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# PR Notice 87-10. Notice to Pesticide Applicants Registrants and Petitioners

(U.S.) Environmental Protection Agency, Washington, DC

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15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document is one in the series of "Pesticide Regulatory Notices", usually called "PR Notices", which supplement the laws and regulations governing pesticide regulation in the US. These notices clarify, interpret and explain regulatory requirements and policies. They are directed at pestici registrants and other parties interested in detailed procedures of regulation.

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Notice to Pesticide Applicants, Registrants and Petitione

ATTENTION: Persons who sponsor or conduct toxicology studie support registration or reregistration of pestic

SUBJECT: Pathology raw data definition as it relates to pathology data trails and independent pathology peer review system

The purpose of this notice is to clarify for the regulated c the meaning of the term "raw data" in pathology and OPTS' po on the audit trail in pathology and to recommend independent peer review be performed on pathology.

## I. "RAW DATA" IN PATHOLOGY

The basic definition of raw data for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is given at 40 CFR 16( as, "...any laboratory worksheets, records, memoranda, notes, exact copies thereof, that are the result of original observa and activities of a study AND are necessary for the reconstru and evaluation of the report of that study." (Emphasis adde

This is further elaborated in Section 160.185(a)(12) and 160. in the requirements for the reporting of study results wherei signed and dated reports are required from each of the indivi scientists who "conducted an analysis or evaluation of data c specimens from the study after data generation was completed.

The requirements for storage of raw data and specimens are delineated in Section 160.190(a). All wet tissues, blocks, s and records thereof are considered to be raw data, and it sho be possible to reconstruct the pathology portion of the study from these retained data even in the absence of the pathologi working notes and interim diagnoses.

Since both the Food and Drug Administration and the EPA use essentially identical language in these sections of the Good Laboratory Practice (GLP) regulations we consider it advisable to maintain a consistent interpretation of these sections. Along with the FDA, the EPA's interpretation of these sections is that the pathologist's interim notes are not essential for the reconstruction and evaluation of the pathology portion of the final report. "Interim notes" are those interpretations made by the pathologist in the development of the first signed and dated version of the pathology report. Any changes to this first signed and dated pathology report are to be documented fully as described in FIFRA GLP regulations.

Although not essential, it is recommended that all records and documentation of readings and interpretations be preserved for possible future inspections by the facility's Quality Assurance Unit and/or the Agency.

## II. INDEPENDENT PATHOLOGY PEER REVIEW

The Agency also recommends the use of an independent pathology peer review system which would include the review of diagnoses of both normal and abnormal tissues. If such a peer review provided the Agency with both the report of the original pathologist as well as that of the reviewing pathologist(s) along with a consens pathology report which resolved any differences of professional opinion between the original pathologist and the independent reviewing pathologist(s) then this would greatly increase the Agency's confidence in the pathology report portion of the study.

The Agency believes that the additional burden placed upon laboratories complying with either this additional record keeping or the extended peer review will result in a reduced need for a particularly rigorous audit of the pathology data.

## III. INFORMATION CONTACT

For further information, contact Dexter S. Goldman, Director of the Laboratory Data Integrity Division, at 202-382-7830.

Edwin F. Tinsworth, Director
Registration Division