

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, decided that an ARfD is unnecessary and concluded that the residue definition for plant commodities for compliance with MRL values and for consumer risk assessments was parent azoxystrobin. The compound was listed by the Forty-second Session of the CCPR for the review of additional MRLs by the JMPR in 2011.

The Forty-fourth Session of the CCPR requested the 2012 JMPR to re-evaluate the processing studies for ginseng processed products to estimate MRLs for ginseng extracts (REP12/PR). Furthermore, the Meeting received information on GAP and residue data for carambola from Malaysia.

RESIDUE ANALYSIS*Analytical methods*

The Meeting received summarized information on an analytical method for azoxystrobin residues in carambola. The samples were extracted with ethylacetate. After clean-up, the residues were determined by GC-ECD with an LOQ of 0.005 mg/kg. The recoveries were reported as 104% (0.005 mg/kg), 93% (0.01 mg/kg) and 96% (0.1 mg/kg). The method was described in summary only, no detailed information or chromatograms were submitted.

Stability of residues in stored analytical samples

No new information on storage stability was submitted for carambola. 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.

USE PATTERN

The information available to the 2012 JMPR on registered uses of azoxystrobin on carambola is summarized in Table 1. The label was made available to the Meeting.

Table 1 Use of azoxystrobin

Crop	Country	Form	Method	No	Application				PHI, days
					Growth Stage	kg ai/hL	Water L/ha	kg ai/ha	
Carambola	Malaysia	EC	foliar	2	Flowering, Fruiting, Mature	0.0115	1000	0.115	1

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information from Malaysia on supervised field trials for azoxystrobin use that produced residues on carambola. 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 underlined.

Carambola

Trials were carried out on mature carambola fruits in Malaysia in 2005 and in 2010 by the Malaysian Agricultural Research and Development Institute. The interval between two spray treatments was 6 to 7 days. The results are shown in Table 2.

Table 2 Azoxystrobin residues in carambola

Country, year, location, (variety)	Application				Sample	PHI, days	Residue, mg/kg	Study No.
	Form	kg ai/ha	kg ai/hL	No				
Malaysia, 2005, Kawasan Biru, 71700 Mantin, (B17)	EC	0.115	0.0115	2	Whole fruit	0	< 0.05	MYF 012005B
						1	< 0.05	
						3	< 0.05	
						7	< 0.05	
						14	< 0.05	
Malaysia, 2010, Ladang Belimbing, 71700 Mantin, (B10)	EC	0.115	0.0115	2	Whole fruit	0	< 0.005	AZX/SF/2010
						1	< 0.005	
						2	0.007	
						4	< 0.005	
Malaysia, 2010, Mukutim Setul, 71700 Mantin, (B10)	EC	0.115	0.0115	2	Whole fruit	0	0.014	AZX/SF/2010
						1	0.011	
						2	0.009	
						3	0.008	
Malaysia, 2010, 72400 Jelebu, (B10)	EC	0.115	0.0115	2	Whole fruit	0	0.024	AZX/SF/2010
						1	0.034	
						2	0.028	

*Fate of Residues in Storage and Processing**In processing—ginseng*

The 2011 JMPR evaluated azoxystrobin residue data for ginseng, raw and processed. No new data were submitted in 2012. The 2011 Meeting estimated the processing factors (median in brackets) for:

- dried ginseng (3)
- red ginseng (2)
- ethanol extract of dried ginseng (5.2)
- ethanol extract of red ginseng (4.9)
- water extract of dried ginseng (4.8)
- water extract of red ginseng (2)

The Forty-fourth Session of CCPR in 2012 allocated new commodity codes: DV 0604 for ginseng, dried including red ginseng and DM 0604 for ginseng extracts. The JMPR was requested to re-evaluate the processing studies for ginseng processed products to the estimation of MRLs for ginseng extracts (RP12/PR).

Based on the data evaluated by the 2011 JMPR, the processing factors were combined according to the new commodity groups.

Table 3 Summary of processing factors for azoxystrobin in ginseng products

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median
Fresh ginseng	Dried and red ginseng	1.0, 1.8, 1.8, 2.0, 2.0, 2.4, <u>2.7</u> , <u>2.8</u> , 3.0, 3.2, 3.8, 4.1, 4.3, 7.1	2.75
	Ethanol and water extracts of dried and red ginseng	1.1, 1.1, < 1.4, < 1.4, < 1.4, 1.8, 2.0, 2.4, 2.6, 2.6, 2.9, 3.1, 4.0, <u>4.8</u> , <u>4.8</u> , 4.9, 4.9, 4.9, 5.2, 5.3, 5.4, 5.7, 6.2, 6.3, 6.7, 7.9, 10.8, 11.3	4.8

APPRAISAL

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 0–0.2 mg/kg bw per day, decided that an ARfD was unnecessary and concluded that the residue definition for plant commodities for compliance with MRL values and for consumer risk assessments was parent azoxystrobin. The compound was listed by the Forty-second Session of the CCPR for the review of additional MRLs by the JMPR in 2011.

