AZOXYSTROBIN (229)

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EXPLANATION

Azoxystrobin, with chemical name of (methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) was first evaluated for toxicology and residues by the JMPR in 2008, where an ADI of 0.2 mg/kg bw per day was derived. It's decided that an ARfD was unnecessary. The residue is fat soluble. The 2008 JMPR concluded that the residue definition for plant and animal commodities for compliance with MRL and for consumer risk assessments was parent azoxystrobin. Maximum residue levels, STMRs and STMR-Ps for a range of commodities were estimated. The compound was re-evaluated for residues by the JMPR in 2011, 2012 and 2013. Azoxystrobin was listed by the 48th Session of the CCPR (2016) for the review of additional MRLs. The 2017 JMPR received GAP information and residue data in guava, dragon fruit, sugarcane and oilseeds.

METHODS OF RESIDUE ANALYSIS

Analytical methods

Method validation including analytical recoveries were tested in the supervised crop field trials, with control samples being fortified with azoxystrobin at 0.005 mg/kg and at higher levels that generally reflected the range of expected residues. The common analytical method EURL-FV QuEChERS was used in trials of guava and dragon fruit. The POPIT MET.068 method was applied in sugarcane trials. A modified TMR0812B method was used in oilseed rape trials.

Method:	EURL-FV QuEChERS
Reference:	EURL-FV (2010-M1)
Commodity:	guava and dragon fruit
Analyte:	Azoxystrobin, R230310
Determination:	LC-MS/MS
LOQ:	0.01 mg/kg on guava and 0.005 mg/kg on dragon fruit
Accuracy:	The mean recovery in guava and dragon fruit was between 101-112% and 86-100% at each fortification level.
Repeatability:	The RSDs of azoxystrobin recoveries at each fortification level and overall during method validation were all below 20%.
Linearity:	The linearity of detector response was confirmed by analysis of six concentrations of standard solutions in the range 1 to 20 ng/mL of azoxystrobin with two injections for each concentration. Linearity of response was demonstrated with a correlation coefficient (r^2) of 0.9881.
Specificity:	No interfering peaks were detected in control samples above the LOD.
Description:	Weigh 10.0 g samples into 50 mL extraction tubes containing 4 g magnesium sulphate anhydrous, 1 g sodium chloride, 1 g trisodium citrate dehydrate and 0.5 g disodium hydrogen citrate sesquihydrate, add 10 mL acetonitrile, shake the tubes vigorously by hand for 1 min, followed by shaking in a mechanical shaker for 10 minutes. Centrifuge the mixture at > 4000 rpm for 5 min. Transfer 6 mL acetonitrile extracts (upper layer) into 15 mL clean-up tubes containing 150 mg primary secondary amine (PSA) and 900 mg magnesium sulphate anhydrous. Close the tubes tightly and mix by Vortex mixer for 1 minute. Centrifuge the clean-up tubes at > 6000 rpm for 2 min. Filter 0.5 mL acetonitrile extract from clean-up Tubes through 0.2 µm PTFE syringe filter into

	the appropriately labelled LC-MS/MS auto-sample vial, add 0.5 mL ultra-pure water, then placed in the auto-sample tray.
Method:	POPIT MET.068
Reference:	POPIT MET.068.Rev32
Commodity:	sugarcane
Analyte:	Azoxystrobin, R230310
Determination:	LC-MS/MS
LOQ:	0.01 mg/kg
Accuracy:	The mean recovery in sugarcane stalks was 103% at 0.01 mg/kg.
Repeatability:	The RSDs of azoxystrobin recoveries at 0.01 mg/kg and overall during method validation were all below 5 %.
Linearity:	The linearity of detector response was confirmed by analysis of seven concentrations of standard solutions of azoxystrobin with three injections for each concentration. Linearity of response was demonstrated with a correlation coefficient (r^2) of 0.9995.
Specificity:	No interfering peaks were detected in control samples above the LOD.
Description:	Azoxystrobin were extracted of the samples with a solution of acetonitrile:water (9:1) (v/v). An aliquot of the extract was removed and evaporated, and then re-dissolved in acetonitrile:water (1:1) (v/v) and centrifuged at high speed. Quantification was performed in a liquid chromatography system coupled to mass selective triple quadrupole detector (MS/MS)
Method:	modified TMR0812B
Reference:	TMR0812 Aug/12/1998
Commodity:	oilseeds
Analyte:	Azoxystrobin, R230310
Determination:	LC-MS
LOQ:	0.01 mg/kg
Accuracy:	The mean recovery in rape seed was between 84–100% at each fortification level.
Repeatability:	The RSDs of azoxystrobin recoveries at each fortification level and overall during method validation were all below 15 %.
Linearity:	The linearity of detector response was confirmed by analysis of six concentrations of standard solutions in the range 5 to 200 ng/mL of azoxystrobin with one injections for each concentration. Linearity of response was demonstrated with a correlation coefficient (r^2) of 0.9999.
Specificity:	No interfering peaks were detected in control samples above the LOD.
Description:	10 g of oilseed samples were weighed into pint jars. Residues were extracted with 9:1 (v/v) acetonitrile:water. After blending, the extraction mixture was vacuum-filtered into a mixing cylinder. The filtrate was brought to volume with acetonitrile. The hexane phase was drained into another separatory funnel and was partitioned once against aqueous 5% sodium chloride and dichloromethane. The lower dichloromethane layer was passed through a powder funnel containing sodium sulfate, and then evaporated to dryness on a rotary evaporator. The sample was dissolved in 1:1 acetonitrile:water for analysis of LC-MS.

