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SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

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TYPE OF PRODUCT(S) : I,D,H,F,N,R,S INSECTICIDE/MITICIDE

DATA ACCESSION NO(S). 414788-01, 02, 03

PRODUCT MANAGER (NO.) D. EDWARDS (12)

PRODUCT NAME(S) OVASYN (Amitraz)

COMPANY NAME NOR-AM Chemical Company

SUBMISSION PURPOSE Review of Supplementary Data Concerning Avian Reproduction in Support of Cotton Use

SHAUGHNESSY NO.	CHEMICAL & FORMULATION(S)	% A.I.
106201	Amitraz	

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

JUL 23 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amitraz Avian Reproduction Data

FROM: James Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division

TO: Dennis Edwards
Product Manager (12)
Insecticide-Rodenticide Branch
Registration Division

Nor-Am Chemical Company has sent the following avian reproduction supplemental data for review:

1. Accession #414788-01: Supplementary information concerning the Wildlife International Avian reproduction study with the Mallard (MRID 0072411) December 1980.

2. Accession # 414788-02: Supplementary information concerning the Wildlife International Avian reproduction study with the Bobwhite Quail (MRID #00072412) December 1980.

3. Accession #414788-03: Supplementary information concerning the Huntingdon Research Center Avian reproduction study with the Bobwhite Quail (MRID #40780504) September 1988.

Each of the above submission has been reviewed and both the previous and current evaluation of the data will be presented.

1. Mallard-Wildlife International:
This study was re-evaluated on 10/2/81 (EEB review 16a) and determined supplemental because the study failed to find a precise NOEL ($\leq$ 40 ppm). The most sensitive parameter was the number of 14-day-old survivors, "...if raw numbers of 14-day-old survivors produced per week by the controls and by the birds fed 40 ppm are compared by ANOVA testing, we find that the birds fed 40 ppm Amitraz produced significantly ($p < 0.05$) fewer offspring. Therefore, this

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study did not find a no-effect level, and must be rated supplemental."

The current submission did not provide the raw data (individual pen data) for the numbers of 14-day survivors produced. Instead the mean number of 14-day survivors per week of egg production were presented. This data was not analyzed by EEB because any "lumping" of avian reproduction data usually decreases data replications, and the power, thereby reducing the applicability of standard ANOVA procedures. Furthermore, any control data that was not generated as part of this study will not be used to determine statistical differences among reproductive parameters. Therefore, the 1981 review of this data remains valid and data requirement 71-4 with the mallard is not fulfilled.

2. Bobwhite Quail - Wildlife International:

This study was reviewed 5/4/81 and judged supplemental because a precise NOEL was not determined. The NOEL was ≤40ppm because of significant increases in eggshell cracking and a reduction in the percentage of 3-week embryos that survived to become normal hatchling were observed at 40, 100, and 250 ppm.

The raw data for numbers of eggs cracked were reanalyzed by ANOVA and a significant increase in cracked eggs was verified at all treatment levels. As previously, the submitted data (mean number per week of eggs production, and paired control data) were not analyzed. Therefore, the 1981 review of this data remains valid and data requirement 71-4 with the bobwhite Quail is not fulfilled.

3. Bobwhite Quail - HRC

The bobwhite quail avian reproduction study conducted by HRC was reviewed on 1/5/89 and determined supplemental due to the lack of a precise NOEL (≤40 ppm). This study was re-evaluated on 8/14/89 and 12/20/89 and maintained at supplemental due to the extremely high incidence of cracked eggs (20-22%).

The currently submitted information has been reviewed by EEB previously. Attached to this memo is EEB's response to Dr. D.H. Christopher of HRC concerning the high egg cracking rate observed in their avian reproduction studies.

In summary 3 avian reproduction studies filed with EEB are all supplemental, and nonrepairable. All 3 show that the NOEL is ≤40 ppm. Data requirement 71-4 for both the mallard and the bobwhite quail are not fulfilled, and it is suggested that new studies be conducted to determine a precise NOEL.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dr. David H. Christopher
Director of Industrial and
and Environmental Studies
Huntingdon Service Centre
Suite 1402, 51 Monroe Street
Rockville, Maryland 20850

Dear Dr. Christopher:

I would like to apologize for the delay in responding to your questions regarding the relatively high rate of egg cracking in several of your avian reproduction studies. Members of my staff and our division statistician have reviewed your paper "High Cracked Egg Rate in Avian Reproduction Studies: Its Implications for Study Validity" by D.O. Chanter. The following provides the reasoning behind our decision to maintain our previous standards relative to this parameter for avian reproduction studies.

1) It is possible that the high rate of egg cracking in the control group may mask the treatment effects on other avian reproduction parameters.

2) In your paper, the power decreased for all of the post-egg laying parameters (number of eggs hatched, infertility, viability of embryos, hatchability, chick survival, and chick weight) except eggs cracked . The avian reproduction test does not achieve high statistical power for its parameters as is and therefore further reduction in power (even a small reduction) is not desirable.

3) There is a need for maintaining consistency to enable my Branch to compare and evaluate studies on other chemicals by different laboratories.

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My Branch urges HRC to pursue its efforts in reducing the rate of eggs cracked by identifying factors that produce thinner eggshells. For the reasons listed above, the studies in question will not be reclassified as meeting EPA Avian Reproduction Test Guidelines.

I hope this letter resolves the issue. If you have further questions on this issue, please contact Ed Fite or Nimish Vyas of my staff.

Sincerely,

James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects
Division (H7507C)