

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Inspection Manual



U.S. Environmental Protection Agency
Office of Enforcement and Compliance Assurance
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DISCLAIMER

This Inspection Manual is an inspection support tool provided by the U.S. Environmental Protection Agency (EPA), for use by EPA regions, states and tribes conducting federal inspections under the Federal Insecticide, Fungicide, and Rodenticide Act. This Inspection Manual is not a regulation and, therefore, does not add, eliminate or change any existing regulatory requirements. The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA, state and tribal officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on analysis of specific-site circumstances. This guidance may be revised without public notice to reflect changes in EPA's policy.

FIFRA INSPECTION MANUAL

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FOREWORD

The purpose of this Manual is to assist inspectors who conduct inspections pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

In order to help us update the Manual so that it remains a viable working tool, readers are encouraged to offer suggestions, amendments and constructive criticism generated by their field experience and use of the Manual. Comments should be forwarded to Helene Ambrosino at EPA Headquarters ambrosino.helene@epa.gov, 202-564-2627.

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REVISIONS

<u>February 2014</u> — Chapter 6 was revised at the request of EPA's Office of Civil Enforcement. The revision sets forth a protocol on obtaining records documenting the distribution and sale of sampled product.

March 2014 — Changed contact for comments on the Manual.

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GENERAL INFORMATION

This manual provides guidance to inspectors conducting pesticide inspections under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). It includes recommended procedures and forms for federal inspections.

Inspections are conducted in five phases: (1) inspection preparation; (2) entry and opening conference; (3) observations and evidence collection; (4) receipt for samples/statement(s), and closing conference; and (5) inspection reporting. Conducting all inspections in this manner will ensure that the inspector fulfills the statutory requirements for conducting inspections authorized under Sections 8 and 9 of FIFRA. EPA has developed forms for use during inspections that will assist the inspector in completing all phases. For a complete listing of the forms, see Exhibit 1-1.

STANDARDS OF PROFESSIONAL CONDUCT

The following standards of ethics must be observed at all times. The inspector shall:

- Conduct investigations within the framework of the United States Constitution and with due consideration for individual rights, regardless of race, sex, creed or national origin.
- Uphold the Constitution, laws and regulations of the United States and all governments therein and never be a party to their evasion.
- Never use any information obtained confidentially in the performance of governmental duties as a means of making private profit.
- Never commit any act (or failure to act) in a manner that might be construed as being motivated by personal or private gain (conflict of interest).
- Never discriminate by dispensing special favors or privileges to anyone, whether for remuneration or not; and never accept, for his/her or their families, favors or benefits under any circumstances.
- Develop and report facts of an investigation completely, objectively and accurately.
- Make no promises of any kind; government employees (inspectors) cannot bind government enforcement.
- Continually attempt to improve professional knowledge and technical skill in the investigative field.

PROFESSIONAL ATTITUDE

Because the inspector is often the initial or only contact between the Agency and industry or the public, he/she must be tactful, courteous and diplomatic, while establishing an atmosphere of cooperation through a firm but responsive attitude.

ATTIRE

Good public relations and practical common sense require appropriate dress for inspection activities. Protective clothing is required for many inspections. Inspectors must wear any safety equipment that may be customary in the establishment being inspected. Chapter 2 provides additional information on personal protective safety equipment.

RELATIONSHIPS WITH INDUSTRY AND THE PUBLIC

It is important to establish good working relationships with industry, the public and consumers. The inspector must introduce himself/herself by name, title and organization, present his/her credentials and explain the purpose of the visit. The inspector must not speak of any product manufacturer or person in a derogatory manner. All information acquired in the course of an inspector's duties is to be used for official purposes only.

There may be times when an inspector is requested to provide advice that amounts to compliance assistance. See the "<u>National Policy on the Role of the EPA Inspector in Providing Compliance Assistance during Inspection.</u>"

If an inspector is approached by a member of the public, including the media, during an inspection, the inspector should respectfully refer any inquiries concerning the inspection to the EPA (or appropriate state/tribal) press office. The inspector must not divulge any information about the inspection. Where the media representative is persistent, it may be necessary to stop the inspection temporarily to allow time to consult with the EPA (or appropriate state/tribal) press office.

GIFTS, FAVORS AND MEALS

An inspector shall not accept anything of value from industry or the public for, or because of, any official act he/she has performed or will perform. However, an inspector may accept refreshments of nominal value in the ordinary course of a luncheon or dinner meeting or other meetings or on inspection tours when it is not proper or feasible for the inspector to pay. For more information on ethics standards, visit the U.S. Office of Government Ethics.

KNOWLEDGE REQUIRED OF A FIFRA INSPECTOR

A FIFRA Inspector must have knowledge of FIFRA and its implementing regulations (at <u>40 C.F.R.</u> <u>Parts 150-189</u>), as well as the other requirements set forth in EPA Orders 1440.2 and 3500.1 go to including all Health and Safety Requirements (see Chapter 2).

A good inspector must have certain communication and intuitive skills in order to complete a thorough investigation. The inspector must know how to:

- Substantiate all statements of witnesses with facts or items of evidence.
- Collect and document evidence to support a successful civil action, criminal prosecution or seizure.
- Accurately and clearly write an inspection report, containing all information, data and other records, such as photos, gathered during the inspection.
- Obtain respect, inspire confidence and maintain the good will of the public, industry and consumers during interviews.
- Conduct sampling procedures in a safe and professional manner, preserving the chain of custody.
- Use good interview techniques and detect discrepancies or lack of good faith during interviews.
- Be accurate, thorough, unbiased and fair while conducting an investigation/inspection and preparing the inspection report.
- Testify in court.

In addition, an inspector should have generalized knowledge of the following federal laws and regulations that could be relevant to an inspection in that the facility being inspected may be subject to additional regulations. Links are included where available on-line:

- Clean Air Act (CAA)
- Federal Water Pollution Control Act (FWPCA)/ Clean Water Act (CWA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Superfund Amendments and Reauthorization Act (SARA)
- Endangered Species Act (ESA)
- Emergency Planning and Community Right-To-Know Act (EPCRA)
- <u>Federal Food, Drug, and Cosmetic Act (FFDCA)</u>
- Hazardous Materials Transportation Act (HMTA)
- Occupational Safety and Health Act (OSHA)
- Resource Conservation and Recovery Act (RCRA)
- Safe Drinking Water Act (SDWA)
- Toxic Substances Control Act (TSCA)
- Appropriate state pesticide and environmental legislation
- Department of Transportation (DOT) Regulations

- Department of Homeland Security (DHS) Customs and Border Protection Regulations at 19
 C.F.R.; in particular sections 12.110 12.117
- Federal Facility Compliance Act (FFCA)

SMALL BUSINESSES

EPA provides a variety of resources to help small businesses understand and comply with federal and state law, in part, due to the Small Business Regulatory Enforcement Fairness Act (SBREFA). This <u>flyer</u> is required to be given out during every inspection. The flyer provides useful information on resources for small business that may be faced with environmental compliance issues.

DISCLOSURE OF OFFICIAL INFORMATION

REQUESTS FOR INFORMATION BY INDUSTRY OR THE PUBLIC

The Freedom of Information Act (FOIA) governs the disclosure of information to industry and the public. Information about FOIA is available at http://www.epa.gov/foia/.

Federal inspectors as well as state or tribal inspectors performing federal inspections shall not release under FOIA or similar state law, any notes, documents, reports, etc. obtained or prepared in connection with a FIFRA inspection until such time as enforcement proceedings are concluded or the inspection is closed (e.g. no further action). Should the state or tribe receive a FOIA or similar request for documentation relative to an open or ongoing FIFRA inspection, the state or tribe shall contact the EPA regional FIFRA program office or headquarters FIFRA Enforcement Office.

CONFIDENTIAL BUSINESS INFORMATION

Sections 10 and 12(a)(2)(D) of FIFRA address the protection of trade secrets and confidential business information (CBI). Only persons authorized by EPA are allowed access to CBI. Information received that is marked "trade secret" or "confidential" must not be copied unless authorized in writing by EPA.

The written authorization to make copies must contain the following information:

- 1. The name of the recipient of the copy.
- 2. The intended purpose for which the copy is to be used.
- 3. The manner in which the copy is to be disposed of after use.

When a member of the public, or a representative from a state, local, tribal or federal agency requests access to any information considered confidential, the person handling the request

must comply with the procedures set forth in Subpart B of <u>40 C.F.R Part 2</u>. All such requests must be referred to the appropriate EPA regional office.

State and tribal inspectors conducting inspections using federal credentials to conduct FIFRA section 8 and 9 inspections **are not authorized** to obtain or access CBI on behalf of EPA unless the claim of CBI has been waived. Additionally, where state or tribal inspectors are conducting an inspection under their own state or tribal authority, they may have CBI authority under state or tribal law.

Where a state or tribal inspector is conducting an inspection on behalf of EPA using federal credentials and records claimed as CBI are necessary to complete the inspection, the inspector must request that the CBI be sent directly to the appropriate EPA regional office Document Control Officer (DCO) using the procedures described below. See Exhibit 1-2 for a current list of EPA DCOs.

PROCEDURES FOR CBI ACQUIRED BY AN EPA INSPECTOR DURING AN INSPECTION

The following procedures must be adhered to when an EPA inspector receives FIFRA CBI:

- 1. The information received shall be marked as "FIFRA CBI" or the red FIFRA CBI cover sheet shall be attached to the information.
- 2. The CBI information shall be placed in an envelope, sealed and marked, "CBI—To Be Opened ONLY by Addressee" and the name of the Regional DCO. This envelope is then to be placed into another envelope which is normally addressed and sealed, with no indication that it contains CBI.
- 3. The envelope shall be given to the Regional DCO to be properly logged in as CBI.
- 4. CBI must be maintained only in a locked filing cabinet or safe.

PROCEDURES FOR CBI REQUESTED BY A STATE OR TRIBAL INSPECTOR

The following procedures apply to state/tribal inspectors using federal credentials and federal authority:

- 1. The inspector shall request that the establishment place any information claimed to be CBI in a double sealed envelope before sending.
- 2. The inspector shall list the requested information claimed to be CBI on the "Receipt for Samples" and/or "Statement Form".
- 3. The inspector shall provide the owner/operator with a correct address for the EPA Regional DCO.
- 4. The inspector shall clearly document the list of requested information claimed to be CBI to be sent to the EPA DCO in the inspection report.

5.	The inspector shall send the inspection report, noting the CBI requested on the "Receipt for Samples" and/or "Statement Form" and in the inspection report, to the EPA Regional Office or Headquarters, as appropriate.

EXHIBIT 1-1: EPA FEDERAL FORMS USED FOR FIFRA

FIFRA INSPECTION FORMS

The FIFRA inspection forms listed below are to be used during all inspections conducted using federal credentials. If a form is not listed, it is obsolete and therefore cannot be used. Any existing supply obsolete forms should be destroyed.

A region can supply the forms to regional staff, state lead agencies or tribal pesticide programs for use during an inspection conducted under federal authority and federal credentials. The forms cannot be changed or modified, unless you first contact the OECA/OC FIFRA Forms Representative, and obtain clearance for the change/modification. If Official Sample Seals (EPA Form 7500-2) are needed, contact the EPA Forms Officer at 202-564-9662 or eme.sunday@epa.gov.

Forms:

- 3540-2 Notice of Inspection
- 3540-3 Receipt for Samples)
- 3540-4 Sample Jacket Cover Page
- 3540-13 Copy of Invoice/Shipping Records
- 3540-17 History of Sample (PDF) (516K, 1 pp)
- 3540-25 Notice of Inspection Use/Misuse (Interactive PDF) (515K, 1 pp)
- 3540-26 Receipt for Samples Use/Misuse (Interactive PDF) (515K, 1 pp)
- 3540-27 Stop Sale, Use, Removal Notice (Interactive PDF) (442K, 1 pp)
- 3540-41 Chain of Custody Form (PDF) (307K, 2 pp)
- 3540-42 Statement (Interactive PDF) (512K, 2 pp)
- 3540-43 FIFRA Photo Log
- Relevant Sections of FIFRA for Inspections
- 7500-2 Official Sample Seal

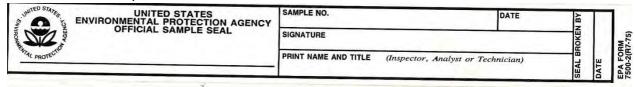


FIGURE 1 - EPA OFFICIAL SAMPLE SEAL

In order to open the forms currently in use, you must use Adobe Acrobat/Reader version 8 or higher. The forms can be completed online and then printed.

OTHER FIFRA FORMS

3540-1 Notice of Arrival of Pesticides and Devices

- 3540-8 Application for Registering a Pesticide, Device or Active Ingredient Producing Establishment
- 3540-16 Pesticide Report for Pesticide-Producing and Device-Producing Establishments

PREPARING FORMS FOR PRINTING

The following are single page EPA forms and can be reproduced on white paper:

- 3540-4
- 3540-13
- 3540-17
- 3540-41 (Note: contains two pages)
- 3540-42 (Note: contains two pages)
- 3540-43

The following EPA forms are 1-page forms requiring a duplicate copy. These forms should be reproduced on paper that creates an automatic duplicate copy (like NCR paper):

- 3540-2
- 3540-3
- 3540-25
- 3540-26

The following form is a full sheet label and must be printed in color:

• 3540-27

Note: The inspector can print out the 2-page document entitled "Relevant Sections of FIFRA for Inspections" to provide to parties being inspected.

States, territories and tribes with FIFRA enforcement cooperative agreement programs with EPA can obtain the above listed forms from the regional office for use when conducting federal inspections using federal credentials.

EXHIBIT 1-2: EPA DOCUMENT CONTROL OFFICERS

FIFRA CBI Document Control Officers and Alternates (DCO/DCA)

EPA Regional Offices	States/Terr. Covered	EPA Regional Offices	States/Terr. Covered
U.S. EPA Region 1 Rosina Toscano (DCO) Telephone: 617-918-1861 Kan Tham (Alternate DCO) Telephone: 617-918-1872 Toxics and Pesticides Unit (OES 05-4) 5 Post Office Square, Suite 100 Boston, MA 02109-3912	CT, MA ME, NH RI, VT	U.S. EPA Region 6 Chuck Ruple (DCO) Telephone: 214-665-6534 Pesticides Section (6PD-P) 1445 Ross Avenue Dallas, TX 75202-2733	AR, LA NM, OK TX
U.S. EPA Region 2 Tara Glynn (DCO) Telephone: 732-906-6183 Michael Kramer (Alternate DCO) Telephone: 732-321-6610 Pesticides Team (MS-500) 2890 Woodbridge Avenue Edison, NJ 08837-3679	NJ, NY PR, VI	U.S. EPA Region 7 Barbara Shepard (DCO) Telephone: 913-551-7759 Jay Hua (Alternate DCO) Telephone: 913-551-7748 Pesticides Section (WWPD/TOPE/PEST) 11201 Renner Boulevard Lenexa, KS 66219	IA, KS MO, NE
U.S. EPA Region 3 Kyla Townsend-McIntyre Telephone: 215-814-2045 Magda Rodriguez-Hunt Telephone: 215-814-2128 Pesticides and Asbestos Programs Branch (3LC62) 1650 Arch Street Philadelphia, PA 19103-2029	DC, DE MD, PA VA, WV	U.S. EPA Region 8 Dennis Jaramillo (DCO) Telephone: 303-312-6203 Jennifer Schuller (Alternate DCO) Telephone: 303-312-6334 Enforcement Division (8ENF-PJ) 1595 Wynkoop Denver, CO 80202 Telephone: 303-312-6049	CO, MT ND, SD UT, WY
U.S. EPA Region 4 Mary Summers (DCO) Telephone: 404-562-8997 Chemical Products & Asbestos Section 61 Forsyth Street, SW 12th Floor Atlanta, GA 30303	AL, FL GA, KY MS, NC SC, TN	U.S. EPA Region 9 Marcy Katzin (DCO) Telephone: 415-947-4215 Glenda Dugan (Alternate DCO) Telephone: 415-947-4204 Pesticides Office (CED-5) 75 Hawthorne Street San Francisco, CA 94105-3901	AZ, CA GU, HI MP, NV
U.S. EPA Region 5 Pamela Grace (DCO) Telephone: 312-353-2833 Gail Muffitt (Alternate DCO) Telephone: 312-886-6008 Pesticides & Toxics Compliance Section (LC-8J) 77 West Jackson Boulevard Chicago, IL 60604	IL, IN MI, MN OH, WI	U.S. EPA Region 10 Erin Williams (DCO) Telephone: 206-553-4627 Chad Schulze (Alternate DCO) Telephone: 206-553-0505 Pesticides and Toxics Unit (OCE-084) 1200 Sixth Avenue, Suite 900 Seattle, WA 98101-1128	AK, ID OR, WA

FOR FOREIGN PRODUCERS:

U.S. Postal Service Mail Address

Michelle Stevenson (DCO for OC only)

U.S. Environmental Protection Agency Pesticides, Waste & Toxics Branch (2227A) 1200 Pennsylvania Avenue, NW Washington, DC 20460-0001 USA

Telephone: 202-564-4203

Courier Delivery Address

Michelle Stevenson

U.S. Environmental Protection Agency Pesticides, Waste & Toxics Branch Ariel Rios Building -- South

1200 Pennsylvania Avenue, NW, Room 6102 Washington, DC 20004 USA

CHAPTER TWO HEALTH AND SAFETY

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HEALTH AND SAFETY

INTRODUCTION

Manufacturing plants, blenders, processors, elevators, mills and warehouses can be hazardous work environments. Inspection of these places will, at times, include potentially hazardous situations. Personal health and safety must be a top priority for every inspector. To ensure maximum protection under any and all conditions:

- Prepare and plan for health and safety.
- Always bring and use safety equipment.
- Be aware of potential dangers posed at each type of establishment.
- Exercise care and use common sense at all times.
- Prevent accidents by specifically requesting and conforming to known safety practices. If there are questions about the safe way to do a job, ask a supervisor for help and instruction.
- Contact regional Safety, Health and Environmental Management Program Manager for pertinent health and safety information and to determine the eligibility and need for medical monitoring.

PERSONAL PROTECTIVE EQUIPMENT

FIFRA inspections take place in locations that may pose health and safety dangers to inspectors. Additionally, industrial solvents, pesticides, or fertilizers can corrode or destroy equipment, clothing and footwear. Therefore, it is critical to use Personal Protective Equipment (PPE) during FIFRA inspections. The following list of PPE is provided. Note that all PPE require regular cleaning, visual checks and maintenance.

EYE PROTECTION

Types of eye protection include:

 Goggles—Goggles form a tight seal around the eye area and provide an impervious barrier against objects getting into the eyes. They often may be uncomfortable and hard to see through because of condensation. Goggles may be directly vented, indirectly vented or non-vented. Directly vented goggles may be used for particle deflection. They

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- will not, however, be impervious to liquids. Indirectly vented goggles will afford protection from particles as well as most liquid spatters. Non-vented goggles should be used when dealing with anhydrous ammonia.
- **Face shield**—Face shields form a plane of protection in front of the eyes. The eyes, nose, and mouth can be protected from direct (perpendicular to the shield) exposure. Objects or substances coming from other directions, however, may get into the face or eyes. When not in use, the face shield may be flipped out of the way to wipe the face. A shield may also be easily used over prescription glasses. A face shield affords only secondary protection and must be used with either goggles or safety glasses.
- Safety glasses—Safety glasses are available in either clear lenses or prescription lenses. Like the shield, they do not afford protection from non-direct exposure. Side guards are available to protect from non-direct exposure and must be used to make them more effective. If glare may be a problem, tinting may be added.

FOOT PROTECTION

Types of foot protection include:

- Footwear (shoes or work boots)—Footwear should be comfortable to wear, fit properly and provide proper support. Secondly, it must have a steel toe or protective support in case objects are dropped on the foot. The sole and heel of the footwear must be appropriate for the working environment. Do not wear slick-soled shoes or sneakers. Use proper protective mechanisms to prevent your feet from being exposed to pesticides or caustic chemicals. Workers have become seriously ill from exposure through shoes or boots due to the footwear material soaking up the pesticide and exposing the person through skin contact. A good practice is to "waterproof" footwear; this function should be performed regularly.
- Rubber or neoprene boots or galoshes—Ordinary work boots or shoes are not suitable
 when handling pesticides. Rubber boots or neoprene boots must be worn. Rubber boots
 provide a protective barrier against water and some solvents. They also may be easily
 cleaned. Neoprene boots will afford protection from various chemicals and solvents.
 Either "gum" boots, pull-over boots, or buckle boots may be used.
- **Tyvek booties**—Tyvek booties can be worn over shoes/boots and add a large degree of protection from absorption of chemicals into shoes, boots, and the body.

HAND PROTECTION

Hand protection comes in many forms. The class and material of gloves used must be taken into account when selecting the proper type for use. Certain gloves may have long shanks and afford

protection for the wrist or lower arm. Be aware that cuffs present a hazard by allowing material to collect in the cuff or getting caught in machinery. When necessary, inspectors must use the following to protect their hands:

- Work gloves (cotton or jersey)—Cotton or jersey work gloves will provide warmth in the winter and some protection from dirt and blisters. Be careful not to use cotton or cloth gloves when working with pesticides, chemicals, or solvents. Cloth gloves will act as a wick and absorb these products, allowing continued contact with the skin.
- **Disposable latex gloves**—Disposable latex gloves are easy to use and afford protection from some fertilizers, seed treatments, dirt, grease, non-corrosive materials or liquids. They are easy to use and readily disposable. However, some people may be allergic to latex. If a rash occurs, seek proper medical attention. A disadvantage of latex gloves is that they do not afford protection against corrosive materials or certain chemicals. When using latex gloves, determine for what products the gloves are rated.
- **Heavy rubber gloves**—Heavy rubber gloves afford the best protection when working around pesticides or other similar products. These gloves are easily rinsed or cleaned when liquids are spilled on them.

EAR PROTECTION

Types of ear protection include:

- **Disposable foam plugs**—Disposable foam plugs are inexpensive, easily stored and used; but they may be uncomfortable to wear. Make sure the plugs are rated with the proper protection for the environment you will be working in.
- **Padded hearing protectors**—Padded hearing protectors are the typical "headphone" type protectors. They afford noise protection as well as a cover for the ear. Usually they are rated higher than typical plugs and prevent compacting in the ear canal.

NASAL, MOUTH AND RESPIRATORY PROTECTION

NOTE: THE USE OF RESPIRATORS AND SELF CONTAINED BREATHING APPARATUSES (SCBA'S) REQUIRES "FIT TESTING" AND A YEARLY CERTIFICATION OF THE "FIT TEST." IN ADDITION, MEDICAL MONITORING IS REQUIRED. ALL CERTIFICATION RECORDS SHOULD BE RETAINED BY THE INSPECTOR'S SUPERVISOR.

Respiratory protection equipment includes:

• **Disposable dust masks**—Disposable dust masks are easily worn and afford little or no protection from pesticides. However, they may be used for general dust and limited airborne particulates. Dust masks only prevent particles from passing through, and offer little or no protection against caustic or dangerous fumes, pesticides, etc.

- Respirator—Respirators usually contain various filters that can be interchanged
 depending upon the hazards of the working environment. Filters are rated for particular
 substances. Be aware of the respirator's rating and the protection it affords. Likewise,
 be aware of the respirator's limitations. Respirators must never be used in oxygendeficient environments.
 - o NOTE: Facial hair may prevent a tight seal.
 - o Test according to the manufacturer's directions to ensure an air-tight seal.
 - Achieving an air-tight seal may present a greater problem for women than for men because many respirators are sized to fit a man's face. Ensure that a tight fit can be achieved prior to leaving the office.
- Air packs—Self-contained breathing apparatuses (SCBA) contain a mask, oxygen tank, and regulator. Before using SCBA, inspectors must have attended the 40-hour Hazard Materials Training course and obtained a physician's approval to wear it. It is extremely important that two SCBA-trained people be on hand when entering oxygen deficient environments. ALL CERTIFICATION RECORDS SHOULD BE RETAINED BY THE INSPECTOR'S SUPERVISOR.

HEAD PROTECTION

Proper head protection is recommended during most inspections. Steel or molded hats protect the head and skull from falling objects or head height obstacles.

BACK PROTECTION

When lifting heavy objects, use a proper back support or lift belt.

CLOTHING PROTECTION

The inspector should wear clothing protection to prevent-cross contamination of sites and/or samples as well as providing protection to the inspector and preventing contamination of the inspector's home or office. Inspectors should use the following:

- Cloth coveralls—Protective outerwear is available to be worn over your normal clothing. Lightweight coveralls can be used during the summer months while insulated coveralls can be used in the winter. These coveralls will keep clothing from receiving stains while in dirty work environments.
- **Tyvek coveralls**—Tyvek is an extremely lightweight, disposable paper-like substance that is extremely hard to tear. Tyvek is the preferred material because, unlike cloth, it does not absorb and, if contaminated, can be discarded. Tyvek is chemical-resistant.

GENERAL SAFETY PRECAUTIONS

Generally, while conducting inspections:

- Inspectors must inform facility personnel where they are going to be within the facility.
 Inspectors should specifically request information on possible dangers or areas to avoid
 during the inspection. Follow all safety requirements established by facility. For
 example, vehicular traffic within the plant grounds may not follow normal movement
 patterns nor obey usual traffic rules. Also, the nature and size of equipment used may
 make it difficult for the driver to see persons working nearby.
- Wearing jewelry, ties, loose flowing clothing, having long flowing hair, etc. can pose a safety hazard to the inspector around equipment or machinery.
- Prior to entering the plant or facility, inquire about the firm's safety polices. Many firms require visitors to wear a hard hat and/or safety glasses. Hardhats should be worn at all times while on manufacturing and warehouse premises.
- Safety shoes with non-slip soles and heels should be worn. Clothing should be close fitting. Make sure laces are tied.
- Flashlights should be carried, especially when work assignments involve the upper floors or basements.
- Dust masks or properly rated respirators should be worn in dust-laden environments.
- If there is a need to use a protective device that has not been supplied or if there are safety concerns, notify a supervisor.
- While in the establishment, make sure equipment is secure during transit. A pen in a shirt pocket may fall out during the inspection and may fall into the firm's equipment or product. A probe, flashlight, or folder may slip or fall during climbing or conducting the inspection. This may cause personal injury or injury to other employees.

AWARENESS

An inspector must not enter a grain elevator, grain mill, warehouse, railroad tank/car, or silo unless the facility's supervisory personnel have been alerted as to his/her presence and the location where he/she will be working. Workers in the area should know who an inspector is and where he/she will be working or planning to work, and what he/she will be doing. Inspectors must not enter areas where they have no official purpose.

Plant, elevator, mill and warehouse fires are not uncommon. Know the location of exits, telephones, and first aid equipment, and especially emergency evacuation routes and procedures. Read and follow all warning signs.

Construction and maintenance work is often being performed during business operations in all plants. This activity may increase the possibility of fire or other mishaps. Keep a safe distance from construction and maintenance activities.

When entering an elevator, mill, or warehouse from bright outside light, vision may be temporarily impaired. Stop and let your eyes adjust before continuing the inspection. Be aware of the surroundings. Avoid stepping on manhole covers since they may slide from underfoot.

Be conscious of the machinery being used in the vicinity. Observe conditions surrounding the various products to be sampled, with emphasis on the danger of front-end loaders, hopper and tank cars, forklifts, conveyor belts, motor drives, mixers or blenders, welding and cutting equipment, drag and screw conveyors, falls from heights and electrical equipment. Stay clear of machinery, whether it is operating or not. The "dead" machinery may be started by a remote control switch located in another part of the plant. Do not sit or step on a motionless conveyor belt. Cross over conveyors only on cross bridges or walk around the belt end.

Watch for wet floors. Dust caused by loading or unloading feed, fertilizer, or related products can mix with the moisture on the floors, making them extremely slippery and hazardous.

When the air is dust laden, the ability to see is reduced. This can be dangerous. In this environment, protect both eyes and respiratory system with the proper equipment.

High pressure air lines must not be used to blow dust from clothing or the body. Foreign matter such as metal fragments, oil, or water can be blown under the skin or into eyes, causing a painful or serious injury.

Grain dust is extremely dangerous, because it is highly explosive, and may cause loss of life and property. There should be NO SMOKING at any time in an elevator, mill, or facility. Additionally, flash attachments to cameras or other equipment that generates sparks may ignite a dust explosion. Therefore, the concentration of grain dust in the atmosphere should be monitored for explosive levels. It is imperative that inspectors discuss their needs with facility staff prior to entering a facility with airborne dust concentrations that might be explosive.

Grain elevators are fumigated frequently. Request the fumigation schedule prior to entering or inspecting the elevator.

MAN-LIFTS AND CAGE-TYPE ELEVATORS

Most mills and elevators have elevating devices to transport personnel between working levels. They are normally cage-type elevators or continuous vertical belt-type lifts. Do not use man-lifts or elevators for emergency evacuation of the plant. Power failure or shutdown will cause equipment to stop, possibly trapping occupants.

CAGE-TYPE ELEVATORS

The cage-type elevator is similar to a passenger elevator, except much smaller. When using the cage-type elevator, keep the door closed, and operate it per the posted instructions. If there are no posted instructions, request instructions from elevator or plant personnel. The maximum load capacity must be posted in the elevators and observed by all persons using the elevators.

MAN-LIFTS

Never attempt to ride a man-lift without getting the proper instruction in its operation. When riding an endless belt man-lift, always take the following precautions:

- Face the belt.
- Keep feet firmly on the steps.
- Hold on to the hand holds with both hands.

Freight, packaged goods, or sampling equipment must not be carried or handled on any manlift. Only tools which fit entirely within a pocket, backpack or tool belt should be carried on man-lifts.

LADDER SAFETY

Take the following precautions when using ladders:

- Never use a ladder that has cracked rails or rungs or has slivers on rails.
- Never use a portable straight ladder that is not equipped with safety feet, unless the ladder is securely fastened in place.
- Always climb and descend a ladder facing the rungs and rails.
- Do not climb movable straight ladders unless the foot of the ladder is about one quarter of the ladder length away from the wall.
- Use only a ladder for climbing; use of chairs, boxes or other makeshift ladders invites injury.
- Always use a ladder with safety feet to enter a boxcar or truck. Do not jump from a boxcar or truck.

LIFTING SAFETY

Never attempt to lift an object that is too heavy to handle alone. Get assistance to lift heavy objects. When lifting heavy objects, make sure to follow these safety precautions:

- Get close to the load.
- Keep your back vertical, bend your legs.
- Lift slowly, feel the load react through your legs.
- If needed or warranted, use a proper back support and lift belt.

MACHINE AND EQUIPMENT SAFETY

When working around machinery, always take the following precautions:

- Never attempt to operate any machinery.
- Never remove a machinery guard or shield on a piece of equipment while it is running.
 Guards must never be removed unless absolutely necessary for equipment inspection. If
 guards are removed, steps need to be taken to ensure the equipment is not started and
 the guards are replaced promptly once the inspection is complete. Some agencies do
 not permit removal under any condition. If an emergency arises, be prepared by
 discussing the topic with a supervisor.

SAFETY SIGNS

Respect all safety signs in the plant; they are posted for everyone's safety. Failure to obey signs can cause injury. The words "caution" and "warning" are there for a reason. Pay attention to directions provided.

ELECTRICAL SAFETY

Never tamper with electrical equipment. Electricity can kill guickly.

CONFINED SPACES

Confined space entry has resulted in more deaths and injury than any other source in the industry, therefore, it is essential to recognize and carefully evaluate the situation prior to entry. See the discussion on "Hazards and Hazardous Materials" starting on page 15 of this Chapter.

The Occupational Safety and Health Administration defines a confined space as a space that:

• Is large enough and so configured that an employee can bodily enter and perform assigned work;

¹ 29 CFR §1910.146.

- Has limited or restricted means for entry or exit (for example, tanks, vessels, silos, storage bins, hoppers, vaults, and pits are spaces that may have limited means of entry.); and
- Is not designed for continuous employee occupancy.

In addition, any space that meets the above criteria, and has a depth of 4.5 feet or more from the plane of entry to the plane upon which the worker will perform their work or when a person's head or feet pass the plane of entry or any other opening is considered a confined space.

A confined space is particularly hazardous when it meets one or more of the following criteria:

- Contains or has a potential to contain a hazardous atmosphere.
- o Contains a material that has the potential for engulfing an entrant.
- Has an internal configuration such that a person could be trapped or asphyxiated by inwardly converging walls or by a floor which slopes downward and tapers to a smaller cross-section.
- o Contains any other recognized serious safety or health hazard.

SAFETY WHILE SAMPLING

Prior to sampling, assess the conditions to be encountered when inspecting trucks, rail cars or storage areas. Be cognizant of fumigant warning-agent odors; however, remember that some toxic fumigants have no odor. Rather than take any chances, check with management to eliminate any risk of exposure. DOT regulations and pesticide labels usually require that warning signs be placed on rail cars containing fumigated commodities. If there is a fumigant notice on the car, especially if it has a recent date (3 days or less), or if you detect a fumigant odor, do not open it. Notify the firm management to have a qualified person determine if it is safe to open the car. The firm's qualified person must open the doors on both sides of the car and allow the car to air out for a prescribed length of time before allowing anyone to enter. Remember, some fumigants may not have a detectable odor, but are still a hazard.

Do not enter trucks, rail cars, or storage areas during the application of these materials, or enter where the materials have been applied unless the atmosphere has been certified safe by a competent person.

SAMPLING NEAR TRUCKS AND TRAILERS

Sampling around moving trucks and trailers presents a hazardous working climate. The key factor to prevention of accidents in this area is alertness. Stay constantly aware of moving

vehicles and the fact that drivers can be careless. Follow these safety guidelines for sampling trucks and trailers:

- Be sure that the driver knows that someone is sampling his load so that he will not move
 the truck until sampling is completed. It may be a good idea to chock or block the
 wheels of the truck or trailer.
- If a fumigant has been applied, reread physical hazards statement on the product label or the MSDS sheet, prior to sampling.
- Use a ladder to get into and out of trailers. If the ladder is slick, wipe it off with paper towels or a cloth prior to ascending.
- Always carry or lift probes and other equipment into trucks and between units. Never toss or throw equipment.
- Do not ride on running boards or crawl under trucks or trailers.
- Always be alert and watch for moving vehicles.
- On van-type trailers, the driver is required to open doors. Always check the security of the doors before entering.

When probing, always be alert for hidden obstructions such as cross braces and bars as well as the sides and bottom of the trailers. Hitting such obstructions with a sudden force can cause serious injuries as well as damage to the trailer and probe. To prevent such occurrences, do not put weight onto the probe from a standing or running position.

Always be alert for overhead obstacles. Power lines, lights, building overhangs, and other potential hazards can cause severe injury. Stay alert.

SAMPLING RAIL CARS

Railroads are always hazardous work environments. Personnel performing sampling on boxcars and hopper cars must be very careful. Minimize the possibility of an accident or injury by knowing and observing the rules of safety.

Notification is required when entering any boxcar or hopper car in a railroad yard or car siding. Inspectors who are part of a team or by themselves must be certain that appropriate personnel are aware of where they are working and the length of time it will take to obtain the samples. Different departments may have specific rules regarding the entry into the box car. Consult a supervisor for all necessary instructions. Persons that must be notified include:

- Manager of the plant.
- Person in charge of unloading.
- Track-master responsible for the movement of trains.

The person or persons notified prior to sampling of boxcars or hopper cars must also be notified when you are finished.

Railcars to be sampled are classified as either boxcars or hopper cars. The physical characteristics of the two are completely different and the hazards involved are unique. Therefore, each will be covered separately.

BOXCARS

First, assess the boxcar's condition. Next, notice the seal that must be broken. A cutting tool such as side cutters or a pry bar must be used to cut or break the seal. Wear protective eye wear when breaking the seal. Seal locking mechanisms often fly apart as they are broken and may also be sharp and cut hands or skin.

Opening and closing car doors can be hazardous. When using a pry bar, push the door away from you. Never stand beside the door; it may come free of its track and fall.

Note the condition of the grain door and watch for protruding nails and steel strapping. Place sampling equipment on the door sill and climb into the car. Never throw sampling equipment into the car before entering.

Check the inside of the car for protruding nails, bolt heads, etc. Older boxcars may have wire, rods, or wooden cross braces; use care not to strike them.

When probing, do not place excessive body weight onto the probe from a standing position. Rib or shoulder injury may occur if the material or product is shallow and the end of the probe strikes the floor.

Use the same care in dismounting from the car as when entering. Do not throw sample or equipment from the car; it could hit someone below or damage the equipment or sample.

HOPPER CARS

The hopper car is a special purpose type carrier that requires sampling from the top through either individual hatches or a continuous opening down the center of the car. Because of its unique construction and the longer and heavier equipment required for sampling, it is probably more dangerous to sample than a boxcar.

The first thing to look for when approaching a hopper car is electric power lines above or close to the car. Inspectors have been seriously injured as a result of the sampling probe coming in contact with electric lines. If lines are present, extreme care and caution must be used during the sampling operation.

Check the condition of the car's ladders. If a ladder is damaged, loose, or bent, go to the other end of the car and check for a more secure ladder. Ascend the ladder carefully.

Watch for the approach of a switch engine or switched car while working atop hopper cars. If, during sampling, the car is moved and there is no time to get down from (or out of) the car, kneel or sit down to lessen the possibility of falling from the car.

Care must be used in breaking seals. Many lids and hatch covers are quite heavy and require proper lifting techniques. A back brace will help prevent injury. When probing is started, care must be taken not to probe into the sides of the hopper car bottoms; this will cause the probe to stop suddenly.

While atop hopper cars, be especially careful if there is spilled, loose, or wet product or dust. In winter, there may be ice, frost, or snow. Safety belts are required by OSHA regulations to enter a hopper car since it is a confined space. It is the inspector's responsibility to decide whether or not the condition presents such a hazard as to deem the car too dangerous for sampling at that time.

High winds during the sampling of a hopper car can blow the hatch covers on the inspector or blow the inspector or his/her equipment off of the car. Such conditions are considered too hazardous for sampling activities.

Never sample a hopper car from above when any partial or incomplete unloading is occurring. Hopper bins may present a false "skin" or layer that can break and trap persons attempting to collect samples. It is a potential deadly situation. Notify the person in charge of unloading when you are finished sampling.

SAMPLING BINS AND TANKS

Be alert and take proper safety precautions in plants, silos, bins, pits and any closed areas where bulk products are stored and asphyxiation hazards exist. If certain products are improperly stored, improperly handled, or decomposing, dangerous amounts of carbon dioxide or other gases may deplete the oxygen supply in these areas. Never enter closed bins or tanks for the purpose of obtaining probe samples without prior approval of a supervisor. Prior to entering a bin or tank, the inspector must determine that the oxygen content of the bin or tank is sufficient to sustain life. Do not enter fumigated or treated bins or tanks until a "Gas Free Certificate" or an "Entry Permit" (with multiple confined space requirements) has been posted.

When it is necessary to enter a bin, advise the facility supervisor and workers in the bin area before entering, and again when the bin is cleared. Turn-heads, spouts and trippers must not be set for that bin. Before entering a bin, it must be inspected first from the top to make sure that no grain is hung up. Do not jump down on top of the grain -- there may be a cavity caused by crusted grain which could break. Do not enter bins without a proper safety belt. People have lost their lives by entering bins without taking the proper precautions.

SAMPLING BAGGED OR PACKED PRODUCTS

Stay alert when collecting samples during the bagging or packaging process, and when samples are stored in a warehouse. Remove any loose-fitting jewelry. Check-weighing requiring the removal of bags or packages from the line can cause injury. Be alert for the movement of forklifts used to move the commodity. Stacked paper or polypropylene bags can shift or may fall easily. When sampling stacked bags or containers on pallets and a ladder is required, ensure the ladder provides stable footing before using.

SAMPLING BULK BAGGED PRODUCTS (LARGE VOLUME BAGS)

One of the trends in some industries is to go to large 2,000-pound bags instead of the typical 50-pound package. Frequently, these bags are transported in a frame and tend to be double lined. The outside bag is a tough canvas or plastic material while the inner bag is a simple plastic liner. Typically, these bags will be six or seven feet tall and can only be accessed from the top. If a ladder is needed, secure it properly before attempting to sample. Also, be aware that the outer material is slippery and weight applied to a stack may cause the stack to shift or slip and induce a hazardous situation.

HAZARDS AND HAZARDOUS MATERIALS

Chemical compounds are commonly used to control or eliminate insect infestations in agricultural products or in containers used to store or transport these products. Such chemical compounds can present a serious hazard when used in an indiscriminate manner or when individuals disregard necessary safety precautions through ignorance or poor judgment. No individual is immune to the toxicity of these chemicals. There may be many different reactions to exposure to these toxic chemicals, such as a reduction in the body's natural resistance that can compound the effect of the exposure.

Chemical applications to agricultural products or to containers used to store or transport these products may be separated into three categories, each offering a different degree of hazard. When describing a chemical application of a commodity or container, proper terminology must be used, as it can indicate the degree of hazard involved in the application.

The following lists the types of hazardous pesticides that are commonly encountered during pesticide inspections:

Contact-type pesticides—Active ingredients such as malathion and pyrethrum are
contact-type pesticides (i.e., their effectiveness depends upon the insects coming in
contact with the material). Contact pesticides can be applied directly to the commodity
or used to eliminate an infestation within a container. Inspectors must not enter or
remain in an area while these materials are being applied as sprays or until all vapors or

mists have settled from the atmosphere. Vapor contact and absorption through the skin and the vapor or mist entering the respiratory system can cause ill effects.

- Smoke and fog-type pesticides—Resmethrin, piperonyl butoxide, pyrethrins, malathion and diclorvos (DDVP) are among the active ingredients typically used in foggers. These pesticides are used to treat unoccupied residential, greenhouse and commercial areas and transportation equipment. Such areas must not be entered until the time specified in the Directions for Use has passed. Most fogger propellants are flammable.²
- Fumigant pesticides—Use of fumigants in elevators, mills, and warehouses is not unusual. If a fumigant or unidentifiable odor is detected, check with plant personnel and determine the source of the odor. Fumigants are hazardous to breathe, even at low concentrations. Spray treatments of grain and storage areas within facilities, elevators and mills are common. Avoid breathing vapor from sprays. If accidental contact is made, wash the area of the body contacted with mild soap and water. Remove and thoroughly wash clothing, including shoes. Report mishaps to the supervisor and seek the recommendation of a physician.

Fumigants are normally liquid or solid chemical compounds which, when released into the atmosphere, readily turn to the gaseous state. These products are extremely toxic to humans and must be handled or dealt with using extreme caution. When a commodity has been fumigated, a percentage of the fumigant is absorbed by the commodity. This fumigant will be desorbed during the aeration process at a retarded rate. After a container has been fumigated, aerated, and resealed, it is possible for a dangerous concentration of the fumigant to build up within the container. When a certificate is issued by a competent person, perform the inspection duties within a two-hour period after testing and issuance of the certificate, provided that the fumigated area has remained open to the atmosphere. In the event the two-hour time period has been exceeded or the container sealed, a new test and certificate by the competent person is required.

Do not enter storage containers during the application of these materials or enter a container where the materials have been applied unless the atmosphere within the containers has been certified safe by a competent person.

Residues remaining on container surfaces, after the application of smoke and fog or fumigant type pesticides, are more toxic than the contact-type residues. When performing vessel storage examinations, inspectors may pick up residue on their hands while climbing or descending ladders. Do not eat, smoke or use toilet facilities until hands are thoroughly washed with soap and water.

² PR Notice <u>98-6</u> (6 pp, 17 K) - Flammability Labeling Requirements for Total Release Fogger Pesticides.

