Preparing Your Quality Assurance Project Plan (QAPP)

(March 2011version)

The attached Pesticide Enforcement QAPP Template is intended to help State agencies that have cooperative agreements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to develop acceptable QAPPs for their pesticide inspection and enforcement programs as required by EPA (Agency) regulations and policies. This template provides the framework for a State QAPP that is generally consistent with the Agency's generic documents "EPA Requirements for Quality Assurance Project Plans: QA/R-5," and "Guidance for Quality Assurance Project Plans: QA/G-5." The QA/R-5 and QA/G-5 documents are available on the Internet at: http://www.epa.gov/quality1/qa_docs.html.

This template is a combination of instructions, example text, and references.

Yellow highlighted (italicized) text is instructions. You should delete this text prior to submitting the QAPP to EPA for review.

[Red text] must be replaced with information specific to your document (e.g., names, dates, etc.) prior to submitting the QAPP to EPA for review.

You may base your QAPP on federal or State inspection, enforcement, sampling and analysis manuals, SOPs or other relevant documents. Provide full reference information and either copies in the appendices or links to electronic versions.

Fill in appropriate information in footer (revision number and date).

Follow other directions as indicated in the document regarding regular text and tables.

Prepare a title sheet. Use the suggested title, or edit.

Quality Assurance Project Plan

For [State],
Pesticide Compliance Monitoring Program

Date of approval: See signature page

Prepare a signature sheet for the QAPP. Include: Highest official responsible for the FIFRA Program; person responsible for Quality Assurance; primary person responsible for program implementation; any other person who has responsibility for program implementation; delete unused rows.

Quality Assurance Project Plan Signature Sheet

_____ _____

[Name of Person] Date
Manager
[Name of Organization],

_____ _____

[Name of Person] Date
Pesticide Program Supervisor
[Name of Organization]

_____ _____

[Name of Person] Date
Laboratory Director
[Name of Organization]

_____ _____

[Name of Person] Date
[Title], [Name of Organization]

_____ _____

[Name of Person] Date
Project Officer, Pesticides Office, U.S. EPA Region 9

_____ _____

Eugenia McNaughton Date
Manager, Quality Assurance Office, U.S. EPA Region 9

Table of Contents is built automatically. Do not change the heading/numbering format in this template. To update, place cursor over any item in the Table of Contents, right (or CTRL) click, select "update field" and select "update entire table."

Table of Contents

This section describes the nature of the document. A policy statement concerning quality assurance would be appropriate. Edit this paragraph as needed.

1 Introduction

This Pesticide Enforcement QAPP is a formal document that describes in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of all pesticide inspection and enforcement activities satisfy stated performance criteria. This QAPP provides sufficient detail to demonstrate that:

- the program's regulatory, technical and quality objectives are identified and agreed upon;
- the intended measurements, data generation, or data acquisition methods are appropriate for achieving program objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

This QAPP is relevant to enforcement activities under FIFRA. Pesticide-related projects and activities conducted under Water, Endangered Species or Worker Health and Safety Programs are covered under separate QAPPs.

This document shall be valid for a period of up to five years from the official date of publication. After five years, it shall either be reissued without change, revised, or withdrawn. Any changes made within five years may be submitted by e-mail. If the QAPP is still needed after five years, the full document must be reviewed, revised, and re-submitted to EPA for approval.

2 Program Management

Edit this paragraph as needed.

This portion of the QAPP demonstrates that the State's pesticide program has defined goals, that program personnel and other stakeholders (such as contractors, laboratories, local agencies) understand the goals and methods for achieving them, and that necessary documents and records are maintained.

It is [State pesticide program agency] policy that sufficient quality assurance activities are conducted to demonstrate that all data collected by and on behalf of [State pesticide program agency] are scientifically and legally valid for the purposes to which they are intended. Data shall be of known and acceptable accuracy and precision. Data shall also be complete, representative, and comparable for its intended use. Furthermore, the quality of all data shall meet agency, state and U.S. EPA program requirements,.

2.1 Distribution List

In the table below, include names, titles, and contact information of individuals, receiving a copy of the QAPP, including EPA Project Officers and Quality Assurance manager. Add rows, if necessary. Delete unused rows.

The following individuals will receive copies of the approved Quality Assurance Project Plan (QAPP) and all subsequent revisions.

Name	Position	Organization
[Name]	Manager	[Organization]
[Name]	[Position]	[Organization]
Eugenia McNaughton	Manager	Quality Assurance Office, U.S. EPA, Region 9
	Project Officer	Pesticides Office, U.S. EPA, Region 9
Contractors, consultants, sub-contractors	[Position]	[Organization]
Others	[Position]	[Organization]
Others	[Position]	[Organization]

2.2 Program/Task Organization

2.2.1 Table of Responsibilities

In the table, list all individuals responsible for decision-making and implementation of the State pesticide inspection and enforcement program, including the person responsible for Quality Assurance.

