



# **Federal Insecticide, Fungicide, and Rodenticide Act**

## **COMPLIANCE/ENFORCEMENT GUIDANCE MANUAL**

**U.S. ENVIRONMENTAL PROTECTION AGENCY  
Washington DC 20460**

**Prepared by**

**Pesticides and Toxic Substances Compliance Monitoring Staff**

**and**

**Office of Legal and Enforcement Policy**

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# Chapter One

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# 1 Purpose of the Manual

The purpose of this manual is to provide guidance to pesticide regulatory personnel on the substantive and procedural requirements necessary for ensuring compliance and preparing enforcement cases under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA).

The manual describes the processes of case development and judicial proceedings including the analyzing of evidence collected during a compliance inspection to determine its sufficiency to document a suspected violation; issuing of an enforcement action; presenting evidence in an adjudicatory hearing; and monitoring compliance with consent decrees.

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## Reservation

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The policies and procedures set forth herein and the internal office procedures adopted pursuant hereto are intended solely for the guidance of U.S. Environmental Protection Agency personnel. These policies and procedures are not intended to be relied upon to create a right or benefit (substantive or procedural) enforceable at law by a party to litigation with the United States Environmental Protection Agency. The Agency reserves the right to take any action alleged to be at variance with these policies and procedures or that is not in compliance with internal office procedures.

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## The Update System

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As revised or additional material is developed for the manual, it will be distributed to all manual holders. A transmittal form will accompany and explain these changes. The revised or additional pages will be identical to the original page, but with added identification at the bottom of the page.

FIFRA Compliance/Enforcement	Page	Guidance Manual (Year) Revised
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When revisions entail the addition of pages into the manual (i.e., when three pages in the manual are replaced by five pages), the additional pages will be numbered as follows:

Original numbering: 3-3, 3-4, 3-5, 3-6, etc.

Addition of pages: 3-3, 3-4, 3-5a, 3-5b, 3-5c, 3-6, etc.

This system will allow updates to be made quickly and easily and will avoid disruption of the chapters. New material will be numbered sequentially by chapter.

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#### Common Acronyms and Abbreviations Used in this Manual

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C.F.R. -- Code of Federal Regulations

CROP -- Consolidated Rules of Practice

EPA -- United States Environmental Protection Agency

FDA -- Food and Drug Administration

FIFRA -- Federal Insecticide, Fungicide, and Rodenticide Act, as amended

HQDO -- Headquarters Case Development Officer

OLEC -- Office of Legal and Enforcement Counsel

PTSCMS -- Pesticides and Toxic Substances Compliance Monitoring Staff

RCDO -- Regional Case Development Officer

RD -- Registration Division

RUP -- Restricted Use Pesticide

SSURO -- Stop Sale, Use, or Removal Order

U.S.C. -- United States Code

## 2 Overview of the Act

The Federal Insecticide, Fungicide, and Rodenticide Act, Public Law 92-516 (1972), as amended by Public Law 94-140 (1975), Public Law 95-396 (1978), and Public Law 96-539 (1980) was passed by Congress as the primary statute for pesticide control and regulation. The Act, referred to as "FIFRA," is codified in Title 7 of the United States Code. Regulations promulgated pursuant to the Act are found at 40 C.F.R. Parts 162 through 180.

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### Purpose and Scope

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FIFRA and its amendments are designed to provide for pre-market clearance of pesticides and post-market surveillance of pesticides and pesticidal devices to ensure prevention of unreasonable adverse effects upon human health or the environment. Under FIFRA, the term "pesticides" includes:

- Substances (other than "new animal drugs" or animal feeds) intended for preventing, destroying, mitigating, or repelling any "pest" defined to include organisms ranging from viruses and bacteria to rodents; and
- Substances intended for use as plant regulators, defoliants, or dessicants.

The Act prohibits (subject to certain exceptions) any individual from distributing, selling, offering or holding for sale, shipping, delivering for shipment, or receiving and (having so received) delivering or offering to deliver any pesticide product not registered with the Administrator of EPA. Registration may be refused, restricted, suspended, or cancelled by the Administrator where appropriate to ensure protection of the environment. Under the Act, all producers of pesticides and pesticidal devices are required to register their establishments with the Administrator.

### Products Not Subject to the Act

Certain products are not classified as pesticides and, therefore, are not subject to the Act. They include:

- Deodorizers, bleaching agents, and cleaning agents for which no pesticidal claims are made;
- Paints and other formulated coatings that are treated with fungicides to protect the coating itself and that bear no claims for protecting other surfaces or objects;
- Building material products (such as lumber, fiber boards, adhesives, and caulking material) that have been treated to protect the material itself against pests and for which no pesticidal claims are made as to protecting other surfaces or objects;
- Fabric products that have been treated to protect the fabric itself from insects, fungi, or other pests and for which no pesticidal claims are made as to protection of other surfaces or objects;
- Fertilizers and other plant nutrients; and
- Intermediate substances intended for the production of a pesticide product by chemical reaction with other substances.

