

AZOXYSTROBIN (229)

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EXPLANATION

Azoxystrobin (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. The Meeting derived an ADI of 0.2 mg/kg bw per day and decided that an ARfD is unnecessary. The 2008 JMPR concluded that the residue definition for plant commodities for compliance with MRL values and for consumer risk assessments was parent azoxystrobin. Maximum residue levels, STMRs and STMR-Ps for 82 commodities or commodity groups were estimated.

The compound was listed by the Forty-second Session of the CCPR for the review of additional MRLs. The 2011 JMPR received residue data for passion fruit, okra, coffee beans and ginseng.

RESIDUE ANALYSIS*Analytical methods*

The Meeting received information on analytical methods for azoxystrobin residues in passion fruit, okra, coffee beans, ginseng and ginseng processed products. The methods are briefly described below and the recoveries are summarized in Table 1.

Method: MA 513-01

Reference: R A6003
Commodity: Passion fruit
Analyte: Azoxystrobin
LOQ: 0.01 mg/kg
Determination: LC-MS/MS

Description: Samples are extracted by blending with acetonitrile/acetic acid 99.9 : 0.1% in the presences of magnesium sulphate and sodium chloride. The extract is purified by solid phase dispersion and analysed using LC-MS/MS.

Method: no Method No.

Reference: PGD-274
Commodity: Passion fruit
Analyte: Azoxystrobin
LOQ: 0.1 mg/kg
Determination: GC-MSD, MS ions monitored: m/z = 344 (ion used for quantification), 372,

388

Description: Samples are extracted by blending with ethyl acetate and sodium sulphate. The extract is poured through a funnel with a non-absorbent cotton wool plug and sodium sulphate and analysed by GC-MS.

Method: PRES/005 (extraction only)

Reference: PIP No 016/22

Commodity: Okra
Analyte: Azoxystrobin
LOQ: 0.01 mg/kg
Determination: no information received

Description: Samples are extracted by maceration with ethyl acetate. The extract is filtered through sodium sulphate and cleaned up with a micro-alumina column.

Method: MET.029Rev30

Reference: POPIT MET.029.Rev30
Commodity: Coffee beans
Analytes: Azoxystrobin and its Z-isomer (R230310)
LOQ: 0.01 mg/kg
Determination: LC-MS/MS

Description: Coffee beans are ground with dry ice to homogeneity and a sub-sample is extracted with acetonitrile : water (9 : 1 v/v, 50 mL) using a homogeniser. An aliquot is evaporated, acetonitrile : water (1 : 1 v/v, 1 mL) added, and the sample sonicated and filtered. This extract is analysed directly by LC-MS/MS with quantification by external standardisation.

Method: POPIT MET.068.Rev28

Reference: POPIT MET.029
Commodity: Coffee beans
Analytes: Azoxystrobin and its Z-isomer (R230310)
LOQ: 0.01 mg/kg
Determination: LC-MS/MS

Description: Coffee beans are ground with dry ice to homogeneity and a sub-sample is extracted with acetonitrile: water (9 : 1 v/v, 50 mL) using a homogeniser. An aliquot is evaporated, redissolved in methanol: water (1 : 1 v:v, 1 mL) and the sample is sonicated and centrifuged at high speed. This extract is analysed directly by LC-MS/MS with quantification by external standardisation.

Method: no Method No.

Reference: KFDA 08082-016
Commodity: Ginseng, fresh, dried, red; ginseng, ethanol extract, water extract
Analytes: Azoxystrobin
LOQ: 0.02 mg/kg (ginseng, fresh), 0.03 mg/kg (ginseng, dried, red), 0.07 mg/kg (extracts)
Determination: HPLC-DAD (diode-array-detector, detector wavelength 225 nm)

Description: Samples are extracted with acetonitrile. The extract is diluted with water and NaCl solution and shaken with dichloromethane. The partition process is repeated and the organic solvent evaporated to dryness. The residue is resolved in n-hexane, cleaned up by Florisil, evaporated to dryness, resolved in acetone and analysed by GLC/ECD.

Method: no Method No.

Reference: KFDA 08072-051

Commodity: Ginseng, fresh, dried, red; ginseng, ethanol extract, water extract
 Analytes: Azoxystrobin
 LOQ: 0.02 mg/kg (ginseng, fresh), 0.04 mg/kg (ginseng, dried, red, extracts)
 Determination: GC-MSD, GC-ECD
 Description: see above for KFDA 08082-016

Method: no Method No.

Reference: KFDA 09072-944, KFDA 09072-945
 Commodity: Ginseng, fresh, dried, red; ginseng, ethanol extract, water extract
 Analytes: Azoxystrobin
 LOQ: 0.003 mg/kg (ginseng, fresh), 0.007 mg/kg (ginseng, dried, red, extracts)
 Determination: GC-ECD
 Description: see above for KFDA 08082-016

Table 1 Recoveries of azoxystrobin.