The Forty-fourth Session of the CCPR requested the 2012 JMPR to re-evaluate the processing studies for ginseng processed products to estimate MRLs for ginseng extracts. Furthermore, the Meeting received information on GAP and residue data for carambola from Malaysia.

Methods of analysis

The Meeting received summarized information on an analytical method for azoxystrobin residues in carambola. The samples were extracted with ethyl acetate. After clean-up, the residues were determined by GC-ECD with an LOQ of 0.005 mg/kg. The recoveries were reported as 104% (0.005 mg/kg), 93% (0.01 mg/kg) and 96% (0.1 mg/kg).

No new information on storage stability was submitted but the studies reported by the 2008 JMPR for fruits and vegetables cover the sample material evaluated by the present Meeting.

Results of supervised residue 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 judgment. 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.

Carambola

Azoxystrobin is registered in Malaysia as foliar spray treatment with 2×0.0115 kg ai/hl (2×0.115 kg ai/ha) with a 1-day PHI. Four trials matching the Malaysian GAP were carried out in Malaysia in 2005 (LOQ 0.05 mg/kg) and in 2010 (LOQ 0.005 mg/kg). The residues were: 0.007, 0.011, 0.034 and < 0.05 mg/kg. Using the OECD MRL calculator, 0.15 mg/kg were calculated as maximum residue level. The Meeting noted that the highest residue value was lower than the LOQ of 0.05 mg/kg and concluded that 0.1 mg/kg would be more appropriate as MRL.

The Meeting estimated for azoxystrobin residues in carambola a maximum residue level of 0.1 mg/kg and an STMR 0.023 mg/kg.

Ginseng processed products

The 2011 JMPR estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.025 mg/kg for azoxystrobin in ginseng.

The 2011 JMPR evaluated ginseng processing studies. 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.

The 2011 JMPR estimated 0.5 mg/kg as maximum residue level for ginseng, processed products (dried, red, ethanol and water extracts).

Based on the STMR of 0.025 mg/kg for fresh ginseng roots, the 2011 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.

At the Forty-fourth CCPR, the Committee decided to separate the commodity “ginseng, processed products” into “ginseng, dried including red ginseng” and “ginseng, extracts”. The Forty-fourth CCPR requested the 2012 JMPR to re-evaluate the processing studies on ginseng to estimate separate maximum residue levels for the two commodities.

The 2012 JMPR agreed to estimate separate maximum residue levels and STMR-P values for the above mentioned commodities. Based on the data evaluated by the 2011 JMPR, the individual processing factors were combined according to the new commodity groups. Median processing factors of 2.75 for dried ginseng (incl. red ginseng) and of 4.8 for ginseng extracts were estimated.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR-P of 0.069 mg/kg for ginseng, dried including red ginseng.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR-P of 0.12 for ginseng, extracts.

The former recommendation of 0.5 mg/kg for ginseng processed products (dried, red, ethanol and water extracts) should be withdrawn.

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	Recommended MRL, mg/kg		STMR or STMR-P mg/kg
		proposed	previous	
FT 0289	Carambola	0.1		0.023
DV 0604	Ginseng, dried including red ginseng	0.3		0.069
DM 0604	Ginseng, extracts	0.5		0.12
	Ginseng processed products(dried, red, ethanol and water extracts)	W	0.5	

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) of azoxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2008, 2011 and the current Meeting. The results are shown in Annex 3.

The ADI is 0–0.2 mg/kg bw and the calculated IEDI were 2–10 % of the maximum ADI. 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.

REFERENCES

Code	Author	Year	Title
AZX/SF/2010	Ngan Chai Keong	2010	Azoxystrobin residue in carambola after two applications of amistar
MYF 012005B	Ma Choon Kwong	2005	Determination of the residue levels of azoxystrobin in star fruit after application of amistar
REP12/PR	FAO	2012	Codex Alimentarius Commission, Joint FAO/WHO Food standard programme, 35 th Session, Geneva, Switzerland, 2–7 July 2012. Report of the 44 th Session of the Codex Committee on Pesticide Residues, Shanghai, China, 23–28 April 2012, paragraph 59–60