



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. 27

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
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Dear

This is in response to your letter of June 7, 1990, to Dr. David Dull regarding EPA policy regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs). That letter was referred to my office for reply.

Specifically, you asked about the standard at 40 CFR 160.10S(c) which requires test substance storage containers to be assigned for the duration of a study. You described this as causing problems during residue field trials, where the standard may result in the retention of many empty or near-empty containers for a substantial period of time; this could result in space and safety problems. As a solution you proposed that a photograph of the container (label intact, and punctured or otherwise rendered unusable) be kept in study files throughout the study. You stated that this would satisfy the requirements of 40 CFR 160.105(c) by providing documented evidence that the container was only used for that particular substance for the duration of the study.

Assignment of test substance containers for the duration of a study can best be assured by container retention, which is normally not a great burden. On several occasions, persons conducting or sponsoring studies have written EPA to explain that, in the case of a specific study which they were conducting or planning to conduct, the retention of empty containers would cause encumbrance or safety problems. We have reviewed such cases and made exceptions on an individual basis, with conditions to assure container accountability.

We are presently continuing our policy of individual review of such cases. Your suggested approach of using photographic evidence may be useful as a supplemental condition to assure container accountability, but only in the case that it is in conjunction with and under the conditions provided for a specific, approved exception.

We currently consider 40 CFR 160.105(c) as requiring retention of test substance storage containers unless such an individual exception is made.

If you have any 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