Matrix	Fortification (mg/kg)	Determination	N	Recovery mean (%)	Recovery range (%)	Reference
Passion fruit	0.01	LC-MS/MS	3	89	85–91	R A6003
	0.10		2	101	100–101	
	3.0		3	98	94–105	
Passion fruit	0.1	GC-MSD	10	92	88–97	PGD-274
Coffee beans	0.01	LC-MS/MS	9	98	93–102	POPIT MET.029.rev30
	0.10		6	101	97–107	
Coffee beans	0.01	LC-MS/MS	7	96	88–105	POPIT MET.068.Rev28
	0.10		5	101	95–108	
Ginseng, fresh	0.02	HPLC/DAD	5	86	83–90	KFDA 08082-016
	0.2		5	99	98–100	
	0.5		5	77	76–78	
Ginseng, fresh	0.02	GC-ECD	5	107	104–110	KFDA 08072-051
	0.2	GC-MSD	5	105	97–109	
	0.5		5	101	86–108	
Ginseng, fresh	0.003	GC-ECD	10	99	88–108	KFDA 09072-944
	0.03		10	102	94–108	
	0.5		10	103	98–109	
Ginseng, fresh	0.003	GC-ECD	10	84	80–100	KFDA 09072-945
	0.03		10	87	71–105	
	0.5		10	84	74–95	
Ginseng, dried	0.03	HPLC/DAD	5	83	81–85	KFDA 08082-016
	0.3		5	92	91–93	
	0.5		5	84	83–85	
Ginseng, dried	0.04	GC-ECD	5	100	90–107	KFDA 08072-051
	0.4	GC-MSD	5	102	95–110	
	0.5		5	104	99–107	
Ginseng, dried	0.007	GC-ECD	10	97	88–109	KFDA 09072-944
	0.07		10	92	85–100	
	0.5		10	105	103–106	
Ginseng, dried	0.007	GC-ECD	10	89	75–102	KFDA 09072-945
	0.07		10	94	86–98	
	0.5		10	94	79–102	
Ginseng, red	0.03	HPLC/DAD	5	92	89–96	KFDA 08082-016
	0.3		5	84	82–86	
	0.5		5	88	86–91	
Ginseng, red	0.04	GC-ECD	5	101	96–107	KFDA 08072-051
	0.4	GC-MSD	5	100	89–108	
	0.5		5	101	88.108	
Ginseng, red	0.007	GC-ECD	10	103	94–112	KFDA 09072-944
	0.07		10	108	102–117	

Matrix	Fortification (mg/kg)	Determination	N	Recovery mean (%)	Recovery range (%)	Reference
	0.5		10	102	96–107	
Ginseng, red	0.007	GC-ECD	10	79	69–97	KFDA 09072-945
	0.07		10	93	78–108	
	0.5		10	88	76–100	
Ginseng, dried ethanol extract	0.07	HPLC/DAD	5	91	88–92	KFDA 08082-016
	0.7		5	94	90–97	
	2.0		5	106	102–107	
Ginseng, dried ethanol extract	0.04	GC-ECD	5	93	82–109	KFDA 08072-051
	0.4	GC-MSD	5	95	91–101	
	2.0		5	98	93–104	
Ginseng, dried ethanol extract	0.007	GC-ECD	10	97	89–101	KFDA 09072-944
	0.07		10	104	98–110	
	0.5		10	95	87–104	
Ginseng, dried ethanol extract	0.007	GC-ECD	10	74	72–79	KFDA 09072-945
	0.07		10	79	69–89	
	2.0		10	84	72–96	
Ginseng, dried water extract	0.07	HPLC/DAD	5	87	85–91	KFDA 08082-016
	0.7		5	99	98–102	
	2.0		5	106	104–106	
Ginseng, dried water extract	0.04	GC-ECD	5	101	91–105	KFDA 08072-051
	0.4	GC-MSD	5	103	95–109	
	2.0		5	101	91–107	
Ginseng, dried water extract	0.007	GC-ECD	10	104	96–109	KFDA 09072-944
	0.07		10	104	96–115	
	0.5		10	97	82–114	
Ginseng, dried water extract	0.007	GC-ECD	10	96	71–120	KFDA 09072-945
	0.07		10	101	96–103	
	2.0		10	89	70–109	
Ginseng, red ethanol extract	0.03	HPLC/DAD	5	94	92–96	KFDA 08082-016
	0.3		5	98	94–101	
	2.0		5	98	96–102	
Ginseng, red ethanol extract	0.04	GC-ECD	5	97	89–105	KFDA 08072-051
	0.4	GC-MSD	5	93	90–96	
	2.0		5	84	78–90	
Ginseng, red ethanol extract	0.007	GC-ECD	10	99	86–106	KFDA 09072-944
	0.07		10	102	99–104	
	0.5		10	93	92–95	
Ginseng, red ethanol extract	0.007	GC-ECD	10	82	76–88	KFDA 09072-945
	0.07		10	95	80–107	
	2.0		10	93	82–109	
Ginseng, red water extract	0.03	HPLC/DAD	5	101	98–106	KFDA 08082-016
	0.3		5	86	84–87	
	2.0		5	100	98–104	
Ginseng, red water extract	0.04	GC-ECD	5	102	97–108	KFDA 08072-051
	0.4	GC-MSD	5	107	102–109	
	2.0		5	98	89–105	
Ginseng, red water extract	0.007	GC-ECD	10	96	86–106	KFDA 09072-944
	0.07		10	97	92–101	
	0.5		10	90	88–92	
Ginseng, red water extract	0.007	GC-ECD	10	86	73–102	KFDA 09072-945
	0.07		10	104	90–120	
	2.0		10	89	69–112	

Stability of residues in stored analytical samples

Detailed information provided for the 2008 JMPR indicated that azoxystrobin residues were stable at ≤ -18 °C in the following crop commodities for the intervals tested, some for 12 months, but 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. Azoxystrobin was

stable in samples of animal origin (beef muscle, liver, kidney, fat, milk and eggs) when stored frozen at ≤ -18 °C up to 10 month.