EXPOSURE TO HAZARDOUS MATERIALS

Indications of exposure to a chemical compound include, but are not limited to, the following symptoms:

- Skin irritation (rash, burning sensation, dryness and sensitivity).
- Watering of the eyes (also burning sensation).
- Dryness of the nasal passages.
- Coughing.
- Shortness of breath.
- Congestion in the chest.
- Nausea and vomiting.
- Light-headedness.
- Intoxication.
- Ashen complexion.
- Agitation.

Make sure there is easy access to the emergency telephone numbers such as police, fire department, medical doctor or hospital, rescue service or state or local poison control center. Inspectors must stay aware of their physical condition and surroundings. Horseplay, in any form, is dangerous and strictly prohibited.

Do not take chances where chemical compounds are involved.

If the inspector has any reason to suspect that an inspection poses a potentially harmful or fatal exposure, check with the company's responsible officer. If, after checking, the inspector still has concerns about the potential for harm, he/she must not perform the inspection. Inspectors should consult with their supervisor when such conditions are found.

Report to a supervisor all injuries, no matter how minor they may seem, as well as unsafe conditions and unsafe acts that might be the cause of an accident.

HAZARDS

Accidents, occupational illness and fatalities can occur through asphyxiation, fire and explosion, exposure to substances, falls, electrocution, and a host of other specific hazards. Flammable atmospheres can result from an enriched oxygen atmosphere, vaporization of flammable liquids, concentrations of combustible dust, workplace byproducts or desorption of chemicals from surface coatings.

Too much oxygen, even a small percent above the 20.9 percent normally found in our atmosphere, will cause an increase in the range of flammability. A flammable atmosphere is created when the oxygen-combustibility mixture is neither too rich nor too lean for combustion to occur. If inadequate ventilation occurs, flammable gasses such as propane, methane or hydrocarbons can be trapped in a confined space. Since a number of these vapors or gases are heavier than air, they may sink and become concentrated at the lower level of the confined space.

Combustible dust concentrations can often be found in grain elevators and silo storage areas.

ENTRY AND EXIT

The size of the entry orifice must be taken into account when considering rescue actions. Barriers to entry, and ladders or the lack thereof, must also be considered. Workers may fall off ladders, develop claustrophobia or become lodged in the entry orifice.

INSPECTOR RESPONSIBILITIES

Inspectors must report any hazardous conditions in connection with confined space entry or any safety equipment defects to the facility manager immediately. Without exception, no inspector shall enter a confined space unless it is absolutely necessary, and only when two or more other persons are present, in case an emergency should arise.

ENVIRONMENTAL BIOLOGICAL HAZARDS

The risk to the inspector of contracting disease from pathogens is extremely small. However, steps should still be taken to minimize exposure during an inspection.

BE AWARE OF PATHOGEN HAZARDS DURING AN INSPECTION

Walking in or around buildings or crawling beneath a building can bring a person into contact with pathogens, stinging or biting arthropods and insects. Rodent, bird and bat feces can be encountered in any attic, crawlspace, garage, basement or feed mill. Bird feces can be found accumulated on the ground outside and on rooftops.

Bacteria are everywhere in the soil and on every surface. Pathogenic bacteria are most likely encountered where animal feces, decaying food, or decaying animal matter is located. Mishandling rodent or animal carcasses also brings contact with potentially pathogenic bacteria.

Histoplasmosis risk is greatest where bird or bat feces have accumulated in or on top of soil. *Cryptococcoses* is most likely in accumulations of pigeon feces in attics, false ceilings, and warehouses.

Hantavirus contact is most likely in areas where rodent activity is detected and there is a large amount of droppings and/or the smell of urine. Attics, closets, storerooms, cellars, basement, garages and warehouses must all be viewed for the potential for encountering mice and other rodents. Hantavirus risk is extremely low.

Bee and wasp stings can occur upon accidental stumbling into a nest of these social insects. Spider bites can occur when putting on shoes or clothes in which the spider is hiding or when moving a board, landscape timber or other item under which the spider is hiding.

PROTECTING AGAINST ENVIRONMENTAL PATHOGENS

Appropriate PPE needs to be worn by each person who enters an area where pathogens may be encountered. PPE that may offer appropriate protection include respirator, protective gloves, unvented goggles, Tyvek coveralls, leather boots/rubber overshoes (or rubber boots), disinfectant soap, disinfectant sprays, and insect repellent. Additionally:

- Recognize areas of potential risk, including: numerous rodent droppings; bird droppings on soil, on floors, in attics, etc.; excessively dusty conditions; excess decaying food debris or other decaying organic matter; presence of dead rodents, birds, or other animals present (presence of blow flies and fly pupae); evidence of raccoons, possums, or skunks living in the structure; and older buildings.
- Wear a respirator, eye protection, and protective gloves in suspect environments.
 Persons who have facial hair (i.e. beard) will not achieve a tight enough seal with any respirator.
- Keep all cuts carefully bandaged, especially on hands. Wear gloves.
- Spray rodent droppings, rodent nests, and dead rodents with a disinfectant spray prior to handling or entering a suspect area. Other dead animals must also be treated with disinfectant before handling. Use a pump type sprayer to dispense the product; an aerosol product may disturb small particles and increase exposure.
- Never attempt to sweep up or vacuum animal droppings, as dust will become airborne.
 Spray such areas with disinfectant, let sit for a short period prior to wiping up with rags or paper towels (if they have to be handled at all).
- Remove and dispose of disposable gloves, Tyvek coveralls, and booties immediately
 after exiting the contaminated area. Continue to wear a respirator and gloves if possible
 when removing coveralls as dust on the coveralls could become airborne.

- Immediately after removing contaminated items, place them in a plastic bag, spray additional disinfectant solution in the bag, tightly-seal the bag, and properly dispose of the bag.
- Disinfect nitrile, rubber, or latex gloves in an approved disinfectant solution. Rinse thoroughly.
- While wearing protective gloves, clean the respirator face piece with disinfectant solution and rinse thoroughly. Store the respirator in a sealed Ziploc-type bag.
- When walking or working in areas where ticks could be present (wooded areas, tall
 grass), tuck pant legs into boots or socks and spray pant legs with insect repellant
 (unless taking residue samples). It should be noted that if collecting samples or entering
 an area where samples may be collected, the use of insect repellants may crosscontaminate the sample.
- Avoid entering any area where a dog or wild mammal may be present. Any animal acting strangely must be avoided.

COMMON PATHOGENS

An inspector should be aware of *some* common pathogens and their epidemiology in order to take appropriate precautions during inspections.

Salmonella

- A bacterium.
- Present in the surrounding environment, including the soil. Especially common where decaying food materials are present.
- Causes food poisoning. Sometimes fatal depending on the type and lack of treatment.
- Enters the body by ingestion, usually in infected food or from contact with unwashed hands.

Staphylococcus

- o A bacterium.
- Present in the surrounding environment, including the soil. Especially common where decaying food materials are present.
- Causes infections in cuts and also in eyes. Severe flesh necrosis can occur.
 Fatalities are rare except if the bacteria enter the bloodstream (septicemia).
- Enters the body through breaks in the skin caused by cuts, abrasions, and blisters.

• E. coli

- A bacterium.
- Present in human and animal feces.
- Causes severe food poisoning. A particular strain, not likely to be encountered, can be fatal.
- Enters the body by ingestion of contaminated food or from contact with unwashed hands.

Histoplasma capsulatum

- A fungus.
- Present in accumulated bird, chicken, and bat feces in contact with the soil. The feces enrich the soil allowing the fungus to proliferate.
- Spores become airborne when feces are disturbed.
- Causes respiratory illness (histoplasmosis) and also blindness. Can be fatal, but fatalities are rare.
- o Enters the body by inhalation of fungal spores and through the eyes.

Cryptococcus neoformans

- A pathogenic yeast (fungus).
- Present in accumulated pigeon feces within buildings. Does not need to be in contact with the soil.
- Spores become airborne when feces are disturbed.
- Causes respiratory illness (cryptocaccosis). Can develop into cryptococcal meningitis that takes the form of severe headaches, vomiting, vertigo, and dizziness. Most serious to persons with existing lung disease, diabetes, Hodgekin's lymphoma or leukemia.
- Enters the body by inhalation of fungal spores.

Hantavirus

- Biosafety Level 4 virus. Twelve different Hantaviruses have been discovered to date but only one type is confirmed to cause human disease.
- o Carried by the white footed mouse or deer mouse, *Peromyscus maniculatus*. Has not been found in house mouse populations. Other types of Hantaviruses have been isolated from other types of rodents, including the cotton rat and voles.

- Virus is spread through aerosolized droplets of deer mouse urine and on microscopic particles of dust infected by urine or associated with deer mouse droppings. Handling deer mouse carcasses also poses a risk.
- Causes Hantavirus Pulmonary Syndrome (HPS), which causes a victim's lungs to fill with fluid, sometimes causing cardiac arrest.
- o Deer mice are found most often in areas bordered by woods and fields.

Rabies

- A virus.
- Spread by the bite of an infected animal or by improper handling of infected animal carcasses.
- o In urban areas, skunks, raccoons, coyotes, and dogs are the primary reservoirs.
- Affects the central nervous system. Always fatal unless treated.

• Borrelia burgdorferi (Lyme Disease)

- A bacterium.
- o Carried and spread by various ticks but especially the deer tick, Ixodes dammini.
- The reservoir in the wild is the deer mouse.
- Causes a myriad of symptoms depending on which body system is attacked.
 Attack of the nervous system is the most serious but can cause arthritic-like symptoms. If undiagnosed and untreated for too long, damage to the body may be irreversible.

Insect and arthopod stings

- o Effects due to venom from bees, wasps, scorpions, and some ants.
- General swelling and localized reactions are normal.
- Sensitive individuals can lapse into anaphylactic shock which can be fatal.

Spider bite

- o Effects are due to the venom of black widow spiders and brown recluse spiders.
- Black widow venom affects the nervous system causing most muscle systems in the body to cramp. Rarely fatal except in young children and the elderly.
- Brown recluse venom causes collapse of microscopic blood vessels in area of bite. Lack of blood and nutrients in affected area leads to tissue death and necrosis. Secondary Staphylococcus infections can lead to more serious necrosis and possibly to loss of the affected limb.

- Plastic surgery is sometimes necessary depending on the seriousness and location of the bite.
- Black Widow –



o Brown Recluse -



TRAVEL SAFETY

Inspectors may be required to travel several thousand miles a year in order to cover assigned areas or territories. This may be in an Agency-owned vehicle or in the inspector's own vehicle. Regardless, a few key safety points or checks will prove valuable in preventing or minimizing breakdowns and accidents.

VEHICLE SAFETY

Before starting the vehicle, make a quick check of the vehicle's condition. Pay close attention to the tires. Worn tires, low tire pressure or punctures in tires may cause a blowout while on the road. Agricultural establishments often will have metal parts, screws, nails, or similar items in the driveway areas of the firm or business. As such, it may be wise to make a visual inspection prior to leaving inspected a firm or business.

It is also important how equipment is arranged in the vehicle. An inspector is required to carry a vast amount of equipment and supplies. This equipment needs to be arranged and secured in case of a quick stop or collision. In such a case, an unsecured piece of equipment may act as a projectile inside the car. Therefore, attention must be paid to how equipment is stored and secured. Take time and make sure everything is in proper position to avoid unnecessary risks.

In addition, inspectors may be required to transport hazardous materials or samples as part of their duties. Ensure that samples are stored in a manner that would not create a hazard if broken, spilled, or otherwise released. Also, vapors from these products may be dangerous and must not be stored in the passenger compartment of the vehicle. Hazardous materials must also be properly packaged to prevent breakage and these packages must be secured to prevent them from rolling around.

Vehicle maintenance cannot be overstated. Depending upon EPA and/or GSA guidelines, make sure to routinely check the maintenance of the vehicle. Tires, brakes, fluids, hoses, belts, etc., must all be checked on a regular basis. Inspectors often find themselves in rural or unpopulated areas. While no examination will guarantee unwanted breakdowns, there is a good chance of minimizing them.

Once in the vehicle, always wear a seat belt.

PERSONAL SAFETY

Always carry a first-aid kit complete with bandages, topical antibiotic dressings and antiseptic cleansers. Cuts, scrapes, and bruises are commonplace when working around equipment. Be prepared to treat them rapidly and effectively.

It is advisable to keep current with immunizations. Pay particular attention to tetanus shots and periodical boosters. Discuss with your physician or the Public Health Service physician potential side effects of new medications, such as nausea, drowsiness, or ability to perform your job safely. Read warnings on over-the-counter medication.

Avoid, if at all possible, becoming involved in a confrontational situation. If, however, a situation becomes confrontational, the inspector should exit the inspection site and contact their management and/or the U.S. Marshal Service, police, etc. Obtain a warrant before reentering the site to continue the inspection.

LODGING SAFETY

When arriving at a motel or hotel, try to park in well-lit areas. Be aware of persons in parking garages and lots. When parked, lock the vehicle. It is best not to leave any type of valuables in the vehicle. If valuables must be stored in the vehicle, try to cover or hide them. Depending on weather conditions (heat and cold), and for security and to ensure chain-of-custody, it may be necessary to remove samples from the vehicle and store them in the motel/hotel room or in a secure area.

Be aware of the people in the lobby when checking in. Pay attention to the surroundings.

Once in the room, pay attention to the security mechanisms provided. If dead bolt locks and chains are in place, use them.

Locate the nearest exit in case of fire or an emergency. Usually, evacuation instructions will be posted in the room. If not, make a visual check of how to get out safely.

Use the peep hole in the door to visually identify persons knocking on the door. If the person claims to be a hotel or motel employee, get the person's name and verify via telephone with the front desk before letting the person into the room. If the person is indeed an employee, they will not mind.

Check your room for pests and unsafe conditions. Bedbug infestations in motels and hotels are increasingly common. Check bedding, closets, dresser drawers, etc. for these pests and other pests before completely settling into the room. Any pests should be brought to the attention of the motel/hotel management. For more information on how to identify bedbugs go to: www.epa.gov/pesticides/bedbugs/index.html.

EXHIBIT 2-1: EPA HEALTH AND SAFETY COURSES

EPA's Office of Compliance has several courses and recorded webinars available that specifically address Health and Safety.

- Recorded Webinars:
 - o Health and Safety Overview for Inspectors (OTH 950)
- Web-based Courses:
 - o Health and Safety for Field Activities (OTH 952)
 - o Health and Safety for Laboratory Activities (OTH 955)
 - o Health and Safety for Radiation Safety (OTH 953)

CHAPTER THREE PESTICIDE LAW, POLICY AND COMPLIANCE STRATEGIES

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PESTICIDE LAW, POLICY AND COMPLIANCE STRATEGIES

STATUTORY AUTHORITY FOR PESTICIDE REGULATION

REGULATIONS

The pesticide regulations are codified and found in Title 40 of the Code of Federal Regulations, Protection of Environment, Chapter 1, Environmental Protection Agency, Parts 150 to 189. Specifically:

40 C.F.R. Part 152	Pesticide registration and classification procedures
40 C.F.R. Part 153	Registration policies and interpretations
40 C.F.R. Part 154	Special review procedures
40 C.F.R. Part 155	Registration standards and registration review
40 C.F.R. Part 156	Labeling requirements for pesticides and devices
40 C.F.R. Part 157	Packaging requirements for pesticides and devices
40 C.F.R. Part 158	Data requirements for pesticides
40 C.F.R. Part 159	Statements of policies and interpretations
40 C.F.R. Part 160	Good Laboratory Practice Standards
40 C.F.R. Part 161	Data requirements for registration of anti-microbial pesticides
40 C.F.R. Part 162	State registration of pesticide products

¹ http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/xml/CFR-2011-title40-vol24-chapl-subchapE.xml

40 C.F.R. Part 164	Rules of practices governing hearings under FIFRA arising from refusals to register, cancellations of registrations, chances of classifications, suspensions of registrations and other hearings called pursuant to section 6 of the Act
40 C.F.R. Part 165	Pesticide management and disposal
40 C.F.R. Part 166	Exemption of Federal and State agencies for use of pesticides under emergency conditions
40 C.F.R. Part 167	Registration of pesticide and active ingredient producing establishments, submission of pesticide reports
40 C.F.R. Part 168	Statements of enforcement policies and interpretations
40 C.F.R. Part 169	Books and records of pesticide production and distribution
40 C.F.R. Part 170	Worker protection standard
40 C.F.R. Part 171	Certification of pesticide applicators
40 C.F.R. Part 172	Experimental use permits
40 C.F.R. Part 173	Procedures governing the rescission of state primary enforcement responsibility for pesticide use violations
40 C.F.R. Part 174	Procedures and requirements for plant-incorporated protectants
40 C.F.R. Part 176	Time-limited tolerances for emergency exemptions
40 C.F.R. Part 178	Objections and requests for hearings
40 C.F.R. Part 179	Formal evidentiary public hearing
40 C.F.R. Part 180	Tolerances and exemptions for pesticide chemical residues in food

COMPLIANCE AND ENFORCEMENT POLICIES AND STRATEGIES

FIFRA inspectors may find the following pesticide policies and enforcement documents to be relevant:

- Pesticide Management and Disposal Compliance Strategy.
- Pesticide Container-Containment Inspection Checklist.
- Pesticide Container Inspection Checklist.
- Fumigation Toolbox.
- Worker Protection Standards Guidance.
- Antimicrobial Sampling Guidance.
- Pesticide Registration (PR) Notices.

- Enforcement Response Policy for FIFRA Container/Containment Regulations Appendix H (March 2012).
- <u>FIFRA Enforcement Response Policy</u> (December 2009).
- <u>Enforcement Response Policy for FIFRA Section 7(c)</u> (May 2010).
- Final Interpretive Rule.

PESTICIDE REGISTRATION

FIFRA section 3 states that no person in any state may distribute or sell to any person a pesticide that is not registered, unless exempted by section 3(b). Implementing regulations at 40 C.F.R. Parts 152-167 establish the requirements for product registration. Inspectors who wish to learn more about pesticide registration procedures may consult:

- <u>Pesticide Registration Manual</u>.
- Fact sheets and information about pesticide registration procedures.
- <u>EPA's online registration kit</u> that includes the various forms required for pesticide registration as well as other relevant information.

Pesticides Requiring Registration

A product is required to be registered if any or all the following conditions exist:

- A product meets the definition of a pesticide in section 2(u) of FIFRA and 40 C.F.R. §152.15.
- The product's labeling and other material make pesticidal claims.
- A product is represented in any manner that implies it is being used as a pesticide.
- The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used or is intended to be used for a pesticidal purpose.

Products Not Considered Pesticides

Certain products do not meet these criteria and are not considered to be pesticides (40 C.F.R. §§152.8 and 152.10). These products include:

- Deodorizers, bleaches, and cleaning agents.
- Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly.
- Products intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints for trees.
- Products intended for use only for the control of fungi, bacteria, viruses or other microorganisms in or on living man or animals, and labeled accordingly.

- Products intended for use only for control of internal invertebrate parasites or nematodes in living man or animals, and labeled accordingly.
- Products intended only to aid the growth of desirable plants.

Pesticides Exempt from Registration

Other classes of products are considered to be pesticide products but are exempt from registration (40 C.F.R. §152.25). These products are, however, subject to the misbranding provisions of FIFRA, which require adequate labeling and identification of products to ensure safe shipment and use. Exempt products include:

- Treated articles or substances. An article or substance treated with, or containing, a
 pesticide to protect the article or substance itself (for example, paint treated with a
 pesticide to protect the paint coating, or wood products treated to protect the wood
 against insect or fungus infestation), if the pesticide is registered for such use.
- Pheromones and pheromone traps. Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps, and pheromone traps in which those compounds are the sole active ingredient(s) (40 C.F.R. §152.25(b)).
- Preservatives for biological specimens (40 C.F.R. §152.25(c)).
- Vitamin hormone horticultural products consisting of mixtures of plant hormones, plant nutrients, inoculants or soil amendments that meet all of the criteria in 40 C.F.R. §152.25(d).
- Products consisting of foods and containing no active ingredients, which are used to attract pests.
- Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling and needles that meet all of the criteria in 40 C.F.R. §152.25(f).
- Minimum risk pesticides. Products containing the active ingredients listed in 40 C.F.R. §152.25(g) are exempt from the requirements of FIFRA, alone or in combination with other substances listed, provided that all of the criteria of 40 C.F.R. §152.25 are met.

UNREGISTERED PESTICIDES

FIFRA inspectors may encounter unregistered products that claim to be pesticides (i.e., product advertising or labeling with statements such as "new formula kills bugs on contact") and are sold or distributed in violation of FIFRA. Inspectors that discover unregistered pesticide products should obtain product labels, samples, marketing or advertising materials and any other evidence that indicates the product is pesticidal. The inspector should include these materials and evidence in the inspection report for EPA to determine whether the product is an unregistered pesticide. If inspectors are not sure whether a particular product is a pesticide, they can call EPA during the inspection and collect evidence for subsequent EPA review.

An unregistered pesticide, or a pesticide whose registration has been cancelled or suspended may be distributed, sold or transferred as follows (40 C.F.R. §152.30):

- An unregistered pesticide may be transferred between registered establishments operated by the same producer. The pesticide must be labeled in accordance with <u>40</u> <u>C.F.R. Part 156</u>.
- An unregistered pesticide may be transferred between registered establishments not operated by the same producer if:
 - 1. The transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered,
 - 2. Each active ingredient in the pesticide at the time of transfer is present as a result of incorporation into the pesticide of either a registered product, or a pesticide that is produced by the registrant of the final product, and
 - 3. The product is labeled in accordance with 40 C.F.R. Part 156.
- An unregistered pesticide may be distributed or sold in accordance with the terms of an experimental use permit issued under FIFRA section 5 if the product is labeled in accordance with 40 C.F.R. §172.6. In addition, an unregistered pesticide may be distributed or sold in accordance with the provisions of 40 CFR §172.3 (use of a pesticide for which an experimental use permit is not required) provided the product is labeled in accordance with 40 C.F.R. Part 156.
- An unregistered pesticide may be transferred within the United States solely for export if it meets the following conditions: (1) the product is prepared and packaged according to the specifications of the foreign purchaser and (2) the product is labeled in accordance with 40 C.F.R. Part 156.
- An unregistered pesticide may be distributed or sold in accordance with the terms of an emergency exemption under FIFRA section 18 if the product is labeled in accordance with 40 C.F.R. Part 156.
- An unregistered, suspended or cancelled pesticide may be transferred solely for disposal in accordance with FIFRA section 19 or an applicable Administrator's order. The product must be labeled in accordance with 40 C.F.R. Part 156.
- Existing stocks of a formerly registered pesticide that has had its registration canceled or suspended may be distributed or sold to the extent and in the manner specified in an order issued by the EPA. The inspector should collect production records and sale/distribution records so that EPA can verify that the products were in existence prior to the date of EPA's cancellation order.

SUPPLEMENTAL DISTRIBUTION (40 C.F.R. §152.132)

A registered product can be supplementally distributed (also known as private labels), which allows a distributor to market the product under his/her own brand name. The following conditions must be met:

- The product must have the same composition as the primary registered pesticide and must be produced, labeled and packaged in a registered establishment operated by the same producer (or under contract in accordance with 40 C.F.R. §152.30).
- The product labeling must bear the same claims as the primary product. Specific claims may be deleted if by so doing no other changes are required.
- The distributed product must not be repackaged (must remain in the producer's unopened container). However, distributors can repackage and re-label provided they are a registered pesticide producing establishment and they have a contract with the registrant for repackaging.
- The label must bear the EPA Registration Number of the primary registered product and the distributor's company number must appear as a suffix to the registration number.
 For example, on supplementally distributed products, the EPA Registration Number will appear as:

EPA Reg. # XXXXX-YYY-ZZZZZ

(The first part of the registration number (XXXXX) is the basic registrant's company number, the second part (YYY) is the registrant's product number and the third part (ZZZZZ) is the distributor's company number. Note, the distributor is a supplemental registrant.)

• Distributor products may bear the name and address of the distributor.

The registrant must submit an Application for Supplemental Registration of Distributor (EPA Form 8570-5) to OPP.

SECTION 24(c) REGISTRATIONS (40 C.F.R. §§162.150-162.156)

Under section 24(c), states may register a federally registered product for additional uses if a special local need exists. In addition, 40 C.F.R. §162.152 allows state registration of new formulations under certain circumstances. States must notify EPA in writing within ten working days from the date a state issues, amends or revokes a registration. Notification of state registrations or amendments to registrations include the effective date of the registration or amendment, a confidential statement of the formula of any new product and a copy of the draft labeling reviewed and approved by the state (provided that labeling previously approved by EPA as part of a federal registration does not need to be submitted). The notification of revocation of a registration by a state must indicate the effective date of revocation and state the reasons

for revocation. Within 60 days after the effective date of the registration or amendment, states must submit a copy of the final printed labeling approved by the state.

EPA may request, when appropriate, that a state submit any data used to determine that unreasonable adverse effects will not be caused when it registers any use described in 40 C.F.R. §162. States are required to submit two copies of the requested data within 15 working days of receipt of this request from EPA.

The state may not issue a section 24(c) registration that requires a new food or feed tolerance.

OPP shares section 24(c) registrations with the regional offices. The inspector will have access to this product information.

CHAPTER FOUR FEDERAL, STATE AND TRIBAL COOPERATION

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FEDERAL, STATE AND TRIBAL COOPERATION

BACKGROUND

State and tribal pesticide regulatory agencies throughout the United States work cooperatively with the EPA to enforce federal, state and tribal pesticide statutes. This collective and collaborative enforcement effort exists due to the contributions of highly qualified and trained government officials working at each of these levels of government.

EPA provides funding and guidance to states and tribes to carry out pesticide enforcement activities to protect human health and the environment. The states and tribes, in turn, direct these resources toward efforts to address both federal and state or tribal pesticide management priorities.

Among the primary objectives of this working partnership include:

- Protecting the public and the environment by ensuring pesticide product compliance and proper use.
- Improving coordination of the federal and state or tribal pesticide enforcement program(s).
- Working together to identify challenges nationally and within the states and tribes, resolve cases and deal with the problems.
- Improving targeting of resources by tailoring the program to meet the local needs and concerns of each state or tribe.
- Providing more efficient use of resources through cooperation with state and tribal offices and personnel.

AUTHORITIES

AUTHORITY OF THE STATES

Section 24 of FIFRA authorizes a state to regulate the sale or use of any federally registered pesticide or device in that state, but only if and to the extent the state regulation does not permit any sale or use prohibited by FIFRA. The state may not impose labeling or packaging requirements in addition to or different from those required by FIFRA.

STATE PRIMACY

Sections 26 and 27 of FIFRA set forth the conditions under which states may receive primary enforcement responsibility (primacy) for pesticide use violations and authorizes the Administrator

to override or rescind primacy in certain situations. On January 5, 1983, EPA published a <u>Final</u> <u>Interpretive Rule</u> in the Federal Register to provide operational guidance for FIFRA sections 26 and 27. Procedures governing the rescission of primacy are codified at <u>40 C.F.R. Part 173</u>.

THE ROLE OF TRIBES

Tribes cannot be granted primacy under FIFRA. However, EPA does provide cooperative agreements to tribes who cooperate with EPA for the enforcement of FIFRA and who have developed their own Tribal Codes for pesticide use on tribal lands. See discussion below on cooperative agreements. If a tribal inspector uses tribal credentials for an inspection, enforcement can be pursued by the Tribal Counsel. If EPA credentials are used for an inspection, the inspection file and all information will be forwarded by the tribe to the EPA regional office.

REFERRAL PROCEDURES UNDER FIFRA SECTIONS 26 AND 27

Section 27 of FIFRA requires EPA to refer any information to the states indicating a significant violation of pesticide use laws. In accordance with the Final Interpretive Rule governing FIFRA sections 26 and 27, EPA, in consultation with each state, will identify priority areas, in writing, for formal referral to the state. These priority areas will consist of those pesticide activities in the state that present the greatest potential for harm to health and the environment. The priority areas will be revised on an annual basis based upon the effectiveness of the programs in reduction of the harm associated with pesticide use in the state. This negotiated written agreement between the state and the region will contain the criteria for the selection of significant pesticide use cases.

All pesticide use cases identified as "significant" are referred to the state by EPA in writing and will be formally tracked as set forth in the Final Interpretive Rule. All other use cases will be referred to the state for information purposes and will not be formally tracked. For any "significant" case referred to the state, only state credentials and procedures shall be used and followed. Upon conclusion of a formally referred significant case, the complete original file must be sent to the EPA Regional office.

In determining the adequacy of a state's enforcement response, the following factors are considered:

- (1) Whether the state followed proper sampling and other evidence gathering techniques.
- (2) Whether the state responded expeditiously to the referral.
- (3) Whether all inculpatory or exculpatory events or information have been documented.

If the state's enforcement response is inadequate and the region is unable to persuade the state to correct any deficiencies through communications with the state, the region may pursue its own enforcement response after notifying the state. That notification should summarize the facts relating to the state inspection, discuss the reasons for EPA's determination that the action is inadequate and state that the EPA will initiate its own enforcement action.

The state has 90 days after the notice to correct any deficiencies. If after that time the Administrator determines that the state program remains inadequate, the Administrator may rescind, in whole or in part, the state's primary enforcement responsibility for pesticide use violations.

Neither sections 26 or 27 of FIFRA limits the authority of the Administrator to enforce the Act where the Administrator determines that emergency conditions exist that require immediate action and the state authority is unwilling or unable to respond to the emergency.

COOPERATIVE ENFORCEMENT AGREEMENTS

While sections 26 and 27 of FIFRA allow EPA to give primary enforcement responsibility to states, it does not extend that authority to tribes. However, section 23 of FIFRA authorizes EPA to enter into cooperative agreements with the states, territories and Indian tribes to delegate the authority to cooperate in the enforcement of FIFRA and to assist in the training and certification of pesticide applicators.

EPA and the states and tribes perform different roles in the cooperative enforcement agreement program. Some areas of responsibility are listed below:

Environmental Protection Agency:

- Provides federal funding to assist the states and tribes through cooperative agreements.
- Provides national focus and program oversight.
- Provides national guidance, compliance/enforcement strategies and policies.
- Provides training for state and tribal inspectors and lab personnel.
- Delegates authority to states and tribes and provides federal credentials for state and tribal inspectors to conduct federal inspections where state or tribal authority is lacking.
- Initiates federal civil and criminal enforcement actions for violations of FIFRA that are referred to EPA by the states or tribes.
- Keeps states and tribes informed of relevant information about pesticide compliance/noncompliance and pesticide use/misuse nationwide

States and tribes:

- Assist with funding for the cooperative enforcement agreement program.
- Participate in the development of national guidance, compliance/enforcement strategies and policies.
- Ensure compliance with both federal and state or tribal pesticide laws by conducting an inspection and sampling program.
- Initiate state or tribal enforcement actions for violations of state or tribal laws.

- Refer fully documented cases of violations of FIFRA to EPA for federal civil or criminal enforcement action.
- Document and refer to EPA potential violations of other federal statutes.
- Keep EPA informed of relevant information about pesticide compliance/non-compliance and pesticide use/misuse within the state or tribal lands.

WHEN TO USE FEDERAL CREDENTIALS/FORMS/SOPS

An inspector must **never** use both state or tribal authority and federal authority for the same inspection.

USING STATE/TRIBAL CREDENTIALS, FORMS AND PROCEDURES

A state inspector must always use state authority, state credentials, state forms and state procedures when conducting inspections where the state has primacy. If the inspector initiates an inspection under state/tribal authority but discovers possible federal, rather than state, violations, the state may refer the federal violations to EPA for further investigation and/or enforcement action. Tribes should use their own credentials when they have authority under their laws and codes to conduct the inspection. Similarly, a tribe may refer any suspected federal violations to EPA for further investigation and/or enforcement action.

USING FEDERAL CREDENTIALS/FORMS/SOPS

The state or tribe must use federal credentials/forms/procedures when conducting inspections that they do not have the authority to conduct under their own state laws or tribal codes or in instances where EPA makes a formal referral to the state or tribe to investigate on behalf of the Agency. Tribes should use federal credentials to inspect where the tribe lacks its own authority or where it lacks authority to monitor and enforce Federal-only requirements. Generally, tribal inspectors will be authorized to conduct inspections on EPA's behalf only within the boundaries of the tribe's Indian Country.

Even with EPA credentials, states are not authorized to conduct inspections on tribal lands unless allowed by a written agreement between the tribe and the state.

When states or tribes with cooperative enforcement agreements use federal credentials, federal inspection forms and federal inspection procedures, the inspector must send the original inspection report and files to the applicable EPA office. The state or tribe may retain a copy of the file, to be used if asked to participate in EPA's enforcement actions. It should be noted that federal law, including FOIA and the requirements pertaining to CBI, apply when states or tribes are conducting any inspection using federal credentials (see Chapter 1).

INTERAGENCY REFERRALS

Section 22(b) of FIFRA directs the Administrator to cooperate with other federal and state agencies in carrying out the provisions of the Act. The objective is to improve management controls and response to pesticide-related cases that are referred between:

- EPA and the Food and Drug Administration (FDA).
- EPA and the United States Department of Agriculture (USDA).
- EPA and United States Customs and Border Protection (CBP).
- EPA and other federal and state agencies.

POLICY

The Memorandum of Understanding (MOU) between FDA, USDA, CBP and EPA on Regulatory Activities Concerning Residues of Drugs, Pesticides and Environmental Contamination in Foods and Imported Pesticides and Devices, provides that:

- 1. FDA district offices will notify appropriate EPA regional offices when they encounter, through investigation or sample analysis, pesticide residues on foodstuffs that may be the result of the misuse of pesticides. EPA, in turn, will notify FDA whenever pesticide misuse is found which might result in illegal pesticide residues in food.
- 2. Each agency is to keep the other agency informed of the results of its follow-up and regulatory actions; specifically:
 - a. EPA and USDA concerning residues of pesticides on agricultural commodities including meat and poultry, and
 - b. EPA and CBP on notification of registered/unregistered and illegally imported pesticides and devices.

PROCEDURES

FDA and USDA Referrals to EPA

Field staff of FDA and USDA will refer cases of suspected pesticide misuse to EPA when:

- (1) They are in possession of evidence that clearly demonstrates a pesticide was used on the food, feed, meat or poultry in a manner contrary to its EPA-approved use and labeling.
- (2) FDA or USDA laboratory results show residues of a pesticide for which FDA regulatory action would be initiated against the food, feed, meat or poultry because:
 - The tolerance for the pesticide is exceeded.
 - No tolerance (or exemption from tolerance) has been established or the tolerance has been revoked and the level of residue appears to be due to purposeful use as opposed to environmental or some other unavoidable source of contamination.

- The misuse occurred while the food, feed, meat or poultry was in domestic production, shipment or storage. (Note: Imports found to contain illegal pesticide residues at time of entry are not to be referred to EPA). FDA and USDA retain authority to detain, seize or destroy any illegal or contaminated commodity.
- The person or firm that misused the pesticide is known or suspected.

FDA and USDA also will inform EPA of any other state or local agencies that have been notified.

The EPA response to FDA and USDA illegal residue referrals will normally be a referral to the appropriate state or tribal lead pesticide agency for follow-up. Referrals will be tracked and reported to FDA and USDA in accordance with procedures established by the regions.

CBP Referrals to EPA

CBP will provide notice to EPA whenever pesticides or devices enter the United States. Notification may be by phone or electronic transfer to EPA regional or headquarters offices.

EPA Referrals to FDA and USDA

The USDA enforces pesticide tolerances on agricultural products including meat, poultry and some egg products. The FDA enforces pesticide tolerances for all other food products. EPA inspectors may discover potentially illegal pesticide residues on food or agriculture products during FIFRA inspections. When EPA discovers potentially illegal residues, it must refer the matter to the FDA or USDA so the product can be intercepted and tested as necessary. Examples of situations that might result in illegal pesticide residues include accidental pesticide spills, excessive pesticide use in a crop nearing harvest, fruit or grain fumigation over the prescribed rates, pesticide misuse in a food-processing facility or the misuse of pesticides in and around slaughterhouses.

EPA Referrals to CBP

EPA will notify CBP to detain or stop pesticide or device imports:

- When EPA has information indicating that an illegal pesticide or device may be presented for entry into the United States.
- When EPA has information that a specific importer or broker may be in violation of FIFRA and may be presenting violative pesticides or devices for entry into the United States.

Referrals between EPA and State or Tribal Agencies

EPA may make formal or informal referrals to the states or tribes and vice versa. Referrals should include the following elements whenever possible:

- Cover letter/memo containing:
 - o A description of the situation.
 - o Requests for specific actions from receiving agency.
 - Recommendations for receiving agency.
 - A description of any enforcement actions planned or taken.
 - A list of important deadlines.

• Complete inspection report (including all attachments and documentation).

INTERAGENCY RESPONSE TO EMERGENCY SITUATIONS

If an inspector encounters an emergency situation, such as pesticide misuse or incidents that may result in harmful human exposure, the inspector should immediately inform an EPA manager and/or supervisor in addition to the inspection target. Emergency situations may require immediate interagency action, and EPA must notify the necessary agencies immediately so that the hazardous situation can be corrected promptly.

EXHIBIT 4-1: INTERAGENCY REFERRAL FORMAT

1. REFERRAL TO	2. REFERRED BY
Agency:	Agency:
Location:	Referring Official:
	Phone Number:
3. DATE REFERRAL FORWARDED	4. OTHER AGENCIES NOTIFIED
Date Mailed:	Other Agencies Notified and Contact Person in Each:
Advance Telephone or other electronic Notification Given:	
• □No	
■Yes	
Date:	
To Whom:	
5. DESCRIPTION OF INCID	DENT/REASON FOR REFERRAL
6. FIRM RESPONSIBLE	7. FIRM (INDIVIDUAL) AFFECTED
Name and Location of Firm Responsible for Problem	: Name and Location of Firm or Individual Affected by Problem:
8. DATE REFERRAL RECEIVED	9. REVIEWING OFFICIAL
Date of Telephone Notification:	Name/Title of Person Responsible for Determining Response to Referral:
Date Received by Mail:	Phone Number:
10. FOLLOV	W-UP DECISION
☐ Immediate Follow-up	☐ No Follow-up Reason:
☐ Non-Immediate Follow-up	Date Follow-up Decision Made:
11 ACI	I TION TAKEN
Describe follow-up and results.	TON TAKEN
12. FEEDI	BACK REPORT
Send a copy of completed form to this address at ref	

Referring Agency: Complete Blocks 1-7 and 12.

Receiving Agency: Complete Blocks 8-11, and send to address in Block 12.

CHAPTER FIVE

GAINING ENTRY

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GAINING ENTRY

STATUTORY INSPECTION AUTHORITIES

FIFRA section 9(a), 7 U.S.C. §136g(a), provides the authority for an inspector to enter, at reasonable times, any establishment or other place where pesticides or devices are being held for distribution or sale, for the purpose of inspecting and obtaining samples of any pesticides or devices packaged, labeled and released for shipment, and samples of any containers or labeling for such pesticides or devices.

In addition, section 9(a) provides authority to enter, at reasonable times, any place where there is being held any pesticide, the registration of which has been suspended or canceled for the purpose of determining compliance with section 19 of the Act.

FIFRA section 12(a)(2)(B), 7 U.S.C. §136j(a)(2)(B), makes it unlawful for any person to refuse to allow any entry, inspection or sampling authorized by FIFRA.

FIFRA section 8(a), 7 U.S.C. §136f(a), describes the Administrator's authority to prescribe regulations requiring producers, registrants and applicants for registration to maintain records with respect to their operations and the pesticides and devices produced and to make these records available for inspection and copying.

FIFRA section 8(b), 7 U.S.C. §135f(b), requires producers, registrants, applicants for registration, distributors, carriers, dealers or any other person who distributes or sells any pesticide or device subject to FIFRA, to make available for inspection and copying all records showing the delivery, movement or holding of pesticides or devices, including the quantity, the date of shipment and receipt and the name of the consignor and consignee, upon request.

FIFRA section 12(a)(2)(B), 7 U.S.C. §136j(a)(2)(B), makes it unlawful for any person to refuse to prepare, maintain, or submit any records and reports required by or under sections 5, 6, 7, 8, 11 or 19. In addition, this section makes it unlawful for any person to refuse to allow any entry, inspection, copying of records or sampling authorized by FIFRA.

GAINING ENTRY TO PRIVATE PROPERTY

To conduct an inspection, the inspector must gain entry to private property. The U.S. Constitution, however, guarantees a reasonable expectation of privacy. Therefore, to gain entry to private property to conduct an inspection, EPA needs to obtain a warrant UNLESS the inspector receives the informed consent from the owner of the property or from a person in control of the property in the absence of the owner. If consent is denied and a warrant is necessary, a warrant can be based on "probable cause" or a "neutral administrative inspection

scheme." "Probable cause" is a reasonable suspicion that a violation has occurred. EPA conducts inspections pursuant to a neutral inspection scheme when it is not doing "for cause" inspections. A neutral inspection scheme allows for a non-arbitrary method of identifying inspection targets and the neutral selection of establishments for inspection. A "neutral inspection scheme" as a basis for inspection was developed by the U.S. Supreme Court in *Marshall v. Barlow's Inc.*, 436 U.S. 307 (1978).

To conduct an inspection using FIFRA authority, inspectors must present EPA credentials, use EPA forms and EPA procedures. Inspections conducted under state pesticide statutory authorities must follow state authorities, presenting state credentials and using state form(s), and in accordance with established state inspectional protocols. Showing appropriate credentials and providing an adequate Notice of Inspection serve an important function in gaining entry, under these circumstances, and informs the property owner as to the purpose and authority for the inspection.

Unless it is to the advantage of EPA, inspection targets are not notified of a pending FIFRA inspection. It is Agency policy that inspections conducted under FIFRA are unannounced inspections. EPA conducts unannounced inspections, with no prior contact with the establishment, company or any individual prior to the arrival of the inspector at the location.

EXCEPTIONS TO THE WARRANT REQUIREMENT

CONSENT

An inspector can enter private property to conduct inspections by obtaining valid consent. For the consent to be valid, it must be freely and voluntarily given and not given because of duress, misrepresentation or coercion (either expressed or implied). While the law does not require that a subject be advised of his/her right to refuse to give consent, if the inspector believes such knowledge may be helpful in validating the consent and in overcoming any taint of implied coercion, he/she may inform the consenting party of his/her right to refuse voluntary entry. In addition, the person granting the consent must be authorized to do so. The inspector must be certain that the consenting party is the owner or has the premises under his/her control and has at least the apparent authority to give consent.

If a FIFRA inspector plans to make multiple visits to the same location for inspection or sampling purposes, the inspector must gain consent for each entry unless the inspector obtained prior consent to cover all necessary entries. Accordingly, at the onset of an inspection, the inspector must seek to gain consent sufficient to authorize all entry and sampling activities he/she contemplates will be necessary to complete the inspection.

OPEN FIELDS

"Open fields" are areas where a landowner normally does not have a reasonable expectation of privacy. While the preferred procedure is to obtain valid consent prior to entry, the courts have established that inspectors may enter open, private lands in the official performance of their duties. The inspector may technically be a trespasser on private property, but this fact will not prevent the lawful use of any evidence obtained in these open fields. This inspection authority does not extend to a residence or the area immediately surrounding a residence.

EXIGENT CIRCUMSTANCES

The law does not require a public official to stand by helplessly while a serious offense endangering human health or the public safety is occurring on private property. If there is insufficient time to procure a warrant before serious harm will occur and if consent to enter cannot be readily obtained, an inspector may enter the property to assist in preventing imminent harm to human life. Because of the heavy burden imposed on the Agency to show that its entry without authority was justified, this doctrine shall be used only in rare and emergency circumstances.

