5.28 SULFOXAFLOR (252)

RESIDUE AND ANALYTICAL ASPECTS

Sulfoxaflor, a sulfoximine insecticide, was first evaluated by the JMPR in 2011 for residues and toxicology where an ADI and ARfD of 0–0.05 mg/kg bw and 0.3 mg/kg bw respectively were established A residue definition of *sulfoxaflor* was established for both compliance and dietary risk assessment in plant and animal commodities.

The residue is not fat-soluble.

The latest residue review was done in 2016.

It was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional new uses at the 2018 JMPR.

For the current Meeting, new GAPs and supervised residue trials on mango, green beans and rice were provided. The current Meeting was also requested to revisit the supervised trials in maize, sorghum, sweet corn, rice and tree nuts, which were previously provided to the 2016 Meeting.

Methods of analysis

Unless otherwise specified, residues of sulfoxaflor in all tested commodities including animal feeds were determined using the LC-MS/MS analytical method 091031, previously reviewed by the 2011 JMPR. The limit of quantitation (LOQ) of the method was 0.01 ppm.

Stability of residues in stored analytical samples

All samples, collected from each of the supervised field trials, were kept under frozen storage up to a maximum of 467 days from the date of sampling to analysis. Previously conducted storage stability studies of sulfoxaflor and reviewed by the 2011 JMPR, have shown acceptable freezer stability for up to 680 days (in a wide variety of crops).

Results of supervised residue trials on crops

Mango

In Taiwan, Province of China, the critical GAP for sulfoxaflor in mango is a maximum of 2 applications, at 7-day re-treatment intervals with a PHI of 14 days. Individual application rates are not specified. The maximum seasonal rate is 106 g ai/ha.

A total of three independent trials were conducted in Taiwan, Province of China, during the 2015 growing season. Sulfoxaflor residues, in ranked order, were 0.03, 0.04 and 0.05 mg/kg.

The Meeting considered three trials insufficient to estimate a maximum residue level for the use of sulfoxaflor in mango.

Legume vegetables

Beans with pods

The critical GAP for sulfoxaflor is in the USA on Succulent, Edible Podded, and Dry Beans, where the rate is 80 g ai/ha, a maximum of 4 applications, a minimum re-treatment interval of 14 days and a PHI of 7 days. The maximum seasonal rate is 298 g ai/ha

As none of the trials matched the critical GAP, the Meeting could not estimate a maximum residue level.

Cereal grains

Data from trials on maize, rice (USA), sorghum and sweet corn, provided to the 2016 JMPR were reconsidered at the current Meeting as the 2016 JMPR could not estimate maximum residue levels for these crops as no GAP was provided to the Meeting or trials were not conducted according to GAP.

Maize

The new critical GAP is in Canada and allows 2 applications at 36 g ai/ha, a 7-day re-treatment interval, seasonal maximum of 72 g ai/ha and 14-day PHI.

The trials were conducted in the USA during the 2012 growing season. Two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment interval of 7 days. Maize grain samples were harvested 13–15 days after the final application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues for maize grain, in ranked order, were < 0.01 (12) and 0.01(2) mg/kg. Using a scaling factors of 1.4, scaled residues are: < 0.007 (12) and 0.007 (2) mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.01(*) mg/kg and 0.007 mg/kg, respectively, for maize.

Rice

In addition to the trials conducted on rice in the USA, provided to the 2016 JMPR, supervised residue trials conducted in Argentina,, Australia, Brazil, China, India, Malaysia and the Philippines were made available to the current Meeting.

The new critical GAP for sulfoxaflor on rice is in Indonesia allows for 4 applications at 100 g ai/ha, a 7-day re-treatment interval, 400 g ai/ha/season, and a 10-day PHI.

In eight independent trials, conducted in the Philippines and Australia, approximating the critical GAP, residues found of sulfoxaflor in paddy rice in ranked order were (n = 8): 0.96, 1.00, 1.2, 1.7, 2.2, 2.4, 3.8 and 4.0 mg/kg.

The Meeting estimated a maximum residue level and STMR of 7 mg/kg, 1.95 mg/kg, respectively for rice.

Sorghum

The new critical GAP for sorghum is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season and a 14-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment intervals of 7 days. Sorghum grain samples were harvested 13–15 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues in sorghum grain were 0.02, 0.03, 0.04 (3), 0.05, 0.08, 0.14 and 0.15 mg/kg. Using a scaling factor of 1.4, the scaled residues in ranked order were: 0.01, 0.02, 0.03(3), 0.04, 0.06, 0.10 and 0.11 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.2 mg/kg and 0.03 mg/kg, respectively for sorghum.

Sweet corn (corn-on-the-cob) (kernels plus cobs with husks removed)

The new critical GAP for sweet corn is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season, and a 7-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and re-treatment intervals of 7 days. Unscaled sulfoxaflor residues in sweet corn (kernels plus cobs with husks removed) were harvested 7–8 days after the last application were all (n = 9) < 0.01 mg/kg.

As all residues were below the LOQ, following treatments at exaggerated rates, the Meeting estimated a maximum residue level and STMR of 0.01(*) mg/kg and 0 mg/kg, respectively for sweet corn (corn on the cob) (kernels plus cobs with husks removed).

Tree nuts

Almonds and Pecans

Data from ten independent trials on tree nuts (almonds (5) and pecans (5)) were resubmitted. The 2016 JMPR did not estimate a maximum residue level as no GAP had not been provided.

The new critical GAP is in the USA which comprises 4 × 101 g ai/ha, a re-treatment interval of 7 days and a PHI of 7 days. The maximum seasonal rate is 298 g ai/ha.

In five independent trials conducted in the USA on almonds and approximating critical GAP (3 × 100 g ai/ha, 6–7 day PHI) residues in almond nutmeat were (n = 5): < 0.01 mg/kg.

In five independent trials conducted in the USA on pecans and approximating critical GAP (3 × 100 g ai/ha; 7–8 day PHI) residues were (n = 5): < 0.01 (4) and 0.02 mg/kg.

The critical GAP in the USA is for tree nuts and a group maximum residue level recommendation may be possible based on the data for almonds and pecans. As the median residues were equivalent for both datasets, the Meeting agreed to combine the residue trial data to estimate a maximum residue level for the tree nuts crop group.

Based on the combined residue data set (< 0.01 (9) and 0.02 mg/kg), the Meeting estimated a maximum residue level, HR and STMR of 0.03, 0.02 and 0.01 mg/kg, respectively, for the tree nuts group.

Animal feeds

Data from trials on maize, rice (USA), sorghum and sweet corn, provided to the 2016 JMPR were reconsidered at the current Meeting as the 2016 JMPR could not estimate residue levels for these feed crops (forage, stover, straw (rice only)) as no GAP was provided to the Meeting or trials were not conducted in accordance with GAP.

Straw, fodder and forage of cereal grains

Maize forage

The new critical GAP for maize is in Canada; and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, a seasonal maximum of 72 g ai/ha with a 7-day PHI.

The trials were conducted in the USA during the 2012 growing season where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment interval of 7 days. Maize forage samples were harvested 7–8 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues for maize forage were (n = 15): 0.03, 0.05, 0.08 (2), 0.09, 0.11 (3), 0.12, 0.13, 0.15, 0.22, 0.31 and 0.35 mg/kg. Using a scaling factor of 1.4, residues were (n = 15): 0.02, 0.04, 0.06 (3), 0.07, 0.08 (3), 0.09(2), 0.11, 0.16, 0.22 and 0.25 mg/kg.

The Meeting estimated a highest residue of 0.25 mg/kg and a median residue of 0.08 mg/kg for maize forage

Sorghum forage

The new critical GAP for sorghum is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, a seasonal maximum of 72 g ai/ha and a 14-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment interval of 7 days. Sorghum forage samples were harvested 6–8 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues at critical GAP. Unscaled sulfoxaflor residues for sorghum forage were (n = 9): 0.02, 0.03, 0.07, 0.08 (2), 0.09, 0.13, 0.16 and 0.20 mg/kg. Using a scaling factor of 1.4, the scaled residues in ranked order were (n = 9): 0.01, 0.02, 0.05, 0.06 (3), 0.10, 0.12 and 0.14 mg/kg.

The Meeting estimated a highest residue of 0.14 mg/kg and a median residue of 0.06 mg/kg for sorghum forage (green).

Corn forage (Sweet)

The new critical GAP for sweet corn is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season, and a 7-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and re-treatment intervals of 7 days. Sweet corn forage samples were harvested 7-8 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching cGAP. Unscaled sulfoxaflor residues for sweet corn forage were 0.05, 0.06, 0.08, 0.09, 0.14 (2), 0.23, 0.24 and 0.37 mg/kg. Using a scaling factor of 1.4, residues in ranked order are 0.04 (2), 0.06(2), 0.10(2), 0.16, 0.17 and 0.26 mg/kg.

The Meeting estimated a highest residue of 0.26 mg/kg and median residue of 0.10 mg/kg for corn forage.

Maize fodder (dry)

The critical GAP is in Canada; 2 applications at 36 g ai/ha, 7-day re-treatment interval, 72 g ai/ha/season and 14-day PHI.

The trials were conducted in the USA during the 2012 growing season where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha

and a re-treatment interval of 7 days. Maize stover samples were harvested 13–15 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues at critical GAP. Unscaled sulfoxaflor residues for maize stover were (n = 15): 0.02, 0.06, 0.09, 0.11, 0.15, 0.18, 0.20, 0.22, 0.23 (2), 0.24, 0.31, 0.40, 0.43 and 0.54 mg/kg. Using scaling factors of 1.4, residues, in ranked order, were (n = 15): 0.01, 0.04, 0.06, 0.08, 0.11, 0.13, 0.14, 0.16 (3), 0.17, 0.22, 0.28, 0.31 and 0.38 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a highest residue of 0.38 mg/kg and a median residue of 0.16 mg/kg for maize fodder (dry).

Rice straw and fodder (dry)

In addition to the trials conducted on rice in the USA, provided to the 2016 JMPR, new supervised residue trials on rice conducted in Argentina, Australia, Brazil, China, India, Malaysia and the Philippines were made available to the current Meeting.

The new critical GAP for sulfoxaflor on rice is in Indonesia and allows for 4 applications at 100 g ai/ha, a 7-day re-treatment interval, 400 g ai/ha/season, with a 10-day PHI.

In eight independent trials, conducted in Australia and the Philippines, approximating the critical GAP, residues found of sulfoxaflor in rice straw (as received) were (n = 8): 0.07, 0.10, 0.22, 1.3, 1.7, 4.9, 5.7 and 10.4 mg/kg.

The Meeting estimated a maximum residue level, highest residue and median residue of 20, 10.4 and 1.5 mg/kg, respectively for rice straw and fodder (dry).

Sorghum straw and fodder (dry)

The new GAP for sulfoxaflor on sorghum is in Canada and allows for 2 applications at 36 g ai/ha, a 7-day re-treatment interval, 72 g ai/ha/season, with a 14-day PHI.

The trials were conducted in the USA in 2012 where two foliar applications of a water-dispersible granule formulation containing sulfoxaflor were made at a target rate of 50 g ai/ha and a re-treatment intervals of 7 days. Sorghum stover samples were harvested 13–15 days after the last application.

The Meeting agreed to utilise the proportionality approach to estimate residues matching critical GAP. Unscaled sulfoxaflor residues in sorghum stover were (n = 9): 0.04, 0.05, 0.10, 0.16, 0.20, 0.27, 0.28, 0.29 and 0.60 mg/kg. Using a scaling factor of 1.4, the scaled residues in ranked order were: 0.03, 0.04, 0.07, 0.11, 0.14, 0.19, 0.20, 0.21 and 0.43 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, a highest residue of 0.43 mg/kg and a median residue of 0.14 mg/kg for sorghum straw and fodder (dry).

Almond hulls

Data from five independent trials on almonds were resubmitted. The 2016 JMPR did not estimate a maximum residue level as no GAP was provided to the Meeting. The new critical GAP is in the USA and allows for a maximum of 4 applications at up to 101 g ai/ha, with a re-treatment interval of 7 days and a PHI of 7 days. The maximum seasonal rate is 298 g ai/ha

In five independent trials conducted in the USA on almonds and approximating critical GAP (3 × 100 g ai/ha, 6–7 day PHI), residues in almond hulls, in ranked order, were (n = 5): 0.54, 0.72, 0.76, 1.69 and 1.71 mg/kg.

The Meeting estimated a median residue of 0.76 mg/kg for almond hulls.

Fate of residues during processing

Processing

The Meeting received information on the fate of sulfoxaflor residues during the processing of rice. Processing factors calculated for the processed commodities of paddy rice are shown in the table below. Processing factors, best estimates and STMR-Ps were calculated.

Rice

Commodity	Calculated Processing Factors	Best Estimate	RAC STMR	STMR-P, mg/kg
Parboiled Rice	0.3, 1.3	0.8 (mean)	1.95	1.6
Hulls	2.4, 4.5, 5.9	4.5 (median)		8.8
Brown Rice	0.10, 0.20, 0.79	0.20 (median)		0.39
Bran	0.74, 0.79, 1.1	0.79 (median)		1.5
Polished Rice	0.01, 0.14, 0.86	0.14 (median)		0.27
Flour	0.01, 0.10, 0.74	0.10 (median)		0.20

Based on the processing factors of 0.20 estimated for husked (brown) rice and 0.14 estimated for polished rice and applying this to the maximum residue level of 7 mg/kg for rice grain, the Meeting estimated maximum residue levels of 1.5 mg/kg for rice, husked and 1 mg/kg for rice, polished.

