



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

May 5, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 45

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, DC 20460

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Dear

This is in reply to your letter of October 7, 1991, to Mr Steve Howie of my staff. In your letter you requested clarification regarding whether a treated seed would be considered the "test substance" when a field residue trial is being conducted in accordance with Good Laboratory Practice Standards (GLPS) with such seed. You stated that you have regarded treated seed as an "extension of the test substance" and have required chain of custody, secure storage, and receipt, use and disposition logs. I am presuming that your request for clarification was in reference to required testing under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Under FIFRA GLPS, at 40 CFR 160.3, the term "test substance" is defined as "... a substance or mixture administered or added to a test system in a study, which substance or mixture:

(1) Is the subject of an application for a research or marketing permit supported by the study, or is the contemplated subject of such an application; or

(2) Is an ingredient, impurity, degradation product, metabolite, or radioactive isotope of a substance described by paragraph (1) of this definition, or some other substance related to a substance described by that paragraph, which is used in the study to assist in characterizing the toxicity, metabolism, or other characteristics of a substance described by that paragraph.

According to this definition, treated seeds would be considered test substances under FIFRA GLPS only if the treated seeds themselves are the subject of or intended to be the subject of a research or marketing application (i.e., a pesticide registration). Thus, it is the pesticide which is used to treat the seed which would normally be considered to be the test substance under GLPS. Test substance requirements, such as retention of containers, would therefore not apply to seeds. While the control measures that you identified, i.e., chain of custody, secure storage, receipt, use, and distribution logs are not actually required of the treated seeds, their implementation will not conflict with the requirements of GLPS and may very well contribute to the overall integrity of the study.

Seeds which are not considered to be the test substance would still be considered part of the test system as defined in the FIFRA GLPS. The seeds would thus be subject to all GLP standards applicable to test systems.

Please note, finally, that if a seed product should become or if it is intended to become the subject of a research or marketing permit under FIFRA, the seed would then be the test substance as defined under the FIFRA GLPS. In that case, the seed would be subject to the GLP requirements that apply to test substances instead of those that apply to test systems.

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  
Anne Lindsay