5.11 FLUENSULFONE (265)

TOXICOLOGY

Fluensulfone is the ISO-approved common name for 5-chloro-2-(3,4,4-trifluorobut-3-en-1-ylsulfonyl)-1,3-thiazole (IUPAC), with the CAS number 318290-98-1. Fluensulfone is a nematicide, and its mode of pesticidal activity has not been determined.

Fluensulfone was evaluated by JMPR in 2013, when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. The 2013 Meeting also evaluated limited toxicological data on three metabolites found in plants and/or animals, characterized as thiazole sulfonic acid (TSA, M-3625), methyl sulfone metabolite (MeS, M-3626) and butene sulfonic acid metabolite (BSA, M-3627). At the 2014 JMPR, additional data on these metabolites were submitted, and a dietary risk assessment of fluensulfone and its metabolites was performed, but an addendum to the toxicological monograph was not prepared.

Fluensulfone was reviewed by the present Meeting at the request of CCPR, as an additional study on one metabolite and information on the mode of action for lung tumours induced by fluensulfone had been made available. Information submitted previously on all other aspects of the toxicity of fluensulfone was not reviewed by the present Meeting.

Toxicological data

In the 18-month carcinogenicity study in mice, a statistically significant increase in lung adenomas was observed in females. Although it was not statistically significantly increased in male mice, it was noted by the current Meeting that the incidence in male controls was high and that the incidence in the high-dose group was clearly above the historical control range. Hence, the current Meeting concluded that there is no convincing evidence of a sex difference in the tumorigenic effects of fluensulfone in the lungs of mice.

Mechanistic studies were carried out to determine the mode of action for the induction of lung tumours in mice by fluensulfone and its relevance to humans. A number of chemicals cause species-specific lung tumours in mice. The underlying cause has been attributed to the high metabolic activity of mouse lung resulting from a relatively high abundance of club cells in mouse lung and high levels of expression of mouse-specific Cyp2f2 in these cells. Rats have appreciably lower metabolic activity in the lungs compared with mice, and metabolic activity in the lungs of humans is reported to be even lower than that in rats.

Fluensulfone is extensively metabolized by male and female mouse lung microsomes, whereas essentially no metabolic activity was seen in human lung microsomes. Treatment with fluensulfone caused increased cell proliferation in the lungs of both male and female mice, evident after 3 days but not after 7 days of exposure. There was evidence using anti-CC10 antibodies, which recognize a major club cell secretory protein, that the proliferating cells were club cells. Studies in Cyp2f2 knockout mice established that fluensulfone-induced cell proliferation depends upon the presence of this P450 enzyme. In wild-type mice treated with fluensulfone at 200 ppm (equal to 56 mg/kg bw per day), cell proliferation increased 5- to 10-fold, whereas in Cyp2f2 knockout mice, there was no observable difference in proliferation rate when compared with the controls.

Alternative modes of action, including genotoxicity, cytotoxicity, inflammation, immunosuppression and receptor-mediated mitogenesis, were investigated and excluded.

The evidence presented supports a mode of action for the induction of lung tumours in mice by fluensulfone that involves initial metabolism by Cyp2f2, leading to proliferation of club cells. The increased proliferation of these cells leads to alveolar/bronchiolar hyperplasia (bronchiolization), resulting in the emergence of neoplasia. Not all of the key events in this mode of action have been

established robustly. However, the dependence of the mode of action on Cyp2f2 and the absence of such metabolism in human lung, together with differences in the number (much lower) and distribution of club cells in human lung, indicate that this mode of action is not relevant to humans.

Based on the previous Meeting's conclusions that fluensulfone is unlikely to be genotoxic in vivo and that the mode of action for lung tumours in mice will exhibit a threshold and is unlikely to be relevant to humans, the present Meeting concluded that fluensulfone is unlikely to pose a carcinogenic risk to humans from the diet.

Toxicological data on metabolites and/or degradates

For three plant metabolites, studies on acute oral toxicity and genotoxicity were included in the 2013 JMPR toxicological monograph. Additional repeated-dose toxicity studies were evaluated by JMPR in 2014, but no addendum to the toxicological monograph was prepared. For a complete overview, and as a new 90-day study with 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA) was submitted, all available toxicological data on these metabolites are presented below.

5-Chloro-thiazole-2-sulfonic acid (thiazole sulfonic acid, TSA, M-3625) was of low acute oral toxicity (LD_{50} > 2000 mg/kg bw) in the rat and was not genotoxic in vitro or in vivo. In a 28-day toxicity study that was not GLP compliant or fully compliant with Organisation for Economic Co-operation and Development (OECD) guidelines (e.g. group size of three animals of each sex per dose), rats received TSA in the diet at 0, 120, 500, 1200 or 12 000 ppm (equal to 0, 10, 41, 113 and 1194 mg/kg bw per day for males and 0, 12, 43, 123 and 1369 mg/kg bw per day for females, respectively). The NOAEL was 1200 ppm (equal to 113 mg/kg bw per day), based on kidney tubule basophilia in males at 12 000 ppm (equal to 1194 mg/kg bw per day).

In a 90-day toxicity study, rats received TSA in the diet at 0, 500, 2500 or 12 000 ppm (equal to 0, 38, 183 and 975 mg/kg bw per day for males and 0, 52, 290 and 1369 mg/kg bw per day for females, respectively). The NOAEL was 12 000 ppm (equal to 975 mg/kg bw per day), the highest dose tested.

2-Methylsulfonylthiazole (MeS, M-3626) had an acute oral LD_{50} of ≥ 300 mg/kg bw in the rat. It was weakly positive in the Ames test for test strain *Salmonella typhimurium* TA100 at the highest concentration tested (5000 µg/plate) in the absence of metabolic activation and equivocal in a forward mutation assay in Chinese hamster V79 cells. Two in vivo genotoxicity studies, for bone marrow micronuclei and unscheduled DNA synthesis in the liver, were negative.

3,4,4-Trifluorobut-3-ene-1-sulfonic acid (butane sulfonic acid, BSA, M-3627) was of low acute oral toxicity (LD_{50} > 2000 mg/kg bw) in the rat and was not genotoxic in vitro or in vivo.

