

US EPA ARCHIVE DOCUMENT

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

**Compliance Monitoring Strategy
For
Federal Insecticide, Fungicide, and
Rodenticide Act
(FIFRA)**

2015

Contents

I. Purpose and Background 4

A. Introduction 4

B. Purpose of CMS 4

C. Background 5

D. Primacy 6

II. FIFRA Inspections 7

A. Federal Inspector Credentials and Training 7

B. For-cause and Neutral Scheme Inspections 7

 1. For-cause Inspections 8

 2. Neutral Scheme Inspections 8

C. Specific Types of FIFRA Inspections 8

 1. Producer Establishment Inspections 8

 2. Import Inspections 8

 3. Use Inspections 9

 4. Certified Applicator Inspections 9

 5. Restricted-Use Pesticide Dealer Inspections 9

 6. Marketplace Inspections 9

 7. Good Laboratory Practice (GLP) Inspections 10

III. Compliance Monitoring 11

A. Background 11

C. Off-Site Compliance Monitoring Activities 12

D. Other Activities 12

IV. Inspection Frequencies 13

V. Priority Setting and Targeting 15

A. Priority Setting 15

 1. Criteria 15

 2. Maintaining a Deterrent Effect 16

B. Targeting 16

 1. “For-Cause” Targeting 17

 2. Neutral Scheme Targeting 17

VI. Data Management and Utilization 19

A. Data Management and Reporting Requirements 19

 1. Agency Enforcement Databases 19

B. Targeting and Evaluation Tools 19

 1. Enforcement and Compliance History Online (ECHO) 19

 2. Agency Databases 20

 3. Other Data Sources 21

VII. Oversight of State and Tribal Programs 22

Appendix – Universe of the FIFRA Regulated Community 23

I. PURPOSE AND BACKGROUND

A. Introduction

EPA works with its federal, state, territorial, and tribal regulatory partners to implement and assure compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to protect human health and the environment. The Office of Enforcement and Compliance Assurance (OECA) mission under FIFRA is to ensure that the environmental and public health protections provided by our nation's environmental pesticide laws are realized through activities to monitor compliance, civil and administrative enforcement to address noncompliance, and criminal enforcement actions when necessary. The ten regional offices carry out EPA's programs and negotiate and oversee cooperative agreements with the states, territories, and tribes for the implementation and enforcement of FIFRA.

The primary goals of FIFRA compliance monitoring include:

- Targeting compliance monitoring activities in accordance with priorities;
- Providing a visible field presence that will encourage compliance and deter noncompliance;
- Assessing and documenting compliance with FIFRA, the implementing regulations, pesticide labels and pesticide registrations;
- Identifying problem areas requiring resolution through regulatory actions by the Office of Pesticide Programs (OPP);
- Collecting evidence to document and support enforcement actions; and
- Monitoring compliance with enforcement orders.

Generally, states¹ and tribes conduct pesticide use monitoring and enforcement, certify and license commercial pesticide applicators, certify private pesticide applicators who use restricted use pesticides (RUPs) and conduct marketplace and pesticide producing establishment inspections on behalf of EPA to assure label and product integrity. Which states and tribes conduct these activities, and the extent of activity, will vary depending upon who has obtained primacy (explained below), the applicability of FIFRA provisions to the states and tribes as well as specific obligations set forth in negotiated agreements. Through State and Tribal Assistance Grants (STAG), there is a working partnership among EPA, states, and tribes to cooperatively enforce federal, state, and tribal pesticide laws and regulations. The success of this national pesticide program is dependent upon good communication and cooperation among all partners.

B. Purpose of CMS

This Compliance Monitoring Strategy (CMS) works in conjunction with the OECA National Program Manager Guidance (NPMG) and the FIFRA Cooperative Agreement Guidance (CAG)

¹ Hereafter, references to "states" includes territories, as well.

to provide national pesticide enforcement program expectations to EPA regions, states, and tribes.

This CMS provides a multi-year framework and national guidance for the FIFRA compliance assurance program to achieve the goals of FIFRA compliance monitoring and enforcement. Specifically, this CMS is intended to:

- Promote an understanding of, and compliance with, minimum program requirements;
- Promote national consistency in program implementation while acknowledging and allowing appropriate flexibility;
- Provide a strategy for setting priorities that focus on the greatest risks to health and the environment;
- Articulate guiding principles of the strategic approach to help EPA headquarters, regions, states, and tribes allocate resources across the FIFRA compliance assurance program;
- Provide inspection frequency goals;
- Clarify the intersections of compliance monitoring for the ongoing FIFRA core program, the national areas of focus, and state or tribal priorities;
- Enhance the use of data collected for priority setting and inspection targeting; and
- Clarify requirements for reporting national program results.

