



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

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

July 11, 1996

MEMORANDUM

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

GLP Regulations Advisory No. 74

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
WASHINGTON, D.C. 20460

OFFICE OF
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Dear

This is in response to your letter of March 22, 1996. In that letter, you requested a waiver of the 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 mixer/loader/applicator and transferable residue studies that X would be conducting over the next three years.

In your letter you stated that conforming to this standard could cause logistical problems. You stated that in lieu of such container retention, X would maintain detailed records of test substance usage and complete inventories. In addition, you stated that the quality assurance unit would provide complete audits.

On May 24, 1996, following a telephone conversation between X and Steve Howie, of my staff, X sent information indicating the identity and quantities of the test substance in question.

X letter indicated that the project would be conducted over a period of three years and involve an as yet undetermined number of studies and containers. However, for the 1996 period, three studies will be conducted on eleven registered products representing three active ingredients.

The first study involves Z by X in five different types of packaging: (1) granular 5% ai, 6000 lb. in 50 lb. bags; (2) wettable powder (WP) 75% ai, 384 lb. in 24 lb. bags; (3) flowable 6 lb ai/gal, 15 gal in 2 1/2 gal containers; (4) water-dispersable granules 75% ai, 125 lb. in 25 lb. bags; and (S) WP, water soluble (WS) 75% ai, 1 50 lb. in 1 lb. WS packages, packaged in 2 lb. non-WS packages. This study would be conducted at two locations in July and August.

The second study involves one container each of four different products made by various manufacturers in the following

formulations: (1) emulsifiable concentrate (EC) 47.8%; (2) WS 96.68%; (3) WP 25.5%; and (4) granular 29.55% . This study was to be conducted on a sod farm near s during the week of June 3.

The third study involves one container each of two different products made by X in the following formulations: (1) EC 12.7% ai; and (2) granular 0.27% ai. This study was to be conducted on the same sod farm near St. Louis as study number 2, during the same week of June 3.

Thus, from your description, a total of 228 containers would be required for 1996.

EPA believes that the provision for assignment of storage containers for the duration of the study at 40 CFR 160.105(c) is a necessary provision that in most cases provides accountability of test material in a manner that imposes no unusual burden. In case, however, we agree that the number of containers may pose unusual logistics burdens.

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 228 separate containers. 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, and we are willing to allow a conditional exception to this requirement.

This exception is applicable to the 1996 testing indicated in your letter as conducted by X and is conditional on the following:

- 1) X 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 article receipt records at each testing facility, (c) complete use logs of material taken from containers; (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) X 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) X 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, X shall report the location of each of these facilities to:

Rick Colbert, Director
Agriculture and Ecosystems Division (2225A)
Office of Compliance
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 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, 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.

Our office will consider extending this exception to additional studies which you indicated may be conducted by X over the next three years. Please specifically identify in writing such studies, as was done in letter of May 24, when requesting such exceptions.

If you have questions concerning this response, please contact Steve Howie of my staff at (202) 564-4146.

Sincerely your,

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

cc:

Frances E. Liem, EPA GLP File