Untreated test portions of ginseng and ginseng products were spiked with azoxystrobin solution and stored at ≤ -20 °C until the analyses of field treated samples. The spiked test portions for testing the stability of residues under deep-frozen conditions were analysed together with the field treated fresh ginseng and various processed products made from them (Chae M Y, 2010; Hur J H, 2009; Kyung K S, 2009 and 2010). The fortification levels and the survived residues after the storage periods are summarized in Table 2. The residues remained were the results of 5 replicate analyses. In the report KFDA 08072-051, samples of two fields were fortified with azoxystrobin at a level of 0.5 mg/kg.

Table 2 Storage stability of azoxystrobin residues in ginseng roots and processed ginseng products

Matrix	Fortification level (mg/kg)	% remaining ^a	Relative standard deviation (%)	Days of storage	Study No
Fresh ginseng	0.2	103	1.01	230	KFDA 08082-016
	0.5	102	1.2	10	KFDA 08072-051
	0.5	100	6.5	10	KFDA 08072-051
	0.03	99	1.68	139	KFDA 09072-944
	0.5	95	1.7	192	KFDA 09072-945
	0.06	75	1.1	6	KFDA 09072-945
Dried ginseng	0.3	103	1.4	232	KFDA 08082-016
	0.5	104	4.8	16	KFDA 08072-051
	0.5	103	2.9	16	KFDA 08072-051
	0.07	83	0.84	151	KFDA 09072-944
	0.1	87	1.5	203	KFDA 09072-945
	0.07	91	1.7	14	KFDA 09072-945
Red ginseng	0.3	97	1.53	231	KFDA 08082-016
	0.5	100	5.9	34	KFDA 08072-051
	0.5	99	3.2	34	KFDA 08072-051
	0.07	107	3.53	139	KFDA 09072-944
	0.1	97	2.4	205	KFDA 09072-945
	0.07	81	1.0	12	KFDA 09072-945
Dried ginseng extract (ethanol)	0.7	96	2.28	234	KFDA 08082-016
	0.5	98	5.5	117	KFDA 08072-051
	0.5	100	4.5	117	KFDA 08072-051
	0.07	100	0.86	175	KFDA 09072-944
	0.1	93	2.7	250	KFDA 09072-945
	0.07	91	4.3	27	KFDA 09072-945
Dried ginseng extract (water)	0.7	87	1.09	234	KFDA 08082-016
	0.5	99	7.9	137	KFDA 08072-051
	0.5	97	8.1	137	KFDA 08072-051
	0.07	99	1.26	154	KFDA 09072-944
	0.1	86	1.6	251	KFDA 09072-945
	0.07	105	1.2	32	KFDA 09072-945
Red ginseng extract (ethanol)	0.5	99	2.61	232	KFDA 08082-016
	0.5	78	1.2	117	KFDA 08072-051
	0.5	80	4.7	117	KFDA 08072-051
	0.07	101	0.38	177	KFDA 09072-944
	0.1	92	3.5	253	KFDA 09072-945
	0.07	84	4.3	28	KFDA 09072-945
Red ginseng extract (water)	0.5	94	0.90	232	KFDA 08082-016
	0.5	103	6.4	137	KFDA 08072-051
	0.5	87	2.3	137	KFDA 08072-051
	0.07	103	2.24	155	KFDA 09072-944
	0.1	81	5.6	254	KFDA 09072-945
	0.07	113	4.0	34	KFDA 09072-945

^a Average of 5 replicate analyses

USE PATTERN

The information available to the 2011 JMPR on registered uses of azoxystrobin is summarized in Table 3. Copies of labels or for coffee (Brazil), ginseng (Korea), okra (USA) and passion fruit (Australia) were made available to the Meeting. The government of Japan submitted GAP data for passion fruit and okra.

The intended use pattern for passion fruit and okra in Kenya and Côte d'Ivoire was provided as part of the field trials conducted within the Pesticide Initiative Programme of COLEACP¹ aiming to provide data for establishing import MRLs in the European Union. The application conditions were based on the requirement of appropriate control of diseases, but they were not supported by label or official declaration of the approved use.

Table 3 Uses of azoxystrobin

Crop	Country	Form	Method	No	Application				PHI, days
					Interval	kg ai/hL	Water L/ha	kg ai/ha	
Registered uses									
Passion fruit	Australia	SC	foliar	3	14	0.02			1
Passion fruit	Japan	SC	foliar	3		0.01			1
Okra	Japan	SC	foliar	2		0.01			1
Okra	USA	SC	foliar					0.11-0.28	0
Coffee	Brazil	SC	foliar	3	60		400	0.1	30
Coffee	Brazil	SC	foliar	2	90		400	0.15	30
Ginseng	Republic of Korea	SC	foliar	4	10	0.00425	run off		7
Ginseng	Republic of Korea	SC	foliar	4	10	0.01	run off		7
Vegetables, e.g. beans, peas, brassica	Kenya	SC	foliar	3		0.025		0.075-0.125	3 (beans, peas)
Intended uses (no registration)									
Passion fruit	Kenya	SC	foliar	3	10		1000	0.19	3
Okra	Côte d'Ivoire	SC	foliar	3	7		604	0.15	2

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information on supervised field trials for azoxystrobin uses that produced residues on the following commodities.

Commodity	Codex No	Group	Table No
Passion fruit	FI 02451	Assorted tropical and sub-tropical fruit	4
Okra	VO 0442	Fruiting vegetables, other than cucurbits	5
Ginseng	VR 0604	Root and tuber vegetables	6
Coffee beans	SB 0716	Seed for beverages and sweets	7

Trials on coffee beans, ginseng and passion fruit were well documented with laboratory and field reports. Laboratory reports included method validation with procedural recoveries from spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analysis or

¹ The COLEACP is a professional association with the objective to harmonise the relationships between producers and exporters from African, Caribbean and Pacific countries (ACP) and EU importers.

duration of residue sample storage were also provided. Undetected residues were generally reported lower than the LOQ.

