

US EPA ARCHIVE DOCUMENT



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

MAY 27 1997

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Dietary Exposure Analysis for Azoxystrobin in/on
Bananas, Peaches, Peanuts, and Tomatoes (PP# 6F4762).

FROM: Brian Steinwand *BS*
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head *E. A. Doyle*
Dietary Risk Evaluation Section
SAB/Health Effects Division *W. J. Metzger*

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

Action Requested

Provide a chronic dietary exposure analysis for the use of azoxystrobin in/on bananas, peanuts, peaches and tomatoes. The petition requests and CBTS recommends establishing a permanent tolerance of 0.5 ppm on bananas (0.05 ppm for banana pulp), 0.8 ppm for peaches, 0.01 ppm and 0.03 ppm on peanuts and peanut oil respectively, 0.2 ppm on tomatoes, juice and puree, and 0.6 ppm on tomato paste and catsup. (See Memo, J. Garbus, 5/20/97).

Discussion

This analysis includes pending uses on grapes, pecans and a Section 18 request on rice, milk, meat, eggs and poultry.

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. Effects seen at the LOEL, 34 mg/kg/day, were reduced body weight and bile duct lesions in males. An uncertainty factor (UF) of 100 was used to account for both the interspecies extrapolation and the intra species variability. (See Memo, RfD Committee, 11/7/96).

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	0.000604	0.335
Non-Nursing Infants (<1 year old)	0.001988	1.104

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

U.S. Population	0.002224	1.23
Non-Nursing Infants (<1 year old)	0.008610	4.78

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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 azoxystrobin. Thus, the chronic dietary risk concern due to azoxystrobin appears to be minimal for this petition on bananas, peaches, tomatoes and peanuts 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)

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TABLE 4

STATUS

TES

DATA GAPS/COMMENTS

REFERENCE DOSES

EFFECTS

STUDY TYPE

CHEMICAL

<p>Azoxytrobilin Caswell #123AZO CAS No. A.I. CODE: 128810 CFR No.</p>	<p>chronic rat NOEL= 18,2000 mg/kg 0.00 ppm LEL= 34,0000 mg/kg 0.00 ppm ONCO: not likely</p>	<p>dec body weight bile duct lesions</p>	<p>ADI UF -->100 OPP RfD= 0.180000 EPA RfD= 0.180000</p>	<p>TES</p>
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FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	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		
05004AA	PEACHES-FRESH	6F04762	0.800000			
05004DA	PEACHES-DRIED	6F04762	0.800000			
06002AA	BANANAS-UNSPECIFIED	6F04762	0.050000			
06002AB	BANANAS-FRESH	6F04762	0.050000			
06002DA	BANANAS-DRIED	6F04762	0.050000			
06016AA	PLANTAINS	6F04762	0.050000			
11005AA	TOMATOES-WHOLE	6F04762	0.200000			
11005JA	TOMATOES-JUICE	6F04762	0.200000			
11005RA	TOMATOES-PUREE	6F04762	0.200000			
11005TA	TOMATOES-PASTE	6F04762	0.200000			
11005UA	TOMATOES-CATSUP	6F04762	0.600000			
15006AA	PEANUTS-WHOLE	6F04762	0.600000			
24004AA	RICE-ROUGH	97LA001	0.010000	4.000000		
24004AB	RICE-MILLED	97LA001		4.000000		
270070A	PEANUTS-OIL	6F04762				
43058AA	WINE AND SHERRY	5F4541		1.000000		
500000B	MILK-NON-FAT SOLIDS	97LA001	0.030000			
50000FA	MILK-FAT SOLIDS	97LA001		0.006000		
50000SA	MILK SUGAR (LACTOSE)	97LA001		0.006000		
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		

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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 ONCO: not likely	dec body weight bile duct testons	ADI UF -->100 OPP Rfd= 0.180000 EPA Rfd= 0.180000	TES	TES

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
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	
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
Azoxytobin 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 ONCO: not likely	dec body weight bile duct lesions	ADI UF --> 100 OPP RfD= 0.180000 EPA RfD= 0.180000	TES	TES

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**	DIFFERENCE AS PERCENT OF RFD	ARC
U.S. POPULATION - 48 STATES	0.000000	0.002223	1.235147	1.235147
U.S. POPULATION - SPRING SEASON	0.000000	0.002123	1.179196	1.179196
U.S. POPULATION - SUMMER SEASON	0.000000	0.002355	1.308369	1.308369
U.S. POPULATION - FALL SEASON	0.000000	0.002243	1.246258	1.246258
U.S. POPULATION - WINTER SEASON	0.000000	0.002173	1.207184	1.207184
NORTHEAST REGION	0.000000	0.002484	1.380100	1.380100
NORTH CENTRAL REGION	0.000000	0.002033	1.129529	1.129529
SOUTHERN REGION	0.000000	0.002032	1.129048	1.129048
WESTERN REGION	0.000000	0.002481	1.378511	1.378511
HISPANICS	0.000000	0.003407	1.892876	1.892876
NON-HISPANIC WHITES	0.000000	0.002080	1.155448	1.155448
NON-HISPANIC BLACKS	0.000000	0.002324	1.291071	1.291071
NON-HISPANIC OTHERS	0.000000	0.004576	2.542223	2.542223
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.004030	2.238839	2.238839
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.008609	4.783037	4.783037
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.001660	0.922434	0.922434
FEMALES 13+ YEARS, NURSING	0.000000	0.002080	1.155593	1.155593
CHILDREN (1-6 YEARS OLD)	0.000000	0.004877	2.709488	2.709488
CHILDREN (7-12 YEARS OLD)	0.000000	0.003091	1.717004	1.717004
MALES (13-19 YEARS OLD)	0.000000	0.002007	1.114881	1.114881
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.001714	0.952490	0.952490
MALES (20 YEARS AND OLDER)	0.000000	0.001810	1.005587	1.005587
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.001534	0.852441	0.852441

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

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TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Azoxystrobin
CASWELL #123AZO

DATE: 05/13/97

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000000	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.000	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000604	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.335	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000604	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	0.335	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.001621	MG/KG/DAY
THIS TMRC WILL OCCUPY	0.900	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.002224	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	1.235	% OF THE ADI.

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000000	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.000	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.001988	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	1.104	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.001988	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	1.104	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.006623	MG/KG/DAY
THIS TMRC WILL OCCUPY	3.679	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.008610	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	4.783	% OF THE ADI.

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