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### Authorities and Responsibilities

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The Administrator of EPA is authorized to administer the Act in a reasonable and prudent manner, often considering the economic, social, and environmental costs and benefits of actions taken under FIFRA. Within EPA, several offices are responsible for providing national guidance for FIFRA compliance enforcement activities. These offices and their responsibilities are discussed in Chapter Two.

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### Synopsis of the Act

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FIFRA authorizes the registration of pesticides as well as pesticide-producing facilities. Specific authorities are provided for the inspection of establishments, books, and records. The Act also provides for classification of pesticides for general use or restricted use; certification of applicators for restricted use pesticides; issuance of experimental use permits; and promulgation of pesticide application standards. Protection is afforded trade secrets and certain other business information deemed confidential by the registration applicant. Provisions are made under the Act for imposition of civil or criminal penalties.

Procedures for issuing a stop sale, use, or removal order (SSURO) or seizing violative pesticides or devices are detailed. The statute also provides authority to enter into cooperative agreements with the States. These sections of FIFRA are briefly reviewed below.

### Registration of Pesticides (Section 3)

Applications for registration must include information relating to the labeling of the pesticide as well as the labeling itself, a statement of all claims made by the manufacturer, and directions for using the pesticide. The Administrator is required to publish guidelines for the submission of information in support of the application. In general, an application will be approved when the information submitted supports the assertion that the pesticide will perform its claimed function(s) and indicates that the pesticide will not present an unreasonable risk to the environment when used properly. The Administrator is required to classify all pesticides for either general or restricted use or both; may conditionally register pesticide products that are identical or substantially similar to those currently registered; and may approve new and added uses of currently registered pesticides. The Administrator is required to accomplish the re-registration of all pesticides in the most expeditious manner practicable.

### Use of Restricted Use Pesticides; Certified Applicators (Section 4)

EPA must establish standards for the certification of pesticide applicators. For those States that do not have a State certification plan approved by the Administrator, the Agency is to conduct its own certification program for pesticide applicators. Approval of a State's certification program may be withdrawn if the Administrator determines that the State program is not being administered in accordance with the terms of the approval.

### Experimental Use Permits (Section 5)

Any person may apply to the Administrator for an experimental use permit for a pesticide. Approval of the experimental use permit is conditional upon the Agency's review of the application and all required supporting data, as well as the applicant's need for information to support the registration. The permit may specify terms and conditions deemed appropriate by the Administrator. Should these terms or conditions be violated, or inadequate to avoid an unreasonable adverse effect on the environment, the permit may be revoked.

### Administrative Review; Suspension (Section 6)

The Administrator shall cancel the registration five years from the date of registration unless the registrant or other interested person requests the continuance of the registration in accord with re-registration regulations

prescribed by the Administrator. The Administrator may cancel or change the classification of a registered pesticide if it is determined that its labeling or other material required to be submitted is not in compliance with the Act or if the pesticide causes unreasonable adverse effects to the environment. The Act requires that notice of the order be sent to the registrant and be made public. A hearing to dispute the order must be provided to any person adversely affected by the notice. The Administrator can also cancel a registration that was issued conditionally if the registrant fails to meet any condition imposed or fails to initiate and pursue appropriate action toward fulfilling any condition imposed. Section 6 further provides that if a pesticide is determined to be an imminent hazard during the period required for cancellation or change of registration proceeding, its use may be immediately suspended by the Administrator upon proper notice and availability of an expedited hearing.

#### Registration of Establishments (Section 7)

Any establishment producing pesticides, active ingredients used in producing pesticides, or pesticidal devices must be registered with the Administrator. Information submitted in this registration process, other than the names of the pesticides or active ingredients used in producing pesticides, will be subject to the confidentiality provisions of Section 10.

#### Books and Records (Section 8)

The Administrator may prescribe regulations requiring producers to maintain records pertaining to their operation as well as pesticide and device records considered necessary for the enforcement of the Act. Financial data, sales data other than shipment data, pricing data, personnel data, and research data other than data relating to a registered pesticide or pending registration are exempt from this rule. Inspection and copying of shipping records or, in the absence thereof, records relating to shipment are permitted upon presentation of proper credentials by a duly authorized employee of EPA or any State.

