2) and 0.07 mg/kg.

Extrapolating these data to the wheat subgroup, the Meeting estimated a maximum residue level of 0.08 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of wheat, similar grains, and pseudocereals without husks.

Noting that the US plant-back interval for barley and oats was the same as for wheat, the Meeting also agreed to extrapolate the wheat data to the barley sub-group and estimated a maximum residue level of 0.08 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of barley, similar grains, and pseudocereals with husks.

In 18 trials where maize was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 18) and total residues were < 0.025 (17) and 0.12 mg/kg.

Extrapolating these data to the maize and sweetcorn subgroups, the Meeting estimated a maximum residue level of 0.15 mg/kg for fluensulfone (total residues), a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroups of maize cereals and sweetcorns and a HR of 0.01 mg/kg for sweet corn (corn-on-the-cob) and baby corn.

In 11 trials where rice was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 11) and total residues were < 0.025 (10) and 0.03 mg/kg.

Extrapolating these data to the rice subgroup, the Meeting estimated a maximum residue level of 0.04 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of rice cereals.

In nine trials where sorghum grain was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 9) and total residues were < 0.025 (8) and 0.03 mg/kg.

Extrapolating these data to the sorghum grain subgroup, the Meeting estimated a maximum residue level of 0.04 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of sorghum grain and millet.

Cereal fodders

In 15 trials where wheat was grown as a rotational crop, residues of fluensulfone in hay were < 0.01 (14) and 0.02 mg/kg (n = 15) and total residues were < 0.025, 0.04, 0.07, 0.09, 0.19, 0.25, 0.30, 0.39, 0.41, 0.65, 3.1, 3.3, 4.0, 5.5 and 6.2 mg/kg (n = 15).

Noting that the US plant-back interval for barley and oats was the same as for wheat, the Meeting agreed to use the wheat data, after correction for an average 88% dry matter content, to estimate a maximum residue level of 15 mg/kg (dw) for fluensulfone (total residues), a median residue of 0.01 mg/kg (as received) and a highest residue of 0.02 mg/kg for fluensulfone (parent only) in hay or fodder (dry) of grasses except maize fodder and rice straw and fodder, dry.

In 15 trials where wheat was grown as a rotational crop, residues of fluensulfone in straw were < 0.01 (15) mg/kg (n = 15) and total residues were 0.03, 0.04 (3), 0.09 (2), 0.16 (2), 0.18, 0.42, 0.64, 1.4, 2.1, 2.3 and 3.7 mg/kg (n = 15).

Noting that the US plant-back interval for barley and oats was the same as for wheat, the Meeting agreed to use the wheat data, after correction for an average 88% dry matter content, to estimate a maximum residue level of 6 mg/kg (dw) for fluensulfone (total residues), a median residue of 0.01 mg/kg (as received) and a highest residue of 0.01 mg/kg for fluensulfone (parent only) in straw or fodder (dry) of cereal grains except maize fodder and rice straw and fodder, dry.

In 20 trials where maize was grown as a rotational crop, residues of fluensulfone in stover were < 0.01 (20) mg/kg (n = 20) and total residues were < 0.025 (11), 0.03, 0.04 (4), 0.09, 0.12, 0.36 and 0.39 mg/kg (n = 20).

After correction for an average 83% dry matter content, the Meeting estimated a maximum residue level of 0.6 mg/kg for fluensulfone (total residues) and a median residue of 0.01 mg/kg (as received) and a highest residue of 0.01 mg/kg (as received) for fluensulfone (parent only) in maize fodder.

In 11 trials where rice was grown as a rotational crop, residues of fluensulfone in straw were < 0.01 (11) mg/kg (n = 11) and total residues were < 0.025 (9), 0.04 and 0.04 mg/kg (n = 11).

After correction for an average 90% dry matter content, the Meeting estimated a maximum residue level of 0.06 mg/kg (dw) for fluensulfone (total residues) and a median residue of 0.01 mg/kg (as received) and a highest residue of 0.01 mg/kg (as received) for fluensulfone (parent only) in rice straw and fodder, dry.

