

General Guidelines
And
Standard Operating Procedures

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Volume II
April, 2006

FOREWORD

This document is a compilation of over 20 years experience in conducting agricultural research under the guidelines set forth by the U. S. Environmental Protection Agency, and was written in an effort to establish the best principles and guidelines for GLP studies. Stoneville R & D, Inc. acknowledges the many companies, many of which are now gone, and colleagues for their contributions to this document. Stoneville R & D, Inc. suspended research in this area in 2005 due to the decline in the number of studies requiring GLP. As a result, the most recent version at that time (April, 2004) was not reviewed or revised for the 2005 season as indicated in SRD SOP 18, rev. 8. Additionally, several personnel changes occurred in 2005 which necessitated the need for personnel re-organization of Stoneville R & D, Inc. in order to meet GLP guidelines. Therefore, it was decided to conduct a major revision and re-organization for the start of the 2006 season. This document represents the newly revised SOPs and newly re-organized Stoneville R &D, Inc., effective April 1, 2006 and designated as Volume II.

CONTENTS

	<u>Page No.</u>
I. Statement of Purpose	7
II. General Guidelines	
A. Confidentiality	7
B. Personnel	7
C. Protocol and Test Initiation	7
D. Inspections	8
E. Precautions	8
F. Raw Data and Record Maintenance	8
G. Facilities	8
H. Maintenance Treatments	9
I. Definitions	9
J. Quality Assurance	13
III. SRD Log Index	14
IV. SRD Form Index	15
V. Company Organization and Personnel Resumes	16
VI. Standard Operating Procedures (SOP)	
	<u>Tab No.</u>
SOP #1. Procedures for Storing Frozen Residue Samples	1
SOP #2. Procedures for Recording Raw Data Including Electronic Field Notebooks	2
SOP #3. Residue Trial Design and Test System Care	3

SOP #4.	Procedures for Collecting and Recording Climatic Data, Irrigation Data, Soil Information, Crop/Pesticide History, and Agronomic Practices Associated with a Study	4
SOP #5.	Equipment Use and Maintenance Log	5
SOP #6.	Calibration Procedures	
6.1	General Calibration and Operation Principles, Maintenance of Liquid Pesticide Application Equipment and Application of Test Substance	6
6.2	General Calibration Principles for Ground Applied Liquid Pesticide Application Equipment	6
6.3	General Calibration Principles for Granular Pesticide Application Equipment	6
6.4	General Calibration and Operation for Liquid Pesticide Application by Aerial Equipment	6
SOP #7.	Operation, Calibration and Maintenance of Recording Thermometers	7
SOP #8.	Procedures for Measuring, Weighing, and Mixing Test Materials and Labeling Reagents	8
SOP #9.	Procedures for Sampling Soil for Pesticide Residue Analysis	9
SOP #10.	Procedures for Sampling Plant Materials for Residue Analysis	10
SOP #11.	Procedures for Sampling Water (Specific-Rice Flood)	11
SOP #12.	Facility Inspections and Study Audit Procedures	12
SOP #13.	Operation, Calibration and Maintenance of Electronic Balances.	13
SOP #14.	Procedures for Receiving, Labeling, Storing, Tracking, Sampling, and Disposing of Test Products	14
SOP #15.	Procedures for Packaging and Shipment of	15

	Residue Samples	
SOP #16.	Use and Maintenance of the Giddings Hydraulic Soil Coring Machine	16
SOP #17.	Use and Maintenance of the Campbell Weather Station	17
SOP #18.	Procedure for Creating, Revising, and Retaining Standard Operating Procedures and Documentation/Reporting Protocol Deviations/Amendments	18
SOP #19.	Soil Sampling Procedures for Soil Characteristics	19
SOP #20.	Use and Maintenance of an Anemometer, Soil Thermometer and pH Meter	20
SOP #21.	Procedure for Personnel Training	21
SOP #22.	Procedures for Creating, Revising, Retaining and Using Field Study Notebooks	22
SOP #25.	Master Study Schedule and Test Status Forms	25
SOP #26.	Facility Inspections and Study Audit Procedures by a Federal Regulatory Agency or by Personnel of a Study Sponsor	26
SOP #27.	Procedures for Company Organization, Job Descriptions, and Company Closure	27
SOP #28.	Rodent Control	28
SOP #29.	Making Exact Copy Documents	29
SOP #31.	Safety for Handling, Storing, Transporting and Disposing of Chemicals	31
SOP #32.	Procedures for Harvesting Cotton and Grain and Ginning Seed Cotton	32
SOP #33.	Archives, Operation and the Archiving and Retrieval of Study Data	33
SOP #34.	Operation of the YSI Model 51B Dissolved Oxygen	34