It is increasingly challenging to monitor compliance and maintain adequate enforcement response capabilities in the face of a regulated community that continues to grow in size and complexity (See, Appendix – Universe of the FIFRA Regulated Community). While still important, our traditional approach of conducting on-site inspections and pursuing enforcement cannot keep up with expanding responsibilities. It is imperative that compliance monitoring and enforcement agencies be flexible and creative in designing approaches to identify and address violations that pose risk to human health and the environment while maximizing available resources. Therefore, EPA is expanding the range of compliance monitoring activities, promoting the use of advanced monitoring and electronic reporting, expanding transparency and sharing of data, and using innovative enforcement approaches to increase compliance with environmental requirements as part of its “Next Generation Compliance” efforts. Next Generation Compliance promotes electronic reporting, advanced monitoring, and transparency to allow the public greater access to pollution and compliance information.

C. Background

FIFRA was enacted originally as the Federal Insecticide Act in 1910 as a pesticide licensing act. In 1947, Congress broadened the federal government's control of pesticides by passing the original Federal Insecticide, Fungicide, and Rodenticide Act. FIFRA required the Department of Agriculture to register all pesticides prior to their introduction in interstate commerce. In 1964, amendments to FIFRA authorized the Secretary of Agriculture to refuse registration to pesticides that were unsafe or ineffective and to remove them from the market. In 1970, Congress transferred the administration of FIFRA to EPA. This was the initiation of a shift in the focus of federal policy from the control of pesticides for reasonably safe use in agricultural production to control of pesticides for reduction of unreasonable risks to human health and the environment.

This new policy focus was expanded by the passage of the Federal Environmental Pesticide Control Act of 1972 (FEPCA), which amended FIFRA by specifying methods and standards of

control in greater detail. Also in 1972, Congress amended FIFRA to provide a mechanism to delegate enforcement responsibilities to states by providing for federal/state cooperative programs. In 1978, Congress further strengthened the responsibility of the states by granting states primary use enforcement authority under certain circumstances. Subsequent amendments have clarified the duties and responsibilities of EPA. In general, the emphasis has shifted from pesticide efficacy issues to minimizing risks associated with toxicity and environmental degradation.

D. Primacy

Section 26 of FIFRA sets forth the conditions for state primary enforcement responsibility (primacy) for pesticide use violations. Section 26 provides for primacy under certain criteria that differ from relationships states or tribes have with EPA in other programs. Section 27 of FIFRA authorizes the Administrator to override or rescind primacy in certain situations. Currently, all states have primacy with the exception of Wyoming. EPA provides oversight to ensure the adequacy of the overall state program and an equal level of protection of human health across the country. In addition, a state may, at any time, request EPA to act upon a pesticide misuse violation utilizing the remedies available under FIFRA.²

EPA issued two Federal Register notices governing how the Agency oversees the states with respect to primacy and rescission of primacy: [FIFRA State Primacy Enforcement Responsibilities: Final Interpretive Rule](#), and [Procedures Governing the Rescission of State Primary Enforcement Responsibility for Pesticide Use Violations](#). Within the parameters of Sections 26 and 27 of FIFRA, the interpretive rule on primacy, and the rule on the procedures governing rescission, EPA may conduct compliance monitoring inspections and initiate enforcement actions for pesticide use violations.

FIFRA does not authorize tribes to be granted primacy. Some tribes participate in the federal FIFRA enforcement program by receiving a pesticide enforcement grant to conduct inspections utilizing EPA inspection credentials. Tribes refer enforcement cases to the EPA regional office; although, a few tribes take enforcement action using their tribal pesticide codes.

²[FIFRA State Primacy Enforcement Responsibilities: Final Interpretive Rule](#). 48 Fed. Reg.407, (Jan. 5, 1983).

II. FIFRA INSPECTIONS

A. *Federal Inspector Credentials and Training*

Inspections to assess compliance with FIFRA regulations must be conducted utilizing EPA credentials and FIFRA inspection authority. All grantees must have at least one inspector with EPA credentials. To be issued EPA inspector credentials, EPA, state, and tribal inspectors must comply with EPA Orders 3500.1 and 1440.2. EPA Order 3500.1 requires, among other things, media specific training requirements and specific training on emerging topics. EPA Order 3500.1 also specifies requirements for supervisors of EPA and state inspectors with EPA credentials. EPA Order 1440.2 provides requirements for health and safety training for inspectors before they can be issued and use EPA credentials.

The Pesticide Inspector Residential Training (PIRT) program trains state and tribal pesticide regulatory inspectors and their supervisors. Objectives of the PIRT program include:

- Providing information on new regulations, technologies and tools to improve the effectiveness and efficiency of all pesticide inspections.
- Training a core group that can train others (“train the trainer”).
- Providing feedback that would offer important information that can be used in future updates of inspection procedures and protocols.
- Networking that would allow for the exchange of information regarding routine or unique inspections.
- Providing a forum for discussion of inspection protocol improvements and “lessons learned.”
- Sharing valuable field information on emerging issues.

