UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

December 4, 1990

MEMORANDUM

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

GLP Regulations Advisory No. 29

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Mr. Peter L. Joseph
Chief, Technology support Staff
Science and Technology
Animal and Plant Health Inspection Service
U. S. Department of Agriculture
Federal Building
Hyattsville, Maryland 20782

Dear Mr. Joseph:

This is in response to your letter of December 12, 1990, in which you requested clarification regarding applicability of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs) to certain data submission required to support pesticide registrations held by APHIS. Specifically, you asked: (1) whether an analytical method submitted under 40 CFR 158.120 (guideline 62-3 ) or under 40 CFR 158.240 (guideline 171-4) is considered a study; and (2) if so, how GLP protocol and quality assurance unit (QAU) record keeping and inspection requirements apply when the "data" is developmental in nature.

The GLPS as stated at 40 CFR 160.1 apply to the conduct of all studies which support, or are intended to support, pesticide registrations. When test method verification work is performed per the cited guidelines for submission to EPA it must be conducted according to GLPs. However, as defined under the FIFRA GLPs, the term “study” does not apply to basic exploratory studies performed to determine whether. . . a test method has at potential utility. Therefore, data which are developmental in nature would not be under GLP protocol and QAU requirements.

Please note that the Federal Register of May 4, 1988, (53 FR 15952) recodified certain data requirement. The enforcement analytical method requirement, previously located at 40 CFR 158.120, is now located at 40 CFR 158.180. The residue chemistry

method requirement is still located at 40 CFR 158.240.

If you have any questions regarding this reply, please contact Steve Howie at (703) 308-8290.

Sincerely yours,

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

cc: David L. Dull
GLP File