

232000
RECORD NO.

SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 11-9-88 OUT 1-6-89

FILE OR REG. NO. 16-758

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 9-8-88

DATE RECEIVED BY EFED 11-8-88

RD REQUESTED COMPLETION DATE 12-8-88

EEB ESTIMATED COMPLETION DATE 12-8-88

RD ACTION CODE/TYPE OF REVIEW 350

TYPE PRODUCT(S) : I, D, H, F, N, R, S Insecticide/Nematicide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. W. Miller/M. Mautz (16)

PRODUCT NAME(S) Counter (Terbufos)

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Registrant submission of minutes of
8/17/88 meeting with EEB personnel request
for concurrence

SHAUGHNESSEY NO. _____ CHEMICAL, & FORMULATION _____ % A.I. _____

2 pages w/ attachments



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

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Registrant Minutes of 8/17/88 Meeting on
Terbufos Field Study

FROM: Ed Fite, Wildlife Biologist
Ecological Effects Branch
Environmental Fate & Effects Division (TS-769C)

Ed Fite 1/10/89

THRU: Norm Cook, Acting Branch Chief
Ecological Effects Branch
Environmental Fate & Effects Division (TS-769)

Norman P. Cook 1.10.89

TO: William Miller
PM Team 16
Registration Division (TS-767C)

Mr. Miller,

We have reviewed the minutes of the Terbufos Meeting submitted by American Cyanamid Company. In general, they appear to reflect the discussions which took place at the meeting. If we can be of further assistance on this issue, please let us know.



American Cyanamid Company
Agricultural Research Division
P.O. Box 400
Princeton, NJ 08540
(609) 799-0400

September 8, 1988

Mr. William H. Miller
Product Manager (16)
Registration Division (TS-767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall, Bldg #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: COUNTER^(R) systemic
insecticide-nematicide
(terbufos)
EPA Reg. No. 241-238

Dear Mr. Miller:

American Cyanamid Company's (ACCO) summary and understanding of the August 17, 1988 meeting pertaining to the avian studies for the referenced product are as follows.

Attendees at the meeting were:

M. Mautz	EPA, Registration Division
J. Akerman	EPA, Branch Chief Ecological Effects Branch
E. Fite	EPA, Ecological Effects Branch
D. Warbourton	EPA, Ecological Effects Branch
J. Gagne	American Cyanamid Company
M. Galley	American Cyanamid Company
W. Steller	American Cyanamid Company

The meeting was introduced by W. A. Steller who stated ACCO's concerns pertaining to conducting a research program under the timeline restraints of the FIFRA Section 3(c)(2)(B) letter.

Dr. Gagne then outlined the chronology and efforts of ACCO to comply with the FIFRA Section 3(c)(2)(B) letter requiring a Level II avian study for terbufos. In the Guidance Document for the registration of terbufos we were required to perform a 71-5 (Level I) study. We performed the study in Maryland and submitted it in 1985. This study although scientifically sound, triggered the requirement for a multi-year, multi-site study in field corn under actual use conditions to

September 8, 1988

address the question of population effects. We were required to develop a protocol for this sophisticated study under the aforementioned 3(c)(2)(B) letter. To accomplish this we retained five experts in this area. (Candidate names were obtained from Chris Wilkinson and Harold Bergman.) Three of these consultants were Ron Kendall, Lyman McDonald, and Richard DiGiulio. After sharing our data and correspondence with them we asked them to help us develop a comprehensive research program to address, as well as possible, the avian population effects of terbufos. This approach was utilized because we realized that we did not have the basic knowledge pertaining to the hazard equation - toxicity and exposure. More specifically we did not know the relationship between time after poisoning, biochemical indicators, and body burden. We were further confounded by the fact that dead birds with no detectable residues were found in the Level I study. We also had no evidence of how various species might be exposed or what species might be tractable experimentally. Hence, we did not know how to design a field study. Therefore we asked our consultants to design a comprehensive laboratory semi-controlled field study, and a full scale field study research program.

This proposed protocol was submitted to the Agency in February 1986. It was reviewed by J. Bascietto and accepted with minor revisions in October 1986. When we were in the process of revising the protocol to address Agency comments we became aware that a Guidance Document was being developed. In spite of the uncertainties we proceeded with our research program in 1987. Attachments I & II, distributed at the meeting, summarize our research efforts. Dr. Gagne explained in detail the difficulties we encountered to obtain the current treatment plots and distributed a copy of one of the contracts (Attachment III). He elaborated on the impracticalities of extending our research program to the thirty plots proposed in the Guidance Document. (This was well explained in Ron Kendall's letter, dated July 8, 1988, attached to W. A. Steller's letter of July 13, 1988.)

At this point J. Akerman stated that he wanted the complete final reports (hopefully one submission but two would be satisfactory) by December 31, 1988 with our proposed research plan for the 1989 season. He was appreciative of Gagne's summary and said that if the reports documented the summary he feels that ACCO has demonstrated a good faith effort and that he would recommend to the Registration Division another time extension if required. He did make it clear that the final decision is Registration Division's. J. Akerman further stated that he desires to continue the dialogue because he understands the difficulty of these studies. The Agency's position with respect to submitting data to satisfy the avian concerns is rigid, however, the Guidance Document is a dynamic document which can be modified in conformance with compound-specific research data.



Mr. W. H. Miller
Terbufos Meeting

-3-

September 8, 1988

When the Agency receives our reports for the 1987 and 1988 avian research (and ACCO's research proposal for the 1989 season on the same field plots as currently being utilized), immediate review will occur and ACCO will be advised as to any modifications for the 1989 program.

ACCO would like to thank the Agency personnel for this opportunity to summarize our research efforts and their desire to continue a dialogue on this important sophisticated research program.

Again, ACCO would like to invite any interested Agency personnel to visit our plots on which this study is being performed.

Very truly yours,

AMERICAN CYANAMID COMPANY
Agricultural Research Division

A handwritten signature in cursive script, appearing to read 'William A. Steller'.

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

WAS:sd

(R) Registered Trademark of American Cyanamid Company

COUNTER® systemic insecticide-nematicide

Avian Research Program

<u>Year</u>	<u>Activity</u>
1987	Iowa site selection (11 plots, 1,760 acres) Pilot study on 2 plots Acetylcholinesterase Inhibition and Recovery - quail and deer mouse Pen study - Bobwhite and house sparrow
1988	Pilot study (9 plots) Toxicity to passerines

Submission of reports on all the studies listed above, even though field study results are not due until 12/31/89.

COUNTER® systemic insecticide-nematicide**Avian Research Program Highlights**

- o Inhibition of brain AChE is not well correlated with symptoms of poisoning and death.

To assess exposure we have switched to plasma acetyl- and butyryl cholinesterases. These are reactivated using 2-PAM, providing degree of inhibition.

- o The onset of poisoning symptoms occurs very quickly, and animals that recover do so within a few days.
- o Quail and sparrows, even when penned directly over soil treated at 1.3 lb ai/acre, are not exposed to lethal doses of COUNTER. Thus, exposure by dermal and inhalation routes is low. Also, these birds obviously do not seek out granules as grit.
- o COUNTER 15-G granules are very difficult for researchers to see. Drag chaining is a very effective method of incorporation.
- o In a very wet year (1987) a major route of exposure was via earthworms. The granules themselves were not a major route of exposure.

Earthworms have also been shown to be a route of exposure for aldicarb - effects were noted in robins and starlings.

- o Earthworms were not an important route of exposure in a very dry year (1988).
- o We demonstrated exposure of rabbits and deer mice, but levels of mortality were low.
- o Quail and pheasant were not exposed.
- o The rate of nest failure is very high in passerines - either on treated or untreated plots.