Average recoveries at two fortification levels in the above trials generally fell within the 80–120% range, and with relative standard deviations all less than 20% except in dragon fruit peel, in which 40% at a fortified level of 0.005 mg/kg was reported. Information on the concurrent recovery rates in the submitted supervised field trials are summarised below.

Table 1 Azoxystrobin analytical concurrent recovery rates in supervised trials

Matrix	Method	Fortification level (mg/kg)	Recovery (%) （Average）	RSD (%)	Reference
Guava (whole fruit)	EURL-FV QuEChERS	0.01 0.1	128, 109, 99 (112) 88,98,91,120,107 (101)	13 13	Report No 11605
Dragon fruit (whole fruit)	EURL-FV QuEChERS	0.005 0.1 1	89,110,85,110,87 (96) 108,83,107,101 (100) 91,71,90,91 (86)	13 12 12	Report No. 10993
Dragon fruit (peel)	EURL-FV QuEChERS	0.005 0.1 1	93,117,54 (88) 104,68 (86) 98,90 (94)	36 30 5.9	
Dragon fruit (flesh)	EURL-FV QuEChERS	0.005 0.1 1	102,103,117 (108) 96,88 (92) 92,86 (89)	7.6 6.0 4.2	
Sugarcane stalks	POPIT MET.068	0.1	105,96,105,99,104,103,101,104,105,104,103,104 (103)	2.7	Report No. M11013 Report No. M11019 Report No. M11007
Oilseed rape	TMR0812B (modified)	0.01 0.5 5	111,102,88 (100) 94,91,112,105 (100) 91,78 (84)	12 9.7 11	Report No. RR 00-53B

Stability of residues

The 2008 JMPR indicated that azoxystrobin residues were stable at freezer conditions in the following crop commodities for the intervals tested, most for 24 months: apples, orange oil, orange juice, orange pulp, peaches, grapes, wine, bananas, tomatoes, tomato juice, tomato paste, cucumbers, carrots, lettuce, oilseed rape, soya bean meal, corn grits, wheat straw, wheat grain, wheat forage, peanuts, peanut oil, peanut meal and pecans.

The current Meeting received residue stability data for guava and dragon fruit spiked at 0.1 mg/kg and stored concurrently with residue trial samples. The stability of azoxystrobin residues in stored samples of guava and dragon fruit was demonstrated for at least 13 and 6 months respectively. Storage stability test was also available for canola, including 0.01, 0.5 mg/kg levels fortification. Storage stability data on sugarcane was not available, though the relevant residue data submitted states that a 6 month storage study was done.

Table 2 Stability of azoxystrobin residues in homogenised guava, dragon fruit and canola samples

Commodity (fortification)	Storage interval (days)	Residues remaining in stored samples [a]		Procedural recovery [b]	
		mg/kg	% [mean]	mg/kg	%[mean]
Guava	403	0.095,0.113,0.125,0.093,0.085, 0.090	95.2,113.7,121.6,93.0,88.9, 90.1[100.4]	0.116,0.122	116,122 [119]
Dragon fruit	189-203	0.075,0.075,0.072	74.5,74.8,71.5[73.6]	n.a	83
Canola	117-146	111,102,88; (0.01 mg/kg) 94,91,112,105 (0.5 mg/kg)	100 101	111, 102 (0.01mg/kg) 94, 91 (0.5 mg/kg)	106 92

n.a , no detailed information.

[a] Azoxystrobin residues in stored samples and % fortified level, mean % in square brackets

[b] Azoxystrobin residues in freshly fortified samples, mean % in square brackets

USE PATTERNS

The Meeting received additional information on recently authorised uses on guava, dragon fruit, sugarcane and oilseed in Egypt, Indonesia, Vietnam, Brazil, the Americas and Canada, respectively. The national GAPs for these crops are summarised in the following table.

Table 3 Registered uses of azoxystrobin (200 g ai/L or 250 g ai/L SC formulations or 100 g ai/L EC formulation or 300 g ai/kg or 800 g ai/kg WG formulations)

Crop	Country	Form	Application				Max applications		PHI (days)	
			kg ai/ha	kg ai/hL	water L/ha	RTI (days)	no	kg ai/ha		
Guava	Egypt	SC	0.1		1000L	7-14	3		10	to control leaf spots disease on guava : 50cm3 / 100 LT water
Dragon fruit	Indonesia	SC	0.08		800L	10	3		7	use at 0.5 ml/L conc.
Sugar cane	Brazil	EC, WG	0.06			30	5		30	use specific adjuvant
Oilseed rape (Canola)	USA/ Canada	SC	0.125 0.25 0.125				3	0.5	30	First application: 0.125kg ai/ha as a broadcast foliar spray at the 2-6 leaf stage; Second application: as a broadcast foliar spray at the early bloom stage (prior to 30% bloom) Third application: as a broadcast foliar spray at the pod stage (90% petal fall)

RESULTS OF SUPERVISED RESIDUE TRIALS ON CROPS

The Meeting received information on supervised field trials involving foliar treatments of azoxystrobin to guava, dragon fruit, sugarcane and oilseed rape.

