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

JAN 30 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil DCI 50534/81901. Memorandum of Telephone Conversation Held 12/11/91. ISK Biotech Corporation Letter Dated 12/31/91.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C) *Mike Flood*

THROUGH: Elizabeth T. Haerberer, Section Chief *Elizabeth T. Haerberer*
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

TO: Andrew Ertman
Reregistration Branch
Special Review and Reregistration Division (H7508W)

ISK Biotech, in a letter addressed to this reviewer by Mr. Jerry R. Lucietta, has submitted its summary of a telephone conversation held on December 11, 1991.

In that conversation, ISK Biotech Corp. discussed residue data requirements on bananas to be imported to the U.S. The company proposed to conduct one field trial in Columbia, Panama, Honduras and Guatemala and two field trials in Costa Rica. These countries represent about 70% of the bananas grown for export in the U.S. However, field trials in Ecuador, which accounts for most of the remaining 30%, were not planned because of difficulties in assuring GLP compliance. I agreed that the proposed field trial plan would be acceptable. During this conversation the particular fungicide was not identified as chlorothalonil. Although the protocol should apply to chlorothalonil, SRRD should verify that our recommendation is consistent with the DCI.

I also noted that we would not automatically reject a study not conducted under GLP. Such a study would be acceptable if the reasons for non compliance did not affect the actual residue data. However each non-GLP study would have to be examined on an individual basis. My interpretation differs from ISK Biotech's understanding that "if a non-GLP study in Ecuador was conducted and submitted it would not be rejected and could be considered as

additional data." ISK Biotech's interpretation should be corrected.

cc: SF, RF, Circu., Reg. Std. File, PIB/FOD(C.Furlow), M.Flood,
C.Giles-Parker(H7505C).
H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):1/29/92.
RDI:SectionHead:ETHaeberer:1/24/92:BranchSeniorScientist:RALoranger:
1/27/92.