	Meter	
SOP #35.	Responsibilities of the Principal Investigator	35
SOP #36.	Procedures for Conducting Trials with Transgenic Crops	36
VII.	Appendix	
APP #1.	Delta Quality Assurance Services	37

I. STATEMENT OF PURPOSE

It is the intent of *Stoneville R & D, Inc.* (SRD) to confidentially conduct quality research in agronomic crops with reliable and reproducible results. This will be done by conducting limited trials in close proximity to the central office which can be monitored daily or as frequently as necessary. While standard operating procedures (SOPs) are necessary for many areas of research work, it is the desire of *Stoneville R & D, Inc.* to conduct research strictly according to the protocols, guidelines, and/or standard operating procedures of the sponsoring company.

II. GENERAL GUIDELINES

A. Confidentiality

All proprietary information from the sponsoring company will be considered strictly confidential and will not be divulged to third parties. Personnel such as Quality Assurance Auditors from the sponsoring company will be allowed access only to that information pertaining to their respective company's studies.

B. Personnel

Each project conducted by *Stoneville R & D, Inc.* will be assigned a principal investigator and alternate principal investigator. The principal investigator will be responsible for timely and correct execution of all phases of the project including maintenance and submission of test data, safety, and other precautions as necessary. A change in principal investigator will be recorded in the permanent data file along with the reason for the change. If the principal investigator is absent, the alternate principal investigator will be responsible for all activities related to the test on that day. The alternate principal investigator must sign the documentation for all activities performed on that day. Current resumes and/or curriculum vitae and training records of all personnel will be kept on file.

C. Protocol and Study Initiation

Each field residue trial must have a protocol that states the objective(s) and general methods of the study. Although these procedures will vary with the specific study, certain procedures can be standardized. *Stoneville R & D, Inc.* will strictly adhere to the protocol provided by the sponsoring company. Any deviation from the protocol or standard operating procedure will be approved in writing by the sponsoring company.

D. Inspections

Stoneville R & D, Inc. will make every effort to ensure that each trial, including facilities, equipment, methods, records, and controls is conducted in accordance with EPA Good Laboratory Practices (40 CFR Part 160, August 17, 1989).

Stoneville R & D, Inc. welcomes and encourages inspections and/or visits by test sponsors.

E. Precautions

Contamination. The possibility of contamination of crops, soils, or samples exists in all phases of a residue field trial. *Stoneville R & D, Inc.* staff will be explicitly aware of contamination sources and strictly follow the appropriate SOP pertaining to that operation or study.

Clothing/gear. Protective clothing as required by the study protocol or potential hazard of the study material will be worn. Protective clothing/equipment will be cleaned as often as necessary to prevent contamination/exposure of participants or samples.

F. Raw Data and Record Maintenance

Definition. Raw data are the originally recorded values, observations, notes, and calculations that pertain to or result from the conduct of the study.

Sponsor Guidelines. Raw data will be recorded in permanent black ink in accordance with guidelines issued by the sponsoring company. In the absence of specific guidelines from the study sponsor, *Stoneville R & D Inc.* SOPs will be followed.

Ancillary Data. Records to be maintained for each trial will be according to sponsor guidelines or as outlined in *Stoneville R & D, Inc.* SOPs.

G. Facilities

Equipment. Equipment used for weighing, mixing, and applying test products in the field residue trials will be properly calibrated and maintained. Operator's manuals will be available to personnel. Records of maintenance/calibration for all pertinent equipment will be kept on file. Standard Operating Procedures will be readily available to all study participants.

Temperature Records. Temperature records for all freezer units used to store residue samples will be maintained in accordance with published SRD SOPs.

Designated Areas. Areas used for test product storage, weighing, and measuring will be separate from areas used for storage of samples and sampling supplies.