In a 28-day toxicity study that was not GLP compliant or fully compliant with OECD guidelines (e.g. group size of three animals of each sex per dose), rats received BSA in the diet at 0, 100, 500, 1000 or 10 000 ppm (equal to 0, 6.4, 30, 82 and 732 mg/kg bw per day for males and 0, 8.6, 39, 120 and 1024 mg/kg bw per day for females, respectively). Dilated renal pelvis was observed in females at 500 ppm (equal to 39 mg/kg bw per day), but there was no dose–response relationship.

In the newly submitted 90-day toxicity study, rats received BSA in the diet at 0, 440, 2200 or 11 000 ppm (equal to 0, 34, 174 and 851 mg/kg bw per day for males and 0, 39, 192 and 974 mg/kg bw per day for females, respectively). The NOAEL was 11 000 ppm (equal to 851 mg/kg bw per day), the highest dose tested.

Toxicological evaluation

The 2014 Meeting concluded that TSA is significantly less toxic than fluensulfone over 90 days of dietary exposure in rats; on this basis, it was concluded that residues of TSA in plants or animals were unlikely to be of any toxicological relevance.

The 2014 Meeting concluded that for MeS, in the absence of any repeated-dose toxicity data, the lack of genotoxicity in vivo supported the comparison of chronic intake estimates with the threshold of toxicological concern (TTC) value of 1.5 µg/kg bw per day for a Cramer class III compound. The international estimated daily intake (IEDI) is below this threshold value. A single-exposure TTC for Cramer class III compounds of 5 µg/kg bw was concluded to be conservative. The international estimate of short-term dietary intake (IESTI) is below this value. On this basis, the current Meeting concluded that MeS is not a relevant plant or animal metabolite of fluensulfone.

The 2014 Meeting concluded that BSA appears to be of similar toxicity to fluensulfone, based on the limited 28-day toxicity study. Based on the more extensive, newly submitted 90-day toxicity study with BSA, the current Meeting concluded that BSA is significantly less toxic than fluensulfone over 90 days of dietary exposure in rats; on this basis, it was concluded that residues of BSA in plants or animals were unlikely to be of toxicological relevance.

An addendum to the toxicological monograph was prepared.

RESIDUE AND ANALYTICAL ASPECTS

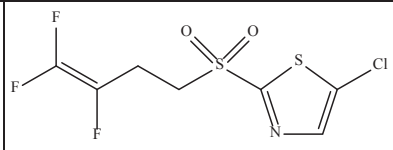
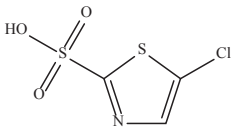
Fluensulfone was evaluated by JMPR for the first time for toxicology in 2013, when an ADI of 0–0.01 mg/kg bw/day and an ARfD of 0.3 mg/kg bw were established. At the 2014 JMPR, the residue aspects were evaluated, and a residue definition of *3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA)* was recommended for plant commodities, for enforcement and for dietary risk assessment. A residue definition for animal commodities was not considered necessary. Maximum residue levels were estimated for fruiting vegetables, cucurbits, and fruiting vegetables, other than cucurbits, except sweet corn and mushrooms.

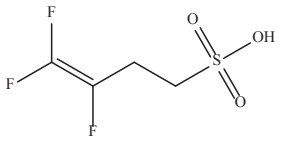
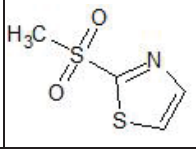
At the 47th Session of CCPR in 2015, fluensulfone was scheduled for evaluation by the 2016 JMPR for consideration of residue data for additional crops.

The Meeting received GAP information, supervised residue trials, processing studies, storage stability data and field rotational cropping trials.

The 2014 JMPR noted that based on the available residue data there was no reasonable expectation of finite residues of parent compound, and established a residue definition excluding parent compound. The current Meeting noted that residues of parent compound may occur in some of the additional crops for which supervised trial data was provided and that it was appropriate to revisit the decision on residue definition.

The following residue components are discussed. Structures and chemical names are tabulated below.

Common name/abbreviation	Chemical name	Structure	Molecular weight
Fluensulfone, MCW-2	5-Chloro-2-[(3,4,4-trifluorobut-3-en-1-yl)sulfonyl]thiazole		291.7
Thiazole sulfonic acid, TSA, M-3625	5-Chloro-thiazole-2-sulfonic acid		199.6

Common name/abbreviation	Chemical name	Structure	Molecular weight
Butene sulfonic acid, BSA, M-3627	3,4,4-Trifluorobut-3-ene-1-sulfonic acid		190.1
MeS, M-3626	2-Methylsulfonylthiazole		131.2

Methods of analysis

Analytical methods for plant and animal commodities were evaluated by the 2014 JMPR. In the residue and storage stability studies provided to the current Meeting, residues of fluensulfone parent compound and its metabolites TSA and BSA were determined using an LC-MS/MS method (method number 1977W). This method was evaluated by the 2014 JMPR and considered to be acceptable. Suitable validation data was generated concurrently with each residue study.

Stability of pesticide residues in stored analytical samples

The stability of fluensulfone residues in tomato, capsicum, cucumber, melon, and tomato puree/paste was considered by the 2014 JMPR. Stability was demonstrated in raw tomatoes for 15 months, processed tomato commodities for 6 months, and in capsicum, cucumber and melon for 16 months.

The Meeting received stability data for residues of fluensulfone, including the metabolites BSA and TSA, in oranges, potatoes (including processed commodities) and carrots. Stability was demonstrated over 18 months of frozen storage for oranges, over 17.5 months in carrots, over 23 months in potato tubers, and over 25 months in dried potatoes and wet peel.

Residues of TSA and BSA were stable in potato chips over 25 months, while residues of fluensulfone parent declined below 70% of the fortified level after storage. However, residues of fluensulfone parent were stable in raw potatoes and are not expected above the LOQ in raw potatoes, or in processed potato products.

Analyses were completed within timeframes verified by the stability studies for all residue studies considered by the Meeting, with the exception of some of the wheat grain, straw and hay samples from the 30-, 60- and 120-day plant back experiments in the rotational cropping study, which were analysed 32–34 months after collection. Results from these plant back intervals are not relied on in consideration of rotational crop residues.

