UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

November 1, 1990

MEMORANDUM

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

GLP Regulations Advisory No. 22

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. 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 FTS-398-8265 or (703) 308-8265.

Attachment

cc: C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in reply to your letter of April 25, 1990, in which you requested interpretations of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs). Specifically, your letter addressed the issue of the study director, as required at 40 CFR 160.33. According to your letter, when conducting studies on pesticides for hops, you find it difficult to comply with the requirements that each study have a single study director.

An approach which uses more than one study director per study would not comply with the GLPs. The requirement at 40 CFR 160.33 states that the study director represents the single point of study control, and is responsible for the overall conduct of the study. Dividing a technical effort into multiple studies creates multiple points of control and means that there is no individual with overall responsibility. The accountability provided by a single study director (who plans, oversees, and controls the interpretation, analysis, documentation, and reporting of the results) is one of the most important aspects of the GLP standards. In addition, the GLPs define a study as a complete experimental effort. The definition does not suggest that separate phases either by location or type of work performed (i.e., analytical versus field) constitute separate studies.

A single study director may take overall responsibility for adequate completion of the study, but does not have to be directly involved in performance of each technical effort. For projects coordinated by N, the study director would oversee the performance of on-site technical directors who are responsible for the individuals carrying out field and analytical duties.

In order to further explain these issues we are enclosing recent correspondence which address the study director issue. If you have any questions concerning this response or would like to set up a meeting, please contact Steve Howie of my staff at (202)

475-7786.

Sincerely yours,

/s/John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

Enclosures

cc: David Dull
GLP File