Group	Crop	Countries	Table no
Assorted Tropical and Sub-Tropical Fruits - Inedible Peel	Guava	Egypt	4
	Dragon fruit	Indonesia, Vietnam	5
Grasses for sugar or syrup production	Sugarcane	Brazil	6
Oilseeds	Oilseed rape	Canada, The U.S.A.	7

Results from replicated field plots are listed and mean values are caculated. The results from trials used for the estimation of maximum residue levels (underlined) have been rounded to two significant digits (or if close to the LOQ, rounded to one significant digit). Residue value was selected for estimating maximum residue levels and for dietary intake assessment at longer PHI instead of that at the GAP, if the value was on a higher level. The highest residue was selected from trials which were considered to be not independent.

In most trials, the actual treatment rates were close to the GAP and the GAP was listed, otherwise the actual treatment rates are listed.

Assorted tropical and sub-tropical fruits - edible peel - medium to large

The results from six supervised trials on guava in Egypt were provided to the Meeting.

Guava

In the guava trials, three foliar applications of 0.1 kg ai/ha azoxystrobin (SC) were applied, at a seven-day interval in 1000 L water/ha to single replicate plots.

Table 4 Residues in guavas from supervised trials in Egypt involving three foliar applications of azoxystrobin (SC formulation).

GUAVA Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			azoxystrobin	mean	
GAP: Egypt	3	0.1		1000		PHI: 7			
Egypt, 2015 Moshtohor (Etmany)	3	0.1	0.01	999-1036	fruit	7	0.045,0.056	0.051	Report: 11605 Trial: 11605.15-EG01 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
Egypt, 2015 Qalama-Qudiouhia (Ghoneimy)	3	0.1	0.01	996-1032	fruit	0 3 7 10 14	0.088, 0.124 0.039, 0.040 0.013, 0.014 0.019, 0.037 0.018, 0.027	0.106 0.040 0.014 <u>0.028</u> 0.023	Report: 11605 Trial: 11605.15-EG02 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
Egypt, 2015 Salheya-Sharqueya (Etmany)	3	0.1	0.01	986-1022	fruit	7	0.056, 0.067	0.062	Report: 11605 Trial: 11605.15-EG03 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
Egypt, 2015 Arab-Al Khanka (Balady)	3	0.1	0.01	985-1060	fruit	7	0.017, 0.041	0.029	Report: 11605 Trial: 11605.15-EG04 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
Egypt, 2015 Qualiobia (Etmany)	3	0.1	0.01	989-1047	fruit	7	0.085, 0.107	0.096	Report: 11605 Trial: 11605.15-EG05 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
Egypt, 2015 Al Manzala (Balady)	3	0.1	0.01	983-1033	fruit	7	0.043, **0.158**	0.10	Report: 11605 Trial: 11605.15-EG06 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting

Assorted tropical and sub-tropical fruits - inedible peel

The results from seven trials on Dragon fruit conducted in Indonesia (6) and Vietnam (1) were provided to the Meeting.

Dragon fruit

In the dragon fruit trials, three foliar applications of 0.15 kg ai/hL azoxystrobin (SC) were applied, at 9–11 day intervals in either 320–900 L water/ha ('concentrate) or 1000–2500 L water/ha ('dilute') to single replicate plots using a high volume foliar mist/spray.

Duplicate samples of whole fruit were frozen immediately and stored for up to 6 months before analysis for azoxystrobin using the EURL-FV analytical method based on the QuEChERS extraction with citrate buffer, with an LOQ of 0.01 mg/kg.

Table 5 Residues in dragon fruits from supervised trials in Indonesia and Vietnam involving three foliar applications of azoxystrobin (SC formulation).

DRAGON FRUIT Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	no	kg ai/ha	kg ai/hL	water (L/ha)			azoxystrobin	Mean	
GAP: Indonesia	3	0.08	0.08	800	Whole fruit	PHI: 7			
Indonesia, 2015 Sragen, Central Java (Red dragon fruit)	3		0.148-0.155	1328-1352	Whole fruit	-1 0 1 7	0.117 0.254 0.170 0.047	0.117 0.254 0.170 0.047	Report: 10993 Trial: 10993.14-ID01 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
	3		0.147-0.156	1074-1183	Whole fruit	-1 0 1 7	0.188 0.316 0.143 0.077	0.188 0.316 0.143 0.077	
Indonesia, 2015 KulonProgo (Red dragon fruit)	3		0.151-0.153	1543-1604	Whole fruit	-1 0 1 3 7 10 14	0.061 0.261 0.160 0.086 0.037 0.031 0.008	0.061 0.261 0.160 0.086 0.037 0.031 0.008	Report: 10993 Trial: 10993.14-ID02 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
	3		0.15-0.151	1606-1621	Whole fruit	-1 0 1 3 7 10 14	0.089 0.167 0.126 0.092 0.036 0.033 0.008	0.089 0.167 0.126 0.092 0.036 0.033 0.008	
Indonesia, 2015 Mojokerto, East Java, (Red dragon fruit)	3		0.15-0.155	1480-1693	Whole fruit	-1 0 1 7	0.041 0.216 0.118 0.110	0.041 0.216 0.118 0.110	Report: 10993 Trial: 10993.14-ID03 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
	3		0.149-0.155	1462-1738	Whole fruit	-1 0 1 7	0.014 0.226 0.205 0.057	0.014 0.226 0.205 0.057	