#### Inspection of Establishments (Section 9)

FIFRA authorizes, upon presentation of proper credentials and notice, the inspection (at reasonable times) of establishments or other places where pesticides and devices are held for distribution or sale. A written notice, detailing the reason for the inspection and noting whether a violation of the law is suspected, must be presented prior to entry. Inspectors may obtain samples of any pesticides or devices that are packaged, labeled, and released for shipment and samples of any such containers and labeling. If necessary, warrants may be obtained from a district court to gain entry, inspect, and reproduce certain records relating to pesticides or devices, or to seize any pesticide or device. For minor violations, a written notice of warning may be issued.



### Protection of Trade Secrets and Other Information (Section 10)

This section of FIFRA provides for the protection of trade secrets and certain business information obtained under FIFRA. Applicants may claim information as confidential or dispute the release by the Administrator of any information the manufacturer feels is confidential. United States employees who willfully disclose trade secrets are subject to criminal penalties.

### Standards Applicable to Pesticide Applicators (Section 11)

Separate standards for licensing and certification are established for commercial and private applicators. Private applicators are not required to maintain any records or to file any reports.

### Unlawful Acts (Section 12)

Section 12 establishes the acts that are unlawful under FIFRA. These include, inter alia, registration, labeling, and use violations. See Chapter Seven for a complete listing.

### Stop Sale, Use, or Removal and Seizure (Section 13)

The Administrator may issue a stop sale, use, or removal order under the following circumstances:

- When, based on inspection or tests, there is reason to believe that a pesticide or device is in violation of the Act or will be sold or distributed in violation of the Act; or
- When the registration of a pesticide has been cancelled or suspended.

Additionally (if certain unlawful acts are being carried out), pesticides or devices may be seized for condemnation upon action in a district court.

### Penalties (Section 14)

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of the Act may be assessed a civil penalty of up to \$5,000 per offense. Should any of the above-mentioned parties knowingly or willfully violate the Act, a criminal penalty of up to \$25,000 and/or imprisonment for up to one year may be imposed. A private applicator or other person not included above who violates the Act after receiving a warning letter or citation for a prior violation may receive a \$1,000 civil penalty for each subsequent offense. "For hire" applicators may be fined \$500 for the first offense and \$1,000

for each subsequent offense. Criminal penalties for private applicators and "for hire" applicators may be a fine of up to \$1,000, 30 days' imprisonment, or both.

#### Indemnities (Section 15)

Under certain conditions EPA may make indemnity payments to persons suffering losses due to the cancellation or suspension of a pesticide registration.

#### Administrative Procedure; Judicial Review (Section 16)

District courts are given authority to review those Agency final actions that are not given to Agency discretion by law. These courts are also vested with jurisdiction to enforce, prevent, and restrain violations of the Act. United States courts of appeals have exclusive jurisdiction to affirm or set aside an order issued by the Administrator. All judgments entered in actions instituted under the Act are to be published.

#### Imports and Exports (Section 17)

Pesticides and pesticidal devices may not be imported for use in the United States if they violate any provision of the Act. Pesticides or pesticidal devices intended solely for export may be produced and packaged according to purchaser specifications but will be subject to certain provisions of Sections 2, 7, and 8 of the Act.

#### Exemption of Federal Agencies (Section 18)

The Administrator may exempt Federal and State agencies from any provision of the Act under emergency conditions.

#### Disposal and Transportation (Section 19)

Procedures and regulations for disposal and storage of pesticides must be established. The Administrator will advise and assist the Department of Transportation in matters relating to the transportation of hazardous materials. If a pesticide is cancelled under Section 6(c), the Administrator, at the request of the pesticide owner, is to provide a safe disposal site. Specific provisions for the disposal of unused quantities of a cancelled pesticide must appear in the notice of cancellation.

Research and Monitoring (Section 20)

Research necessary to carry out the Act is authorized. The Administrator will formulate and carry out a national plan to monitor pesticide exposure and pollution.

Solicitation of Comments; Notice of Public Hearings (Section 21)

The Administrator must solicit the views of the Secretary of Agriculture prior to publishing regulations and may solicit, from other interested persons, views relating to any action authorized under the Act. Timely notice of all public hearings must be published in the Federal Register.

Delegation and Cooperation (Section 22)

The Administrator may delegate to EPA employees any or all vested authority contained in the Act. The Administrator must cooperate with other agencies in carrying out the Act.

State Cooperation, Aid, and Training (Section 23)

The Administrator may enter into cooperative agreements with States and Native American Indian tribes for the purposes of delegating authority to carry out the Act and to train personnel. The Administrator also may assist them with contracts to encourage training certified applicators.

Authority of States (Section 24)

A State may regulate the sale or use of any federally registered pesticide or pesticidal device to meet its special needs, as long as it is in accordance with the Act. The State may register new uses for registered pesticides for use only in the State. The new use may not be a food or feed use unless it is consistent with the Federal Food, Drug, and Cosmetic Act. With just reason, the Administrator may suspend the State's authority to register pesticides under this section.

