US EPA ARCHIVE DOCUMENT

5-27-93

MAY 27 1993

CERTIFIED MAIL

Dennis H. Lade, Ph.D.
Chairperson for Trifluralin Consortium
DowElanco
9002 Purdue Road
Indianapolis, IN 46268-1189

Dear Mr. Lade:

You have been sent this letter because you have product(s) containing the active ingredient Trifluralin. In order to maintain your registration(s), you were required as part of the Registration Standard data requirements or in a separate Data Call-In Notice to provide data for one or more of the following higher tiered ecological effects studies. These studies include guidelines: 71-5a (simulated avian field study), 71-5b (actual avian field study), 72-7a (simulated field tests for aquatic organisms - mesocosm study) and 72-7b (actual field tests for aquatic organisms - pond study).

In May, 1992 the Agency initiated an Ecological, Fate and Effects Task Force to examine the impacts of the higher tiered fate and ecological effects data requirements on the Reregistration program. Two of the major questions addressed by the Task Force were: (1) what is the value added by these data for regulatory decisions, and (2) how can EPA expedite actions to mitigate ecological risk. Although the Task Force also examined environmental fate studies, in particular groundwater studies, this letter only addresses these four guideline studies noted above.

As explained more fully in Linda Fisher's October 29, 1992 memorandum "Decisions on the Ecological, Fate, and Effects Task Force," the Task Force concluded that whenever possible regulatory decisions should be made earlier in the process without waiting for these higher tiered studies. Therefore, avian and aquatic field testing guidelines (71-5a, 71-5b, 72-7a and 72-7b) will no longer be routinely required. Regulatory decisions will be based on available information from laboratory studies, published information and incident data.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

For the active ingredient Trifluralin, a simulated field test for aquatic organisms (72-7a) was imposed in the Registration Standard dated April 1987. The Agency notes that you have submitted other studies in lieu of conducting Guideline 72-7a. The Agency review of one of these studies, "Vertebral lesion study on Fathead Minnows," was sent to you on March 26, 1993 (review dated March 10, 1993). In that review, the Agency noted that 1) the study was unacceptable but Guideline 72-7a "could be waived" and 2) "there is an ecological level of concern for fish that are exposed to low levels of Trifluralin."

Even though the Agency is waiving the Guideline 72-7a requirement, in keeping with the Eco-Task Force's decision to expedite risk mitigation actions, the Agency will convene a meeting this summer with all registrants whose chemicals exceed our avian and aquatic levels of concerns, to discuss the Agency's expectations regarding adequate mitigation measures and establish a timetable for implementing them. A separate letter will be sent to you with the details of this meeting.

Should additional information become available that indicates a need for any of these higher tiered studies, EPA reserves the right to reimpose the data requirement(s).

If you have any questions, you should contact Peter Caulkins or myself at (703) 308-8000.

Sincerely,

/S/

Daniel M. Barolo
Acting Deputy Director
Office of Pesticide Programs

CONCURRENCES

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NOTE ON TRIFLURALIN

The registrant, Dow Chemical Company, has never formally requested a waiver for Guideline 72-7a. However in their attempt to get out of the data requirement, they submitted other studies. In a March 10, 1993 review of one of these studies, vertebral lesions study on Fathead Minnows, the EEB review stated that 72-7a "could be waived." This review was transmitted to Dow on March 26, 1993. Dow believes they have been waived (phone call to Dennis Lade, Dow's representative, 5/5/93), so in this case it seems pointless to ask them to formally submit a waiver request. At issue in all this is whether EEB still has a "level of concern" since Dow did other studies to get out of 72-7a. The 3/10/93 EEB review reaffirms that there is still a level of concern for Trifluralin. Therefore, the waiver letter has been modified to reflect the above. See first paragraph, page 2.