



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

April 15, 2008

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

MEMORANDUM

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

GLP Regulations Advisory No. 82

FROM: Rick Colbert, Director
Agriculture 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 Advisory No. 82



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

February 13, 2008

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Dear Dr.

This is in response to your letter of January 21, 2008 to Francisca Liem, Chief, Laboratory Data Integrity Branch, in which you requested an exception from certain requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS).

Specifically, you requested an exception from test substance containers retention and retaining reserve samples from each batch of test substance for the period of time provided by 40 CFR 160.195.

I am responding pursuant to FIFRA GLPS Questions and Answers, May 12, 1992, Questions 22, 23 and 24.

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 the test substance in a manner that imposes no unusual burden.

Our staff has reviewed this in light of the need to provide complete accountability of test substance and the potential burden involved in storing containers in four different locations in two countries. It is our opinion that certain record keeping steps 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 the study. This alternate method is to include the following:

1. NNNNN, as the sponsor, 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, bill of lading, carrier bills, and monthly inventories of warehouse activity); (b) test substance receipt records at each testing facility; (c) complete use logs of mater material taken from containers; and (d) a record of the final destination of the containers, including the place and date of disposal or reclaiming, and any appropriate receipts.
2. A statement shall be included with the statement of the 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. NNNNN, as the sponsor, 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. NNNNN, as the sponsor, 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, NNNNN shall report the location of each of these facilities to:

Francisca Liem, Chief
Laboratory Data Integrity Branch
Office of Compliance (2225A)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

If you follow the above procedures, please note this letter and its procedures when you make the GLP compliance statement required by 40 CFR 160.12. In addition, you are reminded that storage, disposal, or recycling of containers must be done in a manner pursuant to all applicable local laws.

Your second request for exception is to collect and retain reserve samples of the test substances. You indicated that due to the use of closed-transfer systems in many commercial facilities, it is either impractical or unsafe to attempt to collect reserve samples of the test substances. Francisca Liem discussed the procedure of collecting a reserve sample with you. You do not have to collect the reserve samples from the closed-transfer systems in the commercial facilities, because we realize that it is unsafe to do so. However, you may collect the reserve samples from the original batches. These reserve samples must be of the same batch that you use for the study. If you use a number of batches of the same test substance for the study, you must retain a reserve sample of each batch. You agreed that a reserve sample may already exist at NNNNN. In light of this, we do not see the need for an exception from collecting and retaining reserve samples.

If you have questions concerning this response, please contact Francisca Liem of my staff at (202) 564-2365.

Sincerely,

/s/ Rick Colbert, Director
Agriculture Division

cc: Francisca Liem

Francisca Liem
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 2225A
Washington, DC 20460

Request for Waiver from 40 CFR Part 160.105 (c) and (d)

Dear Francisca:

I am writing to request a waiver of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practices (GLP) requirements at 40 CFR part 160.105(c) and (d), which require the assignment of test substance storage containers for the duration of a study and retention of reserve samples of test substances.

NNNNN is planning a study entitled "Observational Study to Determine Dermal and Inhalation Exposure to Workers in Commercial Seed Treatment Facilities: Mixing/Treating with a Liquid Pesticide Product and Equipment Clean-out" (NNNNN study number XXXXX.) In that study NNNNN will measure exposure to workers treating seed in commercial facilities with the products and containing the active ingredients ZZZZZ. These products are typically handled in commercial seed treatment facilities in either 30 gallon drums or 200 gallon totes.

The study will be performed at four different sites; two in the US and two in Canada. Treatment runs are anticipated to last several days and may require up to 1000 gallons of test substance at each location. Retention of these containers would be problematic and may cause a safety hazard for workers at the seed treating facilities. Additionally, due to the use of closed-transfer systems in many commercial facilities it is either impractical or unsafe to attempt to collect reserve samples of the test substances.

Records of the active ingredients used, manufacturer's lot numbers, amounts of test substance handled, and methods of use will be recorded for all test substances used in the study.

In addition, this study has been determined by EPA's Office of Pesticide Programs to be observational and not fall within the regulatory definition of "research involving intentional exposure" with respect to the use of human subjects. Due to the observational nature of this study we are barred from specifying the test substance(s) used at any given location or the manner in which that material is used, stored or handled. Other than recording the details of the material used, we are not allowed to interfere in the activities being observed. If sample and container retention is required, this would change the normal work processes for handling and storage of active ingredients at these facilities, jeopardize the observational nature of the study, and possibly even change the exposure to workers from that experienced during normal handling practices.

Thank you for your assistance and guidance in this manner.