

5.30 SULFOXAFLOR (252)

RESIDUE AND ANALYTICAL ASPECTS

Sulfoxaflor was first evaluated for residues and toxicological aspects by the 2011 JMPR. The 2011 Meeting established an ADI of 0–0.05 mg/kg bw and an ARfD of 0.3 mg/kg bw. The 2011 Meeting established a residue definition of sulfoxaflor for both compliance and dietary risk assessment in both plant and animal commodities. The 2011 Meeting estimated a number of maximum residue levels prior to registration of sulfoxaflor in any country as a pilot project.

After the subsequent meeting of CCPR, the proposed MRLs for citrus fruits, pome fruits, stone fruits and tree nuts were held at Step 4 because the provisional GAP reviewed by JMPR differed from the GAP finally approved in the USA.

The 2014 Meeting received information on registered use patterns for citrus fruit, pome fruit, stone fruit and tree nuts from the manufacturer and the residue data for those crops evaluated by the 2011 Meeting are reconsidered here against the submitted GAPs.

Results of supervised residue trials on crops

Citrus fruit—Grapefruit, Lemon and Oranges

Registered use patterns from Australia and the USA were submitted. Supervised trial data for citrus were available from Australia, Brazil, and the USA.

Australian GAP for citrus fruit is for application at 9.6 g ai/100L (maximum of two applications, maximum 192 g ai/ha/single application, 1 day PHI).

USA GAP for citrus fruit is for application at 96 g ai/ha (14 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 1 day PHI).

None of the citrus fruit trials were conducted in accordance with the USA GAP. The majority of the Australian trials in oranges and mandarins were conducted at Australian GAP, while USA trials in oranges, grapefruit and lemons approximated Australian GAP after scaling.

The Meeting considered that US and Australian citrus fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8 (Guidance for Use of Residue Trial Data from Different Geographical Locations for Estimation of Pesticide Residue Levels).

The Meeting determined that trials for all fruit will be related to Australian GAP for citrus fruit. The Meeting decided to use the concept of proportionality to estimate residue levels in citrus fruit in comparison to the Australian GAP where required. Scaled results for citrus fruit were within a range of 0.67–2.2× GAP, within the acceptable range for use of proportionality. Scaled results are indicated by an (s).

Grapefruit

Residue trials were conducted in grapefruit in the USA, approximating the critical GAP in Australia after scaling.

The results for grapefruit at a 1-day PHI after 2× 15.1–19.4 g ai/100L applications were: 0.010, 0.013, 0.016, 0.024, 0.11, and 0.13 mg/kg.

Residues in whole grapefruit after scaling to the Australian GAP were ≤ 0.01 (×3, all s), 0.015 (s), 0.064 (s) and 0.066 (s) mg/kg, where (s) indicates a result scaled to account for application rates outside $\pm 25\%$ of GAP.

Residues in pulp of grapefruit, in ranked order after scaling, were ≤ 0.01 (×3, all s) mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for the subgroup shaddocks or pomelos. The Meeting noted that sulfoxaflor has systemic properties and considered that three edible portion data points was not sufficient for estimation of STMR and HR values. Therefore, the Meeting estimated an STMR of 0.0125 mg/kg and an HR of 0.066 mg/kg for sulfoxaflor in shaddocks or pomelos, based on the whole fruit data.

Lemons and limes

Residue trials were conducted in lemons in the USA, approximating the critical GAP in Australia after scaling.

Results for whole lemons at a 1-day PHI after 2× 16.2–21.2 g ai/100L were: < 0.01 (2), 0.083, 0.11, and 0.29 mg/kg.

Residues in whole lemons after scaling to the Australian GAP where required were < 0.01 (×2, both s), 0.038 (s), 0.055 (s) and 0.17 (s) mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for the subgroup lemons and limes, together with an STMR of 0.038 mg/kg, and an HR of 0.17 mg/kg.

Oranges and mandarins

Residue trials were conducted in oranges, in Australia approximating the critical GAP in Australia.

Residues of sulfoxaflor in whole oranges from the Australian trials at a 1-day PHI after 2× 6.4–20.2 g ai/100L applications were: 0.09, 0.15, 0.16, 0.33, 0.41, and 0.43 mg/kg.