Title	Responsibilities	Name	Phone No./ e-mail
Pesticide Program Manager or Supervisor	Makes final decisions about the program; supervises inspectors; negotiates cooperative agreement with EPA	[Name]	[phone/e-mail]
Pesticide Program QA Manager	Responsible for Quality Assurance; ideally is independent of data generators, but alternatives may be acceptable	[Name]	[phone/e-mail]
Laboratory Manager or QA Officer	Ensures that laboratory services meet all internal and project-specific QA/QC requirements.	[Name]	[phone/e-mail]

Title	Responsibilities	Name	Phone No./ e-mail
[Title]	[Responsibilities]	[Name] [Name]	[phone/e-mail]
[Title]	[Responsibilities]	[Name]	[phone/e-mail]
Pesticide Inspector	Conducts routine or for-cause inspections including, but not limited to, misuse, Worker Protection Standard, and marketplace. Provides compliance assistance. Consults in Endangered Species situations. Provides education and outreach. Consults on Water Program issues	[Name]	[phone/e-mail]
Attorney	Provides legal advice to State; takes action against violators where warranted	[Name]	[phone/e-mail]
Agency Administrator	Provides overall Program oversight; makes fiscal decisions for the State	[Name]	[phone/e-mail]

2.2.2 Relationship to Other Local Agencies with Pesticide Program Responsibilities

If part of your program is decentralized to other local agencies, describe the relationship of the FIFRA State Lead Agency to these organizations in terms of data collection and decision making.

2.2.3 Organization Chart

If you have an organization chart, reference it here and include it in an appendix or provide a link to an e-document.

2.3 Program Definition/Background

Describe the purpose of the pesticide regulatory program in general terms. Include all aspects of the program. A mission statement of the program would be appropriate. You may use the following text as a guideline.

In general, the State Pesticide Program monitors agricultural and non-agricultural pesticide use, and sale/distribution of pesticides in the state. The Program aims to achieve full compliance with Federal and State pesticide law via field presence, compliance assistance, compliance monitoring, and enforcement actions.

2.4 Program/Task Description

This section should show each aspect of the inspection and enforcement program carried out by the State.

2.4.1 Program Scope—Inspection Activities

Modify the text below as needed.

See the chart below for the types of pesticide inspections that are conducted and the procedures used. When non-compliance is noted the State takes follow-up enforcement action, if warranted, or forwards an inspection report to EPA for review.

The table below describes information specific to [State], and includes references to appropriate State or Federal manuals, codes, SOPs, or other documents.

Type of Inspection	**Authority Used**	**Procedures Used**	**Types of Samples Collected**[1]
Ag Use	State	FIFRA Inspection Manual, Chapter 12	Tank Mix, Foliage (discrete, grid pattern, composite), Soil (discrete known depth, furrowed field, grid pattern, gradient, composite), Discrete Sediment, Discrete Surface Water, Air, Animals, Fish, Honeybees , Surface (wipe; grid pattern, gradient), Clothing, Drift cards
Non-Ag Use	State	FIFRA Inspection Manual, Chapter 12	Animals, Surface (wipe; grid pattern, gradient), Clothing, Foliage (discrete, grid pattern, composite) Soil (discrete, known depth, grid pattern, gradient, composite), Discrete Surface Water, Air
Worker Safety	State	WPS Inspection Manual, Chapter 3	Clothing, Foliage (discrete, grid pattern, composite)
Marketplace and Dealer/Distributor	State	FIFRA Inspection Manual, Chapter 7	Product Samples (liquid or dry)
Dealer and Applicator Records	State	FIFRA Inspection Manual, Chapter 19;	Documentary Samples Only
Producing Establishment	Federal	FIFRA Inspection Manual, Chapter 7	Product Samples (liquid or dry)
[Type of Inspection]	[Authority Used]	[Procedures Used]	[Types of Samples Collected]
[Type of Inspection]	[Authority Used]	[Procedures Used]	[Types of Samples Collected]

[1] Samples that might be taken include: Product (liquid or dry); Foliage (discrete, grid pattern, composite); Soil (discrete known depth, furrowed field, grid pattern, gradient, composite); Sediment (discrete); Surface Water (discrete); Air (drift card); Pesticide Formulations, Animals, Fish, Honeybees; Surface (wipe, grid pattern, gradient); Clothing.

2.5 Quality Objectives and Criteria for Measurement Data

Describe decisions to be made with the data, and the criteria upon which the decisions will be made. Suggested text is below; modify as appropriate.

2.5.1 Enforcement: Use of Laboratory Data and Decision Criteria

The State Pesticide Program will determine the appropriate enforcement follow-up actions according to its enforcement response policy. A copy of the State's policy is included as [Appendix # or link to e-document].

