



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).

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Science Analysis Branch/HED (7509C)

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

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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**STATUS**

| STATUS |
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|--------|

TOLERANCE (PPM)

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17100-2

## TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/13/97

PAGE: 1

| CHEMICAL INFORMATION                                                       | STUDY TYPE          | EFFECTS           | REFERENCE DOSES   |            | DATA GAPS/COMMENTS | STATUS |
|----------------------------------------------------------------------------|---------------------|-------------------|-------------------|------------|--------------------|--------|
|                                                                            |                     |                   | ADI               | UF --> 100 |                    |        |
| Azoxystrobin<br>Caswell #123420<br>CAS No.<br>A.I. CODE: 128810<br>CFR No. | chronic rat         | dec body weight   | OPP RfD= 0.180000 | TES        |                    |        |
|                                                                            | NOEL= 18.2000 mg/kg | bile duct lesions | EPA RfD= 0.180000 |            |                    |        |
|                                                                            | LEL= 34.0000 mg/kg  |                   |                   |            |                    |        |
|                                                                            | ONCO: not likely    |                   |                   |            |                    |        |

## TOTAL TMRC (MG/KG BODY WEIGHT/DAY)

| CURRENT TMRC* | NEW TMRC** | NEW TMRC AS PERCENT OF RFD | DIFFERENCE AS PERCENT OF RFD | EFFECT OF ANTICIPATED RESIDUES |
|---------------|------------|----------------------------|------------------------------|--------------------------------|
| 0.000000      | 0.002223   | 1.235147                   | 1.235147                     | ARC                            |

## POPULATION SUBGROUP

%RFD

|                                                 |          |          |          |          |  |
|-------------------------------------------------|----------|----------|----------|----------|--|
| 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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