In case of okra, no detailed information on the analytical method (PRES/005) used was received.

Residue values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are double underlined.

Passion fruit

Trials were carried out in Kenya from 2005 to 2007 by the Pesticides Initiative Programme of COLEACP. Azoxystrobin was applied in combination with other fungicides. No GLP certificate was submitted for the field part, the analytical part was carried out according to GLP. The results are shown in Table 4.

Table 4 Azoxystrobin residues in passion fruit

Country, year, location, (variety)	Application			PHI, days	Sample	Residue, mg/kg	Author, Year, Study No. Anal. study
	Form	kg ai/ha	No				
Kenya, 2006, Thika, (purple)	SC	0.19	3	1	Whole fruit	0.99	Delhove G, 2006 KE/PF/2005/1 Analysis by ANADIAG R A6003
				3	Whole fruit	0.67	
				3	Peel	1.24	
				3	Flesh	0.06	
				7	Whole fruit	0.56	
				14	Whole fruit	0.68	
21	Whole fruit	0.42					
Kenya, 2006, Embu, (purple)	SC	0.19	3	1	Whole fruit	1.55	Delhove G, 2006 KE/PF/2005/2 Analysis by ANADIAG R A6003
				3	Whole fruit	2.14	
				3	Peel	2.76	
				3	Flesh	0.21	
				7	Whole fruit	0.94	
				14	Whole fruit	1.23	
21	Whole fruit	0.95					
Kenya, 2006, Karatina, (purple)	SC	0.19	3	1	Whole fruit	0.89	Delhove G, 2006 KE/PF/2005/3 Analysis by ANADIAG R A6003
				3	Whole fruit	1.15	
				3	Peel	2.13	
				3	Flesh	0.08	
				7	Whole fruit	0.75	
				14	Whole fruit	0.43	
21	Whole fruit	0.14					
Kenia, 2007, Thika, (purple)	SC	0.19	3	1	Whole fruit	2.48	Delhove G, 2007 KE/PF/2007/1 Analysis by CSL, PGD-274
				3	Whole fruit	1.49	
				3	Peel	2.69	
				3	Flesh	0.19	
				7	Whole fruit	1.44	
				14	Whole fruit	1.12	
21	Whole fruit	0.37					
Kenia, 2007, Embu, (purple)	SC	0.19	3	1	Whole fruit	1.01	Delhove G, 2007 KE/PF/2007/2 Analysis by CSL, PGD-274
				3	Whole fruit	1.06	
				3	Peel	1.35	
				3	Flesh	0.14	
				7	Whole fruit	0.59	
				14	Whole fruit	0.51	
21	Whole fruit	0.28					

Okra

Six trials were carried out in Côte d'Ivoire in 2004, covering the dry season (sowing in April/May) and the rainy season (sowing in August/September) by the Pesticides Initiative Programme of COLEACP. Azoxystrobin was applied in combination with other fungicides. No GLP certificate was submitted for the field part. The analytical part was carried out according to GLP per declaration but

no detailed information on the analytical method used was received. The results are summarized in Table 5.

Table 5 Azoxystrobin residues in okra

Country, Year <i>Location</i> (variety), season	Application					PHI days	Residues, mg/kg	Author, Year, Study No. Anal. study
	Form	kg ai/ha	water L/ha	kg ai/hL	No			
Côte d'Ivoire, 2004, Dabou, (indiana), dry season	SC	0.16 0.16	489 533	0.033 0.030	2	2 7	0.32 0.08	Levy R, 2005, CI/AIPR/2004/03, Analysis: PIP No 0106/22
	SC	0.16 0.16	489 533 653	0.033 0.030 0.023	3	2 7	0.48 0.11	
Côte d'Ivoire, 2004, Abengourou, (indiana), dry season	SC	0.16 0.16	551 662	0.028 0.028	2	2 7	0.10 0.02	Levy R, 2005, CI/AIPR/2004/03, Analysis: PIP No 0106/22
	SC	0.16 0.16	551 662 733	0.028 0.028 0.021	3	2 7	0.03 0.01	
Côte d'Ivoire, 2004, Dabou, (indiana), rainy season	SC	0.16 0.15	391 471	0.041 0.033	2	2 7	0.25 0.04	Levy R, 2005, CI/AIPR/2004/03, Analysis: PIP No 0106/22
Côte d'Ivoire, 2004, Abengourou, (indiana), rainy season	SC	0.16 0.16	369 449	0.042 0.035	2	2 7	0.07 < 0.01	Levy R, 2005, CI/AIPR/2004/03, Analysis: PIP No 0106/22

Ginseng

Residue trials on ginseng were carried out in the Republic of Korea. The concentration of the spraying solution was 0.00425 kg ai/hL (5 mL of a formulation with 17% ai in 20 L water) for trial KFDA 08082-016. In the other trials, the spray concentration was 0.01 kg ai/hL (10 mL of a formulation with 20% ai in 20 L water). The azoxystrobin residues in fresh ginseng roots are summarized in Table 6.

