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EEB

105001
SHAUGHNESSY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 01/02/86 OUT 03/14/86

FILE OR REG. NO. 16-633

PETITION OR EXP. PERMIT NO. _____

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EEB ESTIMATED COMPLETION DATE 03/05/86

RD ACTION CODE/TYPE OF REVIEW 350

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

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Terbufos Registration Standard

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Registrant response concerning

field monitoring requirements

SHAUGHNESSY NO. CHEMICAL & FORMULATION % A.I.

105001 Terbufos _____

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BASCIETTO:C.Disk:KENCO:3-17-86:eg:MD:TS-769-C:Rm 1102

MEMORANDUM

SUBJECT: 16-633; American Cyanamid Company Response Concerning
Field Monitoring Requirements for Terbufos

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

THRU: Douglas J. Urban, Acting Head Section 3
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Michael W. Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

TO: William Miller, PM 16
Insecticide-Rodenticide Branch
Registration Division (TS-767-C)

Ecological Effects Branch (EEB) has reviewed American Cyanamid's letter to you dated December 8, 1985. This letter discusses a December 6, 1985 meeting between Exposure Assessment Branch, Hazard Evaluation Division (EAB/HED) and American Cyanamid Company. No EEB representatives attended this meeting. Furthermore, prior to this letter, no communications regarding the issues discussed during this meeting were made to EEB. Therefore, we decline to comment on the outcome of this meeting at this time.

The body of Cyanamid's letter discusses modeling (an EAB/HED function) and the Data Call-In requirements to support terbufos. The additional requirement to monitor an estuarine site for terbufos residues was added to the Data Call-In by EPA in a March 11, 1985 letter to Cyanamid. This was partially a result of the estuarine fish kill observed in a Chesapeake Bay tributary after applications of terbufos to corn. Since a very significant amount of corn is grown in U.S. coastal counties, it was judged that applications to corn could present a significant risk of runoff into estuarine environments. Also, EEB is very concerned with the residues of terbufos measured in rivers and streams of the corn belt.

CONCURRENCES							
SYMBOL	TS-769C	TS-769C	TS-769C				
SURNAME	Bascietto	Urban	Slimak				
DATE	3/19/86	4/7/86	4/1/86				

American Cyanamid is wrong in asserting that the request for an additional residue monitoring site did not come from a joint EAB/EEB review. In fact, Registration Division (RD) and Science Integration Staff, Hazard Evaluation Division (SIS/HED), coordinated with both HED Branches to determine the additional monitoring needs (see attachment).

EEB emphasizes at this time that these monitoring studies are not to be confused with "Simulated or actual field testing for fish and aquatic invertebrates" Guideline 158.45 §72-7. The monitoring of residues is a separate requirement of the Data Call-In. We urge you to make this clear to the registrant. The residue monitoring requirements at issue are required under 158.130, Environmental Fate Chapter of the June 1983 reregistration Guidance. The initial three studies must be received no later than June 1986, according to that Guidance Document. It is unnecessary for American Cyanamid to confuse the issue by claiming that the residue monitoring requirements are "a joint EAB/EEB requirement." This is an unnecessary and meaningless exercise to place the exact origination of the requirement. This cannot result in important information and has caused an unnecessary amount of questions between the Agency and Cyanamid, and a very unfortunate drain on EPA's limited resources. Cyanamid should be advised to cease these meaningless arguments concerning the "joint" requirement. The point is that these are Agency requirements of the Data Call-In and all are incorporated to form an integrated hazard assessment.

We urgently suggest that you inform the registrant that time is growing quite short relative to fulfilling the June 1986 deadline for submission of Data Call-In requirements. At this time no scientific information has been received to justify changing the Agency's requirements for ecological effects testing. To the contrary, fish kill and terrestrial poisoning incident reports are increasing, rather than decreasing EER's concern over the active ingredient terbufos.

Our summary of labeling, data and classification requirements for terbufos follows.

Adequacy of Labeling

The current registered terbufos label for ground-applied, soil-incorporated use is inadequate. The label must be changed to read:

This product is extremely toxic to fish, birds and other wildlife. Birds and other wildlife visiting the treated areas may be killed. Cover, or incorporate into soil, granules that are spilled.

Do not apply this product to water or wetlands. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Additional Data Required

A. To support existing registrations of terbufos - (all as per June 1983 reregistration Guidance)

- 72-3 Three (3) Estuarine/Marine Acute LC₅₀'s-(TGAI)*
- 72-4 Fish early Life-Stage and Aquatic Invertebrate Life-Cycle (TGAI)*
- 72-5 Fish Life-Cycle - "Reserved" (TGAI)
- 72-6 Aquatic Organism Accumulation - "Reserved" pending review of other data (TGAI; PAI)
- 72-7 Simulated or Actual Field Test of Aquatic Organisms - "Reserved", pending review of other data (TEP)

- Special Monitoring studies of soil, water, sediments, and fish (TEP).*

- Plus additional pen-by-pen data on two (2) avian reproduction studies submitted under 71-4.*

- 71-5 Field Study of Mammals, Birds and Reptiles

A field study is now required to determine the impact to populations of birds, mammals, and reptiles. This must be a multiyear, multisite study of large-scale corn use under operational conditions.

We currently have a protocol for this study under review.

* Submissions must be received by EPA by June 1986.

B. To support addition of aerial or ground broadcast applications not reviewed at the time of reregistration Guidance:

- All studies cited above plus an aquatic field study as 72-7 under an approved protocol are now required.
- Additional field study under 71-5 to rebut the presumption of hazard (see Special Review Criteria below) by determining the impact to populations of vertebrates. This must be a multiyear, multisite study of large-scale corn use under operational conditions.

Classification

Currently registered ground-applied, soil-incorporated uses must be classified as "RESTRICTED."

No recommendation is made at this time regarding classification of aerial use.

Special Review

Data reviewed suggests that aerial or ground-applied broadcast treatments of terbufos on corn at recommended label rates and in accordance with commonly recognized agricultural practices, may meet or exceed the Special Review Risk Criteria, 40 CFR 154.7.

(3) May result in residues in the environment of non-target organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.

(4) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended.

N.B. - Special Note to the Product Manager and PM Team

Should the Agency not receive the required monitoring data by the established due date (June 1986), EEB will impose the requirement for the aquatic field study (72-7) because of the known hazards to fish, recently reported fish kills, and reported contamination of rivers and streams by terbufos. The imposition of 72-7 will be in the form of a memo advising you of the imposition of this requirement, the ecological evidence linking terbufos to a presumption of hazard, and the need for a 3(c)(2)(B) letter.

Attachment