Definition of the residue

In establishing residue definitions for fluensulfone the 2014 JMPR noted:

- Fluensulfone parent compound was not detected in commodities at harvest in the metabolism studies (potato, lettuce and tomato) or in supervised residue trials (in cucurbit and non-cucurbit fruiting vegetables), with the exception of a single low level in one sample. The 2014 JMPR concluded there was no reasonable expectation of residues of fluensulfone parent compound in plant commodities at harvest.
- BSA and TSA form the major components of the residue in plant metabolism studies and were the only significant residues at harvest in the fruiting vegetable supervised residue trials.

- With the exception of poultry fat, for which finite residues of parent were observed (0.009–0.041 mg eq/kg), and poultry liver in which TSA was found at 0.016 mg eq/kg, no residues of fluensulfone, BSA or TSA were detected in livestock products in metabolism studies. Radioactive residues were predominantly associated with natural products.
- TSA is not toxicologically significant.
- BSA and TSA are quantified in one analytical method with a separate analytical method required to quantify fluensulfone.

Based on the above, the 2014 JMPR established a residue definition of BSA for compliance and risk assessment purposes for plant commodities and a residue definition was not required for animal commodities. It was agreed that the ADI and ARfD for fluensulfone could be used for screening exposure to BSA.

Whilst it is not common practice for a residue definition to be changed except at a periodic review, the Meeting noted that new residue data provided indicates parent fluensulfone is a significant residue in a number of crops not previously evaluated. Furthermore, additional toxicological data are available for the key metabolite BSA. The Meeting therefore considered that the residue definitions for fluensulfone should be revisited.

In supervised trials provided to the Meeting, residues of fluensulfone parent were routinely observed in head lettuce, leaf lettuce, carrots, and celery, at levels of up to 0.017, 0.059, 0.49, and 0.52 mg/kg respectively. Correspondingly, residues of BSA in head lettuce, leaf lettuce, carrots and celery ranged up to 0.27, 0.88, 1.1, and 0.33 mg/kg. No residues of fluensulfone parent were observed in supervised trials provided to the Meeting for strawberries, Brassica vegetables, spinach, komatsuna, mizuna, mustard greens, potatoes, radish, Japanese radish or turnips.

The Meeting noted that the residue profile in the additional crops considered differs from those considered at the 2014 JMPR, with observations of fluensulfone at quantifiable levels. The Meeting considered that parent compounds of pesticides are routinely analysed for, in monitoring programmes. Suitable validated methods for determination of fluensulfone and BSA are available, although multi-residue methods for fluensulfone and its metabolites have not been provided to the JMPR. The Meeting concluded that both parent compound and BSA should be included in the residue definition for enforcement in plant commodities.

Additional repeat dose toxicological data for BSA was received by the Meeting. Based on the more extensive, newly submitted 90-day toxicity study with BSA (M3627), the current Meeting concluded that BSA is significantly less toxic than fluensulfone over 90 days of dietary exposure in rats; on this basis, it was concluded that residues of BSA in plants or animals were unlikely to be of toxicological relevance.

Noting the advice from the WHO panel at the 2014 JMPR regarding TSA and at the current Meeting regarding BSA, only parent compound is of toxicological relevance. Therefore, the Meeting concluded that the residue definition for dietary risk assessment in plant commodities should be parent compound alone.

The Meeting noted that fluensulfone parent compound was observed in poultry fat in the laying hen metabolism study, at levels up to 0.041 mg eq/kg. BSA was not detected in any poultry matrices, while TSA was found only in liver at 0.016 mg eq/kg. No compounds specific to fluensulfone were identified in the lactating goat metabolism study.

The Meeting noted that finite residues of parent compound were observed in carrots, which are a minor feed commodity for mammalian and poultry livestock, resulting in a non-zero livestock dietary burden for fluensulfone. A validated method for determination of fluensulfone parent compound in animal commodities, with an LOQ of 0.01 mg/kg, was evaluated by the 2014 JMPR. Given that fluensulfone was found at higher levels than TSA in animal matrices, while BSA was not

detected, parent compound is the most suitable marker residue for animal commodities. The Meeting concluded that the residue definition for enforcement in animal commodities should be fluensulfone.

Finite residues of fluensulfone parent compound were found in poultry fat (0.009–0.041 mg/kg), while fluensulfone parent residues in muscle were ≤ 0.001 mg/kg. As residues of parent in fat were at least 9 × those in muscle, the Meeting concluded that fluensulfone residues are fat soluble.

Noting that only parent compound is of toxicological relevance, the Meeting concluded that the residue definition for dietary risk assessment in animal commodities should be fluensulfone.

The 2014 JMPR determined that the metabolite MeS was not covered by the toxicological endpoints for parent compound and should be assessed using the Threshold of Toxicological Concern (TTC) approach. The 2014 JMPR determined that the IEDI and the IESTIs for the metabolite MeS should be compared to the Cramer class III TTC value of 1.5 µg/kg bw/day and the single-exposure TTC value for Cramer class III compounds of 5 µg/kg bw respectively.

The Meeting considered that this approach should be re-evaluated based on available data and all proposed GAPs. The WHO panel at the current Meeting noted that no new information was available regarding MeS and that the TTC approach for this metabolite remained appropriate. The Meeting noted that no additional residue data for MeS were available and further noted that the metabolism studies in potatoes, tomatoes and lettuce did not identify MeS. The MeS residue data for cucumber, summer squash, melons, tomatoes, and sweet and chilli peppers first provided to the 2014 JMPR was considered against the new GAPs for fruiting vegetables, cucurbits, and fruiting vegetables other than cucurbits. The calculated IEDI was 4% of the Cramer class III TTC value. The maximum IESTI was 60% of the single-exposure Cramer class III TTC value. The Meeting concluded that MeS was not a relevant metabolite for the crops considered.

Definition of the residue (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.*

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

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

The residue is fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for pre-planting soil application of fluensulfone to strawberries, cabbage, cauliflower, head lettuce, leafy lettuce, spinach, mustard greens, komatsuna (Japanese mustard spinach), mizuna (hot herb mustard), carrots, potatoes, radish (including radish leaves), daikon (Japanese radish), and turnips (including turnip leaves). US GAP information was provided for all crops for which residue data was submitted.

Residue trial data in cucumber, summer squash, melons, chilli peppers, sweet peppers (capsicum), and tomatoes previously considered by the 2014 JMPR were resubmitted, with an amended US GAP.

For the residue trials, residues of parent and the metabolites TSA, BSA, and (where reported), MeS are tabulated as residues of the individual compound.