PLAIN VIEW

There is no reasonable expectation of privacy concerning things in "plain view." The plain view doctrine is an acknowledgment by the courts that an inspector lawfully engaged in the course of his/her duties is not required to wear blinders or close his/her eyes to whatever is occurring around him/her. This principle applies regardless of the nature of the inspection (use, producer, marketplace, etc.). The following elements are required for a plain view observation:

- **Lawfully present**—The inspector must be justified in being where he/she is at the time the plain view observation is made. Lawful presence may be gained through such avenues as statutory authority, a valid search warrant, consent or "open fields."
- Inadvertent discovery—The inspector must discover the evidentiary items accidentally. The plain view doctrine will not apply if the inspector has probable cause to believe that an item is on certain premises and goes on those premises with the intention of searching for that item; such a discovery is not inadvertent.
- Apparently incriminating nature—The inspector must have reasonable grounds to believe immediately, without further investigation, that the item in plain view constitutes evidence of a violation of the law.

MAKING SURE CONSENT IS INFORMED

Both sections 8 and 9 of FIFRA require that the inspector present to the owner, operator or agent in charge, appropriate credentials and a written statement (Notice of Inspection) as to the reason for the inspection and a statement as to whether the inspector suspects a FIFRA violation. If no violation is suspected, the inspector should mark that the inspection is a "neutral inspection scheme" on the Notice of Inspection form. However, if the inspector suspects a violation, the inspector must mark that the inspection is "for cause" and clearly state the suspected violation (ie. suspected unregistered pesticides in violation of FIFRA) on the Notice of Inspection form. The inspector must fill out the Notice of Inspection form properly and completely. If the inspector is unsure whether the inspection is "for cause" or a "neutral inspection scheme" the inspector should contact his or her supervisor before attempting to gain entry.

Upon arrival at the establishment, the inspector must:

- 1. Identify and introduce himself/herself to the owner, operator, or agent in charge of the establishment (responsible official of the facility), in a professional manner.
- 2. Present EPA credentials. <u>Do not relinquish possession of the credential and do not allow anyone to make copies of the credential.</u> As noted above, for FIFRA inspections, the inspector must present only EPA credentials. Do not present both EPA and state credentials during entry.
- 3. Request to discuss the purpose of the inspection with the owner, operator or agent in charge and any other responsible official(s) of the facility.
- 4. Issue the owner, operator, or agent in charge a completed Notice of Inspection (EPA Form 3540-2) (Exhibit 1-1), which contains the reason for the inspection, whether the inspection is "neutral scheme inspection" or "for cause" (including any suspected violations) and signed by the inspector and by the owner/operator.

These entry procedures are critical to ensure that an inspection is conducted legally, with the informed consent of the responsible official of the establishment and that any evidence gathered during the inspection can be used in an enforcement proceeding.

WHAT TO DO IF CONSENT TO INSPECT IS DENIED

The inspector must explain the authority to conduct inspections under sections 8 and 9 of FIFRA and that not permitting the inspection would constitute a violation of section 12(a)(2)(B)(iii). If consent to conduct and complete the inspection is still denied, the inspector must leave the facility and immediately call his/her supervisor and provide information on the denial of entry. The supervisor and/or an EPA attorney may negotiate entry or EPA may seek a warrant to continue the inspection.

WARRANT AUTHORITY

If consent is denied, a warrant can be sought based on "probable cause" or a "neutral administrative inspection scheme". "Probable cause" is a reasonable suspicion that a violation has occurred. EPA conducts inspections pursuant to a neutral inspection scheme when it is not doing "for cause" inspections. A neutral inspection scheme allows for a non-arbitrary method of identifying inspection targets and the neutral selection of establishments for inspection. See, "The Conduct of Inspections after the Barlow's Decision" (GM-5) cited at the beginning of this Chapter. Under FIFRA section 9(b), officers or employees, duly designated by the Administrator, may obtain and execute warrants authorizing the following:

- Entry for the purposes of sections 8 and 9.
- Inspection and reproduction of all records showing the quantity, date of shipment, and names of the consignor and consignee of any pesticide or device found in violation of FIFRA at any establishment and, in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement or holding of the pesticide or device.
- Seizure of any pesticide or device that is in violation of FIFRA.

To support the request for a warrant, the inspector must prepare detailed notes giving the name of the person approached, his/her title, time of denial, reason for denial (if given) and reason for inspection (i.e., "probable cause" or "neutral inspection scheme"). This information is essential to ensuring a warrant is obtained.

Note that refusal of entry is not necessarily a prerequisite to obtaining a warrant. EPA may obtain a pre-inspection warrant where the company has a history of prior refusal, or the distance to a U.S. attorney or a magistrate is so considerable that excessive travel time would be required if entry were denied.

PROCEDURES

OBTAINING THE WARRANT

The inspector plays a significant role in seeking a warrant. His/her knowledge and experience relating to the denial of entry are crucial to the drafting of warrant documents. The inspector is responsible for: (1) obtaining information that specifically describes the premises to be searched; (2) providing specific information with regard to the reason(s) for the inspection, including the items to be inspected; and (3) helping to determine which laws apply or may have been violated.

Drafting warrant documents is a particularly important area where attorneys and inspectors must work as a team.

CONTACTING THE U.S. ATTORNEY

To obtain a search warrant, EPA must contact the U.S. Attorney's Office in the district in which the property is located and assist the assigned Assistant U.S. Attorney in preparing the warrant and any necessary affidavits.

REQUIREMENTS FOR OBTAINING A WARRANT

When seeking a warrant, three documents must be prepared: (1) an application for a warrant; (2) one or more affidavits in support of the warrant; and (3) the warrant itself. Each document must contain a caption with the district court of jurisdiction, the title of the action, and the title of the particular document. Exhibit 2-1 is an example of an affidavit to support an application for a warrant. Exhibit 2-2 is an example of a warrant that may be prepared for the magistrate's signature.

The application for a warrant must identify the statute (FIFRA) and regulations under which the Agency is seeking the warrant and identify clearly the site or establishment to be inspected (including, if possible, the owner and/or operator of the site). The U.S. Attorney or Assistant U.S. Attorney must sign the application.

The affidavits in support of the warrant application are crucial. Each affidavit must consist of consecutively numbered paragraphs describing all of the facts that support the issuance of the warrant (probable cause). If there is no probable cause, the warrant must recite or incorporate by reference the neutral administrative scheme that is the basis for inspecting the particular establishment. Someone with personal knowledge of all the facts stated must sign each affidavit, although that person can rely upon "hearsay" or secondhand knowledge - this person would most likely be the inspector who has been denied entry. Note that an affidavit is a sworn statement that must either be notarized or personally sworn to before the magistrate.

The warrant itself is a direction to an appropriate official (an EPA inspector, law enforcement personnel or other federal officer) to enter a specifically described location and perform specifically described inspection functions. Because the inspection is limited by the terms of the warrant, it is important to specify to the broadest extent possible the areas that are intended to be inspected, any records to be inspected, any sample to be taken, any articles to be seized, etc. Note, however, that a vague or overly broad warrant will probably not be signed by the magistrate and may prove susceptible to constitutional challenge.

The warrant must be ready for the magistrate's signature at the time of submission. Once the magistrate signs the draft warrant, it is an enforceable document.

Either following the magistrate's signature or on a separate page, the draft warrant must contain a "return," which is used to report that the warrant was executed. The return is to be signed and dated by the inspector after completing the inspection (see "Returning the Warrant" below).

EXECUTING THE WARRANT

Once a judge or magistrate signs the warrant, the inspector may execute the warrant. Warrants are executed only by a physical entry onto the premises and must be executed without undue delay. The warrant will usually direct that it be executed during daylight hours and specify the date by which it must be executed. It is customary to show the property owner a copy of the warrant or provide a copy. If more than one person will be conducting the inspection, it is important that the inspection team members determine each member's role (i.e., who is going to do what and when) before going to the facility.

DENIAL OF ENTRY

Where there is high probability that EPA will be refused entry, even with a warrant, or there exists a likelihood of threats of violence, the inspector must be accompanied by a U. S. Marshal, county sheriff, state or local police officer when executing the warrant. For reasons of personal safety, the inspector must not attempt forcible entry of the facility at his/her own initiative.

If the facility representative refuses entry to an inspector holding a warrant but not accompanied by a law enforcement officer, the inspector must leave and so inform the Assistant U. S. Attorney and the designated EPA attorney. They will take appropriate action, such as: (1) sending the inspector back to the facility, accompanied by law enforcement personnel or (2) seeking a citation for contempt.

Where law enforcement personnel accompany the inspector, the law enforcement officer will execute the warrant. If a refusal or threat to refuse occurs, the inspector must abide by the law enforcement officer's decision whether to leave, seek forcible entry or take other action.

INSPECTING WITH A WARRANT

Except as described below, the inspector must conduct the inspection strictly in accordance with the warrant. If the warrant authorizes sampling, the inspector must be sure to follow all procedures carefully, including the presentation of receipts for all samples taken (see Chapter 17 for product sampling procedures). If the warrant authorizes EPA to take records or other property, the inspector must provide a receipt for the property taken and maintain an inventory. The judge or magistrate will examine the inventory as part of the warrant return to ensure that the inspector did not exceed the warrant's authority and will become an exhibit to the original warrant when returned to the court.

Inspectors must keep the following points in mind when conducting an inspection pursuant to a warrant:

• Inspectors should only collect evidence within the scope of the warrant.

- Be aware of other possible evidence of wrongdoing. Such evidence generally is obtainable as long as the inspector has the lawful authority to be where he/she is and the evidence is in "plain view" (as described in this Chapter).
- The warrant will specify whether the inspector needs to split samples and how to handle certain documents on site (i.e., whether documents may be removed or copied and removed). If, for some reason, document removal is not possible or authorized in the warrant, arrange for the documents to be copied, scanned or photographed on site. If the inspector anticipates a large number of records, EPA recommends the use of a portable scanner or laptop, or, if not available, the inspector can dictate the contents of the documents into a recording device.
- As with all inspections, interview as many individuals as possible. There are no restrictions on asking questions, although there is no obligation for the facility's representatives or employees to respond.
- If the inspector believes that the facility may have intentionally destroyed records, the inspector should make observational notes in his/her field notebook and inspection report and contact his/her supervisor as soon as possible. EPA's criminal enforcement division may need to be notified if intentional record destruction is observed.

RETURNING THE WARRANT

A warrant is "returned" when EPA submits a written report to the court describing when and where the warrant was executed, who executed the warrant, an inventory of the records or samples collected and, if a copy of the warrant was given to someone, the return must list that person's name and address. The inspector must work as a team with the EPA attorney to provide the information necessary to return the warrant within the time restriction required by the court. Failure to return the warrant in a timely manner could result in contempt action against the executing officials. The person who executes the warrant (i.e., the person who performs the inspection) must sign the return form and give it and the warrant to the U.S. Attorney, who will formally file the documents with the court.

CHALLENGES TO THE WARRANT

The possibility always exists that a facility representative will challenge a warrant and the evidence obtained. The warrant and all evidence gathered pursuant to it, or portions of evidence obtained in an otherwise valid warrant, can be overturned by the court. Some of the typical bases for challenges to a warrant or evidence (whether or not they are successful) include the following:

- Insufficient cause for issuance of the warrant.
- Insufficient statement or affidavit supporting the warrant.

- Inaccurate information in the supporting statement or affidavit.
- Insufficient description of the premises or items to be seized.
- Searches beyond the scope of the warrant.
- Failure to follow appropriate procedures for serving or returning the warrant.

To avoid challenges relating to EPA's authority under a warrant, all FIFRA inspectors should follow the procedures provided above for obtaining, executing, and returning a warrant.

EXHIBIT 5-1: MODEL WARRANT

United States District Court

		For the	District of		
(Bri	In the Matter of the Search of: (Briefly describe the property to be searched or identify the business by name and address) Docket No. Case No.				
	AFF	FIDAVIT IN SUPF	PORT OF APPLICATION FOR A WARRANT		
de	(your no		, being duly sworn upon his oath, according to law,	,	
1.	I. I am duly authorized(title)_ of the(division), United States Environmental Protection Agency, Region I hereby apply for a warrant pursuant to Section 9 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. Section 136 et seq., for the inspection and/or sampling of the items named below in the possession, custody or control of the (name of company or owner).				
2.		-	ection 9 of the Federal Insecticide, Fungicide, and 7 U.S.C. Section 136g), which provides:		
	to an o the pr design	officer of court of o	of enforcing the provisions of this Act and upon a sho competent jurisdiction that there is reason to believe It have been violated, officers or employees duly nistrator are empowered to obtain and to execute	_	
	"(1)	entry for the purp	rpose of this section;		
	"(2)	shipment, and the device found in the registered (in the and in the event containing such in	eproduction of all records showing the quantity, date ne name of consignor and consignee of any pesticide of the establishment which is adulterated, misbranded, be case of a pesticide) or otherwise in violation of this of the inability of any person to produce records information, all other records and information relating overwent, or holding of the pesticide or device; and	or not Act	

- 3. (Name of establishment, person, or place) is a (describe its business) that the undersigned compliance officer of the United States Environmental Protection Agency has reason to believe is in violation of the Federal Insecticide, Fungicide and Rodenticide Act, as amended. This belief is based upon the following facts and information: (summarize the reasons why a violation is suspected and the facts justifying the suspicions).
- 4. The <u>(inspection, reproduction of records, sampling, issuance of the stop sale, use or removal order)</u> will be carried out with reasonable promptness, and a copy of the results of analyses performed on any samples or material collected will be furnished to the owner or operator of the subject establishment or property.
- 5. The compliance officer may be accompanied by one or more other compliance officers of the United States Environmental Protection Agency.
- 6. The undersigned compliance officer requests immediate entry to (Name of establishment or place) to perform the inspection, reproduction of records, sampling, or the issuance of a stop sale, use or removal order [optional, if necessary].
- 7. A return will be made to the court at the completion of the inspection, reproduction of records, sampling or issuance of a stop sale, use or removal order.
- 8. The authority of the issuance of the inspection warrant is Section 9 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and *Camara v. Municipal Court of the City and County of San Francisco*, 387 U.S. 523 (1967), *See v. City of Seattle*, 387 U.S. 541 (1967), and *Marshall v. Barlow's Inc.*, 436 U.S. 307 (1978).

	Applicant's signature
	Printed name and title
Sworn before and signed in the presence of	f
	Notary public's signature
	Printed name
My Commission expires on	

EXHIBIT 5-2: MODEL WARRANT

	cates District Court District of
In the Matter of the Search of: (Briefly describe the property to be searched or identify the business by name and address)	Docket No. Case No.
Sale, Use or Removal Order of F	Pesticides or Devices Pursuant to the Federal atticide Act, as amended, (7 U.S.C. Section 136).
To <u>(Name)</u> , <u>(Title)</u> , <u>(Division</u> any other duly authorized enforcement o	, Environmental Protection Agency, Region, and officer of said division:
containers found in the establishment de records showing quantity, date of shipme pesticide or device found in said establish in the case of a pesticide or otherwise in Rodenticide Act, as amended, or should savailable records and information relatin pesticide or device which is in violation of	sed pesticides or devices, as well as labeling and escribed below; and for inspection and reproduction of ent, and the name of consignor and consignee of any hment which is adulterated, misbranded, not registered violation of the Federal Insecticide, Fungicide, and such records not be available for inspection, all other ag to such delivery, movement, or holding of any of the said Act; for the issuance or surveillance of any esticide or device which is in violation of the said Act; all peed as:
	Name of establishment or place
	Address
-or-	City, State and Zip Code
	able cause shown, by (Name of Officer), for inspection of the said Act, at the place described as:
	Name of establishment or place
	Address
	

Pursuant to the Federal Insecticide, Fungicide, a regulations promulgated thereunder, and the d	lecisions of Camara v. Municipal Court of the City 7), See v. City of Seattle, 387 U.S. 541 (1967), and ou are authorized to enter (immediately) the swarrant and therein carry out the inspections,
Date and time issued:	Signature of Magistrate
Return	of Service
I hereby certify that a copy of the within warrar (facility owner of agent) on (date) at (location of establi	nt was served by presenting a copy of the same to ishment or place).
Signature of person making service	

Return

Inspection of the establishment described in this warrant was completed on <code>(date)</code>.

Signature of person conducting inspection

Printed name and title

Printed name and title

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CHAPTER SIX PESTICIDE PRODUCT SAMPLING

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PESTICIDE PRODUCT SAMPLING

STATUTORY AUTHORITY

FIFRA section 9(a) authorizes any officer or employee duly designated by the Administrator to enter, at a reasonable time, any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices packaged, labeled and released for shipment and samples of any containers or labeling for such pesticides or devices. This includes the sampling of pesticides and devices that have been produced by the establishment within the past two years and exist elsewhere in the channels of trade.

FIFRA section 9 requires the inspector to offer the establishment representative duplicate samples of physical samples collected during the inspection.

FIFRA section 12(a)(2)(B) makes it unlawful for any person to refuse to allow a "duly designated agent of the EPA Administrator" to take a sample of any pesticide pursuant to FIFRA section 9.

OBJECTIVES

An official sample of a pesticide formulation or device is necessary for use as evidence in many of the enforcement actions taken resulting from a producer, marketplace or dealer inspection. A sample must be suitable to support an allegation that a violation has occurred. Therefore, the sample must conform to the rules regarding admissibility of evidence; specifically, the inspector must establish the chain of custody for the sample(s), where the sample has been and how it was treated once it was collected. A properly collected, prepared and documented sample includes the following:

- A sufficient portion of a batch of a pesticide for laboratory analysis.
- Photographs and copies of records, data or correspondence.
- Labeling and/or literature, or copies of these items, pertaining to the sampled product and/or batch.
- Signed statements from persons who may potentially serve as witnesses.
- Properly filled out chain-of-custody forms

POLICY

Use the procedures outlined in this chapter to collect and prepare samples. The inspector should fully document any deviations from these procedures in his or her field notebook.

Deviations from the procedures in this manual may be very important to the laboratory when analyzing the samples.

Promptly deliver or forward samples and records to the laboratory. Do not hold pesticide formulation samples for more than five working days from the time of collection to the time of shipment to the laboratory.

There are four main potential sources of pesticide product samples: (1) inspections of pesticide producing and device producing establishments (see Chapter 9); (2) marketplace inspections (see Chapter 9); (3) use inspections (see Chapter 8) and (4) import inspections (see Chapter 12). Obtain lists from your EPA regional office of pesticides or devices produced at various establishments. Unregistered pesticides, investigational samples or pesticides or devices that are not available at a producer's establishment may be available for sampling at a marketplace, such as wholesale and retail establishments, farm dealerships, seed, feed and fertilizer outlets and many home improvement stores.

TYPES OF SAMPLES

Official samples may be used as part of legal or regulatory actions. There are four types of official pesticide product samples - physical, induced, documentary and import.

- Physical samples are actual samples of the pesticide formulation or device. The physical sample may include the original labeled packaging, copies of or photographs of the label and all other labeling associated with the pesticide or device. Collect copies of any records showing the distribution or sale of the physical sample for documentary purposes. Shipping records, bills of lading, waybills, etc., are important because they can substantiate the distribution or sale of the pesticide product or device and are vital to all enforcement cases. A sample usually consists of the entire container of the pesticide or device. When large containers are involved or when small amounts of a pesticide are necessary for analyses, the inspector may choose to subsample the pesticide. This type of sample consists of a portion of the pesticide removed from the original container and placed in a sample container and identified properly. In addition, the label and any additional labeling and/or collateral literature and/or photographs must be documented and identified with the same number as the subsample container. The official sample consists of the physical subsample and the label/labeling and is counted as one sample. If a subsample is collected, the original container that the sample was collected from should be properly re-sealed and identified (i.e., "4 oz. removed on 01/01/2012 by EPA for sampling purpose," inspector's initials).
- Induced samples (IND) of pesticides or devices are physical samples that are obtained by mail, telephone, or the internet. Complete documentation is necessary, including the original advertisement. A webpage printout may be advertising of the pesticide product, but consult your supervisor before collecting this evidence

- Documentary samples (DOC) are official samples collected in lieu of or in addition to taking physical samples. Documentary samples may suffice when the chemistry of a pesticide is not suspect. Inspectors have some flexibility when collecting documentary samples, but should strive to collect the best evidence. In order of preference, documentary samples may consist of:
 - Photographs of the entire label of the actual container observed by the inspector at the time of inspection. Photograph all sides, including the top and bottom, and photograph the entire product as observed in its retail or warehouse location.
 - o For products that may have already been produced and are not on hand, authenticate bin labels or specimen labels by having the owner/operator identify them as identical to the labels on product already sold/distributed and covered by invoices and shipping records obtained during the inspection. Further, establish authentication by obtaining a written notation on the reverse side of the label/labeling, as well as a written statement by the owner/operator, that labels obtained during the inspection are identical to the labels on the products sold/distributed.
 - O Specimen labels or other labels obtained by the inspector from sources other than at the establishment or place where the pesticide was observed. The more removed a specimen or other label is from the actual label observed, the greater the effort must be to authenticate the label. These labels must be authenticated by the agent-in-charge, suspect or witness in an official statement on the Receipt for Samples and/or Statement Forms, as identical to the original label observed by the inspector.
- Import samples (IMP) are physical or documentary samples of pesticide formulations or devices imported into the United States from foreign countries. Documentation for imported shipments should include U.S. Customs and Border Protection (CBP) entry papers, foreign invoices, shippers' bills of lading, and records showing movement from the port of entry. See Chapter 12, "Pesticide/Device Import and Export Inspections."

SAMPLE PROCEDURES

Inspectors should ensure that sufficient sampling equipment is on hand prior to conducting the inspection. For a listing of suggested equipment, see Chapter 7, "Residue and Environmental Sampling." Immediately following the collection of a sample, the sample should be: (1) officially sealed; (2) labeled; and (3) documented in inspection notes and inspection forms. Collect official pesticide formulation and/or documentary samples from material that is packaged, labeled and deemed released for shipment by the manufacturer or, in the case of producing establishments, has been introduced into the channels of trade in the past two years. The term "packaged, labeled and released for shipment" refers to the point in the production and marketing of a pesticide/device where (1) the product has been produced and (2) has been

introduced into the channels of trade or it is the intent of the producer that such product be introduced into the channels of trade.

At the producer establishment, document intent to introduce the product into the channels of trade by (1) the producer's assertion that the material being sampled is representative of what is actually sold in the marketplace or (2) storage of the product in a loading dock, warehouse or other area where finished goods are held before sale or distribution.

If an inspector can determine that a product is at a distributor or in a wholesale or retail marketplace, that product has been "released for shipment" by the producing establishment and therefore subject to inspection and sampling.

NUMBERING OF SAMPLES (WHETHER PHYSICAL OR DOCUMENTARY)

Every sample requires an identifying number. An example of a sample number consists of: (1) the date (mmddyy); (2) the inspector's credential number (3) an inspection sample sequence number including subsample numbering (A, B, C, or 001, 002, 003); and (4) the inspector's initials.

For example, 01/09/2012-17942-123-001-MP

- 01/09/2012 = date
- 17942 = inspector credential number
- 123 = inspection sequence number
- 001 = sample or subsample number
- MP = inspector initials

DUPLICATE SAMPLES

The inspector should inquire whether the facility would like duplicate samples. If the inspected facility requests duplicate samples, they should be collected, identified, labeled and officially sealed in the same manner as the inspector's official samples. In the case of a larger sized unit, EPA defines a duplicate sample as an equal amount of the product taken in the same manner from the same container. In the case of small-sized units, a duplicate sample is the same number of units taken from the same shipping containers and bearing the same batch or code numbers, if coded.

Small-sized units should not be subdivided for the following reasons: (1) the integrity of the sample is easier to maintain and defend; (2) contamination during sampling is minimized; (3) the possibility of exposure to the inspector and personnel of the firm is diminished; and (4) the laboratory can conduct a net content check on the unit collected, if necessary.

SMALL-SIZED UNITS

Small-sized units are units intended for retail distribution, containing liquids of one gallon or less or solids weighing 20 pounds or less. Take samples from original, previously unopened shipping cases. If more than one batch or lot number is present, take samples from the predominant code or batch. If it is necessary to sample more than one batch or lot, write all lot and batch numbers on the Receipt for Samples to identify the lots or batches. If the labels are not identical, sample all sizes and submit different sizes under separate sample numbers. In addition, record the number of cases of each size. When only a case code is evident, identify the case code. If different sized containers are present and the labels are identical, except for net contents, sample only one size and record the number of cases of each size in the inspection report. Describe all non-sampled lot numbers in the inspection report.

Table 6-1 provides guidance on the number of units that should be collected. However, the inspector may need to consult with the laboratory to determine the amount of pesticide required for analysis.

TABLE 6-1 - SAMPLE SIZES TO COLLECT FOR PESTICIDE PRODUCTS

Product Type	Quantity to Collect	
Small-Size Units (liquids and solids)		
Active Ingredients more than 1%	Collect enough units to total at least 10 oz.	
Active Ingredients less than 1%	Collect enough units to total at least 10 oz.	
Pressurized containers	Collect at least three units	
Larger Size Units (Liquids and Solids)		
Active ingredients less than 10%	Collect at least 10 oz. from each of two containers*	
Active ingredients more than 10%	Collect at least 10 oz. from each of two containers*	
Tank Mixes	Collect at least one 10 oz. sample in addition to a 10 oz. sample of the formulation (refrigerate immediately)	

^{*} Sample each container in duplicate if any non-uniformity is evident (i.e., layering, sediment, gross particle-size differences or color non-uniformity.)

^{*} For antimicrobial pesticides, please contact the laboratory for volumes necessary for testing.

LARGER-SIZED UNITS

Larger-sized units (also known as "bulk" units) are those units that contain more than one gallon of liquid or weigh more than 20 pounds of solid material and are for commercial use. Because of the size of these units, inspectors should take a sample of contents of the unit. Depending on the size of the bulk unit, the inspector can take a sample of liquid material by pouring it into a sample container or by withdrawing a sample from the exit valve or other existing opening in the bulk unit. When taking a sample from an exit valve, the inspector may need to let the product flow for a short time before taking the sample. When sampling granular or powder product from bulk units, the inspector may draw the sample by using an available pull-out sleeve at the top of the bag or, where there is no existing opening in the bag, use a sharp object (i.e., knife) to create an opening. When creating an opening, the inspector should be cautious not to make a hole larger than necessary to accommodate the sampling equipment.

Special situations may warrant deviations from these guidelines. If so, the inspector should take the entire large-size unit as the sample and submit it to the laboratory.

DRY MATERIAL

A previously unused, disposable plastic tube available from golf equipment suppliers or home supply stores or a clean grain trier should be used for each batch or lot sampled to avoid any possibility of contamination. Clean glass and metal containers and sampling equipment with a proper solvent (hexane, alcohol, etc.) and air-dry prior to placing the sample into the container.

Clean the tube or trier with a proper solvent and insert it diagonally into the bag through the seam or the "dog ear" to obtain a representative sample of the material from different sections of the bag. Use properly cleaned glass or metal (paint type) containers to contain the sample. Use either a non-stick or polyethylene-lined lid in conjunction with the glass containers for formulation samples. Properly dispose of the tube and other contaminated sampling material. Thoroughly clean the trier with soap and water or solvent and dry before each use or reuse.

See Table 6-1 for recommended sample sizes to collect; consult with the laboratory if you are unsure.

LIQUID MATERIAL

A previously unused, disposable plastic tube, clean glass trier or siphon should be used for each batch or lot sampled to avoid any possibility of contamination.

If the label directions so state, thoroughly agitate the material by rolling and shaking the can, barrel, or drum before sampling. Use glass bottles as sample containers. Either non-stick or polyethylene-lined lids are satisfactory for liquid formulation samples. Do not use rubber or paper-lined lids. Properly dispose of the tubing and other contaminated sampling material.

Consult with your sample analysis laboratory if you are unsure of the amount of product to sample.

A vaccutaner with siphon tube, which has a vacuum in the tube, usually used for blood sampling, can be used in some cases to sample liquid material in large containers. It is relatively easy to use and does not have a large amount of waste to be disposed of, other than the tube and sample needle that is used to puncture the end of the vaccutaner. These devices may be purchased from hospital supply stores and are an inexpensive method of sample collection. Decreased exposure to the inspector from the pesticide itself may be an additional advantage to using this type of sampling container.

GAS OR FUMIGANTS

The inspector should NEVER attempt to take a physical sample of a gas or fumigant product. Instead of a physical sample, the inspector should conduct an inspection of the container and obtain a photograph of the container and the label. If efficacy or formulation data is required for a gas or fumigant product, request that information during the inspection or through an information request letter.

LABELS

A duplicate label, copy or photograph of the label must accompany each physical sample. **Do not remove the container labeling**, because this will cause the pesticide to be misbranded. Bin labels may be used for this purpose. The inspector must make a word-for-word comparison of this label with the labeling on the container sampled to ensure that they are identical. If bin labels are not available, fully legible photographs of all portions of the label are necessary. Another photograph of the entire container, showing the position of the label on the container, should also be obtained. Instant processing, 35mm, or digital cameras may provide the word-for-word substitute for a label, if the camera can zoom in on the label language.

An inspector should be careful to view the digital photo, if possible, to see if the image is sharp enough to obtain the word-for-word comparison of specimen and actual product labeling.

SAMPLES VIA INTERNET PURCHASE

An inspector may find potentially violative pesticides or devices online, through web searches and/or tips and complaints. To sample a product from the internet, the inspector may purchase the product and have it delivered to him/her. When collecting an internet sample, the following protocol may be helpful to ensure sample integrity and provide adequate documentation of the sampling process used:

Use an EPA Purchase Card or other secure means of purchasing the product.

- Plan for the delivery point (NOT the EPA office building or address site); this could be a mail box, post office box location or other established location where U.S. Mail, or commercial deliveries can be made.
- Document sample integrity and establish chain-of-custody by documenting in the case file:
 - o The product purchase order and record of payment;
 - The receipt of the product at the specified delivery location or the tracking number and record of delivery by U.S. Mail or commercial carrier;
 - The inspector's observations of the package and photos of all sides of the shipping container prior to opening;
 - Photos of the open package to document the package, packing material, container etc.; and
 - Photos of the actual product ordered (including the full label and container) and any labeling that accompanied the product.
- As with any sample obtained, identify an internet sample using the sample identification protocol described in this Chapter. Chain of Custody begins after the integrity of the sample (official identification and sealing) has been established by EPA.
- If sending the product for testing and analysis, determine if chemistry and/or efficacy testing/analysis are necessary. Then ship the sample to the EPA laboratory for analysis and include the Chain-of-Custody Record Form (EPA Form 3540- 41, see Exhibit 1-1). Ship the sample following DOT and/or commercial carrier shipping procedures for pesticides and keep all documents relating to the chain of custody in the case file.

AFTER SAMPLING

RESTORING LOT TO ORDER

The inspector should attempt to restore a sampled lot on the premises to an orderly condition. Clean up spillage. Close containers. Return hand trucks, tools, rags, glue pots and other supplies or equipment to their proper pre-sampling position. Some facilities will restore lots to order after inspectors sample and may instruct an inspector to allow them to restore the area to its pre-sampling condition.

PREPARING THE RECEIPT FOR SAMPLES

Issue a Receipt for Samples (EPA Form 3540-3; see Exhibit 1-1) for all samples collected. Identify each sample on the Receipt for Samples with the name of the product, EPA Registration

Number, batch/lot number, other identifying product information and sample identification number. The inspector and the owner, operator or agent in charge of the establishment should sign the Receipt for Samples.

The preparation of the Receipt for Samples should be self-explanatory. It is the inspector's responsibility that the facility representative understands that by signing the Receipt, he/she is acknowledging the fact that the physical and documentary samples were obtained from products that were packaged, labeled and released for shipment or, having been shipped, were being held for distribution or sale. Provide the establishment copy of the Receipt for Samples to the facility and retain the inspector's copy. In addition, make a copy of the Receipt for Samples Form and include it with any samples sent to a laboratory.

PAYMENT FOR SAMPLES

Offer to pay for samples collected, no matter how small the amount collected. Distributors and dealers are entitled to invoice costs plus a nominal charge (usually 10 to 15%) for freight, handling and storage. Producers are entitled to their production cost. Make payments in cash; reimbursement will normally be made by a travel voucher. Some companies may accept a government purchase request if arranged by the facility during the inspection. A producer may elect to bill the government for the samples.

SAMPLE DOCUMENTATION

RESPONSIBILITY

Document samples in accordance with this section. Ensure that the records obtained are those covering the specific pesticide product(s) or device(s) sampled.

Do not remove the firm's only copy of any record. If duplicates are not available, photocopy, photograph or hand copy all necessary records. Examine all copies to ensure that they clearly contain all relevant markings that appear on the original. Hand copies of records on EPA forms must be accurate and legible.

Identify all copies (this includes the firm's original copies) with the inspection sample sequence number (any sample or sub-sample number), the date (mm/dd/yyyy), and the inspector's initials (i.e., Sample number-Date -Credential number-Initials). The inspector should mark "EPA," the date and his or her initials in an inconspicuous manner on the reverse side of the original records from which copies were made. If the firm's record has information on both sides, the inspector's identification should appear inconspicuously in a clear space and be circled. These procedures will ensure positive identification of the document copies in question.

For distributor-level suspected violations, the inspector should document the handling and storage of the sampled product and establish the source and distribution for any accompanying literature and or labeling.

See Exhibit 6-1 for types of records that may be collected as documentary evidence relating to a sample.

RECORDS SHOWING SHIPMENT

Collecting records that document the movement of pesticides or devices in the channels of trade is an integral part of sample collection. These records indicate the responsible party in misbranding and/or adulteration cases and are key to shifting primary responsibility away from the retailers. In addition, these records are vital in determining an appropriate penalty since each shipment or sale is a separate violation of FIFRA. When there are suspected FIFRA violations, inspectors should attempt to document sufficient evidence of separate shipments/sales or collect records documenting separate days of shipments or sales. In many situations, collecting one year's worth of records may be sufficient. Obtain invoices, transportation, shipping and/or purchase records for each official sample of a pesticide or device collected. Collect computer-generated records indicating shipments/sales of suspect pesticides or devices. Identify these records in the same manner as the physical or documentary sample itself. A Statement (EPA Form 3540-42; see Exhibit 1-1) signed by the dealer, identifying both the lot sampled, and/or the applicable records should be collected. Have the dealer sign and initial the inspector's copies of the records obtained to prove that he/she provided them on the date of the inspection.

While records collected are not samples, they are identified as "exhibits" to be included and identified in the inspection report and identified with the date of collection and the inspector's initials along with an exhibit number.

Note that distribution and sales records may be in hard copy but also may be in an alternate format. Inspectors should always attempt to obtain hard copy records, if possible, either as copies of individual invoices or as a computer printout of the individual transactions. However, inspectors should be prepared to collect and gather records in other media (electronic records). If distribution/sales records are not available for collection during the on-site inspection, the inspector should request such records by a certain date (i.e., within the next 10 business days).

For inspections conducted using EPA authority, inspectors should obtain records documenting the distribution and sale of each sampled product based on the following protocol:

- When conducting a for-cause inspection or whenever an inspector believes a sample
 collected is in violation of FIFRA, the inspector should obtain a minimum of fifteen (15)
 related distribution and sales records for those sampled pesticide products, if available.
- When conducting a neutral scheme/routine inspection and the inspector obtain pesticide product samples but has no reason to suspect that the sample are violative, collect a

- minimum of five (5) related distribution and sales records per pesticide product sampled, if available.
- Inspectors always have the discretion to collect more than the minimum required distribution and sales records when the inspector believes that, based on his/her observations during the inspection, gathering the additional evidence would be appropriate.
- Inspectors also have the discretion to request additional records by post-inspection information request or through a follow-up inspection in order to obtain the additional records to adequately document the suspected violative distributions and sales of the sampled product.

INVOICE

The invoice shows the seller's intent to offer the pesticide or device for sale or distribution. It may provide such information as the value of the goods, carrier, and date of shipment. If duplicates or photocopies of the invoice are unavailable, photograph the invoice or copy it by hand on EPA Form 3540-13, Section 1, "Copy of Invoice and Shipping Record" (see Exhibit 1-1). In the absence of an invoice, purchase orders, receiving records, canceled checks and correspondence may be substituted.

BILL OF LADING

The shipper who delivers the goods to the carrier for shipment makes out the bill of lading (BL). It is an order for the carrier to move the goods. When the carrier's agent signs the BL, he or she acknowledges receipt of the shipment. Note that the date the carrier's agent signs the BL is the date of the shipment and this may or may not be the same date that the BL is filled out. The carrier's office in the city of origin of shipment will maintain a copy of the BL. Normally, the following information is found on the BL: (1) name and address of shipper; (2) name and address of consignee; (3) date of shipment; (4) name of carrier; (5) rail car number, if applicable; and (6) a description of the goods. If duplicate copies or photocopies are unavailable, the inspector should obtain a photograph or hand copy the BL information onto EPA Form 3540-13; see Exhibit 1-1.

FREIGHT BILL

This record is completed by the transportation company for the purpose of collecting freight charges. It should include the same information as found on the BL, plus information about the carrier's handling of the shipment and cost involved. Railroads prepare freight bills at their destination offices, where copies can be obtained. Steamship and airline companies usually combine the BL and freight bill into one form. Copies are filed at both the origin and destination offices of these carriers. Truck lines prepare freight bills at the originating office, and both the

origin and destination offices should have copies. The pesticide dealer will usually have a freight bill if he/she received the goods directly.

The inspector should obtain a photograph or photocopy of the freight bill or, if necessary, hand copy the freight bill information on to EPA Form 3540-13; see Exhibit 1-1. Enter the type of shipping record in block 23 of the form. Sections 1 and 11 may be executed together on one sheet if necessary. If only one section is used, leave the other section blank and submit the entire page of Form 3540-13.

WAYBILL

A transportation company uses a waybill in its own operations. The waybill accompanies the shipment during transit. Shippers or consignees do not receive copies of waybills but the inspector can obtain them from the carrier, if necessary. Other transportation records are generally more readily available than waybills. Airfreight waybill numbers are designed so that the originating line and point of origin are encoded within the waybill number. Each airline has a numerical code description indicated by the first two digits of the number. The three subsequent letters indicate the point of origin.

For example, waybill number 01LGA designates American Airlines (01) as the carrier and La Guardia Field (LGA) as the point of origin. Most airline offices have a copy of "Official Air Freight Transmittal Manual," which lists all the codes. Photograph or hand copied the waybill into section 11 of EPA Form 3540-13, if duplicate copies or photocopies are unavailable.

MAIL OR PARCEL SERVICE SHIPMENTS

Marketplace samples—Attempt to obtain the original packaging that contains the address sticker. If the original packaging is not available, the inspector should get a signed statement (EPA form 3540-42, see Exhibit 1-1) from an individual with knowledge of the shipment. The statement should contain the facts concerning the shipment.

Induced samples—When the inspector receives an induced sample directly by mail or parcel service, the sample documentation should include the portion of the wrapper showing name and address of the sender, the postmark or postage meter tape or any shipping marks. A copy of the air bill or other shipping record is also to be maintained as part of the sample documentation. Other necessary records include photocopies of the money order or cancelled check, the letter placing the order and the original advertisement.

SHIPMENTS BY NONCOMMERCIAL VEHICLE

When a vehicle operated by the shipper or dealer was used to ship pesticides/devices and no commercial shipping records are available, the inspector should obtain a statement of the facts concerning the shipment. The inspector should use EPA Statement Form 3540-42; see Exhibit 1-

1. The statement should cover the facts known to the dealer regarding the actual point of origin, the date of shipment, the ownership and operator of the vehicle, and the invoice from the shipper or the dealers receiving, warehousing and/or inventory records.

STATEMENT

Obtain a Statement (EPA Form 3540-42, see Exhibit 1-1) from persons who have dealt with the pesticides/devices or records sampled and who have relevant and pertinent knowledge. Statements are in writing and signed by the person writing the statement. A statement fulfills the same function as an affidavit, but differs in that it is not under oath. See, Chapter 16, "Inspection Reports and Supporting Documentation," for more information on Statements.

SAMPLE PREPARATION, CUSTODY AND HANDLING

IDENTIFICATION OF SAMPLES AND LABELS

Identify each sample with the inspection sample sequence number (any sample or subsample number), the date (mm/dd/yyyy), inspector's credential number and inspector's initials. Write this information with permanent ink (e.g., permanent marker) on the container so as not to obscure any portion of the label(ing) or package. When more than one unit is collected, identify each unit with a separate sample number. If it is necessary to take subsamples of the main sample, these can be identified as extensions of the main sample number (eg. 12345-001 or 12345-A). All collateral labeling, including circulars and inner instruction sheets, should be similarly identified. Circulars that have been removed from the sample for identification should be reinserted into the original packages.

Additionally, when identifying larger size unit samples, unless identical bin labels are not available, make a hand-written label for each subsample that provides at least the following information for the safety of those who will handle the sampled product:

- (1) brand name of the product;
- (2) principal active ingredients and labeled concentrations in percent;
- (3) company or name and address as shown on label;
- (4) distinguishing marks or code numbers;
- (5) "poison" and skull and crossbones stamped in red ink if the product's label was so marked (poison labels must also be affixed to the outside of the sample bag); and
- (6) the EPA Registration Number, if present.

The above instructions also apply to all small-sized samples that are wrapped and sealed in such a way as to obscure the product's label. Copies of appropriate bin labels can be taped to each container, if available, in lieu of the above information.

IDENTIFICATION OF DOCUMENTS

RECORDS

Identify all sample records collected, in the inspector's handwriting, by including the inspection sample sequence number, the date and the inspector's initials. This identification should appear as close to the upper right corner as possible. The inspector should also identify each original record in the same manner or on the reverse side of the original document(s). Return the original(s) to the facility at the closing conference after making copies.

ACCOMPANYING LITERATURE, LABELING, PHOTOGRAPHS AND EXHIBITS

Identify this material, in the inspector's handwriting, by including the sample number, date and initials. Do not mark on the face of photographs. All identification marks should be on the border of the photograph. Each photograph should be identified as to which panel of label it represents (i.e., front panel, back panel, left side or right side panel). A photograph showing the entire label and its placement on the container should be submitted. If it is a black and white photo, a notation of the color of the warning statement should be made on the photograph. Document the source of any accompanying labeling or literature collected in the inspection report (or equivalent narrative). When using digital photography the inspector should follow the guidelines in the <u>Digital Camera Guidance for EPA Civil Inspections and Investigations</u>.

SAMPLE CUSTODY AND INTEGRITY

Chain of custody begins when the inspector obtains the sample and properly identifies it; this establishes custody of the sample and ensures integrity of the evidence.

Samples are prepared by placing the sample(s) in an inverted clear polyethylene bag (4-mil thickness). It is important that the sample label be readable through the plastic bag. Seal each sample in a separate bag. In addition to ensuring custody, the polyethylene bag provides some degree of containment in case of breakage or leakage.

Evidence bags are also an acceptable means of securing a sample and establishing custody. NOTE: Evidence bags have an identifying area on the bag to be completed by the inspector with a permanent marker and a tear-away strip to be identified and included with the Inspection Report and/or the Inspector's copy of the Receipt for Samples.

THE EPA OFFICIAL SAMPLE SEAL AND POLYBAGGING

All physical samples are sealed officially by placing a completed EPA Official Sample Seal (EPA Form 7500-2, Exhibit 1-1) with the signature of inspector, sample number, date, name and title of inspector printed. There is also space for a regional office location to be noted on the form.