Table 6 Residues of azoxystrobin in fresh ginseng roots

Country, year, location, (variety)	Application					Interval	PHI, days	Residues, mg/kg	Author, Year, Study No.
	Form	Method	kg ai/ha	water L/ha	No				
Rep. of Korea, 2009, Goesan, (panax)	SC	Foliar spray	0.15 0.15 0.15 0.15	3409 3455 3455 3500	4	10	7	3 field samples 0.05, 0.06, 0.05 Mean 0.05	Kyung K S, 2009 KFDA 08082-016
Rep. of Korea, 2009, Gangwon, (panax)	SC	Foliar spray	0.56 0.56 0.56 0.56	5556 5556 5556 5556	4	10	7	<u>0.05</u>	Hur J H, 2009 KFDA 08072-051
Rep. of Korea, 2009, Gyunggi, (panax)	SC	Foliar spray	0.56 0.56 0.56 0.56	5556 5556 5556 5556	4	10	7	<u>0.03</u>	Hur J H, 2009 KFDA 08072-051
Rep. of Korea, 2009, Chungbuk, (panax)	SC	Foliar spray	0.34 0.34 0.34 0.34	3387 3414 3387 3360	4	10	7	3 field samples 0.012, 0.012, 0.013 Mean <u>0.012</u>	Kyung K S, 2010 KFDA 09072-944
Rep. of Korea, 2010, Chungbuk, (panax)	SC	Foliar spray	0.34 0.34 0.34 0.34	3414 3441 3441 3387	4	10	7	3 field samples 0.021, 0.021, 0.023 Mean <u>0.022</u>	Kyung K S, 2010 KFDA 09072-944
Rep. of Korea, 2009, Chungnam, (panax)	SC	Foliar spray	0.36 0.37 0.36 0.36	3629 3666 3592 3629	4	10	7	3 field samples 0.027, 0.025, 0.025 Mean <u>0.026</u>	Chae M Y, 2010 KFDA 09072-945

Country, year, location, (variety)	Application					Interval	PHI, days	Residues, mg/kg	Author, Year, Study No.
	Form	Method	kg ai/ha	water L/ha	No				
Rep. of Korea, 2010, Chungnam, (panax)	SC	Foliar spray	0.37	3666	4	10	7	3 field samples 0.024, 0.026, 0.025 Mean <u>0.025</u>	Chae M Y, 2010 KFDA 09072-945
			0.36	3592					
			0.37	3666					
			0.35	3629					

Coffee beans

Nineteen trials were conducted in Brazil. In three trials (2002/2003) azoxystrobin was applied three times to parallel plots, to one plot at a rate of 0.1 kg ai/ha and to the second plot at a rate of 0.2 kg ai/ha, both with an application interval of 60 days.

In four trials (SC formulation, 2006/2007) azoxystrobin was applied three times at a rate of 0.15 kg ai/ha with a 60 day application interval. Beans were harvested at PHIs of 14, 21 and 30 days.

In six trials (WG formulation, 2010/2011) azoxystrobin was applied two times pre-flowering at the rate 0.05 kg a.i/ha with 30 days interval and three times at the rate 0.12 kg ai/ha with a 60 day application interval. Beans were harvested at PHIs 21, 28 and 35 days.

In six trials (EC formulation, 2010/2011) azoxystrobin was applied two times pre-flowering at the rate 0.05 kg ai/ha with 30 days interval and three times at the rate 0.1 kg ai/ha with a 60 day application interval. Beans were harvested at PHIs 21, 28 and 35 days.

Following harvest, the coffee berries were sun-dried and mechanically threshed to give bean samples which were shipped to the laboratory for analyses. The results are shown in Table 7.

Table 7 Residues of azoxystrobin in coffee beans

Country, year, location, (variety)	Application					Interval	PHI, days	Residues, mg/kg	Author, Year, Study No.
	Form	Method	kg ai/ha	water L/ha	No				
Brazil, 2002/03, Cravinhos (SP), (catuai)	SC	foliar	0.1	400	3	62 58	0 7 14 21 30	0.02 0.01 < 0.01 < 0.01 <u>< 0.01</u>	Francisco E, 2003, M02037 BAB
Brazil, 2002/03, Cravinhos (SP), (catuai)	SC	foliar	0.2	400	3	62 58	0 7 14 21 30	0.02 0.02 0.02 < 0.01 0.01	Francisco E, 2003, M02037 BAB
Brazil, 2002/03, Patrocínio (MG), (catuai)	SC	foliar	0.1	400	3	60 60	0 7 14 21 30	0.02 0.03 < 0.01 < 0.01 <u>0.01</u>	Francisco E, 2003, M02037 JJB1
Brazil, 2002/03, Patrocínio (MG), (catuai)	SC	foliar	0.2	400	3	60 60	0 7 14 21 30	0.03 0.04 0.01 < 0.01 0.01	Francisco E, 2003, M02037 JJB1
Brazil, 2002/03, Araxá (MG), (catuai)	SC	foliar	0.1	400	3	60 60	0 7 14 21 30	0.02 0.02 < 0.01 < 0.01 <u>< 0.01</u>	Francisco E, 2003, M02037 JJB2
Brazil, 2002/03, Araxá (MG), (catuai)	SC	foliar	0.2	400	3	60 60	0 7 14 21 30	0.03 0.04 0.01 0.01 0.01	Francisco E, 2003, M02037 JJB2
Brazil, 2006/07,	SC	foliar	0.15	400	3	60	14	< 0.01	Roncato C,

