



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

December 4, 1990

MEMORANDUM

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

GLP Regulations Advisory No. 25

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: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear

This is in response to your letter of June 26, 1990. In that letter, you requested a waiver of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practices (GLP) requirements at 40 CFR part 160.105(c) which require the assignment of test substance storage containers for the duration of a study. Your request is in reference to a forest dissipation study using triclopyr and picloram.

According to your letter, this study will involve approximately 200 2.5 gallon containers (500 gallons). You requested the waiver because: (1) all products of each compound are from the same lot number; (2) each product has been assayed for composition; (3) the requirement would cause storage and transportation problems; and (4) the day 0 application dose will be monitored by pre-application tank samples, field-exposed filters, and post application soil samples.

The purpose of 40 CFR 160.105(c) is to assure that test substances are stored in proper containers, and that the containers that are used can be accounted for during the study. Normally, retention of the containers (i.e., assignment for the duration of the study), provides these assurances in a manner that is not a great burden.

Our staff has reviewed your request in light of the need to provide complete accountability of test substance and the potential burden involved in storing and accounting for approximately 200 2.5 gallon containers. 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, 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 maintain records fully accounting for each container, and its contents, from receipt of test substance

to the ultimate disposition (i.e., disposal, reclamation, or recycling) of the container. These records shall be maintained as raw data to this study. These records shall include, but not be limited to: (a) information on shipment pertaining to each container leaving the storage site (examples of such records are shipping request records, bills of lading, carrier bill, and monthly inventories of warehouse activity); (b) test substance receipt records at testing facility and/or testing Site(s); (c) complete use logs of material taken from containers including quantitation of amounts; (d) a record of the disposition of the container, including the place, date, and any appropriate receipts.

2) A statement certifying that all the conditions outlined in this letter were complied with shall be included with the statement of compliance or noncompliance required at 40 CFR 160.12.

3) A copy of this letter and a statement certifying that all the conditions outlined in this letter are being complied with shall be maintained as raw data for this study and shall be presented upon any inspection involving this study.

4) N shall identify the locations of facilities: where test substance is stored; where empty containers are stored prior to disposition; where records of use, shipment, and disposition of containers are maintained; and where the test substance is used in studies (i.e., testing site(s)).

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 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

Should these conditions not be fully met, all of the provisions of 40 CFR 160 (GLPs), including assignment of storage containers for the duration of the study, apply.

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

If you have any questions concerning this response, please

contact Steve Howie of my staff at (202) 475-7786.

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

cc: David L. Dull
GLP File