UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

March 3, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 43

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: M. Stahl
C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in response to your letter of January 31, 1991, in which you described your company's approach to performing pesticide field residue studies in support of marketing permits under the Insecticide, Fungicide, and Rodenticide Act (FIFRA).

You described this approach as incorporating all phases of experimental work from field application to final reporting as a single study. You further stated that it is your company's policy to treat separate field trials of the same crop and product as separate studies when different sites are involved. In your program, each trial is regarded as a full study requiring compliance with all study-specific requirements of the FIFRA Good Laboratory Practice Standards (GLPS), including having a single study director, a separate protocol, and meeting quality assurance unit (QAU) inspectional requirements. You mentioned that the application phase and analytical phase of a study are considered part of the same study.

The approach that you described does not conflict with the requirements of the GLPS, since the residue results of a single location can be considered to demonstrate properties of the pesticide independently of trial performed at other locations. Thus the single location trial is definable under 40 CFR 160.3 as a study. Your described approach of assuring that all aspects of each trial are considered together for that trial is essential since the separate parts of a study do not in themselves demonstrate any properties of the test substance and hence cannot be defined as studies under GLPS. In separately treating each trial as a study you are correct in assigning each trial its own protocol and study director and assuring that each trial (i.e., study) meets QAU inspection requirements separately.

Please note that the approach that you describe is not the only method available to meet GLPS. There is latitude to combine trials performed at several locations into a single study protocol. The choice is purely one of administrative discretion on the part of the persons responsible for the study. Regardless of how many

field sites are involved in a study, however, analytical work must remain part of the same study, and only one study director can be assigned. Thus if a person opted to include several field trials in one study only one study director could be assigned to oversee all sites.

Again, the approach that you described does not appear to conflict with GLP compliance If you have any questions regarding this response, please contact Steve Howie of my staff at (703) 308-8290

Sincerely yours,

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

cc David Dull
GLP File