



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. 24

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 April 18, 1990 regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs). Your letter was referred to my office for reply.

Specifically, you requested a waiver of the requirement under GLPs that test substance storage containers be retained until the end of a study. Your request was in specific reference to a study that involves applying two formulations of Bendiocarb to 28 golf courses. You point out that this study will involve up to a total of 10,000 test substance containers. In your letter you request that you be allowed to dispose of fully used containers and that you be allowed to transfer control of partially used containers to the cooperating golf course.

Our staff has reviewed your request in light of the need to provide complete accountability of test material and the potential burden involved in storing and accounting for up to 10,000 containers in 28 different locations. We would like to suggest, considering the quantities of pesticide involved in these studies, that use of bulk shipping containers may be a preferable means of supplying the test substance for these studies. While it would still be necessary to identify and keep records of each shipment of test substance, the use of bulk shipping container would significantly reduce the number of containers required.

However, should bulk containers not be a viable alternative, 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 a conditional exception to this requirement, provided you notify this office of your intent to adhere to the conditions outlined in this letter.

This exception is applicable to the study that you cited in your letter (Bendiocarb terrestrial field study per guideline reference 71-5 using X and Y) and is conditional on the following:

- 1) N Company shall maintain records fully accounting for

each container, and its contents, from receipt of the 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 shipments pertaining to each container leaving the storage site (examples of such records are shipping request records, bill of lading, carrier bill, and monthly inventories of warehouse activity); (b) test substance receipt records at the 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 Company shall maintain complete records of the transfer of any partially used containers to a cooperator or any other person, including identification and amount of the material transferred, the type of container, and the date of the transfer.

5) N Company 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) 415-7786.

Sincerely yours,

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

cc: David L. Dull
GLP File