Decisions based on laboratory data and the criteria upon which decisions are based depend on the type of samples that were collected, and upon whose authority the samples were collected. Numerous scenarios exist in which the State Pesticide Program may rely on laboratory data. Three more common scenarios are discussed below:

Potential misuse of a pesticide, scenario 1 (residues on non-target sites or locations where the pesticide is not approved for use): As a result of pesticide use, there may be pesticide residues on non-target sites or locations where the pesticide is not approved for use under the EPA-registered label. If a State Pesticide Inspector collects a sample or samples from a non-target site location, then the criterion will be the presence or absence of the pesticide at the location where the sample was taken. Any detection of the pesticide above the detection limit obtainable by the laboratory will be considered a potential violation. The inspector will present the case to the State Case Developer/Attorney for possible action.

In a case where a State inspector is working under a Federal Credential, the State refers the case to EPA Region 9 for possible action.

Potential misuse of a pesticide, scenario 2 (applying a pesticide at a concentration other than allowed by the pesticide's labeling): Due to misuse of a pesticide, a target crop or site could have residues that exceed permitted residue limits (EPA-established tolerances described at 40 CFR Part 180). If the inspector suspects levels that are over allowable residue limits from misuse (from either over-application or over-use) of a pesticide, and as a result collects samples from the target site or crop, the criterion for taking action will be the level of residue on the site or crop exceeding the EPA defined tolerance level. This would be considered a potential violation. The inspector will present the case to the State Case Developer/Attorney for possible action.

In a case where a State inspector is working under a Federal Credential, the State will present the case to EPA Region 9 for possible action.

Potential misuse of a pesticide, scenario 3 (preparing a pesticide for application at a concentration other than allowed by the pesticide's labeling): A tank mix or use-dilution sample may be collected in the field by a State Pesticide Inspector to determine if a pesticide is being used at a concentration other than that allowed by the pesticide's

labeling. Laboratory results that demonstrate the percentage of the pesticide in the tank mix is greater than or less than the allowable concentration will be considered a potential violation. The inspector will present the case to the State Case Developer/Attorney for possible action.

In a case where a State inspector is working under a Federal Credential, the State will present the case to EPA Region 9 for possible action.

Potential sale and distribution of a violative pesticide: Pesticide product samples may also be collected of pesticides available in the marketplace or from pesticide producer establishments. The formulation of these commercially available pesticides must meet product efficacy requirements and be sold in concentrations that conform to the pesticide's registration. Laboratory analyses documenting that a product's efficacy or formulation does not conform to its registration will be considered potential violative products. The inspector will present the case to the State Case Developer/Attorney for possible action.

In a case where a State inspector is working under a Federal Credential, the State will present the case to EPA Region 9 for possible action.

2.5.2 Enforcement File Reviews and Case Development Decisions for Cases Collected Under a State Credential

If an inspection is conducted under State authority, and the inspector suspects a violation of State law, the State will pursue enforcement response according to [List enforcement response policy or other State standard procedure, if applicable].

Under this scenario, the State inspector will develop appropriate case files and the State will follow-up with enforcement action, when appropriate, according to the following possible scenarios:

Violations are well documented in the inspection report: The State inspector, in consultation with the State Case Developer/Attorney may decide to pursue enforcement action as warranted by the State's FIFRA Enforcement Response Policy. While the case is being developed, the file is maintained by the Inspector. EPA Region 9 may be consulted regarding the most effective way to develop the case and document inspection results.

Violations are suspected, but evidence is too weak to pursue a case: The State Inspector, in consultation with the State Case Developer/Attorney, may decide to close the case. Conversely, if the case is of a high priority or violations are strongly suspected, the inspector will follow established protocol and may re-inspect, or otherwise contact, the site to collect additional evidence.

No violations are identified during the inspection or in the sample analyses: The State Inspector, in consultation with the State Case Developer/Attorney, will close the case.

2.5.3 Enforcement File Reviews and Case Development Decisions under Federal Authority

When the State conducts an inspection under federal authority, the inspection report and sampling results will be forwarded to the U.S. EPA Region 9 Pesticides Office for any necessary follow up, as required by the Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA (U.S. EPA Office of Compliance, Office of Enforcement and Compliance Assurance, September 30, 2004). If a case is referred to EPA Region 9, an EPA Case Developer will work with the State Inspector to develop appropriate case files and direct follow-up with enforcement action, when appropriate, according to the following possible scenarios:

Violations are well documented in the inspection report: The EPA Case Developer, in consultation with the State Pesticide Program and the EPA Region 9 Enforcement Team, may decide to pursue enforcement action as warranted by the FIFRA Enforcement Response Policy. While the case is being developed, the file is maintained by the Case Developer.

Violations are suspected, but evidence is too weak to pursue a case: Case Developer, in consultation with the State Pesticide Program and the Region 9 Enforcement Team, may decide to close the case. Conversely, if the case is of a high priority or violations are strongly suspected, the EPA Case Developer may request that the inspector re-inspect the site to collect additional evidence.