DRAGON FRUIT Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	no	kg ai/ha	kg ai/hL	water (L/ha)			azoxystrobin	Mean	
Indonesia, 2015 Bogor, West Java, (Super red)	3		0.15- 0.153	1072-1152	Whole fruit	-1 0 1 3 7 10 14	0.069 0.257 0.072 0.135 0.043 0.069 0.008	0.069 0.257 0.072 0.135 0.043 <u>0.069</u> 0.008	Report: 10993 Trial: 10993.14-ID04 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
	3		0.147- 0.159	541.4-881.9	Whole fruit	-1 0 1 3 7 10 14	0.032 0.546 0.200 0.122 0.055 0.069 0.053	0.032 0.546 0.200 0.122 0.055 0.069 0.053	
Indonesia, 2015 Lampung, South Sumatera, (Red dragon fruit)	3		0.152- 0.158	381.8-1617	Whole fruit	-1 0 1 7	0.199 0.653 0.428 0.135	0.199 0.653 0.428 <u>0.135</u>	Report: 10993 Trial: 10993.14-ID05 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
	3		0.16- 0.182	322-1364	Whole fruit	-1 0 1 7	0.119 0.563 0.327 0.106	0.119 0.563 0.327 0.106	
Indonesia, 2015 Malang, East Java, (Red dragon fruit)	3		0.145- 0.149	2044-2108	Whole fruit	-1 0 1 7	0.025 0.149 0.149 0.021	0.025 0.149 0.149 0.021	Report: 10993 Trial: 10993.14-ID05 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting
	3		0.145- 0.157	2088-2507	Whole fruit	-1 0 1 7	0.026 0.164 0.136 0.034	0.026 0.164 0.136 <u>0.034</u>	
Vietnam, 2015 Nam, Binh Thuan (White flesh variety)	3		0.149 0.152- 0.184	532 Not recorded	Whole fruit	-1 0 1 7	0.104 0.540 0.515 0.350	0.104 0.540 0.515 <u>0.350</u>	Report: 10993 Trial: 10993.14-VN01 Crop stage during applications: 1)fruiting 2)fruiting 3)fruiting

Grasses for sugar or syrup production

The results from 16 supervised trials on sugarcane conducted in Brazil were provided to the Meeting. Four of the trials were conducted in Brazil during 2011 at an exaggerated rate in order to obtain residues sufficient to assess the residues that would be found in the processed commodities of sugarcane.

Sugarcane

Two formulations (EC or WG) were compared in the Brazil sugarcane trials. All replicate plots of trials were applied at 30 day intervals in 200 L water/ha.

Table 6 Residues in sugarcane from supervised trials in Brazil involving five foliar applications of azoxystrobin (EC and WG formulations).

SUGARCANE Country, year, Location (Variety)	Application					DAT	Azoxystrobin (mg/kg)	Reference
	Form	N	kg ai/ha	water (L/ha)	GS (BBCH)			
GAP: Brazil		5	0.06	200		PHI: 30		
Brazil,2011 Mirassol-SP (SP 842025)	EC	5	0.06	200	26 31-32 34 36-37 42	20 30 40	< 0.01 < 0.01 0.02	Report: M11013 Trial: M11013-AMA1
	WG	5	0.06	200	26 31-32 34 36-37 42	20 30 40	0.01 0.01 0.01	Report: M11019 Trial: M11019-AMA1
Brazil,2011 Jaboticabal-SP (RB 5453)	EC	5	0.06	200	31-32 34-35 37 37-38 39	20 30 40	< 0.01 < 0.01 < 0.01	Report: M11013 Trial: M11013-AMA2
	WG	5	0.06	200	31-32 34-35 37 37-38 39	20 30 40	< 0.01 < 0.01 < 0.01	Report: M11019 Trial: M11019-AMA2
Brazil,2011 Jaboticabal-SP (SP 89-1115)	EC	5	0.18	200	32-34	30	< 0.01	Report: M11007 Trial: M11007-AMA2
		5	0.3	200	33-35 37-38 38-39 38-39	30	0.04	
Brazil,2011 Rio das Pedras-SP (85 7515)	EC	5	0.06	200	31 31-32 33-34 37-39 47-48	20 30	< 0.01 < 0.01	Report: M11013 Trial: M11013-RWC1
	WG	5	0.06	200	31 31-32 33-35 37-39 47-48	20 30	0.01 0.02	Report: M11019 Trial: M11019-RWC1
Brazil,2011 Rio das Pedras-SP (RB 85 7515)	EC	5	0.18	200	31	30	0.03	Report: M11007 Trial: M11007-RWC2
		5	0.3	200	34-36 36-37 37-39 37-39	30	0.04	
Brazil,2011 Holambra-SP (85 7515)	EC	5	0.06	200	33-35 35-37 37-39 41-43 47-48	20 30 40	< 0.01 < 0.01 < 0.01	Report: M11013 Trial: M11013-RWC2
	WG	5	0.06	200	35-39 35-37 37-39 41-43 47-48	20 30 40	0.01 0.02 < 0.01	Report: M11019 Trial: M11019-RWC2
Brazil,2011 Holambra – SP (RB 857515)	EC	5	0.18	200	31 32-34	30	0.02	Report: M11007 Trial: M11007-RWC1
		5	0.3	200	35-36 37-38 38-39	30	0.08	

