EEB FILES

9/26/89

NOTE TO TERBUFOS FILE

SUBJECT: Meeting between EEB and American Cyanamid Co. re: status of terrestrial field study (Level II) in corn and data requirements for other uses and formulations of terbufos.

FROM: Dave Warburton, EEB

EEB (Jim Akerman, Norm Cook, Dave Warburton) met with American Cyanamid Company (William Stellar, Jim Gagne, Mark Galley, Tim Peoples) 9/25/89 to discuss EEB's reviews of American Cyanamid's proposed and on-going field study efforts and the new granular formulation of terbufos. Because of the Special Review status of terbufos, Special Review Branch was also present. The meeting was initiated at the request of American Cyanamid (see attached).

The issues/questions raised by American Cyanamid and EEB's response to each are outlined below.

1. American Cyanamid did not receive EEB's review (dated 6/29/89) of their most recently revised protocol for conducting the on-going field study until this month. American Cyanamid is therefore responding to the review at this time, addressing the following issues:

a) Application Rate - American Cyanamid is amending the maximum label rate to be 1.3 lb ai/acre at-plant.

EEB acknowledged this, but repeated the issue raised in the EEB review of 7/7/89 (Record No. 240667) - Registrant Response to FRSTR): that even at a 1.3 lb ai/acre rate, effects may still occur; therefore, screening studies evaluating the use of terbufos at this rate are needed to determine if effects are not occurring.

b) Study Site - American Cyanamid believes they've adequately justified their study sites and requested guidance from EEB on how to further support their case.

EEB suggested American Cyanamid <u>specifically</u> address <u>all</u> concerns and comments raised by EEB in the 6/29/89 and previous protocol reviews.

3 pages w/Attachments

c) Sample Sizes - American Cyanamid justified current design by 1) maintaining that it is difficult to achieve a "classical" repetition in a study such as this, 2) using the "best scientific efforts" to get an understanding of field effects, 3) questioning what a "true replicate" really is - in this case, the individual organism may be considered a replicate, and 4) maintaining they will get "pretty good statistical power" from this design. American Cyanamid questioned if it would be appropriate to analyze data in a manner similar to Clayton Stunkard's design discussed in the Avian Dialogue group meetings.

EEB repeated concerns raised in proposed protocol reviews - that EEB does not understand how the required degree of statistical sensitivity and power can be achieved with the current design. EEB noted that any design needs to be determined based on preliminary study efforts, and should be justified by more than a qualitative (e.g., "pretty good") line of reasoning.

d) Species Selected - American Cyanamid believes the species targeted for study are appropriate and will address EEB concerns noted in the 6/29/89 EEB review.

American Cyanamid concluded by requesting a 2 month extension of the final report due date for this field study - from 12/31/89 to 3/1/90. EEB told American Cyanamid the company would have to make that request through Registration Division.

2. American Cyanamid requested guidance on what data would be required to support terbufos use on sugar beets and sorghum, since these uses would represent the highest label rates after the corn use rate is lowered.

EEB's response was that the current field study (corn) results should be submitted and evaluated by EEB before this issue is addressed.

3. American Cyanamid has not received any reviews from EEB re: data American Cyanamid submitted as an interim report in the field study effort.

EEB will follow up on this to determine if data were reviewed, and will make sure review is forwarded to American Cyanamid as soon as possible. American Cyanamid responded by suggesting the company meet with EEB soon after this review is received by American Cyanamid.

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4. American Cyanamid provided preliminary results of pen study efforts which the company believes adequately demonstrates that the new 20CR formulation of terbufos is less hazardous to nontarget species than the 15G formulation. As a result, American Cyanamid requested a 1-year extension in their Conditional Registration requirements for 20CR which apparently state that a Level II study for this formulation must be initiated during 1990.

EEB's response: 1) American Cyanamid should clarify with Registration Division exactly what is currently required in the Conditional Registration and what the due dates are.

2) American Cyanamid should complete the pen study and submit a final report to EEB.

3) The 15G field study results should be considered in conjunction with the above data to determine what the data requirements for 20CR should be.

CYANAMID

THIS SUBMISSION CONTAINS NO 40 CFR 158 DATA

American Cyanamid Company
Agricultural Research Division
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Princeton, NJ 08540
(609) 799-0400

September 20, 1989

Office of Pesticide Programs
Document Processing Desk (RS-0109)
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attention: Mr. Phil Hundemann

Re: Counter® insecticide-nematicide, EPA Reg. No. 241-238 and
Counter® insecticide-nematicide, EPA Reg. No. 241-314
Agenda for the Meeting with EEB of September 25, 1989

Dear Mr. Hundemann:

As you requested, I am submitting an amended agenda for the referenced meeting with you, Ms Rossi, Mr. Harrison (or his representative), Mr. Akerman and members of his staff.

