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

MAY 21 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

**MEMORANDUM:**

**SUBJECT:** Aldicarb: Additional Data Submitted in Response to DCI. Data for Aldicarb Residues in Composited Samples of Bananas and in Individual Bananas. No MRID No. DEB No. 7978 Barcode D164397

**FROM:** Joel Garbus, PhD., Chemist
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**THRU:** Richard D. Schmitt, PhD., Chief
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**TO:** S. Haddad PM/RM 60
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Special Review Branch (H7505C)

This review is expedited at the request of the Special Review Branch.

In response to the DCI for aldicarb requesting residue data for individual bananas, Rhone-Poulenc, the registrant of aldicarb, has submitted the preliminary results of residue trials conducted in 1990.

## Conclusion

Preliminary results indicate that over tolerance residues of aldicarb and its metabolites can occur in bananas treated in accordance with current label usage. The over tolerance values were found with composited samples (7/50) and in individual fruit (24/120). In individual bananas total residues as high as 3.14 ppm were found. Almost all of the excessive residues were associated with fruit from one site.

These results must be considered preliminary and our final comments and conclusions reserved for the review of a complete acceptable data submission. The registrant will need to provide a complete report

including: detailed information regarding the rates of application, the timing of applications, substantive details regarding sampling procedures, transit and storage conditions, validation of the HPLC method for bananas, details of the analytical methodology for bananas, whether the entire banana or just the pulp was analyzed, raw data such as chromatograms, and certification that the studies met the criteria of GLP.

Background

These trials were conducted under altered usage conditions that were instituted as a result of over-tolerance values detected at growing sites in 1986-1987. (See Rhone Poulenc letter of April 17,1990 to Dennis Edwards proposing an amended Section B incorporating the new usage patterns. This letter states, "Residues have decreased because the use rate applied is lower and the frequency of application has been reduced and positive displacement equipment is now available to accurately deliver the proper rate of aldicarb.... Our stewardship program has educated the growers and has resulted in strict adherence to label directions. The major multinational banana producing companies are now using the lower rates and making no more than two applications per year.")

Also on April 17, 1990, Rhone-Poulenc submitted to the Special Review Branch the results of aldicarb monitoring conducted by three major banana producers. Rhone-Poulenc's cover letter stated; "The data indicate that when the low rates of TEMIK are used with no more than two applications made at least six months apart there are seldom detectable residues of aldicarb present at harvest."

In its cover letter with the present submission, the registrant states that it was believed that the changes would have an impact on the frequency and magnitude of residues from treated banana plants. As a result, five GLP compliant trials were conducted in South and Central America.

Design of Present Residue Trials:

The submission does not provide any detailed information regarding the rates of application, the timing of applications, or substantive details regarding sampling procedures, transit and storage conditions, validation of the HPLC method for bananas, or details of the analytical methodology for bananas. Whether the entire banana or just the pulp was analyzed is not indicated. None of the data is certified as having met the criteria of GLP. CBTS will need this information to conduct its review of these results. As such, the results must be considered preliminary and our final comments and conclusions reserved for the review of a complete acceptable data submission.

The cover letter and the handout given to participants in a May 16th meeting with Linda Fisher states that aldicarb was applied at a rate

of 2.0 grams ai/ mat using a Swiss Mex type backpack pump applicator. Ten samples, each consisting of 5 bananas per mat, (location unspecified) were harvested 60 days after treatment. The registrant states that application was at the maximum commercial rate and sampling was at a PHI that has been shown to result in maximum residues.

Results

Individual residues values are reported for aldicarb and its metabolites, aldicarb sulfoxide and aldicarb sulfone and for total residues in terms of the sulfone. These results were summarized in a table prepared for overhead projection with a minimum of detail as follows: (The import tolerance for bananas is 0.3 ppm)

| Trial | Year | Residue ppm of composited sample (Total toxic residue as sulfone) |
|---|---|---|
| Honduras | 1990 | 0.01-0.02 |
| Costa Rica-1 | 1990 | 0.03-0.14 |
| Costa Rica-2 | 1990 | 0.06-0.16 |
| Ecuador-1 | 1990 | 0.01-0.02 |
| Ecuador-2 | 1991 | 0.17-1.02 |

Individual bananas of the two Costa Rican trials and of Ecuador-2 also were analyzed for aldicarb and its metabolites. Results are given for the individual residues and for total residues in terms of the sulfone. Twenty of the 50 bananas of Costa Rica-1 were studied with total residue values ranging from 0.01 to 0.31 ppm. Forty-eight bananas of the 50 of Costa Rica-2 had individual total residues ranging from 0.01 to 0.49 ppm.

The 50 individual Bananas of Ecuador-2 were analyzed as follows:

| Composite Residue (ppm) (5 bananas) | Residues in Individual Bananas (Range ppm) |
|---|---|
| 0.85 | 0.04 - 1.77 |
| 0.99 | <0.03 - 3.14 |
| 1.02 | 0.13 - 1.97 |
| 0.63 | 0.11 - 1.72 |
| 0.20 | 0.03 - 0.95 |
| 0.64 | 0.11 - 1.30 |
| 0.47 | 0.13 - 0.55 |
| 0.17 | 0.07 - 0.30 |
| 0.28 | 0.04 - 1.29 |
| 0.37 | ND - 1.51 |

Residues in composited samples in 7 of the 10 samples exceeded the import tolerance of 0.3 ppm. Residues in 22 of the 50 individual bananas equaled or exceeded the tolerance value of 0.3 ppm.

The company also submits some summary data of residue trials conducted in the Philippines in 1980 and '81 that resulted in over tolerance residues in 19 of 48 composited samples. For all samples residues ranged from 0.03 ppm to 0.64 ppm. These studies were conducted at a higher total application rate than that currently employed.

Comment

In 43 of the 50 composited banana samples examined from 5 sites in Central and South America, residues of aldicarb and its metabolites did not exceed the tolerance value of 0.3 ppm. In 7 of the composited samples from 1 site and trial in Ecuador, residues ranged from 0.47 to 1.02. Analyses of all bananas from this trial demonstrated residue values ranging from <0.03 to 3.14 ppm. Residues of 0.95 and 1.29 ppm were detected in individual bananas from samples whose composited values were 0.20 and 0.28 ppm respectively.

The registrant has tried to explain the excessive residue found in the Ecuador-2 trials as unique and atypical, an explanation also proffered for the excessive residues found in potatoes from one site. The company also states that the sampled Ecuadoran fruit was small and came from stunted plants but this assertion is not borne out by comparing the weights recorded for the fruit with those from the Costa Rican trials.

These results, together with the finding of an over tolerance residue in a banana from an apparently well controlled study in Costa Rica and the findings of over tolerance bananas in the ANFS adds to our conviction that individual bananas bearing excessive residues of aldicarb are available for consumption in the US.

However from the limited amount of data that we have, it is impossible to assess the incidence of such residue levels in bananas that are commercially available in the US. The toxicological significance of these results we leave to the toxicologists.

cc: Aldicarb Subject File, RF., Circ., Reviewer, FOD/PIB(Furlow), Kariya (SACB), M. Firestone (FAX
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