No violations are identified during the inspection or in the sample analyses: The EPA Case Developer, in consultation with the State Pesticide program and the Region 9 Enforcement Team, will close the case.

2.6 Training

Describe training requirements and credentials that all personnel in the Program must have to carry out their duties. You may use the following text/table as a guideline. Delete unused rows.

2.6.1 Training Requirements

Title	Name	Training Requirements
Pesticide Program Manager/Supervisor	[Name]	[Training Requirements]
Inspector (State; conducting inspections under State authority)	[Name]	Must meet State-specific training and any training agreed to in EPA Cooperative Agreement Workplan

Title	Name	Training Requirements
Inspector (Federally credentialed State Inspector)	[Name]	Must meet "Training Requirements for FIFRA Inspectors" listed in EPA Order 3500.1 (pages 4-10)(see Appendix [#])
Additional personnel (list)	[Name]	[Training Requirements]
[Title]	[Name]	[Training Requirements]
[Title]	[Name]	[Training Requirements]

2.6.2 Training Records

Describe how training records are maintained and state requirements for keeping them current. You may modify the following paragraphs to reflect your State's specific procedures.

Each inspector maintains a separate file containing all copies of classroom or online training certificates, with agendas from the courses completed. Each inspector maintains a list of all on-the-job and field training received. For federally credentialed State inspectors, training is completed and training records are kept in accordance with EPA's September 30, 2004, "Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA)."

The Program Supervisor maintains all documents pertaining to issuance of federal credentials (credential acknowledgement statement(s), authorization agreement, Guidance for Issuing Federal EPA Inspector Credentials to Authorize Employees of State/Tribal Governments to Conduct Inspections on Behalf of EPA).

2.7 Documents and Records

2.7.1 List of Forms

List all forms and paperwork required by the program; include an example of each in an appendix; include state and federal forms; include information as indicated in the table below; you may refer to online resources.

Form Name	Form #	Purpose	Completed by	Submission/ filing details
Inspection Summary	No EPA form; identify State form [Appendix # or link to e-document]	Provides basic information about an investigation; must include narrative information	Inspector	With inspection report
Notice of Inspection	EPA Form 3540-2 [Appendix # or link to e-document]	Explains authority and records consent for inspection of a facility or use site	Inspector	To agent at inspected site; copy is filed with inspection report
Receipt for Samples	EPA Form 3540-3 [Appendix # or link to e-document]	Documents consent for taking samples from inspected facility or use site	Inspector	To agent at inspected site; copy is filed with inspection report
Receipt for Pesticide Use/Misuse Samples	EPA Form 3540-26 [Appendix # or link to e-document]	Documents consent for taking samples during a federal use inspection	Inspector	To agent at inspected site; copy is filed with inspection report
Chain of Custody	EPA Form 3540-41 [Appendix # or link to e-document]	Documents proper transfer of official samples for analysis	Inspector	With sample; Copy is filed with inspection report
Custody Seal	EPA Form 7500-2 [Appendix # or link to e-document]	Documents that samples were not tampered with prior to analysis	Inspector	With sample
Request for Analytical Services	[Appendix # or link to e-document]	Requests sample analysis from a state agricultural laboratory or other acceptable lab	Inspector	To laboratory; Copy is filed with inspection report

Form Name	Form #	Purpose	Completed by	Submission/ filing details
Worker Protection/ Registrant/ Producer/ Marketplace/ Dealer Establishment Checklist	[Appendix # or link to e-document]	[Purpose]	Inspector	Filed with inspection report
Marketplace Establishment Inspection Checklist	[Appendix # or link to e-document]	[Purpose]	Inspector	Filed with inspection report
[Additional Forms]	[Appendix # or link to e-document]	[Purpose]	[Name of person]	[Submission/ filing details]

2.7.2 Filing Procedures (Paper Files)

Provide a general description of filing procedures for the above-listed forms. You may use the following text as a guideline.

The Inspector collects and files all of the above forms in a single folder, along with the inspection report narrative, research print-outs, and other documentary evidence. When the Inspector completes an investigation, s/he photocopies all pages for his/her records, and then distributes it for review by the State Case Developer.

When the case is closed, it is filed alphabetically, by facility or site name, in the Inspection Report filing cabinet, which is located [describe location].

2.7.3 Electronic Record Keeping--Forms

Provide a general description of electronic filing procedures for the above-listed forms. Describe use of Access, Excel or other databases used to track inspections; describe backup, archiving and security procedures.

3 Data Generation and Acquisition

The elements in this group address all aspects of data generation and acquisition to ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and documented. The following QA Project Plan elements describe the requirements related to the actual methods or methodology to be used for the:

- collection, handling, and analysis of samples;
- data obtained from other sources (e.g., contained in a computer data base from previous sampling activities, compiled from surveys, taken from the literature); and
- management (i.e., compiling, handling) of the data.