Authority of the Administrator (Section 25)

The Administrator may prescribe regulations to carry out the Act. Proposed and final regulations must be given to the Secretary of Agriculture for comment. All comments will be published in the Federal Register on a prescribed time schedule. The House and Senate Agriculture committees must also be notified. A scientific advisory panel will comment on the regulations, using the same time schedule as the Secretary of Agriculture, and the comments will also be published in the Federal Register.

The Administrator has the authority to determine what is a pest, to specify which devices are subject to the Act, to establish packaging standards for pesticides and devices, to prescribe regulations requiring pesticides to be colored, to establish suitable names for use in active ingredient statements, and to determine whether pesticides are toxic to human health.

#### State Primary Enforcement Responsibility (Section 26)

A State has the primary enforcement responsibility for pesticide use violations (primacy) if the State laws and regulations are deemed adequate by the Administrator, if sufficient enforcement procedures are adopted and used, and if the State keeps records and makes reports of such compliance as required by the Administrator.

A State may also obtain primacy by entering into cooperative agreement for the enforcement of use violations under Section 23 or by demonstrating that their Section 4 certification plan meets the criteria described above.

The Administrator has primary enforcement responsibility for States that do not have primacy.

#### Failure by the State To Assure Enforcement of State Pesticide Use Regulations (Section 27)

The Administrator must notify the State of any significant allegations of a pesticide use violation of the Act. If within 30 days of the referral the State has not commenced appropriate enforcement action, EPA may bring its own action. The Administrator is empowered to rescind primacy if it is found that the State is not carrying out its pesticide use enforcement responsibility. If an emergency exists and the State is unable or unwilling to respond, the Administrator is authorized to take immediate action.

#### Identification of Pests; Cooperation with Department of Agriculture's Program (Section 28)

The Administrator, in coordination with the Secretary of Agriculture, is to identify those pests that must be controlled. In addition, the Administrator is to coordinate with the Secretary of Agriculture's research and implementation programs in order to determine the safest and most effective pesticides or control methods available.

#### Annual Report (Section 29)

An annual report must be submitted to Congress by the Administrator before February 16 of each year, listing all the applications for conditional

registration and approvals of such applications. The findings, impositions, modifications, and quantities of each conditionally registered pesticide that is produced must be included.



### 3 Federal Insecticide, Fungicide, and Rodenticide Act (As Amended)

(Public Law 92-516, 92nd Congress, H.R. 10729, October 21, 1972

as amended by

Public Law 94-51, 94th Congress, H.R. 6387, July 2, 1975;

Public Law 94-169, 94th Congress, S. 2375, October 10, 1975;

Public Law 94-148, 94th Congress, H.R. 8841, November 28, 1975;

Public Law 95-251, 95th Congress, H.R. 6975, March 27, 1978;

Public Law 95-396, 95th Congress, S. 1678, September 30, 1978;

Public Law 96-539, 96th Congress, December 17, 1980)

#### Act

86 STAT. 973-999

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

Federal  
Environmental  
Pesticide  
Control Act  
of 1972.

*Be it enacted by the Senate and House Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Environmental Pesticide Control Act of 1972."*

#### Amendments to Federal Insecticide, Fungicide, and Rodenticide Act

61 Stat. 163;  
78 Stat. 190.

Sec. 2. The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) is amended to read as follows:

#### "SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) *Short Title* — This Act may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act'.

(b) *Table of Contents* —

P.L. 95-396:

"Section 1. Short title and table of contents.

92 Stat. 838.

"(a) Short title.

"(b) Table of contents.

"Sec. 2. Definitions.

"(a) Active ingredient.

"(b) Administrator.

"(c) Adulterated.

"(d) Animal.

"(e) Certified applicator, etc.

"(1) Certified applicator.

"(2) Private applicator.

"(3) Commercial applicator.

"(4) Under the direct supervision of a certified applicator.

"(f) Defoliant.

"(g) Desiccant.

"(h) Device.

"(i) District court.

"(j) Environment.

"(k) Fungus.

"(l) Imminent hazard.

"(m) Inert ingredient.

"(n) Ingredient statement.

"(o) Insect.

"(p) Label and labeling.

"(1) Label.

"(2) Labeling.

"(q) Misbranded.

"(r) Nematode.

"(s) Person.

"(t) Pest.

"(u) Pesticide.

"(v) Plant regulator.

"(w) Producer and produce.

"(x) Protect health and the environment.

"(y) Registrant.

"(z) Registration.

"(aa) State.

"(bb) Unreasonable adverse effects on the environment.

"(cc) Weed.

