UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

May 17, 1995

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP) Regulation

GLP Regulations Advisory No. 73

FROM: Rick Colbert, Director
Agriculture and Ecosystems Division
TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Agriculture and Ecosystems Division of the Office of Compliance. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at 202-564-2365.

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
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COMPLIANCE ASSURANCE

Dear

This is in response to your letter of December 19, 1994 in which you requested compliance assistance regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). You specifically sought guidance regarding the GLP standard requiring the assignment of a study director.

According to your letter your company has contracted an analytical laboratory to perform a study to determine contaminants in one of your technical ingredients. You stated that this laboratory is to be responsible for the "technical conduct of the study as well as for the interpretation, analysis, documentation and reporting of results." The samples and standards for the study are to be prepared by your parent manufacturing facility, which will also perform characterizations (identity and purity determination) as required by GLPS. Your company, as well as contracting the laboratory, has arranged for the study, will review the protocol, and will receive the final report for submission to EPA.

You stated that the contract laboratory will not assign the study director since they are not in control of sample preparation or the identity and purity determinations. The laboratory believes that your company should assign the study director. However, you stated that a study director based at your company would not be able to make certain assurances required under the GLPS, specifically those at 40 CFR 160.33(b), (c), and (e).

Of the three parties involved, the contract laboratory, your company, or the parent company, you wanted to know where the study director should be located.

The GLPS require the study director to be the central point of control of a study. The study director must therefore exercise control over all study activities. However, the GLPS do not dictate the location of the study director. There is flexibility as long as any needed measures are taken to ensure that the study director can provide the required assurances at 40 CFR 160.33,

When a study is performed at more than one location the study director may not be available on-site to monitor all study

activities. In such cases it would be necessary to delegate tasks and duties, as appropriate, to persons who can provide needed on-site oversight of activities. The study director would still be responsible for compliance and would remain the central point of control of study activities. The study director can make the-assurances required at 40 CFR 160.33 because the delegated on-site tasks are under his oversight.

The fact that a study director is employed by a contract laboratory does not affect the need for all study activities to be under his control. This may mean placing activities conducted at other laboratories, including the sponsor company's laboratory, under the oversight of the contractor employed study director. If such responsibility is not conferred to the study director the study director would not be in a position to make the assurances required at 40 CFR 160.33. It would be inappropriate for the contract laboratory to provide the study director under such an arrangement.

Therefore, the two main options are either to assign oversight responsibilities for the technical conduct of the entire study to the contract laboratory, or to assign the study director at the sponsoring company.

It you have any questions concerning this response, please contact Steve Howie of my staff at (202) 564-4146.

Sincerely yours,

/s/ Rick Colbert, Director,
Agriculture and Ecosystems Division
Office of Compliance (2225A)

cc: GLP File
Francisca E. Liem
David Dull