



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

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

April 15, 1998

MEMORANDUM

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

GLP Regulations Advisory No. 81

FROM: Rick Colbert, Director
Agriculture and Ecosystems 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
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Dear

This is in reply to your letter of March 2, 1998, 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 two worker exposure studies you will be conducting. One study involves NNN systemic insecticide/nematicide with fifteen replicates using a NNNN closed handling system. The amount of test substance to be used in the study is substantial (approximately 12,000 pounds or 300 containers [40 pounds each] at a total of 15 sites). You stated that retention of such a large number of original NNN closed handling containers represent a significant burden to the overall conduct of this study (e.g., storage and safety issues). In addition, you indicated that all commercial containers of this test substance are scheduled to be recycled according to label instructions.

The second study involves NNN systemic insecticide/nematicide with fifteen replicates using test substance sold in commercial bags. The amount of test substance to be used will be approximately 10,000 pounds or 200 bags (50 pounds each) at a total of 15 sites. You indicated that retention of test substance containers creates a significant burden to the overall conduct of this study.

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 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 the containers for the duration of this study. We are willing to allow a conditional exception to this requirement.

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

- 1) XXX 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) XXX shall prepare an inventory of empty containers before disposal/ or reclaiming, 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 or reclaiming . This record shall be maintained as raw data for this study.
- 4) XXX 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, shall report the location of each of these facilities to my attention.

In addition, XXX 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 Cletis Mixon of my staff at (202) 564-4153.

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

cc: David Dull
Francisca E. Liem
GLP File

