



Department of Pesticide Regulation



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Director

MEMORANDUM

Gray Davis
Governor
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Secretary, California
Environmental
Protection Agency

TO: Susan Edmiston, Sr. Environmental Research Scientist **HSM-01001**
Worker Health and Safety Branch *(HSM-13010 supercedes this HSM)*

FROM: Janet R. Spencer, Assoc. Environmental Research Scientist [Original signed by
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DATE: February 14, 2001

SUBJECT: POLICY FOR DESIGNATING FIELD STUDY CONDUCT STANDARDS

Background

In 1989, the US Environmental Protection Agency (US EPA) established Good Laboratory Practice Standards (GLPS; 40 CFR 160) to assure the quality and integrity of data submitted in support of research or marketing permits for pesticide products regulated by the Agency (1). The Worker Health and Safety Branch (WH&S) conducts field studies according to either GLPS or WH&S standards (1,2). This policy serves two functions:

1. it defines the scope and purpose for WH&S studies under each standard, and
2. it provides criteria for determining which standard applies to each WH&S study.

Scope and Purpose

GLPS Studies: WH&S studies conducted according to GLPS standards are *not* intended to support a research or marketing permit. WH&S conducts studies in compliance with GLPS for the following reasons:

- GLPS is the worldwide "gold standard" for study conduct,
- GLPS is the standard which applies to worker exposure studies submitted to DPR for scientific review (3). Since data from WH&S studies are used in DPR's risk assessment process, WH&S studies, when feasible, should adhere to the same standards.

WH&S studies conducted according to GLPS will usually not be in compliance with the requirements to have control of the test substance and mixtures of the test substance (160.105(a),(b),(e); 160.113(a)(1),(2),(3) and (c)). The compliance statement will note any such exceptions.

Studies Conducted According to WH&S Standards: WH&S standards provide the flexibility needed to assess the safety of the pesticide work place when GLPS studies are not feasible, i.e.:

- residue surveys (where the test substance is not known in advance),
- unscheduled studies conducted in response to illness episodes (unable to document pesticide application parameters), and
- range-finding studies for residues of newer pesticide products (no established analytical method)

WH&S standards differ from GLPS in the following ways:

- the test substance and/or spray mix are not required to be evaluated prior to use in the study,
- the final report does not contain a GLPS compliance statement,
- final reports may be amended according to WH&S branch policy, and
- archiving requirements differ.

Requirements and Criteria for Designating Study Standard

The following standard selection criteria and requirements apply:

1. When WH&S management assigns a study to a study director, the standard for study conduct shall be specified in writing.
2. Studies shall be conducted according to GLPS when either:
 - specified in a contract or other signed agreement with the study sponsor, or
 - WH&S management determines GLPS is the appropriate standard.
3. Each GLPS final report shall reference this policy.
4. All studies not conducted according to GLPS shall be conducted according to WH&S standards.

References

1. Code of Federal Regulations, United States Federal Register, Vol. 54, No. 158, Part IV, U. S. Environmental Protection Agency, 40 CFR Part 160, Federal Insecticide, Fungicide and Rodenticide Act, Good Laboratory Practice Standards. U. S. Government Printing Office, Superintendent of Documents, Mail Stop: SSOP, Washington, D. C. 20402-9328
2. California Department of Pesticide Regulation, Worker Health and Safety Branch, Exposure Monitoring Policies and Standard Operating Procedures for Exposure Monitoring Staff
California Department of Pesticide Regulation, Worker Health and Safety Branch, 1001 I Street, Sacramento, California, 95814-2828
3. Thongsinthusak, T., Ross, J. R., and Meinders, D. (1993) Guidance for the Preparation of Human Pesticide Exposure Assessment Documents, HS-1612. California Department of Pesticide Regulation, Worker Health and Safety Branch, 1001 I Street, Sacramento, California, 95814-2828