



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

March 22, 1990

MEMORANDUM

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

GLP Regulations Advisory No. 5

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-475-9864.

Attachment

cc: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dear

This is in response to your letter of February 19, 1990. 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 a worker exposure study with Bromoxynil (EPA Reg. No 264-229).

In your letter you stated that the study, conducted at 20 different sites throughout the country, would require about 1100 containers of the product, and that saving these for the 6-9 months of the study would present storage problems. You also mentioned that all of the product used would be from the same batch, with analysis of material done prior to study initiation.

EPA believes that the provision for assignment of storage containers for the duration of the study at 40 CFR 160 105© is a logical and necessary provision that in most cases provides accountability of test material in a manner that imposes no unusual burden. In this particular case; however, the number of containers may pose unusual encumbrance problems.

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 1100 containers in twenty different locations. 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 are willing to allow a conditional exception to this requirement.

This exception is applicable to the specific case of the approximately 1100 containers of test substance used for the Bromoxynil worker exposure study (EPA Reg No 264-229) 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: © 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 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

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, N 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 (202) 475-7786

Sincerely yours,

/s/John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

cc: David L. Dull
GLP File