1-17-90

257117
RECORD NUMBER

036101
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 12/29/89 DATE: OUT

FILE OR REG. NO. 0179

PETITION OR EXP. NO.

DATE OF SUBMISSION 12/26/89

DATE RECEIVED BY EFED 12/28/89

RD REQUESTED COMPLETION DATE 1/12/90

EEB ESTIMATED COMPLETION DATE 1/12/90

RD ACTION CODE 666

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

DATA ACCESSION NO(S).

PRODUCT MANAGER (NO.) C. Grubbs (PM 74)

PRODUCT NAME(S) Trifluralin

COMPANY NAME Dow Elanco and Co.

SUBMISSION PURPOSE Review revised protocol to test for vertebral lesions

SHAUGHNESSY NO.	CHEMICAL & FORMULATION(S)	% A.I.
	Trifluralin	

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Vertebral lesion study protocol to be conducted with trifluralin

TO: C. Grubbs, Product Manager (74)
Insecticide and Rodenticide Branch
Environmental Fate and Effects Division (H-7505-C)

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

EEB submitted comments on the vertebral lesion study proposed by Dow Elanco and Company on August 8, 1989 after a meeting with company representatives. The attached document from Dow Elanco and Co. is a response to EEB's comments.

Basically EEB concurs with the Dow Elanco and Co. responses and amendments to the study protocol. EEB's comments follow the company responses by number.

The protocol will be acceptable with the following clarifications and changes.

Comments 1&2. EEB agrees with starting the test with 30 day old fathead minnows and exposing the animals to trifluralin for 35 days. A post-exposure depuration phase to the study is not necessary.

2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

SUBJECT: Vertebral lesion study protocol to be conducted with trifluralin

TO: C. Grubbs, Product Manager (74)
Insecticide and Rodenticide Branch
Environmental Fate and Effects Division (H-7505-C)

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

EEB submitted comments on the vertebral lesion study proposed by Dow Elanco and Company on August 8, 1989 after a meeting with company representatives. The attached document from Dow Elanco and Co. is a response to EEB's comments.

Basically EEB concurs with the Dow Elanco and Co. responses and amendments to the study protocol. EEB's comments follow the company responses by number.

The protocol will be acceptable with the following clarifications and changes.

Comments 1&2. EEB agrees with starting the test with 30 day old fathead minnows and exposing the animals to trifluralin for 35 days. A post-exposure depuration phase to the study is not necessary.

CONCURRENCES								
SYMBOL	H7507C	H7507C	H7507C					
SURNAME	[signature]	Matheny	Akerman				3	
DATE	1/5/90	1/7/	1/17/90					

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

Comment 3. EEB agrees that the radiographic technique may not be appropriate and a preliminary evaluation of the technique by Dow Elanco is encouraged. However, radiographic data must be submitted along with histological data (from the same fish) to support Dow Elanco's earlier conclusions from the trifluralin field study. To be an acceptable protocol, inclusion of the data generated by the techniques of Couch et al. (1979) will be required.

Comment 4. The proposed range of test concentrations, from 0.6 to 50.0 ppb (about ½ the LC50; nominal concentrations 83, 28, 9, 3, 1 and 0 ppb) is appropriate. This range will also encompass the 1.95 ppb NOEC from a fathead minnow life-cycle study.

Comment 5. The proposed sampling of test concentrations and the proposed analyses scheme is sufficient to meet this specific data need. As proposed, this includes biweekly sampling from each replicate, pooling of samples within each replicate concentration per collection time for analyses, and separate analyses of all replicate samples collected during weeks 1 and 5 of the study to insure no significant difference in exposure concentrations among replicates within a treatment. A total of 112 samples will be analyzed.

Comment 6. The analytical techniques must provide the detection limits stated by Dow Elanco; these are 0.3 ppb in water and the equivalent of 2.0 ppb in 5 gm fish tissue (assuming a concentration factor of 2000 X).

Comment 7. EEB agrees that a minimum of one-third of the 120 fish exposed at each treatment be examined for vertebral anomalies. EEB assumes that these forty fish will be examined both by radiographic and histological methods so that 1) a comparison can be made to determine if both methods give similar results and 2) that the results of this study can be used to interpret the results of a previous field study.

Comment 8. EEB understands that it may not be possible to measure residues on individual fish (see Comment

6). EEB concurs with the pooling of fish within each replicate for each treatment level as necessary to obtain measurable and defensible tissue concentrations.

Comment 9. Inclusion of all raw data in the final report will be required.

A one year period of time is recommended for this study to be completed and submitted to the EPA and is consistent with the amount of time required for an early life-stage study (§ 72-4). EEB recommends that the final report be due no later than December 28, 1990.

This study does not replace a field study. A field study may be required to support continued registration of trifluralin. A continued EEB concern is the need for adequate documentation that surface water concentrations of trifluralin well below the vertebral effect concentrations.

Trifluralin Science Reviews

Page _____ is not included in this copy.

Pages __6__ through _15__ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product inert impurities.

_____ Description of the product manufacturing process.

_____ Description of product quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action

__X__ FIFRA registration data.

_____ The document is a duplicate of page(s) _____

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.