"(dd) Establishment.

"(ee) To use any registered pesticide in a manner inconsistent with its labeling.

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## "SEC. 2. DEFINITIONS.

7 USC 136

"For purposes of this Act—

"(a) *Active Ingredient*.—The term 'active ingredient' means—

"(1) in the case of a pesticide other than a plant regulator, defoliant, or desiccant, an ingredient which will prevent, destroy, repel, or mitigate any pest;

"(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

"(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant; and

"(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue.

"(b) *Administrator*.—The term 'Administrator' means the Administrator of the Environmental Protection Agency.

"(c) *Adulterated*.—The term 'adulterated' applies to any pesticide if:

"(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

"(2) any substance has been substituted wholly or in part for the pesticide; or

"(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

"(d) *Animal*.—The term 'animal' means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and the shellfish.

"(e) *Certified Applicator, Etc.*—

"(1) *Certified applicator*.—The term 'certified applicator' means any individual who is certified under section 4 as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or use dilutions of registered pesticides consistent with section 2(ee) of this Act, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this Act.

"(2) *Private applicator*.—The term 'private applicator' means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

"(3) *Commercial applicator*.—The term 'commercial applicator' means an applicator (whether or not he is private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

"(4) *Under the direct supervision of a certified applicator*.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

"(f) *Defoliant*.—The term 'defoliant' means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

"(g) *Desiccant*.—The term 'desiccant' means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

"(h) *Device*.—The term 'device' means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

"(i) *District Court*.—The term 'district court' means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

"(j) *Environment*.—The term 'environment' includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

7 USC 136b.  
P.L. 95-396;  
92 Stat. 819.

"(k) *Fungus*.—The term 'fungus' means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

"(l) *Imminent Hazard*.—The term 'imminent hazard' means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 91-135.

83 Stat. 275;  
16 USC 660cc-1.

"(m) *Inert Ingredient*.—The term 'inert ingredient' means an ingredient which is not active.

"(n) *Ingredient Statement*.—The term 'ingredient statement' means a statement which contains—

"(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

"(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

"(o) *Insect*.—The term 'insect' means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

"(p) *Label and Labeling*.—

"(1) *Label*.—The term 'label' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

"(2) *Labeling*.—The term 'labeling' means all labels and all other written, printed, or graphic matter—

"(A) accompanying the pesticide or device at any time; or

"(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health, Education, and Welfare, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

"(q) *Misbranded*.—

"(1) A pesticide is misbranded if—

"(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

"(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 25(c)(3);

"(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

"(D) its label does not bear the registration number assigned under section 7 to each establishment in which it was produced;

"(E) any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

"(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environment;

"(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment; or

"(H) in the case of a pesticide not registered in accordance with section 3 of this Act and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness

7 USC 136a

7 USC 136c

7 USC 136a

7 USC 136a

P.L. 95-396; 92 Stat. 819;

7 USC 136a

(as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: 'Not Registered for Use in the United States of America'.

"(2) A pesticide is misbranded if—

"(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if:

"(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

"(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

"(B) the labeling does not contain a statement of the use classification under which the product is registered;

"(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

"(i) the name and address of the producer, registrant, or person for whom produced;

"(ii) the name, brand, or trademark under which the pesticide is sold;

"(iii) the net weight or measure of the content; *Provided*, That the Administrator may permit reasonable variations; and

"(iv) when required by regulation of the Administrator to effectuate the purposes of this Act, the registration number assigned to the pesticide under this Act, and the use classification; and

"(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this Act—

"(i) the skull and crossbones;

"(ii) the word 'poison' prominently in red on a background of distinctly contrasting color; and

"(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

"(r) *Nematode*.—The term 'nematode' means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

"(s) *Person*.—The term 'person' means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

"(t) *Pest*.—The term 'pest' means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1).

"(u) *Pesticide*.—The term 'pesticide' means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant: *Provided*, That the term 'pesticide' shall not include any article (1)(a) that is a 'new animal drug' within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)), or (b) that has been determined by the Secretary of Health, Education, and Welfare not to be a new animal drug by a regulation establishing conditions of use for the article, or (2) that is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. 321(x)) bearing or containing an article covered by clause (1) of this proviso."

"(v) *Plant Regulator*.—The term 'plant regulator' means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term 'plant

7 USC 136w.  
P.L. 94-140;  
89 Stat. 754.

regulator' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are non-toxic, nonpoisonous in the undiluted packaged concentration.

P.L. 95-396;  
92 Stat. 819.

"(w) *Producer and Produce*.—The term 'producer' means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term 'produce' means to manufacture, prepare, compound, propagate, or process any pesticide or device, or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of 'producer' for the purposes of this Act."