The purpose of this section is to provide detailed information on the methods already described more generally in this document (Section 6). If the designated methods are well documented and are readily available to all project participants, citations are adequate; otherwise, detailed copies of the methods and/or SOPs must accompany the QA Project Plan either in the text or as attachments.

3.1 Sampling Design

Describe procedures for selecting sample locations or cite relevant sections of the FIFRA Inspection Manual or State manuals/SOPs. You may use the following text as a guideline. Include manuals/SOPs in the appendices or provide links to e-documents.

The Program will take product samples from sites identified [under the "Sources of Pesticide Samples" section on page 9-2 of the FIFRA Inspection Manual or state manuals/SOPs] ([Appendix # or link to e-document]), and residue/environmental samples as listed in [Chapter 13 of the FIFRA Inspection Manual or State manuals/SOPs]. Samples may be taken for the following reasons:

a. An incident such as human illness or environmental harm is reported to the Program
b. A complaint is filed with the state regarding pesticide misuse
c. The Program has reasonable cause to believe that pesticide use, sale, or distribution is being conducted in violation of federal or State pesticide laws.

3.2 Sampling Methods Requirements

3.2.1 Purpose/Background

This section describes sample collection, preparation, and decontamination procedures.

3.2.2 Sampling Equipment

- Sample Collection Record Forms
- Paper, plastic bags, jars (various sizes) and aluminum foil
- Personal safety equipment and clothing as required for sample collection:
    - coveralls
    - respirator
    - goggles
    - hard hat

    - disposable & rubber gloves
    - boots
    - rain suit
    - waders
- Labels, tape, stapler, evidence tags, official seals or evidence tape
- Shovel, hand spade, knife, pruning shears, trowel, spatula, or leaf punch
- Hexane, isopropyl alcohol, distilled water, and paper towels
- Sterile wipes and precut templates
- Measuring tapes, stakes, camera, film and accessories
- Ice chests (coolers, styrofoam)
- "Blue-Ice," wet ice, dry ice (Caution: *do not* handle dry ice with bare hands or allow samples to directly contact the dry ice)
- Permanent markers, pencil, pen, note pad, record book
- County or city map, aerial maps, topographical maps
- Disposable core tubes, siphon tubes

3.2.3 Sample Collection

You may use the following text as a guideline; modify as appropriate.

The program will collect and assign numbers to samples according to the procedures outlined in the [FIFRA Inspection Manual or State manuals/SOPs]. Copies of these procedures are excerpted in the following appendices or e-documents:

Type of Sample	**Page # (FIFRA Inspection Manual, unless otherwise noted)**	**Appendix or link to e-document**
Product Sample: Small Sized Units	9-6	[Appendix or link to e-document]
Product Sample: Larger Sized Units	9-7	[Appendix or link to e-document]
Product Sample: Dry Material	9-7	[Appendix or link to e-document]
Product Sample: Liquid Material	9-8	[Appendix or link to e-document]
Selection of Residue and Environmental Samples (all types)	13-4 to 13-5	[Appendix or link to e-document]

Type of Sample	Page # (FIFRA Inspection Manual, unless otherwise noted)	Appendix or link to e-document
Foliage (discrete, grid pattern, composite)	13-9 to 13-18	[Appendix or link to e-document]
Soil Sampling (discrete known depth, furrowed field, grid pattern, gradient, composite)	13-18 to 13-21	[Appendix or link to e-document]
Discrete Sediment Sampling	13-21	[Appendix or link to e-document]
Discrete Surface Water Sampling[1]	13-21 to 13-22	[Appendix or link to e-document]
Air Sampling	13-22 to 13-23	[Appendix or link to e-document]
Pesticide Formulation Sampling (Technical Grade)	13-23 to13-24	[Appendix or link to e-document]
Tank Mix Sampling	13-24 to 13-25	[Appendix or link to e-document]
Animals, Fish, Honeybee Sampling	13-25 to 13-26	[Appendix or link to e-document]
Surface (Wipe) Sampling (grid pattern, gradient)	13-26 to 13-27	[Appendix or link to e-document]
Clothing	13-28 to 13-29	[Appendix or link to e-document]

[1] Surface water sampling for enforcement purposes is covered under this QAPP. Sampling for surface and groundwater monitoring programs is covered under the State FIFRA Water Quality Project QAPP.

3.2.4 Equipment Decontamination

The program follows decontamination procedures that are listed in the [FIFRA Inspection Manual, pages 13-5 and 13-6; or in State manuals/SOPs]. A copy of this section is included as [Appendix # or link to e-document].

3.2.5 Preservation and Holding Time Requirements

Describe the State's requirements for sampling containers, preservation, and holding times. You may use the following text as a guideline.

