

JUN 12 1991

Mr. John J. Arthur
 American Cyanamid Company
 Agricultural Research Division
 P.O. Box 400
 Princeton, NJ 08540

Dear Mr. Arthur:

Subject: Continuation of Review of Application/Petitions
 AMDRO[®] Technical Insecticide
 EPA Registration No. 241-270
 Pesticide Petition No. 2F2609
 AMDRO[®] Roach Control PCO Gel Insecticide
 EPA Registration No. 241-GRG
 Pesticide Petition No. 2F2627
 Your Submission Dated October 7, 1988

As a result of the September 19, 1990 meeting of the Health Effects Division Peer Review Committee, the Agency's classification for Amdro was changed from B2 to "Group C, Possible Human Carcinogen." As such, we are now prepared to continue review of the subject petitions for tolerance in all raw agricultural commodities (RAC) and in pineapples and sugarcane, as well as pending applications/amendments for Section 3 registration.

This review would essentially consist of the quantification of human dietary risk involved in the subject use patterns, based on the "Reference Dose" (RfD) approach. However, before review of these petitions is resumed, we would like to have the following issue addressed:

1. Since the petition for pineapples and sugarcane (PP No. 2F2609) is covered by the petition for all raw agricultural commodities (PP No. 2F2627), please state whether it is the intention of American Cyanamid Company to pursue both petitions for pesticide tolerance independently or whether one of these petitions will be dropped.

2. With respect to the Section 3 applications for registration and amendments, the Agency concluded and informed you that it had not received adequate data, nor did it have adequate surrogate data, to evaluate loader/applicator exposure to Amdro for uses on sugarcane and pineapples (worst case exposures for crop uses). Has American Cyanamid generated such data to enable us to

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make an accurate assessment of loader/applicator exposure for crop uses and also non-crop applicators; i.e. foam and gel products. If not, you would need to develop an exposure study protocol consistent with Subdivision 4 of the Pesticide Assessment Guidelines to cover worker exposure to Amdro use on crops and non-crop areas. Our main cause for concern is that there is an adequate margin of exposure from use when considering the liver and testicular effects seen in the chronic and sub-chronic studies.

Is there any additional data or information that American Cyanamid Company would like to present to this Agency in support of the subject petitions and Section 3 registrations?

Please respond within 75 days from the date of this letter stating your intentions to comply with the information/data requests cited above. If no resubmission is received during the 75-day period, the petitions for pesticide tolerance and applications for registration will be administratively withdrawn.

Sincerely,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7505C)