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TYPE PRODUCT(S): I, D, H, F, N, R, S Herbicide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. R. Mountfort(23)

PRODUCT NAME(S) Trifluralin

COMPANY NAME Elanco Products Company

SUBMISSION PURPOSE Registrant response concerning EEB data requirements in registration standard

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
036101	trifluralin	

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Richard Mountfort, PM (23)
Registration Division (TS-767)

FROM: Les Touart, Fisheries Biologist
Section 1

THRU: Raymond Matheny, Head Ray W. Matheny 10-13-87
Section 1

THRU: Henry T. Craven, Acting Chief Henry T Craven 10/13/87
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Comments on Registrant Response to Requested Aquatic Field Monitoring Study

The Ecological Effects Branch reaffirms the requirement for an additional aquatic field monitoring study made under the Registration Standard for trifluralin. The registrant contention that no scientific basis exists for requesting another study and that the completed aquatic study and accessory tests (e.g., laboratory tests with brown trout) adequately resolves the concerns is unfounded. Briefly, a presumption of risk was made that trifluralin residues could transport to aquatic habitats from treated sites, that these residues would be bioavailable to aquatic biota and that these residues could produce vertebral anomalies in finfish. To address these presumptions, a Data Call-In Notice was issued on 8/25/82 for an aquatic field study. The study was conducted and a review completed 6/25/86. The field study unequivocally demonstrated that trifluralin residues did indeed transport to aquatic habitat and was indeed bioavailable to the aquatic biota. The study also, albeit equivocally, provides suggestive evidence that an increase in vertebral anomalies among finfish occurred in the pond receiving trifluralin runoff. The bottom line remains that the registrant has failed to negate the presumptions of risk initially made.

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The registrant declares that trifluralin residues in the catchment pond were below NOEL values determined in fish life-cycle tests, below the LEL for vertebral dysplasia and well below levels showing vertebral lesions in laboratory fish after acute exposures. It is important to note that a NOEL for vertebral dysplasia from chronic exposure to trifluralin has not been determined. Also, lesions resulting from acute exposures and associated body burdens of trifluralin cannot be used in evaluating suspected vertebral anomalies which may result from chronic exposures.

The registrant states that the EPA review of its data does not consider "that fish living in ponds surrounded by agricultural land are subject to many simultaneous stresses during and immediately following runoff events," yet cites a statement from the EPA review that "trifluralin may also contribute at non-detectable residues with other environmental and/or chemical influences to increased incidences of vertebral anomalies in finfish," which clearly indicates such consideration. It is worth noting here that the increased occurrence of anomalies in fish was observed in the trifluralin catchment pond and no such observation was made in the control pond which received similar stresses and included other pesticide residues. It was unfortunate that at a time of heavy rainfall and increased occurrence of suspended sediment that no collections of fish were made at the control site. Since trifluralin can be associated with sediment, the study does not differentiate between anomalies which result from sediment alone or from trifluralin contaminated sediment, even if the trifluralin residues are below a detectable limit. The study clearly demonstrates that trifluralin residues in pond water and sediment which are below detectable limits are still bioavailable and accumulated by finfish. The study does not unequivocally demonstrate that these residues do not affect the vertebral integrity of finfish.

An additional monitoring study must be performed to alleviate concerns which have arisen on the potential vertebral effects in finfish from trifluralin residues. The study is intended to augment the previously conducted study and remove any ambiguity concerning potential vertebral effects in finfish. The study must be conducted over 2 or more years in major use areas of trifluralin and at several sites (> 5). Body burden residues in finfish are of principal interest. The study need not be involved or complex, the intent is to obtain representative samples of finfish in historical trifluralin use areas to determine if residues are at or increasing towards levels which could result in vertebral lesions. The registrant must submit data which demonstrate that trifluralin does/is not accumulate(ing) to effect levels in fish associated with high trifluralin use areas. If residues do occur at or approach concern levels, then extensive finfish population monitoring could be warranted.