Samples will be preserved according to [Table 13-1 of the FIFRA Inspection Manual, page 13-31, or according to State manuals/SOPs]. A copy of this table is included as [Appendix # or link to e-document].

If samples must be stored temporarily, the inspector will follow the procedures for preservation and handling outlined in the [FIFRA Inspection Manual, pages 13-29, or according to State manuals/SOPs]. A copy of this section is included as [Appendix # or link to e-document].

The State Inspector will work directly with the Laboratory to determine the number of sample containers, and associated sizes/volumes and materials, needed for collection of different types of samples which might be encountered during inspections. A supply of these various containers will be maintained on hand at the State office. A small supply of preservatives will also be kept. Ice, dry ice, or other such materials will be acquired prior to going on an inspection if the likelihood exists that a sample might be collected that requires chilling or freezing. Containers will either be provided pre-cleaned from the laboratory or acquired by the State from commercial sources. Either way, the containers will not require washing, rinsing, or other preparation steps by the field inspectors prior to sample collection.

Container and preservative information will be documented in the field logbook.

3.3 Sample Handling and Custody Requirements

3.3.1 Purpose/Background

This section describes how samples must be transported from the inspection site to the laboratory, and the chain of custody procedures that are followed to ensure that samples are not tampered with or adulterated, delivered in a timely way, or otherwise compromised.

3.3.2 Sample Custody and Sample Shipping Procedures

Describe chain-of-custody procedures, and how samples will be sent to the laboratory. You may refer to federal or State manuals/SOPs.

3.3.2.1 Sample Preparation

The field inspector/investigator will prepare samples for shipment to the laboratory according to the procedure outlined [on pages 9-15 to 9-18 in the FIFRA Inspection Manual or according to State manuals/SOPs] A copy of this section may be found [in Appendix # or link to e-document].

3.3.2.2 Chain of Custody Procedures

The field inspector/investigator will prepare a "Chain of Custody" Record, using [EPA Form 3540-41 or equivalent State form] ([Appendix # or link to e-document]) to accompany any samples that will be transferred from the possession of that inspector.

A sample is considered to be in the one's custody if:

- The sample is in one's physical possession;
- The sample has been in one's physical possession and is within one's sight;
- The sample is in a designated, secure area, and/or;
- The sample has been in one's physical possession and is locked up.

The field inspector/investigator is responsible for custody of the samples until they are delivered to the laboratory or picked up for shipping. (Note: As few people as possible will handle the samples to ensure sample custody.) Chain-of-custody forms must be completed in the field. Each time one person relinquishes control of the samples to another person, both individuals must complete the appropriate portions of the chain-of-custody form by filling in their signature as well as the appropriate date and time of the custody transfer.

During transport by a commercial carrier, the air bill will serve as the associated chain-of-custody. Once at the laboratory, the sample receipt coordinator will open the coolers, inspect the samples to ensure that seals are intact and that samples have been properly maintained, and sign and date the chain-of-custody form. Laboratory personnel are then responsible for the care and custody of samples.

Copies of the completed chain-of-custody report and all shipping documents are filed with the inspection report.

3.3.2.3 Shipping Procedures

Describe shipping procedures; you may use the following text as a guideline.

The inspector/investigator will follow the shipping procedures outlined [on pages 13-32 to 13-41 in the FIFRA Inspection Manual or State manual/SOPs]. A copy of this section may be found [in Appendix # or link to e-document].

> Note: some samples collected for enforcement purposes may be considered hazardous materials that will require special handling if they are to be shipped by commercial carrier. Such materials must be shipped according to rules, regulations and guidance from U.S. Department of Transportation, the Federal Aviation Administration, the International Air Transport Association, and the commercial carrier.

All sample containers will be placed in a sturdy shipping container (e.g., an ice chest). The

following outlines the packaging procedures that will be followed:

1. Line the bottom of the cooler with a large trash bag to minimize leakage of water.
2. Place bubble wrap around the inside edge of the cooler to prevent breakage during shipment, and/or wrap bottles individually if bottles have been used. Plastic bags or plastic bottles would be secured so that they would not move around.
3. Seal the drain plug of the cooler with fiberglass tape to prevent potential leakage from the cooler (should sample bottles or bagged ice leak assuming that ice is necessary).
4. Prepare bags of ice to be used to keep the samples cool during transport. Ice will be used. Pack the ice in doubled, zip-locked plastic bags.
5. Check the sample bottle screw caps for tightness. Secure sample bottle/container tops and place a custody seal over the container's top.
6. Ensure sample labels are affixed to each sample container and protected by a cover of clear tape.
7. Wrap all glass sample containers in bubble wrap to prevent breakage.
8. Seal all sample containers in heavy duty plastic zip-lock bags. Write the sample numbers on the outside of the plastic bags with indelible ink.
9. Place sample containers (wrapped and sealed) into the cooler. Place the bagged ice on top and around the samples to chill them to the correct temperature.
10. Fill the empty space in the cooler with bubble wrap, Styrofoam peanuts, or any other available inert material to prevent movement and breakage during shipment.
11. Enclose the appropriate chain-of-custody(s) in a zip-lock plastic bag and affix to the underside of the cooler lid.
12. Close the lid of the cooler. Tape the cooler shut with fiberglass strapping tape.
13. Affix custody seals across the openings of the cooler both front and back to ensure that samples are not tampered with during transport. Include sample packer's initials and date on the custody seals.