For enforcement, the residue definition is the sum of fluensulfone and BSA, expressed as fluensulfone.

Residues of fluensulfone according to the enforcement definition are calculated by summing the fluensulfone residues plus the BSA residues multiplied by a factor of 1.53 based on the molecular weights of fluensulfone (291.7) and BSA (190.1).

The method LOQ was 0.01 mg/kg for each analyte, or 0.01, 0.015, and 0.015 mg/kg as parent equivalents for parent compound, TSA and BSA respectively.

Where a residue below the LOQ was detected, the value is reported in parentheses after the < LOQ. Where residues were undetected, a value of zero was used for the summation to give total residues. Where a detectable residue < LOQ was reported, a value of the LOQ (0.01 mg/kg) was used for the summation.

For dietary risk assessment, only fluensulfone parent compound is included in the definition.

In the sections below for each individual crop, residues of parent plus BSA as parent equivalents are reported as 'residues addressing the definition for enforcement'. Residues of fluensulfone only for dietary risk assessment are reported as 'residues addressing the definition for dietary risk assessment'.

Berries and other small fruits

The GAP in the USA for the low-growing berry subgroup (US Crop Group 13-07G, including bearberry, bilberry, lowbush blueberry, cloudberry, cranberry, lingonberry, muntries, partridgeberry, strawberry cultivars, and varieties or hybrids of the above) is a single 3.9 kg ai/ha soil application of an EC formulation made by broadcast, banded or drip irrigation application 7 days before transplanting.

Strawberry

Residue trials in strawberry in accordance with the US GAP were conducted in the USA.

Residues addressing the definition for enforcement at harvest were < 0.015 (3), 0.023, 0.025, 0.077, 0.14, and 0.26 mg/kg.

Residues addressing the definition for dietary risk assessment at harvest were < 0.01 (8) mg/kg.

The Meeting noted that the berries covered by the US GAP included all members of the Codex low growing berries subgroup and that strawberries are a representative crop for the subgroup. The Meeting agreed to extrapolate the recommendations for strawberry to low-growing berries.

The Meeting estimated a maximum residue level of 0.5 mg/kg for fluensulfone in low-growing berries, together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg.

Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas

The US GAP for Brassica (cole) leafy vegetables (US Crop Group 5, which covers the Codex Brassica vegetable group) is a single 3.9 kg ai/ha soil broadcast, band or drip irrigation application of an EC formulation made 30 days before sowing or transplanting.

Residue trials in accordance with the US GAP were conducted in the USA for cabbage, head and cauliflower.

Residues addressing the definition for enforcement in head cabbage at harvest were 0.040, 0.055, 0.12, 0.18, 0.23, and 1.1 mg/kg.

Residues addressing the definition for dietary risk assessment in head cabbage at harvest were < 0.01 (6) mg/kg.

Residues addressing the definition for enforcement in cauliflower at harvest were < 0.015, 0.060, 0.091, 0.12, and 0.26 mg/kg.

Residues addressing the definition for dietary risk assessment in cauliflower at harvest were < 0.01 (5) mg/kg.

The Meeting noted that the US GAP applied to the Brassica vegetable group, and that the GAP was for pre-plant soil application rather than foliar application so plant form was less likely to have an impact on residues. The Meeting considered a group maximum residue level for Brassica vegetables. Noting that the median residues for cabbage and cauliflower differed by a factor of < 5 (1.2 ×), and considering that the datasets were similar (Mann-Whitney test), the Meeting agreed to combine the residue datasets for cabbage and cauliflower for estimation of a group maximum residue level.

Combined dataset addressing the definition for enforcement: < 0.015, 0.040, 0.055, 0.060, 0.091, 0.12 (2), 0.18, 0.23, 0.26, and 1.1 mg/kg.

Combined dataset addressing the definition for dietary risk assessment: < 0.01 (11) mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg for fluensulfone in Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas, together with an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg.

Fruiting vegetables, Cucurbits

Residue data in cucurbit fruiting vegetables (cucumber, summer squash and melons) was considered by the 2014 JMPR. and maximum residue levels were estimated based on a US GAP of a single broadcast, band or drip irrigation application at 2.8 kg ai/ha 7 days before transplanting or 14 days before direct seeding, using data proportionally adjusted for application rate.

The new US GAP for cucurbit vegetables Crop Group 9, corresponding to the Codex classification fruiting vegetables, cucurbits, is a single soil application by broadcast, band or drip irrigation application of an EC formulation at 3.9 kg ai/ha 7 days before transplanting or 14 days before direct seeding.

Residue data from trials conducted in the USA and Canada in cucumber, summer squash, and melons considered by the 2014 JMPR were considered against the new GAP.

A number of trials were conducted with a shorter interval between application and planting than specified on the label (3 days rather than 7 days). However, the Meeting considered that this difference of 4 days was insignificant when compared to the total expected time between application/planting and harvest and would not have a significant effect on residues.

In trials matching GAP, residues addressing the definition for enforcement in cucumber at harvest were < 0.015 (2), 0.015 (2), 0.025, 0.092, 0.097, 0.11, 0.25, and 0.34 mg/kg (highest individual result 0.54 mg/kg).

Residues addressing the definition for dietary risk assessment in cucumber at harvest were < 0.01 (10) mg/kg.

After treatment in accordance with GAP, residues addressing the definition for enforcement in summer squash at harvest were < 0.025, 0.091, 0.10, 0.14, 0.30, 0.32, 0.33, and 0.39 mg/kg.

Residues addressing the definition for dietary risk assessment in summer squash at harvest were < 0.01 (7), and 0.014 mg/kg (highest individual result 0.017 mg/kg).

After treatment in accordance with GAP, residues addressing the definition for enforcement in melons at harvest were < 0.015 (3), 0.015, 0.038, 0.049, 0.075, 0.098, and 0.17 mg/kg (highest individual result 0.18 mg/kg).

Residues addressing the definition for risk assessment in melons were: < 0.01 (9) mg/kg.

The Meeting noted that the US GAP is for the cucurbit fruiting vegetables group and considered a group maximum residue level. However, the median residues for summer squash differed from that for melons by more than a factor of 5 × (5.8 ×). Therefore, a maximum residue level for the whole group is not appropriate.

The Meeting estimated a maximum residue level of 0.3 mg/kg for melons (except watermelons), together with an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg. The Meeting agreed to extrapolate these estimations to watermelons.

