Department of Pesticide Regulation

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M E M O R A N D U M

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SUBJECT: **BRANCH POLICY ON FIELD STUDY CONDUCT STANDARDS**

This Health and Safety Memorandum (HSM) HSM-13010 supersedes HSM-01001, which was dated February 14, 2001.

Scope

The Worker Health and Safety Branch (WHS) conducts field studies to characterize human exposure to pesticides and pesticide residue. This policy defines two standards for conducting field studies: 1) WHS Standards; and 2) Good Laboratory Practice Standards (GLPS). The policy also specifies who decides the standard for each study.

Background

Since 1973, WHS has been conducting field studies in a variety of settings to characterize human exposure to pesticides and pesticide residues. Most of these studies have been conducted in agricultural settings. Over the years, WHS instituted written standards of conduct (WHS Standards) by creating a set of Standard Operating Procedures (SOPs) to follow when conducting field studies. The WHS Standards were designed to ensure the quality and integrity of the data generated during a study.

Both the US Food and Drug Administration and the US Environmental Protection Agency (U.S. EPA) responded to concerns over fraudulent research that supported medicinal drugs and pesticides in the 1970's and 1980's by implementing GLPS. In 1989, US EPA established GLPS (Title 40 Code of Federal Regulations Part 160 (40 CFR 160)) for the conduct of pesticide research studies to assure the quality and integrity of data submitted to US EPA in support of research or marketing permits for pesticide products regulated by the agency.

In 1993, WHS issued the document, *Guidance for the Preparation of Human Pesticide Exposure Assessment Documents*. The document states "In all cases, Good Laboratory Practices must be

observed for all studies whenever applicable." In 2001, WHS issued the *Branch Policy on Field Study Conduct Standards*. The policy references the guidance document in stating "GLPS is the standard which applies to worker exposure studies submitted to DPR for scientific review." The policy further states: "Since data from WHS studies are used in DPR's risk assessment process, WHS studies, when feasible, should adhere to the same standards." Under this policy, WHS management determines the appropriate standard for the conduct of each study.

Since the implementation of these standards, WHS has followed one of these standards while conducting field studies. Generally, WHS followed WHS Standards for observational and foliar residue studies and GLPS for worker exposure studies. The studies conducted under GLPS typically did not comply with all of the GLPS requirements and the non-compliances were noted in the compliance statement of the study report.

Study Standards

The Department of Pesticide Regulation (DPR) reviews pesticide research studies submitted by registrants to support the registration or continued registration of pesticide products in California. Many of these studies are conducted under GLPS because of US EPA requirements. Many other studies, such as efficacy studies, are not conducted under GLPS. For product registrations, DPR's Registration Branch does not require studies to be conducted under GLPS. The Registration Branch may accept a study as long as it is conducted with appropriate scientific standards and meets the department's data requirements.

Whenever applicable, WHS' Human Health Assessment and Human Health Mitigation Programs may require that studies follow GLPS. These programs have used exposure measurements and dislodgeable foliar residue data from WHS field studies conducted under either WHS Standards or GLPS, with the appropriate standard chosen to meet departmental requirements. Studies conducted under WHS Standards are acceptable if the studies include quality assurance measures that ensure the quality and integrity of the data. These measures include replication (duplicate samples, or number of sites or workers monitored), quality control samples (matrix blanks and spikes), and thorough documentation of procedures.

The goal of both WHS Standards and GLPS is to ensure the quality and integrity of the data generated. A brief description of each standard is listed below:

> WHS Standards provide flexibility to assess the safety of humans when exposed to pesticides and for field studies that do not involve monitoring of humans such as field surveys and dislodgeable foliar residue studies. The flexibility of this standard also allows WHS to conduct studies in response to illness episodes where a quick response is critical.
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> GLPS is the set of standards specified in 40 CFR 160 and applies to studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by US EPA. GLPS requires comprehensive documentation to allow reconstruction of the study, and a statement of compliance or non-compliance in the study report.

The following table shows staff responsibilities and study conduct for studies following WHS Standards and GLPS:

Staff Responsibilities and Study Conduct	GLPS	WHS Standards
Responsibility for the overall conduct of the study.	Study Director	Study Director
Responsibility for ensuring compliance with the applied scientific standard and protocol.	Study Director	Study Director
Responsibility for quality assurance measures, even when a quality assurance officer is assigned to evaluate the conduct of the study.	Study Director	Study Director
Evaluation of the test substance and/or spray mix prior to the study.	Required. For most studies, WHS does not have control of the test substance and cannot meet this requirement.	Can be required, if applicable
Adheres to SOPs.	Required. Deviations from SOPs must be documented.	Required. Deviations from SOPs must be documented.
Compliance with quality assurance measures such as replication (duplicate samples or number of sites or workers monitored), quality control samples (matrix blanks and spikes), and thorough documentation of procedures.	Required.	Required.
Quality Assurance Unit (QAU) inspection of the study at adequate intervals to ensure the integrity of the study. Note that QAU can be one person.	Required	Not required; EPM II can assign a QAU to conduct inspections
Study Report includes documentation of the procedures, important conditions, and raw data. Data includes the results of the quality control samples.	Required.	Required.
Compliance statement included in the study report.	Required. The Study Director signs the compliance statement.	Not required
Archiving procedures (see SOP WHS-AR02).	Raw study data for each project archived in locked GLP file cabinets. The GLP archivist controls access to the files.	Raw study data for each project stored in archive boxes. Any staff can check out the project files.

Designation of the Study Standard

The study sponsor will be either WHS or an outside organization. The study sponsor specifies the standard to use for the conduct of a study.

WHS: The WHS Environmental Program Manger II (EPM II) will determine the study standard by conferring with the WHS managers, requiring GLPS when applicable.

Outside Organization: The sponsor will specify the study standard in the contract or other signed agreement.

The protocol will specify the study standard approved for the study.

*(original signed by L. Ross)*_____ December 16, 2013_____

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