Results of supervised residue trials on crops

Supervised trials were available for the use of fluensulfone on citrus fruit, pome fruit, stone fruit, grapes,

guava, sugar cane, tree nuts, coffee and black pepper.

Product labels were available from Australia, Brazil and the USA.

When calculating total fluensulfone residues (defined as the sum of fluensulfone and the BSA metabolite, expressed as fluensulfone), the concentration of BSA in each sample was multiplied by 1.53 (the ratio of the molecular weights of fluensulfone and BSA) and the resulting product added to the concentration of fluensulfone. Residues reported as <LOQ were assumed to bear residues at the LOQ.

Citrus fruit

The critical GAP for fluensulfone on citrus in the USA is for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation) with a PHI of 60 days.

In independent trials on citrus, conducted in the USA and matching this GAP:-

Fluensulfone residues in oranges (eight trials) were: < 0.01 (7) and 0.014 mg/kg Total residues were: < 0.025 (2), 0.027 (2), 0.030, 0.040, 0.042 and 0.046 mg/kg (n = 8).

Fluensulfone residues in mandarins (three trials) were: < 0.01 (3) mg/kg Total residues were: 0.032, 0.058 and 0.072 mg/kg (n = 3).

Fluensulfone residues in lemons (five trials) were: < 0.01 (4) and 0.049 mg/kg Total residues were: < 0.025 (3), 0.087 and 0.13 mg/kg (n = 5).

Fluensulfone residues in grapefruit (six trials) were: < 0.01 (5) and 0.014 mg/kg Total residues were: < 0.025 (4), 0.026 and 0.077 mg/kg (n = 6).

Noting that the residues arising from an early season soil application to oranges, lemons, mandarins and grapefruit trees were not statistically different (Kruskall-Wallis), the Meeting agreed to estimate a group maximum residue level based on a combined total residue data set of < 0.025 (9), 0.026, 0.027 (2), 0.03, 0.032, 0.04, 0.042, 0.046, 0.058, 0.072, 0.077, 0.087 and 0.13 mg/kg (n = 22).

For dietary intake estimation, the combined fluensulfone data set for whole fruit is: ≤ 0.01 (19), 0.014 (2) and 0.049 mg/kg and the highest individual residue was 0.063 mg/kg (in lemons).

The Meeting estimated a maximum residue level of 0.2 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg and a HR of 0.063 mg/kg for fluensulfone in citrus fruit.

Pome fruit

The critical GAP for fluensulfone on pome fruit (except persimmons) is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

In independent trials on pome fruit, conducted in Canada and the USA and matching this GAP, fluensulfone residues in apples (16 trials) and pears (eight trials) were all < 0.01 mg/kg. Fluensulfone residues were also < 0.01 mg/kg in two exaggerated-rate (5×) trials on apples.

In these trials, total residues were:

Apples: < 0.025 (10), 0.028 (3), 0.031, 0.037 and 0.16 mg/kg (n = 16);

Pears: < 0.025 (5), 0.026, 0.11 and 0.17 mg/kg (n = 8).

Noting that the residues arising from an early season soil application to apple and pear trees were not statistically different (Kruskall-Wallis), the Meeting agreed to estimate a group maximum residue level based on a combined total residue data set of < 0.025 (15), 0.026, 0.028 (3), 0.031, 0.037, 0.11, 0.16 and 0.17 mg/kg (n = 24).

The Meeting estimated a maximum residue level of 0.2 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg and a HR of 0 mg/kg for fluensulfone in pome fruit (except persimmon, Japanese).

Stone fruit

The critical GAP for fluensulfone on stone fruit is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

In independent trials on stone fruit, conducted in the USA and matching this GAP, fluensulfone residues in the flesh of cherries (five trials) and peaches (nine trials), plums (five trials) were all < 0.01 mg/kg (n = 19). Fluensulfone residues were also < 0.01 mg/kg in two exaggerated-rate (5×) trials on plums.