H. Maintenance Treatments

In the event that pesticides other than those being tested are needed to maintain plot integrity and/or optimum crop growth, the sponsoring company will be notified of needed applications. Products that do not have, as public information, a recovery and analytical determination, will not be used. Prior approval will be solicited from the sponsoring company before any application of non-test material.

I. Definitions

The following terms, as defined below, are used throughout this document:

Batch means a specific quantity or lot of a test or control substance that has been characterized according to 40 CFR 60.105 (a).

Carrier means any material (e.g., feed, water, soil, nutrient media) with which the test substance is combined for administration to test organisms.

Check - A control. See untreated check.

Control substance means any chemical substance or mixture or any other material other than a test substance, feed, or water that is administered to the test system in the course of study for the purpose of establishing a basis for comparison with the test substance for no-effect levels.

Cooperator - Persons or institutions who are involved in the direction, conduct, and completion of field studies in cooperation with *Stoneville R & D, Inc.* A cooperator may conduct the entire field study; provide land and/or equipment to be used by the field representatives in the conduct of the study; or may help in treatment applications; growing and harvesting of crops and/or shipping of residue samples. See also testing facility.

Efficacy Trial - Field study conducted to determine: (1) spectrum of activity of chemical compounds; (2) efficacy of compounds compared to labeled standards; (3) most efficacious rates and timings of applications including but not limited to, application volumes, sequential and tank-mix applications, and applications based on crop and/or target organisms growth stage. See also study.

Experimental Termination Date - means the last date on which data are collected directly from the study.

EPA - means the U.S. Environmental Protection Agency.

FDA - means the U.S. Food and Drug Administration.

FFDCA - means the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 310 et seq.).

FIFRA - means the Federal Insecticide, Fungicides and Rodenticide Act (7 U.S.C. 136 et seq.).

Person - includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organization unit thereof, and any other legal entity.

Pesticide Residue - Any substance or mixture of substances in food for humans or animals resulting from the use of a pesticide including any derivatives, such as degradation and conversion products, metabolites, reaction products and impurities which are considered to be of toxicological significance. See also test substances.

Principal Field Investigator - The scientist that performs the actual study (i.e., administers the test substance to a test system) also including the preparation, maintenance, sampling, and data recording for the study. See also testing facility.

Protocol Date - means the date the study protocol is signed by the study director. See study initiation date.

Quality Assurance Unit - 1) Any person or organizational element, except study director or field representative, designated by corporate management to perform duties relating to quality assurance of field efficacy and residue trials. 2) Any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.

Raw Data - 1) means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature); the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media

including dictated observations and recorded data from automated instruments. 2) Any field worksheets (e.g., Test Initiation, Treatment Plot Plan, Chemical Work Sheet, Calibration Record, Evaluation Sheets, Rainfall and Temperature Data Sheets, Results and Summary Sheets), notes, records, or exact copies of the above that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study.

Reference substance - means any chemical substance or mixture or material other than a substance, feed, or water that is administered to or used in analyzing the test system in the course of a study for purposes of establishing a basis for comparison with the test substance for known effect levels. Sometimes referred to as a "Spike Sample".

Residue Sample - See specimen.

Residue Trial - A field study conducted to obtain samples for analysis to determine the maximum residue level resulting when the chemical compound is applied according to the directions for use. See also Study.

Specimen - means any material derived from a test system for examination or analysis. The term residue sample is within this category of materials.

Sponsor - 1) A person or group who initiates and supports, by provision of financial or other resources, a study, 2) A person or group that submits a study to the EPA in support of an application for a research or marketing permit, 3) A testing facility, if it both initiates and actually conducts the study.

Study - means any experiment in which test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy as required by 40 CFR 158,160), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term does not include basic exploratory studies carried out to determine whether a test substance has any potential utility. The term trial, efficacy trial, and residue trial fit within this definition.

Study Completion Date - means the date the final report is signed by the study director.

Study Director - the individual responsible for the overall conduct of efficacy and/or residue trials. The study director is usually the

appropriate technical Product Manager or the Environmental Coordinator. In the case of projects managed externally, the study director may be a contractor, not in direct employment of the sponsoring company.

Study Initiation Date - means the date the study director signs the protocol.

