



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

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

June 28, 1991

MEMORANDUM

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

GLP Regulations Advisory No. 33

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 398-8333 (703) 308-8333.

Attachment

cc: C. Musgrove



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Dear

This is in response to your letter of June 10, 1990, to Mr. Steve Howie, of my staff. In that letter you requested clarification on Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practices standard (GLPs) with respect to analytical method development and validation.

You asked whether a company must revalidate a method under GLPs in the case where it had established the analytical methodology and included validation data in an EPA study submitted prior to the effective date of the GLPs requirements.

The GLPs do not specifically require that each method used in a study be revalidated under GLPs. However, there are certain cases where such method validation, or the gathering of data to support method validation, would be required to be performed under GLPs:

(1) If the protocol of the study includes method validation, this information must be gathered under GLPs.

(2) Regardless of whether a separate validation study is performed, calibration data must be gathered and maintained under GLPs, and any other applicable portions of GLPs must also be adhered to, i.e. maintenance and calibration of equipment, standard operating procedures, etc.

(3) If the EPA determines that revalidation of a particular method must be performed as part of a study, or for subsequent use in studies, that would be under GLPs regardless of whether a previous study had been submitted.

If there is a question concerning the acceptability of an analytical method, i.e., whether further validation is required, it is appropriate to contact the Office of Pesticides Programs, EPA.

If you have any questions please call Steve Howie of my staff at (703) 308-8290.

/s/ John J. Neylan III, Director  
Policy and Grants Division  
Office of Compliance Monitoring (EN-342)

cc: David Dull  
GLP File