UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 10, 1993

MEMORANDUM

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

GLP Regulations Advisory No. 61

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

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Dear

This is in reply to your letter of April 14, 1993 to Dr David L. Dull of the Laboratory Data Integrity Assurance Division. Your letter referred to the requirements of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) and was directed to my office for response.

In your letter you requested clarification regarding the need to retain wet specimens under tho GLP regulations. Specifically, you were interested in knowing retention requirements for wet samples of biological tissue from microcosm/mesocosm studies. According to your letter, your facility stores such samples in formalin solution in vials which cannot be sufficiently sealed to prevent evaporation. This necessitates periodic checks to replace evaporation losses so that samples do not deteriorate. You stated that auditors from the Environmental Protection Agency had suggested that it may be permissible for you to discard the samples following quality assurance verification as provided at 40 CFR 160 195(c).

The FIFRA GLPS at 40 CFR 160 195(c) specifically state that "[w]et specimens...and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage shall be retained only as long as the quality of the preparation affords evaluation." This provision does not appear to generally apply in your case. While you did mention a problem inherent to sample retention you also mentioned that your archiving procedures accounted for this through periodic chocks and replenishment of evaporated material. Presumably, when such specimens are archived under your procedure they continue to afford evaluation indefinably.

The same provision of the regulations also provides that "[s]pecimens of mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. " While this provision clearly allows plant tissues to be discarded after quality assurance verification, it does not provide a similar allowance for animal tissues. Presuming that the tissue samples you are dealing With are of animal origin, this provision would not allow for their disposal.

Consequently, under the provisions given at 40 CFR 160.195

(c), you are required to maintain your samples as long as they afford evaluation . Should you find that the samples you are keeping no longer afford evaluation, i.e., because of deterioration, the provisions at 40 CFR 160.l95(c) become effective and you may discard them. However, you are cautioned that the regulations state at 40 CFR 160.190(b) that the conditions of storage of specimens must minimize their deterioration in accordance with the nature of the specimens. Thus, if samples should deteriorate as a result of improper archiving, this would itself indicate a violation of the regulations.

Finally, please note that 40 CFR 160.195(h) does allow for specific samples to be discarded after notification by EPA that such samples are no longer required. This is allowed only on a case-by-case basis and generally provides that such samples may be discarded after an EPA or FDA audit has confirmed that the study they pertain to was conducted in accordance with FIFRA GLPS.

If you have any 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
GLP File