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19
REVIEW NO.

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DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller

PRODUCT NAME(S) Counter 15G

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Submission of Protocol For Review

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105001	terbufos	15

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

13 APR 1984

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Marilyn Mautz, PM Team 16
Registration Division TS-767c

THRU: Dave Coppage, Head Sec. 3
Ecological Effects Branch/HED TS-769c

THRU: Clayton Bushong, Chief
Ecological Effects Branch/HED TS-769c

SUBJECT: Comments on American Cyanamid's Proposed Terrestrial Field Study Protocol for Counter 15G (Terbufos)/Corn Use.
(Re: Wildlife International Protocol 032084/P5; Draft 4).

American Cyanamid has again proposed a protocol to study the potential effects of terbufos on terrestrial non-target organisms, when used on corn field study protocol drafted by Wildlife International - protocol No: 032084/P5, Draft 4; submitted 3-28-84). This study is required by the terbufos registration standard.

The submitted protocol is not acceptable to EEB because the information to be derived from this protocol will not be of use to EPA in assessing potential field hazards, nor will this protocol suffice to demonstrate environmental safety.

guidelines criterion

American Cyanamid's protocol proposes to use Bobwhite quail (Colinus virginianus). While this species is usually acceptable for guidelines laboratory studies, the Agency may require other species to be tested if information available indicates such a need. In the case of terbufos, EEB is aware that Bobwhite quail is not the most sensitive bird species expected to be exposed in the corn use. EEB's scientists have determined, in actual laboratory tests, that passerine species such as redwinged blackbirds (Agelaius phoeniceus) and House sparrows (Passer domesticus) are killed by as little as 5-10 granules of Counter 15-G (average granule estimated to contain 0.015 mg a.i. terbufos). It is estimated that on the basis of technical terbufos toxicity two-hundred sixteen (216) 0.1 mg granules would be required to achieve the bobwhite quail LD_{50} = 26 mg ai/kg. Extrapolations from laboratory findings (see terbufos Disciplinary Review by Felkel, 12/16/82) indicate that with an an LD_{50} of ten (10) 0.1 mg granules per redwinged blackbirds, the LD_{50} is estimated as 0.15 mg. a.i./bird. Counter 15G granules are less toxic as a formulation than technical terbufos to Bobwhite quail in laboratory studies (technical terbufos LD_{50} = 15 mg. a.i./kg.; Counter 15G LD_{50} = 26 mg ai/kg - Pers. Comm. R. Balcomb, EEB, based on the work of E. Hill of Patuxent Wildlife Research Center, USFWS, Laurel, MD.). For the above reasons EEB believes that Bobwhite quail is not the test species of choice for a simulated pen or actual field study of terbufos. The proposed protocol

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may not directly expose small mammals, which may be much more sensitive than birds, yet the protocol purports to "provide a more comprehensive evaluation of potential effects of Counter 15G on terrestrial species".

American Cyanamid's protocol is a "simulated" field study. The terbufos registration guidance issued June, 1983 clearly calls for an "actual" field study. The utility of a "simulated" field study at this point in the terbufos review is very questionable. The Agency has already reviewed and accepted a "simulated" field study of terbufos (Labisky, 1974). It is concluded however, that the "simulated" pen study of pheasants could not provide the data necessary to evaluate the potential effects on terrestrial organisms because the most sensitive species (passerine birds, small mammals) were not examined and because the exposure in the "simulated" pen study did not represent the potential exposure of "actual" use. A pen study does not provide a realistic setting in which to properly assess potential field hazards, but can serve to indicate the need for actual field testing. The results of a "simulated" test may be interpreted in different ways; e.g., one might argue that any adverse effects observed are due to the "unrealistic" (intensive) exposure in cages or pens, and therefore the utility of the "penned" study would be equivocal at best. Since terbufos has been estimated to be used in 25% of all corn insecticide treatments, it is judged imperative that a complete, realistic, and unequivocal field study be designed in order to obtain the maximum amount of useful information about the potential effects of this very highly toxic and widely used pesticide.

Such a field study would of necessity require careful controls. The proposed protocol does not provide the necessary assurance of control. The protocol states that "control sites for both bird nesting surveys and for penned bobwhite may be used if desired". The protocol proposes to use "pre-treatment evaluations" as "controls". This is unacceptable. Field studies must use concurrent untreated control areas throughout the entire course of the study.