- 1. Use the sample preparation procedures described above.
- 2. Invert the polybag (turning inside out) to have the sealed seam inside the polybag.
- 3. Place the identified sample(s) in the polybag.
- 4. Twist the top of the polybag and tie a knot in the bag. Note: leave enough room at the top of the bag to fold down over the knot.
- 5. Fold the top of the polybag down over the knot and re-twist the bag.
- 6. Apply monofilament, masking or other type tape around the polybag, at the area just below the knot.
- 7. Complete the EPA Official Sample Seal (EPA Form 7500-2,see Exhibit 1-1) and peel away the backing of the Seal.
- 8. Apply the Seal around the taped area of the bag by bringing the two ends of the seal together, and then press the seal together until it reaches the bag area.
- 9. Secure the sample(s) assuring chain-of-custody procedures until the sample(s) are sent or delivered to the laboratory.

If it becomes necessary to break an official seal, remove the seal from the bag and then initial and date the seal. Then mount the broken seal on a piece of paper and include it with the inspection report to provide a continuous history of the sample. Re-seal the sample with a new EPA Official Sample Seal. This should be noted in the Chain-of-Custody Record (EPA Form 3540-41; see Exhibit 1-1).

SAMPLE INTEGRITY AND TRANSFER

The procedures governing sample integrity and sample custody begin from the point of collection and continue through each transfer of the physical sample. Sample integrity refers to steps necessary to ensure that nothing has compromised the chemical or physical integrity of the sample. Sample custody refers to the steps necessary to verify where the sample has been and what has happened to it, documented in a Chain-of-Custody Record (EPA Form 3540-41; see Exhibit 1-1).

Following collection, documentation, and initiation of chain-of-custody, samples must be stored in a secure area prior to transfer to the laboratory. Transfer pesticide product samples to the laboratory, in order of preference, either by: (1) direct personal transfer or (2) common air or ground carrier.

General guidelines:

- (a) Samples should be submitted to the laboratory within five days of collection;
- (b) Glass containers must never be packaged directly against each other, either within the same plastic bag or within the shipping container;
- (c) If necessary, provide refrigeration or freezing during shipment;
- (d) The sample label, whether for a prepackaged unit or for sub-sampled material, should always be readable through the plastic bag;
- (e) Liquid samples should not be packaged with solids in the same outer shipping container;
- (f) A copy of the Investigation Summary Report or equivalent form should be included with the samples, protected in a protective bag or sleeve;
- (g) The laboratory director or designee should be notified by telephone that the samples are being shipped, the mode of transfer and the expected arrival date;
- (h) Use packing materials and adsorbent materials to help prevent spills and contamination during shipment; and
- (i) Provide the lab with any pertinent information with regard to the sample(s), including information on the solvents(s) that were used to clean the sample container, sampling equipment.
- (j) Material Safety Data Sheet (MSDS) for the product should be included in the shipment.

MODE OF TRANSFER

HAND DELIVERY

Hand delivery to the laboratory is the preferred method of sample transfer. Follow all requirements for sample integrity and sample custody, as set forth above. Any authorized individual may transfer official samples to the testing laboratory as long as all such transfers are fully documented with respect to dates and signatures on the Chain-of-Custody Form (EPA Form 3540-41; see Exhibit 1-1).

COMMON CARRIER

If pesticide formulation or related samples cannot be hand-delivered to the laboratory, the services of a commercial shipping or overnight package firm (either surface or air) are preferred. Note that the United States Department of Transportation (DOT) regulates transportation by common carrier, particularly concerning the conveyance of hazardous

materials, which includes many pesticides. DOT requires that persons responsible for working with hazardous materials (hazmat) must have hazmat training.

Because DOT regulations are frequently updated, the pesticide inspector is advised to obtain the latest edition of these regulations to ensure full knowledge of pertinent additions and deletions (49 C.F.R. 105 through 199). Many pesticides are listed in the Hazardous Materials Table in 49 C.F.R. 172.101 or are listed according to their hazardous properties as being poisons, oxidizers, corrosives, flammables or pressurized gases.

In most cases, the pesticide label can be used to identify the hazard category, as the EPA Pesticide Registration Division classification system is almost identical to that being used by DOT. The DOT table cites the appropriate labeling, maximum quantity that can be shipped per package and specific regulation requirements and exemptions for packaging. The Hazardous Materials Table also contains an appendix that gives the reportable quantities for certain materials. These are quantities that must be reported on the shipping papers, if appropriate, to meet EPA reportable release requirements.

For quick reference, see the DOT publication, "How to use the HMR."

Two major parcel service companies, United Parcel Service and Federal Express, each have toll free numbers to assist the inspector in the use of their services for transporting hazardous materials.

Federal Express 1-800-463-3339 http://www.fedex.com/us/

United Parcel Service 1-800-322-1333 http://www.ups.com/

Pesticide formulations that do not fall under any of the hazardous categories may be shipped as unrestricted. However, packaging should at least meet the requirements of the DOT ORM-A classification (49 C.F.R. Part 173).

U.S. POSTAL SERVICE

Except in emergencies, the U.S. Postal Service should only be used to transfer small quantities of nonhazardous solid pesticides formulations to the laboratory, such as antimicrobial pesticides of low concentration (below 5%). Specific restrictions exist on the mail-ability of poisons, flammables, oxidizers and corrosives and explanations are provided in the USPS
Publication 52 - Hazardous, Restricted and Perishable Mail. Ship all samples by Registered or Certified Mail with a Return Receipt Request in order to maintain proper chain-of-custody.

EXHIBIT 6-1: EXAMPLES OF RECORDS

The following are examples of records that an inspector may obtain during an inspection:

Market Place Inspection and Sampling

- o Invoices
- Shipping records
- Bills of lading
- Freight bills
- Waybills—if imported by or exported by air
- o U.S. Mail or commercial carrier shipping records

Producer Establishment/Dealer/RUP Dealer Inspection and Sampling

- o Invoices
- Shipping records (of received manufacturing use or technical products)
- Bills of lading
- o Freight bills
- Waybills as above
- U.S. Mail or commercial carrier shipping records
- Export records
- o Foreign Purchaser Acknowledgement Statement
- Child resistant packaging records
- Certification statement
- Test verification
- Packaging /Re-packaging agreement(s) or contracts
- Supplemental registration agreements and re-packaging agreements
- Sources of all technical (manufacturing use) pesticide products or chemicals (copies of all documentation of the purchase of these materials (invoices, shipping records, bills of lading, etc.)
- Guarantees offered for each product (copies)
- o Records of disposal of residues, old chemicals, etc.
- Records of sale of RUP products to certified applicators

CHAPTER SEVEN RESIDUE AND ENVIRONMENTAL SAMPLING

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RESIDUE AND ENVIRONMENTAL SAMPLING

INTRODUCTION

Residue and environmental sampling may be necessary when there has been a spill or when there is suspected pesticide misuse. Suspected human, animal, crop, or environmental contamination can require quick action to determine exposure or to prevent contaminated commodities from entering the food chain. Pesticides that degrade quickly will require sampling soon after their application to detect their presence.

A sample should support an allegation that a violation has occurred. Therefore, the sample must conform to the rules regarding admissibility of evidence; specifically, the inspector must document how the sample was obtained and then establish the chain of custody by proving where the sample has been and how it was treated since it was collected.

GENERAL SAMPLING GUIDELINES

The following general guidelines apply:

- Make a sampling plan and be prepared to adapt it to the requirements of the individual investigation.
- Have and use the necessary sampling tools, containers and personal protective equipment appropriate for the particular inspection.
- Do not contaminate yourself or cross-contaminate the samples. Always wear clean disposable gloves, protective clothing and safety equipment as required by the pesticide label, regulations and policy when entering fields/areas or handling samples. Change gloves between each sample collected. Change protective clothing as needed. See Chapter 2, "Health and Safety."

Composite sample - A combination of two or more sub-samples to produce a homogeneous sample. Composite samples are used to identify suspected chemicals when the area, crop or material is suspected to be uniformly contaminated.

Duplicate samples - Two or more samples collected from the same area having comparable conditions.

Split sample - The division of a sample into two equal and identical portions. This is usually done at the laboratory.

Use dilution sample - A use dilution is a formulated pesticide that has been blended with a carrier such as water, and is ready to be applied by an end user. If the use dilution is made with a concentrate, a sample of the concentrate should also be obtained for analysis. Additionally, a photograph of label(ing) and container of the concentrate should be obtained.

Residue sample - A residue sample is usually collected from the natural environment (soil, water, vegetation, bees, hives, fish, animals), but may be from non-environmental sources. A residue sample is collected for a variety of reasons, but usually to determine if pesticide residues are present in the media sampled. Swab samples may also be taken to detect residue on an object. Collect residue samples in accordance with federal sampling procedures. Sample containers must be identified with the sample number, the date and the inspector's initials. Take photographs and draw a diagram of the area so that they will be accurate depictions of what the inspector did and/or observed in the sampling area. Photographs should be identified in the same manner as the sampling container.

Control Sample - Prior to sampling, take a control sample when investigating an incident site. Take the control sample from an area outside of the incident site. This will help establish the boundaries of the incident.

SAMPLING PLAN

A sampling plan is necessary as a framework for the inspection. It enables the inspector to gather all relevant information needed before, during and after the inspection. At times there may be information that can be gathered prior to sampling. However, often there will be time constraints that reduce the ability to collect certain data prior to sampling. To develop a sampling plan, review any available notes, statements, permits, use reports and technical data on the alleged pesticides involved.

TECHNICAL DATA

Technical data will assist in determining sample types, methods and location, a time frame in which to collect samples and whether there should be any special handling or sample preparation procedures. The inspector may benefit from referring to the *Farm Chemicals Handbook, Crop Protection Chemicals Reference, Pesticide Product Description,* which contains information on toxicology and is commercially available. The following represents technical data that may be useful to the inspector:

- Chemical properties
 - o Formulation
 - o Half-life

- Metabolites
- o Physiological and biochemical behavior
- Foliar absorption characteristics
- Translocation action
- Behavior in or on soils
- Absorption and leaching characteristics
- o Microbial breakdown
- o Loss from photodecomposition and volatilization
- o Hydrolysis
- Toxicological properties
 - Toxicity to humans/wildlife/fish
 - Acute/chronic toxicity
 - o Poisoning symptoms
- Laboratory qualifications
 - Method of analysis
 - Analytical sensitivity
 - Availability of method and/or reference standard(s)

WEATHER DATA

Weather data, at the time and place of incident occurrence, if available, will help in determining drift patterns, volatilization rates, off-target movement of pesticides, etc. This information can be obtained from the National Weather Service, local agencies and airports:

- Wind speed and direction
- Rainfall
- Temperature
- Inversion
- Humidity

SAMPLE SELECTION

Selecting the sample type(s) will depend on the type of incident that allegedly occurred. For example, if the incident involved:

- Drift of a pesticide on people—the sample type could include total foliage (i.e., total residue on foliage) in a gradient pattern and clothing of the contacted person(s).
- Drift of pesticide on people harvesting a commodity—the sample types may include total foliage in gradient pattern, total commodity, dislodgeable foliage and clothing.
- Misuse of a pesticide resulting in animal, fish or bee kills the sample types may include dead animals, fish, bees, honey and pollen as well as foliage samples or swab samples.
- Misuse of a pesticide in a confined space —the sample types may include various soil samples and surface wipe samples.
- Crop damages from run-off containing a pesticide—the sample types may include total soil or total foliage in a gradient pattern, total commodity and total plant.
- Fumigation of places like railcars, ships, containers, grain silos, or bins, homes or structures —the sample types may include a sample of the commodity and a photograph of any placard that provided notice of the fumigation.

Note that when sampling in confined spaces, such as crawlspaces, railcars, ships and containers, additional safety precautions should be followed. See Chapter 2, "Health and Safety."

The purpose of sampling is to collect evidence to determine if a violation occurred. An investigator will have to use his/her best judgment in selecting the appropriate sample types based on the information gathered. For drift incidents, the inspector will need to determine when the pesticide in question was applied, so as to decide whether to sample vegetation or soil. If the available plants have a heavy canopy, thus allowing limited soil exposure to direct spray, vegetation should be chosen as the sample of choice. If vegetation at the incident site is limited, excessive time has passed since the application, there is new plant growth or heavy rains could have reduced the concentration, soil should be the sample of choice.

Whatever sample type is used, a sample must be representative of the media being sampled if it is to provide the basis on which to determine that a violation exists. This requires the selection of sampling points that will be representative. In addition, keep in mind the statistical considerations that affect representative sampling, such as variability in sample collection methods; frequency of samples taken over a period of time; and number of samples collected.

SAMPLING EQUIPMENT

Use clean sampling containers. Sampling containers may include bottles, metal cans, triers and aluminum foil. Sampling containers should be new or have been properly cleaned. Prior to use, containers should be washed and rinsed with hexane or isopropyl alcohol, and permitted to air dry. (NOTE: Decontaminate containers used to sample sulfonyl urea pesticide products in a 5% solution of chlorine for 1 minute of contact time.) Note what solvent was used to clean and decontaminate all sampling equipment and sampling containers on the Receipt for Samples.

All sampling equipment must be stored in the office or locked vehicle in an uncontaminated designated location. For smaller equipment, an enclosed, airtight container is recommended. Larger equipment can be wrapped in an uncontaminated cloth or stored in a polyethylene bag but will need to be cleaned and decontaminated again prior to use.

Equipment, gear and items that may be useful for taking samples include:

- Notebook, notepaper, computer or other electronic device used to record information, camera.
- Clear plastic bags (4 mil thickness), jars and/or cans with lids (various sizes) and aluminum foil.
- Commercially available evidence bags that are pre-printed with chain-of-custody and evidence fields to be filled in by the inspector.
- Personal safety equipment and clothing, such as coveralls, respirator, goggles, hardhat, powder free disposable and rubber gloves, boots, rain suit, waders.
- Labels, tape, stapler, evidence tags, official sample seals or evidence tape, masking 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 of a size equal to 4"x4" opening in the center.
- Measuring tapes, stakes, camera, film, extra batteries, extra SD Card and accessories.
- Ice chests (coolers, styrofoam), re-useable freezer packs, wet ice or 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 and record book.
- County or city map, aerial maps and topographical maps, global positioning system (GPS) device.
- Disposable core tubes and siphon tubes.

INCIDENT SITE

Survey the incident site and create a site diagram depicting the following:

- Structures.
- Crop type, maturity, acreage.
- Physical surroundings as landmarks:
 - o Telephone poles (note the ID number on the pole) adjacent to crops.
 - Roads, streets, buildings and other important identifying factors.
 - Sampling medium (foliage, surface areas, etc.)
 - o Trees.

- o Waterways.
- Location of workers.
- Crop/plant damage.
- Spotting on leaves, walls, floors, vehicles.
- Pesticide containers in storage.
- Location of odor complaint, if applicable.

Draw the diagram of the incident site as near to scale as possible with north at the top. As samples are collected, identify their location(s) and distances on the diagram. The diagram must be large enough to include all of the details and be legible.

SAMPLE CONTAINERS

Identify all samples collected with the sample number (and sub-sample number, if applicable), date and inspector's initials and place them in a large 18"x 30", inverted, heavy polyethylene bag or evidence bag. Seal the polyethylene bag as follows:

- Twist the top of the bag and tie a knot in the inverted bag.
- Fold the top of the bag down over the knot and twist the bag around the knot.
- Apply several wraps of masking, duct or monofilament tape below the knot.
- Apply the EPA Official Sample Seal (EPA Form 7500-2, see Exhibit 1-1)(or if a state/tribal inspection, the equivalent state/tribal sample seal) around the tape. Identify the official sample seal with the sample number, date, city and state of collection and the inspector's name and signature.

For one-liter amber containers:

- Tape individual containers around the cap and deep into the neck with masking, monofilament or duct tape.
- Place the inspector's initials across the tape.
- Follow all other procedures for identifying, logging and sealing the sample.

RECEIPT FOR SAMPLES

Fill out a Receipt for Samples in ink and include a copy with the samples sent to the laboratory. Place the Receipt for Samples in a separate sealed plastic bag to prevent moisture absorption. Note that this is in addition to the Receipt for Samples given to the owner or operator of the

property where the sample collection is being conducted. On the Receipt for Samples being sent to the laboratory:

- Identify the sample material as accurately as possible.
- If possible, identify specific pesticides or classes (e.g., organophosphates, phenoxys) suspected to have caused the problem. Also include the phrase "WARNING PESTICIDES" on the Receipt for Samples to warn laboratory personnel.
- Copy identifying numbers on the sample container exactly on the Receipt for Samples to identify the sample for the laboratory.
- Identify the solvent (if any) used to clean sampling equipment.

SAMPLE COLLECTION AND PRESERVATION

Physical pesticide sampling may include concentrated pesticide formulations, diluted pesticide solutions, and any substance or material suspected to be contaminated (environmental residue samples).

GRID SAMPLING

Grid pattern sampling is recommended for incident sites because it represents a logical, systematic approach to collecting samples. The particular grid pattern is created once the inspector arrives at the incident site. The grid is intended to measure the extent of contamination at the whole site. Each point on the grid represents a location where a sample is taken. Grids should be constructed to begin sampling at the point of least suspected contamination and working towards the point of greatest suspected areas of contamination. The number of points on the grid, as well as the distance between each point, will be at the inspector's discretion. Note the grid location for each sample taken. When grid sampling is completed, the inspector should create a diagram of the grid and include it with the inspection report. Grid sampling will be discussed with more specificity in the sections below on the Types of Residue and Environmental Samples.

FOLIAGE SAMPLING

Pesticide drift or other misapplications of pesticides are often documented by sampling and analyzing foliage or whole plants for residues. The sampling techniques described below are applicable for most agricultural crops as well as nonagricultural vegetation.

DISCRETE FOLIAGE SAMPLING

Collect foliage from specific areas in the field. The purpose of collecting the sample from specific areas is to identify residue delineation between the sample areas and to maintain sampling uniformity. It is important to identify the location of the sample site within the field because the sample and incident site diagram may be used as evidence in an administrative or judicial action. The size of the sample area will vary with the type of location.

At all sites, collect a control sample from an area with vegetation similar to that within the affected areas. It is absolutely critical that the control sample be taken from an area known to be free of any contamination from the pesticides in question. A contaminated control sample will destroy the usefulness of other samples as evidence.

Collect samples in a sequential order from the least anticipated residue concentration to the greatest anticipated concentration (i.e., control, suspected drift area, then target area). This will help reduce the potential for cross-contamination of samples. Take enough samples to establish boundaries of contamination. (The lab can always discard unnecessary samples later. It is rarely possible to collect additional samples afterward.)

For field crops and non-crop areas (weeds, fallow fields, etc.), the size of the sample site should be approximately a 25-foot square (or 625 square feet).

For orchards and ornamentals, collect samples from approximately four mature trees/vines (rectangle or square area). The area will vary depending on the size of the incident site, the size of the plants and foliage within the site and the number of samples intended to be collected.

Remember, measure the sample area and record it in the investigative notes.

Try to collect foliage of similar type (e.g., grasses or broadleaves only), if possible. It will make it easier to extrapolate the data. If similar type foliage is not available throughout the sampling area, collect different types of foliage. Place each type of foliage in different containers.

Select foliage from all sides of the plant or tree unless drift is suspected. In this case, collect the foliage from the side of the plants allegedly exposed to the drift. For most situations, collect the foliage from the outer leaves of the plant or tree. It may be necessary to uproot the whole plant if systemic pesticide absorption is suspected. Do not select foliage that is in contact with soil. Only collect leaves; do not include twigs or branches. Remember, new growth which was not subject to chemical application may affect the results of an analysis.

Collect enough foliage from the specific sample area to permit proper analysis or screening. If composite, duplicate or split samples are requested, increase the sample size accordingly. Contact the laboratory if in doubt regarding sample size.

Vegetation samples must be wrapped in aluminum foil (pre-rinsed with hexane or isopropyl alcohol and air dried) and placed in large 18" x 30", inverted, heavy polyethylene bags or evidence bags; alternately, vegetation samples can be collected in glass containers.

Chill, refrigerate, or freeze samples as soon as possible. An ice chest, containing bagged ice or re-useable freezer packs, can be carried into the field for this purpose. If samples are frozen after collection, they must remain frozen. See section on Sample Storage, Preservation and Shipping.

Ship samples to the laboratory as soon as possible after they are collected, following proper chain-of-custody procedures.

COMPOSITE FOLIAGE SAMPLING

Composite samples are taken to determine whether an area is contaminated and to determine whether more thorough, discrete sampling is warranted. After taking a control sample, a composite sample is made up of several sub-samples that are of equal volume or weight and are combined to represent a field or site.

GRID PATTERN FOLIAGE SAMPLING

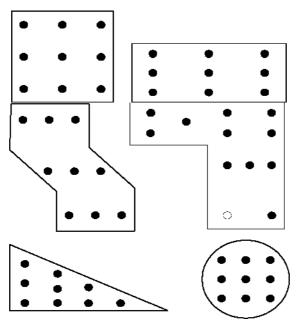


FIGURE 7-1: GRID PATTERN EXAMPLES FOR FOLIAGE

If misapplication to part of a field is suspected, but the treated area is unknown, this type of sampling pattern should be used to help identify the treated area.

Collect samples in a grid pattern following the procedures indicated for a discrete foliage sample. Each sample represents one point on the grid for that field or site, therefore, do not composite them.

After a control sample is taken, the sampling grid pattern in the incident site should start from the edge of the field, depending on the field size. As a rule of thumb, the distance from the edges should represent approximately 10 percent of the width and length of the field or site. For example, a site 1,000 feet wide and 2,000 feet long (approximately 46 acres) has a starting point 100 feet in from the width and 200 feet in from the length. Samples should be in line with, and at an equal distance apart from, one another in the grid pattern. Record the sample locations in the investigative notes and diagram(s).

If using the grid pattern to establish drift, collect at least one additional sample from each of the adjacent fields that are suspected of being the source of contamination.

Each foliage sample from a site should be of similar type and taken from the same location on the plant/tree. Identify the location and area from which each sample was taken on the diagram with distances from landmarks, from field borders and between samples clearly indicated.

CROP DAMAGE RESIDUE INCIDENTS

After taking a control sample, take samples in a line, at approximately equal intervals, from a non-suspected area to the target treated area.

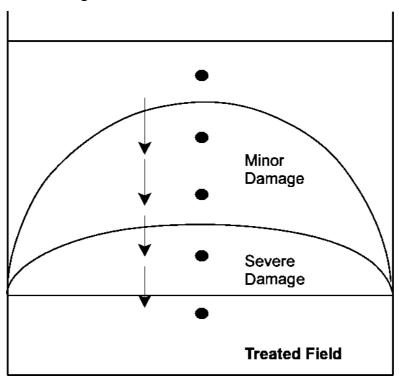


FIGURE 7-2: GRID SAMPLING DIAGRAM - CROP DAMAGE RESIDUE INCIDENT

HUMAN EXPOSURE INCIDENTS

After taking a control sample, take samples in a line, at approximately equal intervals, starting from where there is suspected human exposure and moving outward toward the treated area. These samples will be in addition to wipe samples from vehicles, vegetation/soil samples in grid pattern and clothing samples, if appropriate.

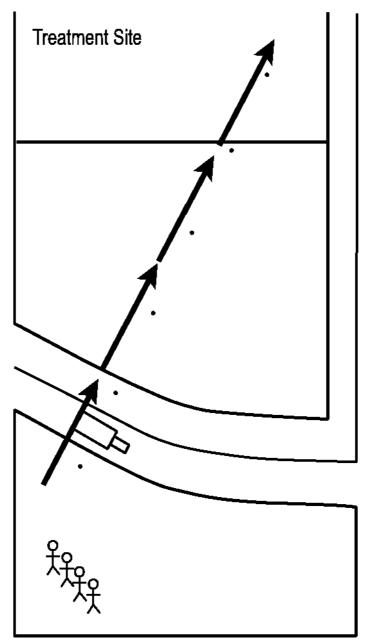


FIGURE 7-3: GRID SAMPLING DIAGRAM - HUMAN EXPOSURE INCIDENT

PROPERTY LOSS INCIDENTS

Where there is suspected property loss or damage that does not involve crop damage or foliage, take samples of the suspected damaged property, as well as vegetation/soil samples in a grid pattern, wipe samples from vehicles and clothing samples, if necessary.

When taking vegetation/soil samples in a grid pattern, take a control sample from outside the treatment site, and then collect samples in a line, at approximately equal intervals, starting from an area of suspected property damage and moving toward the treated area.

When there are multiple areas where pesticide(s) have been applied, the same grid pattern is used as previously described, but samples are obtained in two directions toward the treated areas.

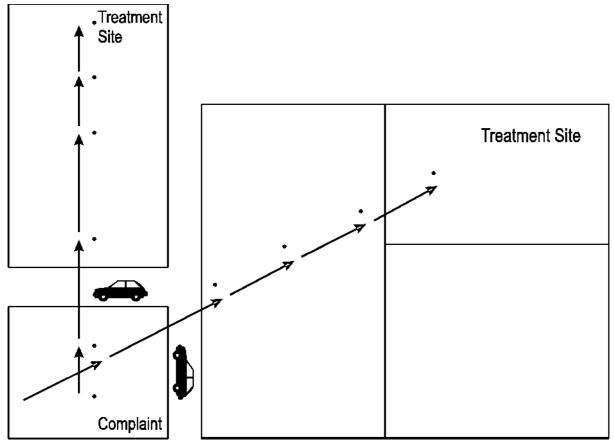


FIGURE 7-4: GRID SAMPLING DIAGRAM -PROPERTY LOSS INCIDENT

AGRICULTURAL PESTICIDE MISUSE

After taking a control sample, take samples in a line, at approximately equal intervals, starting from an area outside the treatment site, ideally where there is suspected exposure, and move toward the treated area. Take vegetation/soil samples in a grid pattern, samples of commodities, wipe samples from vehicles and clothing samples, if necessary.

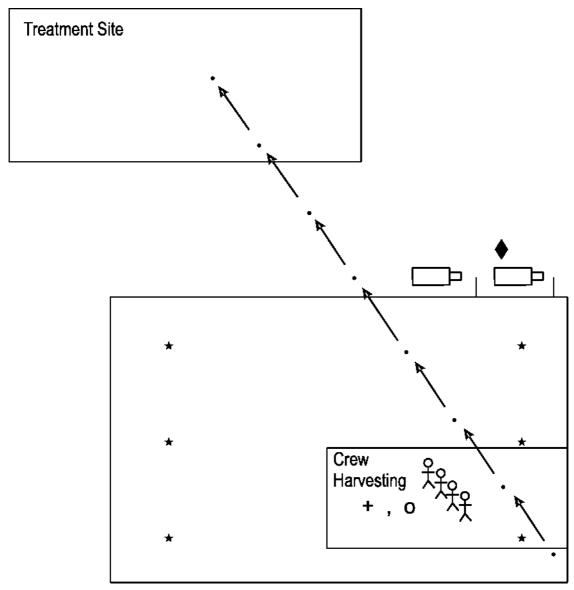


FIGURE 7-5 - GRID SAMPLING DIAGRAM - AGRICULTURAL PESTICIDE MISUSE

STRUCTURAL PESTICIDE MISUSE

Where there is suspected structural pesticide misuse, take a control sample from outside the treatment area. Begin grid sampling outside the treated area and move inward toward the treated area.

Take samples of the suspected damaged property, as well as vegetation/soil samples in a grid pattern, wipe samples from vehicles and clothing samples, if necessary.

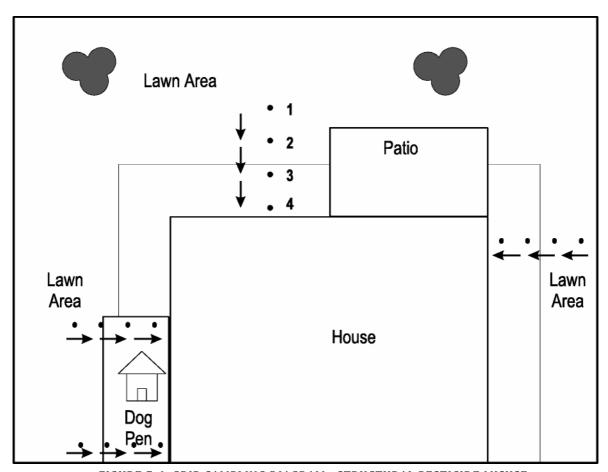


FIGURE 7-6: GRID SAMPLING DIAGRAM - STRUCTURAL PESTICIDE MISUSE

SOIL SAMPLING

DISCRETE SOIL SAMPLING (KNOWN DEPTH)

Collect soil samples at a known depth when the pesticide is suspected of being incorporated, band treated, shanked or moved below the soil surface through leaching. If the samples are not collected at the proper depth, the sample results will be misleading. This type of sampling may be collected in a grid pattern within a field or site.

After taking a control sample, select a specific sample location and measure an area of approximately one square foot. Record the measured sample area in the investigative notes.

If it is suspected that chemical leaching has occurred at the sample site, dig a sampling hole and collect soil from various depths (e.g., 3-6 inches, 6-9 inches). After digging the hole, decontaminate the sampling instrument and clear away the soil at the depth desired to obtain the sample. Decontaminate the sampling instrument and use a clean container to collect the sample.

If a soil probe is available, remove the soil to the beginning depth to sample. Take several core samples to the desired depth using the probe. NOTE: It is not recommended to use the probe when a band or side-dress treatment was used. Since it is difficult to determine where the band treatment is located, the probe technique could miss the pesticide and give misleading results.

SOIL SAMPLING IN FURROWED FIELDS

Chemicals may have been applied in bands or side-dressed in furrowed fields. In order to sample from the appropriate area, a shovel is needed to cut across sections perpendicular to the direction of the furrow at each sample site.

SINGLE ROW

After taking a control sample, start at the center of the furrow and sample across the bed to the center of the opposite furrow. Collect soil from an area 3–6 inches wide and 12-14 inches deep as measured from the top of the bed.

DOUBLE ROWS

If the field is laid out in double row beds, sample from center of furrow to center of bed at 3–6 inches width and 12-14 inches depth.

Mark the location of the sample area on the diagram indicating distances from each sample, depth and width of sample, landmarks and field borders.

Single row beds: combine soil from the area outlined in the figure below and place in a 1 quart container.

Double row beds: Center furrow to center bed.

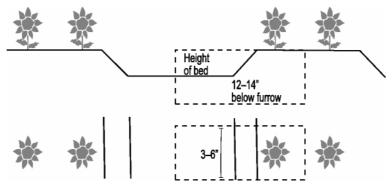


FIGURE 7-7: SOIL SAMPLING IN FURROWED FIELDS

GRID PATTERN FOR SOIL SAMPLING

There are several pesticides (e.g. DCPA and chlorothalonil) that are long-lasting in the environment and adhere to soil particles. Cultivating practices (i.e., disking) and wind can move these particles from adjacent fields to a crop, creating a potential residue problem. Therefore, grid pattern sampling results can be used to document the transport of the soil particles. Grid soil sampling is usually conducted to prove drift from a treated area. If drift is suspected to have occurred to a field and the pesticide can be detected in soil, then grid sampling may be of use.

Collect soil samples at the appropriate depth in a grid pattern following the procedures indicated for a discrete soil sample. Each sample will represent one point on the grid for that field or site. Do not composite these samples.

After taking the control sample, start the sampling grid pattern from the edge of the field, depending on the field size. As a rule of thumb, the closest sample distance from the edges should represent 10 percent of the width and length of the field or site. Each sample should be in line with, and at an equal distance apart from, the other samples in the grid pattern. Record the sample locations in the investigative notes.

Always take samples from an area of suspected lowest concentration and move in a direction towards the area of highest concentration, most likely the treatment site.

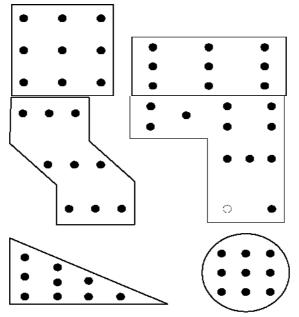


FIGURE 7-8: GRID PATTERN EXAMPLES FOR SOIL

COMPOSITE SOIL SAMPLING

The composite sample is made up of several sub-samples that are combined to represent a field or site. For example, in Figure 7-8, all the grid point samples taken from one area would be combined to make one composite sample. Composite sampling is appropriate in certain specific instances. Where there is a need to merely establish that a pesticide was applied, composite sampling may be used.

DISCRETE SEDIMENT SAMPLING

Pesticide residues can accumulate in the bottom sediment of lakes and streams. It may be necessary to conduct sediment sampling to determine the pesticide source.

There are commercially available devices for sediment sampling, but these devices often require extensive cleaning between sampling to prevent cross-contamination. Directly scooping sediment into a glass container is recommended for shallow sampling situations. Alternatively, a disposable core tube can be used to collect sediment.

To collect the sample, carefully lower the disposable core tube, the container or other sampling device through the water into the sediment. Minimize disturbing the sediment. Retrieve approximately one quart of sediment. Transfer sediment directly into a clean container. Seal with a Teflon or foil-lined lid.

Mark the location of the sample area on the diagram indicating distances from each sample, landmarks and field borders.

Dispose of or clean sampling tools. Rinse the collection container, if used, with hexane or isopropyl alcohol and allow to air dry prior collecting additional sediment samples.

WATER

Pesticide residues may be found in surface water such as lakes, streams or ponds resulting from some type of misuse (i.e., off-site drift, overspray). If pesticide contamination of groundwater is suspected, contact the supervisor to determine the appropriate federal, state or local agency for follow-up.

DISCRETE SURFACE WATER SAMPLING

When sampling surface water, sample as close as possible to the apparent source of contamination. If the suspected pesticide is water soluble, the sample must be drawn from a lower depth. If the pesticide is oil-based, or oil is a part of the tank mix and the alleged misapplication was made across the water surface, then the sample can be drawn from the surface layer.

Use two clean one-liter amber glass containers with an aluminum foil or Teflon seal under a screw cap. If amber glass containers are not available, use two one-quart large mouth containers and wrap each container with aluminum foil to exclude light.

Lower the glass container to the desired depth with the cap on. Remove the cap under water and allow the container to fill. Replace the cap and lift the container out of the water. For samples taken from the surface, dip the container into the water surface and allow it to fill. Containers must be filled completely to the rim, with no air space between lid and the container contents so pesticides cannot volatilize.

It is preferable to take several samples from different locations. Alternatively, a composite sample may be taken by combining sub-samples from different locations around the body of water and combining in two clean one-liter/quart containers.

Mark the location of the sample area on the diagram indicating distances from each sample, landmarks and field borders.

Samples must be chilled or refrigerated and shipped as soon as possible, following proper chain-of-custody procedures. DO NOT ALLOW SAMPLES TO FREEZE. An ice chest can be carried into the field for this purpose.

AIR

Generally, EPA laboratory staff conducts volume air sampling in concert with the inspector. Since they have the unique equipment, chemicals, knowledge and experience needed to operate air sampling equipment, it is recommended that they be contacted if volume air

sampling is needed. The inspector will retain the lead for the investigation and other personnel will assist.

There are two types of air samplers used. High volume samplers are used to measure low concentrations of pesticides over long periods of time and low volume samplers are used to measure high concentrations of pesticides over shorter periods of time. EPA laboratory staff or ESD will make the decision as to which air sampler will be used. Both high volume and low volume sampling equipment draws air through glass cylinders containing a medium designed to capture the pesticides of interest for analysis by the laboratory.

AIR SAMPLING INDOORS

Either high-volume or low-volume sampling equipment can be used depending on expected concentrations. Air sampling equipment produces a moderate noise. It should be positioned where it will not unnecessarily disturb other persons in the structure, if possible.

High-volume sampling equipment must be vented out of the dwelling to ensure that air will not be recycled through the machine.

Rooms with cigarette smoke or gas appliances must be avoided; any gases or suspended smoke particles in the area will contaminate the sample.

AIR SAMPLING OUTDOORS

Sampling equipment must be positioned to avoid exposure to engine exhausts, running motors, cigarette smoke or any other non-target air contaminants.

Sampling equipment must also be protected from rain and direct sprays from application machinery. Shelter hoods are used to protect the equipment in such situations.

Air samples must be sealed and delivered directly to the lab, following proper chain-of-custody procedures.

ANIMAL, BIRDS, FISH AND BEE SAMPLING

Where there has been an animal, bird, fish or bee kill, samples must be taken to substantiate the cause. If possible, sample dead animals, birds, fish and bees before they decompose.

Using disposable gloves, place the small animals, birds and fish in a heavy, inverted polyethylene bag and chill, as soon as possible. At least 500 grams (approximately 1 pound) is needed per sample.

Collect a minimum of four ounces (approximately 1 cup) of dead bees or honey and a minimum of one ounce of pollen from the affected honey bee colonies. It may also be desirable to collect foliage samples or swab samples from around the hive. Since bees can forage several miles

from the colony, samples can be collected of various blooming plants in the foraging area if it can be determined. Remember to collect enough for each analysis. Place each sample in a clean, unused container. See "Guidance for the Inspection of Alleged Cases of Pesticide-Related Bee Kill Incidents" Also, the following website has more information: http://extension.oregonstate.edu/catalog/pdf/pnw/pnw591.pdf.

Chill all animal, fish, birds and bee samples upon collection to prevent further degradation. If decomposition is evident, note on the Receipt for Samples and the Inspection Report.

SURFACE WIPE SAMPLING

Surface wipe sampling is conducted to establish the presence of a pesticide on a surface.

DISCRETE SURFACE SAMPLING

When possible, select a site showing visible residue. Try to avoid areas known to contain waxes because they may interfere with the analysis. Smooth "inert" surfaces are the preferred area to collect the sample (i.e., windshield). Sampling uneven surfaces (such as rugs, furniture, walls, walkways, counters), however, is also possible. Before entering the area to be sampled, take a control sample.

While wearing disposable latex gloves, tape a template to the sample surface. A template can be a piece of cardboard with a four inch square opening. The purpose of the template will be to delineate the sample area at the target site. A new template and gloves must be used for each sample location so prepare as many templates as necessary ahead of time. If a template cannot be placed on target site, delineate the sample area using masking tape laid out to create a four inch sampling square. Photograph the area and templates.

Surface areas are sampled using sterile cotton pads (2" x 3") or filter paper discs moistened with solvent. While wearing disposable latex gloves, pour isopropyl alcohol or hexane over the cotton pad and moisten it completely. Shake off excess solvent. Do not contaminate the solvent by placing the cotton pad over the mouth of the solvent bottle. The target area of the template is to be thoroughly wiped. If it is an irregular surface, the sample may be obtained by dabbing.

Place the sampling pad or disc in a clean container. Using a permanent marker, identify the sample collection number, date and inspector's initials on the sample container. Place each sample collected in a large polyethylene bag.

Record the surface area type and sample location on the Receipt for Samples, on the incident diagram, and in the investigative notes. Other information recorded on the Receipt for Samples includes the solvent used, the suspected ingredients in the pesticide spray solution and whether the surface sample represents pesticides in concentrate, tank mix or residue from drift or overspray.

Store the samples in the freezer or refrigerator and ship to the laboratory in a manner that maintains the integrity of the sample, following proper chain-of-custody procedures.

GRID PATTERN FOR SURFACE SAMPLING

Grid patterns can be used for surface wipe sampling to establish the extent of contamination. For example, it may necessary to establish that a broadcast carpet treatment occurred when labeling only allowed a baseboard treatment. Grid surface samples can also be taken to establish a drift pattern in or on a structure.

Always collect a control sample prior to any other sampling. At a treatment site, sample from an area of lowest concentration and move in a direction towards the area of highest concentration to prevent contamination of samples. The grid pattern should be in straight lines and all grid points should be an equal distance apart.

Create a diagram of the sampling area. On the diagram, identify the location from which each sample was taken. Include distances from landmarks, such as walls, and distances between samples.

Follow the procedures for taking discrete surface samples, as described above. Each sample represents one point on the grid for that site. Do not composite the samples.

CLOTHING

Collect footwear and clothing only when contamination is suspected. It may be necessary to collect clothing and footwear samples away from the incident site. The applicator or the person(s) who reported the incident may not be found at the incident site.

Should the history of the clothing be unknown, attempt to find out about the integrity of the clothing sample. Ask if the clothing has been washed since the incident. If the clothing has been washed, the inspector should not collect the sample.

Inform the individual who is providing the clothing that the clothing will not be returned.

Wrap each article in aluminum foil prior to placing it into an inverted 18"x 30", or larger, heavy clear polyethylene bag. Properly knot and seal each bag. Identify and officially seal samples immediately as they are taken.

SAMPLING IN SUPPORT OF RESIDUE AND ENVIRONMENTAL SAMPLING

While conducting residue and environmental sampling the inspector may encounter technical pesticide formulations and tank mixes used during the suspected mis-application that has given rise to the inspection. Samples of these products should be taken to check

for mis-formulation, adulteration, cross-contamination and other potential problems. The results of this sampling and analysis will be relevant to the inspection.

While safety issues are important when conducting residue and environmental sampling, different safety issues may be present when collecting samples of formulations and tank mixes. Therefore, review Chapter 2, "Health and Safety", and any precautionary statements on product labeling prior to collecting the sample.

PESTICIDE FORMULATIONS (TECHNICAL GRADE)

Read and follow all precautionary statements on the label before sampling a formulated pesticide material (i.e., protective clothing and equipment requirements). If a label is not available, wear the maximum safety equipment (respirator, Tyvek suit, coveralls, rubber gloves, rubber boots and goggles).

Chapter 6, "Pesticide Product Sampling", provides guidelines on sampling a pesticide product. However, if possible, collect the entire container with its contents. Smaller samples can always be collected from the larger container.

Sample tools, if re-useable, must be cleaned with hexane or isopropyl alcohol and air dried before collecting additional samples.

Avoid cross-contaminating samples by keeping these samples separate from all other samples (i.e., residue) at all times.

To avoid cross-contamination:

- Liquid bulk samples are to be collected in 8 oz. amber glass bottles with Teflon lined caps.
- Dry bulk samples are to be collected in glass pint or quart containers, or pint or quart size metal paint containers.

Review the pesticide label for storage instructions. Chill the sample to store and ship, unless otherwise stated on the label. Do not allow the sample to freeze.

TANK MIX

Laboratory analysis of tank mix samples will help to identify the active ingredient and any possible contaminants in the tank mixture, or other characteristics of the mixture.

Use 8 or 16 ounce amber glass containers with Teflon-lined lids to collect samples. Do not allow tank mix solutions to contact rubber or plastic as these materials may affect the analytical results. Thoroughly agitate the liquid in the tank before sampling.

Using a clean or decontaminated siphon and bulb suction apparatus, collect a sample from the tank. If the solution is adequately mixed to ensure uniformity, a sample can be collected from

the drain system. Application rigs can be sampled at spray boom nozzles. Following actual application, have the operator loosen boom nozzles and drain the pesticide mix into the sample container. Be sure that the operator tightens the nozzles on the boom after the sample has been taken.

Chill the sample to store and ship. Do not allow the sample to freeze. Do not store or ship tank mix samples with or near foliage or soil samples.

Decontaminate all tools and change or wash gloves to prevent cross-contamination of samples.

SAMPLE STORAGE, PRESERVATION AND SHIPPING

The proper collection, storage and shipping of samples are all critical elements of the sampling process and can affect the analysis results. Steps must be taken early in the sampling process to avoid anything that could compromise the integrity of the sample, such as loss, contamination or tampering.

Ideally, samples should be analyzed as soon as possible after they are collected. In many situations, however, this may not be possible and consideration must then be given to assuring the integrity of the sample by utilizing proper storage, preservation and shipping methods.

STORAGE AND PRESERVATION

If samples must be stored temporarily, it is best to refrigerate or even freeze them to prevent deterioration of the sample and degradation of the chemical. Contact the supervisor or laboratory if in doubt about the specific requirements for storage of a particular kind of sample.

All samples should be stored in an insulated cooler to protect from extreme heat and cold during transit to the laboratory from the time of collection. In extremely hot conditions, it may be necessary to include ice inside the cooler in order to maintain the integrity of the sample. The inspector should read and follow the label statement for storing the samples under or over the listed temperatures.