The Pesticide Regulatory Education Program (PREP) trains managers, supervisors, and senior staff of state and tribal agencies who are responsible for FIFRA regulatory programs. The program is governed by a Steering Committee that decides the annual themes of the courses, based on the most pressing needs of the states. The objective of the program is to provide training on all aspects of the pesticide program and improve consistency and efficiency in the national program as a whole. Course themes include topics on core work, as well as new regulatory/enforcement initiatives, and emerging issues in science and technology. A major benefit of the program since its inception in 1990 has been the networking and exchange of information among the states, tribes, and EPA.

B. *Inspections*

Inspections conducted under FIFRA authority must be consistent with EPA’s [FIFRA Inspection Manual](#).

To conduct an inspection, the inspector needs the *informed consent* to enter from the owner of the property or from a person in control of the property in the absence of the owner, such as an operator or agent-in-charge. If consent is denied and a warrant is necessary, the request for 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 or is occurring and is commonly referred to as a “for-cause” inspection. 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.

1. For-cause Inspections

Under FIFRA, a for-cause inspection is initiated as a follow-up to an on-going investigation or in response to a tip or complaint, damage report, or referral of a known or suspected violation. Due to the potential for harm to human health and the environment, it is important that a “for-cause” inspection be initiated as soon as possible after receiving information of a suspected violation of FIFRA or state law.

2. Neutral Scheme Inspections

A neutral scheme inspection monitors compliance based on a set of criteria rather than based on information that a violation has occurred or is occurring. The plan must be neutral, and applied in a neutral manner to the particular establishment. To establish the requisite neutrality, the plan can rely on random selection, or selection by relevant statistics that have no individual human component. The statistics cannot have an individual human component because this would impermissibly allow a subjective input into the equation. An inspection cannot be the product of an agency’s arbitrary decision. This CMS, in conjunction with the NPMG and the FIFRA Cooperative Agreement Guidance, constitutes a critical part of the neutral scheme inspection plan for FIFRA. See Chapter V for information on targeting neutral scheme inspections.

C. Specific Types of FIFRA Inspections

1. Producer Establishment Inspections

A producer establishment inspection (PEI) is an inspection of an establishment where pesticides or devices are produced and held for distribution or sale. There are a variety of activities that are conducted during a PEI inspection, including, but not limited to, the examination of products, product labels, refillable and non-refillable containers, containment and records to determine compliance with statutory and regulatory requirements.

2. Import Inspections

An import inspection is an inspection of a pesticide product being imported into the United States to determine whether the product is in compliance with FIFRA. Inspections of imported pesticide products can be conducted at the U.S. Customs and Border Protection central examination sites located in designated ports or Customs bonded warehouses associated with the ports. Some import inspections may also be conducted post-entry at a designated destination facility, as indicated on the imported product’s entry documents. When EPA, state, or tribal credentialed inspectors conduct an import inspection, it is initiated at the request of the EPA regional office.

3. Use Inspections

A use inspection is an observation of an actual pesticide application or an inspection following an application. Use inspections include the many facets of pesticide use, including storing, handling, mixing, loading, and disposal. Pre- and post- application activities are appropriate for inspection. Use inspections should be used to determine label comprehension and directions for use compliance by applicators. Use inspections can also detect non-compliant labels in the channels of trade or being used by consumers. An experimental use permit (EUP) inspection is conducted to determine compliance with an experimental use permit and may be an actual observation of an application or an inspection of records.

Use inspections are generally classified as agricultural or non-agricultural:

- Agricultural inspections include the inspection of pesticide applications in conjunction with the production of agricultural commodities. Agricultural commodities are defined in 40 CFR section 171.2(a)(5) as, “[a]ny plant, or part thereof, or animal, or animal product, produced by a person (including farmers, ranchers, vineyardists, plant propagators, Christmas tree growers, aquaculturists, floriculturists, orchardists, foresters, or other comparable persons) primarily for sale, consumption, propagation, or other use by man or animals.” Worker Protection Standard (WPS) inspections are a type of agricultural inspection conducted to monitor compliance with the WPS requirements.
- Non-agricultural inspections include the inspection of non-agricultural pesticide applications such as pest control in industrial or residential settings.

4. Certified Applicator Inspections

The purpose of the certified applicator inspection is to determine if the applicator is properly certified and/or licensed and whether the required records are being maintained. Additionally, to the extent it is possible through a record review, the inspector will determine whether the applicator is applying pesticides only in those areas for which certification has been issued; and whether the records indicate that all applications have been made in compliance with all applicable laws and regulations.

5. Restricted-Use Pesticide Dealer Inspections

This type of inspection is conducted on-site at dealers who sell restricted-use pesticides. The purpose of the inspection is to determine if: (1) the dealer is properly licensed or certified (if required) and maintaining the required records and (2) restricted-use pesticides are being sold only to certified applicators or other properly authorized persons by reviewing the dealer’s records.

6. Marketplace Inspections

A marketplace inspection is conducted at the retail, distribution, wholesale, or user level for the purpose of determining product registration status, proper storage and display, any labelling violations, any product decomposition, and for collecting official samples.

