

1-23-90

JAN 23 1990

File
J. [Signature] → [Signature]Ref. # 2
550CERTIFIED MAIL

Dr. Dennis H. Lade
Project Manager, Plant Science Projects
Development and Registration Division
Elanco Products Company
P. O. Box 708
Greenfield, Indiana 46140

Subject: Waiver Requests-Trifluralin Reregistration Standard

Dear Dr. Lade:

The Agency has reviewed your request for a waiver of the requirements for Guideline 171-4(j) "Magnitude of the Residue in Meat, Poultry, and Eggs" and Guideline 171-4(d) "Residue Analytical Methods-Animal". Your request was based on the results of your animal metabolism studies (MRID numbers 41233100, 41233101, and 41233102). These studies show that the qualitative nature of the residue in animals is adequately understood. However, to validate the reported feeding levels, you should report the weight of the hens and the dairy cow used in the studies, and the amount of feed consumed per day by the hens and the steers. Further explanation may be found in the enclosed Agency review of these studies. Please submit the requested information within thirty days.

We agree that the animal metabolism studies show that guidelines 171-4(j) and 171-4(d) are not necessary and we therefore waive these requirements. In addition, no tolerances for trifluralin or its metabolites need be proposed in animal products.

CONCURRENCES							
SYMBOL	H7508C	H7508C	H7508C	H7508C			
SURNAME	B. Baker	V. [Signature]	Rospi	Tinsworth			
DATE	1-4-90	1/4/90	1/17/90	1/23/90			

If you have any further questions concerning this matter,
please contact Bert Baker of my staff at (703) 557-0592.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Edwin F. Tinsworth", with a horizontal line extending to the right.

Edwin F. Tinsworth, Director
Special Review and
Reregistration Division

Enclosure

JUN 19 1992

CERTIFIED MAIL

Dennis H. Lade, Ph.D.
Product Registration Manager
DowElanco
9002 Purdue Road
Indianapolis, IN 46268-1189

SUBJECT: Review of DowElanco's Response to the Trifluralin Dermal Absorption Study Review Dated 07/16/91 and a Request to Resubmit Waivers for the Acute Toxicity to Estuarine/ Marine Organisms

Dear Dr. Lade:

The Agency has completed its review of your response to the Agency's review dated 07/16/91 for the trifluralin dermal absorption study (Guideline 85-2). The Agency has concluded that the study is unacceptable and the data cannot be used for risk assessment purposes. If this study is not repeated, the Agency will assume a 100% dermal absorption. A copy of the 01/15/92 review is enclosed.

In response to your request for a meeting with the Agency to discuss this requirement, please contact Terri Stowe of my staff at (703) 308 - 8043 to arrange a meeting. In addition, please resubmit your waiver request (with full justification) for the Acute Toxicity to Estuarine/Marine Organisms studies (Guidelines 72-3A Fish and 72-3B Mollusk).

Sincerely yours,

Lois A. Rossi

Lois Rossi, Chief
Reregistration Branch
Special Review and
Reregistration Division

Enclosure**CONCURRENCES**

SYMBOL	H7508W	H7508W	H7509A				
SURNAME	T. Stowe	Walsh	Saito				
DATE	06/08/92	6/11/92	06/15/92				

