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DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Terbufos (Counter 15G)

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Submission of extension request to perform avian field study to support corn use

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% AI
	Terbufos	15

8 pages

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

22 MAY 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: American Cyanamid's Request for Extension of Time to Perform an Avian Field Study and Submission of Study Plans for Terbufos Avian Field Study

Record No. 192538

FROM: John Bascietto, Wildlife Biologist
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Hazard Evaluation Division (TS-769C)

THRU: Douglas J. Urban, Section Head
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THRU: Michael W. Slimak, Chief
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TO: William H. Miller, PM 16
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Registration Division (TS-767C)

Background

American Cyanamid Company has submitted a study plan for an avian field study of terbufos. The Agency required an advanced study after a previous carcass search study of terbufos (Dingledine 1985) failed to rebut the presumption of hazard. An advanced level field study under 158.145 (71-5) is required to quantify the hazard.

Cyanamid submitted a protocol, dated February 24, 1986, which attempted to address the level II study. EEB conditionally accepted the protocol (EEB review of protocol signed-off in July 1986 - attached), but conditioned acceptance upon incorporation of modifications contained in EEB's review and upon a meeting with the Cyanamid to discuss questions we had, and to clarify the modifications to the protocol. Cyanamid

has failed to address our questions, and no meeting has occurred on the conditionally accepted protocol. EEB had not been contacted further on the protocol until this submission. Therefore, EEB has determined that the conditions of accepting the February 24, 1986 protocol have not been met.

Cyanamid contends that the current submission (i.e., the "study plan" herein reviewed) demonstrates that they are working to address the Agency's concerns for terbufos' effects on birds. Cyanamid further contends that a time extension for the advanced field study under 158.145 (71-5) is justified based on a letter from Dr. John Moore (AA/OPTS) to Dr. Jack Early (NACA) dated February 10, 1987, which indicates that a revised terrestrial field study Guidance Document will be available in April 1987 (Dr. Moore's letter is attached). Cyanamid requests that they be allowed to submit a "revised February 24, 1986 protocol" after a revised Guidance Document issues. The company estimates that it will require about 1 month to study the revised guidance and modify their protocol to comply with it.

EEB's Review of Study Plans

The "study plans" submitted do not constitute a revised protocol. The study plans are inadequate in this respect because:

1. The registrant fails to address the issues, criticisms, comments, and questions in EEB's review of the previous (1986) protocol.

2. The study plans merely provide a cursory description of the approach they plan to take. There are no specific discussions on theory justifying their approach or methodologies.

3. There is no site description.

4. There are no schedules.

5. There are no lists of personnel or facilities.

6. There are no provisions for QA.

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It is unclear just how the acetylcholinesterase study will be useful in the larger context of the avian field study.

The numbers, size, and independence of the study plots appeared to be unchanged from the 1986 protocol, but even this is unclear. It appears that they are proposing three test blocks for each banded and in-furrow application, plus a control block. Thus, a hypothetical test would appear to be planned. A problem with this approach is that it sets the limits of the study plots before deciding on which species will be studied for population parameters. It is unclear whether the plots described in the 1986 protocol are sufficient for the population study. The study plan did not discuss the design, or how the design is relevant to the issues being investigated.

The study must be designed to measure population parameters and to provide information which the Agency can use to understand possible changes in population levels that may be due to the effects of the pesticide. This will likely necessitate performing a study over multiple years. The study should be replicated, but to make it practicable, a realistic number of replicates will probably mean that the investigators will have to sacrifice rigorous statistical power.

The study plan does mention some of the appropriate approaches for the advanced level field study, which include:

- Residue analysis;
- Enzyme analysis;
- Behavioral analysis;
- Organism density estimation;
- Radio telemetry;
- Nest monitoring; and
- Mark recapture.

The investigators should now incorporate these approaches into a systematic and purposeful protocol document.

Identification of appropriate study species is going to be of paramount importance to this type of study. Cyanamid should identify the susceptible bird species to focus on in the population study. This can be done by using the available data base. EEB noted that the company plans to study bobwhite quail and starlings. Although nest box methods may be available

for starlings, their sensitivity to terbufos is unknown (EEB has no LD_{50} data for terbufos vs. starlings); bobwhite quail are not the most sensitive species to terbufos, although they may be satisfactory for the enzyme study.

