UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

GLP Regulation Advisory No. 18

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 Liem at FTS-475-9864.

Attachment

cc: C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

Your letter of March 13, 1990, to Dr. David Dull regarding study design under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs) was referred to my office for response.

Specifically, you asked about what you consider to be a contradiction between Standard Evaluation Procedures (SEP) for Terrestrial Field Dissipation studies and the GLPs. The SEP in question states that the report should contain: 1) a stated goal of the study; and 2) sufficient information on the test protocol and the analytical protocol. You suggested that since separate protocols are mentioned in the SEP for the test and the analysis, that these should be allowed to be separate studies under GLPs.

Your suggested approach does not comply with the GLP requirements. The GLPs define a study as an experiment to determine or help predict the effects or characteristics of a test substance. The separate analytical phase of an experiment does not meet this criteria. Further, the SEP that you cited refers to a single study and would itself be contradicted by breaking the experimental effort into two separate studies.

The SEPs may be used to provide guidance for the performance of studies, but they do not supersede the requirements of the GLP regulations. Should there be a terminology difference between the GLPs and an SEP, the requirements of the GLPs take precedence.

To comply with GLPs, each study must have one protocol and one study director. As stated in the GLPs, the protocol must contain but is not limited to the information stated at 40 CFR 160.120(a). The separate test and analytical methodologies must be included or referenced in the single protocol that covers the entire study.

If you have any questions concerning this response please contact Steve Howie my staff at (202) 475-7786.

Sincerely yours,

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

cc: David L. Dull

Anne Barton
GLP File