



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

November 1, 1990

MEMORANDUM

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

GLP Regulations Advisory No. 21

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

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PESTICIDES AND TOXIC SUBSTANCES

Dear

This is in response to your letter to Steve Howie, dated March 17, 1989, concerning FIFRA Good Laboratory Practice (GLP) compliance in 90-day feeding studies. In that letter you described a proposed setup where mixed feeds would be stored in the same rooms as the feeding studies, following preparation elsewhere. You requested clarification concerning the acceptability of your procedures in relation to FIFRA GLP standards.

Your procedures include storage of the unmixed test material in a separate, locked room, while preparation of the mixtures is performed in another separate room on a weekly basis. Storage of each mixture is in protected containers (double bagged, tied, in a separate covered, labeled container) on a non-wooden pallet covered with plastic sheeting in a far corner of the animal room. The animal room, as described in your letter, is designated to that study only.

The GLPs at 40 CFR 160.47(a) require separate areas for test and control substance receipt and storage, mixing, and mixture storage. At 40 CFR 160.47(b), the storage areas for test and control substances and mixtures are required to be separate from areas housing the test systems, as well as adequate to preserve the identity, strength, purity, and stability of the substances and mixtures.

There is a need to exercise judgement, since there is no specific definition of separate area or of the time frame intended by the term storage. Consideration must be given to the use of animal testing rooms primarily as testing rooms and not as storage rooms. EPA interprets the rule as allowing working quantities only of a mixture to be kept in the room housing the test system. Working quantities of a feed mix are typically considered to consist of a one to two-week supply. It would not normally be acceptable to store longer-term supplies of mixtures in a room that is dedicated to housing test systems. It would in any case be necessary to follow procedures that assure that the placing of working quantities of the mixture in the test room does not compromise the integrity of the mixture or otherwise jeopardize the study.

The procedures that you described in your letter are in accordance with our interpretation of 40 CFR 160.47 and would thus be considered by our office to comply with the FIFRA GLP rule. If you have any questions concerning this response, please call Steve Howie of my staff at (202) 382-7825.

Sincerely,

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

cc: David L. Dull
GLP File