While residues were not measured in whole fruit, the 2017 Meeting concluded that in general, the contribution of the pit to the weight of the whole fruit is approximately 10% and that the flesh residues could be used to estimate maximum residue levels for stone fruit.

In these trials, total residues in flesh were:

Cherries: < 0.025 (2), 0.028, 0.031 and 0.050 mg/kg (n = 5);

Peaches: < 0.025 (6), 0.035, 0.046 and 0.075 mg/kg (n = 9);

Plums: < 0.025 (3), 0.026 and 0.028 mg/kg (n = 5).

Noting that the residues arising from an early season soil application to cherry, peach and plum trees were not statistically different (Kruskall-Wallis), the Meeting agreed to estimate a group maximum residue level based on a combined total residue data set of < 0.025 (11), 0.026, 0.028, 0.028, 0.031, 0.035, 0.046, 0.050 and 0.075 mg/kg (n = 19).

The Meeting estimated a maximum residue level of 0.09 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg and a HR of 0 mg/kg for fluensulfone (parent only) in stone fruit.

Small fruit vine climbing

Grapes

The critical GAP for fluensulfone on small fruit vine climbing crops is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

In independent trials on grapes, conducted in the USA and matching this GAP, fluensulfone residues in berries were all < 0.01 mg/kg (n = 9). Fluensulfone residues were also < 0.01 mg/kg in two exaggerated-rate (5×) trials on grapes.

In these trials, total residues were: < 0.025 (6), 0.027, 0.050 and 0.48 mg/kg (n = 9).

Noting that grapes is a representative commodity for the small fruit vine climbing sub-group, and that the US GAP includes all commodities in this sub-group, the Meeting estimated a maximum residue level of 0.7 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg and a HR of 0 mg/kg for fluensulfone (parent only) in the small fruit vine climbing sub-group.

Guava

The critical GAP for fluensulfone on guava is in Brazil, for a banded within-row soil treatment of 0.96 kg ai/ha, at the beginning of the rainy season, when trees are growing new roots. No PHI is specified.

In four Brazilian trials where single banded soil applications of 0.96 kg ai/ha were applied during mid-late March (about the end of flowering), fluensulfone residues in fruit sampled at intervals from 60–90 DAT were all < 0.08 mg/kg and total residues were all < 0.2 mg/kg (n = 4).

The Meeting concluded that since the validated LOQ of 0.08 mg/kg was higher than the level that can be achieved using current analytical techniques (0.01 mg/kg), maximum residue levels for guava could not be recommended.

Sugar cane

The critical GAP for fluensulfone on sugar cane is in the USA, for a soil broadcast or band application of 3.92 kg ai/treated ha at planting.

In independent trials on sugar cane, conducted in Australia (four trials) and the USA (seven trials) and matching this GAP, fluensulfone residues in the canes/billets were all < 0.01 mg/kg.

In these trials, total residues were: < 0.025 (9), 0.027 and 0.045 mg/kg (n = 11).

The Meeting estimated a maximum residue level of 0.06 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg and a HR of 0.01 mg/kg for fluensulfone (parent only) in sugar cane.

Tree nuts

The critical GAP for fluensulfone on tree nuts is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

Almonds

In five independent trials on almonds conducted in Canada and the USA and matching this GAP, fluensulfone residues in nutmeat were all < 0.01 mg/kg (n = 5).

In these trials, total residues in nutmeat were: < 0.025 (5) mg/kg (n = 5).

Pecans

In five independent trials on pecans conducted in Canada and the USA and matching this GAP, fluensulfone residues in nutmeat were all < 0.01 mg/kg (n = 5).

In these trials, total residues in nutmeat were all < 0.025 mg/kg (n = 5).

Noting that the residues arising from an early season soil application to almond and pecan trees were relatively consistent the Meeting agreed to estimate a group maximum residue level.

The Meeting estimated a maximum residue level of 0.025 (*) mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg and a HR of 0.01 mg/kg for fluensulfone (parent only) in tree nuts.