Table 7-1 summarizes the general requirements for preserving various sample types during storage (i.e., field and laboratory) and shipping to the laboratory. Refer to the specific sample type in the "Sampling Procedures" section of Chapter 6 in this manual for additional information.

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TABLE 7-1: SAMPLE PRESERVATION

Sample Type	Container	Field	Storage	Ship
Foliage				
Discrete	РВ	С	F	DI
Grid	РВ	С	F	DI
Composite	РВ	С	F	DI
Dislodgeable	GJ	С	R	WI
Commodity (field, packed)	РВ	С	R	WI
Soil				
Discrete (surface)	GJ	С	F	DI
Discrete (known depth)	GJ	С	F	DI
Discrete (furrowed field)	GJ	С	F	DI
Grid	GJ	С	F	DI
Composite	GJ	С	F	DI
Sediment	GJ	С	F	DI
Water	GJ	WI	R	WI
Air	GJ	DI	F	DI
Animals, fish, birds, bees	GJ	С	F	DI
Surface		•		
Wipe	GJ	С	F	DI
Grid	GJ	С	F	DI
Clothing	РВ	С	F	DI
Tank-Mix	GJ	С	R	WI

NOTE: All sample containers are to be sealed in a plastic bag in the field.

- (C) Chill (wet Ice or freezer pack)
- (DI) Dry Ice
- (F) Freeze
- (GJ) Glass Jar/sealed in Plastic Bag
- (R) Refrigerate
- (PB) Sealed in Plastic Bag
- (WI) Wet Ice

SHIPPING PROCEDURES

Packaging and shipping samples must be done properly, using care to ensure that they remain intact when they arrive at the laboratory. Maintain the chain of custody. Pesticide formulation

samples must be packaged to avoid spillage, leakage or deterioration and the possibility of endangering the safety of persons or the environment. Ship samples in accordance with Department of Transportation (DOT) regulations. See Chapter 6, "Pesticide Product Sampling", for shipping information.

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CHAPTER EIGHT USE INSPECTIONS

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USE INSPECTIONS

STATUTORY AUTHORITY

FIFRA section 12(a)(2)(G) states, "it shall be unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling."

FIFRA section 2(ee) states that the phrase "to use any registered pesticide in a manner inconsistent with its labeling" means to use a pesticide in a manner not permitted by the labeling. For example, if an inspector finds a person using a pesticide outdoors that is labeled "for indoor use only," the person has used the pesticide "in a manner inconsistent with its labeling" in violation of FIFRA. FIFFRA Section 2(ee) does not include:

- Applying a pesticide at a rate, concentration or frequency less than specified on the labeling, unless the labeling specifically prohibits deviation from the specified rate, concentration or frequency.
- Applying a pesticide against any target pest not specified on the labeling if the
 application is to the crop, animal or site specified on the labeling, unless the
 Administrator has required that the labeling specifically state that the pesticide may be
 used only for the pests specified on the labeling after the Administrator has determined
 that the use of the pesticide against other pests would cause an unreasonable and
 adverse effect on the environment.
- Employing any method of application not prohibited by the labeling.
- Mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling.
- Any use of a pesticide in conformance with FIFRA sections 5 (Experimental Use Permits), 18 (Exemption of Federal or State Agencies — Emergency Exemption) or 24 (Authority of the States).
- Any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of the Act.

FIFRA section 26 authorizes primary enforcement responsibility to states for pesticide use violations. However, EPA retains pesticide use authority for the advertising related to 40 C.F.R. Part 168.22(b)(5) and Federal Register at 57 FR 19,174, May 28, 1986. See Chapter 4.

OBJECTIVES

The objectives of use inspections are to:

- Determine whether pesticides are being used in accordance with label instructions.
- Collect information about pesticide use and pesticide label and labeling materials.
- Determine compliance with Worker Protection Standards, if pesticides are used in an agricultural setting.

USE INSPECTIONS

In states without primacy, and on federal and tribal lands, EPA conducts (1) a routine inspection program and (2) for cause investigations of reported cases of misuse and suspected pesticide related incidents. Additionally, EPA conducts use inspections where: (1) states have waived their FIFRA section 26 authority; (2) states have not acted in a timely manner (FIFRA section 27); or (3) at the request of states or tribes.

Pesticide use inspections encompass a wide variety of circumstances and inspection sites. The primary focus of a use inspection is to determine whether pesticides are being used properly, in accordance with the pesticide label and applicable Worker Protection Standards. Pesticide use inspections include, but are not limited to, the following locations:

- Agricultural (commercial and private)
 - Field crops
 - Orchards/groves
 - Greenhouses/nurseries
 - Sod farms
 - o Forests
 - Vegetable and specialty crops
- Nonagricultural (commercial, public and not-for-hire)
 - Residential sites
 - Structures
 - o Rights-of-way
 - Aquatic environments

- Hospitals/nursing homes/clinics
- Veterinary sites
- Lawns, ornamentals and golf courses
- o Grain elevators
- Use inspections can be initiated at either the site of application or the applicator's place of business.

Pesticide use activities include storage, handling, mixing/loading, transportation, application and disposal. Use inspections may be performed during any use activity. Use inspections may also occur where pesticides have previously been applied, including inspections at the end of a growing season when the crops are being harvested.

HEALTH AND SAFETY DURING A USE INSPECTION

In addition to the requirements and recommendations contained in Chapter 2 on Health and Safety, at all times during use inspections, the inspector should be aware of biosecurity. See EPA's <u>biosecurity guidance</u> for guidelines to be followed when entering and exiting farms, ranches, etc.

INSPECTOR OBLIGATIONS AND PROCEDURES

Before beginning any federal use inspection, the owner, operator or agent in charge must be issued a written Notice of Use/Misuse Inspection (EPA Form 3540-25; see Exhibit 1-1). The Notice must include the reason for the inspection and whether the inspection is "for cause" or based on a "neutral inspection scheme". If the inspection is "for cause" the Notice must indicate the nature of the suspected violations. The Notice of Use/Misuse Inspection Form contains a "consent" statement that the inspector shall read to the person from whom consent is sought. The form also has a space for the person to sign to provide a written record of the authorization to enter and/or sample based on consent. See, Chapter 5, "Gaining Entry," for more information.

USE INSPECTION PROCEDURES

Collecting records that document pesticide use is an essential part of every use inspection. Inspectors should obtain records that contradict or corroborate statements regarding pesticide use. Evidence of any incidents or accidents concerning pesticide use should also be collected.

Records collected should be identified as exhibits and attached to the Inspection Report. See, Chapter 16, "Inspection Report and Supporting Documentation," for more information.

Specifically, FIFRA inspectors should gather the following information during a use inspection and then include the information in the Inspection Report:

- Person interviewed—Name, address and telephone number.
- Applicator—Name, address, telephone number and certification number.
- **Site of application**—Name, address, telephone number; type of business (hospital, aerial applicator, golf course, etc.); crop; area or object treated; target pest; date and time of application; weather at time of application; and any other relevant information.
- **Pesticide applied**—Brand name, EPA Registration Number, EPA Establishment Number, batch number, classification (i.e., general or restricted use) and type of formulation.
- Rate of application—Method of application, dilution rate, diluted material applied per unit and actual active per unit.
- Samples collected Physical samples can be taken of formulation, diluted material and residue. It is essential to collect documentary samples as well as physical samples when misuse is suspected. Collect a physical sample of the product if a problem is suspected with product chemistry or where misuse is suspected. Samples may also be collected to substantiate that pesticides were properly mixed and applied. The inspector must give the owner, operator, applicator or agent in charge of the establishment a copy of the completed and signed Receipt for Pesticide Use/Misuse Samples (EPA Form 3540-26; see Exhibit 1-1). For specific sampling procedures, see Chapters 6 "Pesticide Product Sampling" and Chapter 7 "Residue and Environmental Sampling." Types of samples:
 - O **Documentary evidence:** Collect documentary evidence when a physical sample of the product is not necessary or available, including those circumstances where no problem with the chemistry of the pesticide is suspected. Documentary evidence consists of anything other than a physical sample (e.g., bin labels or photographs of labels or labeling, advertising, invoices, shipping records or bills of lading, etc.). When collecting a bin label, the inspector must obtain a statement by a company representative that the bin label is/was identical to the label on the product that was sold or distributed as per the sales records.

Physical samples:

 Formulation samples—If the user is obtaining unusual or adverse results from the use of a product and his/her use is in accordance with label directions, collect a sample of the commercially packaged pesticide to

- determine whether it was mis-formulated, contaminated or adulterated. Also collect a formulation sample for each use dilution to verify that problems associated with the use dilution are not related to the pesticide itself. Make a reasonable effort to collect a sample at the user and/or dealer/distributor level. If it is necessary to obtain a sample from a previously opened container, obtain a statement from the user that the product has not been altered (see Chapters 6 and 7 on formulation sampling).
- **Diluted material**—Sample pesticides that are diluted or mixed for use at the user level whenever there is reason to believe that the pesticides may have been diluted or mixed in a manner inconsistent with the label. NOTE: Dilution samples may also be used to show that the diluted pesticide was consistent with the label directions, however, it is best to reserve use of these samples for when it is believed that mixing differs from the label directions or an improper pesticide was selected – since they are often difficult to collect and preserve. Obtain a copy of the registered product's pesticide label to accompany the sample of diluted material. If a photograph of the label and/or an identical label copy cannot be obtained to accompany the sample, hand write the pertinent portions of the label (ingredient statement and applicable dilution/mixing directions) and include them with the sample. If not observed first hand, obtain a statement and/or record copy from the user telling how the material was diluted and mixed. Because the dilution rate may vary with the specifications of the application equipment used, obtain information regarding the type of application equipment used and its calibration. If the pesticide is being applied in accordance with FIFRA section 2(ee) recommendations, document the source of those recommendations with a copy of the recommendations and/or a statement from the applicator.
- Residue samples—Residue samples are obtained to determine the residual presence of pesticides on articles. These may include plant materials, animal tissues, soil, drinking water, surfaces, air, runoff water and other inanimate materials. Collect a residue sample when there is reason to believe that a pesticide may have been misapplied.
- Were the labeling instructions followed?—Include a thorough review of the label(s) encountered and documentation that the pesticide(s) was/were used as specified by the label. Individual pesticide labels vary greatly, so it is critical that the inspector carefully document the correct label(s) involved and how the various use directions were

followed. Specific areas of pesticide use to be addressed should include but are not limited to the following areas:

- Target pest
- Method and rate of application
- Re-entry interval
- Crop, area, or object treated
- Applicator certification
- Disposal (rinsate/containers)
- Mixing/loading instructions
- Diluent/additives
- Worker Protection Standards
- Protective clothing and equipment
- Precautionary statements
- Environmental precautions
- Transportation/storage
- Pre-harvest intervals
- Spray intervals or application intervals
- Classification
- Relevant weather restrictions
- Endangered species protection restrictions
- Groundwater protection restrictions
- Records Review—Review records required to be maintained under federal and/or state regulations, and obtain copies. Determine what records are being maintained by the applicator/firm, review pertinent records and document the pesticide application in question. Pesticide application records for adjoining properties and field history(s) can be used to document pesticide drift. Request a copy of any record that may substantiate violations. Under federal law, applicators are only required to keep records for restricted use pesticide (RUP) use. However, state requirements may specify that all pesticide applicator records be maintained by the applicator.

- Storage Facility Conditions—Take note of the types of pesticides in storage (i.e., restricted, canceled, suspended). Inspect the storage area and take note of: (1) any leaking containers; (2) the security of restricted use pesticides; and (3) the proper segregation of pesticide types (for example, rodenticides should be segregated from other pesticides).
- Worker Protection Standard (agricultural use only)—The applicability of the Worker
 Protection Standard should be determined. The regulation governing the Worker
 Protection Standard is found at 40 C.F.R. Part 170. Inspectors may use the EPA Worker
 Protection Inspection Guidance and the EPA Worker Protection Field Inspection Pocket
 Guide. Address the following items during the inspection if the Worker Protection
 Standard applies:
 - Information at the central location
 - Application records
 - Pesticide safety training
 - Decontamination supplies
 - Notice of application and posting of application
 - o Early entry requirements
 - o Emergency assistance procedures

The Use Investigation Report (EPA Form 3540-20; see Exhibit 1-1) or equivalent may be used to assist the inspector in documenting use information.

DISCUSSIONS WITH OWNER/OPERATOR/APPLICATOR OR AGENT IN CHARGE OF PROPERTY

Inspectors should discuss proper pesticide use with the owner/operator, applicator or agent in charge, such as: (1) the existence and purpose of FIFRA; (2) the importance of following label directions; and (3) the need to use pesticides safely, so as to protect human health and the environment by observing all label precautions during all phases of use, including mixing, application, storage, and disposal. If any problems or discrepancies noted during the inspection require immediate corrective action, these problems should be brought to the attention of the applicator or owner/operator so that immediate corrective action may be taken.

The inspector should note in the Inspection Report what was discussed and any voluntary corrective actions. FIFRA inspectors should also report any problems and discrepancies to EPA

and should not discuss potential civil or criminal action that EPA may take to address misuse violations with the owner/operator or pesticide applicator.

INSTRUCTIONS FOR CONDUCTING FOR CAUSE USE INSPECTIONS

EPA may conduct a "for cause" pesticide use inspection in response to suspected pesticide misuse incidents or Worker Protection Standard violations to develop the necessary evidence to support a civil or criminal FIFRA enforcement action.

In a "for cause" use inspection, the inspector may be required to visit a number of sites, interview various persons, and collect a number of pesticide samples. The inspector investigating a case of alleged misuse is trying to find and document answers to a number of specific questions. Typical persons that may be questioned include, but are not limited to the following:

- Complainants (i.e., the person who complained of an incident, such as pesticide exposure, drift, injury)
- Physicians/veterinarians
- Pesticide applicators
- Pest control operators
- Pesticide dealers/distributors
- Eye witnesses
- Other federal, state and/or local agencies
- Cooperative Extension operators
- Other experts
- Property owners
- Agricultural employers/employees

INSPECTOR OBLIGATIONS AND PROCEDURES

Due to the potential for harm to humans and the environment posed by pesticide misuse and the need to be responsive to public concern, it is important that the inspector initiate "for cause" inspections as soon as possible. Time is of the essence; the chances of finding pesticide residues in environmental samples can decrease over time.

- The Notice of Inspection For Use/Misuse inspections use EPA Form 3540-25, see Exhibit 1-1.
- Interview complainant, witnesses, applicator and other parties involved. Take statement(s) using EPA Form 3540-42, see Exhibit 1-1.
- Thoroughly collect and document evidence pertaining to the pesticide use including, but not limited to:
 - o Photographs, originals or copies of labels and labeling for pesticides used.
 - Photographs or video tapes showing actual pesticide misuse and/or damage caused by an alleged misuse.
 - Application records and central location information (if involving WPS—refer to WPS guidance).
 - o Copies of the applicator certification documents.
 - Statements from the property owner, applicator, owner/operator or witnesses that can attest to the relevant circumstances.
 - Statements from physicians or copies of medical records (may require a medical release).
 - Copies of any available investigation reports completed by other agencies or companies such as state or local agencies or insurance companies.
 - o Sketches, diagrams or maps of the area treated and surrounding properties.
 - o Samples (physical or documentary).
 - Written recommendations (advisor, consultants, USDA/Cooperative Extension Service bulletins, etc.).
 - o State and/or locally required permits and/or notifications.
 - Weather records.
 - o Certification/licensing records.
 - Additional labeling (supplemental labels).
 - o Regulations/standards.
 - Work order or mix/load sheets.
 - Application records from application(s) to adjoining properties.
 - Employee records (WPS).

• Complete a narrative report of the investigation to include details of the inspection.

REPORTS

Write a narrative inspection report as soon as possible following the completion of the pesticide use/misuse inspection. At a minimum, an inspection report for a suspected use violation should include reference to all information gathered. Include what pesticide was used; where it was applied (site/crop/residential area, etc.); how it was applied (method, dilution rate, application rate, application equipment, safety equipment, etc.); weather conditions (if appropriate); who the suspected responsible party is; and when the pesticide was applied. In addition, include all other relevant information such as consequences of the application (drift, crop damage, illness or injury); explanation of samples, photographs and other evidence collected; and a description of any follow-up that may be warranted. Attach all completed forms and documents gathered during the course of the inspection to the narrative report as exhibits. See, Chapter 16, "Inspection Report and Supporting Documentation" for more information.

CHAPTER NINE ESTABLISHMENT INSPECTIONS

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ESTABLISHMENT INSPECTIONS

ESTABLISHMENT INSPECTION OBJECTIVES

The objectives of establishment inspections are to:

- Deter and reduce noncompliance by maintaining a strong, timely and active enforcement presence to achieve environmental and human health protection.
- Deter noncompliance by maintaining appropriate levels of compliance monitoring activity, particularly in noncompliant sectors of the regulated community.
- Identify those establishments where a pesticide, device or active ingredient used in producing an end-use pesticide is being produced, or locations where pesticides are being packaged, re-packaged, labeled or re-labeled, to monitor industry compliance with the registration requirements of producing establishments.
- Ensure industry compliance with product registration, formulation, packaging and labeling requirements prior to and during the distribution of pesticides and devices in the channels of trade; and detect and obtain samples of any unregistered, adulterated or misbranded pesticides or devices being distributed or sold.
- Ensure that restricted use pesticides (RUP) are distributed or sold in accordance with FIFRA.
- Ensure that books and records required by FIFRA and the implementing regulations are being prepared, maintained and/or submitted to the Agency, so that EPA can:
 - Identify areas of potential future harm to human health or the environment for purposes of possible suspension, cancellation or enforcement action;
 - Identify the responsible establishment in the event of a recall or stop sale order which may be issued to curtail any adverse effects to human health or the environment;
 - Increase the completeness and effectiveness of EPA recalls of suspended or canceled pesticides;
 - o Identify and locate violative batches of pesticides;
 - o Identify and locate shipments of violative pesticides and devices;
 - Determine compliance with requirements concerning disposal and storage of pesticides, pesticide containers and pesticide-related wastes (on the label/labeling of the product).
- Collect and develop evidence to support legal actions when violations of FIFRA are found at establishments that produce, distribute and sell pesticides or devices.

 Verify compliance with annual production reporting requirements of section 7 of FIFRA.

INSPECTION PROCEDURES

Establishment inspections may be conducted at a variety of facilities. For example, an establishment can be the facility of a registrant, pesticide formulator, bulk re-packager, toll manufacturer, importer, broker, shipper, dealer, retailer or distribution center. Note, if an establishment inspection concerns "Restricted Use Pesticides: Dealer and Applicator Records Inspections", also see Chapter 11. If an establishment inspection concerns "Pesticide/Device Import/Export Program", also see Chapter 12. Other information pertinent to establishment inspections can be found in Chapter 1, "General Information," Chapter 2, "Health and Safety," Chapter 5, "Gaining Entry", Chapter 16, "Inspection Reports and Supporting Documentation," Chapter 6, "Pesticide Product Sampling" and Chapter 7, "Residue and Environmental Samples".

SCOPE OF ESTABLISHMENT INSPECTIONS

The scope of the inspection will depend on the type of activities in which the establishment is engaged. For example, the scope of an inspection at a pesticide/device producing establishment will be broader than an inspection at a U. S. Customs and Border Protection (CBP) central examination site or CBP bonded warehouse holding a shipment of an imported pesticide/device. Establishments may be engaged in a combination of activities, including repackaging, bulk repackaging, retail sale of restricted use pesticides, retail sale of general use pesticides, custom blending, and/or commercial application. The inspector must be familiar with the regulatory requirements that pertain to the particular establishment.

The scope of an inspection, including the number and type of samples to be collected, may be based on the type of establishment and other inspection-specific information gathered during the pre-inspection preparation. Exhibits 9-1 through 9-5 may serve as guides for planning the scope of and completing an establishment inspection.

When collecting samples of pesticides or devices that have been packaged, labeled and released for shipment (PLRS), samples may include pesticides or devices produced by the establishment within the past two years and exists elsewhere in the channels of trade.

PRE-INSPECTION PREPARATION

The quality of an establishment inspection can be enhanced by conducting pre-inspection research to prepare for the inspection:

 Identify the name and address of the establishment and the products produced (by name and EPA Registration Number). Obtain a minimum of two years of data for all pesticide and device production from the EPA FIFRA Section Seven Tracking System (SSTS).

 Obtain copies of all labels, supplemental labels and confidential statements of formula (CSFs) for each pesticide produced at the establishment. Labels are publically available from OPP's Pesticide Product Labeling System (PPLS). The latest CSF provides information on the source(s) of the technical or manufacturing product(s) the establishment uses to produce the end-use product or other products that are produced at the establishment and are available from the product registration jacket at OPP.

NOTE: The CSF is CBI and cannot be provided to state or tribal inspectors.

- Review inspection history—state, tribal and EPA inspection files.
- Review enforcement history—state, tribal and EPA enforcement files, including any settlements, notices of warning or stop sale orders.
- Identify EPA Establishment Numbers assigned under section 7, if the site is (or was) a pesticide/device producing establishment, or the EPA company number assigned by EPA if the site is a registrant or manufacture of its registered pesticide products.

ENTRY AND OPENING CONFERENCE

See Chapter 5, "Gaining Entry." During the opening conference, the inspector must begin obtaining necessary information on the facility to complete the narrative portion of the establishment inspection report. Obtain copies of all documents discussed during the opening conference. This information includes, but is not limited to, the following:

- Confirm the proper business name, site address, mailing address and telephone number(s) of the establishment. If there is a related and/or parent company, include the proper business name(s), site address(es), mailing address(es) and telephone number(s) of all related firms.
- The names and titles of the principal officers, partners or owners of the establishment.
- The person(s) attending the opening conference (complete names, titles and telephone numbers of the responsible officials of the establishment present at the opening conference).
- The number of pesticides registered, produced, sold or distributed by the establishment (including the brand names and EPA Registration Number of the pesticides).¹

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¹ Though the Agency tracks pesticide registrations, the establishment may believe that they have "additional" pesticide products registered with EPA, when in actuality some registrations have been

- Supplemental or distributor registration agreements or contracts, contract manufacturing agreements, bulk repackaging agreements obtain copies of each.
- Authorizations and/or toll repackaging agreements with other businesses regulated under FIFRA.
- Guarantees provided by the establishment or to the establishment, pursuant to section 12(b)(1) of FIFRA.
- Records showing the pesticides distributed or sold by the establishment, sorted by
 product name, EPA Registration Number (manufacturing/batch codes or lot numbers,
 if present), and indicating the quantity and date of each sale or distribution. Note
 that FIFRA defines "distribute or sell" as "to distribute, sell, offer for sale, hold for
 distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for
 shipment, or receive and (having so received) deliver or offer to deliver.

NOTE: Sales and distribution records may be claimed as CBI and, if so, cannot be provided to state or tribal inspectors.

- Obtain records of pesticides/devices being imported, including the name and address of a contract import broker, if used to broker the product, as well as the name and address of the person the product is being imported to.
- Obtain records of consignees who received the pesticide/devices.
- Obtain records of any exported pesticides/devices including a copy of the Foreign Purchaser Acknowledgment Statement (FPAS) and other records.
- Record all manufacturing use product information, including the name of the product, the EPA Registration Number, EPA Establishment Number and the name and address on the label or container.

Note: Although EPA maintains some of this information in data bases and compliance files, inspectors should go over this information during the inspection to confirm the information that is on file with EPA.

CONDUCTING THE INSPECTION

LABEL REVIEW

Label reviews are used to determine compliance with the required elements identified in <u>40</u> <u>C.F.R. 156.10(a)</u>. The inspector should collect bin labels or photographs of pesticides or devices packaged, labeled and released for shipment (PLRS). PLRS pesticides or devices include those which may have been produced by the establishment within the past two years and exist elsewhere in the channels of trade. Compliance determinations based on the

suspended or canceled. The inspector should include this list in the inspection report, and note any discrepancies or differences between the establishment's records and EPA's records.

inspector's label review are the purview of the regional EPA enforcement team (case officer and attorney).

Elements of pesticide product labels:

- Name, brand name or trademark under which product is sold.
- The name and address of the producer, registrant, supplemental registrant, distributor or person for whom the pesticide is produced.
- Net contents.
- EPA Registration Number.
- EPA Establishment Number.
- Ingredient statement totaling 100% of ingredients (active ingredients must be listed by the percentage).
- Precautionary statement (i.e., "Caution," "Warning," "Danger," "Keep out of Reach of Children") as prescribed by 40 C.F.R 156, subpart D.
- Directions for use.
- Disclaimer statement.
- Worker protection directions—if applicable.
- Legibility and typeset (6 point or larger).
- If the use classification is "Restricted Use Pesticide," this statement must appear on the front panel of the pesticide product.
- Any suspected false or misleading statements as described in 40 C.F.R 156.10(a)(5).

If the pesticide product is for agricultural use and subject to the WPS requirements, the label must have the following required WPS statements:

- Specific worker protection statements—40 C.F.R 156, subpart K.
- Application restrictions.
- Product-type identification statements.
- Warning statements using an alternate language commonly spoken and read by workers.
- Restricted-entry statements.
- Personal protective equipment statements.
- Specific container labeling—40 C.F.R 156, subpart H.

NOTE: Copies of the "EPA accepted" label can be obtained from the Pesticide Product Labeling System (PPLS) at: http://www.epa.gov/pesticides/pestlabels. If PPLS does not

have the latest accepted label, the inspector and/or manager should obtain the label from the product registration file.

The inspector should document any pesticide labels which are damaged, obscured or illegible. All words, statements, graphic representations, designs or other information required on the label and labeling must be clearly legible to a person with normal vision and must be placed with such conspicuousness (as compared with other words, statements, designs or graphic matter on the label) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The location of the label on the pesticide product package is critical—for example, a label inside a box or beneath a dust cover does not meet the prominence and legibility requirement. Inspectors should document any labeling practices which do not make FIFRA labeling requirements prominent and legible.

When labeling is collected, the inspector should collect a statement from the establishment which states clearly that the label provided to the inspector is the identical label to the label attached to the pesticide/device for distribution and sale. If multiple labels exist for one product, the inspector should clarify which label was associated with which sales/distributions of the product.

Note that the Agency has the authority to take photographs of any pesticide or device being inspected that is labeled and released for shipment in lieu of or in addition to obtaining samples of bin labeling. Take a photograph of all relevant pesticide/device labels and containers. Should management object to the use of cameras in their establishment, the inspector should request that the material to be photographed be moved to a non-sensitive area of the establishment (such as the loading dock).

See Exhibit 9-4 for more information on conducting a label review for a producer establishment inspection.

EPA ESTABLISHMENT NUMBER AND EPA REGISTRATION NUMBER

The EPA Establishment Number (EPA Est. No.) is a facility identifier comprised of a company number, a <u>two letter state</u> or <u>three letter country code</u>, and a number indicating the order of the establishment registered in a given state or country. For example: EPA Est. No. 80156-NY-002 would indicate the second establishment registered for company number 80156, which is located in the State of New York.

In addition to labeling requirements at 40 C.F.R. Part 156, the establishment number must appear on the product label, or on the immediate container of the product. If the establishment number cannot be seen or clearly read through the wrapping or packaging, it must also appear on the outside container or wrapper of the product. (40 C.F.R 156.10(f)) The establishment number is often grouped together with the EPA Registration Number (EPA Reg. No.), but such placement is not required.

Devices must be produced in registered producing establishments and they must have an EPA Establishment Number on the device or the device's label; however, devices do not require an EPA Registration Number.

Producers may seek approval from the EPA Office of Enforcement and Compliance Assurance (OECA)—Office of Compliance (OC), Washington, D.C., 20460, for various techniques or formats for displaying the establishment number.

The following are examples of approved formats that may be adapted for use by pesticide producers:

```
EPA Est. No. 123-IN-1, 123-IN-2, 123-MA-1 or 
EPA Est. No. 123-IN-1, -2, -MA-1
```

Where an inspector encounters a label with multiple establishment numbers, the label must indicate which establishment was the producing establishment of the pesticide product or device. For example, a company (registrant number 123) that has three registered establishments (two in Indiana (IN) and one in Massachusetts (MA)), may print all three establishment numbers on the label or immediate container. However, the establishment where the product was produced must be clearly denoted, i.e., with a clear marking such as a saw-cut, notch, arrow or other similar indicator. It must be clear which EPA establishment produced the pesticide product or device.

A producer may add its own code number to identify the actual production site. A statement following the numbers tells the inspector where to look on the container for the actual producing establishment. For example,

```
"EPA Est. No. 123-IN-1 (a), 123-IN-2 (b), 123-MA-1 (c)
See the last letter on the bottom of the container for actual establishment."
```

BOOKS AND RECORDS

A books and records inspection is an integral part of every establishment inspection. See Exhibit 9-5. FIFRA section 8(b) authorizes the inspector to have access to and to copy (1) all records showing the delivery, movement or holding of any pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee, or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement or holding of the pesticide or device. Note: Any inspection with respect to any records and information shall not extend to financial data, sales data other than shipment data, pricing data, personnel data and research data (other than that for a registered pesticide or to a pesticide for which an application for registration has been filed).

An inspector should collect documentary evidence which is representative of how the firm maintains its records. This may include photographs and/or photocopies of records of receiving, production, distribution, sales, manufacturing, contract agreements, labeling, etc.

The inspector also should photograph products and their container packaging to support a books and records inspection. Typical records reviewed and collected include, but are not limited to:

- Pesticide sales and/or distribution records.
- Shipping records.
- Manifests.
- Invoices.
- Bills of lading.
- Any record that documents the product's production and movement in the channels
 of trade. This may include the product's name, EPA Registration Number. or other
 information identifying the product.

The inspector should make every effort to collect sufficient evidence of pesticide/device sale and/or distribution records for the products at the establishment. In many situations one year's worth of evidence may be sufficient. Many establishments keep records electronically, and can print out or provide pesticide/device sale and/or distribution records on a CD or portable USB (memory stick/thumb drive). FIFRA inspectors have the authority to review electronic records and to request that they be copied and presented in paper form. If paper copies of electronic records cannot be generated at the time of the inspection, the inspector must note on the Receipt for Samples and/or Statement form the records requested to be sent to EPA as a follow-up to the inspection. The inspector shall specify the date by which EPA should receive the requested records. Provide mailing instructions to the establishment.

CONFIDENTIAL BUSINESS INFORMATION

See Chapter 1, "General Information" and Chapter 16, "Inspection Reports and Supporting Documentation." Some records obtained during establishment inspections may be claimed as FIFRA confidential business information (CBI). If the owner, operator or agent in charge of the establishment declares certain records as FIFRA CBI, the inspector must follow the procedures in Chapter 1 of this Manual.

SAMPLING

See Chapter 6, "Pesticide Product Sampling." Prior to sampling:

- Determine if the owner or operator in charge wants duplicate samples.
- Make a stock survey of all the pesticides/devices in inventory and packaged, labeled and released for shipment into the channels of trade.

• Inspect all technical or manufacturing use chemicals or registered products, to obtain the evidence necessary to determine whether the claims made on the label are in compliance with FIFRA. Collect samples for chemistry analysis, as necessary.

During sampling:

- Collect physical samples only from pesticides/devices that are packaged, labeled and released for shipment.
- As an official sample, inspectors may collect "bin labels" for all pesticides/devices that
 the producing establishment is or may be producing or are held in inventory or that
 may have been produced by the establishment within the past two years and may
 exist elsewhere in the channels of trade.
- As an official sample for all pesticide products used in the manufacturing process, the
 inspector may collect a documentary sample of the product (photograph of the entire
 label and entire container). Collect records on how, where and from whom the
 establishment obtained each product.

RECEIPT FOR SAMPLES

FIFRA section 9(a)(2) requires the inspector to provide to the owner, operator or agent in charge of the establishment a receipt for any samples taken during the inspection, describing the samples obtained and, if requested, to provide a portion of each sample equal in volume or weight to the portion retained. If an analysis of the samples is made, a copy of the results must be provided. Carefully complete a Receipt for Samples (EPA Form 3540-3; Exhibit 1-1), clearly identifying each sample collected by:

- Sample number with subsample, if any. An example of a sample number consists of: (1) the date (mmddyy); (2) the inspector's credential number (3) the inspection sequence (including sample or subsample numbering (A, B, C, or 001, 002, 003)); (4) the inspector's initials. For example, 01/09/2012-17942-123-001-MP
 - o 123 = inspection sequence number
 - o 001 = sample or subsample number
 - o 17942 = inspector credential number
 - o 01/09/2012 = date
 - MP = inspector initials
- Quantity of pesticide/device collected from a total quantity of product in inventory.
- Brand name.
- EPA Registration Number.
- EPA Establishment Number.
- Active ingredient.

- Net content.
- Batch codes or lot number(s).
- Name of registrant, producer, supplemental registrant, distributor or person for whom the pesticide/device is produced.

The Receipt for Samples Form must be completed in its entirety, and signed by both an establishment representative and the inspector. A copy of the Receipt for Samples must be left with the owner, operator or agent in charge of the establishment.

STATEMENTS

It may be necessary to also obtain a statement during an inspection detailing any facts told to the inspector during the inspection which may be relevant to the inspection and/or documentation, samples, etc. For example, a statement may be a critical piece of evidence to establish that a collected label is identical to the label associated with documented sales. Use Statement Form 3540-42; Exhibit 1-1. The inspector should prepare the statement by printing or scripting very legibly, describing the facts (as heard) or any relevant points that were made to the inspector. Upon completion of the statement, the inspector should ask the owner/operator to read the statement and sign in the appropriate block. If the inspector has made an incorrect statement on the statement form, the inspector should ask the owner/operator to put a line through the statement and initial the location. If the owner/operator refuses to sign the statement, the inspector should note this fact on the statement form or in the operator's signature block and the inspector should initial that block and sign the form in the appropriate inspector signature block. The inspector should retain the original statement form and a leave copy with the owner/operator at the closing conference.

CLOSING CONFERENCE

Always hold a closing conference with the establishment representative(s). The conference can be used to:

- Clarify any outstanding issues found during the inspection.
- Identify any documentation that was not readily available during the inspection that
 may need to be collected and sent to the EPA-DCO. Items to be provided at a
 specified later date should also be listed on the Receipt for Samples Form, the
 statement form or both. A confirmation letter should also be sent to the
 establishment to reiterate the documents required and the due date for providing the
 documents.
- Answer any questions and address any concerns that the owner, operator or agent in charge of the establishment may have. The inspector must be careful to answer only those questions that are within his/her knowledge and expertise or direct the

establishment representative(s) to appropriate EPA regional personnel on those issues that cannot be readily answered.

• Avoid making any statements regarding compliance status or enforcement.

PREPARING THE INSPECTION REPORT

A narrative report or inspection report must be completed for each establishment inspected. The inspection report should be completed as soon as possible after the inspection. See Chapter 16, "Inspection Reports and Supporting Documentation."

MARKETPLACE ESTABLISHMENT INSPECTIONS

See Exhibit 9-3. In addition to the general objectives of an establishment inspection, the following objectives are relevant for marketplace inspections:

- To detect and obtain samples of any unregistered or misbranded pesticides or devices being sold, distributed or marketed to the public.
- To determine whether restricted-use pesticides are being sold in accordance with FIFRA.
- To review labeling, advertising material, as well as accompanying literature, and other claims to determine whether any false or misleading claims are being made for the product.
- To document and/or review the label and any accompanying literature to determine if the product is an unregistered pesticide or a misbranded pesticide or device.
- To obtain samples of products that were not available for sampling at the producer's establishment.
- To follow-up on recalls, stop sales, suspensions and cancellations.
- To obtain samples of products subject to deterioration.
- To determine whether supplementary FIFRA sections 18 or 24(c) labeling has been provided by registrant/producer.

ADDITIONAL INFORMATION FOR MARKETPLACE INSPECTIONS

Once lawful entry has been gained, the inspector should survey the pesticides and devices being offered for sale as follows:

- Review the labels and/or labeling.
- Inquire whether there are supplemental FIFRA section 18 or 24(c) labels and whether they are provided to those receiving the products. Obtain copies for review.
- If a violation is discovered, collect a sample to support findings.

- If the label violation is serious enough that it may create a hazard, the regional supervisor should be called immediately to discuss the advisability of placing a Stop Sale, Use, or Removal Order (SSURO) on the misbranded or unregistered product. (See Chapter 14, "Stop Sale, Use or Removal Orders" for instructions on issuing SSUROs.)
- If a cancelled or suspended product is encountered, this fact should be brought to the attention of the inspector's supervisor, who will determine the appropriate course of action.

Photographic evidence should be taken whenever appropriate and possible. Voluntary corrective actions should be noted in the inspection report.

WHEN TO CONDUCT MARKETPLACE INSPECTIONS

In general, marketplace inspections should be scheduled by seasonal demands. For example, during the growing season, feed, seed and fertilizer outlets are good sources of agricultural pesticide products. Spring and summer are good seasons to inspect for swimming pool and spa products. During the winter months, urban outlets could be surveyed for household pesticide products. Additionally, such inspections might be triggered at any time by a citizen complaint or tip.

PLACES TO INSPECT

An inspector must always remain alert to the distribution pattern of pesticides/devices in his/her area. Both wholesale and retail distributors should be kept under surveillance to be sure that only registered and properly labeled pesticides and devices are being sold. The following lists some suggested distribution points for inspecting pesticides and devices:

- Animal health and veterinarian suppliers.
- Veterinarians.
- Hardware stores.
- Barber and beauty supply dealers.
- Chemical suppliers.
- Dairy equipment supply dealers.
- Medical and dental suppliers.
- Feed, seed and fertilizer dealers.
- Hotel and restaurant suppliers.
- Janitorial supply dealers.
- · Paint dealers.

- Pest control operations.
- Swimming pool, spa and waterbed dealers.
- Retail and wholesale grocers.
- Lawn and garden supply dealers.
- Retail outlets, including "big box stores."

Additional leads to new sources of unregistered pesticides include the following:

- Dealers (question dealer regarding others in the same business).
- Local newspaper advertisements.
- Trade journals.
- Yellow Pages telephone directories.
- Information from state officials.
- E-commerce (internet samples).
- Pool shooters (see below).

Note: Antimicrobials, treated articles, pet products, swimming pool and pond products, paints, etc., are excellent products for review in addition to typical farm, home, and garden pesticides.

WHAT IS A "POOL SHOOTER"?

A "pool shooter" is an individual or company who, as part of its business, obtains large bulk quantities of swimming pool chemicals to treat residential and commercial pools. Pool shooters fill their application equipment from bulk container(s) of pesticide, and then apply the pesticide directly to pools or into dispensing or metering equipment for later use by pool staff. In this instance the container on the vehicle of the pool company vehicle is known as a "service container." Inspectors that encounter pool shooters should pay special attention to container/containment regulations, proper handling and use, and pesticide label directions to ensure that the chemicals are being used properly and that the pesticides used are labeled properly and registered for use in pools. It should also be noted that although the pool shooter is not considered a producing establishment, if the pool shooter obtains its swimming pool chemicals by a bulk delivery to its facility or by having its own tank truck or other bulk container filled at a distributor facility, the facility from which it obtains its product must be registered as an EPA pesticide producing establishment and must comply with the FIFRA section 7 reporting requirements for this bulk repackaging/product transfer activity. Inspectors should verify the registered status of the pool shooter supplier facility.

PESTICIDE PRODUCT REVIEW

- Note any products requiring child resistant packaging (CRP). CRP requirements are found at 40 C.F.R. Part 157. Whether a particular pesticide must comply with these requirements is determined at registration. The inspector needs to determine if the registration requires compliance with CRP. If the registration requires compliance with CRP, the inspector should check for proper packaging.
- Note and document any canceled/suspended pesticides.
- Observe products for leaking containers.
- Note security/safety of restricted use pesticides in storage.

SHIPPING RECORDS

Inspectors should follow the same procedures for marketplace inspections as for establishment inspections, and should collect pesticide/device sale and/or distribution records, including shipping records, manifests and invoices, to document movement in the channels of trade. Document the product back to the distributor and/or producer of the product. Make every effort to document sufficient (one year) sales and distribution records for each suspected violative product. If only computer generated records are available, these should be collected by the inspector. If actual records are unavailable, document this fact in a statement form signed by the agent-in-charge with an explanation of where the records are and how they can be obtained. Clearly convey the nature of records, the time frame of records and deadlines by which the records must be provided.

In some large chain stores or big-box stores, it may be difficult to obtain records. However, records linking the product back to a distribution center may still be obtained. If the distribution location is not within the region or state, the inspector may need to work closely with an inspector in the other region or state to have that inspector obtain the needed records, tracking back to the production of the product. Ensure that this is documented completely in the inspection report and also in the field notebook.

Once the inspector has obtained records linking the product back to a distribution center, it is then necessary to go to the distribution center to obtain documentation linking the product back to the producing establishment. This may require cooperation with other regions or other states.

BULK REPACKAGER INSPECTIONS

With the growing trend for pesticides to be shipped and held in bulk quantities, inspectors may inspect establishments that handle bulk pesticides. Most bulk establishments handle agricultural herbicides; however, other industries use bulk quantities of chemicals such as sodium hypochlorite and quaternary ammonium disinfectants. In some cases (certain herbicides) a bulk amount could be a very small quantity. In addition to the general

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objectives of an establishment inspection, the following objectives are relevant for bulk repackager inspections:

- Ensure industry awareness of its obligations for packaging, labeling and recordkeeping.
- Document any potential violations.
- Verify evidence necessary to determine compliance with the container/containment regulations.
- Verify evidence necessary to determine compliance with annual production reporting requirements of section 7 of FIFRA.

If the facility receives bulk quantities of pesticides intended to be dispensed into a customer's spray tank for subsequent use, the inspection should proceed as a marketplace inspection. If the facility receives pesticides in bulk quantities (under contract to the basic registrant) and subsequently repackages the product (without alteration) into other labeled tanks for the purpose of distribution, the inspection should proceed as a producer establishment inspection.

Particular items to check at a bulk site include, but may not be limited to, the following:

- Labels on all bulk storage tanks.
- If the firm is repackaging, verify that there is a manufacturing contract between the firm and the basic registrant that authorizes the firm to repackage the product. Obtain a copy of this record.
- Conduct a label review in accordance with Exhibit 9-4.
- Take samples, as appropriate, in accordance with established procedures in Chapter
 6.
- Review sales invoices to verify if transfer is occurring in bulk quantities.
- If any production activities are taking place (i.e., labeling, relabeling, packaging, repackaging, producing, or otherwise changing the container of the pesticide or device) verify that the establishment is registered with EPA and that production reports are accurate.

For berms, pads, and other containment structures:

- Ascertain whether there is information on the construction of the containment(s).
- Check, observe and note in the inspection report the conditions of containment(s). Document any problems with containment(s).
- Conduct a capacity verification for each containment to ensure that it meets the capacity and the regulations at 40 C.F.R. 165.

For containers:

- Visually inspect containers.
- Obtain records for the testing of each refillable container and each container's specific identifying number.
- Obtain records for cleaning and residue removal of each container prior to refilling.
- Obtain records of any containers removed from service.
- Labeling of containers—Does the registrant of the product provide the refiller/repackager with container labels for each product produced/refilled?
- The Compliance Strategy for Containers and Containment, the Pesticide Container Inspection Checklist and Pesticide Container-Containment Inspection Checklist

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EXHIBIT 9-1: PRODUCER ESTABLISHMENT INSPECTION CHECKLIST

May be used as an inspection tool.