The Meeting noted that the median residues for summer squash and for cucumbers differed by less than a factor of 5 × (3.8 ×), and further that the data sets were similar (Mann-Whitney). The Meeting agreed to combine the cucumber and summer squash data sets for mutual support for determination of appropriate maximum residue levels.

Residues addressing the definition for enforcement at harvest: < 0.015, < 0.015, 0.015 (2), < 0.025, 0.025, 0.091, 0.092, 0.097, 0.10, 0.11, 0.14, 0.25, 0.30, 0.32, 0.33, 0.34, and 0.39 mg/kg (highest individual result 0.54 mg/kg).

Residues addressing the definition for dietary risk assessment at harvest: < 0.01 (17), and 0.014 mg/kg (highest individual result 0.017 mg/kg).

The Meeting estimated maximum residue levels of 0.7 mg/kg for cucumber and summer squash, together with STMRs of 0.01 mg/kg, and HRs of 0.017 mg/kg (highest individual analytical result).

The Meeting withdrew the previous maximum residue level recommendation of 0.3 mg/kg for fruiting vegetables, cucurbits.

Fruiting vegetables, other than Cucurbits

Residue data in fruiting vegetables other than cucurbits (tomato, sweet pepper (capsicum), and chilli pepper) was considered by the 2014 JMPR. Maximum residue levels were estimated based on a US GAP of a single broadcast, band or drip irrigation application at 2.8 kg ai/ha, 7 days before transplanting or 14 days before direct seeding, using data proportionally adjusted for application rate.

The new US GAP for fruiting vegetables crop group 8–10, corresponding to the Codex group of fruiting vegetables, other than cucurbits, except sweet corn and mushroom, is a single soil application by broadcast, band or drip irrigation application of an EC formulation at 3.9 kg ai/ha, 7 days before transplanting or 14 days before direct seeding.

Residue data in tomato, sweet peppers (capsicum), and chili peppers considered by the 2014 JMPR were considered against the new GAP.

A number of trials were conducted with a shorter interval between application and planting than specified on the label (3 days rather than 7 days). However, the Meeting considered that this difference of 4 days was insignificant when compared to the total expected time between application/planting and harvest and would not have a significant effect on residues.

In trials matching GAP, residues addressing the definition for enforcement in tomatoes at harvest were < 0.015 (4), 0.019, 0.026, 0.035, 0.039, 0.052, 0.068, 0.11, 0.13, 0.14, 0.26, 0.30, 0.35, and 0.41 (2) mg/kg.

Residues addressing the definition for dietary risk assessment in tomatoes at harvest were < 0.01 (18) mg/kg.

After treatment in accordance with GAP, residues addressing the definition for enforcement in peppers at harvest were < 0.015 (2), 0.032, 0.061, 0.063, 0.074, 0.084, 0.096, 0.11 (2), 0.13, 0.21, 0.28, and 0.36 mg/kg.

Residues addressing the definition for dietary risk assessment in peppers at harvest were < 0.01 (14) mg/kg.

The Meeting noted that the GAP applied to fruiting vegetables other than cucurbits, except sweetcorn and mushrooms, and considered a group maximum residue level. The Meeting further

noted that the median residues differed by less than a factor of 5 × (2.0×), that the data sets were similar (Mann-Whitney), and agreed to combine the datasets:

Residues addressing the definition for enforcement at harvest: < 0.015 (6), 0.019, 0.026, 0.032, 0.035, 0.039, 0.052, 0.061, 0.063, 0.068, 0.074, 0.084, 0.096, 0.11 (3), 0.13 (2), 0.14, 0.21, 0.26, 0.28, 0.31, 0.35, 0.36, and 0.41 (2) mg/kg (highest individual result 0.42 mg/kg).

Residues addressing the definition for risk assessment at harvest: < 0.01 (32) mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for fruiting vegetables, other than cucurbits (except sweet corn and mushrooms), together with an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 0.3 mg/kg for fruiting vegetables other than cucurbits (except sweetcorn and mushrooms).

Based on the estimated group maximum residue level and applying a processing factor of 10×, the Meeting estimated a maximum residue level of 7 mg/kg for Peppers, Chili, dried, together with an STMR of 0.10 and an HR of 0.10 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 2 mg/kg for peppers, chilli, dried.

Leafy vegetables (except Brassica leafy vegetables)

The US GAP for leafy vegetables (Crop Group 4) is a single soil broadcast, band or drip irrigation application of an EC formulation at 3.9 kg ai/ha a minimum of 7 days before transplanting or a minimum of 14 days before direct seeding.

Residue trials matching the US GAP were conducted in the USA for lettuce, head, lettuce, leaf, and spinach.

Residues addressing the definition for enforcement in head lettuce at harvest were < 0.015 (3), 0.025, 0.066, and 0.41 mg/kg (highest individual result 0.43 mg/kg).

Residues addressing the definition for dietary risk assessment in head lettuce were: < 0.01 (5), and 0.017 mg/kg (highest individual result 0.018 mg/kg).

Residues addressing the definition for enforcement in leaf lettuce at harvest were 0.018, 0.044, 0.13, and 1.4 mg/kg (highest individual result 1.5 mg/kg).

Residues addressing the definition for dietary risk assessment in leaf lettuce were < 0.01 (2), 0.013, and 0.030 mg/kg (highest individual result 0.035 mg/kg).

Residues addressing the definition for enforcement in Cos lettuce at harvest were 0.048 and 0.36 mg/kg (highest individual result 0.36 mg/kg).

Residues addressing the definition for dietary risk assessment in Cos lettuce were 0.017 and 0.059 mg/kg (highest individual result 0.060 mg/kg).

Residues addressing the definition for enforcement in spinach at harvest were < 0.015, 0.21, 0.49, 0.58, 0.78, and 1.8 mg/kg (highest individual result 1.8 mg/kg).

Residues addressing the definition for dietary risk assessment in spinach were < 0.01 (6) mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg for lettuce, head, together with an STMR of 0.01 mg/kg, and an HR of 0.018 mg/kg (highest individual result).

The Meeting considered that there were insufficient trials to estimate maximum residue levels for leaf lettuce or Cos lettuce.

The Meeting estimated a maximum residue level of 4 mg/kg for spinach, together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg.