Daily, the inspector/investigator will notify the Laboratory of the sample shipment schedule (note: Friday shipments must be reported no later than noon). The laboratory will be provided with the following information:

1. State's name
2. Name and location of the site or sampling area
3. Type of pesticide for which analysis is required
4. Total number(s) and matrix of samples shipped to the laboratory; sample will be identified as a market or misuse type of sample
5. Carrier, air bill number(s), method of shipment (e.g., priority next day), if sent by carrier, otherwise, when inspector or courier can be expected
6. Shipment date and when it should be received by the laboratory
7. Irregularities or anticipated problems associated with the samples
8. Whether additional samples will be shipped or if this is the last shipment

3.4 Analytical Methods Requirements

Describe or reference methods by which samples will be analyzed. You may use the following text as a guideline.

All samples will be analyzed at [Name of Laboratory]. The State has established a Memorandum of Understanding to cover its analyses. Analyses will be performed following either EPA-approved methods (e.g., SW-846), methods from the most current edition of *Standard Methods for the Examination of Water and Wastewater* methods from the Association of Analytical Chemists, or methods developed in-house at the laboratory. Methods are available as Standard Operating Procedures from the laboratory upon request. The State has on file the QA Plan for the laboratory and also copies of the Standard Operating Procedures for the methods which the laboratory routinely performs on the State's behalf. These are included in this QAPP as [Appendix # or link to e-document]. The laboratory's quality system and analytical methods, or approach to the development of analytical methods, have been reviewed by EPA.

Note: If samples are sent to a commercial laboratory regularly, information concerning that laboratory's quality system will be obtained and submitted to EPA for review prior to its use. Information might include, but not be limited to the QA Manual for the laboratory and appropriate SOPs for the types of analyses and matrices which the State might request. EPA's QA Office will then advise the State regarding its perspective on the ability of the laboratory to meet the State's data quality requirements.

The State will use the following laboratory to analyze all samples taken as a part of pesticides investigation:

[Lab name]
[Lab address]
[Primary contact person]
[Phone number]

This lab is operated by [State, EPA, Commercial, etc.].

When data are received from the lab, they will be reviewed for usability by the Quality Assurance Manager and the Inspector, to indicate whether an enforcement action is warranted.

3.5 Quality Control (QC) Requirements

3.5.1 Quality Control Procedures

Describe Quality Control checks. You may use the following text as a guideline.

The laboratory will summarize the data and associated Quality Control (QC) results in a data report, and provide this report to the State's inspector within the time frame agreed upon by the State and the laboratory. In general, the laboratory will provide a report containing the results of the analyses and the detection limits for the method. Additional quality control information generated by the laboratory will be retained by the laboratory for a minimum period of three years from the receipt of the samples. If required, a more detailed report containing calibration, spike recovery, surrogate recovery, laboratory blank analyses, or other information is available from the laboratory upon request. The State Inspector or FIFRA Project Manager/QA Officer will review the data reports and, if necessary, associated QC results to make decisions concerning the usability of the data prior to proceeding with any enforcement case.

3.5.2 Corrective Action

Describe what you will do if the data from the laboratory are not useable, either because of sample problems or laboratory analysis problems. Example language is provided below.

If the laboratory reports that there were problems with the samples, an effort will be made to determine the source of the problem. First the laboratory will be requested to explain the nature of the problem in a written report. If the problem is due to QC checks in the laboratory, the laboratory's input will be sought concerning whether a repeat analysis is possible. If this is not feasible, because there is insufficient sample, or the sample is no longer valid due to holding time or other factors, the State will consider re-sampling if it is felt that the field conditions will not have changed significantly. If the problem is due to matrix interference, the State will determine in conjunction with the laboratory if an alternative analysis might provide more defensible results. If not, the State will make a decision concerning whether the data are sufficiently valid to proceed. If additional perspective is needed in making these decisions, the State will consult with the EPA Project Officer and/or the EPA Quality Assurance Office before deciding how to proceed.

3.6 Calibration and Operation of Field Instruments: Instrument/Equipment Testing, Inspection, and Maintenance Requirements

Describe how you operate instruments used to take field measurements (if applicable). Modify the text below to reflect specific field instruments used by your program. Cite any applicable SOPs and include copies in an appendix or provide links to e-documents.