7. Good Laboratory Practice (GLP) Inspections and Data Audits

GLP inspections and data audits focus on compliance with GLP regulations and the quality and integrity of test data submitted to EPA by a registrant to ensure compliance with the FIFRA requirements. A GLP inspection and data audit is the process by which EPA verifies that the data from a completed study is consistent with the final report that was submitted to the Agency. This is accomplished by documenting GLP practices and by examining raw data and other records generated during a study and comparing them with results provided in the study report. GLP inspections and data audits are conducted by EPA inspectors under a separate compliance monitoring strategy.

III. COMPLIANCE MONITORING

A. Background

Historically, EPA has relied upon on-site inspections as the primary activity to monitor compliance with FIFRA. This CMS, however, suggests the consideration of a wider range of activities to provide EPA, states and tribes with increased flexibility to monitor compliance and reach more regulated entities effectively and efficiently. Compliance monitoring activities that are part of a Cooperative Agreement must be documented in the state or tribe's cooperative agreement workplan and reported to the relevant EPA data system to ensure transparency, accountability, and appropriate follow-up.

To qualify as a compliance monitoring activity:

- The activity must be conducted for the purpose of making compliance determinations;
- “On-site activities” must be conducted by an authorized inspector (consistent with appropriate federal, state, or tribal authority);
- “Off-site activities” must be conducted by an authorized inspector (consistent with appropriate federal, state or tribal authority) or other EPA, state or tribal representative with sufficient knowledge, training, or experience to conduct the activity.

Compliance monitoring does *not* include:

- Compliance assistance³;
- Compliance incentives, such as Compliance Assistance Program (CAP) initiatives; or
- Case Development and Enforcement (e.g., preparing notices of violation, warning letters, or formal complaints; or developing evidence where an area of concern or potential violation has been identified).

B. On-site Compliance Monitoring Activities

On-site activities may include inspections designed to assess compliance of the establishment as a whole, or inspections targeted to focus on a specific pesticide product, pesticide, or regulatory requirement. During an inspection, an inspector may conduct the following activities:

- Make observations, take notes and pictures;
- Gather information from witnesses or establishment representatives;
- Review records, including establishment records, dealer records as well as applicator license and records;

³ Agency policy limits the extent to which an inspector may provide compliance assistance in connection with an inspection. See *National Policy: Role of the EPA Inspector in Providing Compliance Assistance During Inspections* (June 25, 2003), http://kodiak.r07.epa.gov/intranet/enviroprograms/role_of_inspector.pdf.

- Collect samples of pesticide products;
- Collect residue and environmental samples;
- Use advanced monitoring technologies, when available, at sites of suspected pesticide drift.

C. Off-Site Compliance Monitoring Activities

Off-site activities may include compliance evaluations designed to assess compliance of the establishment as a whole, but generally will be targeted to focus on only a portion of an establishment, such as a specific process, pollutant, or regulatory requirement. Off-site evaluations may include any of the following activities:

- Review of establishment reports or other documents, such as annual production reports required by FIFRA Section 7 or notifications under FIFRA Section 6(a)(a);
- Review of agency-gathered testing, sampling and monitoring data, such as results of formulation and efficacy analysis of samples of anti-microbial pesticides;
- Review of relevant process and inventory information, such as records documenting a registrant's implementation of a pesticide recall plan;
- Review of records produced under FIFRA Section 8; and

D. Other Activities

Regions, state and tribes may conduct other activities that are not compliance monitoring activities but which may create a FIFRA compliance presence in the regulated community which encourages and facilitates compliance, although these other activities are not considered compliance monitoring. For example, the region may:

- Employ integrated strategies that include compliance assistance and compliance incentives *in combination* with traditional inspection and enforcement approaches.
- Partner with OPP to *combine* outreach with compliance and enforcement, particularly in specific requirements, geographic areas/watersheds and/or vulnerable populations.
- Employ ambient environmental screening using advanced monitoring technologies for a group of facilities or geographic area of interest for use in subsequent compliance evaluations and determinations, such as analysis of pesticides in vulnerable watersheds.; and
- Review company website wherein internet sites are examined for potential FIFRA violations.

If EPA regions, states, or tribes have other ideas of additional compliance monitoring activities they are encouraged share them with OECA.

IV. INSPECTION FREQUENCIES

Inspection frequencies are intended to help EPA, the states and tribes to understand and meet today's challenges by providing benchmarks that set aspirational compliance monitoring goals. The frequencies presume adequate funding and resources and, therefore, the actual number of inspections conducted may differ from the frequencies set forth below.

