



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. 30

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 February 23, 1990, to David Dull requesting clarification concerning Good Laboratory Practice standards (GLPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Your letter was referred to my office.

In your letter you specifically requested clarification concerning mixtures of substances with carriers, for which the FIFRA GLP requirements are stipulated at 40 CR 160.113. You stated that this standard appears to require that an analytical chemistry analysis be performed each time that a disinfectant is diluted for efficacy testing under the GLPs. You suggested that this is impractical due to the capabilities of laboratories that normally perform such testing and the fact that such dilutions must be prepared fresh for each test.

The GLPS state at 40 CFR 160.113 (a) that for each test, control, or reference substance that is fixed with a carrier, tests by appropriate methods shall be conducted to determine, "...periodically, the concentration of the test, control, or reference substance in the mixture." This requirement clearly applies to dilutions of disinfectants used in efficacy testing, just as it would for dilutions of agricultural pesticides used in studies involving field application.

However, this requirement does not apply to each batch of mixture prepared. The term "mixture" means a particular combination of ingredients, but is not restricted to mean only a particular batch or preparation involving those ingredients. Therefore, requirements regarding a mixture used in a particular test may be met by testing any preparation or batch of the mixture involving the same combination of ingredients. This testing must be sufficient to assure that the parameters stated in 40 CFR 160.113 are adequately supported, but need not be repeated for each batch or preparation unless there is a special reason to do so. Further, there is flexibility concerning where, when, and by whom such testing is performed, except that solubility and stability testing have time constraints as specified at 40 CFR 160.113(a)(2) and (3).

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, Director
Policy and Grants Division
Office of Compliance Monitoring

cc: David L. Dull
GLP File