Sampling equipment under the care of the State FIFRA Pesticide Program will be operated, calibrated, and maintained according to the manufacturer's instructions and/or program SOPs. Maintenance logs will be kept in the State office. Each piece of equipment will have its own maintenance log. The log will document any maintenance and service of the equipment. A log entry will include the following information:

- Name of person maintaining the instrument/equipment

- Date and description of the maintenance procedure
- Date and description of any instrument/equipment problem(s)
- Date and description of action to correct problem(s)
- List of follow-up activities after maintenance (i.e., system checks)
- Date the next maintenance will be needed.

3.7 Data Acquisition Requirements (Non-Direct Measurements)

Describe data you might obtain from sources other than direct sample collection. Discuss steps you take to verify data. Modify the text below, as needed, to reflect your program.

To support enforcement efforts, the State may need to acquire data from "external" data sources. These sources include, but are not limited to, the California Department of Pesticide Regulation, the county agricultural department, the U.S. EPA, or [other entity]. Most of these data will be informational in nature and will not be used directly in any decision making. Data from the collection and analysis of field samples will always be done directly by the State. The State is not in a position to evaluate the pesticide use records or other records which will be obtained from these sources.

3.8 Data Management—Electronic Record Keeping

Describe any electronic record keeping. You may use the following text as a guideline. Add or delete subsections as needed.

3.8.1 Data Tracking

When the State Inspector opens an enforcement case, s/he enters basic information about the case into the case tracking spreadsheet. The spreadsheet is stored on the network share drive, which is accessible by Pesticide Office personnel only. The spreadsheet tracks the following information about each case:

- Site/Facility Name
- Inspector
- Attorney
- Violation (FIFRA Section)
- Product/Violation notes (include relevant laboratory data)
- Date Show-Cause Letter Sent
- Proposed Penalty/ Settlement-In-Principle
- Date Consent Agreement/Final Order (CAFO) or Civil Complaint (CC) mailed
- Additional Notes

3.8.2 Reporting

The State Pesticides Manager monitors and reviews data from the above-listed spreadsheet on a weekly basis. Data are incorporated into Mid- and End-of-Year Reports to EPA.

3.8.3 Data Storage and Retrieval

Data from inspections are maintained in locked file cabinets in the State office, accessible only by State Pesticide Program staff. Data will be retained for a period of ten years, at which time they will be destroyed unless there is pending litigation.

4 Assessment and Oversight

4.1 Assessment and Response Actions

You may use the following text as a guideline.

4.1.1 Field Oversight

Assessment activities under this program will consist primarily of readiness reviews conducted by the Project Manager or State Inspector Supervisor. These are described below.

State Inspectors will be properly trained by qualified personnel before any sampling begins and will also be trained in evidentiary procedures as well as having completed the EPA's inspector training. Adequate supplies of all preservatives and bottles or storage containers will be obtained and stored appropriately before heading to the field. Sampling devices will be checked to ensure that they have been properly cleaned (for devices which might be reused) or are available in sufficient quantity (for devices which are disposable). Proper paperwork, logbooks, chain of custody forms, etc., will be assembled by the State inspector. The State's Project Manager will review all field equipment, instruments, containers, and paperwork to ensure that all is in readiness prior to the first day of each sampling event. Any problems that are noted will be corrected before the sampling team is permitted to depart the State's facilities.

4.1.2 Field Activity Audits

During at least two inspections involving sample collection per year, the State Project Manager/QA Officer will assess the sample collection methodologies, field measurement procedures, and record keeping of the field inspector to ensure activities are being conducted as planned (and as documented in this QA Project Plan). Any deviations that are noted will be corrected immediately to ensure all subsequent samples and field measurements collected are valid. (Note: If the deviations are associated with technical changes and/or improvements made to the procedures, the Project Manager/QA Officer will verify that the changes have been documented by the State Inspector in the Field Log Book and addressed in an amendment to this

QA Project Plan.) The State Project Manager may stop any sampling activity that could potentially compromise data quality.

4.1.3 Laboratory Oversight

If any audits of the laboratory used for this program are required, the State will rely upon the EPA Region 9 QA Office to perform them.

4.2 Reports to Management

4.2.1 Frequency, Content, and Distribution of Reports

Describe frequency, content, and distribution of audit reports for internal purposes and those for submission to EPA, if they have not been described previously. If they have, reference the appropriate section.

If the State quality assurance manager conducts oversight reviews of sampling procedures, s/he will use a field audit checklist to prepare a report according to State requirements. Reports will include but not be limited to the following: whether sampling protocols were followed; whether proper paperwork was completed and filed; whether decontamination procedures were followed; and whether samples were preserved, packed and shipped properly.

5 Data Validation and Usability

5.1 Data Review, Validation, and Verification Requirements

At the present time, the FIFRA enforcement program does not require that laboratory data be validated. If this requirement changes in the future, the QAPP will be revised.

6 Appendices