MEMO TO FILE 7-20-89

SUBJECT: Meeting with Rhone Poulenc and Wildlife International to discuss Mocap Field Study Protocol

FROM: Dan Rieder 7-20-89

On July 20 Denny McLane and Dan Rieder met with Phil Hundeman of SRRD and representatives of Rhone Poulenc (RP) and Wildlife International (WI) to discuss the field study protocols for both mocap EC and granular mocap.

Background

In the October 23, 1987 Reg. Std. on ethoprop EEB indicated that avian field testing would be required for both granular and EC formulations of mocap. At that time, we required testing on turfgrasses (EC formulation) and a field crop (Granular). Turf grass was chosen because of its high use rate and high exposure potential to birds. The registrant dropped the turf use and we substituted the pineapple use because of its high use rate. The registrant then proposed to substantially reduce the use rate for pineapples and change the method of application such that exposure to birds was essentially eliminated. Thus, EEB has indicated that field testing is still needed for the EC formulation, since rates as low as 2 lbs ai per acre were considered hazardous to birds. Thus, Rhone Poulenc has submitted a protocol for the EC use on potatoes at 12 lbs ai per acre. That protocol was reviewed and rejected in a 6-9-89 review.

In the meantime, Rhone Poulenc has submitted and EEB judged invalid, a field study with granular mocap on potatoes. They had submitted a protocol for field testing with the 20G formulation, but we had not seen that protocol yet.

Current Issues

The meeting today was to answer some questions RP and WI had some details of their EC protocol. They had not seen my 6-9-89 review of that protocol. These questions were previously provided to me and I had answers prepared. See that attached letter. We discussed numerous problems, but the bottom line was that the protocol was rejected because it failed to fully justify their proposed protocol. Many of the questions they had could not be answered since they did not fully explain how the various parts of their proposed field study could be used to show safety. For example, they had suggested in their protocol that they would search 3.5 acres for carcasses, measure residues and survey birds to determine effects. They asked us how we would interpret the results; we responded we could not tell until they provided more

information[1].

They closed by indicating they would be back in very soon with a complete justification for both their EC and 20G protocol. At that time, Phil will route the 20G protocol for review. They hoped to do the study next year, but James Hobson indicated that there was no deadline for study completion[2].

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[1] In later discussion, Denny and I decided we should have responded that unless they provide adequate rationale for something besides an adequate carcass search, we would likely reject the study.

[2] Note for future reference: We need to indicate in the next protocol review that the protocol is acceptable with specified modifications and the study(s) should be completed in 2 years. Note that in the 10.23.87 Reg Std EEB indicated the study should be completed in 2 yrs, no mention of protocol was made.

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RHÔNE-POULENC

TOXICOLOGY DEPARTMENT

TO: Warren A. Davis

DATE: 7 June 1989

FROM: James F. Hobson JFH

CC: G.S. Simon
M.A. Cherny
J.V. Boyne

RE: Meeting with the EEB to discuss the Ethoprop Level I Avian Field Programs

We have now submitted to the EPA two protocols for Level I avian field studies to be conducted in 1989/90. One study involving the EC formulation will be conducted in New Jersey on potatoes; another involving the 20G formulation in Washington State on potatoes. The Registration Standard states "The Agency encourages registrants to consult with the EEB staff for assistance as needed". We need to request a meeting with the EEB to discuss these protocols and the overall program for avian field studies.

These two studies are required to be completed and submitted in late 1990. In order to characterize the sites and prepare for the 1990 in-life portion of these studies RPAC needs to have the review and advice from the EEB by the first of August 1989. This will still allow time for characterization of additional sites during August and September, if any additional sites are necessary.

The contractor for these studies is Wildlife International, Inc. (WIL). WIL staff and I have developed these protocols in accordance with the Guidance Document for Conducting Terrestrial Field Studies (EPA 1988); however, the guidance provided by this document is very general. Accordingly, we must seek the advice from the EEB as to the appropriateness of the methods proposed to an assessment of the potential impact of MOCAP® on birds. This is especially important in light of the recent EEB determination that our previous Level I avian field study on corn was declared "invalid" based on technical issues.

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Warren A. Davis
7 June 1989
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There are a number of specific technical issues that need to be addressed in a meeting with a reviewer(s) in EEB:

A WIL proposal for combining search efficiency and predator removal rates (this is included in both protocols which have been submitted). *fine, but avoid specifying [illegible] and explain rationale for number eventually used*

Adequacy of the number and diversity of residue analyses needs to be addressed. WIL and RPAC have proposed a residue program within each Level I protocol, but would like to have EEB advise that the proposed analytical programs are adequate. The Guidance Document is very general in this area. *Difficult to tell since protocol does not tell how residue data will be used.*

Are the number of fields per study area adequate? We have proposed to study 8 treatment and 4 control plots. *probably [illegible] possible [illegible] since protocol differs from recommended [illegible]*

Will the granular study with MOCAP® 20G serve to protect the other granular products, 15G, 10G, and 5G. *[illegible] it works this way but must be justified*

Is the current program with two Level II studies in 1989 adequate to protect all other crops, geographic regions, and use patterns? *(do you mean Level I) possibly*

RPAC should pursue these specific technical questions and the general questions. The most important question is when will the EEB sign off on these protocols? *[illegible]*

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