

US EPA ARCHIVE DOCUMENT

MAY 4 1989

242229
Record No.

128825
Shaughnessey No.

44
Review No.

EEB REVIEW

DATE: IN 03-27-89 OUT 05-03-89

FILE NUMBER 279-3069

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 03-15-89

DATE RECEIVED BY HED 03-24-89

RD REQUESTED COMPLETION DATE 04-24-89

EEB ESTIMATED COMPLETION DATE 04-24-89

RD ACTION CODE 300

TYPE PRODUCT Synthetic Pyrethroid

DATA ACCESSION NO. _____

PRODUCT MANAGER G. LaRocca (15)

PRODUCT NAME Capture 2 EC (bifenthrin)

COMPANY NAME FMC Corporation

SUBMISSION PURPOSE Registrant response to previous EEB review
of fish full life cycle study.

| SHAUGHNESSEY NO. | CHEMICAL | %AI |
|------------------|-------------------|-------------|
| <u>128825</u> | <u>bifenthrin</u> | <u>25.1</u> |



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

MAY 4 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Bifenthrin Life Cycle Toxicity Test [Acc. No. 407913-01]

FROM: James W. Akerman, Chief *Norman J. Cook for*
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: George La Rocca (PM-15)
Registration Division (H7505C)

FMC's response to our review of the fish life cycle study (completed 01/25/89) has been determined to be non-persuasive and the study classification remains invalid. The three major contentions by FMC and EEB's response are as follows:

- 1) Control survival was well within the norm for this type of test ...

EEB strongly disagrees. For a life cycle test to be considered acceptable, the average survival of controls (dilution water or solvent controls) must not be less than 80% from 48 hours to 30 days post-hatch and 70% at the end of the test. This is consistent with already established criteria from the ASTM Standard Guide for Conducting Early Life-Stage Toxicity Tests with Fishes and EEB's Fish Early Life-Stage SEP. Minimum control responses established for early life-stage tests are relevant to life-cycle tests because the first 30 days of a life cycle test typically are performed under identical conditions as for an early life-stage test. Stringency is necessary here because the test will generally continue for over 300 days and fish stressed in early development will likely respond unpredictably as adults even if they survive. Likewise, in the bifenthrin test mortalities associated with the first photographic growth measurements indicate a stressful procedure rendering equivocal future responses of surviving fish.

- 2) the variability in reproduction parameters was well within the limits observed in other chronic studies ...

A study where egg production in the lowest dose fish differ from controls by 57% and 76% for solvent control and dilution water control fish, respectively, and which does not allow for a conclusion of statistical significance, as reported by FMC for the bifenthrin study, cannot be considered acceptable for assessing potential reproductive impairment. Impairment of egg production greater than 20% is considered by EEB to be biologically significant and life cycle tests ought to detect effects of this magnitude. An inability to detect a 20% difference is not considered sufficient justification alone to invalidate a study, but it may justify downgrading from a core classification.

- 3) the Agency accepted study protocol ...

The acceptance of a study protocol does not guarantee acceptance of a study. The results of a test must be assessed to ensure scientific credibility. Poor responses in controls indicate stresses or other uncontrolled conditions which prevent unequivocal conclusions. Responses reported for the bifenthrin test do not allow for unequivocal conclusions.

Another fish life cycle test must be performed to fulfill the conditions imposed for Capture registration.