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

APR 8 1987

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Reg. No. 476-2134. Fonofos (Dyfonate®).

Request for Time Extension for Submission of the
Report of Studies Required under FIFRA §3(c)(2)(B).

RCB No.: 2117. MRID/Access. No.: None.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

mjn

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

RM

TO: William H. Miller, Product Manager 16
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

By letter dated February 27, 1987, Stauffer Chemical Company, the registrant for fonofos, has requested a time extension for the submission of six studies required under the Fonofos Registration Standard.

Two of those studies address Residue Chemistry data requirements. The two studies involved and the new dates requested are:

1. 171-4 Nature of the Residue, Poultry Metabolism; from 3/31/87 to 9/30/87.
2. 171-4 Nature of the Residue, Lactating Ruminant (Goat) Metabolism; from 3/31/87 to 9/30/87.

The following reason was given for requesting the time extension for these studies:

"During the course of our data development program, technical difficulties have been encountered in conducting several of the required studies. These difficulties, and the additional research required to resolve the problems associated with the conduct of the studies, will result in unavoidable delays for submission of the final reports to the Agency by the due date of 3/31/87."

PR Notice 85-5 ("Policy Regarding Time Extensions for Submitting Additional Data to Support Existing Registrations", dated 8/22/85) states that "on a case-by-case basis, consideration will be given to extension requests due to unavoidable analytical problem(s).... However, registrants will be required to demonstrate the validity of the problem(s) and show good faith effort towards resolution."

Attached to the registrant's letter of 2/27/87 were status reports (dated 2/9/87) of the poultry and lactating ruminant metabolism studies. Those interim reports indicate that analyses for total ^{14}C residues in tissues, excreta, milk, and eggs have all been completed, and that tissue residue characterization is currently underway.

Those status reports also state the "Contract laboratory (ADC) indicates that more time will be required for metabolite identification. Problems have been encountered in preparing tissue extracts for chromatographic analysis."

As verification of this, the registrant has also submitted a copy of a letter dated 2/20/87 which they received from the contract laboratory (Analytical Development Corporation, Monument, CO) stating:

"This letter represents a formal request for a 6-month extension of the March 31 deadline for the ^{14}C -Dyfonate goat and poultry metabolism studies. The March deadline would have been reasonable only if no problems were encountered. Currently, due to extraction difficulties and cleanup problems, the total number of metabolites and their nature are still unknown. It is still impossible to predict an exact completion date; however, we feel that a reasonable completion date would be the end of September."

Conclusions

The requested time extension, until September 30, 1987, for the submission of the final reports on the poultry and lactating ruminant (goat) metabolism studies is reasonable from a residue chemistry standpoint, and RCB has no objections to it. However, the granting of time extensions is an administrative decision.

cc: RF, Circ., Reviewer (M. Nelson), PM#16, Fonofos Registration Standard file, PMSD/ISB (Eldridge).
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):4/7/87.
RDI:SectionHead:RSQuick:4/7/87:DeputyChief:RDSchmitt:4/8/87.