"(x) *Protect Health and the Environment*.—The terms 'protect health and the environment' and 'protection of health and the environment' mean protection against any unreasonable adverse effects on the environment.

"(y) *Registrant*.—The term 'registrant' means a person who has registered any pesticide pursuant to the provisions of this Act.

"(z) *Registration*.—The term 'registration' includes reregistration.

"(aa) *State*.—The term 'State' means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

"(bb) *Unreasonable Adverse Effects on the Environment*.—The term 'unreasonable adverse effects on the environment' means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

"(cc) *Weed*.—The term 'weed' means any plant which grows where not wanted.

"(dd) *Establishment*.—The term 'establishment' means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

P.L. 95-396;  
92 Stat. 819.

"(ee) *To Use Any Registered Pesticide in a Manner Inconsistent With Its Labeling*.—The term 'to use any registered pesticide in a manner inconsistent with its labeling' means to use any registered pesticide in a manner not permitted by the labeling: Provided, That the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, (2) 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 adverse effect on the environment, (3) employing any method of application not prohibited by the labeling, or (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling: Provided further, That the term also shall not include any use of a pesticide in conformance with section 5, 18, or 24 of this Act, or any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act: And provided further, That after March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

7 USC 136c, 136p, 136v

7 USC 136w-4 note.

7 USC 136c

### SEC. 3. REGISTRATION OF PESTICIDES.

"(a) *Requirement*.—Except as otherwise provided by this Act, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) delivery or offer to deliver, to any person any pesticide which is not registered with the Administrator.

"(b) *Exemptions*.—A pesticide which is not registered with the Administrator may be transferred if—

"(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

"(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

"(c) *Procedure for Registration*.—

(1) *Statement required*.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

"(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

"(B) the name of the pesticide;

"(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

"(D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

P.L. 95-396;  
92 Stat. 820.  
(See note below)

"(i) with respect to pesticides containing active ingredients that are initially registered under this Act after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticides: Provided, That such permission shall not be required in the case of defensive data;

Exclusive  
use of data

"(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the 'applicant') within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant

Compensation.

Arbitration.

Note:

Section 2(b) of the Federal Pesticide Act of 1978 provides, The amendment to section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act made by this section shall apply with respect to all applications for registration approved after September 30, 1978.

7 USC 136a note.

has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take actions and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

"(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data;

"(E) the complete formula of the pesticide; and

"(F) a request that the pesticide be classified for general use, for restricted use, or for both.

"(2) (A) *Data in support of registration.*—The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

"(B) *Additional data to support existing registrations.*—

"(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

"(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.

"(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and

P.L. 95-396;  
92 Stat. 824.

7 USC 136h.

P.L. 95-396  
92 Stat. 822.

Notification.

Joint data  
development.

Arbitration.

conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator.

Payment of  
arbitrator.

"(iv) Notwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act: Provided, That the only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

Hearing.

7 USC 136d.

"(v) Any data submitted under this subparagraph shall be subject to the provisions of subsection (c)(1)(D) of this section. Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data."

"(C) *Simplified procedures.*—Within nine months after date of enactment of this subparagraph, the Administrator shall by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

P.L. 95-396;  
92 Stat. 824.

"(D) *Exemption.*—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

P.L. 95-396;  
92 Stat. 824.

"(i) submit or cite data pertaining to the safety of such purchased product; or

"(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data."

"(3) *Time for acting with respect to application.*—The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of his determination that it does not comply with the provisions of the Act in accordance with paragraph (6).

"(4) *Notice of application.*—The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient

Publication in  
Federal Register.

or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

"(5) *Approval of registration.*—The Administrator shall register a pesticide if he determines that, when considered with any restrictions imposed under subsection (d)—

"(A) its composition is such as to warrant the proposed claims for it;

"(B) its labeling and other material required to be submitted comply with the requirements of this Act;

"(C) it will perform its intended function without unreasonable adverse effects on the environment; and

"(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 24(c) of this Act, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

"(6) *Denial of registration.*—If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, he shall notify the applicant for registration of his determination and of his reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, he shall notify the applicant of his decision and of his reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6.

"(7) *Registration under special circumstances.*—Notwithstanding the provisions of subsection (c)(5) of this section—

"(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under subsection (c)(5) of this section: Provided, That, if the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

"(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human

P.L. 95-396:  
92 Stat. 825.

7 USC 136v.

Publication in  
Federal Register.

P.L. 95-396:  
92 Stat. 825.



dietary exposure enumerated in regulations issued under this Act, and during the pendency of any risk-benefit evaluation initiated by such notice, if (i) the additional use of such pesticide involves a major food or feed crop, or (ii) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under subsection (c)(5) of this section: Provided, That, if the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

“(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, and on such other conditions as the Administrator may prescribe: Provided, That a conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is, in the public interest.