Radish leaves (including Radish tops)

The US GAP for the root vegetables subgroup 1B (including radish) is a single soil application of a granular formulation at 4.0 kg ai/ha 10 days before sowing.

Residue data for radish leaves from trials conducted in the USA in accordance with GAP are available.

Residues of for enforcement in radish leaves at harvest were 1.5, 1.7, 6.9, and 21 mg/kg (highest individual result 23 mg/kg).

Residues addressing the definition for dietary risk assessment in radish leaves were < 0.01 (4) mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg for Radish leaves (including Radish tops), together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg.

Brassica leafy vegetables

The US GAP for Brassica (cole) leafy vegetables (Crop Group 5), covering the Codex Brassica leafy vegetables subgroup is a single broadcast, band or drip irrigation soil application of an EC formulation at 3.9 kg ai/ha a minimum of 30 days before transplanting.

Residue trials in accordance with the US Brassica leafy vegetables GAP were conducted in the USA for mustard greens, komatsuna, and mizuna. Residue trials were conducted in turnips, using a GAP that matches the Brassica leafy vegetables GAP, and data for turnip leaves are available.

Residues addressing the definition for enforcement in komatsuna at harvest were 0.54, 0.59, 0.61, and 4.0 mg/kg (highest individual result 5.5 mg/kg).

Residues addressing the definition for dietary risk assessment in komatsuna were < 0.01 (4) mg/kg.

Residues addressing the definition for enforcement in mizuna at harvest were 0.77, 0.83, 1.3, and 8.0 mg/kg (highest individual result 9.1 mg/kg).

Residues addressing the definition for dietary risk assessment in mizuna were < 0.01 (4) mg/kg.

Residues addressing the definition for enforcement in mustard greens at harvest were 0.11, 0.16, 4.6, 6.1, and 6.5 mg/kg (highest individual result 7.5 mg/kg).

Residues addressing the definition for risk assessment in mustard greens were < 0.01 (5) mg/kg.

Residues addressing the definition for enforcement in turnip greens at harvest were 0.036, 0.53, 1.4, and 4.8 mg/kg (highest individual result 5.1 mg/kg).

Residues addressing the definition for risk assessment in turnip greens were < 0.01 (4) mg/kg.

The Meeting noted that the GAP was for Brassica leafy vegetables and considered a maximum residue level for the subgroup. However, the median residue for mustard greens differs from that for komatsuna by more than a factor of 5 × (7.7 ×). Therefore, the Meeting considered that a group maximum residue level was not appropriate and individual commodity limits were estimated.

The Meeting estimated a maximum residue level of 9 mg/kg for komatsuna, together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg for mustard greens, together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg for turnip greens, together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg.

The Meeting noted that no Codex classification was available for mizuna, and therefore a maximum residue level could not be estimated.

Root and tuber vegetables

The US GAP for the root vegetables subgroup 1B (except sugar beet), including carrot, radish, turnip, garden beet, edible burdock, celeriac, turnip-rooted chervil, chicory, ginseng, horseradish, turnip-rooted parsley, parsnip, oriental radish, rutabaga (swede), salsify, black salsify, Spanish salsify, and skirret is a single broadcast or banded soil incorporation application of a granular formulation at 4.0 kg ai/ha applied 10 days before planting.

The US GAP for the tuberous and corm vegetables subgroup 1C, including potato, sweet potato, yam, arracacia, arrowroot, Chinese artichoke, Jerusalem artichoke, edible canna, cassava (bitter and sweet varieties), chayote root, chufa, taro (dasheen), ginger, lerén, tanier, turmeric, yam bean and true yams is a single broadcast or banded soil incorporation application of a granular formulation at 4.0 kg ai/ha, with application permissible pre-planting or at planting.

Carrot and radish

Residue trials in accordance with the US GAP were conducted for carrots and radish in the USA and Canada.

Residues addressing the definition for enforcement in carrot at harvest were < 0.015, 0.091, 0.29, 0.33, 0.56, 0.58, 0.68, 0.79, 0.80, 1.5, and 2.2 mg/kg (highest individual result 2.3 mg/kg).

Residues addressing the definition for dietary risk assessment in carrot were < 0.01 (2), 0.050, 0.058, 0.10, 0.12, 0.17, 0.20, 0.26, 0.47, and 0.49 mg/kg (highest individual result 0.50 mg/kg).

Residues addressing the definition for enforcement in radish at harvest were 0.12, 0.28, 0.35, and 2.8 mg/kg (highest individual result 3.4 mg/kg).

Residues addressing the definition for dietary risk assessment in radish were < 0.01 (4) mg/kg.

The Meeting noted that the median residues for carrots and radish differed by less than a factor of 5 × (1.8 ×), and that the data sets were statistically similar (Mann-Whitney), and agreed to combine the results for mutual support:

Residues in carrots and radish in accordance with the definition for enforcement: < 0.015, 0.091, 0.12, 0.28, 0.29, 0.33, 0.35, 0.56, 0.58, 0.68, 0.79, 0.80, 1.5, 2.2, and 2.8 mg/kg (highest individual result 3.4 mg/kg).

The Meeting estimated maximum residue levels of 4 mg/kg for fluensulfone in carrot and radish. The Meeting estimated an STMR of 0.12 mg/kg and an HR of 0.50 mg/kg (highest individual result) for carrot and radish, based on the carrot dataset.

The Meeting noted that the GAP for the root vegetables subgroup 1B represented the critical GAP for a number of other root vegetables, and agreed to extrapolate the estimations for carrots and radish to beetroot, celeriac, horseradish, Japanese radish, parsnips, swede (rutabaga), turnip rooted chervil, and turnip.

The Meeting estimated maximum residue levels of 4 mg/kg for fluensulfone in beetroot, celeriac, horseradish, Japanese radish, parsnip, swede, turnip-rooted chervil, and turnip, together with STMRs of 0.12 mg/kg and HRs of 0.50 mg/kg.

Potato

Residue trials in accordance with the US GAP for tuberous and corm vegetables (subgroup 1C) were conducted for potatoes in the USA and Canada.

Residues addressing the definition for enforcement in potatoes at harvest were 0.084, 0.087, 0.10, 0.11, 0.12, 0.13, 0.15 (3), 0.17 (2), 0.19, 0.20, 0.28, 0.30, 0.41, 0.48, and 0.51 mg/kg (highest individual result 0.64 mg/kg).

