



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
June 10, 1993

MEMORANDUM

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

GLP Regulations Advisory No. 60

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 reply to your letter of March 19, 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 be waived with respect to a study (identified by your identification code as (ALPHA) which you are performing. The study in question is an applicator exposure study which your company is conducting in conjunction with the California Department of Pesticide Regulations.

You stated in your request that the number of replicates (40), the amount of test substance (400,000 to 700,000 pounds), and the size of the containers (1280 pound bags) creates a logistical dilemma with respect to container retention. You also stated that as part of your company's environmental stewardship, all commercial containers are recycled.

In a telephone discussion on May 18, 1993, with Steve Howie of my staff, you further identified the test substance as X (10% granular), EPA Registration No. N, Establishment No. N. You described the study as a worker exposure study which began (protocol signature date) on April 19, 1993, with applications of the test substance to the test system occurring during the period of May 1 - June 15, 1993.

EPA believes that the provision for assignment of storage containers for the duration of the study at 40 CFR 160.105(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 of containers may pose unusual encumbrance problem.

Our staff has reviewed this request and proposal in view of the need to provide complete accountability for the test and the potential burden involved in storing and accounting for the number of containers mentioned described above. It is our opinion that certain record keeping steps could provide a basis for establishing an acceptable alternative method for the accounting of test

substance storage containers in lieu of actual storage of the containers for the duration of this study. We are willing to allow N a conditional exception to this requirement.

This exception is applicable to the study that you your letter and described above and is conditional on the following:

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