“(8) *Interim administrative review.*—Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms ‘validated test’ and ‘other significant evidence’ as used herein shall be published by the Administrator in the Federal Register.”

P.L. 95-396;  
92 Stat. 826.

Notice of  
Definitions.  
Publication in  
Federal Register.

“(d) *Classification of Pesticides.*—

“(1) *Classification for general use, restricted use, or both.*—

“(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use, provided that if the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, he shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses: *Provided, however,* That the Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

P.L. 95-396;  
92 Stat. 826.

“(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, he will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

“(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including

injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

"(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

"(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

Publication in  
Federal Register.

"(2) *Change in classification.*—If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, he shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 6(b).

7 USC 136d;  
P.L. 95-306;  
92 Stat. 827.

"(3) *Change in classification from restricted use to general use.*—The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 16 of this Act.

7 USC 136e.

"(e) *Products With Same Formulation and Claims.*—Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

"(f) *Miscellaneous.*—

"(1) *Effect of change of labeling or formulation.*—If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this Act.

"(2) *Registration not a defense.*—In no event shall registration of an article be construed as a defense for the commission of any offense under this Act: *Provided*, That as long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act.

"(3) *Authority to consult other Federal agencies.*—In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

P.L. 95-306;  
92 Stat. 827.

"(g) *Reregistration of Pesticides.*—The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided*, That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process.

**"SEC. 4. USE OF RESTRICTED USE PESTICIDES; CERTIFIED APPLICATORS.**

7 USC 136b

**"(a) Certification Procedure.—**

**"(1) Federal certification.**—In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides: *Provided*, That such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the commercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification: *Provided, however*, That the certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by his completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this Act, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by him.

P.L. 95-396  
92 Stat. R27

Public hearings.

Standards.

P.L. 94-140;  
89 Stat. 733.

**"(2) State certification.**—If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose. The Administrator shall approve the plan submitted by any State, or any modification thereof, if such plan in his judgment—

**"(A)** designates a State agency as the agency responsible for administering the plan throughout the State;

**"(B)** contains satisfactory assurances that such agency has or will have the legal authority and qualified personnel necessary to carry out the plan;

**"(C)** gives satisfactory assurances that the State will devote adequate funds to the administration of the plan;

**"(D)** provides that the State agency will make such reports to the Administrator in such form and containing such information as the Administrator may from time to time require; and

**"(E)** contains satisfactory assurances that State standards for the certification of applicators of pesticides conform with those standards prescribed by the Administrator under paragraph (1).

Any State certification program under this section shall be maintained in accordance with the State plan approved under this section.

**"(b) State Plans.**—If the Administrator rejects a plan submitted under this paragraph, he shall afford the State submitting the plan due notice and opportunity for hearing before so doing. If the Administrator approves a plan submitted under this paragraph, then such State shall certify applicators of pesticides with respect to such State. Whenever the Administrator determines that a State is not administering the certification program in accordance with the plan approved under this section, he shall so notify the State and provide for a hearing at the request of the State, and, if appropriate corrective action is

Hearing.

not taken within a reasonable time, not to exceed ninety days, the Administrator shall withdraw approval of such plan.

P.L. 94-140,  
89 Stat. 754

7 USC 136a

"(c) *Instruction in Integrated Pest Management Techniques.*—Standards prescribed by the Administrator for the certification of applicators of pesticides under subsection (a), and the State plans submitted to the Administrator under subsection (a) and (b), shall include provisions for making instructional materials concerning integrated pest management techniques available to individuals at their request in accordance with the provisions of section 23(c) of this Act, but such plans may not require that any individual receive instruction concerning such techniques or be shown to be competent with respect to the use of such techniques. The Administrator and States implementing such plans shall provide that all interested individuals are notified of the availability of such instructional materials."

7 USC 136c

P.L. 95-396,  
92 Stat. 828

#### "SEC. 5. EXPERIMENTAL USE PERMITS.

"(a) *Issuance.*—Any person may apply to the Administrator for an experimental-use permit for a pesticide. The Administrator shall review the application. After completion of the review, but not later than one hundred and twenty days after receipt of the application and all required supporting data, the Administrator shall either issue the permit or notify the applicant of the Administrator's determination not to issue the permit and the reasons therefor. The applicant may correct the application or request a waiver of the conditions for such permit within thirty days of receipt by the applicant of such notification. The Administrator may issue an experimental use permit only if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 3 of this Act. An application for an experimental use permit may be filed at any time.

7 USC 136a

"(b) *Temporary Tolerance Level.*—If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, he may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit.