Scaled residues in whole oranges from the Australian trials with scaling to the Australian GAP where necessary were 0.09, 0.15, 0.19 (s), 0.24 (s), 0.33, and 0.43 mg/kg.

Residues trials were conducted in mandarins in Australia, at GAP.

Residues in whole mandarins from the Australian trials at a 1-day PHI after 2× 7.6–9.6 g ai/100L applications were: 0.15, 0.28, 0.34, and 0.44 mg/kg.

The Meeting noted that the medians for the Australian datasets for oranges and mandarins differed by less than fivefold (medians differed by a factor of only 1.4×). The similarity of the datasets was further confirmed by the Mann-Whitney U-test. The Meeting concluded that the orange and mandarin datasets were mutually supportive and agreed to combine them for the purpose of estimation of maximum residue levels for the subgroups oranges, sweet, sour and mandarins.

The combined Australian data set for oranges and mandarins is 0.09, 0.15 (2), 0.19, 0.24, 0.28, 0.33, 0.34, 0.43, and 0.44 mg/kg.

The Meeting estimated maximum residue levels of 0.8 mg/kg for the subgroup oranges, sweet, sour and the subgroup mandarins, together with STMR values of 0.26 mg/kg and HR values of 0.44 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 0.9 mg/kg for sulfoxaflor in citrus fruit.

Pome fruit—Apples and Pears

Registered use patterns from Australia and the USA were submitted. Supervised trials data were available for apples and pears from Australia/ New Zealand, Europe, and the USA.

Australian GAP for pome fruit is for application at 9.6 g ai/100L (maximum of two applications, maximum 192 g ai/ha/ single application, 7 day PHI).

USA GAP for pome fruit is for application at 96 g ai/ha (7 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7 day PHI).

The Meeting noted that none of the trials were conducted in accordance with the USA GAP, while a number of the trials from both Australia/New Zealand and the USA matched the Australian GAP.

The Meeting considered that the US and Australian pome fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8.

The Meeting determined that trials for both apples and pears will be related to Australian GAP for pome fruit. The Meeting decided to use the concept of proportionality as appropriate to estimate residue levels in pome fruit in comparison to the Australian GAP (trials for which proportionality was used were within 1.3–2.2× GAP, within the acceptable range).

Residue trials were conducted in apples and pears in Australia/ New Zealand, approximating the GAP in Australia.

Results in apples and pears from the Australia/New Zealand trials at a 7-day PHI after 2× 9.1–16.1 g ai/100L applications were 0.02, 0.065, 0.07, 0.11, 0.14, 0.19, and 0.22 mg/kg.

Residues in apples and pears from the Australia/New Zealand trials were 0.015 (s), 0.039 (s), 0.07, 0.11, 0.14, 0.19, and 0.22 mg/kg (STMR = 0.11 mg/kg), where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

Residue trials were conducted in apples and pears in the EU. Results at a 7-day PHI after 2× 10.1–21.0 g ai/100L applications were: 0.052, 0.058, 0.074, 0.078, 0.099, 0.10, 0.18 (3), and 0.27 mg/kg.

Residues in apples and pears from the European trials scaled according to the Australian GAP are: 0.025 (s), 0.028 (s), 0.036 (s), 0.048 (s), 0.071 (s), 0.078, 0.082 (s), 0.082 (s), 0.086 (s), and 0.13 (s) mg/kg (STMR = 0.075 mg/kg).

Residue trials were conducted in apples and pears in the USA.

USA apple and pear results at a 7-day PHI after 2× 7.4–19.8 g ai/100L applications were: < 0.01, 0.039, 0.040, 0.043, 0.056, 0.063, 0.064, 0.066, 0.068, 0.072, 0.075, 0.089, 0.12, 0.13, 0.16, 0.18, and 0.26 mg/kg.

Residues in apples and pears from the USA trials scaled to the Australian GAP where necessary were < 0.01 (s), 0.039, 0.040, 0.043, 0.043 (s), 0.045 (s), 0.055 (s), 0.056, 0.057 (s), 0.063, 0.066, 0.068, 0.075 (s), 0.092 (s), 0.16, 0.18, and 0.23 mg/kg (STMR = 0.057 mg/kg).