Country, year, location, (variety)	Application					Interval	PHI, days	Residues, mg/kg	Author, Year, Study No.
	Form	Method	kg ai/ha	water L/ha	No				
Monte Carmelo (MG), (mundo novo)						60	21 30	< 0.01 < 0.01	2008, M06024 JJB1
Brazil, 2006/07, Indianopolis (MG), (mundo novo)	SC	foliar	0.15	400	3	60 60	14 21 30	< 0.01 < 0.01 < 0.01	Roncato C, 2008, M06024 JJB2
Brazil, 2006/07, Araxa, (MG), (catuai)	SC	foliar	0.15	400	3	60 60	14 21 30	< 0.01 < 0.01 < 0.01	Roncato C, 2008, M06024 JJB3
Brazil, 2007, Santa Amelia (PR), (IAPAR 59)	SC	foliar	0.15	400	3	60 60	14 21 30	< 0.01 < 0.01 < 0.01	Roncato C, 2008, M06024 LZF
Brazil, 2010/11, Taiuva (SP), (catuai amarelo)	WG	foliar	0.05 0.12	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11085 AMA
Brazil, 2010/11, São Gonçalo do Sapucaí (MG), (mundo novo)	WG	foliar	0.05 0.12	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11085 RWC1
Brazil, 2010/11, Campinas (SP), (catuai vermelho IAC 144)	WG	foliar	0.05 0.12	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11085 RWC2
Brazil, 2010/11, Linhares (ES), (conilon)	WG	foliar	0.05 0.12	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11085 RWC3
Brazil, 2010/11, Indianópolis (MG), (mundo novo)	WG	foliar	0.05 0.12	400 400	2 3	30 60	21 28 35	0.02 < 0.01 < 0.01	Oliveira F, 2011, M11085 JJB1
Brazil, 2010/11, Araguari (MG), (mundo novo)	WG	foliar	0.05 0.12	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11085 JJB2
Brazil, 2010/11, Taiuva (SP), (catuai amarelo)	EC	foliar	0.05 0.1	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11074 AMA
Brazil, 2010/11, São Gonçalo do Sapucaí (MG), (mundo novo)	EC	foliar	0.05 0.1	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11074 RWC1
Brazil, 2010/11, Campinas (SP), (catuai vermelho IAC 144)	EC	foliar	0.05 0.1	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11074 RWC2
Brazil, 2010/11, Linhares (ES), (conilon)	EC	foliar	0.05 0.1	400 400	2 3	30 60	21 28 35	0.02 < 0.01 0.01	Oliveira F, 2011, M11074 RWC3
Brazil, 2010/11, Indianópolis (MG), (mundo novo)	EC	foliar	0.05 0.1	400 400	2 3	30 60	21 28 35	0.02 < 0.01 < 0.01	Oliveira F, 2011, M11074 JJB1
Brazil, 2010/11, Araguari (MG), (mundo novo)	EC	foliar	0.05 0.1	400 400	2 3	30 60	21 28 35	< 0.01 < 0.01 < 0.01	Oliveira F, 2011, M11074 JJB2

FATE OF RESIDUES IN STORAGE AND PROCESSING

In processing - ginseng

Fresh ginseng was harvested 7 days after the application of azoxystrobin at each site and washed with tap water to remove soil particles. Fresh ginseng roots were blended. These samples were individually packed in a 20 g pack and stored at -20 °C or -70 °C until processing.

Dried ginseng

Fresh ginseng was dried in a hot air drying machine set to 60 °C to reach the water content lower than 14%. The dried product was blended.

Red ginseng

Fresh ginseng was steamed for 3 hours at 98 °C. The steamed samples were dried in a hot air drying machine set to 65 °C to reach the water content about 50–55%. The smaller roots were removed from the dried samples. Further drying process was carried out under the sunlight to reach the water content lower than 14%. The dried product was blended.

Ethanol extracts of dried ginseng and red ginseng

Dried or red ginseng were cut into about 1 cm in size and extracted 3 times in refluxing extractor with 70% ethanol at 70 °C for about 18 hours. The solvent was evaporated to reach the 65 °Brix.

Water extracts of dried ginseng and red ginseng

Dried or red ginseng were cut into about 1 cm in size and extracted 3 times in refluxing extractor with water at 85 °C for about 18 hours. The solvent was evaporated to reach the 72 °Brix.

The results of azoxystrobin residues in RAC and processed fractions of dried or red ginseng are shown in Table 8 or 9. The residues reported are average values of 3 analyses of each sample.

Table 8 Summary of residues in fresh ginseng, dried ginseng and extracts of dried ginseng

Country, year, location, (variety)	Residues in mg/kg				Author, Year, Study No.
	Fresh	Dried	Ethanol extr.	Water extr.	
Rep. of Korea, 2009, Goesan, (panax)	0.05	0.19	< 0.07	< 0.07	Kyung K S, 2009 KFDA 08082-016
	0.06	0.18	< 0.07	< 0.07	
	0.05	0.19	< 0.07	< 0.07	
	Mean 0.05	Mean 0.19	Mean < 0.07	Mean < 0.07	
Rep. of Korea, 2009, Gangwon, (panax)	0.05	0.12	0.26	0.24	Hur J H, 2009 KFDA 08072-051
Rep. of Korea, 2009, Gyunggi, (panax)	0.03	0.13	0.34	0.17	Hur J H, 2009 KFDA 08072-051
Rep. of Korea, 2009, Chungbuk, (panax)	0.012	0.034	0.035	0.037	Kyung K S, 2010 KFDA 09072-944
	0.012	0.034	0.035	0.037	
	0.013	0.034	0.035	0.038	
	Mean 0.012	Mean 0.034	Mean 0.035	Mean 0.037	
Rep. of Korea, 2010, Chungbuk, (panax)	0.021	0.060	0.101	0.100	Kyung K S, 2010 KFDA 09072-944
	0.021	0.063	0.103	0.102	
	0.023	0.067	0.106	0.101	
	Mean 0.021	Mean 0.063	Mean 0.103	Mean 0.101	
Rep. of Korea, 2009, Chungnam, (panax)	0.027	0.048	0.173	0.070	Chae M Y, 2010 KFDA 09072-945
	0.025	0.049	0.166	0.067	
	0.025	0.048	0.155	0.068	
	Mean 0.026	Mean 0.048	Mean 0.165	Mean 0.068	
Rep. of Korea, 2010, Chungnam, (panax)	0.024	0.178	0.270	0.134	Chae M Y, 2010 KFDA 09072-945
	0.026	0.179	0.274	0.133	
	0.025	0.175	0.268	0.133	
	Mean 0.025	Mean 0.177	Mean 0.271	Mean 0.133	