SUGARCANE Country, year, Location (Variety)	Application					DAT	Azoxystrobin (mg/kg)	Reference
	Form	N	kg ai/ha	water (L/ha)	GS (BBCH)			
Brazil,2011 Bandeirantes-PR (RB 72454)	EC	5	0.06	200	29 34 37 39 39	20 30 40	0.02 0.03 0.02	Report: M11013 Trial: M11013-DMO
Brazil,2011 Bandeirantes-PR (RB 72454)	WG	5	0.06	200	29 34 37 39 39	20 30 40	0.04 0.03 0.02	Report: M11019 Trial: M11019-DMO
Brazil,2011 Tupaciguara-MG (SP 86155)	EC	5	0.06	200	18 19-31 34 36 38	20 30 40	< 0.01 < 0.01 < 0.01	Report: M11013 Trial: M11013-JJB
Brazil,2011 Tupaciguara-MG (SP 86155)	WG	5	0.06	200	18 19-31 34 36 38	20 30 40	0.01 0.01 < 0.01	Report: M11019 Trial: M11019-JJB
Brazil,2011 Santa Lucia – SP (SP 81-3250)	EC	5	0.18	200	32-34	30	0.02	Report: M11007 Trial: M11007-AMA1
		5	0.3	200	34-36 37 39 45	30	0.02	

Oilseeds

The results from 22 supervised trials on oilseed rape conducted in Canada and the USA were provided to the Meeting.

Oilseed rape

In the oilseed rape trials in Canada and the USA, three applications were applied (one application at 125 g ai/ha at BBCH 12–16, a second application at 250 g ai/ha at BBCH 60–63 and third application at 125 g ai/ha at BBCH 67–79). Samples of oilseed rape seeds were collected at normal commercial harvest, 28–31 days after the last application.

Samples were frozen immediately and stored for up to 5 months before analysis for azoxystrobin using the analytical method TMR0812B with an LOQ of 0.01 mg/kg.

Table 7 Residues in oilseed rape from supervised trials in Canada and U.S.A. involving three foliar applications of azoxystrobin (SC formulation).

RAPE Country, year	Application				GS	DAT	Residues (mg/kg)		Trial Reference
	no	kg ai/ha	kg ai/hL	water (L/ha)			azoxystrobin	mean	
GAP: USA/Canada	3	0.125 0.25 0.125				30			
Canada,2000 Elm Creek, Manitoba, (46A65)	3	0.124 0.257 0.123			6 Leaf Full flower BBCH 75	29	0.11	0.11	Report: RR 00-053B Trial: ABC-MB-00-101 :
	3	0.126 0.263 0.127			6 Leaf Full flower BBCH 75	29	0.17	0.17	
Canada,2000 Dundurn, Saskatchewan,	3	0.125 0.248 0.124			6 Leaf 25% petal fall BBCH 75-79	28	< 0.01	< 0.01	Report: RR 00-053B Trial: ABC-SK-

RAPE Country, year	Application				GS	DAT	Residues (mg/kg)		Trial Reference
	no	kg ai/ha	kg ai/hL	water (L/ha)			azoxystrobin	mean	
(Exceed)	3	0.123 0.247 0.125			6 Leaf 25% petal fall BBCH 75-79	28	< 0.01	< 0.01	00-102
Canada,2000 Leduc, Alberta (Agass 12)	3	0.127 0.254 0.124			BBCH 12 25% petal drop BBCH 79	29	0.02	0.02	Report: RR 00-053B Trial: ABC-AB-00-103
	3	0.125 0.258 0.124			BBCH 12 25% petal drop BBCH 79	29	0.02,0.02	0.02	
Canada,2000 Wetaskiwin, Alberta, (Agass 12)	3	0.126 0.248 0.124			BBCH 14 BBCH 63 BBCH 77	28	0.06	0.06	Report: RR 00-053B Trial: ABC-AB-00-104
	3	0.126 0.250 0.124			BBCH 14 BBCH 63 BBCH 77	28	0.04	0.04	
Canada,2000 Lacombe, Albert (LG 3235)	3	0.123 0.260 0.126			5-Leaf 30% flower BBCH 75	31	< 0.01	< 0.01	Report: RR 00-053B Trial: ABC-AB-00-105
	3	0.126 0.246 0.120			5-Leaf 30% flower BBCH 75	31	< 0.01	< 0.01	
Canada,2000 Rostern, Saskatchewan, Manitoba (46A76)	3	0.126 0.250 0.127			3-4 leaf 50% flower BBCH 77-79	28	0.01	0.01	Report: RR 00-053B Trial: ABC-SK-00-106
	3	0.128 0.246 0.124			3-4 leaf 50% flower BBCH 77-79	28	0.01, 0.01	0.01	
Canada,2000 Wakaw, Saskatchewan, North (45A71)	3	0.127 0.245 0.126			4-6 Leaf 25% petal fall BBCH 69-73	28	0.01	0.01	Report: RR 00-053B Trial: ABC-SK-00-107
	3	0.125 0.244 0.125			4-6 Leaf 25% petal fall BBCH 69-73	28	0.02	0.02	
USA 2000 Brookdale, Manitoba, (45A51)	3	0.122 0.248 0.125			4-6 Leaf 25% petal fall BBCH 71-75	30	0.13	0.13	Report: RR 00-053B Trial: ABC-MB-00-108
	3	0.126 0.246 0.125			4-6 Leaf 25% petal fall BBCH 71-75	30	0.03	0.03	
USA 2000 Brandon, Manitoba, Washington, (1867RR)	3	0.122 0.238 0.127			BBCH 14-15 BBCH 64-65 BBCH 77	28	0.11	0.11	Report: RR 00-053B Trial: ABC-MB-00-109
	3	0.123 0.251 0.126			BBCH 14-15 BBCH 64-65 BBCH 77	28	0.23, 0.23	0.23	
Canada,1996 Airdrie, Alberta, (Hyola 401)	1	0.150		100	2.2 - 2.4	70	< 0.02	< 0.02	Report: RJ2342B Trial: CA40-96-S982
	1	0.150		100	2.2 - 2.4	70	< 0.02	< 0.02	
	1	0.300		100	2.2 - 2.4	70	< 0.02	< 0.02	
	3	0.150 0.150 0.300		100 100 100	2.2-2.4 4.2 4.4	23	0.03, 0.04	0.04	
Canada, 1996 Saskatchewan, Saskatchewan, (Innovator)	1	0.150		100	2.5	61	< 0.02	< 0.02	Report: RJ2342B Trial: CA50-96-S981
	1	0.150		100	2.5	61	< 0.02	< 0.02	
	1	0.300		100	2.5	61	< 0.02	< 0.02	
	3	0.150 0.150 0.300		100 100 100	2.5 4.1 4.4	23	0.10, 0.12	0.11	
Canada,1996 Fort Whyte, Winnipeg,	1	0.150		100	2.2 - 2.6	66	< 0.02	< 0.02	Report: RJ2342B Trial: CA60-96-S980
	1	0.150		100	2.2 - 2.6	66	< 0.02	< 0.02	
	1	0.300		100	2.2 - 2.6	66	< 0.02	< 0.02	