The Meeting considered that the seven data points from the Australia/New Zealand apple and pear trials were not sufficient for estimation of a group maximum residue level for pome fruit. The Meeting noted that results from Europe and the USA, relevant to the Australian GAP, were available and combined the Australian, European and USA data sets. The residue found were: < 0.01, 0.015, 0.025, 0.028, 0.036, 0.039 (2), 0.040, 0.043, 0.043, 0.045, 0.048, 0.055, 0.056, 0.057, 0.063, 0.066, 0.068, 0.07, 0.071, 0.075, 0.078, 0.082 (2), 0.086, 0.092, 0.11, 0.13, 0.14, 0.16, 0.18, 0.19, 0.22, and 0.23 mg/kg

The Meeting estimated a maximum residue level of 0.3 mg/kg for sulfoxaflor in pome fruit, together with an STMR of 0.067 mg/kg and an HR of 0.23 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 0.4 mg/kg for sulfoxaflor in pome fruit.

Stone fruits

Registered use patterns from Australia and the USA were submitted. Supervised trial data were available for apricot (Australia and New Zealand), cherries (Australia, EU and USA), nectarine (Australia and New Zealand), peach (Australia, EU and USA) and plums (Australia and USA).

Australian GAP for stone fruit is for application at 7.2 g ai/100L (maximum of two applications, maximum 144 g ai/ha/ single application, 7-day PHI).

USA GAP for stone fruit is for application at 96 g ai/ha (7-day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7-day PHI).

Insufficient trials were conducted in accordance with the USA GAP, while a significantly greater number were conducted in accordance with the Australian GAP, and further trials could be related to the Australian GAP through the use of proportionality (trials for which results were scaled were within 1.3–2.9× of GAP, within the acceptable range).

The Meeting considered that the US and Australian stone fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8.

Therefore trials for all stone fruit will be related to the Australian GAP for stone fruit.

Cherries subgroup

A total of 14 trials on cherries were available from Australia/ New Zealand (1 each), Europe (6), and USA (6).

Australia/New Zealand cherry results at a 7-day PHI after 2×9.7 –16.3 g ai/100L applications were 0.35 and 0.38 mg/kg.

Residues of sulfoxaflor in cherries from Australia were: 0.17 (s) and 0.35 mg/kg (STMR = 0.26 mg/kg) where (s) indicates a result scaled to account for application rates outside $\pm 25\%$ of GAP.

European cherry results at a 7-day PHI after 2×10.1 –20.1 g ai/100L applications were: 0.54, 0.77, 0.80, 0.90, 0.98 and 1.5 mg/kg.

Residues of sulfoxaflor measured in cherries from in Europe in accordance with Australian GAP (scaled where necessary) were: 0.29 (s), 0.32 (s), 0.33 (s), 0.38 (s), 0.42 (s), and 0.54 (s) mg/kg (STMR=0.355 mg/kg).

USA cherry results at a 7-day PHI after 2×8.6 –21.0 g ai/100L applications were: 0.55, 0.59, 0.76, 1.0, and 1.2 (2) mg/kg.

Residues of sulfoxaflor in cherries from USA in accordance with the Australian GAP (scaled where necessary) were: 0.24 (s), 0.26 (s), 0.26 (s), 0.42 (s), 0.46 (s) and 1.2 mg/kg (STMR=0.34 mg/kg).

The Meeting noted that there were insufficient residue trials conducted in Australia/New Zealand in accordance with the Australian GAP, and combined the Australia, American and European datasets for the purpose of estimating a maximum residue level for the cherries subgroup.

Residues in cherries from trials conducted in Australia/New Zealand, EU countries and the USA. Sulfoxaflor residues found were: 0.17, 0.24, 0.26 (2), 0.29, 0.32, 0.33, 0.35, 0.38, 0.42 (2), 0.46, 0.54, and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg for the subgroup cherries, together with an STMR of 0.34 mg/kg, and an HR of 1.24 mg/kg (unrounded result).

Peaches subgroup

A total of five trials on nectarines were available from Australia and New Zealand. The results for nectarines at a 7-day PHI after 2×9.8 –19.7 g ai/100L applications were: 0.10, 0.11, 0.12, 0.14, and 0.18 mg/kg.