At this time, inspection frequencies are not being offered for Marketplace, Certified Applicator, Use and WPS inspections. The size of those regulated communities coupled with clear regional/state differences, make one, standard inspection frequency challenging for these inspection types without further delineation. *Strategic targeting is particularly important where an inspection frequency is not proposed to ensure the greatest possible deterrent effect.* For example a strategic plan may focus on key times of the growing cycle, the applicator type (i.e. aerial), a particular pesticide or a certain geography. The relative size of a particular sector of the regulated community may also be considered. States should consider how to balance inspections and potential risk in developing a plan for these inspection types. For the WPS program, critical to the protection of human health, EPA will work with states to develop criteria and expectations to guide the WPS inspection program.

Actual annual program commitments for ALL inspection types are negotiated as part of the cooperative agreement process or are subject to the annual commitment system process. Individual regional, state and tribal circumstances, including resource and workload issues, are addressed during those processes. The inspection frequencies listed below are goals for an important subset of all FIFRA inspections, and can serve as a starting point for cooperative agreement negotiations, knowing that there needs to be flexibility to adapt to particular situations, as necessary. Cooperative agreement negotiations address the unique mix of regulated entities and pesticide issues in particular states or tribes.

<u>Type of Inspection</u>	<u>Proposed Inspection Frequency</u>	<u>Approximate Size of Regulated Community</u>	<u># of Inspections Needed Nationally to Meet Frequency/Year</u>
PEI	All at least once every 5 years	14,000	2,800
Imports	2% of all annually	24,000 NOAs	480
EUP	All annually	760	760
RUP Dealers	All at least once every 5 years	Exact # Unknown. Some states maintain data; ex. 1412 in Iowa. Assume approximately 50,000.	10,000
Marketplace*	No inspection frequency at this time but must be part of a balanced state inspection plan.	Large. Everywhere pesticides are sold. Retail, wholesale, etc.	
Certified Applicators*	No inspection frequency at this time but must be part of a balanced state inspection plan.	900,000	
Use *	No inspection frequency at this time but must be part of a balanced state inspection plan.	Large; Everywhere pesticides are used;	
WPS*	No inspection frequency at this time but must be part of a balanced state inspection plan.	Large; Every farm/nursery that hires farmworkers.	

* No inspection frequency is listed at *this* time but may be offered in the future.

V. PRIORITY SETTING AND TARGETING

Priority setting, targeting and commitments are part of a dialog between EPA, states and tribes. This dialog is the foundation of cooperative agreement negotiations. Decisions made as to priorities, targets and commitments should be reflected in cooperative agreement work plans. As part of that process, regions need to assess their own resource levels in relation to each state and tribe's identified priorities, targets and commitments. Workplans should be made available to OECA, upon request, to provide a picture of compliance monitoring activities in a given year.

A. Priority Setting

The goal of priority setting is to focus compliance monitoring efforts on program areas with the greatest need first. Consistent with the NPMG and the FIFRA Cooperative Agreement Guidance, priorities should be based on risk to human health and the environment. Regions, states and tribes should use the criteria listed below to determine risk-based priority setting. Once the greatest needs are identified, a holistic compliance monitoring strategy must be developed that addresses priorities but also provides an overall deterrent effect for the FIFRA program as a whole.

1. Priority Setting Criteria

Risk-based prioritization should reflect the following criteria:

a. Potential harm to human health or the environment.

Take into account the degree of harm to human health or the environment, whether actual or potential, when setting priorities. Factors to consider are the toxicity of the pesticide, whether it is a restricted use pesticide (RUP), the amount of the pesticide used, the occurrence and use patterns, and the potential impact on health or the environment if misuse occurs. Pesticide risks can be ranked by their relative contribution to harm that may result from pesticide use or misuse. Reducing chemical risks and protecting underserved and vulnerable populations is of particular concern; in particular, the disparate exposure in environmental justice communities and the likelihood of exposure to children and workers. Consideration of newly implemented regulatory requirements is also part of this criteria.

b. Types and number of violations that occur.

The types and number of violations is an indicator of the level of compliance with formulation and labeling requirements. It provides real-time information about regulatory issues that need to be addressed. The criteria used to evaluate violations include: violations that resulted in injury to humans, animals or the environment; facilities or users with major violations as determined by the [FIFRA Enforcement Response Policy](#); and facilities or users with multiple violations, repeat violations, patterns of violations, violations involving highly toxic pesticides or violations that caused economic harm. Pesticides may be ranked by their relative contribution to use or product related violations.

c. Health and environmental indicators.

The analysis should consider relevant ecological and health studies when available. For example, a groundwater survey may reveal high levels of contamination from pesticides used in center-pivot systems. A health survey may reveal unacceptable levels of pesticide exposure.

2. Maintaining a Deterrent Effect

EPA, states, and tribes can provide a deterrent effect by maintaining a visible presence in the FIFRA regulated community as a whole. Core areas for deterrence purposes include:

- Producer establishment inspections (PEIs);
- Dealer, distributor, and retailer inspections;
- Worker Protection Standard;
- Use and misuse;
- Cancellations, suspensions, other major regulatory actions, recalls, and national high risk initiatives;
- Imports;
- Exports;
- Section 18, Section 24(c), and experimental use permits monitoring;
- Antimicrobial pesticides;
- e-Commerce;
- Container/containment inspections.