Residues addressing the definition for dietary risk assessment in potatoes were < 0.01 (18) mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg for fluensulfone in potato, together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg.

Noting that the US GAP covered the US crop group tuberous and corm vegetables, the Meeting agreed that the maximum residue level, STMR and HR estimations above could be extrapolated to sweet potato.

Celery

The US GAP for celery and rhubarb is a single soil application (broadcast, band or drip irrigation) of an EC formulation at 3.9 kg ai/ha applied 7 days before transplanting.

Residue trials were conducted in the USA for celery in accordance with GAP.

Residues addressing the definition for enforcement in celery at harvest were < 0.015, 0.12, 0.36, 0.63, 0.78, and 1.0 mg/kg (highest individual result).

Residues addressing the definition for dietary risk assessment in celery were < 0.01, 0.028, 0.087, 0.13, 0.36, and 0.52 mg/kg (highest individual result 0.55 mg/kg).

The Meeting estimated a maximum residue level of 2 mg/kg for fluensulfone in celery, together with an STMR of 0.1085 mg/kg, and an HR of 0.55 mg/kg (highest individual residue result).

The Meeting noted that the US GAP for rhubarb was the same as that for celery but considered that extrapolation of the estimations from a temporary crop (celery) to a semi-permanent perennial crop (rhubarb) was not appropriate for a pre-planting soil application.

Rotational crops

A field rotational cropping study conducted in the USA was presented to the Meeting. A single application of fluensulfone was made to bare soil at 4.0 kg ai/ha, with following crops (wheat, radish, lettuce and beans) planted at intervals of 28, 60, 120, 180, 270 and 365 days after application.

Instructions on US fluensulfone labels provided to the Meeting regarding following crops are that no more than 4.0 kg ai/ha is to be applied to a plot in one year. Immediate plant-back of crops for which a registered GAP exists (i.e. strawberries, Brassica vegetables, cucurbits, fruiting vegetables other than cucurbits (except sweetcorn and mushrooms), leafy vegetables, root and tuber vegetables, celery and rhubarb) is permitted. A plant back interval of one year is mandated for crops for which there is no registered use, with no planting of cereals permitted after a fluensulfone application.

Radish and lettuce have GAPs for direct application. At the shortest planting interval, 28 days (or a later interval if a higher residue was observed at the site), the following residues of fluensulfone at harvest were observed: radish roots (in accordance with the definition for enforcement), 0.08 and 1.4 mg/kg; radish roots (in accordance with the definition for dietary risk assessment), < 0.01 (2) mg/kg; radish leaves (in accordance with the definition for enforcement), 0.63 and 6.1 mg/kg; radish leaves (in accordance with the definition for dietary risk assessment), < 0.01 (2) mg/kg; lettuce (in accordance with the definition for enforcement), < 0.015 and

0.52 mg/kg; and lettuce (in accordance with the definition for dietary risk assessment), < 0.01 (2) mg/kg.

The Meeting noted the label instruction that no more than 4.0 kg ai/ha of fluensulfone are to be applied to a plot in one year, which precludes a second application to a crop planted back within one year of a failed treated crop. The Meeting considered that rotational residues of fluensulfone in radish roots, radish leaves, and lettuce would be covered by the maximum residue levels estimated by the Meeting (5, 50, and 0.8 mg/kg respectively). The Meeting further considered that this reasoning could be extrapolated to other root and leafy crops.

Based on the radish root data, the Meeting estimated a maximum residue level of 3 mg/kg for root and tuber vegetables (not specified elsewhere), together with an STMR and an HR of 0.01 mg/kg.

Based on the lettuce data, the Meeting estimated a maximum residue level of 1 mg/kg for leafy vegetables (not specified elsewhere), together with an STMR and an HR of 0.01 mg/kg.

Noting that a further application could be made for a following crop one year after an application to a previous crop, the following residues addressing the enforcement definition were observed in radish and lettuce after a 365-day plant back interval: radish roots, < 0.015 (2) mg/kg; radish leaves, < 0.015 and < 0.025 mg/kg; and lettuce, < 0.015 (2) mg/kg.

Finite residues of fluensulfone were not observed in radish roots or leaves, or in lettuce when these crops were planted one year after a fluensulfone at GAP. The Meeting therefore considered that no carry-over of residues into following crops of root or leafy vegetables planted one year later would occur, and no adjustment of maximum residue level estimations to account for residues from previous applications was required.

At the 365-day planting interval, the following residues of fluensulfone were observed for wheat and bean crops: wheat grain (in accordance with the definition for enforcement), < 0.015 (2) mg/kg; wheat grain (in accordance with the definition for dietary risk assessment), < 0.01 (2) mg/kg; beans with pods (in accordance with the definition for enforcement), < 0.015 and 0.054 (270-day PBI, 365-day PBI crop failed) mg/kg; and beans with pods (in accordance with the definition for dietary risk assessment): < 0.01 (2) mg/kg.

As residues were not detected in wheat grain, and further, the label carries an instruction not to plant cereals following a fluensulfone application, the Meeting considered that it is not necessary to estimate maximum residue levels for cereal grains or feed items planted in rotation with crops treated with fluensulfone.

Based on the beans with pods data, the Meeting estimated a maximum residue level of 0.1 mg/kg for legume vegetables, together with an STMR of 0.01 mg/kg, and an HR of 0.01 mg/kg, to cover residues arising in following crops.

Fate of residues during processing

Tomato

A processing study in tomatoes was considered by the 2014 JMPR. The processing factors determined for the metabolite BSA from that study are tabulated below. Residues of parent compound were < 0.01 mg/kg in all samples, and processing factors could not therefore be determined.

Processing factors for the BSA metabolite of fluensulfone in tomatoes

Tomato commodity	Average (best estimate) BSA processing factor	STMR-P mg/kg [a]	HR-P mg/kg [a]
Canned	0.33	0.01	0.01
Dry pomace	11	0.01	–

Tomato commodity	Average (best estimate) BSA processing factor	STMR-P mg/kg [a]	HR-P mg/kg [a]
Peeled	0.33	0.01	0.01
Dried	1.8	0.01	0.01
Juice	0.75	0.01	–
Paste	1.8	0.01	–
Puree	1.0	0.01	–
Wet pomace	2.6	0.01	–

[a] Fluensulfone only, in accordance with the dietary risk assessment definition. Residues of parent compound were < 0.01 mg/kg in all raw commodity and processed tomato samples.