Firm Inspected:
EPA Establishment Number:
Authorized Representative:
Address:
City: State: Zip:
Telephone Number:
Credentials Presented:
Notice of Inspection Issued:
Reason for Inspection:
/iolation Suspected:
Names, Titles and Telephone Numbers of Principal Officers, Partners or Owners:
Related Firms and Addresses of Said Companies:
DESTIGIDE (DEVISE LABEL LABELING AND DAGVACING INSPECTION
PESTICIDE/DEVICE LABEL, LABELING AND PACKAGING INSPECTION
Pesticides Packaged, Labeled and Released for Shipment/FIFRA section 9(a)
L. Brand Name(s):
2. EPA Registration Number(s):
B. Label and Labeling Review/40 C.F.R. 156:

	d-Resistant Packaging Requirements for Each Pesticide Product Packaged, Labeled and ased For Shipment/40 C.F.R. 157
1.	Criteria Requiring Child-Resistant Packaging:
2.	Unit Packaging:
REC	CORDS RETENTION REQUIREMENTS FOR PESTICIDE PRODUCTION
Reco	ords of Production of Pesticides/40 C.F.R. 169.2(a)
1.	Brand Name:
2.	EPA Registration Number/Experimental-Use Permit Number:
3.	Amounts Produced per Batch:*
4.	Batch Identification:
5.	Length of Retention of Records:
Reco	ords of Production of Devices/40 C.F.R. 169.2(b)
1.	Brand Name:
2.	Quantities of Device(s) Produced:*
Reco	ords of Receipt of Pesticides, Devices and Active Ingredients/40 C.F.R. 169.2(c)
1.	Brand Name of Pesticide, Device or Common or Chemical Name of Active Ingredient:
2.	Name and Address of Shipper:
3.	Name of Delivering Carrier:
4.	Date Received by Establishment:
5.	Quantities Received:
6.	Retention of Records:
Reco	ords of Shipment of Pesticides and Active Ingredient/40 C.F.R. 169.2(d)
1.	Brand Name of Pesticide, or Common or Chemical Name of Active Ingredient:
2	Name and Address of Consigned:

3.	Where the Pesticide Under a FIFRA Section 5 Permit, Section 18 Exemption or section
	24(c) Registration is/was Produced:
4.	Name of Originating Carrier:
5.	Date Shipped or Delivered for Shipment:
6.	Quantities Shipped or Delivered for Shipment:
7.	Retention of Records:
Othe	er Records/40 C.F.R. 169.2
1.	Inventory Records:
2.	Copies of All Domestic Advertising of the Restricted Uses of Any Pesticide Registered
	for Restricted Use:
	Retention of Records:
3.	Copies of Guarantees Given Pursuant to FIFRA section 12(b)(1):
	Retention of Records:
4.	Records on the Method of Disposal, Dates of Disposal, Location of the Disposal
	Site(s), and the Types and Amounts of Pesticides, Device or Active Ingredients
	Disposed of by the Producer/Contractor:
5.	FIFRA Records:
J .	Retention of Records:
	Neterition of Necords.
6.	RCRA Records:
Reco	ords Retention Requirements of Child Resistant Packaging/40 C.F.R. 157.36
1.	Description of the Packaging for Each Registration:
2.	Certification Statement for Each Registration:
3.	Test Data Verification of Child Resistance for Each Registration:
4.	Records Verifying that the Packaging Meets the Compatibility and Durability
	Standards:

Records Requirements under the Pesticide Export Policy/40 C.F.R. 168, Subpart D

1.	Confidential Statement of Formula for Pesticides Not Registered Under FIFRA:*
2.	Specifications or Directions of the Foreign Purchaser:
3.	Bilingual Labeling and Other Required Labeling:
4.	Foreign Purchaser Acknowledgment Statements:
5.	Establishment/Foreign Purchaser Contracts:
REC	ORDS REPORTING REQUIREMENTS FOR REGISTRANTS/ PESTICIDE
<u>PRC</u>	DDUCING ESTABLISHMENTS
1.	Application for Amended Registration/40 C.F.R. 152.44:
2.	Modifications to Registration Not Requiring Amended Applications/40 C.F.R. 152.46:
3.	Currency of Address of Record and Authorized Agent/40 C.F.R. 152.122:
4.	Submission of Information Pertaining to Adverse Effects/FIFRA section 6(a)(2), 40
	C.F.R. 152.125, and 153, Subpart D:
5.	Supplemental Distribution/40 C.F.R. 152.132:
6.	Transfer of Registration(s)/40 C.F.R. 152.135:
7.	Initial Production Reports/Section 7(c) and 40 C.F.R. 167:*
8.	Annual Production Reports / Section 7(c) and 40 C.F.R. 167:
9.	Notification of Stored Pesticides With Canceled or Suspended Registrations/FIFRA
	section 6(g):
<u>POL</u>	ICY ON BULK PESTICIDE REPACKAGING
1.	Bulk Repackaging/Contract Bulk Repackaging Agreements:
2.	Complete End-Use Labeling/Bulk Containers:
3.	Complete End-Use Labeling/Mini-Bulk Containers:
ADI	DITIONAL INFORMATION
1.	Private Labeling by a Contractor:
2.	Private Labeling Under Contract for Another Registrant/Distributor:
3.	Contract Manufacturing Agreements:

TECHNICAL OR MANUFACTURING USE PESTICIDES OR CHEMICALS

- 1. Ensure that products that require registration have the appropriate EPA Registration Number, EPA Establishment Number and proper labeling.
- 2. Collect invoices, shipping records, bills of lading manifests, and common carrier records that pertain to each technical or manufacturing use product.
- 3. Collect any contract manufacturing agreements where the establishment is producing a pesticide from another firm, etc. (e.g., supplemental distributor, supplementally registered product, distributor product).

(*) – Note – This is CBI information which can only be viewed by federal inspectors.

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EXHIBIT 9-2: MARKETPLACE INSPECTION CHECKLIST

May be used as an inspection tool

Firm Ins	spected	:
Authori	ized Rep	presentative:
Address	s:	
City:		State: Zip:
Telepho	one Nun	nber:
Creden	tials Pre	sented:
Notice	of Inspe	ction Issued:
Reason	for Insp	pection:
Violatio	n Suspe	ected:
•	Names	, Titles and Telephone Numbers of Principal Officers, Partners or Owners:
•	Related	d Firms and Site Addresses of Said Companies:
PESTI	CIDE L	ABEL, DEVICE LABEL, LABELING, AND PACKAGING INSPECTION
Pesticio	des Pack	taged, Labeled and Released for Shipment/FIFRA section 9(a)
	1.	Brand Name(s):
	2.	EPA Registration Number(s):
	3.	Label and Labeling Review/40 C.F.R. 156:
Child-R	esistant	Packaging Requirements for Each Pesticide Product Packaged, Labeled and
Distribu	uted-Sol	l d /40 C.F.R. 157
	1.	Criteria Requiring Child-Resistant Packaging:

2.	Unit Packaging:					
Records of	Records of Shipment of Pesticides, Devices and Active Ingredients/40 C.F.R. 169.3					
1.	Brand Name of Pesticide or Device:					
2.	Name of Originating Carrier:					
3.	Date Shipped or Delivered for Shipment:					
4.	Quantities Shipped or Delivered for Shipment:					
5.	Bill of Lading, shipping records, invoices, etc.:					
Other Reco	rds					
1.	Copies of All Domestic Advertising of Pesticide/40 C.F.R. 168.22:					
2	Conject of Guarantees Given Pursuant to EIERA section 12(h)(1):					

EXHIBIT 9-3: FORMAT FOR ANY ESTABLISHMENT INSPECTION REPORT

Report on Establishment Inspection to Determine Compliance with FIFRA

Establishment Name
Street Address
[Mailing Address if different]
City, State Zip Code

Date of Inspection Month Day, Year

Performed by:
U.S. Environmental Protection Agency
Office/Division/Branch
Address
City, State Zip Code
FIFRA Establishment Inspection Report
[Inspection No. 01FIFRA ___]

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I. Company Information

- A. Company Name
- B. Establishment Registration Number
- C. Responsible Official
- D. Type of Ownership

II. Date of Inspection

III. Participants

- A. Company
- B. U.S. EPA/State

IV. Objectives

To inspect/investigate ... the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

V. Company Background

VI. Inspection Summary

- A. Opening Conference
- B. Inspection Observations and Sample Collection
- C. Closing Conference

VII. Attachments

- A. Establishment Inspection Report Form
- B. FIFRA Notice of Inspection
- C. FIFRA Receipt for Samples
- D. EPA Chain of Custody
- E. Statements
- F. Labeling
- G. Sample Reports of Analysis
- H. Photographs
- I. Diagrams

(Inspector's Signature)

(Date)

(Inspector's Name)

(Title)

EPA region, state or tribal affiliation

EXHIBIT 9-4: CONDUCTING THE LABELING REVIEW FOR PRODUCER ESTABLISHMENT INSPECTIONS

When conducting a producer establishment inspection, a *word-for-word* comparison with the registered label, when available, should be made of all labels being reviewed. The inspector should ascertain compliance with all stipulations of the letter of acceptance.

The inspector may perform label comparisons to "bin" labels. Official samples may only be collected from the products that are packaged, labeled and released for shipment. However, a "bin" labeling review can provide a valuable background for follow-up sampling at consignees and obtaining voluntary corrective action at the producer level. Copies of all "bin labels" should be collected as documentary evidence ("DOC") and identified on the Receipt for Samples Form. Additionally, a Statement Form (EPA Form 3540-42), signed by the company official, should be obtained to link the "bin label" to the actual labeled product or specific batches of product previously produced, sold or distributed.

Establishment Inspections (Marketplace, Producer, Dealer, Bulk Facility, etc.)

When conducting a basic label review, the inspector should be aware of labeling requirements and be alert for products that may be violative. The following paragraphs list some of the things an inspector should be aware of:

Product name, brand or trademark.

Name of manufacturer, registrant or person for whom manufactured—If the product is not produced by the registrant, the name must be qualified by "packed for...," "distributed by...," "sold by...," or a similar statement.

EPA Registration Number—The EPA Registration Number may be listed as "EPA Registration No. XXXX-XX," "EPA Reg. No. XXXX-XX," or "EPA Reg. No. XXXX-XX-YYYY." (The "YYYY" is the supplemental registrant's company number.)

EPA Establishment Number—The EPA Establishment Number may appear in any location on the label or immediate container; however, it must appear on the outside container or wrapper of the package if the EPA Establishment Number on the immediate container cannot be clearly read through the outside wrapper or container. It must be listed as "EPA Est. XXXX-(state abbreviation)-XXX," or "EPA EST NO. XXXX (state abbreviation)-XXX"; EPA Est. XXXX-XXX (foreign abbreviation).

Net content statement—The net contents must be given in units commonly used in the United States (i.e., pounds, ounces, pints, quarts, gallons). Metric units may also be listed. Liquid units must be used if the product is liquid and weight units must be used if the product is solid, semisolid or viscous. Contents must be expressed in terms of the largest unit present.

Ingredient statement—The ingredient statement usually appears on the front panel. The names used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. Ingredients should total 100%. The common name may be used alone if it is well known.

NOTE: The ingredient statements for products containing arsenic must have a substatement giving the percentage of total and water-soluble arsenic, each calculated as elemental arsenic.

Warning or citation statements—The signal words, "Danger," "Warning" or "Caution" and the statement "KEEP OUT OF THE REACH OF CHILDREN" must appear on the front panel of the label. Any substances in quantities highly toxic to humans must bear <u>all</u> of the following on the label: (1) a skull and crossbones; (2) the word "POISON" in red on a contrasting background; and (3) a statement of practical treatment. In addition, the label must contain precautionary statements necessary to prevent injury to humans and the environment.

Directions for use—Directions for using the product must include the following: (1) the site of application; (2) the rate of application; (3) instructions for frequency and timing applications; (4) restrictions and warnings; (5) any other pertinent information necessary for the protection of the public; and (6) target pest.

Legibility of labeling—Product labeling must be clearly legible and easy to read by a person with normal vision. All required label or labeling text shall appear in the English language.

However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text is necessary, all labeling requirements will be applied equally to both the English and other language versions of the labeling.

Statement of use classification—All restricted use products (RUPs) must have the RUP statement on the top center of the label.

If a review of "bin" labels, for which there is no product packaged, labeled, and released for shipment, reveals a discrepancy, it should be brought to the attention of the producer establishment management. Names and addresses of the consignees of the misbranded product should be obtained to follow up the investigation and collect samples of the product.

The inspector should collect labels, samples, and take photographs of all products found with potential violations. The inspector should exercise care in obtaining the proper shipping records such as the sale and distribution records associated with the actual or potential labeling violations.

If the inspector discovers a serious violation that may require immediate action, he/she should call his/her EPA supervisor while still in the vicinity of the establishment to determine what follow-up might be necessary to address the violation.

Accompanying labeling—Copies of accompanying labeling initialed and dated by a responsible company representative should be collected and documented.

When violative labeling is collected, it should be documented with a statement signed by a responsible individual of the firm, which clearly states that relationship of the labeling to the goods including the following:

Description of labeling—Describe briefly each piece of literature by name and also the manner in which the literature was received. State the quantity of such labeling on hand.

Location of labeling—Report the location of each piece of literature and how much each is on hand.

Methods of distribution—Determine how the labeling is distributed (i.e., accompanied product, shipped under separate cover).

Source of Labeling—Was the labeling sent to the dealer by the shipper of the product or was it prepared by the dealer? If received from the shipper of the product, document the shipment of the labeling. If prepared by the dealer, determine whether the producer provided the test.

Instructions to dealer—The manufacturer or shipper sometimes provides sales promotion instructions to the dealer. Obtain copies of such instructions, if available, as well as any verbal instructions on how to use them.

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EXHIBIT 9-5: BOOKS AND RECORDS MAINTENANCE AND RETENTION—PRODUCER ESTABLISHMENT INSPECTION

Establishment:	Inspection Date:	

	De courd a /De course contra	40 C E D	Maintained?		Retention
	Records/Documents	40 C.F.R.	Yes	No	Period
1.	Pesticide Production (batch)	169.2(a)			2 years
	a. Product name				
	b. EPA reg. no. or EUP no.				
	c. Amount per batch & batch identification number				
2.	Device Production	169.2(b)			2 years
	a. Brand name				
	b. Quantity produced				
3.	Receiving	169.2(c)			2 years
	a. Brand name of the pesticide or device, or common or				
	chemical name of the active ingredient				
	b. Name and address of shipper				
	c. Name of delivering carrier				
	d. Date received				
	e. Quantities received				_
4.	11 0	169.2(d)			2 years
	a. Brand name of the pesticide or device, or common or				
	chemical name of the active ingredient				
	b. Name and address of consignee				
	c. Where the pesticide is produced under an EUP,				
	special exemption or special local need				
	d. Name of originating carrier				
	e. Date shipped or delivered for shipmentf. Quantities shipped or delivered for shipment				
5.		169.2(e)			replace by
٥.	Inventory a. Types and amounts of pesticide or active ingredients	109.2(e)			•
	b. Quantities of device in stock				current
	b. Quantities of device in stock				inventory
6.	Advertising for RUPs	169.2(f)	1		2 years
	a. Copies of all domestic advertising for RUPs to include	, ,			,
	any advertising the producer has prepared, including				
	any radio or TV scripts for such products				
7.	Guarantee	169.2(g)			1 year after
	a. Copies of all guarantees given pursuant to FIFRA				expiration
	§12(a)(2)(C)				27.10.1.011

8. Exp	ort	169.2(h)	2 years
	 a. Copies of the specification or directions for the foreign purchaser for production of pesticide, device or active ingredient b. Copies of product labels and labeling c. Copies of signed foreign purchase acknowledgement statements d. Copies of instructions provided to foreign purchasers e. Copies of exporter certification f. Identity of coded research products 	168.75(c)(3) 168.85(a)	after expiration of contract
9. Dis	a. Method of disposal b. Dates of disposal c. Location of disposal sites d. Types of pesticides and active ingredient disposed of e. Pesticide container statement f. Deviation from normal practice	169.2(i)	20 years ²
10. Tes	ts on Humans a. Names and addresses of subject tested b. Dates and types c. Written consent of subjects to test d. Information and instructions given subjects e. Adverse effects	169.2(j)	20 years
11. Res	earch Data a. All raw data, interpretations, evaluations and reports supporting a product registration or tolerance petition	169.2(k)	Permanent while registration is valid & producer is in business
12. Chi	d Safe Packaging a. Description of packaging b. Certification statements c. Test data verification d. Verification of compatibility & durability of package	157.36	as long as registration is in effect

Inspector Signature:	Date:	

Comments:

 $^{^{\}rm 2}$ May be sent to EPA for maintenance after 3 years

CHAPTER TEN EXPERIMENTAL USE PERMIT INSPECTIONS

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EXPERIMENTAL USE PERMIT INSPECTIONS

AUTHORITY

FIFRA section 12(a)(2)(H) makes it unlawful for any person to use any pesticide that is under an experimental use permit (EUP) contrary to the provisions of such permit.

FIFRA section 5 authorizes the Administrator to grant an application for a EUP when it has been determined that the applicant needs such a permit in order to accumulate information necessary to register a pesticide. Regulations governing EUPs are found in 40 C.F.R. Part 172.

FIFRA section 5(c) states that use of a pesticide under an EUP shall be under the supervision of the Administrator and subject to the terms, conditions and periods of time prescribed in the permit. The permit will authorize EUP inspections.

FIFRA section 5(e) authorizes the Administrator to revoke any EUP, at any time, if he/she finds that the terms or conditions of the permit are being violated or that the terms or conditions are inadequate to avoid unreasonable adverse effects on the environment as that term is defined by FIFRA.

The Office of Pesticide Programs (OPP), Registration Divisions (Antimicrobial Division, Biopesticides and Pollution Prevention Division, and the Registration Division) review EUP applications and issue the EUP permit. OPP also has the authority to modify or revoke an EUP permit.

OPP will furnish a copy of each EUP, the accepted label, names of the participants, and terms of the program to the region where the pesticide testing will occur.

A state may issue EUPs (40 C.F.R. §§172.20 through 172.26). However, tribes may not issue EUPs.

REGIONAL EUP INSPECTION PROGRAM

The objectives of FIFRA section 5 inspections are to (1) determine whether the terms and conditions of the permit are adequate to avoid unreasonable adverse effects on the environment and (2) determine whether the terms and conditions of the permit are being met. Each regional office is responsible for the supervision of the experimental uses conducted in its region. State agencies participating in cooperative enforcement agreements may conduct EUP inspections on behalf of EPA consistent with the procedures in this Manual. Procedures will be the same as for EPA unless modified by grant agreements or regional policy.

Each regional office will establish its own inspection schedule based on the following list of priorities:

- EUPs for pesticides that are completely new classes of compounds (e.g., juvenile hormones).
- EUPs for chemicals with special potential hazards to humans or the environment, such as:
 - Highly toxic products.
 - Products with propensity to drift.
 - o Products with high terrestrial or aquatic mobility.
 - o Products of a particularly persistent nature.
- EUPs for chemicals with previously registered uses that were subject to adverse action by EPA.
- EUPs for chemicals manufactured by companies that have a history of noncompliance, inadequate supervision or other indications of problems.
- EUPs for those chemicals that may potentially have a widespread major use (e.g., chemicals that will replace a major pesticide that has been canceled by the Agency).
- Any other EUPs for which OPP or OECA has requested special information or monitoring.

CONDUCTING THE EUP INSPECTION

The inspector must obtain and review a copy of the specific EUP and its accepted label. Specifically, the inspector should ensure that all unregistered pesticides, shipped or used as part of a EUP, have a label with the following elements:

- The prominent statement, "For Experimental Use Only";
- The Experimental Use Permit number;
- The statement, "Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program";
- The name, brand or trademark;
- The name and address of the permittee, producer or registrant;
- The net contents;
- An ingredient statement;
- Warning or caution statements;

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- Any appropriate limitations on entry of persons into treated areas;
- The EPA Establishment Number, except in those cases where application of the pesticide is made solely by the producer; and
- The directions for use, except that the Administrator may approve the use of the experimental program as labeling provided that such program is to be distributed with the product.

If a registered pesticide is shipped or used as part of an EUP, the product should either bear the EPA accepted label, or a supplemental label that EPA approved specifically for use in the EUP. Inspectors should document the pesticide labels and include in the inspection report both the EPA accepted labels and the labels in use at the EUP site, so EPA can verify that the permit holder is in compliance with FIFRA.

In addition, the FIFRA inspector should verify that the EUP terms, such as the total acreage and use site, match the actual acreage and use site of the EUP. Any variation between what the EUP allows and what is occurring at the EUP site may be a FIFRA violation and should be documented in the inspection report.

The following items must be checked for compliance with the EUP provisions in addition to any specific instructions issued by the regional office:

- The pesticide label and labeling in use at the EUP site must be the same as the EUP accepted label and labeling (see above for the required elements of an EUP label).
- The products must be applied in accordance with the EUP accepted label directions and precautions, and within the terms of the permit.
- If testing activities are taking place, such activities must be supervised by a representative of the permittee.
- The inspector should check for evidence of adverse effects (e.g., worker complaints, signs of plant/crop damage from the application of non-herbicides, etc. See list below.).
- If evidence of adverse effects is observed, the inspector should ask for documentation to prove that EPA headquarters has been notified of this adverse effect.
- The amount of pesticide sold or provided must be consistent with the amount in the EUP.
- The quantities of product shipped and/or received must be consistent with the quantities in the EUP and the shipments must have been made to designated participants only.
- Food or feed that is not covered by a tolerance must be disposed of in accordance with the EUP.

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• Unused pesticide must be disposed of in accordance with EUP instructions.

In certain instances, follow-up inspections may be required to verify crop rotation, crop destruction, grazing restrictions, etc.

ADVERSE EFFECTS

The following adverse effects must be documented and reported to EPA:

- Accidents observed or claimed.
- Non-target animal or bee kills (domestic or wild).
- Phytotoxicity to non-target plants (in or out of the target site).
- Unique problems with handling, preparing, mixing or applying the pesticide.
- Other complaints.

INSPECTION REPORT

See Chapter 16, "Inspection Reports and Supporting Documentation." If follow-up inspections are required to verify crop rotation, crop destruction, grazing restrictions, or other practices, the inspector should note this in the report and submit additional reports for each follow-up inspection.

The inspector should document any discrepancies between the EUP terms and the actual conditions of the EUP site and include evidence of any potential violation (such as photographs, statements, documentation and samples) in the inspection report. Since EUPs may involve experimental and/or toxic products, the inspector must immediately report any suspected violation to the EPA regional office and should expedite the preparation of the EUP inspection report.

The inspector must submit a written report to EPA where the inspection was conducted by the state.

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CHAPTER ELEVEN RESTRICTED-USE PESTICIDES: DEALER AND APPLICATOR RECORDS INSPECTIONS

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RESTRICTED-USE PESTICIDES: DEALER AND APPLICATOR RECORDS INSPECTIONS

STATUTORY AUTHORITY

FIFRA section 11 and 40 C.F.R. Part 171 (see, in particular, 171.11(g)) require dealers and commercial applicators to maintain records of sales, distribution and application of restricted-use pesticides (RUPs).

FIFRA section 8(b) states that any producer, distributor, carrier or dealer shall furnish, upon request of any officer or employee of EPA, all records showing the delivery, movement or holding of pesticides.

FIFRA section 12(a)(2)(F) states that it shall be unlawful for any person to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with FIFRA section 3(d) and any regulation thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator.

OBJECTIVES

The restricted use pesticide (RUP) classification restricts a product, or its uses, to use by a certified pesticide applicator or under the direct supervision of a certified applicator. Because RUPs may be applied only by or under the direct supervision of trained and certified applicators, inspectors should review Chapter 8, "Use Inspections," and Chapter 9, "Establishment Inspections" to become familiar with records maintained by retail dealers and commercial applicators that distribute and/or use RUPs. When inspecting facilities that use, produce, sell or distribute RUPs, the inspector should review these records to establish:

- Compliance with FIFRA record keeping requirements regarding sales, distribution and application of RUPs.
- That RUPs are sold only to certified applicators or non-certified persons for application by a certified applicator who is specifically certified for the use of the particular RUP.

This chapter provides direction for inspections conducted under federal authority in states and in Indian country. Under 40 C.F.R. Part 171, EPA may approve state and tribal plans for certification of applicators of restricted use pesticides. Federal inspectors can, under the

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authority of FIFRA section 8(b), conduct dealer record inspections in states and Indian country that have EPA-approved plans for the certification of RUP applicators under 40 C.F.R. Part 171. Since many state and tribal pesticide laws and regulations, including those pertaining to record keeping, may be more extensive than federal requirements, federal inspectors should familiarize themselves with the state or tribe's pesticide laws and regulations prior to conducting these inspections. In cases where state or tribal violations are documented, the inspection file and inspection report must be forwarded to the respective state or tribe for follow-up and/or or enforcement action.

INSPECTION PROCEDURES

The inspector should follow the procedures outlined in Chapter 8, "Use Inspections," and Chapter 9, "Establishment Inspections".

Review records to determine compliance with FIFRA and to ascertain whether all the required information is being maintained. Document any deficiencies (e.g., through photocopies, photographs, statements).

RUP DEALER INSPECTION

Under 40 C.F.R. § 171.11(g), every retail dealer of RUPs in states or Indian country where EPA conducts the applicator certification and training program must report to EPA the dealer's business name and the name and address of each of its dealerships. The dealer must submit revisions to this report as necessary. The inspector should check for evidence to establish compliance with this requirement. The inspector should also note and record any state dealer license held and its expiration date. A dealer that makes RUPs available to a certified applicator or an uncertified person must keep a record of each transaction. A dealer that is also an applicator of restricted-use pesticides must comply with the record keeping requirements that pertain to applicators.

RUP dealers are required to maintain two primary types of sales records which are subject to Agency review: (1) sales to certified applicators and (2) sales to uncertified persons.

For sales to certified applicators, records of each transaction must be retained for 24 months and must include the following information:

- Name and address of each certified person to whom the pesticide was made available for use.
- Certified applicator's certification number, expiration date, certification categories and name of state or other governmental unit issuing the certificate.
- Product name, EPA Registration Number and state Special Local Need Registration Number (if any) on the pesticide label.

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- Amount of the pesticide sold and made available for use in the transaction.
- Date of the transaction.

For sales to uncertified persons, records of each transaction must be retained for 24 months and must include the following information:

- Name and address of the uncertified person to whom the pesticide was made available for use by a certified applicator.
- Name and address of the certified person who will use the restricted-use pesticide.
- Certified applicator's certification number, expiration date, certification categories and name of state or other governmental unit issuing the certificate.
- Product name, EPA Registration Number and state Special Local Need Registration Number (if any) on the label of the pesticide.
- Amount of pesticide sold and made available for use in the transaction.
- Date of the transaction.

RUP dealers' stocks should be inspected and RUPs inventoried. The inspector should document the following situations:

- Sales to non-certified persons or for use by non-certified persons.
- Discrepancies between physical inventories and the amount of product documented in transactions (determined by a books and records inspection including computer inventories).
- Improperly labeled products, including agricultural pesticides lacking worker protection label statements.
- Suspended or canceled products sold and/or held for sale and distribution.
- Damaged products and any corrective actions taken.
- Improperly stored products.

RUP APPLICATOR INSPECTION

In any state or Indian country that does not have an EPA-approved certification plan, anyone who uses or supervises the use of any RUP must be certified by EPA. The inspector should check the certified applicator's certification number, certification categories and expiration date.

Commercial applicators and those who contract with commercial applicators to apply RUPs to property owned by another person must maintain applicator records for at least 24 months from the date of pesticide use. Records should include the following information (40 C.F.R. §171.11(c)(7)):

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- Name and address of the person for whom the pesticide was applied.
- Location of the pesticide application.
- Target pests.
- Specific crop or commodity and site to which the pesticide was applied.
- Date and time of application.
- Product/trade name and EPA Registration Number of the pesticide applied.
- Amount of pesticide applied and percentage of active ingredient per unit of pesticide used.
- Disposal information.

Pesticide stocks should be inspected and RUPs inventoried. The inspector should document the following occurrences:

- Discrepancies between physical inventories and amount used (determined by a books and records inspection including computer inventories).
- Improperly labeled products, including agricultural pesticides lacking worker protection label statements.
- Suspended or canceled products being held for use.
- Damaged products and any corrective actions taken.
- Improperly stored products.
- Improper disposal of container, excess pesticide or rinsate.
- Application of an RUP outside a category for which the applicator is certified.

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CHAPTER TWELVE PESTICIDE/DEVICE IMPORT AND EXPORT INSPECTIONS

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PESTICIDE/DEVICE IMPORT AND EXPORT INSPECTIONS

AUTHORITY

FIFRA section 17 governs the importation and exportation of pesticides and devices. Sections 17(a) and 17(b) govern pesticides and devices intended for export and notifications to foreign governments. Section 17(c) governs the importation of pesticides and devices.

See FIFRA section 17 and 40 C.F.R. Part 168, Subpart D (Export Policy and Procedures for Exporting Unregistered Pesticides). Additionally, see 19 C.F.R. 12.110 - 12.117 (U.S. Customs and Border Protection (CBP) regulations pertaining to import of pesticides and devices).

EXPORTS

Pesticides may be exported from the United States whether they are registered, unregistered, canceled or suspended—provided certain criteria are met. For example, all pesticides, devices or active ingredients intended for export are subject to the labeling requirements of FIFRA regulations at 40 C.F.R. Part 156. In addition, certain label items must be in both the English language and in the language of the importing country, if English is not the predominantly spoken language or the language used in conducting official business in the importing country. Examples of these label items are the warning, caution, ingredient and practical treatment (first aid) statements; and the word "poison" when it is required on the label.

For the purposes of regulating the exportation of pesticides, the export regulations at 40 C.F.R. Part 168, Subpart D, divide exported pesticides into categories, as outlined below, with differing requirements for each category. For information on labeling requirements for exported pesticides, see PR Notice 99-1 and the Export Policy.

EXPORT OF EPA REGISTERED PESTICIDES

EPA registered pesticides must be exported with EPA approved labels and must bear labeling in both the English language and in the language of the importing country, if English is not the predominantly spoken language, or the language used in conducting official business in the importing country.

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EXPORT OF UNREGISTERED PESTICIDES

Unregistered pesticides and pesticide devices must have bilingual labeling when exported to non-English speaking countries. The labels of these products also must include the statement "Not Registered for Use in the United States of America."

Anyone exporting unregistered pesticides must first obtain a signed statement from the foreign purchaser acknowledging that the purchaser understands that the pesticide is not registered for use in the United States and cannot be sold in the United States. This statement is called a Foreign Purchaser Acknowledgment Statement (FPAS) and must be obtained prior to the first export shipment of a particular unregistered pesticide to a particular purchaser for each country on an annual basis. The seller must send a copy of the FPAS to the EPA Office of Pesticide Programs (OPP), Field and External Affairs Division (FEAD); the inspector can find this form on file with OPP.

On January 18, 2013, EPA revised the regulations on labeling of pesticide products and devices intended solely for export. Unregistered pesticide products shipped between registered establishments operated by the same producer will have to follow the labeling requirements in 40 CFR Part 168. This rule is intended to ensure appropriate handling of unregistered pesticide products as they move in commerce before they actually leave the United States.

INSPECTION AND SAMPLING

Export inspections are generally conducted at producing establishments, but pesticides and devices intended for export may be encountered during port visits where pesticides might be stored pending export.

PROCEDURES

For routine inspections, the general procedure is to obtain evidence necessary to establish compliance with FIFRA and the export regulations. A checklist is provided to assist inspectors to ensure that all requisite activities have been covered (see Exhibit 12-1). For "for cause" inspections, follow the specific instructions on the EPA referral.

Most export inspections will be included along with FIFRA section 8 books and records inspections, conducted at producing establishments. These will involve the review and collection of export pesticide/device labels, shipping documents, sales invoices, statements, and other documents which can be used to document the export of pesticide/device products. Pesticides for export can be contract produced and shipped domestically to another company for exportation. In these cases, it may be necessary to conduct inspections at both the producing establishment and the company that is actually responsible for the exportation of the product. (See Chapter 9, "Establishment Inspections", for more information on producer establishment inspections).

The inspector should obtain a copy of the FPAS for each unregistered pesticide and cross-reference the date of the exporter's receipt of the FPAS with the actual date of sale or distribution of the unregistered pesticide. The unregistered pesticide cannot be legally exported until the FPAS is received by the U.S. exporter. Any sale or distribution of the unregistered pesticide prior to the exporter's receipt of the FPAS is unlawful, unless otherwise exempted by FIFRA section 17.

During export inspections, the inspector, through discussions with responsible company officials and subsequent review of company records, must be able to clearly document the items identified below. When information is not available or cannot be clearly documented by obtaining copies of records, the inspector must obtain a statement (use EPA Statement Form 3540-42; Exhibit 1-1) from responsible company officials that clearly documents the procedures used by the company when exporting pesticides or devices.

Some of the information to be obtained during these inspections may be claimed as FIFRA Confidential Business Information (CBI). See Chapter 1, "General Information", for more information on CBI.

PRE-INSPECTION ACTIVITIES (REGIONAL OFFICE FUNCTION)

The federal EPA inspector should conduct the following pre-inspection activities:

- Review and copy section 7 establishment production data submitted to the region and found in the Section Seven Tracking System (SSTS) or on copies of EPA Form 3540-16 submitted to the region for all registered/unregistered products or devices exported for the targeted calendar year(s).
- Develop a comprehensive list of registered/unregistered products or devices exported in the targeted calendar year(s) by the targeted establishment. Regional listings of registered/unregistered products or devices, product name and establishment name/address and other establishment and company information should be obtained from SSTS.
- Review and copy all Confidential Statements of Formula (CSFs) or chemical formulation statements, if available at the region, or obtained from the Office of Pesticide Programs for all products identified above. Develop a list of all unregistered products identified as not having product formulas on file prior to the inspection so that the inspector can obtain any missing formulas at the time of the inspection. Note on this listing if product formulas were not submitted to the region along with the production data in EPA Form 3540-16 for each calendar year. Product formulas may be CBI and shall not be shared with states that may conduct or be part of inspection activities.
- Assemble sampling equipment that will be taken on inspection. See a listing of suggested equipment in Chapter 7.

ON-SITE INSPECTION ACTIVITIES (REGIONAL/STATE FUNCTION)

The inspector must present credentials and issue a Notice of Inspection (NOI) (see Form 3540-2; Exhibit 1-1) to the owner/operator, or agent-in-charge. The reason for the inspection must be stated in the NOI and, if a violation is suspected, this must be disclosed in writing on the NOI.

For each registered/unregistered product or device exported in the targeted calendar year(s):

- Obtain evidence that clearly shows the company responsible for the product and its
 export. Obtain evidence that describes past and present corporate relationships, such as
 mergers, takeovers and/or other corporate transactions and any agreement expressing
 the nature and responsibilities between the companies involved in the export of the
 pesticide/device.
- Obtain copies of the CSF, if available; otherwise, obtain a copy of the complete formula
 of the product. (Note: The CSF and formula of the product contain confidential business
 information (CBI) and cannot be viewed, copied or obtained by a state inspector. An EPA
 federal inspector cannot view/copy the CSF unless cleared for CBI; state inspectors using
 federal credentials cannot obtain copies of the CSF's or any CBI materials. See Chapter 1
 of this Manual.)
- Obtain copies of the specification or directions from the foreign purchaser for the production of such pesticides, devices or active ingredients. (40 C.F.R. 169.2(h)(1))
- Obtain copies of label(s) and supplemental labeling, including bilingual label(s), used for each export. (40 C.F.R. 169.2(h)(2)) If product label(s)/labeling are not available, obtain bin labels/labeling. In either case, the inspector shall obtain a statement (see Statement Form 3540-42; Exhibit 1-1) from the responsible company official certifying that the labels/labeling collected are identical to those used on the exported product. If a particular product label is being used for more than one country, the statement must include the name of each country.
- If registered/unregistered pesticides or devices are packaged, labeled and released for shipment at the time of the inspection, obtain a physical sample or obtain documentary evidence (labels/labeling and photographic evidence) of all such products.
- Obtain copies of all FPAS of a particular product to a particular purchaser for each importing country. (40 C.F.R. 169.2(h)(3))
- Obtain documentation showing the dates and amounts of each registered/unregistered product or device shipped and country of destination (e.g., bills of lading, manifests, invoices, consignee lists). (40 C.F.R. 169.2(d)) If these documents contain CBI, only federal EPA inspectors can obtain this documentation. See Chapter 1 for more information on CBI.
- Note in the inspection report if any of the documents above were not maintained by the facility. If the facility does not maintain records listed above, obtain a statement from

- the responsible official as to why the records were not maintained by the facility and the actual location of the records/documents, if known.
- Request that copies of all missing records and/or product labels be sent to the EPA regional office by a specific date.

For instances where the facility/establishment claims that a product is for "research and development" or "experimental" purposes and a FPAS, therefore, was not required:

• Obtain a statement from the responsible company official specifically describing the basis for any such claims.

The FIFRA Export Inspection Checklist (Exhibit 12-1) will assist the inspector covering all the above items.

IMPORTS

Imported pesticides and devices are subject to the same registration, labeling requirements, and exemptions as domestically produced pesticides and devices.

IMPORT OF UNREGISTERED PESTICIDES

Under certain conditions, unregistered pesticides will be allowed to enter the United States. A Notice of Arrival of Pesticides and Devices (NOA), EPA Form 3540-1 (see Exhibit 1-1), will be required for these unregistered products. These conditions are found in 40 C.F.R. 152.30 and in PR Notice 99-1. An unregistered pesticide may be imported if:

- (1) It is transferred between registered establishments operated by the same producer (all EPA label requirements must be met, except the product should not have an EPA Registration Number or EPA Establishment Number). Where the establishments are not operated by the same producer, see 40 C.F.R. 152.30 for additional requirements;
- (2) It is distributed for use under an experimental use permit (EUP);
- (3) It is distributed for use under an emergency exemption;
- (4) It is imported solely for the purpose of formulation or packaging; and for subsequent export provided certain requirements are met; see PR Notice 99-1, or
- (5) It is imported for research and development purposes not requiring an experimental use permit (EUP).

IMPORT OF RESEARCH & DEVELOPMENT PESTICIDES

Substances, including mixtures of substances, being imported for research and development (R&D) must comply with FIFRA section 17(c) and 19 C.F.R. 12.110 through 12.117.

Substances are regulated either by FIFRA, the Toxic Substances Control Act (TSCA) or the Federal Food, Drug, and Cosmetics Act (FFDCA). If the substance is characterized as a pesticidal chemical, then it is regulated under FIFRA. If the substance is characterized as a pharmaceutical chemical, then it is regulated under FFDCA. Substances that are neither pesticidal nor pharmaceutical most likely are regulated under TSCA. TSCA exempts TSCA regulated R&D chemicals from the import requirements of the TSCA statute and regulations. FIFRA does not exempt pesticidal R&D chemicals from the import requirements.

An R&D product is deemed to be a pesticide when it has been determined by the company to have potential pesticidal potential properties. At that time, the company has determined that the product has pesticidal value and further research will be conducted to support registration. The inspector may encounter an R&D product at universities, laboratories or sponsors performing research, or possibly ports of entry for imports.

IMPORT OF REGISTERED PESTICIDES AND DEVICES

Before registered pesticides or devices can be imported into the United States, the importer must submit a Notice of Arrival of Pesticides and Devices (NOA), EPA Form 3540-1 (see Exhibit 1-1), prior to the arrival of the shipment in the United States. The EPA regional office shall:

- Complete Part II of the NOA, indicating the disposition to be made of the shipment of pesticides or devices upon its arrival in the United States.
- Return the completed NOA to the importer or its agent.

Normally, an import broker will represent the importer in obtaining CBP clearance.

Upon the arrival of a shipment of pesticides or devices, the importer (or broker) shall present to CBP at the port of entry the NOA completed by the EPA regional office indicating the appropriate CBP action to be taken with respect to the shipment.

REGIONAL OFFICE

The EPA regional office supervisor/import coordinator and pesticide inspectors should maintain a cooperative working relationship with CBP and customs brokers. This is vital to understanding the way each different port of entry conducts its business. Upon receipt of the NOA, the regional office should review the NOA for completeness and determine whether to inspect and/or sample based on the following:

- Pesticides/devices suspected of noncompliance (e.g., unregistered pesticides and/or unregistered establishments).
- Pesticides/devices with a violative history (the region may have knowledge of a violative product or company).
- First-time import of a pesticide/device to the region.

 Pesticides/devices imported regularly with a good history of compliance (i.e., high volumes).

If a decision is made to inspect the imported pesticide/device, indicate in Part II of the NOA what action to take. The options are:

- Detention of the pesticides/devices by CBP for inspection by EPA. The expenses associated with the detention must be borne by the importer. It is important that the inspection be conducted as soon as possible since the fate of the shipment is determined by the inspection. This type of inspection is likely to occur at the port of entry, as the shipment is not usually released to the importer until EPA determines compliance. The shipment may have been picked up by the consignee under an immediate delivery entry (usually an electronic entry) (19 C.F.R. 142.21-142.22). In such cases, the shipping company or the import broker should be requested to locate and hold the product for inspection.
- Release of the shipment of pesticides/devices under bond. See 19 C.F.R. 113.61 and 113.62. In accordance with section 17(c) of FIFRA, EPA may instruct CBP to release a shipment of pesticides/devices under a bond for the return of the imports to the custody of CBP. When this option is chosen the shipment is technically being detained because the pesticides/devices cannot be used or otherwise disposed of until EPA conducts an inspection and makes a determination. This type of inspection will take place at the consignee's facility and must proceed following normal protocol for establishment inspections. Whenever circumstances permit, EPA should consult with CBP personnel at the port of entry to ensure that the bond set by CBP is of an amount significant enough to compel the importer to hold the shipment for inspection. Circumstances such as prior knowledge of the quantity and/or estimated value of the shipment as well as the status of the cooperative working relationship between EPA and CBP personnel at the port of entry will dictate the feasibility of such a consultation. In special circumstances where concern exists that a bond may not stop distribution of the products, the EPA regional office should consider issuing a Stop Sale, Use or Removal Order (SSURO).

If the EPA regional office instructs CBP either to detain the imported pesticides/devices, or to release the shipment under a bond, an EPA inspector must be prepared to conduct an inspection. Documentary samples of labels and/or pesticides/devices can be taken to determine compliance with FIFRA.

If released under bond, the commodity may likely be moved to a "bonded warehouse", or other location under bond away from the port of entry. The container(s) are still under CBP control, but the Notice of Inspection and Receipt for Samples will be issued to the bonded warehouse owner, or responsible party (not to CBP). NOTE: At a bonded warehouse only the stevedores can open and unload a container of imported or exported goods at ports of entry or bonded warehouses. The location of detained pesticide import shipments is determined by CBP and

carried out by the import broker. The location will be a CBP licensed and bonded warehouse operated by a private storage/warehouse company, or to a location taken under bond and determined by CBP.

INSPECTIONS AND SAMPLING

Imported pesticides/devices can be inspected at different ports of entry or other locations depending on how the shipment arrived in the United States and the CBP status of the shipment.

Upon arrival at the inspection site, the inspector must introduce himself/herself to CBP, the warehouse owner and other parties and must present federal credentials (as all import inspections are conducted under FIFRA sections 8 and 9), explain the purpose of the inspection and issue a Notice of Inspection (Form 3540-2, see Exhibit 1-1) with the reason for inspection. The Notice of Inspection must be issued to the person who has control of the product at the time of the inspection. CBP never takes custody of the product during the importation/entry of the shipment. Thus, the Notice of Inspection is never issued to CBP; rather, it will be issued to the importer, import broker, bonded warehouse owner or shipper of the import.

An inspector's checklist for imports is provided at Exhibit 12-2.

