STANDARD OPERATING PROCEDURE		
SOP NO.: GLP-DA-04		Page No.: 1 of 7
Title: **AUDITING RESIDUE AND ENVIRONMENTAL FATE STUDIES - FIELD PORTIONS**		
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1. PURPOSE

To provide guidance and a standard procedure for auditing records comprising the field portions of residue and environmental fate studies. Such studies were submitted to the Agency in support of applications for research or marketing permits for pesticide products regulated by EPA [Sections 3, 4, 5, 8, 18, and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended].

2. SCOPE

This standard operating procedure (SOP) will be used in auditing records comprising the field portions of studies conducted to determine the nature and magnitude of residues of pesticides and their metabolites and degradation products in soil, water, and raw agricultural commodities. These studies include residue chemistry, field rotational crop, and field dissipation (terrestrial, aquatic, forestry, long-term soil, and prospective/ retrospective groundwater monitoring).

3. OUTLINE OF PROCEDURES

Test System (Site/Plot) Selection

- Site-specific maps
- Site description
- Site product use, history, and application

Characterization of the Test Substance

Shipping and Receipt Records of Test Substance

Test Substance Application

- Application of test substance
- Calibration of field equipment
- Test substance sampling

Other Agrochemical Application and Field Maintenance

Test System Sampling and Sample Shipment

Meteorological Conditions

Protocol

Standard Operating Procedures

4. REFERENCES

4.1 EPA OPPTS Test Guidelines Series 835, Fate, Transport and Transformation, U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances (OPPTS), Washington, DC.

4.2 EPA OPPTS Test Guidelines Series 860, Residue Chemistry, U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances (OPPTS).

4.3 SOP GLP-C-02, Determining Compliance of Audited Studies with GLP Standards.

4.4 SOP GLP-DA-01, Auditing Field Studies - Analytical Chemistry

5. SPECIFIC PROCEDURES

The following outline should be used as a guide to ensure that all applicable records relating to a study are reviewed during the data audit. This is intended to provide guidance and cannot anticipate every potential problem area. The professional experience and knowledge of the auditor should serve as a primary resource in conducting an adequate data review. The study audit should include a review of the following records comprising the study:

5.1 TEST SYSTEM (SITE OR PLOT) SELECTION

5.1.1 Field Description - All Studies:

Records should be available which address the following issues relating to test system (site or plot) description and soil characteristics:

- Location of the test system (site) including directions to field site and name of cooperator
- Site description, including plot size, the relation of the site to the rest of the field, and direction and degree of slope
- Test system soil characterization, including texture, percent sand, silt and clay, organic matter, pH, cation exchange capacity and field capacity, as required by the study protocol. Determine if these characterizations were conducted under GLP Standards
- Site history, including crop and agrochemical use and application history for the previous 3 years, at a minimum

5.1.2 Aquatic Field Dissipation Studies:

In addition to the records listed above, records should be available which address the following issues relating to the aquatic test system:

- The aquatic test system characterization (i.e., pH, hardness, sediment load, etc.)
- Flow data in terms of volume or linear flow

5.1.3 Groundwater Studies:

In addition to the records listed above, records should be available which address the following issues relating to the test system (site):

- Soil description, including order, group, and series to the saturated zone.

- Site-specific maps showing location of piezometer, well, and lysimeter clusters.
- Geologic boring logs, well and piezometer construction diagrams, groundwater flow maps, calculations of groundwater flow velocities, and water-level data.
- Soil characterization, including type (USDA classification), texture, organic matter, pH, and cation exchange capacity down to the saturated zone.
- Calibration of equipment for determining pH and conductivity measurements of water specimen samples in the field.

5.2 CHARACTERIZATION OF THE TEST SUBSTANCE

Records should be available which address the issues relating to the characterization of the test substance. Audit of these records is covered in SOP No. GLP-C-02, Section 5.5.1.

5.3 TEST SUBSTANCE SHIPPING AND RECEIPT RECORDS

Records should be available which address the issues relating to the shipment of test substance by the test sponsor and receipt by the field personnel. Audit of these records is covered in SOP No. GLP-C-02, Section 5.5.2.

5.4 TEST SUBSTANCE APPLICATION

Records should be available which address the following issues relating to the test substance application by the field personnel:

- Dates of application and subsequent sampling events
- Dilution procedure used prior to application
- Calibration of field equipment including balances for weighing, application equipment, and field analytical equipment (e.g., for water samples, pH and conductivity measurements), see SOP No. GLP-C-02, 5.3
- The preparation, sampling, and analysis of mixtures of test substance with diluent/carrier is addressed in-SOP No. GLP-C-02, 5.5.3

- Description of application of test substance, including multiple applications

5.5 OTHER AGROCHEMICAL APPLICATIONS AND FIELD MAINTENANCE

Descriptions of other Agrochemical applications during the course of the study including fertilizer or other pesticides. Were such applications approved by the study director prior to their application?

Descriptions of other field maintenance practices including rotational crop planting, tilling, weeding prior to and after application of test substance

5.6 TEST SYSTEM SPECIMEN SAMPLING AND SAMPLE SHIPMENT

Records should be available, where applicable, which document the following issues relating to the test system specimen sampling and specimen sample shipment by the field personnel:

- Randomization of test system sampling sites
- Description of the soil sampling device and procedure
- Decontamination of equipment between sampling events
- The location of each core (soil) recorded on a plot map
- Composting of soil cores
- Interval between last application and harvesting
- Crop sampling procedures, including, crop parts harvested, growth stage, presence of wrapper leaves any washing of crop parts
- Storage and handling of samples prior to shipment to the laboratory
- Sample chain-of-custody (COC) for each specimen shipment to analytical laboratory, including project and plot designation, sample description and code number, date and time of sampling, name of individual doing sampling, signature(s) of individual(s) involved in sampling
- Documents relating to sample shipments or transfer to the laboratory

5.7 METEOROLOGICAL CONDITIONS

Records should be available which address the following issues relating to reporting and compiling the meteorological conditions during the conduct of the study (as specified in the Study Protocol):

- Daily weather observations and conditions
- Air temperature, including maximum and minimum

- Soil temperature
- Relative humidity
- Wind direction and velocity
- Pan evaporation
- Rainfall, including irrigation and source of irrigation water
- Meteorological conditions at time of test substance application

5.8 PROTOCOL

The study protocol should be reviewed, as described in SOP Number GLP-C-02, Section 5.6, to ensure that all required protocol elements were present. The auditor should ensure that any protocol amendments and/or deviations were properly documented, as required by the GLP Standards, using the above SOP for guidance.

5.9 STANDARD OPERATING PROCEDURES (SOPS)

The auditor should verify that SOPs were in effect at the time of the study which described routine procedures. Examples of critical SOPs include, but are not limited to, the following (as applicable):

- Shipping and Receiving Test, Control, and Reference Substances
- Shipping and Receiving study specimens
- Calibration of Application and Other Field Equipment
- Operation of Key Equipment
- Test System Sampling and Storage prior to Shipment
- Meteorological Equipment and Measurements
- Preparation of Test Substance mixtures
- Cleaning of Application Equipment
- Preparation of Test System Plots
- Maintenance of Test System Plots Including Routine Farming Practices

/s/ _____ 06/01/99
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