Table 9 Summary of residues in fresh ginseng, red ginseng and extracts of red ginseng

Country, year, location, (variety)	Residues in mg/kg				Author, Year, Study No.
	Fresh	Red	Ethanol extr.	Water extr.	
Rep. of Korea, 2009, Goesan, (panax)	0.05	0.09	0.12	< 0.07	Kyung K S, 2009 KFDA 08082-016
	0.06	0.10	0.12	< 0.07	
	0.05	0.09	0.12	< 0.07	
	Mean 0.05	Mean 0.09	Mean 0.12	Mean < 0.07	
Rep. of Korea, 2009, Gangwon, (panax)	0.05	0.05	0.31	0.09	Hur J H, 2009 KFDA 08072-051

Country, year, location, (variety)	Residues in mg/kg				Author, Year, Study No.
	Fresh	Red	Ethanol extr.	Water extr.	
Rep. of Korea, 2009, Gyunggi, (panax)	0.03	0.06	0.20	0.12	Hur J H, 2009 KFDA 08072-051
Rep. of Korea, 2009, Chungbuk, (panax)	0.012 0.012 0.013 Mean 0.012	0.032 0.032 0.031 Mean 0.032	0.031 0.031 0.030 Mean 0.031	0.024 0.025 0.024 Mean 0.024	Kyung K S, 2010 KFDA 09072-944
Rep. of Korea, 2010, Chungbuk, (panax)	0.021 0.021 0.023 Mean 0.022	0.071 0.071 0.072 Mean 0.071	0.107 0.107 0.113 Mean 0.109	0.106 0.110 0.105 Mean 0.107	Kyung K S, 2010 KFDA 09072-944
Rep. of Korea, 2009, Chungnam, (panax)	0.027 0.025 0.025 Mean 0.026	0.053 0.052 0.052 Mean 0.052	0.029 0.028 0.027 Mean 0.028	0.027 0.028 0.029 Mean 0.028	Chae M Y, 2010 KFDA 09072-945
Rep. of Korea, 2010, Chungnam, (panax)	0.024 0.026 0.025 Mean 0.025	0.099 0.101 0.109 Mean 0.103	0.197 0.199 0.198 Mean 0.198	0.133 0.132 0.141 Mean 0.135	Chae M Y, 2010 KFDA 09072-945

The transfer factors reflect commercial processing as outlined below.

Table 10 Summary of processing factors for azoxystrobin residues in ginseng products

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median
Fresh ginseng	Dried ginseng	1.8, 2.4, 2.8, <u>3.0</u> , 3.8, 4.3, 7.1	3
	Red ginseng	1.0, 1.8, 2.0, <u>2.0</u> , 2.7, 3.2, 4.1	2
	Ethanol extract of dried ginseng	< 1.4, 2.9, 4.9, <u>5.2</u> , 6.3, 10.8, 11.3	5.2
	Ethanol extract of red ginseng	1.1, 2.4, 2.6, <u>4.9</u> , 6.2, 6.7, 7.9	4.9
	Water extract of dried ginseng	< 1.4, 2.6, 3.1, <u>4.8</u> , 4.8, 5.3, 5.7	4.8
	Water extract of red ginseng	1.1, < 1.4, 1.8, <u>2.0</u> , 4.0, 4.9, 5.4	2

APPRAISAL

Azoxystrobin was evaluated by the JMPR at the first time in 2008 when an ADI of 0–0.2 mg/kg bw per day was established. The Meeting decided that an ARfD is unnecessary. In addition, the 2008 JMPR concluded that the residue definition for plant commodities for compliance with MRL values and for consumer risk assessments was parent azoxystrobin. Maximum residue levels, STMRs and STMR-Ps for 82 commodities or commodity groups were estimated. The compound was listed by the Forty-second Session of the CCPR for the review of additional MRLs. The 2011 JMPR received residue data for passion fruit, okra, ginseng and coffee beans.

Methods of analysis

The Meeting received information on analytical methods used for the determination of azoxystrobin residues in samples derived from supervised trials on passion fruit, coffee beans, ginseng roots and for ginseng processed commodities.

In the methods, the macerated samples are typically extracted by blending with acetonitrile or ethyl acetate. The extract is cleaned by a solid phase clean-up (e.g., Florisil, alumina or sodium sulphate). The residue is determined by LC-MS/MS or by GLC with ECD or MS detection. LOQs are 0.01 mg/kg for passionfruit and coffee beans. In cases of ginseng and its processed products, the LOQs are 0.003 mg/kg for fresh ginseng, 0.007 mg/kg for dried and red ginseng as well as for ethanol and water extracts of dried and red ginseng.