Test Substance - means a substance or mixture administered or added to a test system in a study. This substance or mixture: 1) is the subject of an application for a research or marketing permit supported by the study, or is the contemplated subject of such an application; or 2) is an ingredient, impurity, degradation product, metabolite, or radioactive isotope of a substance described by 1 above of this definition, or some other substance related to a substance described by in 1 above, which is used in the study to assist in characterizing the toxicity, metabolism or other characteristics of a substance described by that paragraph. 3) See also Pesticide Residue.

Test System - means any animal, plant, microorganism, chemical or physical matrix (e.g., soil or water), or subparts thereof, to which the test or control substance is administered or added for study. "Test System" also includes appropriate groups or components of the system not treated with the test, control, or reference substance.

Testing Facility - means an organization, contract laboratory, contract experiment station or person who actually conducts a study, (i.e., actually uses the test substance in a test system). "Testing facility" encompasses only those operational units that are being or have been used to conduct studies. See also cooperator and principal investigator.

Trial - see Study.

Untreated Check - 1) A test system that has not been treated with the test substance, control substance, or any other substance that could cause an analytical interference with methods utilized in determination of levels of residues or metabolites (see also test system). 2) A control.

Vehicle - means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

J. Quality Assurance

Stoneville R & D, Inc., will enlist the services of an independent cooperator to conduct quality assurance audits. This cooperator will have training in the Biological Sciences with no less than a BS degree.

Once enlisted, this Quality Assurance Agent (QAA) will be given a master schedule of the studies conducted by *Stoneville R & D, Inc.* so that audits can be scheduled with the *SRD* Principal Investigator.

The Vice President-Operations will maintain a master schedule of all studies conducted by *Stoneville R & D, Inc.* and provide up-to-date copies to the QAU in order for inspections of each study to take place at intervals adequate to ensure the integrity of the study.

The QAU will submit a written report of each periodic inspection to the President of *Stoneville R & D, Inc.* and the sponsor's Study Director and study director management.

QAU reports will include information as outlined in the "Quality Assurance Inspection Report" (Form SRD-8).

LOG INDEX

Tab	Index
A.	Title Page
B.	GLP Compliance Statement
C.	Chronological Log
D.	Directions to Field Location
E.	Plot Information and Layout
F.	Crop and Pesticide History
G.	Field and Crop Characteristics
H.	Chemical Log
I.1	Sprayer Calibration Work Sheet
I.2	Liquid Calibration Log
I.4	Ground Sprayer Calibration Summary
J.1	Spray Mix Calculation Work Sheet
J.2	Treatment Mixing Table
K.	Application Data Table
L.1	Sampling Information
L.2	Sample Identification Sheet
L.3	Sample Shipment Information
M.	Freezer and Chemical Storage Log
N.1	Maintenance Chemicals
N.2	Fertilizer and Cultural Practices
O.1	Study Site Rainfall Records
O.2	Study Site Irrigation Records
P.	Rotational Crop Summary
Q.	Crop Disposition
R.	Quality Assurance Inspection
S.	Summary of SOP Deviations
T.	Summary of Protocol Deviations
U.	SOP References
V.	Additional Information

SRD FORM INDEX

SRD	1	Freezer Log
	2	Rainfall Data Record
	3	Study Site Irrigation Records
	4	Equipment Use and Maintenance Log
	5	Aerial Calibration Information
	6	Aerial Calibration Procedure
	7	Quality Assurance Facility Inspection
	8	Quality Assurance Inspection Report
	9	Balance Calibration
	10	Experimental Compound Log
	11	Tracking Form
	12	Facilities/Equipment Temperature Log
	13	Deviation Documentation
	14	Training Record
	15	Liquid Calibration Log
	16	Granular Calibration Log
	17	Application Data Table
	18	Test Status Form
	19	Archives Log
	20	Flood Water Parameters
	21	Flood Water Parameters
	22	Maintenance Chemical Use and Field History
	23	Conversation Record
	24	Application Verification
	25	SOP Review
	26	Training Record
	27	Documentation of Study/Facility Audits
	28	Rodent and Other Pest Control Log
	29	Backup Log for Software and Notebooks
	30	Computer Maintenance Log
	31	Computer Systems Change Control Form
	32	Transgenic Seed Log
	33	Composite Signature List
	34	Respirator Fitting and Testing
	35	Mixing & Application Data

**III. Company Organization, Job Descriptions and
Personnel Resumes**

