



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

October 21, 1993

MEMORANDUM

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

GLP Regulations Advisory No. 67

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: M. Stahl
C. Musgrove



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear

This is in response to N's letter of August 24, 1992 to Ms. Lois Rossi of the Office of Pesticide Programs. Her letter was referred to my office for reply. In her letter N requested on behalf of N a waiver of the Good Laboratory Practices (GLP) requirement that test substance storage containers be assigned for the duration of a study (40 CFR part 160 105(c)) The request is in reference to field crop trial study. According to N's letter this study involves applications in locations throughout the United States and will involve approximately 60 fifty-five-gallon drums and 2,640 five-gallon pails of ultra-low volume formulation; 120 five-gallon pails of 51% emulsifiable concentrate; and 600 five gallon pails of ready-to-use formulation. N stated that conforming to this standard would represent a safety hazard that may conflict with State and local regulations. She proposed that N be permitted to comply with several record keeping and notification steps in lieu of container retention.

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 material in a manner that imposes no unusual burden. In this particular case we agree that the number of containers may pose unusual encumbrance or safety problems.

Our staff has reviewed this request and proposal in view of the need to provide complete accountability for the test material 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 N 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 N a conditional exception to this requirement.

This exception is applicable to the study cited in N's letter (X field crop trial study) 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 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) 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 retain as raw data for the study a copy of the waiver and a statement certifying that all conditions of the waiver were complied with this statement to be presented upon any inspection involving the study.

5) N 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 N shall report the location of each of these facilities to:

David L. 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

Please note that with the exception of the additional third item (inventory of containers), these conditions parallel the actions proposed in N's letter. 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.

If you have questions concerning this response please contact Steve Howie of my staff at (703) 308-8290

Sincerely yours,

/s/John J. Neylan III, Director,
Policy and Grants Division
Office of Compliance Monitoring(EN-342)

cc: David L. Dull
Lois Rossi
Peg Perreault
GLP File