



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 21 1997

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Dietary Exposure Analysis for Azoxystrobin in/on Grapes
(PP# 5F4541) and Pecans PP# 6F4642).

FROM: Brian Steinwand *BS*
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Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: M. Metzger, Chief
RCAB (7509C)

Action Requested

Provide a chronic dietary exposure analysis for the use of azoxystrobin in/on grapes and pecans. The petition requests and CBTS recommends establishing a permanent tolerance of 1.0 ppm on grapes and 0.01 ppm for azoxystrobin on pecans respectively. (See Memos, J. Garbus, 6/26/96).

Discussion

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.18 mg/kg bwt/day, based on a NOEL of 18.2 mg/kg/day. An uncertainty factor (UF) of 100 was used to account for both the interspecies extrapolation and the intra species variability (See Memo, G. Ghali, 1/14/97).

Currently, azoxystrobin is classified as a "not likely" carcinogen (See TES document, 12/10/96).

No acute endpoint was identified by the TES (Toxicology Endpoint Selection) committee 12/10/96.

Residue Information

Being a new chemical, tolerances for azoxystrobin have yet to be published in 40 CFR. Tolerance level residues and 100 percent crop treated assumptions were made for all commodities.

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 1 and 2.

Chronic Exposure Analysis

Exposure from Existing Tolerances for azoxystrobin:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population	0.000000	0
Non-Nursing Infants (<1 year old)	0.000000	0

Proposed new Tolerances on the proposed commodities:

U.S. Population	0.000301	0.17
Non-Nursing Infants (<1 year old)	0.000293	0.16

If all pending tolerances (including the new petition) are approved the TMRC will be:

U.S. Population	0.002110	1.17
Non-Nursing Infants (<1 year old)	0.007280	4.04

The chronic analysis for azoxystrobin is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with cyclanilide. Thus, the chronic dietary risk concern due to azoxystrobin appears to be minimal for this petition on grapes, and pecans and does not exceed the RfD for any of the DRES subgroups.

Attachments

cc: DRES; Caswell 123AZO; RD PM 22 C. Giles-Parker; CBTS (J.
Garbus) ---

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF		
Azoxystrobin Caswell #123AZO CAS No. A.I. CODE: 128310 CFR No.	chronic: rat NOEL= 18.2000 mg/kg 0.00 ppm LEL= 34.0000 mg/kg 0.00 ppm ONCO: not likely	dec body weight bile duct lesions		-->100		YES

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			PENDING	PUBLISHED
01014AA	GRAPES-FRESH	5F4541	1.000000	
01014DA	GRAPES-RAISINS	5F4541	1.000000	
01014JA	GRAPES-JUICE	5F4541	1.000000	
03008AA	PECANS	6F4642	0.010000	
24004AA	RICE-ROUGH	97LA001		4.000000
24004AB	RICE-MILLED	97LA001		4.000000
43058AA	WINE AND SHERRY	5F4541		
50000DB	MILK-NON-FAT SOLIDS	97LA001		0.060000
50000FA	MILK-FAT SOLIDS	97LA001		0.060000
50000SA	MILK SUGAR (LACTOSE)	97LA001		0.060000
53001BA	BEEF-MEAT BYPRODUCTS	97LA001		0.060000
53001BB	BEEF(ORGAN MEATS)-OTHER	97LA001		0.060000
53001DA	BEEF-DRIED	97LA001		0.010000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	97LA001		0.010000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	97LA001		0.060000
53001LA	BEEF(ORGAN MEATS)-LIVER	97LA001		0.300000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	97LA001		0.300000
53002BA	GOAT-MEAT BYPRODUCTS	97LA001		0.060000
53002BB	GOAT(ORGAN MEATS)-OTHER-	97LA001		0.060000
53002FA	GOAT(BONELESS)-FAT	97LA001		0.010000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	97LA001		0.060000
53002LA	GOAT(ORGAN MEATS)-LIVER	97LA001		0.300000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	97LA001		0.010000
53003AA	HORSE	97LA001		0.300000
53005BA	SHEEP-MEAT BYPRODUCTS	97LA001		0.060000
53005BB	SHEEP(ORGAN MEATS)-OTHER	97LA001		0.060000
53005FA	SHEEP(BONELESS)-FAT	97LA001		0.010000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	97LA001		0.060000
53005LA	SHEEP(ORGAN MEATS)-LIVER	97LA001		0.300000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	97LA001		0.010000
53006BA	PORK-MEAT BYPRODUCTS	97LA001		0.200000
53006BB	PORK(ORGAN MEATS)-OTHER	97LA001		0.200000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	97LA001		0.010000
53006KA	PORK(ORGAN MEATS)-KIDNEY	97LA001		0.010000
53006LA	PORK(ORGAN MEATS)-LIVER	97LA001		0.200000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	97LA001		0.010000
55008BA	TURKEY-BYPRODUCTS	97LA001		0.400000
55008LA	TURKEY-GIBLETS (LIVER)	97LA001		0.400000
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	97LA001		0.010000
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)	97LA001		0.010000