IMPORT SAMPLING

Physical samples should be collected if EPA suspects that the pesticide product has been adulterated or suspects that the composition of the pesticide product is different from the CSF in connection with the registration of the product. For all other suspected or observed violations, documentary samples are sufficient to demonstrate a violation of FIFRA and provide sufficient weight of evidence to instruct CBP to refuse entry of the import shipment, if necessary. Documentary samples will always include photographs of the label and labeling on the pesticide, cases or containers in the import shipment.

The inspector must take the following steps when obtaining samples:

- Issue a Receipt for Samples for any samples taken. Use EPA Form 3540-3, see Exhibit 1-1. Give the Receipt to the individual that received the Notice of Inspection.
- If physical samples are obtained, submit the sample to the appropriate laboratory and ask the laboratory to expedite the analysis, following chain-of-custody procedures.
- Inform the EPA supervisor/import coordinator that a sample has been collected and sent for analysis, specifying the name of the laboratory.
- When taking a sample, it is recommended that the inspector also obtain a statement to document information about the sample. Use EPA Form No. 3540-42, Exhibit 1-1.

Following a sample collection, and while waiting for chemical analysis or case review, the pesticide will have to be detained. The import broker and CBP agent must determine the location where the pesticide is held. The shipment must be kept intact until EPA makes a determination of compliance. The inspector should exchange telephone numbers with all parties involved, so as to expedite communication regarding further actions with regard to the commodity.

INSPECTION WITHOUT SAMPLING

Prior to inspection of detained shipments, a copy of the label should be obtained from the EPA product manager in the Office of Pesticide Programs or from the Pesticide Product Labeling System (PPLS) at: http://www.epa.gov/pesticides/pestlabels.

When conducting an inspection without sampling, the inspector should complete the following steps:

- Present credentials.
- Issue the Notice of Inspection.
- Review the labeling for mandatory label requirements.
- Check for collateral labeling such as booklets and pamphlets.
- Check condition of the lot or batch of product.
- Review and copy all import records, bills of lading, manifests and other documentation.

If a label or labeling violation is noted, the inspector should photograph or photocopy the label for documentary evidence. See Chapter 6 for more information on sampling procedures.

EPA REGIONAL OFFICE PROCEDURE AFTER INSPECTION

MERCHANDISE IN COMPLIANCE WITH FIFRA

If the imported pesticide/device is found to be in compliance with FIFRA, the regional office must notify CBP that the shipment may be released to the consignee. A model Release Notice is included as Exhibit 12-3.

One way to standardize the way EPA regions notify CBP that the shipment may be released may be to "cc" the District Director of CBP at the port of entry on a Release Notice addressed to the importer of record. For purposes of expediting the Notice, EPA regional personnel should fax a copy of the release notice to their CBP staff counterpart at the port of entry.

MERCHANDISE IN VIOLATION OF FIFRA

If the imported pesticide/device is found to be in violation of FIFRA, the EPA regional office must refuse admission of the pesticides/devices into the country. EPA must notify the consignee of this refusal. This procedure is consistent with the CBP regulation in 19 C.F.R.

12.117(b). A model Notice of Refusal of Admission is found at Exhibit 12-4. See Exhibit 12-5 for a Notice of Detention and Hearing. The consignee is given 20 days to submit written material or, at the option of the consignee, appear before EPA and introduce testimony to show cause why the shipment must not be destroyed or refused entry. If no hearing is requested or, after consideration of the evidence, it is still the opinion of EPA that the shipment is in violation of FIFRA, the importer has 90 days from the date of receipt of the Notice of Refusal of Admission to export the violative products out of the U.S.

One way to standardize the way regions notify CBP that the shipment has been refused admission may be to "cc" the District Director of CBP at the port of entry on a Notice of Refusal of Admission addressed to the importer of record. For purposes of expediting the Notice, EPA Regional personnel should fax a copy of the Notice to their CBP staff counterpart at the port of entry. If this does not occur, CBP, in cooperation with EPA, may oversee the destruction of the pesticides/devices, although this is done as a last resort because of the expense to CBP and the public.

Possible violations of FIFRA can include any of the unlawful acts described in sections 12(a)(1) and 12(a)(2) of FIFRA. These include but are not limited to: distribution of an unregistered pesticide, distribution of a misbranded or an adulterated pesticide or device, and failure to file reports required by FIFRA. Stop Sale, Use, Removal Orders (SSUROs) and Seizures under section 13 of FIFRA can be issued for imports suspected of being in violation of the Act. **NOTE:** There is always an importer of record for every import shipment and it is this person who is held liable for any violations. Import brokers act as agents of the importer of record and become jointly liable if a violative product is found to be distributed (imported) into the United States. A FIFRA import inspection checklist (Exhibit 12-2) will assist the inspector.

Pesticides and devices may also be inspected by CBP and sampled following release of the product to a point of destination (not released under bond). The FIFRA Notice of Arrival of Pesticides and Devices (EPA Form 3540-1, Exhibit 1-1) will list the destination of the shipment. Therefore, the inspector can also conduct an import inspection at the destination location. Should there be any discrepancies, the inspector should notify the EPA supervisor immediately to determine the next steps by EPA and/or CBP.

EXHIBIT 12-1: FIFRA EXPORT INSPECTION CHECKLIST

Compa	any: Establishment No.:	
Addre	ss:	
Inspec	tion Date:	
Inspec	tor's Name and Phone Number:	
Produ	ct(s) Name and (EPA Reg. #):	
EPA Es	tablishment Number:	
 2. 3. 	Are §7 production reports (EPA Form 3540-16) included for this product for each targeted calendar year? [If reporting discrepancies were found, note in "Comments" section on page 2 of this form.] Is the Confidential Statement of Formula or chemical formula included for this product? Are production specifications/directions of the foreign purchaser included for this product? If not, take a statement from the appropriate company official as to why these records are not maintained by the facility. Is the actual location of the records known and included? Are label(s)/supplemental labeling included for this product for each country to which it was exported? No. of countries: No. of labels:	Yes/No/Exhibit #
	If product labels/labeling were not available, are bin labels included for this product? Take a statement from the responsible company official which should state whether or not the labels/labeling or bin labels/labeling collected are identical to those used on the exported product(s)? Is photographic evidence of the product that was packaged, labeled and released for shipment at the time of the inspection included? If labels were not available for inspection, is a statement from the appropriate company official included as to why labels were not maintained by the facility? Is the actual location of the labels known	
7.	and included? Are Foreign Purchaser Acknowledgment Statements (FPAS), as	

required by §17(a)(2), included for the first shipment each year of a

particular product to a particular purchaser for each importing country?

If not, is a statement included?

Use Pesticide)

- 8. If the unregistered product was claimed to be a "research & development" or an "experimental" pesticide, is a statement included from the responsible company official specifically describing the basis for such claims?
- 9. **OPTIONAL**: If the unregistered product is claimed "substantially similar" to an EPA registered product, is a copy of the label for the registered product and Confidential Statement of Formula or chemical information for the registered product included?
- 10. Is evidence of exported shipments included that **clearly** shows the product name, date(s) of each shipment, amounts of each shipment, and country of destination for each shipment? (This can include Bills of Lading, Invoices and List of Consignees.)
- 11. Is evidence included that clearly shows the company responsible for the product and its export? Is evidence included that clearly describes past and present corporate relationships, such as, mergers, takeovers and/or other corporate transactions/agreements?
- 12. Was information included for this product for all periods requested?

COM	лмеnts:			
Par	t II - Labeling Requirements and Review			
	s the label/labeling for this exported product arate Part II sheet for each product label and f	_	ation? Attach a	
Product Name:		Foreign Destination:		
		Yes	<u>No</u>	
1.	EPA Establishment Number?			
2.	Ingredient statement?			
3.	Name/address of producer/registrant?			
4.	Statement of net weight or measure?			
5.	Use Classification statement? (Restricted L	Jse or General		

- 6. Precautionary statements? (Warning and caution statements)
- 7. If highly toxic, are "skull & crossbones," the word Poison and statement of practical treatment shown?
- 8. For unregistered products, does label bear the statement "Not Registered for Use in the United States of America"?
- 9. If the predominant language of the importing country is not English, are #'s 2, 6, 7 and 8 above also expressed in the language of the importing country? (Note that this information is required on both **registered and unregistered** products.)

Label Comments:	 	

EXHIBIT 12-2: FIFRA IMPORT INSPECTION CHECKLIST

For use after the regional office import coordinator determined that a shipment is to be inspected and setup a location for the inspection.

1. Insp	ector's name/numbe	r:			
2. Loca	ation of shipment to b	oe inspected:			
	Obtain the following information from the Notice of Arrival (NOA) Form 3540-1 or the papers accompanying the shipment.				
3. Impo	rter/Consignee Addre	ess	4. Shipper Address		
5. Broke	er Agent Address		6. Carrier		
7. EPA I	Registration Number		8. EPA Establishment Number		
10. Major Active Ingredients and Percentage of Each					
11. Uni	t Size	12. Quantity	13. Total Net Weight		

Inspection Procedures

Check if applicable

- 14. Obtain a copy of the EPA approved label from the EPA regional office.
- 15. Prior to inspecting a shipment of pesticides and/or devices, request from the importer/consignee or customs broker copies of the product label and, if available, other advertisements accompanying the sale of the product.
- 16. Issue NOI and show federal credentials to appropriate person.
- 17. Collect photographs of the label(s) and labeling on the container(s) of the import shipment. Review for conformity with label requirements. (Procedures for conducting label reviews can be found in the FIFRA Inspection Manual.)

19. Review other label information in books, pamphlets, circulars and

18. Collect all records regarding import of shipment such as:

Copies of NOA
Foreign invoices
Shipping records (i.e., manifests or waybills)

- ybills)
- displays—if applicable.
- 20. Document the physical condition of the lot.21. Photograph containers and the labels thereon.

If physical samples are taken, follow these additional steps

- 22. Note on the Receipt for Sample that it is an import sample and identify with "IMP" preceding the sample number.
- 23. Request that the laboratory expedite the analysis.
- 24. Ensure that the product container is properly resealed.
- 25. Notify the regional office that the samples have been collected.

EXHIBIT 12-3: MODEL RELEASE NOTICE

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Name Title Company Name Company Address

Re: RELEASE NOTICE

Entry Number (Assigned by Customs and Border Protection) (Product Name)

Dear (Company President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act), 7 U.S.C. 136 *et seq.*, the United States Environmental Protection Agency has completed its consideration of the following shipment. Base on examination of samples or other evidence, the Agency concludes that, pursuant to section 17(c) of the Act, you need not further detain the merchandise.

Sample Number (if an inspection has been conducted):

Product Name:

Shipper/Manufacturer:

Consignee:

Entry Number:

Date of Importation:

Port of Entry:

This Notice does not constitute assurance that the merchandise involved complies with all provisions of the Act and in no way precludes further action should the Agency determine that the merchandise is in violation of any federal environmental requirement.

Sincerely,

/s/

(Name and Title)

EXHIBIT 12-4: MODEL NOTICE OF REFUSAL OF ADMISSION

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Name Title Company Name Company Address

Re: NOTICE OF REFUSAL OF ADMISSION

Entry Number (Assigned by Customs and Border Protection) (Product Name)

Dear (Company President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act), 7 U.S.C. 136 *et seq.*, the United States Environmental Protection Agency has examined samples or other evidence with respect to the following shipment and is granting you an opportunity for a hearing.

Sample Number (if an inspection has been conducted):

Product Name:

Shipper/Manufacturer:

Consignee:

Entry Number:

Date of Importation:

Port of Entry:

It appears that the product is not in compliance with the Act and is subject to refusal of admission due to the following violations (Describe violations).

The Agency hereby notifies you that your merchandise has been refused admission. You must export this merchandise, under supervision of the U.S. Customs and Border Protection (CBP), within ninety (90) calendar days from the date of this Notice (or within such time as otherwise specified by EPA) or within such additional time as the District Director of CBP specifies. Failure

to do so may result in either the destruction of the merchandise as authorized by the Act, or, if the shipment has been released to you under bond, in any action necessary to enforce the terms of said bond.

Sincerely,
/s/
(Name and Title)

EXHIBIT 12-5: MODEL NOTICE OF DETENTION AND HEARING

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Name Title Company Name Company Address

Re: NOTICE OF REFUSAL OF ADMISSION

Entry Number (Assigned by Customs and Border Protection) (Product Name)

Dear (Company President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA or the Act), 7 U.S.C. 136 *et seq.*, the United States Environmental Protection Agency has examined samples or other evidence concerning the shipment described below, and has determined that said shipment is in violation of the Act. You should continue to withhold the merchandise from distribution or sale pending a final decision as to whether it shall be admitted or refused admission.

Pursuant to Section 17(c) of the Act, the Agency hereby affords you an opportunity to offer such explanation as you wish for the Agency's consideration. You should file your answer, signed by you or your attorney, with this office within twenty (20) calendar days after your receipt of this Notice. Please indicate in your response if you wish to present your views verbally so that we may set a date for such presentation to be held in this office or via teleconference.

Sample Number (if an inspection has been conducted):

Product Name:

Shipper/Manufacturer:

Consignee:

Entry Number:

Date of Importation:

Port of Entry:

Upon examination, it appears the product(s) failed to comply with the provisions of the Act in that (describe violation). I am enclosing a copy of EPA's FIFRA Enforcement Response Policy.

Sincerely, /s/ (Name and Title)

CHAPTER THIRTEEN CANCELLATION AND SUSPENSION

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CANCELLATION AND SUSPENSION

STATUTORY AUTHORITY

FIFRA sections 3(c)(2)(B), 4(d) and 4(f) provide the Administrator with the authority to cancel and/or suspend the registration of a pesticide for failure of the registrant to provide, or commit to provide, data required by the Agency.

FIFRA section 6 provides the Administrator with the authority to cancel the registration of a pesticide for unreasonable adverse effects on the environment or to suspend the registration if it is necessary to prevent an imminent hazard.

FIFRA section 13 provides the Administrator with the authority to issue Stop Sale, Use, Removal Orders (SSURO) and Seizure whenever there is reason to believe on the basis of inspection or tests that a pesticide or device has been or is intended to be distributed or sold in violation of FIFRA or when the pesticide has been cancelled or suspended.

The Administrator cancels the registration of a pesticide at the end of five years unless the registrant (or other interested party acting with the registrant's concurrence) requests renewal of the registration before the end of the five years.

FIFRA section 12(a)(2)(J) makes it unlawful to violate any suspension order issued under sections 3(c)(2)(B), 4 or 6.

FIFRA section 12(a)(2)(K) makes it unlawful to violate any cancellation order issued under the Act or to fail to submit a notice in accordance with section 6(g).

FIFRA section 12(a)(1)(A) makes it unlawful to distribute or sell any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under FIFRA.

CANCELLATION

EPA is authorized to cancel a pesticide registration when existing risks related to the use of the pesticide are unacceptable and registrants either have not made, or cannot make, necessary changes to the terms and conditions of the registration to address the unacceptable risks. In addition, EPA can cancel a pesticide registration for reasons unrelated to risk, such as nonpayment of maintenance fees. Registrants can voluntarily cancel pesticide registrations at any time. When the Agency decides to cancel the registration of a pesticide product, it prepares a Notice of Intent to Cancel (NOIC) that is published in the Federal Register and sent to registrants. The Agency then provides a Final Cancellation Order, which is also published in the

Federal Register and sent to registrants. The Cancellation Order includes the date by which the product may no longer be produced, sold and distributed.

SUSPENSION

EPA may suspend pesticide registration pursuant to FIFRA section 3(c)(2)(B) to halt further distribution and sale of a pesticide product by the registrant and any supplemental registrants or supplemental distributors until the suspension is lifted by EPA. Consumers who have already purchased such products may continue to use them according to the labels. Product suspension is most common when EPA determines that additional data is required to support an existing registration of a pesticide. In such cases, the Agency notifies all registrants of the pesticide through issuance of a FIFRA Data Call-In Notice (DCI). The DCI will require each affected registrant to provide evidence within 90 days that the affected registrant is taking appropriate steps to respond to the DCI. It also sets deadlines for the data submission and may specify interim deadlines. If a registrant fails to comply with a DCI requirement, EPA may issue a Notice of Intent to Suspend (NOIS) the registration of the pesticide. If the registrant fails to submit timely or adequate data to satisfy the DCI or fails to take any additional step required by the DCI, EPA may suspend the pesticide. The suspension becomes final and effective 30 days after EPA issues the NOIS, unless within that time period, one of the following two things happens:

- The registrant demonstrates that it has fully complied with the requirements that served as a basis for the NOIS, or
- A person adversely affected by the Notice makes a timely and adequate request for a hearing. If a hearing is requested, it will be conducted according to the requirements of FIFRA section 6(d) and the procedural regulation at 40 C.F.R. Part 164.

Under special circumstances, a registrant may be allowed continued sale or use of existing stocks of canceled and/or suspended pesticide products.

INSPECTION OBJECTIVE

The inspector's role is to gather the information necessary for EPA to determine compliance with the Agency's suspension or cancellation order. It is the policy of EPA to follow up all suspension and/or cancellation orders with appropriate surveillance and regulatory action, as dictated by the nature of the suspension or cancellation order. Compliance monitoring strategies are generally developed for each suspension and/or cancellation order.

The inspector should be aware that not all suspended pesticides present a risk or imminent hazard. If there is any question about the basis for the suspension, treat the product as posing a potential hazard. Inspectors may find an updated list of all currently suspended pesticides at http://epa.gov/pesticides/regulating/registering/suspensions.htm.

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PROCEDURES DURING INSPECTIONS

The regional office can provide the inspector with a copy of the suspension order, which will include the basis for the suspension. The inspector must carefully review and be familiar with the terms of the suspension or cancellation order, since terms may vary. For example, producers cannot continue to produce cancelled products and may only sell "existing stocks" of products (i.e., products already produced and packaged for sale as of the date of the cancellation order).

PRODUCER ESTABLISHMENT INSPECTIONS

If canceled or suspended pesticides are discovered during a producer establishment inspection, the inspector should take the following steps:

- Immediately notify his/her EPA supervisor about the production of a canceled or suspended product. The EPA supervisor will decide whether a SSURO or other action is appropriate.
- Gather production records associated with the cancelled or suspended product, showing the date, quantity, batch number (if available) of production.
- Gather the dates and distribution records associated with the cancelled or suspended product, showing the date, quantity and recipient of each shipment.
- Obtain an official sample of the product.
- Determine whether the products are being held for disposal. If held for disposal, inventory the lot and determine what disposal steps have been taken.
- Determine if and when the establishment was notified of EPA's order.

MARKETPLACE INSPECTIONS

If canceled or suspended pesticides are discovered during marketplace inspections, the inspector should take the following actions:

- Immediately notify his/her EPA supervisor about the production of a cancelled or suspended product. The EPA supervisor will determine if a SSURO or other action is appropriate.
- Document the receipt of the shipment by the marketplace establishment.
- Document the further sale or distribution by the marketplace establishment.
- If the product was shipped in violation of a cancellation/suspension order, visit the producer to determine whether other consignees may be involved. This may require

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that the inspector/EPA supervisor coordinate this activity if the producing establishment is in another state or EPA region.

- In documenting shipment, distribution, sale, etc. of canceled or suspended products, document individual batch numbers of the products as well as sales records for products.
- Link the product from the marketplace back to the producing establishment (by way of a dealer) to the registrant of the product.

USE INSPECTIONS

If canceled or suspended pesticides are discovered during use inspections, the inspector should contact his/her supervisor to initiate the process for issuing a SSURO.

STORAGE AND DISPOSAL OF SUSPENDED OR CANCELED PESTICIDES

FIFRA Section 19 provides EPA with the authority to regulate the storage, transportation and disposal and recall of pesticides. In addition to the authority to require data on storage and disposal methods, FIFRA also authorizes EPA to establish labeling requirements for transportation, storage and disposal of the pesticide and its container. The law also enables EPA to take enforcement action for violations (see FIFRA sections 19(a) and 6(g)). EPA may require registrants and distributors to recall suspended and canceled pesticide products. The Agency is authorized, pursuant to FIFRA section 19(a)(1)(c) to require registrants to give evidence of their financial capacity to carry out such a recall.

To facilitate any recalls of this kind, EPA may require all persons who sell, distribute or commercially use pesticides to notify EPA, state, local and tribal officials of the quantities and locations of suspended and canceled pesticides in their possession.

A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall must submit a plan of storage and disposal of the pesticide that meets criteria set forth in FIFRA Section 19. Registrants will be reimbursed for portions of their storage costs that are attributable to delays in approval of storage plans.

A producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide who possesses a pesticide that has had its registration canceled or suspended must notify the Administrator and appropriate officials in accordance with the Order. The notification must include the following information:

- The quantity of the pesticide in possession.
- The place at which the pesticide is stored.

Chapter 13 Page 5

CHAPTER FOURTEEN STOP SALE, USE, OR REMOVAL ORDERS

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STOP SALE, USE, OR REMOVAL ORDERS

STATUTORY AUTHORITY

FIFRA section 13(a) authorizes the Administrator to issue a Stop Sale, Use, or Removal Order (SSURO) to any person who owns, controls or has in their custody any pesticide or device where:

- The Administrator has reason to believe that the pesticide or device is in violation of any provision of the Act;
- The violative pesticide or device has been or is intended to be distributed or sold in violation of FIFRA; or
- The pesticide has been suspended or cancelled.

After EPA issues a SSURO against a pesticide or device, no person can sell, use, or remove the pesticide or device except in accordance with the provisions of the SSURO.

FIFRA section 13(b) authorizes the seizure of any pesticide or device for confiscation and condemnation. Section 13(c) sets forth requirements for the disposition of pesticides or devices after condemnation.

FIFRA section 12(a)(2)(I) makes it unlawful for any person to violate any order issued under section 13.

BACKGROUND

SSUROs may be issued any time a pesticide or device is in violation of the Act. SSUROs, however, are generally reserved for situations involving a potential hazard to health or the environment. A SSURO:

- Can be expeditiously issued when EPA has a reason to believe a product is in violation of FIFRA.
- Extends to all of the violative pesticide material or devices under the custody or control of the person to whom the order is served.
- Keeps the responsibility for product disposal with the person to whom the order is served.

A SSURO will be prepared by EPA headquarters or a regional office. See Exhibit 14-1 for an example of a SSURO. The following summarizes the steps in the SSURO process:

• Identify the violation and develop evidence to support the existence of the violation.

- Prepare a complete description of the pesticide or device for EPA to include in a SSURO, such as the address of the product location, the EPA Registration Number, EPA Establishment Number, active ingredients, or product batch or lot codes.
- Prepare and issue the SSURO.
- Monitor compliance with the SSURO.
- Amend the SSURO as necessary to allow movement of the product for final disposition.
- Vacate the SSURO upon compliance with FIFRA or disposal or reconditioning of the material.

PROCEDURES

SERVING THE SSURO

Only EPA may issue federal SSUROs. However, EPA may request that a state inspector serve SSUROs at specified locations. The SSURO is served to the owner, operator or agent in charge of the establishment which has custody of the violative pesticide product or device. SSUROs are also served upon the registrant at its headquarters location if the establishment with custody/control isn't the same as the owner. EPA headquarters or the regional office may elect to serve the SSURO in person or by certified mail (return receipt requested).

The inspector should begin the service of the SSURO like an inspection, with presentation of credentials and Notice of Inspection. The "Violation Suspected" section of the Notice of Inspection must match the violation described in the SSURO. The inspector must explain to the recipient the scope and meaning of the SSURO and the obligation which it places on him/her as recipient. The explanation must include the fact that the product covered by SSURO cannot be sold, used or removed unless the SSURO is amended or vacated by a further SSURO issued by the EPA regional office or headquarters. The inspector must also provide the name of the EPA contact person.

The inspector can then review and collect records, as necessary, to document violative activity, and take inventories, if not done previously. If any samples or documents are collected, the proper inspection and sample collection procedures must continue to be followed.

The inspector will determine the amount of the product covered by the SSURO that is under the control of the person to whom the order is served. This information can be listed on a Notice of SSURO (EPA Form 3540-27; see Exhibit 1-1), affixed to the product(s) and also reported to the EPA regional office and/or headquarters. This Notice of SSURO is not to be used in lieu of a SSURO, but may be used to identify product inventory which is subject to a SSURO already issued.

REFUSAL TO ACCEPT SSURO

In the event that the person to whom the order is served refuses to accept the SSURO, the inspector shall leave a copy of the order at the establishment and explain the following to the recipient:

- The SSURO becomes effective when delivered and is binding on the recipient whether or not he/she accepts it.
- The recipient may discuss the SSURO with the contact person at EPA who is named in the SSURO.
- The recipient may be liable for a civil and/or criminal penalty for violating the terms of the SSURO as well as for the violation described in the SSURO.

The inspector should make a detailed record in his/her field notebook of this conversation and his/her actions for possible use at any subsequent hearing or court action.

NO ONE AVAILABLE TO ACCEPT SERVICE OF THE SSURO

If an inspector attempts to deliver a SSURO and the owner or agent is not present, a copy of the SSURO may be attached to the entry door of the establishment but another copy must be served by certified mail (return receipt requested) or similar method and tracked. The inspector should keep a record of his/her actions.

DISPOSING OF PESTICIDES COVERED BY A SSURO

EPA may issue a subsequent SSURO to permit the custodian of the product to bring the product into compliance or to properly dispose of it. Such orders can either be served in person, by certified mail or a method where delivery can be tracked. The original SSURO must be amended or terminated to permit movement of the product.

FOLLOW-UP INSPECTIONS

Inspectors should consult with EPA prior to follow-up inspections to assure compliance with a SSURO. Standard inspection procedures should be followed. Presentation of credentials and a written Notice of Inspection must be issued stating that the purpose of the inspection is to assure compliance with the SSURO issued on the pesticide(s) or device(s) listed in the SSURO. The inspector must confirm that the owner or agent received the SSURO and record the date received, if possible. The stock affected by the SSURO must be counted and documented, including package sizes and lot numbers. Any discrepancies between quantities in inventory and amounts stated in the SSURO must be resolved and documented.

In addition to the above information, the inspector should:

- Confirm that the company satisfied the data requirements that were the basis of the suspension or voluntarily cancellation, if applicable, by obtaining a copy of an official notification by the Office of Pesticide Programs that the requirements were satisfied and the SSURO was lifted. After obtaining this documentation the inspector may terminate the inspection.
- Determine if the company has requested or received any additional guidance from EPA concerning disposal. If so, copy and identify the guidance document(s). Provide the name of the state organization that will assist the company with disposal.
- Determine if the company has informed producing distributors and/or contacted manufacturers. If so, copy and identify record(s) of these contacts.
- Inspect production records for products named in the order and compare them to the effective date of the SSURO.
- Photograph or photocopy records showing production after the effective date of the SSURO or last production prior to the effective date. Depending on the specifics of the SSURO, production may not be prohibited but sale and distribution of the violative product are prohibited. To determine whether there have been unlawful sales, it is necessary to look at production records. The volume of production after the notification must physically remain in stock at the producing establishment. Shipping records can also be reviewed to establish whether or not products have been sold or distributed. If the SSURO is batch/lot specific, the SSURO may not prohibit production or sale/distribution of product not included in the violative batch/lot.

Some information obtained during the follow-up inspections may be claimed as FIFRA CBI (Confidential Business Information). For more information on CBI, see Chapter 1.

VIOLATIONS OF A SSURO

If a violation of a SSURO is discovered during a follow-up inspection, the inspector must:

- Report the violation to the EPA regional or headquarters office immediately.
- Document the violation (including the name, title and duties of the person responsible for the violation) and send a written report to the EPA regional or headquarters office.

EXHIBIT 14-1: MODEL STOP SALE, USE, OR REMOVAL ORDER

(Note – Currently, EPA's OECA is developing an improved model SSURO that will be inserted as Exhibit 14-1 when it becomes available.)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION __
STREET ADDRESS
CITY, STATE ZIP CODE

IN THE MATTER OF)	Stop Sale, Use or Removal Order
Respondent's Name)	
Respondent's Address)	DOCKET NO: FIFRA- (docket number)
Respondent's City, State and Zip Code)	
)	
)	

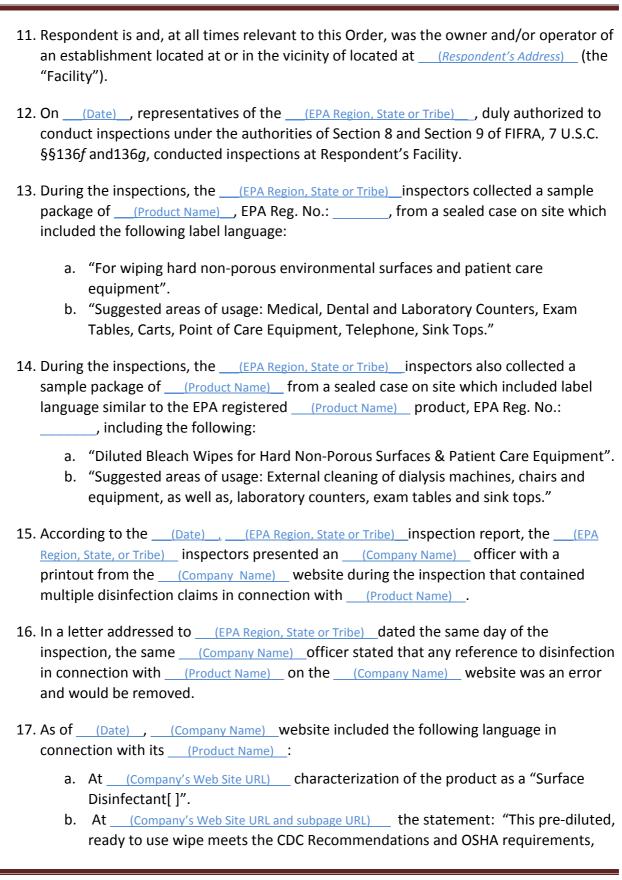
I. AUTHORITY

- 1. This Stop Sale, Use, or Removal Order ("Order") is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency ("EPA") by Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (AFIFRA"), 7 U.S.C. §136k(a), which authorizes the Administrator of the EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that, ___(Name of the pesticide, device or product) ___, the pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA. This authority was redelegated to the Regional Administrator of EPA Region ___ on ___(date) ___ by Delegation No. 5-12, and was further redelegated within EPA Region ___ to the Director of ___(division name) ___ Division and to the Associate Director for ___(office name) ___ on ___(date) ___.
- 2. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. §136*j*(a)(1)(A), makes it unlawful for any person in any State to sell or distribute to any person any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. §136*a*, or whose registration has been canceled or suspended unless otherwise authorized by EPA under FIFRA.

- 3. Pursuant to Section 3(a) of FIFRA, 7 U.S.C. §136 α (a), no person in any State may distribute or sell to any person any pesticide that is not registered under FIFRA.
- 4. Pursuant to Section 2(u) of FIFRA, 7 U.S.C. §136(u), the term "pesticide" includes "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."
- 5. Pursuant to Section 2(t) of FIFRA, 7 U.S.C. §136(t), the term "pest" includes fungus, bacteria and "other microorganisms."
- 6. The regulations implementing FIFRA give further guidance on what constitutes a pesticidal purpose, stating that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if, among other things, the person who distributes or sells the substance "claims, states or implies (by labeling or otherwise) . . . [t]hat the substance . . . can or should be used as a pesticide." 40 C.F.R. §152.15(a)(1). In addition, a substance is considered to be a pesticide requiring registration if the person who distributes or sells the substance "has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose." 40 C.F.R. §152.15(c).
- 7. Pursuant to Section 2(gg) of FIFRA, 7 U.S.C §136(gg), to Adistribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.
- 8. Sections 2(gg) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§136(gg) and 136j(a)(1)(A), make it unlawful for any person to "offer for sale" any pesticide if it is unregistered. EPA's regulations at 40 C.F.R. §168.22 clarify that such prohibition extends to advertisements in any advertising medium to which pesticide users or the general public have access.
- 9. This Order requires <u>(Respondent's Name)</u> to stop the sale, use, or removal of unregistered pesticides owned, controlled, or in its custody at or from its establishment located at or in the vicinity of <u>(Respondent's Address)</u>, or at or from any other establishment wherever located. <u>(Respondent's Name)</u> shall undertake all actions required by this Order, and comply with all requirements of this Order, including any subsequent modifications to this Order.

II. BASIS FOR ORDER

10. <u>(Respondent's Name)</u> ("<u>Respondent Name</u>") or "Respondent"), located at <u>(Respondent's Address)</u>, is a Aperson" as that term is defined at Section 2(s) of FIFRA, 7 U.S.C. §136(s).



while being consistent with many medical equipment manufacturers' recommendations for surface decontamination".

- c. At <u>(Company's Web Site URL)</u>, the statements:
 - (i). "___(Product Name)__ meet the CDC Recommendations and OSHA requirements (1:100 dilution is consistent with many medical equipment manufacturers' recommendations)".
 - (ii). <u>(Product Name)</u> reduce the risk of cross contamination . . . and eliminate stability problems associated with bleach buckets, or diluted spray".
 - (iii). a "Stability of Bleach" table illustrating the concentration of bleach over thirty (30) minutes of exposure.
 - (iv). "APPROPRIATE FOR THE FOLLOWING MARKETS: Medical & Health Care Labs, Dialysis, Long Term Health Care, Acute Hospital, Dentistry, Ambulatory Care, Veterinary".
- d. At <u>(Company's Web Site URL)</u>, the statements:
 - (i). "Would you like a convenient, time saving method for surface contamination?".
 - (ii). <u>(Product Name)</u> meet the CDC Recommendations and OSHA requirements (1:100 dilution is consistent with many medical equipment manufacturers' recommendations)".
 - (iii). <u>(Product Name)</u> reduce the risk of cross contamination . . . and eliminate stability problems associated with bleach buckets, or diluted spray".
 - (iv). a "Stability of Bleach" table illustrating the concentration of bleach over thirty (30) minutes of exposure.
 - (v). "APPROPRIATE FOR THE FOLLOWING MARKETS: Medical & Health Care Labs, Dialysis, Long Term Health Care, Acute Hospital, Dentistry, Ambulatory Care, Veterinary".
 - (vi). procedures for use for "Decontamination of Surfaces".
 - (vii). under "CDC Guidelines and Recommendations for 1:100 Diluted Bleach Solution":

Environmental Infection Control of Healthcare Facilities- June 2003

"If the surface is nonporous ...and sodium hypochlorite solution is used, a dilution of 1:100 for decontaminating assuming that A) the worker assigned to clean the spill is wearing gloves and other personal protective equipment to the task, B) most of the organic matter of the spill has been removed with absorbent material and C) the surface has been cleaned to remove residual organic matter."

Recommendation for Preventing Transmission of Infections among Chronic Hemodialysis Patients MMWR50 (RR05); 1-43

"Intermediate level disinfection kills bacteria and most viruses and is accomplished by using a 1:100 dilution of bleach (300-600 mg/L free chlorine). For a blood spill, immediately clean the area with a 1:100 dilution of household bleach."

Draft Guideline for Disinfection and Sterilization in Healthcare Facilities HICPAC 2/20/2002

"If sodium hypochlorite solutions are selected use a 1:100 dilution (500 ppm available chlorine) to decontaminate nonporous surfaces after cleaning a small spill of either blood or OPIM [other potentially infectious material]."

Guideline for Infection Control in Dental Healthcare Settings - 2003, 2003MMWR (RR17)

"Sodium hypochlorite is an inexpensive and effective intermediate level germicide. Concentrations ranging from 500 ppm to 800 ppm of chlorine (1:100 dilution of 5.25% bleach and tap water, or approximately 1/4 cup of 5.25% bleach to 1 gallon of water) are effective on environmental surfaces that have been cleaned of visible contamination."

- e. at ((Company's Web Site URL) the following statements:
 - (i). procedures for use for "Disinfection of Surfaces".
 - (ii). "Wipe the desired surface to be disinfected".
 - (iii). under "CDC Guidelines and Recommendations for 1:100 Diluted Beach Solution":

Environmental Infection Control of Healthcare Facilities- June 2003

"If the surface is nonporous ...and sodium hypochlorite solution is used, a dilution of 1:100 for decontaminating assuming that A) the worker assigned to clean the spill is wearing gloves and other personal protective equipment to the task, B) most of the organic matter of the spill has been removed with absorbent material and C) the surface has been cleaned to remove residual organic matter." (for more detailed information click here)

Recommendation for Preventing Transmission of Infections among Chronic Hemodialysis Patients MMWR50 (RR05); 1-43

"Intermediate level disinfection kills bacteria and most viruses and is accomplished by using a 1:100 dilution of bleach (300-600 mg/L free chlorine). For a blood spill, immediately clean the area with a 1:100 dilution of household bleach." (for more detailed information click here)

Draft Guideline for Disinfection and Sterilization in Healthcare Facilities HICPAC 2/20/2002

"If sodium hypochlorite solutions are selected use a 1:100 dilution (500 ppm

available chlorine) to decontaminate nonporous surfaces after cleaning a small spill of either blood or OPIM [other potentially infectious (<u>for more detailed information click here</u>) material]."

Guideline for Infection Control in Dental Healthcare Settings - 2003, 2003MMWR (RR17)

"Sodium hypochlorite is an inexpensive and effective intermediate level germicide. Concentrations ranging from 500 ppm to 800 ppm of chlorine (1:100 dilution of 5.25% bleach and tap water, or approximately 1/4 cup of 5.25% bleach to 1 gallon of water) are effective on environmental surfaces that have been cleaned of visible contamination." (for more detailed information click here)

- 18. At <u>(Company's Web Site URL)</u>, <u>(Product Name)</u> "09301-100 <u>(Product Name)</u>
 Singles 1:100 Quantity: 100 pkgs per Box" and "09302-50 <u>(Product Name)</u> Doubles 1:100 Quantity: 50 pkgs per Box" are available to the public for online purchasing.
- 19. Together, the language described in paragraphs 14 and 17, above, claim, state, or imply that <u>(Product Name)</u> can or should be used as a pesticide.
- 20. <u>(Product Name)</u> is a pesticide, as defined in Section 2(u) of FIFRA, 7 U.S.C. §136(u), and 40 C.F.R. §§152.3 and 152.15.
- 21. <u>(Product Name)</u> is not registered with EPA as a pesticide, and has never been so registered.
- 22. Respondent owns, controls and/or has custody of the <u>(Product Name)</u> described herein, and has sold or distributed or intends to sell or distribute such product to other persons, in violation of Sections 12(a)(1)(A) of FIFRA, 7 U.S.C. §§136*i*(a)(1)(A).

III. ORDER

- 23. This Order requires Respondent to stop the sale, use, or removal of unregistered pesticides owned, controlled, or in the custody of Respondent at or from an establishment located at or in the vicinity of (Establishment Address), or at or from any other establishment wherever located. Respondent shall undertake all actions required by this Order, and comply with all requirements of this Order, including any subsequent modifications to this Order.
- 24. EPA hereby orders the Respondent to stop the sale, use or removal of <u>(Product Name)</u>.
- 25. This Order shall pertain to all quantities (in all packaging types and sizes) of (Product Name), owned, controlled, or in the custody of Respondent or any parties acting as

agents for Respondent wherever they may be located. The product covered by this Order shall not be distributed, sold, offered for sale, held for distribution, held for sale, held for shipment, shipped, delivered for shipment, released for shipment, received and (having been so received) delivered or offered for delivery, moved, used or removed for any reason, other than in accordance with the provisions of this Order or any such further order as may be issued by EPA in connection with the pesticide product identified in this Order.

- 26. Violation of the terms or provisions of this Order may subject Respondent and/or any responsible individuals to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. §136/.
- 27. The issuance of this Order shall not act as a waiver by EPA of any enforcement or other authority available to EPA under FIFRA or any other federal statute.
- 28. This Order shall be effective immediately upon receipt by Respondent or any agents of Respondent.
- 29. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified, in writing, by EPA.
- 30. For instructions as to the ultimate disposition of all existing stocks of (Product Name), and for technical assistance regarding any matter addressed in this Order, please contact:

```
(Regional Pesticide Staff Person Name)
(Region Division / Branch, and Mail Code)
U.S. EPA, Region ???
(Regional Address)
Phone: ( ) #
Fax: ( ) #
E-mail:
```

31. For questions regarding legal matters relating to this Order, you or your attorney may contact:

```
(ORC Attorney's Name), Esq. (Mail Code)
(Division / Branch)
U.S. EPA, Region ???
(Regional Address)
Phone: ( ) #
Fax: ( ) #
E-mail:
```

Date (Name of EPA Director), Director (Name of Division)

CHAPTER FIFTEEN RECALLS

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RECALLS

STATUTORY AUTHORITY

FIFRA section 19(b) authorizes the recall of products if the registration of a pesticide has been suspended or canceled under section 6 or when the Administrator finds that a recall is necessary to protect health or the environment.

VOLUNTARY RECALL

If, after determining that a recall is necessary, the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to submit, within 60 days of the request, a plan for the voluntary recall of the pesticide. If such a plan is requested and submitted, the Administrator shall approve the plan and order the registrant to conduct the recall in accordance with the plan unless the Administrator determines, after an informal hearing, that the plan is inadequate to protect health or the environment.

MANDATORY RECALL

If, after determining that a recall is necessary, the Administrator does not request the submission of a voluntary recall plan or finds such a plan to be inadequate, the Administrator shall issue a regulation that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor or seller of the pesticide or any successor in interest to such a person.

A regulation prescribing a mandatory recall may require any person that is subject to the regulation to:

- Arrange to make available one or more storage facilities to receive and store the
 pesticide to which the recall program applies and inform the Administrator of the
 location of each such facility.
- Accept and store at such a facility those existing stocks of such pesticide that are tendered by any other person who obtained the pesticide directly or indirectly from the person that is subject to such regulation.
- On the request of a person making such an offer, provide for proper transportation of the pesticide to a storage facility.
- Take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pesticide of the terms of the recall regulation and how those persons

may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

CONTENTS OF RECALL PLAN

A recall plan established under FIFRA section 19(b) shall include:

- The level in the distribution chain to which the recall is to extend and a schedule for recall.
- The means to be used to verify the effectiveness of the recall.

Failure to comply with a voluntary/mandatory recall may result in the issuance of a stop sale, use or removal order to the consignees of the pesticide in question.

OBJECTIVES

The recall program is designed to remove any violative product from the market as expeditiously as possible. Recalls may be initiated in any case in which the available information indicates that the product is (1) potentially hazardous when used as directed or (2) ineffective for the purpose(s) claimed in the registration. A product will be considered for recall when, among other things, its use as directed would likely result in the following:

- Economic or physical injury to the user or handler of the product.
- Injury to animals or plants where direct application is made.
- Injury resulting from illegal residues.
- Injury to fish or wildlife.
- Other adverse effects on the environment.

A recall may be made after the cancellation by EPA of a product due to lack of existing tolerance, environmental damage caused by a pesticide's labeled uses, or EPA actions taken under the Food Quality Protection Act of 1996 during a pesticide's registration or reregistration, such as cancellation due to harm to workers, or human health risk analysis.

RECALL PROCEDURES

PROCESS

The following summarizes the steps by Office of Pesticide Programs and the Office of General Counsel in the recall process:

- Identify the violation and develop evidence to support the violation and the hazard presented.
- Prepare a complete description of the material to be recalled and the level in the distribution chain to which the recipient will be requested to remove the product.
- Prepare and issue the recall.

Inspectors participate in the process by monitoring the quantities returned from each location and by monitoring the disposition of all returned material.

LEVELS OF RECALLS

The level of recall refers to the point in the distribution chain from which the product is to be recalled. The determination of that point is based on the potential hazard, use pattern and distribution pattern of the product. The levels of recall can extend to the following:

- Pesticide products under the registrant's control.
- Products in the chain of distribution not under the control of the registrant.
- User-level recalls. Recalls at this level generally are requested only in cases where there is a very serious hazard to human health or the environment.