Coffee beans

The critical GAP for fluensulfone on coffee is in Brazil, for a banded within-row soil treatment of 0.96 kg ai/ha, at the beginning of the rainy season, when bushes are growing new roots. No PHI is specified.

In eight Brazilian trials where single banded soil applications of 0.96 kg ai/ha were applied mid-late February (over flowering and up to early fruit formation), fluensulfone residues in fruit sampled at intervals from 150–210 DAT were all < 0.08 mg/kg and total residues were all < 0.2 mg/kg (n = 8).

In a further set of Brazilian trials conducted in 2017, where single banded soil applications of 0.96 kg ai/ha (eight trials) were applied early-mid February (early fruit formation), fluensulfone residues in fruit sampled at intervals from 150–210 DAT were: < 0.01 (7) and 0.01 mg/kg. Fluensulfone residues were also < 0.01 mg/kg in three exaggerated-rate (5×) trials on coffee. Total residues in the eight (1× rate) trials were: < 0.025 (5), 0.025 (2) and 0.041 mg/kg (n = 8).

Based on the results of the 2017 trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg for fluensulfone (parent only) in coffee bean.

Pepper, black

The critical GAP for fluensulfone on black pepper is in Brazil, with a banded within-row soil treatment

of 0.96 kg ai/ha, at the beginning of the rainy season, when vines are growing new roots. No PHI is specified.

In four Brazilian trials where single banded soil applications of 0.96 kg ai/ha were applied during early fruit formation (mid-July), fluensulfone residues in fruit sampled at intervals from 55–70 DAT were all < 0.08 mg/kg and total residues were all < 0.2 mg/kg (n = 4).

The Meeting agreed that the number of trials was not sufficient to recommend a maximum residue level for fluensulfone in pepper, black, white, pink, green.

Residues in animal feeds

Almond hulls

In five independent trials on almonds conducted in Canada and the USA and matching the US GAP, fluensulfone residues in almond hulls were all < 0.01 mg/kg (n = 5) and total residues were: 0.78, 1.8, 2.3, 2.4 and 3.0 mg/kg.

The Meeting estimated a maximum residue level of 7 mg/kg (dw) for fluensulfone (total residues) and a median residue of 0.01 mg/kg (as received) for fluensulfone (parent only) in almond hulls.

Fate of residues during processing

The Meeting received new information on the fate of fluensulfone residues during processing in apples, plums and grapes. Processing studies on citrus and sugar cane were evaluated by the 2017 JMPR.

For dietary risk assessment, in the citrus processing studies, fluensulfone residues were present in orange oil, but not detected in whole fruit. Processing factors could therefore not be calculated. However, since residues concentrated in oil, the Meeting agreed to use proportionality to estimate dietary exposure to fluensulfone in citrus oils.

In the processing studies involving an application rate of 8.1 kg ai/ha, the highest fluensulfone residue in orange oil was 0.7 mg/kg. When scaled to the GAP application rate (3.92 kg ai/ha), the Meeting estimated a STMR-P of 0.34 mg/kg for fluensulfone in citrus oil.

For estimating maximum residue levels, processing factors for total residues (sum of fluensulfone + BSA, expressed as fluensulfone) in the commodities considered at this Meeting are summarized below.

Table 1 Fluensulfone (total residue) processing factors for maximum residue level estimation

Raw commodity [MRL]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	RAC MRL × PF (mg/kg)	MRL (mg/kg)
Orange fruit [0.2 mg/kg]	Pulp (dry)	5.1, 6.3	5.7	1.1	1.5
	Oil	12, 0.72	6.3	1.3	1.5
Apple [0.2 mg/kg]	Juice (raw)	1.4, 2.1	1.7	0.35	0.4
	Sauce	1.0, 1.0	1.0	0.2	Not required
	Dried	3.7, 5.9	4.8	1	1
Plum [0.09 mg/kg]	Dried (prunes)	2.6, 3.1	2.9	0.26	0.3
	Juice	1.1, 1.3	1.2	0.11	Not required
Grape [0.7 mg/kg]	Dried (raisins)	2.4	2.4	1.7	2
Sugar cane [0.06 mg/kg]	Molasses	7.4	7.4	0.5	0.5