B. Targeting

The goal of targeting is to focus on the most significant environmental problems *within* a priority area by identifying *specific* pesticide products/producers, applicators and use patterns that may pose the greatest risk of harm to human health or the environment due to noncompliance. Risk mitigation is achieved, in part, through targeting activities to deter unlawful pesticide production, distribution, sale, or use. Targeting may be for inspections or other activities that are designed to raise compliance rates (e.g., screening activities conducted by other media inspectors that may provide useful information for the FIFRA program, working with manufacturers or retail food producers to set up audit programs for pesticide users and crop growers). Targeting also may include off-site activities such as record reviews that do not have to take place on-site.

Generally, targeting should consider:

- Collaborative discussion between co-regulators;
- Review of relevant data and information, e.g., monitoring and violations data, toxicity data, and tips and complaints;
- Location factors, such as proximity to underserved and vulnerable populations, as well as to impaired watersheds;
- Pesticide products labeling and the chemical composition of registered pesticides distributed or sold in the United States;
- Prevention of unlawful formulations, unapproved claims, or adulterated and misbranded pesticides from being distributed, sold, or subsequently used;
- Improper or inadequate use directions or safety precautions on the product labeling which may constitute misbranding or where the accepted labeling has been determined inadequate;

- Improper use of pesticide products that may result in serious exposure incidents potentially leading to death or hospitalization;
- Production factors (including production volume, and product);
- Use/application factors (including use patterns of concern and volume or frequency of use);
- PEIs which focus on high toxicity pesticides;
- Use compliance in application settings (e.g., agricultural sites, structural, grain, or soil fumigation) with a focus on chemicals with a high risk for exposure or harm;
- Worker safety.
- Compliance history.

Specific targeting strategies for any given time period should be influenced by priorities emphasized in National Program Management Guidance as well as state and tribal priorities. Targeting strategies need to include three types of inspection components: for cause, neutral scheme, and pesticide formulation sampling.

1. “For-Cause” Targeting

For-cause inspections are typically time-sensitive. Any strategy that is intended to help prioritize for-cause inspections should provide for expeditious referrals and coordinated effort among EPA and state and tribal partners towards specific sectors of the regulated community, non-compliant behavior in the marketplace or by pesticide users. For-cause compliance monitoring often focuses on specific and suspected non-compliant situations and is conducted primarily by the regional offices for targeted products and by the state and tribal partners for pesticide misuse.

2. Neutral Scheme Targeting

Targeting strategies for neutral scheme inspections should consider the length of time since the last inspection, with longer times increasing the priority of the inspection, and emphasize specific sectors of the regulated community including:

- Pesticides that are highly toxic or are potentially hazardous to human health or the environment;
- Pesticides with disinfectant or antimicrobial claims;
- Pesticides produced in foreign establishments and imported into the United States;
- Pesticides packaged, labeled, and released for distribution, sale, and use by persons other than the primary registrant;
- Pesticides that are marketed and sold and found to be unregistered;
- Pesticides that have undergone significant registration amendments to address human health or environmental concerns;
- Pesticides whose registrations include the requirement for efficacy testing and submission; and
- Pesticides whose registrations or specific uses have been cancelled and are subject to specific existing stocks provisions.

3. Pesticide Formulation Sampling

To gain the most benefit from a pesticide establishment inspection program, a formulation sampling strategy is necessary to identify which products should be collected. Both the establishment inspection program and the formulation sampling strategy should be developed jointly through negotiations among the state and tribal program offices, the state laboratories, and the EPA regional offices.

VI. DATA MANAGEMENT AND UTILIZATION

Data must be collected in accordance with an approved Quality Management Plan (QMP) and collection must follow QA/QC requirements. Data quality, accuracy and completeness are essential. Regions should ensure federal data is entered into ICIS in a timely fashion. States and tribes must provide data and information to EPA in a timely and accurate manner, as set forth in state cooperative agreements.

A. Data Management and Reporting Requirements

1. Agency Enforcement Databases

EPA regional offices report pesticides enforcement information into two Agency electronic data systems:

a. Integrated Compliance Information System (ICIS)

Federal case information, including the environmental benefits of enforcement, is reported into ICIS. Data from ICIS help monitor and track the status of ACS measures for FIFRA compliance monitoring activities and target future activities. Accurate and timely ICIS data entry is of the utmost importance to monitor progress toward goals for FIFRA compliance monitoring activities.

b. Annual Commitment System (ACS)

The ACS assists National Program Managers (NPMs) and Regional managers in negotiating and agreeing on annual regional performance commitments. The ACS captures key program measures identified in National Program Guidance documents and is used to facilitate agreement on the final annual regional commitments that are made for each measure. The Regions report in ACS the number of inspections conducted using EPA credentials twice a year.