The proposed protocol does not specify the size of plots to be tested (a blank space for size of plots is given, with what appears to be an erased figure for plot square footage- p. 2 and 4). This is unacceptable. The proposed protocol (p.1) purports to provide an "extensive field monitoring program". EEB agrees with the treatment schedule and monitoring schedule but disagrees that the efforts proposed represent "extensive" field monitoring. The authors apparently refer to the number of monitoring events. The size of the field study (30 acres with adjacent fields and woods) is not considered "extensive" by EEB. Even if dead birds and mice were found, the size of the experiment would preclude drawing any meaningful conclusions concerning potential non-target effects. We already know the pesticide will kill birds and small mammals. Treating a single 30-acre field is judged inadequate to provide enough potentially exposed, sensitive terrestrial non-targets in order to draw useful information to assess overall risk to local, regional, or national populations.

Fields studies recently evaluated by EEB show that very useful data is obtained by evaluating a pesticide's potential impact on 8-10 different fields, utilizing concurrent untreated control fields and extensive search methods; preferably with "sentivity" of the searchers and search methods tested by pre-treatment searches, utilizing real (dead) birds placed out for

searchers to locate. Real birds rather than "decoys" should be used to simulate disappearance of carcasses under actual field conditions (i.e., real carcasses may last as little as one (1) day or less before disappearing e.g., due to scavengers).

The multiple treated field technique should utilize 8-10 actual corn fields, preferably of approximately 20 acres each. Concurrent control fields should be available. Carcass searches include field edges, adjacent woods, hedgerows, fallow fields, etc. to account for birds and/or mammals dying outside the corn field. A collection of living passerine and mammal species should be made. These should be examined for GI tract residues and contents and measurement of cholinesterase inhibition. All dead carcasses should be similarly examined. The results from live-collected passerines could be compared to results from Bobwhite quail pen studies concurrently run. (EEB believes this would be the proper role for "simulated pen" studies at this point in the terbufos hazard assessment).

Cholinesterase (AChE) determinations should be made on the same sampling schedule as used for carcass searches (we agree with the sampling schedule on p. 6 of the proposed protocol). EEB has strong reservations concerning the use of "photometric" cholinesterase determinations such as the "Ellman method" proposed by this protocol. Photometric methods introduce many uncontrolled variables (e.g., pH, gas bubbles, non-enzymatic hydrolysis, color complexing agents), generally do not characterize the enzyme, and may not use "normal" or appropriate enzyme substrates. The uncontrolled variables may contribute to a lack of a good diagnostic correlation between enzyme activity and treatments. Unless a good diagnostic correlation between AChE inhibition and mortality is demonstrated in the results of the registrant's field study, the entire cholinesterase effort may not be acceptable. This could contribute to rejection of the field study or at least lead to serious questioning of its usefulness in hazard evaluation. EEB strongly suggests that the registrant consider using the "pH-stat" method (Coppage 1971, 1977; Coppage et al 1975) and characterization of the enzyme, for the cholinesterase work because of the demonstrated greater accuracy of this method (Dixon & Webb, 1964; O'Brien, 1960; Witter, 1963).

We approve of the protocol's "Residue Sampling" section on p. 7 - "Birds/ Mammals", "Invertebrates", and "Soil & Vegetation Sampling" but would like to see more details worked up on numbers, schedule, and residue methods. Again we would need to add the GI tract residues and AChE work for "living" passerines. All work should be duplicated for the caged bobwhite portion of the field study.

Cholinesterase work-ups should not be postponed "14 days after each application "as proposed on p.8 of the protocol. Enough caged birds should be available for sacrifice at each of the field monitoring events, so that a statistically valid analysis of cholinesterase effects, if any, can be made. Of course concurrent control birds must also be analyzed. Wild birds should be compared to the caged results at each field monitoring event.

Complete residue and cholinesterase work-ups must be performed on all dead animals.

Finally, we must agree on the method of transect analysis for the carcass searches. This is not adequately described and the details are proposed to be "further identified once specific sites are selected". The registrant has the options of consulting with EEB for final approval of transect methods, which must be detailed in writing, or of accepting a method provided by EEB in writing. The registrant is advised that the transect sampling method is considered to be of primary importance in determining the acceptability of the final study report. If a problem arises with the transects (i.e., registrant fails to obtain written approval of transect method, and the method is rejected) we could be left with an unacceptable field study.

At this point it looks as if EEB and the American Cyanamid are quite far apart on what needs to be done in order to achieve a useful and valid field study for terbufos. We advise that many issues should be resolved to our mutual satisfaction before any field work is undertaken.

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Ecological Effects Branch/HED TS-769c

(1) Attachment: Refernces cited

cc. R. Balcomb, EEB

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