EEB noted similar species issues for the proposed secondary mortality work. The study plans mention American kestrels and red-tailed hawks. EEB notes that kestrels may not be suitable for the study because of their insectivorous habits. Although they do take mice they are also insectivorous when insects are available. This may result in an insufficient secondary exposure. With granular formulations (Counter 15G is a granular) the hazardous secondary exposure may be more frequent through ingestion of contaminated mice and small bird carcasses killed after applications (although insects will probably contain some residue from granular applications also). Red-tailed hawks could be an appropriate species for radiotelemetry experiments if they are susceptible to terbufos (laboratory experiments should be performed first to determine the toxicity of terbufos to the species which will ultimately be radiotagged).

As written, the study plan will probably fail as a study of secondary mortality, primarily because it appears that the secondary toxicity study will be dependent on the sites chosen for the larger population study. Based on experience with previous secondary toxicity studies performed incidental to the other field work, there will likely not be appropriate exposure of a sufficient number of raptors if the study sites are selected without regard to the home ranges of the subject raptors. Radiotelemetry should first be used to establish sufficient home range data on raptors. Treatments of pesticide should be made within the home ranges. This will likely require separate, multiple sites, and it is recommended that the secondary toxicity study be performed independently of the other population studies.

The study plans also mentioned meadowlarks, mourning doves, rufous-sided towhees, song sparrows, and robins as "ecologically appropriate" species to study. The LD_{50}/LC_{50} for terbufos should be determined prior to selecting study species.

The reproduction study for bobwhite quail and ring-necked pheasant called for three hens per species. This appears to be a rather limited effort.

The granule counting study is not an EEB requirement. Exposure is not at issue for EEB's purposes. However, an exposure study may be useful for estimating the effects of

banded or in-furrow treatments, if the potential effects can be influenced by reducing the surface exposure of granules. The methodology described for the granule counting study ("blow-up" photographs of soil surfaces will be used to "count" granules per unit area) is of unknown utility. Studies using fluorescent granules are discussed in the literature (Erbach and Tollefson 1983) and have had limited success in estimating granule exposure.

Request for Extension of Time to Submit Protocol

Issuance of a revised terrestrial field study Guidance Document notwithstanding, EEB indicated a willingness to work "case-by-case" with Cyanamid on the 1986 protocol (see attached EEB review). Indeed, EEB conditionally accepted the 1986 protocol; Cyanamid has apparently failed to fulfill the conditions of acceptance. Since EEB indicated its willingness to give specific guidance to Cyanamid on the advanced study, the extension request does not appear justifiable on the basis of the guidance issue.

EEB recommends that American Cyanamid be required to submit a protocol which will address this field study requirement within 3 months of being notified by EPA of this determination. EEB anticipates that the scope of the study necessary to quantify potential population effects will be 2-4 years at a minimum. Therefore, EEB recommends that a data call-in letter be issued to American Cyanamid immediately, which in addition to requiring the protocol, also indicates that a full report of the first year's work of this multi-year study be filed with EPA no later than December 31, 1988. This will allow a sufficient amount of time to receive and review the protocol, notify Cyanamid of protocol adjustments, if any are necessary, and allows Cyanamid to begin field work with the 1988 spring planting season (May, 1988).

The results of the initial studies will be essential when planning the nature and extent of subsequent work. The proposed schedule should allow for a logical transition to subsequent year's work. The object of this review schedule is to minimize disagreements on the protocols and the progress of work, and should result in the most expedient conclusion of the multi-year study. The conclusion of the study will

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largely depend on what, if any, effects are detected in bird populations, and on what work is proposed to quantify said effects should any be detected. However, in any case the data call-in letter should indicate that a final report is due on Dec. 31, 1991. Other due dates notwithstanding, annual reports are due on 31st of December of each year of the study.

Based on EEB's experience with other registrants performing avian field studies, December due dates for the annual reports is ample time for the registrants and consultants to file their report of work initiated in the spring.

Summary of Due Dates for the Data Call-In
On The Terbufos Multi-year Avian Field Study

90 days after notification to American Cyanamid of results of this review	protocol
Dec. 31st, 1988	1st annual report
Dec. 31st, 1989	2nd annual report *
Dec. 31st, 1990	3rd annual report *
Dec. 31st, 1991	final report **

* a determination may be made at this time to conclude the study, in which case a final report will be due 3 months after notification to American Cyanamid.

** This due date applies if the study has not been determined to be concluded by earlier reviews.

References

Dingledine, J. (1985) An evaluation of the effects of Counter 15G to terrestrial species under actual field use conditions. Performed by Wildlife International, Ltd.; submitted by American Cyanamid Corporation, Princeton, NJ; OPP Accession No. 256982.

Erbach, D.; Tollefson, J. (1983) Granular insecticide application for corn rootworm control. Transactions of the ASAE - 1983. American Society of Agricultural Engineers 0001-2351/83/2603-0696.

Attachments