129016 DE-498 3/30/92

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

MEMORANDUM MAR 30 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Discussions with DowElanco Concerning Non Target Plant Testing with Oryzalin and Flumetsulam

FROM: Douglas J. Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Divisions H7507C

3/30/92

TO: Joanne Miller, PM
Herbicide/Fungicide Branch
Registration Division H7505C

3/30/92

Charles Lewis of EEB has received a letter (copy attached) from Dow ELanco concerning a telephone conversation O. Dean Decker had with him.

The conversation, which took place on March 24, 1992 revolved around the design of plant testing with Oryzalin and Flumetsulam. Dow Elanco asked Charles if it was appropriate that the between dosage level be extended from 2X to 3X given the differences in sensitivity of plants to the test materials. Charles indicated that based on the information provided over the telephone that it seemed like an appropriate thing to do. Charles also specifically indicated that Dow should submit a request to make such a change in study design to the Registration Division so EFED could officially respond to, and if appropriate approve it. He clearly stated that an informal discussion should not be the basis for a decision by the company to modify a study design. Charles did not indicate that it was sufficient for Dow to simply discuss with, and gain verbal approval from, the Registration Division. The letter submitted by Dow clearly reflects a misinterpretation of the content and intent of the discussion between Charles Lewis and O. Dean Decker.

The intent of Charles' discussion with Dow Elanco was not to circumvent the correct procedure for obtaining approval for modifying study designs. It was rather to help Dow more efficiently formulate their submission to gain approval of a study design modification.

I am therefore informing you; and this information should be communicated to Dow Elanco; that they do not have EEB approval to modify their study design and should submit a request in writing through the Registration Division. If any questions arise concerning this issue, please contact Daniel Rieder.

DowElanco
9002 Purdue Road
Indianapolis, IN 46268-1189

March 25, 1992

DowElanco

Joanne I. Miller (H7505C)
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Charles R. Lewis (H7507C)
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RE: Non Target Plants - Guideline Ref. No.'s 122-1 and 123-1
Oryzalin and Flumetsulam

On March 24 and 25, 1992, DowElanco, in conversations of O. Dean Decker with Charles R. Lewis (Ecological Effects Branch) and Dennis Lade with Joanne I. Miller (Registration Division) discussed the possibility of modifying the above-mentioned protocols using the above-mentioned products. Both of you saw no issues with the deviation and verbally agreed to the discussed protocol modification. Joanne asked that DowElanco provide a confirming letter indicating a brief overview of the discussions.

As part of the Non Target Plant study, one set of samples are treated at the maximum use rate to satisfy the Tier I Guideline Study 122-1. Since the maximum active ingredient application rate of oryzalin is 6 lb/A (a high application rate) and DE-498 (flumetsulam) is 0.0675 lb/A (a low application rate), it was agreed that the dilution rates may need to be changed from the two-fold dilution rate to a three-fold dilution rate. It is believed that due to the high application rate of oryzalin and the activity of the DE-498, the EC25, EC50 or the NOEL might not be attained using the two-fold dilution regime on a sensitive specie.

For Comparison, the dilution rates would be modified as follows:

Concentration in Lb/Acre

Oryzalin		DE-498	
2xDilution	3xDilution	2xDilution	3xDilution
6.00	6.00	0.068	0.068
3.00	2.00	0.034	0.023
1.50	0.67	0.017	0.0076
0.75	0.22	0.0085	0.0025
0.38	0.074	0.0043	0.00084
0.19	0.025	0.0021	0.00028
0.01	0.008	0.0011	0.00009
0.00	0.00	0.00	0.00

As mentioned, this scenario was discussed by O. Dean Decker with Charles Lewis who felt that requesting the three-fold dilution would be acceptable. However, he indicated that it must be discussed with and OK'd by the Registration Division before proceeding.

Based upon the verbal approvals and this confirmatory letter, DowElanco will modify the protocols as indicated above. These studies will be initiated in April, 1992.

If questions, you may reach Mr. Decker at (317) 277-4342 or Dr. Lade at (317) 870-7269.

Sincerely,

Dennis H. Lade, Ph.D.
Product Registration Manager

O. Dean Decker
Sr. Scientist Study Monitor

DL6/kle