Residues of sulfoxaflor in nectarines from Australia and New Zealand were: 0.037 (s), 0.054 (s), 0.061 (s), 0.10 (s) and 0.12 (s) mg/kg (STMR=0.061 mg/kg) where (s) indicates a result scaled to account for application rates outside $\pm 25\%$ of GAP.

Two trials on apricots were available from Australia and New Zealand. The results for apricots at a 7-day PHI after 2×9.5 – 14.8 g ai/100L applications were: 0.15 and 0.42 mg/kg.

Residues of sulfoxaflor apricots from Australia/New Zealand in accordance with the Australian GAP (scaled where necessary) were: 0.11 (s) and 0.20 (s) mg/kg (STMR=0.155 mg/kg).

Eight trials in peaches were conducted in Australia and New Zealand. The results at a 7-day PHI after 2×9.7 – 19.8 g ai/100L applications were: 0.012, 0.11, 0.11, 0.12, 0.14, 0.15, 0.24, and 0.27 mg/kg.

Residues of sulfoxaflor in peaches from Australia and New Zealand (scaled to the Australian GAP where required) were: < 0.01 (s), 0.040 (s), 0.050 (s), 0.052 (s), 0.057 (s), 0.094 (s), 0.16 (s) and 0.20 (s) mg/kg (STMR=0.0545 mg/kg).

The Meeting noted that the GAP under consideration is for Australia, and that a large regional (Australia/New Zealand) data set for the peach group is available (15 trials in total for peaches, nectarines and apricots), and that the median values of these data sets are within a factor of $5 \times$ each other (the medians differed by a maximum factor of $2.8 \times$). The Meeting agreed to combine the Australia/New Zealand peach, nectarine and apricot data for the purpose of estimating a maximum residue level for the peach subgroup. Sulfoxaflor residues found were: < 0.01 , 0.037, 0.04, 0.05, 0.052, 0.054, 0.057, 0.061, 0.094, 0.10, 0.11, 0.12, 0.16, and 0.20 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for the subgroup peaches, together with an STMR of 0.061 mg/kg and an HR of 0.2 mg/kg.

Plums

A total of seven trials on plums were available from Australia (1) and USA (6).

The Australian result for plums at a 7-day PHI after 2×19.2 g ai/100L applications was: 0.020 mg/kg.

Residues of sulfoxaflor measured in plums from Australia were: < 0.01 (s) mg/kg where (s) indicates a result scaled to account for application rates outside $\pm 25\%$ of GAP.

The USA results for plums at a 7-day PHI after 2×6.9 – 20.9 g ai/100L applications were: 0.030, 0.054, 0.066, 0.090, 0.11, and 0.26 mg/kg.

Residues of sulfoxaflor in plums from the USA in accordance with the Australian GAP (scaled where necessary) were: 0.020 (s), 0.028 (s), 0.038 (s), 0.039 (s), 0.06 (s) and 0.26 mg/kg.

Residues in plums from trials conducted in Australia and the USA were: < 0.01 , 0.020, 0.028, 0.038, 0.039, 0.06, and 0.26 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg for the subgroup plums, together with an STMR of 0.038 mg/kg, and an HR of 0.26 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 3 mg/kg for sulfoxaflor in stone fruit.

Tree nuts

USA GAP for tree nuts (Crop Group 14) including almonds, cashew, chestnut, hazelnut, macadamia, pecan and walnut is for application at 96 g ai/ha (7 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7 day PHI).

Residues data from trials conducted in the USA were available for almonds and pecans. However, the trials do not match the USA GAP, with only two applications being made at a rate of 200–205 g ai/ha with a 7-day PHI. The Meeting therefore did not estimate maximum residue levels, STMRs or HRs for the tree nut group.

The Meeting agreed to withdraw the previous maximum residue level recommendation of 0.015 mg/kg for sulfoxaflor in tree nuts.

Animal feeds

Almond hulls

Residue data for sulfoxaflor in almond hulls were available to the Meeting. However, as the trials were not conducted in accordance with the USA GAP for almonds, the Meeting did not estimate a median residue value.

