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

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

AUG 13 1980

MEMORANDUM

SUBJECT: Ecological Effects Branch Review of the Incremental Risk from Registration of Treflan® for use on barley, grain sorghum and grain corn.

TO: Edwin L. Johnson
Deputy Assistant Administrator
for Pesticide Programs (TS-766)

Background

On February 8, 1979, Elanco submitted a petition 9F2172 and an amendment to the product Treflan® EPA Registration No. 1471-35 to allow the use of trifluralin on grain sorghum and barley. They also submitted an amendment for a federal registration of the use of trifluralin on grain corn. At the present time, there are 24(c) state registrations for this use in corn in Georgia, North Carolina, Kansas, New Mexico, Kentucky, South Carolina, and Alabama.

The scientific review of the petition has been completed and tolerances can be established for trifluralin in grain sorghum and barley now that it has been removed from the nitrosamine moratorium.

As specified in the May 11, 1979 Conditional Registration Regulations, the amendments were routed to Ecological Effects Branch (EEB) for an incremental risk assessment due to the possible increased exposure to non-target species from registration of these new crops.

The February 20, 1980, EEB review did not concur with the amended registration and stated that a number of studies are required for an environmental hazard assessment. On March 20, 1980 the requirements were given to Elanco by the Product Manager. They immediately objected and contacted you and Mr. Jellinek on this subject. EEB still objects to the registrations although fewer studies are now required by EEB.

Issues

After meetings and telephone conversations with HED, EEB's position remains unchanged. The following issues raised by their review are being brought to your attention.

1. Incremental Risk review versus a full 3(c)(5) review:

The May 11, 1979 Regulations specify that in the case of addition of new crops review would consist of determination of the increased exposure and assessment of the risks associated with extending these effects by introduction of more pesticide into the environment.

In the case of trifluralin it is already registered for use on alfalfa, cotton, soybeans, fruit and nut trees, vegetables, and winter wheat. The review did not assess the difference in exposure to non-target organisms between the registered crops and use in barley, sorghum and corn. It stated only that these users would add 100 million acres. However, considering the similar sites and the same method of application, use on barley, sorghum and corn may not expose new non-target organisms and the hazards may only relate to the additional pounds applied which was not determined.

The review instead appears to be based on the data requirements for a re-registration under 3(c)(5) of FIFRA for all uses of trifluralin. For example, the review indicates that additional information is needed before classification can be made. Trifluralin and new conditional uses will not be classified until the Registration Standard is completed.

2. Requirements of studies not in the Guidelines:

Based on possible hazards of bioaccumulation and body burden for aquatic organisms, studies not in the Guidelines are required to assess the environmental hazards. Registrants are required to meet with EEB, develop protocols for studies that they believe are not necessary and which haven't been reviewed and approved by the scientific community.

3. Requirements for a complete data base conducted in accordance with the July 10, 1978 Guidelines:

The review stated that an avian dietary study for the Bobwhite Quail and Mallard Duck are necessary to support registration. Yet, the review indicates endangered birds should not be adversely affected by the proposed registration.

4. Reviews that do not reflect other actions of the Agency:

The trifluralin Position Document 1/2/3 dated August 22, 1979 on page 117 states that when trifluralin is applied and incorporated into the soil as recommended, toxic quantities of the compound do not move into water. The Agency has found that trifluralin accumulates in various fish and a species of snail, but toxic responses to this accumulation have not been reported. The Agency's analysis of the risks to terrestrial organisms indicates that the acute toxicity level for trifluralin ranges from 2,000 mg/kg to greater than 10,000 mg/kg. These levels are so high that the Agency does not consider the compound to pose a hazard to terrestrial wildlife.

PD 4 will be completed shortly returning the compound to Registration Division indicating that it does not cause an unreasonable adverse effect to the environment; yet, the proposed uses have been rejected due to "data gaps."

Recommendation

Based on my review of the facts before me, I cannot make the conclusion that the proposed uses present a significant increase in risk over the registered use patterns. An extensive risk assessment was applied to the registered uses during the trifluralin RPAR process. I recommend that the additional uses in grain corn, grain sorghum and barley be conditionally registered.

I am moving forward to propose tolerances based on completion of the review relative to safety of residues in food.

Douglas D. Campt
Director
Registration Division (TS-767)

Concur Ed Johnson

Nonconcur _____

Date 8/15/80

Discussed w/ Herb Harman et. al.
Decision transmitted verbally at that time.