

178642
RECORD NO.

113201
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

OCT 10 1986

DATE: IN 8-12-86 OUT _____

FILE OR REG. NO. 7969-53

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 8-07-86

DATE RECEIVED BY HED 8-11-86

RD REQUESTED COMPLETION DATE 9-11-86

EEB ESTIMATED COMPLETION DATE 9-05-86

RD ACTION CODE, TYPE OF REVIEW 450

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

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Ronilan

COMPANY NAME BASF Corporation

SUBMISSION PURPOSE Review of Mallard Duck Special

Reproduction Protocol

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>113201</u>	<u>Vinclozolin</u>	<u>Unknown</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____



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

OCT 10 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Protocol for special avian study
with vinclozolin (Ronilan)

FROM: Larry Turner, Biologist *Larry Turner*
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Norman J. Cook, Head-Section 2 *Norman J. Cook*
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

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

TO: Henry Jacoby, PM-21
Fungicide/Herbicide Branch
Registration Division (TS-767-C)

The Ecological Effects Branch (EEB) has reviewed the special study protocol to investigate the effects of vinclozolin on male fertility in the mallard. This study was initially requested by the Canadian Wildlife Service (CWS) following their review of standard avian reproduction studies. They have reviewed the protocol and found it acceptable with some proposed modifications (see attached letter). In an EEB memorandum of August 23, 1984, R. Balcomb, requested that EPA be provided all relevant information, and in the EEB review by E. Zucker (6-25-85), special studies (i.e., the study requested by the CWS) were required to support registration actions.

In general, EEB concurs with the review by the CWS. In addition, the batch number and degree of purity of the vinclozolin used in the test should be reported along with the composition of the basal diet and any supplements or additives.

EEB notes that there is to be only a four week exposure to treated diets prior to the onset of laying. This appears to be appropriate for the one or two applications per year for uses in Canada. The registrant has requested up to four applications per year, at 14-21 day intervals, for use on peanuts in the U.S. Consequently, exposure could be over a period of 8-12 weeks. The EEB chemical profiles indicates that the octanol-water partition coefficient is 1000, with fish bioconcentration factors of 318x and 16x in bluegills and catfish, respectively. After two weeks of depuration, residues were less than 10%. These data suggest some, but only a moderate propensity for partitioning to fat, but with repeated exposures in the field, the four week pre-laying exposure may not be sufficiently representative of use patterns on peanuts. On the other hand, the 8 week exposure during laying may compensate for this. Although EEB does not object to pre-laying exposure period proposed by the registrant to address CWS concerns, depending upon the results of the study at the various levels and the actual residues on avian food items in the peanut use, the duration may not be sufficient to support the multiple applications requested for this crop.

3



Ottawa, Ontario
K1A 0E7

Your file Votre référence

August 21, 1986

Our file Notre référence

Ms. Christiane Poirier
Registration Specialist
Agricultural Products Department
BASF Canada Inc.
10 Constellation Court
Rexdale, Ontario
M9W 1K1

Dear Ms. Poirier:

RE: Vinclozolin - Avian Reproduction Study - Sub. No. 83-1347

We have reviewed the "Draft Protocol: Reproduction Study with Vinclozolin in the Mallard Duck (*Anas platyrhynchos* L.) after administration in the diet; testing for male fertility." (BASF Aktiengesellschaft 12/06/86).

As you observed in your review of the protocol, there are several deviations from that which we proposed.

- 1) Group Size: The conditions of husbandry, etc., proposed should greatly decrease variability and confounding factors. We therefore accept the use of 20 replicates per group and the proportionate decrease in sample size at each sacrifice point.
- 2) Dose levels: We accept the dose levels of 2.5, 10, and 50 ppm proposed. On the basis of data currently available to us this should represent the range of dietary exposures expected in wild birds.
- 3) Pathology observations: Length, breadth and weight of both testes as well as weight of the penis (an androgen - dependent parameter) should be recorded for all dead and sacrificed birds.

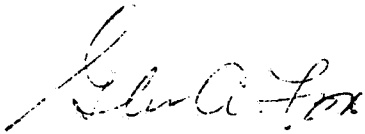
We regret that no details of the parameters to be observed and/or measured in the histopathological and histometrical evaluation of the testes have been included in this protocol. We feel very strongly that this aspect of the study could be the most informative and feel that those parameters we outlined should be included particularly the relative counts of the various stages of the development of the spermatazoa. We wish to review whatever BASF Ag. decides upon before we meet.

.../2

Although we omitted this from our proposed protocol, we feel that the collection of blood at sacrifice, and the preservation of frozen serum/plasma for possible future analyses of testosterone content should be included in the protocol. This would provide excellent back-up and/or clarification information to supplement the histological and fertility observations.

- 4) Meeting Dr. Munk of BASF: We look forward meeting with Dr. Munk at any time concerning this study.

Yours sincerely,



Glen Fox , Msc.(Zool), Msc.(Tox)
Pesticides & Environmental
Contaminants Evaluator
Toxic Chemicals Programs Section
Wildlife Research and
Interpretation Branch
National Wildlife Research Centre

c.c.: H. Thompson
F. Turk
N.Y. Khan
F. Wandelmaier

August 5, 1986

Henry Jacoby (PM 21)
Environmental Protection Agency
Registration Division (TS-767)
401 M Street, S.W.
Washington, D.C. 20460

Subject: Ronilan Fungicide - EPA Reg. No. 7969-53

Reference: Your letter dated March 24, 1986

Dear Mr. Jacoby:

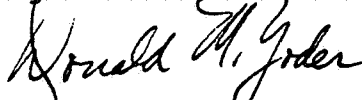
We respond to item 2 of your letter of reference by submitting in duplicate the protocol of a specially designed study of reproduction in the mallard duck. This protocol was prepared with special attention to the concerns of the Canadian Registration Authorities. We are in contact with EEB/EPA regarding this protocol and the concerns of Canadian Authorities, and are looking forward to meeting with EEB in this regard in a month or so.

Further to your letter of reference, we are unable to understand the reference to further testing under 70-1(d) of the Guidelines (Special Tests). We find the citation in Subdivision E, page 25. Is this cited as justification for the additional study or is it intended to imply that other additional studies may be required? Please illuminate.

We will respond to other items of your letter in the near future.

Sincerely yours,

BASF CORPORATION CHEMICALS DIVISION
Agricultural Chemical Group



Donald M. Yoder
Acting Manager
Registration

DMY:dj

Enclosure

RIN 5715 - 93

VINCLOZOLIN EEB REVIEWS

Page is not included in this copy.

Pages 7 through 21 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of 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.
- 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.