Fate of residues during processing

The 2011 Meeting received information on the fate of sulfoxaflor residues during the processing of apple to juice, sauce and wet and dry pomace; cherry to dried cherries, jam and juice and oranges to juice, wet and dry pulp, oil and peel.

Calculated processing factors are summarized in the following table based on the JMPR 2014 recommendations for MRLs and STMRs. Factors are indicated with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity).

Processes included in the table are those that lead to STMR-P or HR-P values useful for dietary intake estimations or for livestock dietary burden calculations.

Raw Agricultural Commodity (RAC)	Processed Commodity	Best Estimate Processing Factor (PF)	RAC MRL (mg/kg)	RAC STMR (mg/kg)	RAC HR (mg/kg)	Processed commodity STMR-P (mg/kg)	Processed commodity HR-P (mg/kg)
Apple	Wet pomace	1.1	0.3	0.067	0.23	0.074	–
	Dry pomace	4.2				0.28	–
	Juice	0.4				0.027	–
	Sauce	0.6				0.040	–
Cherry	Juice	0.8	1.5	0.34	1.24	0.27	–
	Jam	1.1				0.37	–
	Dried	5.1				1.73	6.32
Orange	Juice	0.14	0.8	0.26	0.44	0.036	–
	Wet pulp	2.5				0.65	–
	Dried pulp	8.3				2.16	–
	Oil	< 0.2				< 0.052	–
	Peel	5.6				1.46	2.45

Animal commodities

The Meeting recalculated the livestock dietary burden based on the uses considered by the current Meeting and by the 2011 Meeting on the basis of diets listed in the FAO Manual Appendix IX (OECD Feedstuff Table).

The maximum dietary burden is 3.22 ppm for beef and dairy cattle, while the mean dietary burden is 1.26 ppm for beef and dairy cattle. The values calculated by the 2011 Meeting were: maximum dietary burden of 3.04 ppm for beef cattle and 2.68 ppm for dairy cattle, and a mean dietary burden of 0.91 ppm for both dairy and beef cattle. Interpolation of these values between the appropriate feeding levels in the lactating cattle feeding study considered by the 2011 Meeting showed that no changes to the maximum residue levels estimated by the 2011 Meeting for milks, edible offal (mammalian) or meat (from mammals other than marine mammals) were required.

The maximum and mean dietary burdens for poultry (both layers and broilers) are 0.93 and 0.31 ppm respectively. These have changed very little from the values determined by the 2011 Meeting (maximum and mean values of 0.89 and 0.30 ppm respectively).

The Meeting confirmed its previous recommendations for meat (from mammals other than marine mammals), edible offal (mammalian), milks, poultry meat, poultry, edible offal of, and eggs.

The Meeting noted that the 2011 Meeting did not estimate maximum residue levels for mammalian fats (except milk fats) or poultry fats.

The Meeting noted the STMR values of 0.03 mg/kg and HR value of 0.073 mg/kg estimated by the 2011 Meeting for the fat compartment of mammalian meat (from mammals other than marine mammals). Noting that the dietary burden has not significantly increased, the Meeting estimated a maximum residue level of 0.1 mg/kg for mammalian fats (except milk fats), together with an STMR of 0.03 mg/kg and an HR of 0.073 mg/kg.

The Meeting noted the STMR values of 0.005 mg/kg and HR value of 0.021 mg/kg estimated by the 2011 Meeting for the fat compartment of poultry meat. Noting that the dietary burden has not significantly increased, the Meeting estimated a maximum residue level of 0.03 mg/kg for poultry fats, together with an STMR of 0.005 mg/kg and an HR of 0.021 mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *sulfoxaflor*

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of sulfoxaflor has resulted in recommendations for MRLs and STMRs for raw and processed commodities. The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on estimated STMRs were in the range 1–7% of the maximum ADI of 0.05 mg/kg bw (Annex 3 to the 2014 Report).

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

Short-term intake

The International Estimated Short Term Intake (IESTI) for sulfoxaflor was calculated for the plant and livestock commodities (and their processing fractions) for which new STMRs and HRs were estimated and for which consumption data were available. The results are shown in Annex 4 to the 2014 Report.

The IESTI varied from 0–9 % of the ARfD (0.3 mg/kg bw). The Meeting concluded that the short-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern