



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

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

September 19, 1996

MEMORANDUM

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

GLP Regulations Advisory No. 75

FROM: Rick Colbert, Director
Agriculture and Ecosystems Division
TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Agriculture and Ecosystems Division of the Office of Compliance. 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 202-564-2365.

Attachment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Dear

This is in response to your letter of August 26, 1996 in which you requested compliance assistance with respect to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). You wanted to know who in the EPA should be notified when data are transferred to the archives of a sponsor when a facility that conducts testing or that is contracted to archive data goes out of business. They require this notification under GLPS at 40 CFR 160.195(g).

You specifically referred to X which conducted the field portion of residue studies for Y. According to your letter, X went out of business and the non-study-specific archives were transferred to Y archives. These records were then transferred to a contract facility to provide better accessibility by other sponsors who had contracted with X. You stated that X had assured you that the other sponsors had been notified of the disposition of the records.

Our office is the correct office to notify in writing, as required at 40 CFR 160.195(g), when data are transferred after a facility goes out of business. In your written notification, please identify both the archiving facility and the studies that are affected by the transfer. If the affected archives apply to only the field portion of the studies, please indicate that in your notification

Sincerely yours,

/s/ Rick Colbert, Director
Agriculture and Ecosystems Division
Office of Compliance

cc: Francisca E. Liem
GLP File