Estimated dietary burdens of farm animals

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

	Livestock dietary burden, sulfoxaflor							
	US/Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	1.3	0.85	3.5	1.4	8.8[a]	2.6	6.4	0.95
Dairy Cattle	2.1	1.4	4.0	1.9	6.9[b]	4.0[c]	3.1	0.51
Poultry, broiler	0.50	0.50	0.10	0.08	1.2	1.2	0.04	0.04
Poultry, layer	0.50	0.50	1.1	0.45	1.15[d]	1.15	0.04	0.04

[a] Suitable for maximum residue level estimate for meat, fat and edible offal of mammals

[b] Suitable for maximum residue level estimate for milk

[c] Suitable for STMR estimate for milk, meat, fat and edible offal of mammals

[d] Suitable for maximum residue level and STMR estimates for eggs, meat, fat and edible offal

Animal commodities residue level estimation

Anticipated residues resulting from the dietary burdens and based on the feeding studies are summarised below:

Sulfoxaflor feeding study	Feed level for milk residues (ppm)	Residues in milk (mg/kg)	Feed level for tissue residues (ppm)	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
maximum residue level estimation – Beef and Dairy Cattle							
Feeding Study	6.8	0.288	6.8	0.311	0.758	0.566	0.139
	35.0	1.679	35.0	1.691	4.03	2.422	0.915
Dietary burden and anticipated	6.9	0.293	8.8	0.390	0.952	0.676	0.185

Sulfoxaflor feeding study	Feed level for milk residues (ppm)	Residues in milk (mg/kg)	Feed level for tissue residues (ppm)	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
residues							
STMR estimation – Beef and Dairy Cattle							
Feeding Study	2.4	0.090	2.4	0.105	0.283	0.184	0.039
	6.8	0.243	6.8	0.271	0.744	0.461	0.099
Dietary burden and anticipated residues	4.0	0.143	4.0	0.162	0.442	0.280	0.060
maximum residue level and STMR Estimations - Poultry							
Feeding Study	0.76	0.06	0.76	0.42	0.15	0.01	
	2.10	0.10	2.10	1.09	0.23	0.05	
Dietary burden and anticipated residues	1.2	0.07	1.2	0.64	0.18	0.02	

The Meeting estimated maximum residue levels of 0.3 mg/kg for milks, 0.2 mg/kg for mammalian fat (except milk fats), 0.4 mg/kg for meat (from mammals other than marine mammals) and 1 mg/kg for edible offal (mammalian) based on liver residue. These recommended maximum residue levels replaces the Meeting's previous recommendations of 0.2 mg/kg for milks, 0.1 mg/kg for mammalian fat (except milk fats), 0.3 mg/kg for meat (from mammals other than marine mammals) and 0.6 mg/kg for edible offal (mammalian). The estimated STMRs and HRs are 0.14 mg/kg, and (no HR required) for milks, 0.06 mg/kg and 0.19 mg/kg for fat, 0.16 mg/kg and 0.39 mg/kg for muscle, 0.44 mg/kg and 0.95 mg/kg for edible offal (mammalian), based on liver.

For poultry, the Meeting recommends a maximum residue level of 0.7 mg/kg for poultry meat to replace its previous recommendation of 0.1 mg/kg. The Meeting estimated STMRs and HRs of 0.07 mg/kg and 0.07 mg/kg for eggs, 0.02 mg/kg and 0.02 mg/kg for poultry fat, 0.18 mg/kg and 0.18 mg/kg for edible offal (poultry) and 0.64 mg/kg and 0.64 mg/kg for meat of poultry.

RECOMMENDATIONS

On the basis of the data obtained from supervised field trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue levels and for IEDI and IESTI assessments.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: *sulfoxaflor*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for sulfoxaflor is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for sulfoxaflor 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 2018 JMPR Report. The IEDIs ranged from 2–9% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of sulfoxaflor from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for sulfoxaflor is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for sulfoxaflor 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 2018 JMPR Report. The IESTIs varied from 0–20% of the ARfD for children and 0–10% for the general population.

The Meeting concluded that acute dietary exposure to residues of sulfoxaflor from uses considered by the present Meeting is unlikely to present a public health concern.