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EEB BRANCH REVIEW

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

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. W. Miller

PRODUCT NAME(S) Counter

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Submission of Revised Terrestrial

Field Protocol

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

105001 terbufos _____



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

MAY 17 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

THRU: Dave Coppage, Head Sec. 3 *Dave Coppage*
Ecological Effects Branch
Hazard Evaluation Division, TS-769c

THRU: Clayton Bushong *Clayton Bushong*
Branch Chief
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SUBJECT: Review of Revised Avian Field Study Protocol - Counter 15G/Corn;
No. 050284/P6 by Wildlife International, Ltd. (W.I.).

The subject protocol was submitted by American Cyanamid to support re-registration of terbufos, specifically Counter 15G granular insecticide for corn.

The submission is acceptable and incorporates most of what was agreed upon by EEB and the Company at our meeting of April 25th, 1984. Since this field study is already underway, all parties (EEB, American Cyanamid and W.I.) agreed to remain "flexible" in terms of adjustments to the protocol, as long as the basic thrust of the study was not affected. This is a result of the refusal of the registrant to take EEB's repeated advice to plan this study in less haste by performing "pilot" studies in 1984 and to doing the definitive work in 1985. American Cyanamid however, insisted that both the "pilot" and definitive work be done in 1984. As a result, the study was planned very hastily. The registrant has been advised that this is not prudent. However, we agreed that if "flexibility" to field conditions is maintained, and if a good quality field study would result, that the effort could be made this year (1984).

Specifically, EEB interprets "flexibility" to include adjusting the protocol in terms of the methods used to study birds, i.e., transects of fields v. border searches and total bird "census" v. carcass searches. Methods used will be dictated by prevailing field conditions at each application (8-12 weeks apart), which are expected to be quite different in terms of bird population make-up and levels of difficulty in sampling the various habitats involved (which will not be limited to corn fields). It is specifically for these reasons that EEB repeatedly advised doing "pilot" studies in 1984 and designing a definitive study for 1985 based on the preliminary work.

Not specifically included in this protocol, but yet a very intergral part of this field study, is the subject of residue analysis of dead birds and mammals v. the issue of AChE analysis. The registrant and consultants proposed an AChE method (Ellman or photometric). With this method brain AChE inhibition in both birds which die and those which survive, maybe below the level (50%) at which an AChE inhibition would be implicated in mortality. EEB proposed a more diagnostically reliable method, i.e., "pH stat". The registrant and consultants (W.I.) disagreed.

In our meeting on April 25th, 1984 we specifically agreed to waive brain AChE analysis in favor of residue analysis of body tissues and stomach content analysis. The registrant proposed that they be required only to do "whole body" residue analysis. EEB agreed to this only under the condition that American Cyanamid conclusively demonstrates, through submission of valid laboratory data, that their method of residue analysis is sufficiently sensitive so as to be able to detect "whole body" residues in passerine birds specifically dosed with "minimum levels of terbufos causing mortality". It was agreed that this "minimum dose" will be on LD₂₀ and that laboratory data validating the dose and the methods be submitted to EEB as an integral part of the field study.

The interpretation of the results of this field study may heavily depend on the residue work as outlined above. Thus, this point should be stressed and reiterated to American Cyanamid so that there will be no doubt as to EEB's intentions to view the residue work as an essential part of the study.


John Bascietto
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Ecological Effects Branch Reviews - Terbufos

Pages 4 through 13 are not included. The pages contain a detailed test protocol submitted by American Cyanamid.