Using the estimated maximum residue levels for the raw commodities and applying the calculated mean processing factors, the Meeting estimated maximum residue levels of 1.5 mg/kg for citrus oil (extrapolated from orange oil) and citrus pulp, dry; 0.4 mg/kg for apple juice; 1.0 mg/kg for apples, dried; 0.3 mg/kg for prunes, 2 mg/kg for dried grapes and 0.5 mg/kg for sugar cane molasses.

For livestock dietary burden calculation, no processing factor could be calculated for citrus pulp, dry, since there were no measurable residues of fluensulfone in the whole fruit in the processing studies. However, by scaling the fluensulfone residues (0.02 mg/kg) in citrus pulp, dry from fruit treated with 8.1 kg ai/ha to the GAP application rate of 3.92 kg ai/ha, the Meeting estimated an median residue of 0.01 mg/kg for citrus pulp, dry.

Farm animal dietary burden

The highest maximum dietary burdens in beef cattle and dairy cattle calculated by the 2016 JMPR, based on the commodities considered by that Meeting, were 2.1 and 1.0 ppm respectively (about 5× less than the 10 ppm dose used in the goat metabolism study).

The Meeting estimated that the additional feed commodities considered by the current Meeting (cereal grains and forages, citrus dried pulp, almond hulls and hays of cereals except maize and rice) would not contribute more than 0.04 ppm to these maximum and mean dietary burdens, and agreed there was no need to revise the previous maximum residue level recommendations for mammalian commodities.

For poultry, the highest maximum dietary burden for broiler and layer poultry estimated by the 2016 JMPR was 0.51 ppm. The additional dietary burden from fluensulfone residues in the new feed commodities (cereal grains and forages) is not more than 0.015 ppm. The Meeting agreed that a revision of the previously estimated maximum residue level recommendations for poultry commodities was unnecessary.

RECOMMENDATIONS

On the basis of the data obtained 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 assessments.

Definition of the residue for compliance with the MRL (plant commodities): the sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents.

Definition of the residue for compliance with the MRL (animal commodities): *fluensulfone*

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

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for Fluensulfone is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fluensulfone 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 1–3% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of fluensulfone from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for fluensulfone is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for fluensulfone were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs varied from 0–1% of the ARfD for children and 0–1% of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of fluensulfone from uses considered by the present Meeting is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

MeS (2-Methylsulfonylthiazole)

The 2016 JMPR applied the TTC approach to assess the metabolite MeS. Based on the uses considered by the 2014 and 2016 Meetings, the estimated dietary exposure of 0.07 µg/kg bw per day was below the TTC for Cramer Class III compounds of 1.5 µg/kg bw per day. The 2016 Meeting concluded that dietary exposure to MeS was unlikely to present a public health concern for the crops considered by that Meeting.

For the food commodities considered at the current Meeting (citrus fruit, pome fruit, small fruit vine climbing, sugar cane, tree nuts, coffee and cereal grains), residues of MeS were not measured in the field trials. However, MeS is predominantly a minor soil degradate (with a half-life of about 30 days) and was not found in the plant metabolism studies (tomato, lettuce, potato), nor in the rotational crop metabolism studies. In field trials where MeS residues were measured, residues above the LOQ were only found in peppers, cucumber and summer squash. For permanent crops, the Meeting considered that any uptake of MeS from soil would be insignificant. Based on the rotational crop metabolism studies (including wheat as a rotational crop), where MeS was not found, significant residues of MeS are not expected in sugar cane and cereal grains.

The Meeting recalculated its estimation of dietary exposure to residues of MeS resulting in a revised exposure estimate of 0.077 µg/kg bw per day, below the TTC for Cramer Class III compounds of 1.5 µg/kg bw per day. The Meeting concluded that dietary exposure to MeS in the commodities considered by the JMPR is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.