



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

OFFICE OF  
ENFORCEMENT AND  
COMPLIANCE ASSURANCE

August 7, 1997

MEMORANDUM

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

GLP Regulations Advisory No. 78

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 Agriculture and Ecosystems Division of the Office of Compliance. 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 202-564-2365.

Attachment



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF  
ENFORCEMENT AND  
COMPLIANCE ASSURANCE

Dear

This is in reply to your letter of May 30, 1997, 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 chlorpyrifos exposure study you are planning in 1997. The study in question is a mixer/loader applicator exposure study during aerial application of X or Y. The study is to be conducted under ((protocol number)), involving determining exposure to about 15 mixer/loaders at three or more separate locations. You calculated that this will require fifty 10 pound (2.5 gallon) containers per replicate, for a total of 750 containers.

You stated in your request that the number of test containers potentially generated by this study would make retention of the containers by shipment back to ({location}), costly and time consuming. You stated that the origin of the test substance, shipment to test site, and storage conditions at the test site will be documented, as will disposal of the test containers. You stated that you intended to retain in archives a sample of each lot of test substance.

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 substance in a manner that imposes no unusual burden. In your particular case we agree that the number of containers may pose unusual encumbrance problems.

Our staff has reviewed this request and proposal in view of the need to provide complete accountability for the test substance and the potential burden involved in storing and accounting for the number of containers mentioned described above. It is our opinion that certain recordkeeping 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. We are willing to allow DowElanco a conditional exception to this requirement.

This exception is applicable to the study that you cited in 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 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 substance 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 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 this study.

4) N shall identify the locations of facilities: where test substance 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 my attention.

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 (202) 564-4146.

Sincerely yours

/s/ Rick Colbert, Director  
Agriculture and Ecosystems Division (2225A)  
Office of Compliance

cc: David L. Dull  
Francisca E. Liem  
GLP File