B. Targeting and Evaluation Tools

There are several targeting and evaluation tools available to EPA's pesticide compliance and enforcement program:

1. Enforcement and Compliance History Online (ECHO)

The [Enforcement and Compliance History Online](#) (ECHO) is the Agency's primary website for providing public access to regulatory compliance and enforcement data. ECHO includes information to determine whether compliance inspections have been conducted by EPA, states, or tribes, if violations were detected or enforcement actions taken, and any penalties assessed in those actions. This database has limited application for FIFRA since it only includes federal inspections and enforcement actions, which are obtained from ICIS.

2. Agency Databases

A wide variety of government databases and data systems support regulatory programs or serve as inspection targeting and compliance assessment tools. Some databases have limited access. The list below describes some of the databases available.

a. Section 7 Tracking System (SSTS)

The Section 7 Tracking System (SSTS) includes registration information about domestic and international pesticide producing establishments. Additionally, the database includes the type and amount of pesticide production for each establishment. SSTS includes the name and address of the producing establishment and the company which operates the facility. Currently, facility data recorded in SSTS does not include latitude/longitude information. The system has been transferred into the OPP data system PRISM.

b. Pesticide Registration Information System (PRISM)

The Pesticide Registration Information System (PRISM) has comprehensive electronic pesticide registration information. PRISM acts as a gateway to all pesticide registration information for the Agency's partners and stakeholders.

c. Office of Pesticides Programs Information Network (OPPIN)

The Office of Pesticides Programs Information Network (OPPIN) contains information about the registration status of products, data submission information, and correspondence with registrants and pesticide labeling. Because the data system contains FIFRA Confidential Business Information, access is limited.

d. Pesticide Product Labeling System (PPLS)

PPLS is a collection of images, in multi-page PDF format, of pesticide labels that have been accepted by OPP. The collection contains initially accepted labels for pesticide products registered under FIFRA, subsequent versions of labels that have changed via amendment or notification and associated correspondence about the terms of registration, specifying any changes which the registrant was required to make in the final printed label. Regional staff, states, tribes, and the public have access to information in PPLS.

e. State Labeling Information Tracking System (SLITS)

Currently, states and tribes use the State Labeling Information Tracking System (SLITS) to identify label issues to EPA for compliance evaluation. This database has the potential for broad use by states and tribes to facilitate compliance monitoring of individual regulated pesticide products. The database also is a useful tool for EPA regions.

f. Public Health Tracking Network

The National Environmental Public Health Tracking Network is a system of integrated health, exposure, and hazard information and data from a variety of national, state, and city sources. It includes information on pesticide exposure.

3. Other Data Sources

a. National Pesticide Information Retrieval System (NPIRS)

The National Pesticide Information Retrieval System (NPIRS) is a collection of pesticide-related databases available by subscription. NPIRS is under the administration of the Center for Environmental and Regulatory Information Systems (CERIS) at Purdue University. The system contains labeling information about pesticides registered by EPA and many states. The PPLS is accessible to the public through NPIRS. A subset of NPIRS is the National State Pesticide Information Retrieval System (NSPIRS) that focuses on state registrations.

b. State Inspection Data

State inspection data is currently collected on Form 5700-33. Many states have electronic data systems to track inspections, enforcement, other field activities, and results.

c. Performance Measures

In 2012, a workgroup of EPA, state, and tribal pesticide regulators began efforts to develop new performance measures to replace the 2006 Government Performance and Results Act measures. The process and procedures for reporting data on the final new performance measures have been incorporated into the FIFRA Cooperative Agreement Guidance.

d. Sentinel Event Notification System for Occupational Risk (SENSOR)

Operated by the National Institute of Occupational Safety and Health, Center for Disease Control, SENSOR offers data on acute occupational pesticide-related illness and injury.

e. American Association of Poison Control Centers National Poison Data System (NPDS)

The NPDS is a comprehensive poisoning exposure surveillance database maintained by the American Association of Poison Control Centers containing information from the human poison exposure case phone calls taken by all 55 poison centers across the country.

VII. OVERSIGHT OF STATE AND TRIBAL PROGRAMS

Regions conduct state and tribal enforcement program oversight as part of the state and tribal cooperative agreements, performance partnership agreements (PPAs) and/or performance partnership grants (PPGs). Cooperative agreement reviews, including reviews of performance under this CMS, must be conducted at least annually. End-of-year reports received from the state and tribe typically form the basis for the review. The purpose of these reviews is to determine whether cooperative agreement commitments were met and evaluate the adequacy of the state or tribal pesticide program. These reviews also aid in determining how state and tribal programs have targeted monitoring and enforcement activities in their respective programs. Regional reviews of state information should include an evaluation of pesticide monitoring and enforcement case files to determine whether actions taken by the state or tribe were consistent with the national and state policies approved as part of the pesticide program delegation.

