



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. 28

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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Dear

This is in response to your letter of February 4, 1991, to Connie Musgrove. In that letter you requested written guidance regarding the Federal Insecticide, Fungicide, and Rodenticide Act, (FIFRA) Good Laboratory Practice standards (GLPS).

Specifically, you requested guidance regarding the applicability of GLPS to certain product performance (efficacy) studies. You stated that it was your understanding that GLPs do not apply to horn fly and tick control on cattle, ked control on sheep, lice control on swine, flea control on dogs, etc., during the research phase prior to submission for registration and product approval. You further stated that you did not believe that there could be subsequent imposition of GLPs to such studies "after the fact" if the EPA calls in such data after product registration.

The GLPs state at 40 CFR 160.3 under the definition of the term "study" that it applies to efficacy studies as required at 40 CFR 158.640. The table at 40 CFR 158.640 lists only antimicrobial agents, nematocides and fungicides, and vertebrate control agents. It does not currently include herbicides or insecticides, and hence does not cover the testing you mentioned, except when specific requests for such data are made under FIFRA 3(c)(2)(B).

If EPA specifically requires an efficacy study to be submitted, it is considered to be required under 40 CFR 158.640 which states: "The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration." Even though such data may not be explicitly listed in the data requirement table of that section, and may involve an insecticide or herbicide, it must be accompanied by a statement of compliance or non-compliance.

Where GLPs were not required at the time that a study was performed (e.g., the study was not performed specifically to meet the requirements of a data call in), the EPA does not expect to find such study in total conformity with GLPs after the fact, and will not automatically reject the data submission for failure to comply. However, the EPA reserves the right to determine the adequacy of such data, including whether it can be reconstructed, and to reject data of questionable or unknown integrity. A non-GLP

study submitted without a statement (i.e., as specified at 40 CFR 160.12) which states whether or not the study did meet all GLP requirements or which identifies all discrepancies with GLPs may be rejected as not providing sufficient information for the Agency to make an informed decision. Finally, deviations from the GLPs may in fact result in rejection of the study as insufficient to meet the data requirement.

If you have any questions regarding 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: Connie Musgrove
David L. Dull
John Carley, OPP
GLP File