RAPE Country, year	Application				GS	DAT	Residues (mg/kg)		Trial Reference
	no	kg ai/ha	kg ai/hL	water (L/ha)			azoxystrobin	mean	
Manitoba, (Horizon)	3	0.150 0.150 0.300		100 100 100	2.2-2.6 4.1-4.2 4.4	29	0.11, 0.13	0.12	
USA 1996 Carrington, Forster County, North Dakota, (Reward)	1	0.150		100	2.2 - 2.6	60	< 0.02	< 0.02	Report: RJ2342B Trial: US15-96-S985
	1	0.150		100	2.2 - 2.6	60	< 0.02	< 0.02	
	1	0.300		100	2.2 - 2.6	60	< 0.02	< 0.02	
	3	0.150 0.150 0.300		100 100 100	2.2-2.6 4.1-4.2 4.4	25	0.41, 0.74	0.58	
USA 1996 Ephrata, Grant County, Washington, (Hyola 401)	1	0.150		100	2.2 - 2.6	66	< 0.02	< 0.02	Report: RJ2342B Trial: US34-96-S983
	1	0.150		100	2.2 - 2.6	66	< 0.02	< 0.02	
	1	0.300		100	2.2 - 2.6	66	< 0.02	< 0.02	
	3	0.150 0.150 0.300		100 100 100	2.2-2.6 4.1-4.2 4.4	31	< 0.02, 0.02	0.02	
USA,1996 (Hyola 401)	1	0.448		127	2.2 - 2.6	71	< 0.01	< 0.01	Report: RJ2353B Trial: 34-ND-96-310 Crop stage during applications: 1)2.2-2.6 2)4.1-4.2 3)4.4
	3	0.448 0.897 0.448		127 142 143	2.2-2.6 4.1-4.2 4.4	36	0.01	0.01	
USA,1996 (Norseman)	1	0.448		94	Prior to Bolting	65	< 0.01,0.01	0.01	Report: RJ2353B Trial: 36-MN-96-311
	3	0.448 0.897 0.897		94 94 94	Bolting Flowers dropping 95-97% petal drop	22	1.10,1.60	1.35	
Canada ,1997 Stonewall, Manitoba,	3	0.150 0.300 0.300		100 100 100	2.2-2.6 4.4 -	31	0.01	0.01	Report: RJ2571B Trial: CA40-97-S983
Canada,1997 Fort Whyte, Manitoba,	1	0.150		100	2.3 - 2.5	74	< 0.01	< 0.01	Report: RJ2571B Trial: CA40-97-S984
	3	0.150 0.300 0.300		100 100 100	2.3-2.5 4.2 4.4	32	< 0.01	< 0.01	
	3	0.150 0.300 0.300		100 100 100	2.3-2.5 4.2 4.4	32	< 0.01	< 0.01	
Canada,1997 Borden, Saskatchewan,	1	0.150		100	2.4	48	< 0.01	< 0.01	Report: RJ2571B Trial: CA40-97-S985
	3	0.150 0.300 0.300		100 100 100	2.4 4.1 4.4	25	0.03	0.03	
	3	0.150 0.300 0.300		100 100 100	2.4 4.1 4.4	25	0.03	0.03	
Canada ,1997 Osler,Saskatchewan,	1	0.150		100	2.5	56	< 0.01	< 0.01	Report: RJ2571B Trial: CA40-97-S986
	3	0.150 0.300 0.300		100 100 100	2.5 4.2 4.4	29	0.02	0.02	
	3	0.150 0.300 0.300		100 100 100	2.5 4.2 4.4	29	0.02	0.02	
Canada,1997 Calgary, Alberta,	1	0.130		100	2.5	70	< 0.01	< 0.01	Report: RJ2571B Trial: CA40-97-S987
	3	0.130 0.250 0.300		100 100 100	2.5 4.2 -	28	0.11	0.11	
	3	0.130 0.250 0.300		100 100 100	2.5 4.2 -	28	0.07	0.07	
Canada,1997	1	0.130		100	2.6	63	< 0.01	< 0.01	Report: RJ2571B

RAPE Country, year	Application				GS	DAT	Residues (mg/kg)		Trial Reference
	no	kg ai/ha	kg ai/hL	water (L/ha)			azoxystrobin	mean	
Airdrie, Alberta,	3	0.130 0.260 0.300		100 100 100	2.6 4.2 4.4	29	0.04	0.04	Trial: CA40-97-S988
	3	0.130 0.260 0.300		100 100 100	2.6 4.2 4.4	29	0.05	0.05	