NOTIFICATION TO THE COMPANY

A notification will be sent to the registrant's headquarters ordering a recall. The letter will include:

- A brief summary of why EPA is requesting a recall.
- A request that the company provide EPA with the amount and location of product that is being recalled (if it is known).
- A request that EPA be provided with information on all steps taken in connection with the recall and an accounting of the amount that was actually recalled.

Additionally, EPA may provide draft recall letters for the company to send to their primary and secondary distributors and for those distributors to send to their customers.

The company is encouraged to contact EPA and discuss the notice. In urgent cases, EPA will initially notify the company by telephone and/or facsimile.

INSPECTION PROCEDURES

After the company has received notification of recall from EPA, an inspector will be assigned to monitor the recall. EPA will provide the inspector with the recall notification. In some instances,

the inspector may receive a strategy from EPA's Office of Enforcement and Compliance Assurance for monitoring the recall. If OECA has not provided a strategy, the EPA regional supervisor and the inspector must develop their own strategy before proceeding. The inspector will receive a copy of any recall agreement between the registrant(s) and EPA. Each recall is unique. The inspector must review and understand the terms of the recall before conducting an inspection.

INITIAL VISIT TO COMPANY(S) IDENTIFIED IN THE RECALL

An initial visit must be planned to occur approximately 30 days after the date of the recall notification. The 30-day time period provides adequate time for the company to respond to the recall notification and decide upon a course of action. The inspector must review the progress of the recall with the responsible company official and obtain copies of documents, records and correspondence used by the company in the recall. If the inspector discovers that the terms of the recall are not being met (e.g., failure to notify distributors as required), the inspector must document the noncompliance. This may be accomplished by photocopying appropriate documents or taking statements from knowledgeable persons.

FOLLOW-UP TO RECALL

The inspector may conduct interim visits to the company or receive status reports from the company to document how the recall is proceeding.

FOLLOW-UP AFTER COMPLETION OF RECALL

Once EPA receives information that the inspector located all available pesticide products and that the products were either returned or held, the regional EPA pesticide supervisor may decide to visit a select number of consignees to determine the effectiveness of the recall. Each consignee visited must be asked whether the firm received a recall letter, whether any of the pesticide products in question was on hand and, if so, whether the company complied with the recall letter. The inspector should document responses.

REPORTING

All inspection reports must be provided to the regional supervisor for evaluation and a summary of the inspection reports must be forwarded to EPA headquarters.

INITIAL RECALL REPORT

The initial visit report must be a narrative that reflects the company's efforts to implement the recall and will include:

- When appropriate, a list of consignees to whom the recall letters were mailed and the date(s) sent.
- Any documentation obtained during the visit.

INTERIM REPORTS

Interim reports must be submitted on: (1) a regular basis as required by the compliance strategy, and (2) whenever any new information becomes available.

FINAL RECALL REPORTS

The final recall report is the inspector's narrative summarizing actions taken by the company and must be submitted as soon as the recall is completed in accordance with the recall notification. This report must include the following information:

- Name of the product being recalled.
- EPA Registration Number of the product being recalled.
- Batch number(s) of the product being recalled.
- Name, address and contact for the company that received EPA's letter requesting the recall of the product.
- Action taken by the company, such as:
 - Number of consignees the company had and number of consignees they contacted.
 - o Actual amount of the product the company distributed to consignees.
 - Amount of products the consignees still have in their control.
 - Number of consignees that returned product.
 - Total amount of product returned for all of the consignees.
- What the company did with the product. (Did they dispose of it or reuse it?)
- Which consignees the inspector visited; dates of inspections; and documented discrepancies.

CHAPTER SIXTEEN INSPECTION REPORTS AND SUPPORTING DOCUMENTATION

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INSPECTION REPORTS AND SUPPORTING DOCUMENTATION

INTRODUCTION

Information gathered and presented by inspectors is essential to the success of the enforcement program. The inspector must be able to prepare clear, objective and well-documented written inspection reports.

PURPOSE OF WRITTEN REPORTS

COMMUNICATE

The main purpose of a written inspection report is to clearly and concisely communicate a complete and factual record of the inspection process, observations and results to the reader, from the opening conference, through the inspection/collection of samples, to the closing conference. To communicate effectively, the report must be a complete and accurate record of what was discovered and what occurred during the inspection. The report shall not contain any opinions of the inspector and shall not make any conclusions of law.

PROVIDE A BASIS FOR COMPLIANCE DETERMINATION/ACTION

The inspection report must contain information and documentation about the inspection that will enable a case review officer to determine:

- the facility's compliance with FIFRA and
- that the inspector followed statutory requirements for:
 - presenting credentials,
 - o issuing a Notice of Inspection, containing a reason for the inspection,
 - o collecting evidence and issuing a Receipt for Samples.

If enforcement action is warranted, the inspection report must contain all the elements necessary to support any alleged violations. For example, if an inspector discovers an unregistered pesticide, the inspector must gather the complete pesticide label (i.e., front and back panels and any associated booklets or labeling materials) and/or take high resolution digital photographs of the product, and collect shipment and/or distribution information for the product, along with any other relevant information about the product and include this

information in the inspection report. If an inspection report is not complete or accurate, EPA may have to expend additional time and resources.

RELEASABILITY OF WRITTEN REPORTS AND RECORDS

The regulated community sometimes requests copies of written reports and records associated with inspections. The Freedom of Information Act (FOIA) governs the disclosure of information to industry and the public and is discussed in Chapter 1. Federal inspectors, as well as state or tribal inspectors performing federal inspections, shall not release any notes, documents, reports, etc. obtained or prepared in connection with a FIFRA inspection until such time as enforcement proceedings are concluded or as advised by counsel. To assist in keeping inspection reports internal, inspectors should mark all written reports and records as "ENFORCEMENT CONFIDENTIAL". If an inspector receives a request for a written inspection report, the inspector should contact the EPA regional FIFRA program office or headquarters FIFRA enforcement office.

FIVE STEPS IN WRITING A NARRATIVE REPORT

STEP 1—PLAN

By planning how facts must be presented in the inspection report prior to the inspection, the inspector can improve the quality of the inspection report as well as the inspection itself. It should be noted that some elements that will need to be included in or with the report (i.e., samples analysis) may not be available at the time of report preparation. Do not delay preparing the report while waiting for sample analysis. Sample analysis can be added as an exhibit to the report when it becomes available.

STEP 2—ORGANIZE THE MATERIAL

All information gathered during the inspection must be reviewed for relevance and completeness. This includes inspection report forms, field notebooks and checklists. The field notebook and/or inspection checklists are useful tools for developing the narrative report, but cannot replace a narrative report. Any identified gaps in the information must be resolved by follow-up telephone calls or follow-up inspections. The material must then be organized in the order that it will be presented in the report.

STEP 3—WRITE

While writing the inspection report, keep the following in mind:

- The inspection report should be a complete record of what occurred at the inspection, including conversations that took place, documentation that was collected and physical samples that were collected. Photographic evidence should be included when appropriate.
- Just report the facts as to what was observed. Do not include opinions or conclusions of law. Keep the reader in mind. When preparing an inspection report, assume that the reader knows nothing about the case except what is in the report. The report must construct a complete and accurate picture of the entire inspection, step-by-step.
- The report should be peer-reviewed before it is finalized.

STEP 4—EVALUATE

After writing the report, review the report from the viewpoint of the reader and answer the following questions:

- Does it answer the questions—who, what, when, where, why and how?
- Is each asserted fact supported, with a citation provided, by a document, picture, sample, recorded observation or statement from an individual?
- Is it fair, concise, complete, accurate and logical? Is any part ambiguous?
- Does it communicate clearly?
- Is there any other information needed to fulfill the purpose of the investigation?
- Can supervisors and reviewers make appropriate decisions based on this report?
- Are any further inquiries necessary?

Proofread the report to check for inconsistencies, unnecessary repetition, tone, omissions and typographical errors.

STEP 5—REWRITE

Correct those portions of the narrative that were identified as needing improvement.

ESSENTIALS OF A GOOD REPORT

- Fairness—The report must be objective, impartial, unbiased and unemotional. Convey facts so they speak for themselves. Avoid rumors, gossip, or offensive remarks or language. To test for fairness, read the material aloud to ensure the report is conveying the proper tone for the reader and the purpose of the report.
- Accuracy—The information must be stated precisely and accurately in plain language.
 The inspection report must under no circumstances include the inspector's conclusions

regarding compliance or noncompliance. The goal is to present the facts clearly. If the inspector wants to communicate certain opinions to the reviewer, these opinions must be contained in a memorandum to the file or legal office separate from the inspection report and be marked "enforcement confidential" and "attorney-client privileged." These memoranda are usually "to the file" and identified as "Not for FOIA release." In an enforcement case, the entire inspection report is subject to discovery by the opposing side. If conclusions of law or opinions are in the report, it may weaken the inspector's credibility. In addition, the inspector may have been wrong about a violation. Attorney-client privilege typically protects a separate memorandum of findings or conclusions from discovery.

- **Completeness**—Include all information observed. Something that may seem irrelevant at the time of the inspection may prove relevant later on. All known facts should be reported either in the text or as an attachment, so that no further explanation is needed. The report must answer the questions "who, what, when, where, why and how." Each asserted fact should be supported, with a citation provided, by a document, picture, sample, recorded observation or a statement from an individual.
- **Sources of evidence**—Always report the source of information (including their job title) and document where samples were obtained.
- Attachments—The report will consist of a narrative portion with appropriate
 attachments that are labeled and consistently referenced in the report so that they are
 easy to follow and find. The attachments will support and document that the inspector
 followed statutory requirements and will be used as the basis to make a decision as to a
 facility's compliance status. Always reference attachments parenthetically in the
 narrative portion of the report and consecutively number in the order mentioned.
- Facts indicating weaknesses in the case—Explanations from the individuals being
 interviewed or important facts that point to weaknesses in the case should not be
 omitted. Subsequent disclosure of facts indicating weaknesses that were known by the
 report writer but not disclosed may compromise any potential enforcement action.
 Disclosure of any potential weaknesses in the report will give reviewers an opportunity
 to determine the appropriate a course of action.
- **Conciseness**—Concise writing includes facts, details and necessary explanation, but is free of all that is elaborate or non-essential. Conciseness is not what is said, but how it is said. Use short sentences with active verbs and paragraphs whenever possible.
- **Clarity and logical presentation**—The report must be written clearly in order to avoid misinterpretations. Writing takes time and effort. Order thoughts and arrange them logically, and select the words that will best convey the thoughts to the reader.

CBI CONSIDERATIONS

An inspector may encounter Confidential Business Information (CBI) during an inspection. Examples of CBI may include:

- Establishment's pesticide production records,
- Batch records,
- Product formulation, and/or
- Annual pesticide production reports.

Those portions of the report that contain CBI must be treated in accordance with FIFRA CBI procedures. See Chapter 1 for more information on CBI procedures.

REPORT FORMAT

The inspection report consists of a narrative report with several attachments. See Exhibits 16-1 and 16-2 for examples of inspection report outlines.

SUPPORTING DOCUMENTATION

In addition to physical samples, documentary support is necessary for an enforcement case. These documents may include field notebooks, statements, copies of records, photographs, drawings and maps, printed matter and mechanical recordings. Establishing a chain of custody is just as important for supporting documentation as it is for pesticide product sampling and residue and environmental sampling. The chain of custody establishes where the document has been and how it has been treated since it was collected. See Chapter 6 (Pesticide Product Sampling) and Chapter 7 (Residue and Environmental Samples) for additional information.

FIELD NOTEBOOKS

The field notebook is the core of all inspection documentation. The field notebook (preferably bound) is part of the Agency's files and is not the inspector's personal record. Notebooks must be held indefinitely as supporting documentation to the inspection file. The field notebook is intended to provide accurate and inclusive documentation of all inspection activities and to provide a basis for written inspection reports. Inspectors shall record only facts and pertinent observations using objective language, free of personal feelings.

It is essential for the inspector to keep detailed records of inspections, investigations, samples collected, etc. to serve as an aid in writing reports and giving testimony. The following types of information shall be included in the field notebook:

- **Observations**. Record all conditions, practices and other observations that will be useful in preparing the inspection report or will contribute to establishing valid evidence.
- **Unusual conditions and problems**. Note and describe in detail any unusual conditions and problems encountered during the course of the inspection visit.
- **General information**. List names and titles of personnel encountered and the activities they perform, along with any statements they may have made and other general information.

Inspectors should either have separate field notebooks for each inspection or clearly identify each inspection separately in the field notebook so that copies of the notes applicable to the inspection can be included in the case file should enforcement action be taken.

STATEMENTS

An inspector should obtain statements from persons having knowledge of the facts pertinent to a potential violation. Use EPA Statement Form 3540-42 (Exhibit 1-1). The purpose of obtaining a statement is to have a written record containing factual information to be used to determine if there has been a violation or to document an alleged violation. Statements are similar to affidavits except that the statement is not made under oath. The following procedures and considerations may be helpful in developing a proper statement:

- Determine the need for a statement. Will a statement provide useful factual information that will help to determine whether a violation occurred or to show a violation occurred? Is the person making the statement qualified to do so by having personal knowledge?
- Identify the person making the statement (name, position, address, etc.).
- Explain why the person is qualified to make the statement.
- Use a simple narrative style (avoid stilted language).
- Narrate the facts in the words of the person making the statement (use the first-person singular).
- Present the facts in chronological order, unless the situation calls for some other arrangement.
- Read the statement to the person (preferably in the presence of a witness) and make any necessary changes, initialing all corrections or changes.
- Ask the person making the statement to write a brief concluding paragraph indicating that he/she read and understood the statement. This safeguard will counter a later claim that the person did not know what he/she was signing.
- Have the person sign the statement. The inspector must also sign and date the statement. Be sure to provide a copy of the statement to the signer, if requested.
- If he/she refuses to sign the statement, elicit a verbal acknowledgment that it is true and correct, and then record that acknowledgement on the statement. The inspector

should initial or sign the statement nearby the written verbal acknowledgement, and also sign the statement in the appropriate block at the bottom of the form.

PHOTOGRAPHS

Photographs are valuable as evidence as they provide an objective record of the conditions at the time of inspection. EPA encourages inspectors to use high-resolution digital photography to document the products and devices observed during inspection. When taking photographs during an inspection, follow these steps:

- Follow the guidelines in the <u>EPA Digital Camera Guidance for EPA Civil Inspections and</u> Investigations.
- All photos should be recorded on the EPA Photo Log, EPA Form 3540-43 (see Exhibit 1-1).
- Chain-of-custody procedures apply to photos. Keep all digital and/or original hard copy photos in a secure location and do not alter photos in any way. If an alteration is necessary (cropped, enlarged, etc), save a copy of the original for reference.
- Digital photographs are preferable, but if photographs are taken on film, the inspector
 must immediately identify the location, date, inspector's initials and related sample
 number (if applicable). The field notebook should identify the order in which
 photographs are taken and, once developed, the same information should be written on
 the back of the photo itself.
- It is sometimes useful to photograph a subject from a point that will indicate the location and direction of the subject. The addition of an object of known size, such as a person, car, coin or ruler will help indicate the size of the subject. This is known as using a reference by which to judge size, distance or location.
- Do not take photographs of written records or reports that are or may be considered CBI. However, pesticide products, product labels and establishments are generally not considered CBI and not subject to confidentiality claims. Although EPA has the authority to take photographs during inspection, if there is sensitive or confidential material in the establishment, the inspector shall request that pesticides be moved to a non-sensitive area of the establishment (such as the loading dock) for photographs.
- Videography is also appropriate in enforcement documentation. The same recommendations apply to videography as apply to photography.

DRAWINGS AND MAPS

Schematic drawings, maps, charts and other graphic records may be useful in documenting a violation. Drawings and maps should be simple and free of extraneous details. Basic

measurements must be included to provide a scale for interpretation and compass points must be included.

All drawings, maps, etc. must be identified with the inspector's initials, the date, sample number and any other pertinent information (e.g., "not drawn to scale"). It would be useful to identify the source of any commercial map, chart or other graphic record.

PRINTED MATTER

Brochures, literature, labels and other printed matter can provide important information regarding a firm's conditions and operations. These materials may be collected as documentation. All printed matter must be identified with date, inspector's initials and related sample numbers.

MECHANICAL RECORDINGS

Records produced electronically or by mechanical apparatus can be used as evidence. Follow normal chain-of-custody procedures in collecting electronic records.

EXHIBIT 16-1: FIFRA ESTABLISHMENT INSPECTION REPORT EXAMPLE

Establishment Name
Street Address
(Mailing Address, if different)
City, State Zip Code

Date of Inspection

Performed by:
U.S. Environmental Protection Agency (or state/tribal government)
Office/Division/Branch
Address
City, State Zip Code
FIFRA Establishment Inspection Report
[Inspection No. __ FIFRA ____]

VI.	Inspection Summary A. Opening Conference B. Inspection Observations and Sample Collection C. Closing Conference
VII.	Index of Attachments
	A. Standard Forms
	 FIFRA Notice of Inspection Receipt for Sample Chain of Custody
	B. Evidence
	 Photographs Copy of Label on Physical Sample Copy of Records a. Records of Inbound Shipments b. Production Records c. Inventory Records d. Shipping Records Product, Device or Bin Labels/Labeling Statements
	6. Laboratory Analysis

Company Information

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EXHIBIT 16-2: FIFRA USE/MISUSE INVESTIGATION REPORT EXAMPLE

Name of Suspected Violator Street Address (Mailing Address, if different) City, State Zip Code

Date of Inspection

Performed by:
U.S. Environmental Protection Agency (or state/tribal government)
Office/Division/Branch
Address
City, State Zip Code
FIFRA Use Inspection Report
[Inspection No. __ FIFRA _____]

I. Participants

- A. Complainant/Address/Telephone Number
- B. Certified Applicator/Company Name/Address/Telephone Number
- C. Suspected Violator/Company Name/Address/Telephone Number
- II. Circumstances
 - A. What Happened and Where
 - B. How and What was Reported
- III. Chemical Information (EPA Reg. No., brand name, specific language on the label that is relevant to the investigation)
- IV. Investigation
 - A. Investigator's Activities in Sequential Order
 - B. Statements (who, when and what)
 - C. Mapping/Photographs (where, what)
 - D. Sampling (what type of sample(s) were collected and where, what analyzed for)
 - E. Records (sales or application)
 - F. Weather Data (what records were obtained, from whom, date obtained, what do the records show)
- V. Attachments

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ENFORCEMENT

If violations of law are detected during an inspection and documented properly, EPA may initiate a civil or criminal enforcement action. EPA typically initiates a civil enforcement action by filing an administrative complaint with the Office of Administrative Law Judges, pursuant to the procedural rule set forth in 40 C.F.R. Part 22. EPA may also initiate a criminal action in federal court to address knowing and willful FIFRA violations. This chapter will focus on the role of the FIFRA inspector during enforcement proceedings.

CIVIL ENFORCEMENT

HEARINGS

At a FIFRA enforcement hearing, the inspector may serve several roles. As part of the enforcement team, the inspector's knowledge is critical in determining the violations and preparing documents for hearings. Most importantly, the inspector may be called upon to serve as a fact and/or expert witness in civil and criminal proceedings and may be required to provide testimony and documents in support of EPA's enforcement action.

PREHEARING PREPARATION

Any inspection may result in an enforcement action. Therefore, inspectors should approach each and every inspection as if it will go to trial—scrupulous attention to procedure, highly professional conduct and detailed, solid documentation. To prepare for a hearing, the inspector may be asked to:

- Ensure the inspection file is complete and organized. Go over the facts of the case with
 the assigned attorney before any complaint is filed. If you suspect there are any
 problems with the potential evidence in the case, bring those problems to the attention
 of your attorney right away.
- Meet with the assigned attorney to determine your involvement in the hearing and to go
 over expected testimony. Ask what the attorney intends to prove by your testimony, and
 how the attorney intends to use any documents or items of potential evidence collected
 during the inspection. Ask any questions of the attorney at the earliest opportunity. It
 will be too late to find out what you are supposed to do once the hearing begins.
- Clear your calendar for the days you will be needed as a witness. Your attendance will be mandatory.

SERVING AS A WITNESS IN A HEARING

Demeanor matters when serving as a witness. An inspector's demeanor must reflect the serious nature of the proceeding. Here are some tips:

- Do not discuss the case with anyone that is not part of the EPA team. Hold discussions
 among the EPA team only when you are in a location where no one else can overhear.
- Do not whisper, talk or cause any disturbances in the courtroom.
- Sit in the seats provided for the spectators but as near the front as possible since the EPA attorney may need to consult with you during the hearing.
- Do not bring magazines or newspapers into the courtroom. The inspector should listen intently to the proceeding while in the courtroom.
- Do not react to testimony given by other witnesses or at statements made by the defense attorney. Negative reactions make the witness appear unprofessional.
- Be on time and be available immediately when called to testify.
- Expect to stay in the courtroom when not testifying to listen to the testimony of other witnesses. It may trigger a forgotten fact, a memory or an interpretation. Note that you may be instructed to leave the courtroom and, if so, leave calmly.
- Do not interrupt the attorney while the hearing is in progress. If you must convey information, write it down and hand him/her the note. He/she will look at it when he/she can concentrate. If necessary, he/she can ask for a recess and talk to you.
- When in doubt about anything, consult the government attorney.
- When called to the witness stand go directly to the desk of the clerk of the court (or the judge) to be sworn in.
- The judge or clerk will ask you to swear that your testimony will be true. The answer is "yes" or "I will" depending on how the oath is worded. If you cannot in good conscience "swear under oath," state that you wish to "affirm" your testimony. Inform the government attorney of this prior to the hearing.
- Your testimony will be taken down by tape recording or manual transcription by the court reporter. Therefore, answers to questions must be made verbally rather than by shaking or nodding your head. Dimensions and directions must be given verbally rather than demonstrated.
- Always pause before answering clearly and distinctly. Pausing gives the attorney time to object to the question, if necessary.
- The judge may ask you a question from the bench. Address him/her as "Your Honor" and answer the question.

- You must be objective and professional. A calm demeanor projects confidence.
 Therefore, do not show hostility toward the defendant or the opposing counsel.
- If you need to use acronyms or technical terms, make sure you explain what they mean. You must make sure your attorney knows the terms before the hearing and that the court reporter knows what they are and how to spell them. Try to use everyday language when possible.
- Always tell the truth.
- Answer only the question asked. Do not volunteer additional information.
- Do not be afraid to say, "I do not know," or "I do not understand the question," if indeed you do not know the answer. This answer must never be used to be evasive. You may be qualified as an "expert witness" but this does not mean you are infallible; you can only answer the questions to the best of your ability.
- Do not give personal opinions unless qualified as an expert witness.

THE DIRECT EXAMINATION

Direct examination is conducted by the EPA attorney. Before the hearing, the EPA attorney will prepare the inspector by reviewing every question you will be asked during direct examination and every answer you will give.

The EPA attorney will ask the witness to identify themselves and describe their connection to the case. This will "lay the foundation" for the witness's testimony. Inspectors will then be asked about their first-hand knowledge of pertinent facts in the case. This will establish the witness as a fact witness and will identify the intended subject of the testimony.

Most inspectors will serve as a fact witness and will testify to what they did, saw and heard. However, if the inspector will also serve as an expert witness, a foundation will be laid to establish the specialized knowledge or skills that qualify him/her as an expert. Typically, questions that will establish the requisite expertise will focus on education, training or experience.

CROSS EXAMINATION

Cross examination is conducted by opposing counsel. The purpose of cross examination is to cast doubt on the direct testimony. This can be done by attacking credibility, showing inconsistencies, attacking underlying facts and by attacking opinions, amongst other methods. The inspector should project a calm, professional demeanor and avoid being defensive. Under cross examination, you will be subject to more vigorous questioning than under direct examination. Special tips for cross examination:

- Opposing counsel may try to confuse you or get you angry. This is intentional. Remain calm, do not react and answer the question to the best of your ability.
- Opposing counsel may challenge your truthfulness, your credentials, your ability to do
 your job or your conclusions. This is intentional. Remain calm, do not react and answer
 the question to the best of your ability.
- Opposing counsel may ask compound questions (more than one question at a time) or rapid questions. Remain calm and answer at your own pace. You may ask for questions to be repeated or restated.
- Do not be argumentative.
- Opposing counsel will deliberately ask questions to elicit a "yes" or "no" answer. However, if you need to elaborate, do so.
- Opposing counsel may pose hypothetical questions that require you to give an opinion or draw a conclusion. As a fact witness (as opposed to an expert witness) you may not give opinions. Therefore, avoid answering hypothetical questions.
- Do not agree with the opposing attorney just to get him/her to stop badgering you.
- If the cross-examiner should misquote any of your earlier testimony when asking a question, you should correct them before answering the question.
- If you make an error while testifying, correct it at the first opportunity. If you discover the error after you have completed your testimony and have been dismissed as a witness, discuss the matter with the government attorney as soon as possible. If you have made an error, admit it and explain it, if possible.

CRIMINAL ENFORCEMENT

The mission of EPA's criminal enforcement program is to investigate, help prosecute and deter the most egregious environmental offenders. Our nation's environmental laws include criminal provisions that address knowing and negligent environmental violations. Criminal enforcement brings to bear the possibility of incarceration and monetary fines that are EPA's strongest sanctions.

FIFRA inspectors are among the pesticide enforcement personnel most likely to initially detect criminal environmental violations. Any FIFRA inspector who uncovers what he/she believes to be any type of criminal environmental offense must bring this fact promptly to the attention of their EPA supervisor and, in turn, notify the EPA criminal enforcement counsel of Special Agents. Many environmental criminal investigations and prosecutions can trace their beginnings to a single telephone call by an alert inspector.

The Federal Law Enforcement Training Center in Brunswick, Georgia, can provide special training for interested FIFRA inspectors (and other environmental technical personnel) involved in criminal investigations.

THE CRIMINAL PROVISIONS OF FIFRA

FIFRA section 14(b) makes the knowing violation of any provision of FIFRA punishable as a crime subject to criminal penalties consisting of fines and/or a term of imprisonment. More severe criminal penalties are provided for convicted defendants who are pesticide registrants, applicants for registration, pesticide producers and commercial applicators than for private pesticide applicators. See FIFRA sections 14(b)(1) and 14(b)(2).

FIFRA section 12 specifically lists the unlawful acts that are subject not only to civil and administrative enforcement, but also to criminal investigation and prosecution. A FIFRA inspector must be alert to the fact that the commission of any of these unlawful acts may potentially represent a criminal case.

FIFRA'S RELATIONSHIP TO OTHER FEDERAL CRIMINAL LAWS

Individuals and companies that commit environmental crimes often commit additional violations of the U.S. Criminal Code (Title 18), such as conspiracy, obstruction of justice, mail fraud and wire fraud. When these offenses are associated with alleged environmental crimes, EPA investigates and assists in the prosecution of such matters by the Department of Justice (DOJ). Criminal environmental conduct may also be prosecuted under one of the other environmental laws or one of the general criminal laws. For example, submission of false information as part of a pesticide registration may not only constitute a violation of FIFRA but also the federal false statement statute and conspiracy laws. See 18 U.S.C. Sections 1001 and 371, respectively.

Criminal activity involving pesticides may violate other environmental statutes enforced by EPA. For example, the unlawful disposal of pesticides may be a criminal violation of the Resource Conservation and Recovery Act (RCRA) or if the disposal was into a river, such conduct could amount to a criminal violation of the Clean Water Act (CWA). The prosecution team will decide under which statute to proceed and what other factors may be relevant, including the evidence available to establish an offense and the different penalty levels of the involved statutes.

SPECIAL ATTENTION TO DEFENDANT'S RIGHTS

Investigations of alleged criminal activities place even greater responsibilities on EPA's Special Agents. Because more severe penalties may be imposed on individuals convicted of violating the criminal provisions of environmental laws or other statutes, there are greater constitutional safeguards to protect their rights. Thus, it is of critical importance that all participants in criminal investigations be fully aware of these safeguards and conduct themselves accordingly. Special

Agents of the Criminal Investigation Division (CID) provide the necessary instructions and directions to the investigation team on these matters. The constitutional rights of defendants must be fully protected, from the beginning of a criminal investigation until it is completed, and established investigation procedures must be followed. The potential defendant may desire to conceal his or her criminal activities and, upon detection, frequently challenge to the procedures used to apprehend them and seize evidence of their criminal misconduct.

These challenges to the government's case principally stem from the Fourth Amendment's "Exclusionary Rule" which prohibits the use of evidence during the prosecution of a defendant whose constitutional rights were violated by the procedures used to collect that evidence. Also excluded is any information subsequently derived from improperly collected evidence. The procedures used by EPA's CID are designed to ensure protection of the defendant's rights and leave a documentary record of the investigation that will support admission of the resulting evidence into a prosecution.

Another frequent procedural challenge occurs when a suspect provides statements to a law enforcement officer after being taken into custody. The Special Agent must first issue a "Miranda Warning" and obtain a knowing waiver of such rights if the statements are to be admissible evidence. Defendants also have a right against self-incrimination. This means that a defendant can be silent and make the government prove its case. Thus, Special Agents are specially trained in their responsibilities relative to advising individuals of their constitutional rights during non-custodial and custodial interviews.

CRIMINAL ENFORCEMENT AT EPA

The Criminal Investigative Division (CID) staff is a part of the Office of Criminal, Enforcement, Forensics and Training (OCEFT) in Washington, D.C., with Special Agents operating out of field units at all regional offices. EPA Special Agents are federal law enforcement officers with the full authority to conduct investigations, carry firearms, make arrests for any federal crime and execute search and arrest warrants.

OCEFT works closely with the Department of Justice (DOJ) and state agencies that prosecute environmental crimes; federal, state and tribal law enforcement agencies; and with other EPA programs. OCEFT works primarily with DOJ's Environmental Crimes Section and the United States Attorneys to build strong cases for prosecution and occasionally works with state and tribal prosecutors. During investigations, OCEFT frequently combines its expertise with that of other law enforcement groups (such as the Department of Interior's Fish and Wildlife Service or the Department of Agriculture's Forest Service) to investigate cases with possible violations of a wide variety of laws. Criminal enforcement also relies on scientists, regulators, permit writers and other experts working in sister EPA offices such as the air, water and hazardous waste programs and civil enforcement.

During the execution of a criminal search warrant, support for forensic evidence collection such as sampling, monitoring and site documentation is provided by National Enforcement Investigations Center (NEIC) personnel, with additional support provided by Field Operations Program (FOP) personnel. EPA technical personnel, such as engineers and field inspectors, have received special training to assist the criminal investigative staff when needed. NEIC's specialized laboratories employ scientists, engineers, analysts, technicians and environmental and computer specialists to perform the essential science for environmental investigations. In addition to its accredited field support, the NEIC also provides forensic analytical support with its accredited laboratory. The NEIC Field Branch provides sampling and evidence collection support to CID. This support is provided both by the Lakewood staff and six outplaced technical staff stationed in six of the ten CID offices across the country. The Field Branch also provides multidisciplinary teams that conduct investigations in support of civil case development. The investigations include multi-media and single-media inspections led by NEIC regulatory and technical experts who work closely with regional and state enforcement partners to identify potential compliance deficiencies.

CID's National Computer Forensics Laboratory (NCFL) has Special Agents trained to seize and analyze digital evidence, such as that found on computers, "PDAs" and cell phones. NEIC and NCFL all play critical roles, as do a number of other forensic, investigative, legal and prosecutorial partners, in successfully making cases.

Attorneys specializing in environmental crimes prosecutions advise on environmental regulations, enforcement-related legislation and other complex legal issues that arise during day-to-day operations of a national law enforcement program. The Legal Counsel Division's attorneys are experienced in both criminal and environmental law (as well as the civil enforcement program) and work with the investigators and DOJ in the investigation and prosecution of criminal cases. They provide legal guidance and training in criminal enforcement matters. A FIFRA inspector should not hesitate to contact any Special Agent or criminal enforcement counsel to ask questions or discuss any aspect (general or specific) of the criminal enforcement program. However, please note that the criminal enforcement program generally cannot discuss grand jury materials or privileged information with its civil enforcement counterparts.

RECOGNIZING POTENTIAL CRIMINAL VIOLATIONS

FIFRA inspectors should not attempt an in-depth investigatory analysis of whether criminal conduct has occurred or is occurring at regulated sources. Special Agents are specifically trained to collect evidence necessary to support any criminal charges.

FIFRA inspectors should refer to the Criminal Investigation Division (CID) any conduct or action that may potentially constitute criminal violations, such as:

Knowing or willful behavior—defined as criminal under all federal statutes, or

• **Fraudulent reporting**—defined under all statutes and the United States code as criminal behavior.

The primary factor distinguishing a criminal case from a civil case is the **INTENT of the VIOLATOR**. Environmental crimes are committed either knowingly or willfully which means that the violator intends to commit an unlawful act, or engage in the prohibited conduct (i.e., not by accident or mistake) and should know or has full knowledge that the act is prohibited by law or regulation. Although environmental crimes usually are not committed with the specific goal of harming other people or the environment, they generally involve putting personal financial gain over public health and safety. In other words, most environmental crimes involve lying, cheating and stealing based upon a strong financial incentive.

Evidence of criminal wrongdoing may be blatant or subtle. The FIFRA inspector must try to learn as much as possible when one of the scenarios listed below is detected. The following should be brought to the attention of CID:

- **Conflicting data** When two sets of books or inconsistent pesticide production, sale or distribution reports exist for the same product and/or facility.
- **Conflicting stories**—When an inspector is told one thing and learns something quite different through a record review, personal observation, or interview with a different person.
- **Unsubstantiated data**—When record keeping and reporting information cannot be verified or substantiated.
- Deliberate actions—When an employee says he/she was told or ordered to do something by his/her supervisor(s) that the FIFRA inspector knows to be illegal.
- Claims of ignorance about requirements—When those interviewed deny any knowledge
 of FIFRA requirements, yet documentation displaying knowledge is discovered in records,
 statements or interviews.

FIFRA inspectors are in a unique position to identify possible criminal activities such as falsified information in records and reports and illegal pesticide use. Facility staff employees may also volunteer information to inspectors about possible criminal activities. If any of these or other problems raise the inspector's suspicions, he/she must attempt to obtain further information through interviews, observations and records reviews and promptly refer findings to CID.

SEARCHES

Criminal Investigators/Special Agents may search a person or the person's property when seeking evidence of alleged criminal activity only under the following circumstances: (1) with the person's consent; or (2) after obtaining a warrant based upon sworn testimony that demonstrates the existence of "probable cause" to believe that a crime has been committed and

that the search is necessary to obtain evidence of the crime. The probable cause standard for obtaining a warrant in a criminal investigation is far more stringent than for a warrant in a civil enforcement case.

EPA's Special Agents seek and execute criminal warrants, but FIFRA inspectors may be requested to accompany criminal investigators to aid in the investigation. In such cases, FIFRA inspectors must follow the instructions of the criminal investigator since any evidence collected outside the authority of the search warrant would be considered to be illegally obtained and generally inadmissible at trial.

It is important to point out, however, that evidence of a crime discovered through civil enforcement activity is generally admissible in court to prove the crime. For example, information collected by a FIFRA inspector during a routine inspection (with consent or in an administrative warrant) could be admitted as evidence in a criminal case provided it was lawfully obtained during his or her normal course of duties. Similarly, evidence of a crime obtained in accordance with the open fields doctrine (e.g., an observation of illegal pesticide use from a public road) may be admissible.

Inspectors frequently ask how the reading of Miranda rights applies to the facility staff they interview, particularly if the interviewee's answer to questions begins to suggest that there may be criminal activity. Miranda rights only apply when a person is placed in custody, that is, once he or she has been arrested or otherwise deprived of freedom of action in any significant way by a law enforcement officer. Information provided in routine interviews is lawfully obtained evidence that may be used in furtherance of a criminal investigation and prosecution.

COMPELLING THE PRODUCTION OF INFORMATION

In addition to obtaining evidence through a search warrant, a prosecutor may subpoena witnesses to provide information through testimony to a grand jury. Although someone may be subpoenaed to require him/her to provide information in a civil proceeding, the prosecutor's ability to compel information in a criminal investigation is more powerful:

- A witness who fails to appear in response to a subpoena is subject to immediate arrest.
- An uncooperative witness can be forced to provide information through an enforceable court order.

For long-established and compelling policy reasons, testimony provided to a grand jury is secret and severe penalties are imposed on anyone who violates that secrecy. These secrecy rules may severely limit what can be disclosed by an agent concerning an investigation to persons not on the grand jury list of approved individuals. However, other non-grand jury information may be shared with the civil enforcement program.

Persons subpoenaed for a civil proceeding are obligated as follows:

- If a witness fails to comply with a subpoena, penalties can only be obtained after a hearing (a process that can take weeks).
- In addition, the information provided by the witness cannot be kept confidential if it falls within the scope of the other side's discovery requests.

DISCOVERY

Defense counsel may attempt to learn information about the government's case by directly contacting an EPA inspector. While an inspector is not prohibited from communicating with defense counsel, the inspector is in no way required to talk to defense counsel and should not do so without first consulting with an EPA attorney and having counsel present during the conversation.

INITIATING CRIMINAL INVESTIGATIONS

Criminal leads arise from a variety of sources, including tips from EPA regions, states and tribes, calls from disgruntled workers, anonymous tips and information from other law enforcement organizations. Leads are evaluated by the Special Agent in Charge (SAC) and an assigned agent, with a determination made within 45 days as to whether the lead should be opened as an investigation or referred elsewhere (e.g., civil enforcement at EPA, the state regulatory authority, or another federal agency). The factors involved in determining whether to open an investigation include whether the alleged violation resulted in real or potential harm, what type of conduct was involved, and various legal, technical and regulatory considerations. The initial assessment of a lead may also involve legal personnel—the Regional Criminal Enforcement Counsel (RCEC)—and technical personnel—NEIC Technical Coordinator (NTC)—working closely with the case agent. Both RCECs and NTCs are commonly co-located in the SAC offices.

If the reliability of the lead is unclear, the Special Agent will conduct a preliminary inquiry to determine the credibility of the allegation and make an initial assessment for the need of a more thorough investigation. This initial inquiry is brief and involves no extensive commitment of resources or time. The purpose is to reach an initial determination of the need for a complete investigation. The agent may consult with program enforcement personnel and legal staff to help determine whether a particular violation warrants criminal enforcement action.

CONDUCTING A CRIMINAL INVESTIGATION

If a decision is made to pursue a criminal investigation, the Special Agent contacts the regional legal program and other appropriate offices to determine whether any civil enforcement action is pending or contemplated against the investigative target. If technical support for the investigation is needed, CID requests that the appropriate regional program Division Director(s)

designate specific individuals to work on the investigation. All these activities are carried out in consultation with the Office of Criminal Enforcement, Forensics and Training.

CID uses investigative techniques similar to those employed by its law enforcement counterparts. After the receipt of lead information, state and federal environmental records and databases may be reviewed to determine a suspect company's regulatory history or an individual's criminal history. In all cases, interviews are conducted to gain a detailed view of the facts, and that often leads to more detailed investigative steps, such as surveillance of a facility or suspected individuals, issuance of grand jury subpoenas (through the Department of Justice), execution of search warrants where probable cause of criminal violations exists and the use of traditional covert and technical investigative techniques. Special agents review documents and data from environmental, inspection and other databases and files and determine what additional expertise is needed to prove the crime in court. The Special Agent manages the investigation, under the supervision of the SAC, and is responsible for the following:

- Determining the basic investigative approach.
- Conducting interviews.
- Assembling and reviewing records.
- Planning and performing surveillance.
- Coordinating with the U.S. Attorney's office and other federal, state and local law enforcement agencies.
- Communicating with informants.
- Contacting other witnesses.
- Performing other investigative functions.
- Completing all required reports.
- Carrying out all coordination and notification requirements.

Inspectors may be assigned to assist the Special Agent in one or more of these above duties as requested by CID.

SECURITY OF CRIMINAL INVESTIGATIONS

FIFRA inspectors who have knowledge of criminal investigations should not disclose the information or discuss any criminal investigations with anyone outside of the Agency.

Agency policy is to neither confirm nor deny the existence of a criminal investigation. If a FIFRA inspector receives a written or verbal request for information from a third party (e.g., the news media), it must be immediately referred to the CID Special Agent who will determine the

response in consultation with other Agency offices. In general, the Department of Justice (DOJ) responds to such inquiries.

If a FIFRA inspector possesses written materials pertaining to a criminal investigation, he/she must treat these materials with special care and attention and ensure that they are stored in secure office space, in locked filing cabinets and/or evidence vaults.

PARALLEL CRIMINAL AND CIVIL PROCEEDINGS

FIFRA includes both civil and criminal enforcement authorities and EPA may use both authorities to identify and resolve FIFRA violations. FIFRA inspectors should note that the Agency may pursue criminal and civil enforcement actions on separate but "parallel" tracks. Even if the parallel criminal and civil enforcement actions relate to the same violation, EPA maintains a clear distinction between the two proceedings. FIFRA inspectors must follow these guidelines when involved in ongoing parallel proceedings:

- 1. Until the Agency refers a matter to the DOJ for possible criminal prosecution, all FIFRA inspectors who are EPA employees may continue to collect information/data from potential defendants with the understanding that it may be used in either a civil or a criminal enforcement action. However, once the Agency has referred a matter to the Department of Justice for possible criminal prosecution, all FIFRA inspectors and other EPA employees should not continue to collect information/data from potential criminal defendants, unless they are acting as an investigator for the prosecutor's office or CID and have clear authority to obtain such information/data for an existing regulatory purpose that is wholly separate and independent of the criminal investigation.
- EPA reserves the right to take criminal or civil enforcement action based on information obtained by FIFRA inspectors. Therefore, FIFRA inspectors (whether EPA employees or not) shall never tell a person or entity that EPA will not use the information obtained during an inspection as evidence in a criminal or civil case.
- 3. Direct any questions concerning parallel proceedings to the criminal or civil enforcement counsel at EPA.

COMPLIANCE WITH THE JENCKS ACT

The purpose of the federal Jencks Act (18 U.S.C. §3500) is to allow the defendant in a criminal prosecution to have, for impeachment purposes, all of the relevant and competent statements of a governmental witness. If the defense's ability to cross-examine a witness is impeded because the government lost, either deliberately or inadvertently, the Jencks Act material, the Court may decide either not to allow the witness to testify or to strike the witness's entire testimony. Needless to say, the effect of excluding a government witness's testimony could be

significant. Courts expect law enforcement agencies, including EPA, to have procedures to preserve potential Jencks Act material.

Essentially, the Jencks Act provides that the relevant notes, records and reports of a witness who has testified for the government in a criminal prosecution must be turned over to the defense if the defense requests them through the court. The request can only be made after direct examination of the witness, and material that does not relate to the subject matter of the testimony is exempt from disclosure. The effect is limited, after-the-fact discovery. (In civil cases, discovery processes give the other side almost unlimited access to government information on the case prior to trial.)

For the inspector, the principle effect of the Jencks Act is to underscore one of the major points of this Manual—that accurate and complete notes, records and reports are not only good practice, but essential for ensuring a successful enforcement action whether administrative, civil or criminal. Further, notes and records must be factual and contain no opinions or biases of the inspector. Finally, to avoid any potential appearance that Jencks Act material has been lost or intentionally destroyed, the inspector must not throw anything away, not even a scrap of paper with rough calculations on it, without first consulting with the criminal investigation team. All materials associated with a criminal investigation must be stored in accordance with security procedures.

PARTICIPATION IN GRAND JURY INVESTIGATIONS

If a FIFRA inspector that is an EPA employee is called upon to assist in a grand jury investigation under DOJ's supervision, he/she must follow the "Agency Guidelines for Participation in Grand Jury Investigations." Copies of these guidelines are available from the RCECs and OECA.