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Azoxystrobin Caswell #123AZO CAS No. A.I. CODE: 128810 CFR No.	chronic rat NOEL= 18,2000 mg/kg 0.00 ppm LEL= 34,0000 mg/kg 0.00 ppm OMCO: not likely	dec body weight bile duct lesions	AD1 UF -->100 OPP RfD= 0.180000 EPA RfD= 0.180000	TES	TES

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			PENDING	PUBLISHED
55008MC	TURKEY-UNSPECIFIED	97LA001	0.010000	
55013BA	POULTRY, OTHER-BYPRODUCTS	97LA001	0.400000	
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	97LA001	0.400000	
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	97LA001	0.400000	
55014AA	EGGS-WHOLE	97LA001	0.400000	
55014AB	EGGS-WHITE ONLY	97LA001	0.400000	
55014AC	EGGS-YOLK ONLY	97LA001	0.400000	
55015BA	CHICKEN-BYPRODUCTS	97LA001	0.400000	
55015LA	CHICKEN-GIBLETS(LIVER)	97LA001	0.400000	
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	97LA001	0.010000	
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	97LA001	0.010000	

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CHEMICAL INFORMATION		STUDY TYPE		EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Azoxystrobin		chronic rat		dec body weight	AD1 UF -->100	TES	YES
Caswell #123420	NOEL= 18,2000 mg/kg	bile duct lesions		OPP RfD= 0.1800000			
CAS No.	0.00 ppm			EPA RfD= 0.1800000			
A.I. CODE: 128810	LEL= 34,0000 mg/kg						
CFR No.	0.00 ppm						
		ONCO: not likely					

POPULATION SUBGROUP	TOTAL THRC (MG/KG BODY WEIGHT/DAY)		NEW THRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT THRC*	NEW THRC**			ARC	XRFD
U.S. POPULATION - 48 STATES	0.000000	0.002110	1.172201	1.172201		
U.S. POPULATION - SPRING SEASON	0.000000	0.002034	1.129917	1.129917		
U.S. POPULATION - SUMMER SEASON	0.000000	0.002131	1.183639	1.183639		
U.S. POPULATION - FALL SEASON	0.000000	0.002181	1.211765	1.211765		
U.S. POPULATION - WINTER SEASON	0.000000	0.002095	1.163637	1.163637		
NORTHEAST REGION	0.000000	0.002363	1.312968	1.312968		
NORTH CENTRAL REGION	0.000000	0.001863	1.034943	1.034943		
SOUTHERN REGION	0.000000	0.002012	1.117943	1.117943		
WESTERN REGION	0.000000	0.002300	1.277553	1.277553		
HISPANICS	0.000000	0.003354	1.863549	1.863549		
NON-HISPANIC WHITES	0.000000	0.001915	1.064030	1.064030		
NON-HISPANIC BLACKS	0.000000	0.002488	1.382286	1.382286		
NON-HISPANIC OTHERS	0.000000	0.004682	2.600956	2.600956		
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.003234	1.796722	1.796722		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.007279	4.044059	4.044059		
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.001519	0.844016	0.844016		
FEMALES 13+ YEARS, NURSING	0.000000	0.001843	1.024141	1.024141		
CHILDREN (1-6 YEARS OLD)	0.000000	0.004521	2.511681	2.511681		
CHILDREN (7-12 YEARS OLD)	0.000000	0.002788	1.548867	1.548867		
MALES (13-19 YEARS OLD)	0.000000	0.001907	1.059383	1.059383		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.001615	0.897329	0.897329		
MALES (20 YEARS AND OLDER)	0.000000	0.001823	1.012922	1.012922		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.001486	0.825826	0.825826		

*Current THRC does not include new or pending tolerances.

**New THRC includes new, pending, and published tolerances.

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TOLERANCE ASSESSMENT SUMMARY FOR Azoxystrobin
CASWELL #123A20

DATE: 04/11/97

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A THRC OF:	0.000000	MG/KG/DAY
THE EXISTING THRC IS EQUIVALENT TO:	0.000	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A THRC OF:	0.000310	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.172	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT THRC WILL BE:	0.000310	MG/KG/DAY
THE NEW THRC WILL OCCUPY	0.172	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A THRC OF:	0.001801	MG/KG/DAY
THIS THRC WILL OCCUPY	1.000	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT THRC WILL BE:	0.002110	MG/KG/DAY
THE TOTAL THRC WILL OCCUPY	1.172	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A THRC OF:	0.000000	MG/KG/DAY
THE EXISTING THRC IS EQUIVALENT TO:	0.000	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A THRC OF:	0.000293	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.162	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT THRC WILL BE:	0.000293	MG/KG/DAY
THE NEW THRC WILL OCCUPY	0.162	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A THRC OF:	0.006987	MG/KG/DAY
THIS THRC WILL OCCUPY	3.882	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT THRC WILL BE:	0.007280	MG/KG/DAY
THE TOTAL THRC WILL OCCUPY	4.044	% OF THE ADI.

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