



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 17, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 51

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 (703) 308-8333.

Attachment

cc: M. Stahl
C. Musgrove



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear

This is in response to your letter of July 29, 1992 in which you requested relief from certain requirements under the Federal Insecticide, Fungicide, and rodenticide Act (FIFRA) good Laboratory Practice Standards (GLPS). Specifically, you requested relief from the requirement under these standards for the retention of tests substance storage containers for the duration of a study, as provided at 40 CFR 160.105(c).

Your request was restricted to your study number (Beta) X banana fruit magnitude of residue study. You described this study as involving X liquid formulation, batch number (Echo). It is to involve six sites in five foreign countries: Guatemala (1035 liters); Honduras (1035 liters); Costa Rica, site 1 (1550 liters); Costa Rica, site 2 (1295 liters); Panama (1550 liters); and Columbia (1035 liters). The test substance is packaged in 10 liter containers, 2 per box.

You stated that long-term retention of containers would represent a safety hazard that may conflict with the regulations in the countries involved in the study.

Our staff has reviewed you request in light of the need to provide complete accountability of test material and the potential burden involved in storing and accounting for over 700 containers in six different locations in five countries. It is our opinion that certain record keeping steps could provide a basis for establishing an acceptable alternate method for the accounting of test substance storage containers in lieu of actual storage of the containers for the duration of this study, and are willing to allow a conditional exception to this requirement.

This exception is applicable to the study that you cited in your letter, and is conditional on the following:

- 1) N shall assure the following records are maintained as raw data for this study: (a) information of shipments pertaining to each container leaving the storage site (examples of such records are shipping request records, bills of lading, carrier bills, and monthly inventories of warehouse activity; (b) test article receipt records at such testing facility; (c) complete use of logs and material taken from containers (d) a record of the final destination of the container, including the place and date of disposal or recycling, and any appropriate receipts.

2) A statement shall be included with the statement of compliance or noncompliance required at 40 CFR 160-12 describing that this exception to Good Laboratory Practices is in accordance with the conditions provided in this letter.

3) N shall prepare an inventory of empty containers before disposal, including sufficient information to uniquely identify containers, and shall maintain this inventory in an up-to-date manner recording all arrivals of empty containers and their disposal. This record shall be maintained as raw data for the study.

4) N shall identify the locations of facilities: where test material is stored; where empty containers are stored prior to disposal; where records of use, shipment, and disposal of containers are maintained; and where the test substance is used in studies (i.e., testing facility). Within two weeks of receipt of notification of any pending inspection involving this study, N shall report the location of each of these facilities to:

David L. Dull, Director,
Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342)
Office of Pesticides and Toxic Substances
Environmental Protection Agency
401 M Street SW
Washington, DC 20460

In addition N is reminded that storage, disposal, or recycling of containers must be done in a manner pursuant to all applicable local laws.

If you have questions concerning 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

cc: David L. Dull
GLP file