The freezer storage stability studies carried out with fresh ginseng and ginseng processed products showed that the residues were stable for the longest period (days) for which the samples

were stored at or below -20°C . The studies reported by the 2008 JMPR cover the other commodity matrices evaluated by the present Meeting.

Results of supervised trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Passion fruit

As part of the field trials conducted within the Pesticide Initiative Programme that aimed to provide data for establishing import tolerances in the European Union, azoxystrobin was applied as foliar spray treatment with 3×0.19 kg ai/kg and a PHI of 3 days in five trials carried out in Kenya. The residues in whole fruits were 0.68, 1.06, 1.15, 1.49 and 2.14 mg/kg.

The application conditions were based on the requirement to provide appropriate control of passionfruit diseases. However, supplied data was not supported by labels or official declarations of approved use. Therefore, the Meeting could not estimate a maximum residue level for azoxystrobin in passionfruit.

Okra

As part of the field trials conducted within the Pesticide Initiative Programme aiming to provide data for establishing import tolerances in the European Union, azoxystrobin was applied as foliar spray treatment with two or three applications at 0.16 kg ai/kg and a PHI of 2 days in two trials carried out in Côte d'Ivoire. The residues found after three applications were 0.03 and 0.48 mg/kg and after two applications 0.07, 0.1, 0.25 and 0.32 mg/kg at a PHI of two days. Detailed information on the analytical methods used was not submitted.

The application conditions were based on the requirement of appropriate control of diseases in okra, but were not supported by labels or official declarations of approved uses from Côte d'Ivoire. The trials from Côte d'Ivoire were also not according to the GAP of Kenya for vegetables (3×0.075 – 0.125 kg ai/kg, no information on PHI). Based on the data submitted, the Meeting could not estimate a maximum residue level for azoxystrobin in okra.

Nevertheless, the 2008 JMPR estimated an MRL for fruiting vegetables, other than cucurbits, except fungi and sweet corn, of 3 mg/kg and an STMR of 0.35 mg/kg. This recommendation is applicable for okra.

Ginseng

The maximum GAP in Korea permits four foliar applications of azoxystrobin at 10 day intervals at a rate of 0.01 kg ai/hL and a PHI of 7 days.

Ready to harvest ginseng plantations of 4–6 years old were treated four times at 10 days interval with 0.34–0.56 kg ai/kg in 3400–5556 L water/ha, equivalent to 0.01 kg ai/hL spray concentration. The root samples were collected 7 days after the last application on each field. The residues found in fresh ginseng roots were: 0.012, 0.022, 0.025, 0.0257, 0.03 and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.025 mg/kg.

Coffee beans

In Brazil, the registered use of azoxystrobin in coffee is as a foliar spray treatment at a rate of 2×0.15 kg ai/kg (interval 90 days) or 3×0.1 kg ai/kg (interval 60 days) and a PHI of 30 days. Four

Brazilian trials with treatments of 3×0.15 kg ai/kg and 15 trials with 3×0.10 – 0.12 kg ai/kg were available. The spray interval was about 60 days and the PHI 28–30 days.

The residues found after treatment with:

3×0.10 kg ai/kg were: < 0.01 (7), 0.01 (2) mg/kg

3×0.12 kg ai/kg were: < 0.01 (6) mg/kg

3×0.15 kg ai/kg were: < 0.01 (4) mg/kg.

The Meeting estimated, for azoxystrobin residues in coffee beans, a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg.

Fate of residues during processing

Fresh ginseng roots were dried to produce dried or red ginseng, which was extracted for about 18 hours with ethanol at 70 °C or water at 85 °C. The solvent was evaporated to reach the 65 °Brix for the ethanol extract and 72 °Brix for the water extract.

The following median processing factors were calculated: 3 for dried ginseng, 2 for red ginseng, 5.2 for ethanol extract of dried ginseng, 4.8 for water extract of dried ginseng, 4.9 for ethanol extract of red ginseng and 2 for water extract of red ginseng.

Based on the STMR of 0.025 mg/kg for fresh ginseng roots, the Meeting estimated the following STMR-P-values: 0.075 mg/kg for dried ginseng, 0.05 mg/kg for red ginseng, 0.13 mg/kg for ethanol extract of dried ginseng, 0.12 mg/kg for the water extract of dried ginseng, 0.12 mg/kg for the ethanol extract of red ginseng and 0.05 mg/kg for the water extract of red ginseng.

The Meeting estimated 0.5 mg/kg as maximum residue level for ginseng, processed products (dried, red, ethanol and water extracts).

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: *azoxystrobin*.

The residue is fat soluble.

CCN	Commodity Name	MRL, mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
		proposed	previous		
SB 0716	Coffee beans	0.02		0.01	
VR 0604	Ginseng	0.1		0.025	
	Ginseng processed products	0.5			
	Ginseng, dried			0.075	
	Ginseng, red			0.05	
	Ethanol extract of dried ginseng			0.13	
	Water extract of dried ginseng			0.12	
	Ethanol extract of red ginseng			0.12	
	Water extract of red ginseng			0.05	

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of azoxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2008 and the current Meeting. The ADI is 0–0.2 mg/kg bw and the calculated IEDIs were 2–10% of the maximum ADI. The results are shown in Annex 3 of the 2011 JMPR REport. The Meeting concluded that the long-term intake of residues of azoxystrobin resulting from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2008 Meeting decided that an ARfD for azoxystrobin is unnecessary and concluded that the short-term intake of residues resulting from the use of azoxystrobin is unlikely to present a public health concern.

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