UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

June 11, 1990

MEMORANDUM

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

GLP Regulation Advisory No. 14

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-475-9864.

Attachment

cc: C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in response to your letter of May 17, 1990, to Dr. David L. Dull, in which you asked for clarification regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs). Your letter was referred to my office for response.

Specifically, you asked whether GLP compliance it required of an independent confirmatory method trial performed to gather data for a petition involving new analytical methods for determining pesticide residues in agricultural commodities or processed foods. You further asked for guidance for determining the point at which basic exploratory work may develop into a study that must be performed under GLP compliance.

The scope of the FIFRA GLP requirements covers studies conducted to support tolerance petitions. As such, the confirmatory method trials fall under the scope of GLP requirements.

The FIFRA GLPs are explicit in stating that “basic exploratory studies carried out to determine whether a test substance or test method has any potential utility" do not fall under the definition of “study" and consequently are not under GLPs. Confirmatory method trials are not basic exploratory studies since it is assumed that their potential utility has been established by the time that such trials are performed.

General guidance regarding the point at which an "exploratory" study should be regarded as potentially requiring GLP compliance is provided directly by the GLP regulation. At 40 CFR 160.1 the standards state that GLPs are prescribed for the conduct of studies "intended to support applications for research or marketing permits..." Thus, at any time where it is known that study data are intended to be submitted to EPA under the scope and definition given in the regulation, that study must be performed according to GLPs. However, we would advise that at any time that it is known that the data from a study may be submitted to EPA under the scope and definition given in the regulation, that study should also be conducted according to GLPs. Such data, if later reported to EPA, would be required to be accompanied by a valid compliance statement. The data submission may be rejected if the compliance

statement indicates GLPs were not followed regardless of whether the data were intended for submission to EPA at the time that the study was performed.

If you have any questions concerning this response, 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

cc: David L. Dull
GLP File