



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

August 3, 1993

MEMORANDUM

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

GLP Regulations Advisory No. 63

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, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear

This is in reply to your letters of May 21, 1993, and June 6, 1993, in which you requested a waiver for certain requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPs).

Specifically you requested that the retention requirement for test substance storage containers, as provided at 40 CFR 160.105(c), be waived with respect to a study identified by the code, 934110 which you are performing. The study in question is a drift and worker exposure study which your company is conducting for the sponsors.

You stated in your letters that the reason you asked for a waiver resulted from the nature of the containers involved in the study. The containers in question are large steel cylinders, with weight capacity from 250 to 1500 pounds which are refilled with methyl bromide after each fumigation application. The canisters need to be available for refilling for other applications throughout California and other states. Retaining the canisters would require storage of hundreds of containers and would create a hardship on the applicator companies as their supply of containers would soon be depleted for future use.

In your July 6, 1993 letter you further described the trial as starting sometime in July, 1993 and ending in October, 1993 in Santa Barbara County. Your letter indicated the amount to be applied was up to 300 pounds per acre of the 98% formulated material, within one trial on a ten acre plot. EPA believes that the provision for assignment of storage containers for the duration of the study at 40 CFR 105(c) is a logical and necessary standard. In most cases this provision provides accountability of test material in a manner that imposes no unusual burden. In this particular case we agree that the number and type of containers may pose unusual problems.

Our staff has reviewed this request and proposal in view of the need to provide complete accountability for the test material and the potential burden involved in storing and accounting for the number of containers mentioned. 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 containers for the duration of this study. We are willing to allow a conditional exception to this requirement.

This exception is applicable to the study that you cited in your letter and describe above 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 (example of such records are shipping requests records, bills of lading, carrier bills, and monthly inventories of warehouse activity); (b) test article receipt records at each testing facility; (c) complete use logs of material taken from containers; and (d) a record of the final destination of the container including the place and date of disposal or reclaiming and approximate receipts.

2. A statement shall be included with the statement of compliance or noncompliance for study required at 40 CFR 160.12 describing that this exception to FIFRA Good Laboratory Practices is in accordance with the conditions provided in this letter.

3. If disposal of containers occurs, N will 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 this study.

4. N shall identify the locations of facilities where test materials are stored, where recycling of containers occurs, where empty containers are stored prior to disposal or recycling, where records of use, shipment, and disposal/disposition of containers are maintained, and where the test substance is used in studies (i.e. the 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-W)
Office of Prevention, Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

In addition, 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

Virginia Lathrop of my staff at (703) 308-8292.

Sincerely yours,

/s/ John J. Neylan III, Director,
Policy and Grants Division,
Office of Compliance Monitoring

cc: David Dull GLP File