The items that need immediate review and decisions are as follows:

1. To discuss the June 29, 1989 EEB review of American Cyanamid's Protocol for carrying out the required Level II Terrestrial Field Study for use of COUNTER 15G on corn.

2. To review the July 7, 1989 EEB review of American Cyanamid's June 22, 1989 (Nine Month Required Submission of the Second Round Registration Standard) proposed new COUNTER 15G and 20 CR labels where proposed lowering of the corn use rate leaves the highest rates on the label for sugar beets and sorghum and thus may 'alter the emphasis of the field test requirement specified in the standard'!

3. To review the EEB review of the data submitted on February 1, 1989 in the report titled Laboratory Simulated and Actual Field Testing to Assess the Impacts of COUNTER on Non-target Organisms (Guideline No. 71-5, Level II). American Cyanamid has not received this review as yet?

4. To present results from a recently carried out pen study comparing the formulations COUNTER 15G and 20 CR under banded and in-furrow treatments with Quail and Brownheaded Cowbirds.

5. To review with EEB, Registration and Reregistration Branch personnel the Conditional Registration Requirement for a Level II Terrestrial Field Study for COUNTER 20 CR (XL).

Respectfully submitted and requested,

AMERICAN CYANAMID COMPANY
Agricultural Research Division

Mark W. Galley

Mark W. Galley
Sr. Product Registration Manager
U. S. Regulatory Affairs

MG:sd
Enc.

cc: Mr. J. Akerman
Mr. H. Harrison
Mr. W. Miller
Ms L. Rossi ✓

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CYANAMID

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September 1, 1989

Mr. William H. Miller
Product Manager (16)
Registration Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall, Bldg #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Avian Level II Studies on COUNTER® systemic insecticide-nematicide and COUNTER® XL systemic insecticide-nematicide, EPA Reg. Nos. 241-238 and 241-314, Respectively

Dear Mr. Miller:

American Cyanamid Company requests a meeting with representatives of the Registration Division (at least to the Branch Chief Level) and scientific reviewers in the Ecological Effects Branch who are familiar with our efforts to conduct a satisfactory Level II avian study in Iowa. We also request the presence of the Branch Chief of Ecological Effects. As you are well aware, we are in the second and final full year of the Level II study for our EPA Reg. No. 241-238 under 3(c)(2)(B) timeline constraints. As you are further aware, our letter of February 6, 1989 requesting final approval of the protocol for the 1989 study has NEVER BEEN ANSWERED. Because of the 3(c)(2)(B) constraints we proceeded with the program utilizing procedures that were considered the best scientific approaches by our advisor, Dr. Ronald Kendall. Further, in our letter of June 22, 1989 addressed to Mr. Phil Hundemann, we pointed out on page 3:

> "As a follow-up to our August 17, 1988 meeting, we invited Agency personnel to observe the study while it was in progress. From May 30 to June 1, 1989, EEB personnel visited the study sites and observed the study. At that time we were surprised to learn that the Agency had not completed its review of our data or our proposed protocol. Obviously, we are deeply concerned that this circumstance occurred. We, therefore, respectfully request a meeting with J. Akerman and his designees to learn, after the fact, what the Agency's position on our study might be." (The data referred to was submitted on February 14, 1989, and described the results for 1987 and 1988 of our Level II study.)

Our continuing efforts to satisfy the Agency's concerns for avian species by conducting this advanced study program in an evolving dynamic scientific area which will cost approximately 3.5 million dollars (twice a full human toxicology package) coupled with the Agency's complacency is disturbing. Hence, our request for a meeting on this issue is being repeated.

Further, we require a discussion with respect to the conditional requirement for an additional Level II study on the other end-use product of the same active ingredient, COUNTER XL (EPA Reg. No. 241-314). There are two aspects to this discussion:

1) We do not believe this study is necessary because of the results obtained in a recently conducted confined pen study comparing the 15-G and 20 XL formulations. We will present a summary of this data at the September meeting and commit to a report timeline.

2) If we perform the study, we will need a one year extension. The scientific rationale for this extension is as follows: We have the sites in our Iowa study for the 15-G formulation which have been studied thoroughly for two years. Hence, we have a very complete and unique data base. However, these plots need to be rotated to soybeans because they have been in continuous corn for two or three years. When we rotate to soybeans all of the plots can be considered as "controls" and utilized in a reduced program to estimate the variances of key response variables in the species selected for study. We would also track how these response variables change over time. With this information in hand, we could further refine our study design for a study on 20 XL in the 1991 growing season, if such a study is required.

We request that this meeting be conducted during the weeks of September 18 to 22 or September 25 to 29. If you require any additional information, please feel free to contact me at your convenience on (609) 799-6315.

Sincerely,

AMERICAN CYANAMID COMPANY
Agricultural Research Division

William A. Steller, Manager
U.S. Regulatory Affairs

WAS:sd

cc: J. Akerman
H. Harrison