It is recommended that regions conduct joint or oversight inspections with state or tribal pesticide inspectors to monitor the quality of field work and expand the knowledge base. EPA regions should review state and tribal inspection reports to ensure that inspections are conducted properly, appropriate inspection procedures are followed, and sufficient evidence is collected as part of EPA's routine actions. This review should be conducted as part of EPA's routine oversight of the cooperative agreement program during mid-year and end-of-year reviews, but, ideally would be conducted more frequently.

Where states and tribes are not meeting performance expectations, regions should take action to address serious shortcomings. Regions need to take action when necessary to communicate what needs attention to achieve the goals of federal environmental laws and ensure a level playing field among states.

APPENDIX – UNIVERSE OF THE FIFRA REGULATED COMMUNITY

The definition of a pesticide is very broad and includes: (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and (3) any nitrogen stabilizer.

The FIFRA regulated community is very broad and includes pesticide registrants, producers, retailers, distributors, and pesticide applicators. Regulated products include, but are not limited to, pesticide products used in commercial production of agricultural crops, products for landscaping, disinfectants and other antimicrobials, pesticides for structural and indoor pests, and pesticide products purchased and used by homeowners.

EPA has primary responsibility for compliance monitoring of products and establishments. States have primary responsibility for use enforcement. In addition to providing guidance and establishing priorities, EPA Headquarters plays a large role in enforcement activities, which relate to the registration, cancellation, and labeling of pesticides (OPP) and compliance (OECA). The regions' resources are mainly directed at compliance monitoring and enforcement of pesticide product registrations and establishment requirements under FIFRA Sections 7 and 8. A significant portion of the national pesticide compliance and enforcement program's resources are directed at use activities, primarily by the states and tribes working under cooperative agreements.

As the regulated universe is so vast, a targeted approach is used to focus efforts on those segments that pose the greatest potential risk to human health and the environment.

EPA is able to quantify much of the regulated universe, but not all. For instance, certification requirements enable EPA to track the number of certified applicators licensed to apply restricted use pesticides. However, the Agency can make only general estimates of the much greater number of individuals who apply general use pesticides for which no certification is required.

The universe of regulated entities and products is described in the following table.

Type	Number	Comments
Registrants	1,709 ^a	Companies holding at least one active section 3 or 24(c) registration.
Registered Pesticide Products	18,681 ^a	
Active Distributor Registrations	58,035 ^a	Distributor registrations are based on section 3 registrations. A single section 3 registration may have many distributor registrations associated with it, thus the large number of distributor registrations in comparison to section 3 registrations.
Pesticide-Producing and Device-Producing Establishments	14,162 ^b	Including foreign and domestic establishments.
Pesticide Retailers/Dealers/Marketplaces, including web-only dealers	Very large	The exact number is unknown. This segment of the regulated universe is so large and includes every location where general use pesticides (insect repellants, disinfectants, rodenticides, etc) are sold. Some states maintain a database of all dealerships, retailers, and other marketplaces at which restricted use pesticides (RUPs) and general use pesticides (GUPs) are sold.
Applicators certified to use RUPs <ul style="list-style-type: none"> • Private • Commercial Total	481,008 413,361 894,369 ^c	Certified applicators are licensed to use restricted use pesticides.
Laboratories Conducting FIFRA Studies	1,400 ^d	1,400 labs have submitted studies to EPA in the last 3 years.
Imports: Notice of Arrivals Received	24,246 ^e	
Exports: Exports Notices	2402 ^f	Foreign Purchasers' Acknowledgement Statements.
Experimental Use Permits	760 ^a	
Section 18 Exemptions - Emergency Use Exemptions	4,456 ^a	Emergency Use Exemptions are granted by the Administrator upon application from a state if certain criteria are met.
Section 24(c) Registrations – Special Local Needs -	2,589 ^a	A state may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that state to meet special local needs if the registration for such use has not previously been denied, disapproved, or canceled.

Section 25(b) Product	Very large ^g	These products are exempted from FIFRA registration although some states may require registration. The regulatory and compliance monitoring status of this segment of the universe is very diverse and complex. Thirty seven states regulate these products with varying levels of oversight; some states require a complete product data review and/or efficacy testing, while others only require a registration fee, and yet others review some portions of the label for compliance issues.
Farms	2,226,956 ^h	This number represents the number of farms in the states and territories. Information on farms on tribal lands is collected under a separate process by USDA beginning in 2007. The data on tribal farms is limited at this time.

a—Data through July 2009 from the Information Technology and Resources Management Division, OPP

b—Data through June 2013 from the Section Seven Tracking System, Pesticides, Waste and Toxics Branch, OC

c—Data for 2011 from the Certification and Worker Protection Branch, OPP

d—Data from the Laboratory Data Integrity Section, MAMPD, OC

e—Data estimates from Regions, in general through July 2009

f—Data as of calendar year 2008 from the Field and External Affairs Division, OPP

g—Information and comment from the Policy and Regulatory Services Branch, OPP

h—Data from the [2007 USDA Ag Census](#)