FATE OF RESIDUES IN STORAGE AND PROCESSING

Processing

Four processing studies on sugarcane were conducted in Brazil during 2011. Five foliar applications were made at a nominal rate of either 180 or 300 g azoxystrobin/ha (3–5 times the maximum label rate of 5×60 g as/ha), with RTI 30 days, PHI 20, 30, 40 days. Treated and untreated field samples of sugarcane stalks (RAC) were received frozen (-20 °C) at the processing facility and stored frozen until processing. Sugarcane samples were allowed to reach room temperature and then pressed. Juice and bagasse samples were collected and the remaining juice used for sugar and molasses production. One fraction of juice was used to produce crystal sugar and another to produce VHP sugar. VHP sugar was produced by adding a $Ca(OH)_2$ solution to the juice at a pH of 6.8–7.2 and heating to 100–105 °C, followed by allowing for crystallization. Molasses were separated from the sugar before centrifugation. The VHP sugar was then dried and collected. The effects of processing on residues of azoxystrobin in sugarcane were summarized as below. The crystal white sugar was produced by including an additional step, where sulphurous acid solution (pH 3.0–4.3) was added to the juice before the $Ca(OH)_2$.

Table 8 Summary of processing factors for azoxystrobin

Matrix	Residue of azoxystrobin (mg/kg) In processed commodity/in RAC	Azoxystrobin [a]	
		Calculated processing factors (ranked)	PF median or best estimate
Bagasse	0.38/0.04, 0.22/0.03, 0.29/0.08, 0.18/0.02, 0.23/0.04, 0.15/0.02, 0.17/0.02	3.6, 5.8, 7.3, 7.5,8.5,9, 9.5	7.5
VHP sugar	< 0.01/0.04, < 0.01/0.03, < 0.01/0.08, < 0.01/0.02, < 0.01/0.04, < 0.01/0.02, < 0.01/0.02	<0.13, <0.25,<0.25 , <0.33,<0.5,<0.5, <0.5	<0.33
Crystal sugar	< 0.01/0.04, < 0.01/0.03, < 0.01/0.08, < 0.01/0.02, < 0.01/0.04, < 0.01/0.02, < 0.01/0.02	<0.13,<0.25, <0.25,<0.33,<0.5,<0.5, <0.5,	<0.33
Molasses	0.02/0.38, < 0.01/0.03, 0.02/0.08, < 0.01/0.02, 0.01/0.04, < 0.01/0.02, < 0.01/0.02	<0.33,<0.5,<0.5, <0.5, 0.25,0.25,0.5	0.25 [b]

[a] Each value represents a separate study where residues were above the LOQ in the RAC. The factor is the ratio of azoxystrobin residues in the processed item divided by the residue of azoxystrobin in the RAC.

[b] Best estimate on detectable residues in processed commodity

APPRAISAL

Azoxystrobin was first evaluated for toxicology and residues by the JMPR in 2008. The Meeting derived an ADI of 0–0.2 mg/kg bw per day, decided that an ARfD was unnecessary and concluded that the residue definition for plant and animal commodities for compliance with MRL values and for consumer risk assessment was parent azoxystrobin. The compound was re-evaluated for residues by the JMPR in 2011, 2012 and 2013.

Azoxystrobin was listed for the review of additional MRLs by the JMPR in 2017. The Meeting received information on GAP and supervised residue trials on guava, pitaya (dragon fruit), sugar cane and rape seed.

Methods of analysis

The meeting received recovery data on analytical methods for guava and dragon fruit. After extraction with acetonitrile, the residues were determined by LC-MS/MS with an LOQ of 0.01 mg/kg. Analytical methods for sugarcane and rape seed utilised extraction with acetonitrile: water (9:1) (v/v) and quantification by LC-MS/MS and LC-MS, respectively. The LOQs of the two methods were both 0.01 mg/kg.

Stability of residues in stored analytical samples

The 2008 JMPR indicated that azoxystrobin residues were stable at freezer conditions in the following crop commodities for the intervals tested, most for 24 months: apples, orange oil, orange juice, orange pulp, peaches, grapes, wine, bananas, tomatoes, tomato juice, tomato paste, cucumbers, carrots, lettuce, oilseed rape, soya bean meal, corn grits, wheat straw, wheat grain, wheat forage, peanuts, peanut oil, peanut meal and pecans.

The Meeting received storage stability data on guava, dragon fruit, and rapeseed. Residues of azoxystrobin in these commodities stored frozen are stable for at least 403, 203, 146 days, respectively.

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

Results of supervised residue trials on crops

The Meeting received new supervised trial data for foliar applications of azoxystrobin on guava, dragon fruit, sugarcane and rape. If two field samples were taken or results of two replicate plots were submitted, the mean value was calculated. From two trials carried out side-by-side the higher residue was chosen. Residues from trials which were not matching the cGAP were scaled if they were in an acceptable range for scaling data.

Assorted tropical and sub-tropical fruits - edible peel

Results from supervised trials on guavas conducted in Egypt were provided to the Meeting.

Guava

The critical GAP for azoxystrobin on guava from Egypt is for up to 3 foliar applications of 0.1 kg ai/ha applied at least 7–14 days RTI with a PHI of 10 days.

Six trials on guavas in Egypt were considered not to match GAP.

