



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

December 4, 1990

MEMORANDUM

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

GLP Regulations Advisory No. 26

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: 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 March 15, 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 terrestrial and aquatic field studies where large amounts of pesticide may be used as part of the study.

In your letter you stated that conforming to this standard could cause safety hazards and potential violations of state and local laws. You listed the amounts required of seven pesticides being applied to a total of 11 sites, ranging from 120 gallons (in 5 gallon cans) at one site to 121,000 lbs (in 50 lb bags) at another, and listed an additional pesticide and site for which the precise amount to be used was not yet known. You requested a general waiver for these studies, and for any others in 1990 where more than 20 gallons or 50 pounds of pesticide are to be used. Finally, you included a draft copy of your chain of custody standard operating procedures and forms to be used to document receipt, use, storage and disposition of test substances during field studies.

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 over 2400 containers in twelve 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 studies that you cited in your letter, except for the Pennsylvania apple insecticide study, which will require a separate waiver request when the precise amount of pesticide and number of containers is known, and is conditional on the following:

- 1) N shall maintain records fully accounting for each container, and its contents, from receipt of the test

substance to the ultimate disposition (i.e., disposal, reclamation, or recycling) of the container. These records shall be maintained as raw data to this study. These records shall include, but not be limited to: (a) information on 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 the testing facility and/or testing site(s); (c) complete use logs of material taken from containers, including quantitation of amounts; (d) a record of the disposition of the container, including the place, date, and any appropriate receipts.

2) A statement certifying that all the conditions outlined in this letter were complied with shall be included with the statement of compliance or noncompliance required at 40 CFR 160.12.

3) A copy of this letter and a statement certifying that all the conditions outlined in this letter are being complied with shall be maintained as raw data for this study and shall be presented upon any inspection involving this study.

4) N shall identify the locations of facilities: where test substance is stored; where empty containers are stored prior to disposition; where records of use, shipment, and disposition of containers are maintained; and where the test substance is used in studies (i.e., testing sites)). Within two weeks of receipt of notification of any pending inspection involving this study, Wildlife International shall report the location of each of these facilities to:

David 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

We have reviewed the copy of standard operating procedures that you included and believe that these procedures do provide a

good basis for test substance container accountability provided that the conditions stated in this letter are incorporated into your standard operating procedures.

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