



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

September 19, 1996

MEMORANDUM

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

GLP Regulations Advisory No. 76

FROM: Rick Colbert, Director
Agriculture and Ecosystems Division
TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Agriculture and Ecosystems Division of the Office of Compliance. 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 202-564-2365.

Attachment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Dear

This is in response to your letter of November 7, 1996, to David L. Dull in which you requested an interpretation regarding the Good Laboratory Practice Standards (GLPS). Specifically, your question related to data retention requirements under the Toxic Substances Control Act (TSCA) GLPS. You asked whether the five-year retention period for raw data (including wet tissue specimens) begins: (1) on the day the study is completed; (2) on the day the study results are submitted to the agency (even if the reports are submitted one year after the study has been completed); or (3) on the day the study is recognized as being received by the agency (even if the study report is not reviewed until two or three years after the study is submitted.)

The TSCA GLPS data retention requirements differ depending upon the reason that the study was performed. Studies performed to comply with a TSCA section 4 test rule have a data retention requirement extending at least ten years from the effective date of the test rule (40 CFR 792.195(b)(1)). Negotiated testing agreements contain a provision requiring retention of data for at least ten years following the publication date of the acceptance of the agreement (40 CFR 792.195(b)(2)). Data supporting testing submitted under TSCA section 5 are to be retained for at least five years following the date of submittal (40 CFR 792.195(b)(3)). Note that certain specimens and samples as specified at 40 CFR 792.195(c) can be disposed of earlier than the durations stated at 40 CFR 792(b).

As described in the rule, the data retention requirements under TSCA are not linked to the criteria you mentioned except in the case of data developed under section 5, where the beginning of the minimum retention period is defined by the time of submission to EPA. Neither the dates of study completion (i.e., signing of the final report by the study director) nor the date of receipt (or review) of the study by EPA are normally used to determine the start date for data retention requirements under TSCA GLPS. Note that under section 5 the data retention period explicitly begins with the date of submission of the study, regardless of when the study is completed. The longer such study is held before submission to EPA, the longer the raw data will have to be retained.

If you have questions regarding this response, please call Steve Howie of my staff at (202) 5644146.

Sincerely

/s/ Rick Colbert, Director
Agriculture and Ecosystems Division (2225A)
Office of Compliance

cc: Francisca E. Liem
GLP File