



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. 77

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

Dear

This is in response to your letter of February 5, 1997, in which you requested an interpretation regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). Specifically, you asked whether storage stability studies fell under full GLPS applicability as stated at 40 CFR 160.135(a). You stated that some of your clients had been informed that storage stability studies (EPA Product Chemistry Guideline 63-17) were subject only to partial GLPS as described at 40 CE 160.135(b).

The GLPS state at 40 CFR 160.135(a) that all provisions of the GLP standards shall apply to physical and chemical characterization studies designed to determine stability..."Storage stability studies are considered to fall into the category of stability studies. Therefore the full standards apply to storage stability studies.

If you have any questions regarding this response, please contact Steve Howie of my staff at (202) 564 4146.

Sincerely yours,

/s/ Rick Colbert, Director  
Agriculture and Ecosystems Division (2225A)  
Office of Compliance

cc: Stephen Johnson, OPPIRD  
Jesse Baskesaille, ORL/TPED  
David L. Dull  
Francisca E. Liem  
GLP File