Based on the maximum residue level of 0.7 mg/kg estimated for fruiting vegetables, other than cucurbits, except sweet corn and mushrooms, and the processing factors of 1.8 for both dried tomatoes and tomato paste, the Meeting estimated maximum residue levels of 1.5 mg/kg for both dried tomatoes and tomato paste, together with STMR-Ps of 0.01 mg/kg and HR-Ps of 0.01 mg/kg.

The Meeting withdrew the recommendations of the 2014 JMPR for maximum residue levels of 0.5 mg/kg in dried tomatoes and tomato paste.

Potato

A processing study for potato was provided to the Meeting. The Meeting received data illustrating the concentration or diminution of residues during processing of potatoes into potato chips, and dried potato flakes, including wet peel as a by-product.

Processing factors for BSA in potatoes

Potato commodity	BSA processing factors	STMR-P mg/kg [a]
Dried potato flakes	2.4	0.01
Wet peel	0.3	0.01
Potato chips (crisps)	1.6	0.01

[a] Fluensulfone only, in accordance with the dietary risk assessment definition. Residues of parent compound were < 0.01 mg/kg in all raw commodity and processed potato samples.

The Meeting estimated a maximum residue level of 2 mg/kg for potato, dried based on the raw commodity maximum residue level estimate of 0.8 mg/kg for potato, and the processing factor (2.4), together with an STMR-P of 0.01 mg/kg, and an HR-P of 0.01 mg/kg.

Residues in animal commodities

Farm animal feeding studies

Farm animal feeding studies were not available.

Livestock dietary burden

Dietary burden calculations for cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual.

Summary of livestock dietary burden (ppm in diet on a dry weight basis)

	USA-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.04	0.04	2.05 [A]	0.53 [B]	0.53	0.15	0	0

	USA-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Dairy cattle	0.44	0.12	1.04 [C]	0.28 [D]	0.50	0.12	0	0
Broiler hens	0	0	0.51	0.13	0	0	0	0
Laying hens	0	0	0.51 [E]	0.13 [F]	0	0	0	0

[A] Highest maximum dietary burden for beef cattle suitable for estimation of MRLs for mammalian meat and offal

[B] Highest mean dietary burden for beef cattle suitable for estimation of STMRs for mammalian meat and offal.

[C] Highest maximum dietary burden for dairy cattle suitable for estimation of MRLs for milk.

[D] Highest mean dietary burden for dairy cattle suitable for estimation of STMRs for milk.

[E] Highest maximum dietary burden for broiler and layer poultry suitable for estimation of MRLs for poultry meat, offal and eggs.

[F] Highest mean dietary burden for broiler and layer poultry suitable for estimation of STMRs for poultry meat, offal and eggs.

Animal commodity maximum residue levels

Cattle feeding studies are not available. In a lactating goat metabolism study considered by the 2014 JMPR, animals were dosed at 10 ppm. No residues of any compounds specific to fluensulfone were detected in goat milk or tissues. The highest maximum dietary burdens in beef cattle and dairy cattle are 2.1 and 1.0 ppm respectively. The metabolism study dose exceeds the maximum dietary burden by a factor of approximately 5×. The Meeting concluded that maximum residue levels for mammalian commodities should be estimated at the LOQ, with dietary parameters at 0. An analytical method for fluensulfone parent compound in animal commodities is available, with a validated LOQ of 0.01 mg/kg.

The Meeting estimated maximum residue levels of 0.01* mg/kg for edible offal (mammalian), mammalian fats, milks, and meat (from mammals other than marine mammals).

The Meeting estimated STMR and HR values of 0 mg/kg for edible offal (mammalian), mammalian fats, and meat (from mammals other than marine mammals).

A poultry feeding study is not available. In a laying hen metabolism study considered by the 2014 JMPR, birds were dosed at 9.8 ppm in feed. Residues of fluensulfone parent compound were observed at up to 0.041 mg/kg were observed in poultry fat. Residues of parent fluensulfone were not quantified in any other poultry matrices (eggs, offal or muscle). The highest maximum dietary burden for broiler and layer poultry is 0.51 ppm. The metabolism study dose exceeds the maximum dietary burden by a factor of 19. The Meeting concluded that maximum residue levels for eggs, poultry meat and poultry offal should be estimated at the LOQ, with dietary parameters at 0.

The Meeting estimated maximum residue levels of 0.01* mg/kg for eggs, poultry meat, and poultry, edible offal of.

The Meeting estimated STMR and HR values of 0 mg/kg for eggs, poultry meat, and poultry, edible offal of.

Scaling poultry fat residues from the metabolism study for the maximum feeding level, the expected highest residue in poultry fat is 0.0021 mg/kg (= 0.041 × 0.51/9.8). Scaling poultry fat residues from the metabolism study for the mean feeding level, the expected median residue in poultry fat is 0.0005 mg/kg (= 0.041 × 0.13/9.8).

The Meeting estimated maximum residue levels of 0.01 mg/kg for poultry fats.

The Meeting estimated STMR and HR values of 0.0005 and 0.0021 mg/kg for poultry fats.

RECOMMENDATIONS

On the basis of the data obtained from supervised residue 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.

The Meeting withdrew the previous recommendation for the residue definition for enforcement and dietary risk assessment in plant commodities: *3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA).*

Definition of the residue (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.*

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

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

The residue is fat soluble.

DIETARY INTAKE ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDIs) of fluensulfone were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting. The results are shown in Annex 3 of the 2016 Report.

The ADI for fluensulfone is 0–0.01 mg/kg bw. The calculated IEDIs for fluensulfone were 1–3% of the maximum fluensulfone ADI. The Meeting concluded, on the basis of the information provided to the Meeting, that the long-term exposure to residues of fluensulfone are unlikely to present a public health concern.

Short-term dietary exposure

The International Estimated Short Term Intakes (IESTIs) of fluensulfone were calculated for food commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting. The results are shown in Annex 4 to the 2016 Report.

The ARfD for fluensulfone is 0.3 mg/kg bw.

The calculated maximum IESTI for fluensulfone was 9% of the ARfD for children and 5% for the general population. The Meeting concluded that the short-term dietary exposure to residues of fluensulfone, when used in accordance with GAPs that have been considered by JMPR, are unlikely to present a public health concern.