The Meeting noted that as the trials did not match GAP no maximum residue level or STMR values could be estimated.

Assorted tropical and sub-tropical fruits - inedible peel

Results from supervised trials on dragon fruits (pitaya) in Indonesia and Vietnam were provided to the Meeting.

Pitaya

The critical GAP for azoxystrobin on dragon fruit (Pitaya) in Indonesia and Vietnam is for up to 3 foliar applications of 0.08 kg ai/ha applied at 10 days RTI, with a PHI of 7 days.

The applications of azoxystrobin were 3 foliar of 0.15 kg ai/ha in the 7 independent trials on dragon fruit in Indonesia and Vietnam. The residues were (n=7): 0.034, 0.037, 0.069, 0.077, 0.11, 0.14 and 0.35 mg/kg. The Meeting decided that the proportionality principle could be applied in this case. Therefore, residues were divided by scale factor of 1.875 and the scaled data set was (n=7): 0.018, 0.020, 0.037, 0.041, 0.059, 0.075 and 0.19 mg/kg.

The Meeting estimated an STMR of 0.041 mg/kg, and a maximum residue level of 0.3 mg/kg for azoxystrobin on pitaya.

Grasses for sugar or syrup production

Results from supervised trials on sugarcane conducted in Brazil were provided to the Meeting.

Sugar cane

The critical GAP for azoxystrobin on sugar cane in Brazil is for up to 5 foliar applications of 0.06 kg ai/ha applied at 30 days RTI and with a PHI of 30 days.

Four trials with an exaggerated rate of 0.18 kg ai/ha, which were for processing studies, were not considered in the data set for estimation of a maximum residue level or an STMR. In six trials from Brazil matching Brazilian GAP residues in sugar cane stalks were (n=6): < 0.01, 0.01, 0.02 (3) and 0.03 mg/kg.

The Meeting estimated an STMR of 0.02 mg/kg, and a maximum residue level of 0.05 mg/kg for azoxystrobin on sugar cane.

Oilseeds

Oilseed rape

The Meeting received GAP information for canola use in USA and Canada. The GAP allows max. 3 applications: 0.125 kg ai/ha at BBCH 12–16, 0.250 kg ai/ha at BBCH 60–63 and 0.125 kg ai/ha at BBCH 67–79 with a PHI of 30 days.

Nine trials in USA and Canada matched this cGAP. Residues in rape seeds were (n=9): < 0.01 (2), 0.01, 0.02 (2), 0.06, 0.13, 0.17 and 0.23 mg/kg.

The Meeting estimated an STMR of 0.02 mg/kg and a maximum residue level of 0.5 mg/kg for azoxystrobin on rape seed.

Fate of residues during processing

Four processing studies on sugarcane were conducted in Brazil during 2011. Azoxystrobin was applied at 3-5 times exaggerated rates in five foliar applications, with RTIs and PHIs consistent with GAP. Sugarcane stalks were pressed, separated into juice and bagasse. Fractions of juice were further processed to sugar and molasses. The effects of processing on residues of azoxystrobin in sugarcane processed fractions are summarized below.

Summary of selected processing factors and STMR-P values for azoxystrobin

RAC	Matrix	Processing factor	Best Estimate Processing Factors a	STMR (mg/kg)	STMR-P (mg/kg)
Sugarcane				0.02 mg/kg	
	Bagasse	3.6, 5.8, 7.3, 7.5,8.5,9, 9.5	7.5		0.15
	Refined sugar	< 0.13,< 0.25, < 0.25,< 0.33,< 0.5,< 0.5, < 0.5,	0.33		0.0066
	Molasses	< 0.33,< 0.5, < 0.5, < 0.5, 0.25,0.25,0.5	0.25		0.005

[a] Each PF value is the median of 2–4 separate studies where residues were above the LOQ in the RAC. The PF in each study was the ratio of the azoxystrobin residues in the processed item divided by the residues in the RAC.

The Meeting noted that in the above studies, azoxystrobin residues did not concentrate in processed commodities except for Bagasse.

Residues in animal commodities

Estimation of livestock dietary burdens

The only commodities used as a livestock feed and for which the JMPR has made recommendations are rape seed and molasses. The additional contribution to the dietary burden using the estimated median and highest residue levels is less than 10% of the total. Based on the minor change in livestock dietary burden, the Meeting did not recalculate residues in animal commodities or revise its recommendations for maximum residue levels.

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 assessments.

Definition of the residue (for MRL-compliance and estimation of dietary intake) for plant commodities: *azoxystrobin.*

Definition of the residue (for MRL-compliance and estimation of dietary intake) for animal commodities: *azoxystrobin.*

The residue is fat soluble.

	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P	HR
CCN	Name	New	Previous		
FI 2540	Pitaya	0.3		0.041	
GS 0659	Sugar cane	0.05		0.02	
SO 0495	Rape seed Bagasse	0.5		0.02 0.15	
	Refined sugar			0.0066	
DM 0659	Sugar cane molasses			0.005	

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intake (IEDI) for azoxystrobin was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of azoxystrobin for the 17 GEMS/Food Cluster diets, based on estimated STMRs were 2–20% of the maximum ADI of 0.2 mg/kg bw (Annex 3). The Meeting concluded that the long-term dietary exposure to residues of azoxystrobin from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The 2008 JMPR decided that an ARfD for azoxystrobin was unnecessary. The Meeting therefore concluded that the short-term dietary exposure to azoxystrobin residues is unlikely to present a public health concern.

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