"(c) *Use Under Permit.*—Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

"(d) *Studies.*—When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator may specify that studies be conducted to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. All results of such studies shall be reported to the Administrator before such pesticide may be registered under section 3.

7 USC 136a

"(e) *Revocation.*—The Administrator may revoke any experimental use permit, at any time, if he finds that its terms or conditions are being violated, or that its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment.

"(f) *State Issuance of Permits.*—Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as he may by regulations prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of section 4 relating to State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

7 USC 136b

P.L. 94-140,  
89 Stat. 754

"(g) *Exemption for Agricultural Research Agencies.*—Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Administrator may require: *Provided*, That such pesticide may be used only by such research agency or educational institution for purposes of experimentation."

7 USC 136d

#### "SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

"(a) *Cancellation After Five Years.*—

"(1) *Procedure.*—The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with

regulations prescribed by the Administrator that the registration be continued in effect: *Provided*, That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

Publication in  
Federal Register.

"(2) *Information*.—If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

"(b) *Cancellation and Change in Classification*.—If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

"(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for his action, or

"(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Hearing

P.L. 94-140;  
89 Stat. 751.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection (b) and section 25(d), in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to subsection (b) and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c). The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

Publication in  
Federal Register.

USC 136a

In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact.

P.L. 95-396;  
92 Stat. 828.

P.L. 94-140;  
89 Stat. 751.

"(c) *Suspension*.—

"(1) *Order*.—If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings he may, by order, suspend the registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide.

Except as provided in paragraph (3), the Administration shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of 'imminent hazard'. The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Agency on the question of whether an imminent hazard exists.

"(2) *Expedite hearing.*—If no request for a hearing is submitted to the Agency within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Agency agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of title 5, of the United States Code, except that the presiding officer need not be a certified hearing examiner. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

"(3) *Emergency order.*—Whenever the Administrator determines that an emergency exists that does not permit him to hold a hearing before suspending, he may issue a suspension order in advance of notification to the registrant. In that case, paragraph (2) shall apply except that (i) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (ii) no party other than the registrant and the Agency shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purpose of section 16(b).

"(4) *Judicial review.*—A final order on the question of suspension following a hearing shall be reviewable in accordance with Section 16 of this Act, notwithstanding the fact that any related cancellation proceedings have not been completed. Petitions to review orders on the issue of suspension shall be advanced on the docket of the courts of appeals. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceeding under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

"(d) *Public Hearings and Scientific Review.*—In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpoena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpoena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made

80 Stat. 381;  
81 Stat. 54;  
5 USC 551.

7 USC 136n.

Subpoena.

28 USC app.

Report.

public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this Act. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before him and issue an order either revoking his notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

**“(e) Conditional Registration.—**

**“(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 3(c)(7) of this Act if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met: *Provided*, That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment.**

**“(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section: *Provided*, That the only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.**

**“(f) Judicial Review.—**Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 16.

P.L. 95-396;  
92 Stat. 828.

Notice.  
7 USC 136a.

7 USC 136n.

**“SEC. 7. REGISTRATION OF ESTABLISHMENTS.**

**“(a) Requirement.—**No person shall produce any pesticide subject to this Act or active ingredient used in producing a pesticide subject to this Act in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

**“(b) Registration.—**Whenever the Administrator receives an application under subsection (a), he shall register the establishment and assign it an establishment number.

**“(c) Information Required.—**

**“(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—**

**“(A) which he is currently producing;**

**“(B) which he has produced during the past year; and**

**“(C) which he has sold or distributed during the past year.**

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

**“(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 13, inform him of the name and address of any recipient of any pesticide produced in any registered establishment which he operates.**

7 USC 136e

P.L. 95-396;  
92 Stat. 829.

92 Stat. 829.

92 Stat. 829

7 USC 136h.

7 USC 134f

Regulations.

“(d) *Confidential Records and Information.*—Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 10.

## “SEC. 8. BOOKS AND RECORDS.

“(a) *Requirements.*—The Administrator may prescribe regulations requiring producers to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act. No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

“(b) *Inspection.*—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such 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. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

P.L. 95-396;  
92 Stat. 829.

Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.

7 USC 136g

## “SEC. 9. INSPECTION OF ESTABLISHMENTS, ETC.

“(a) *In General.*—For purposes of enforcing the provisions of this Act, officers or employees duly designated by the Administrator are authorized to enter at reasonable times, 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.

Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

“(b) *Warrants.*—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

“(1) entry for the purpose of this section;

“(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any



pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act 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; and

"(3) the seizure of any pesticide or device which is in violation of this Act.

"(c) *Enforcement.*—

"(1) *Certification of facts to attorney general.*—The examination of pesticides or devices shall be made in the Environmental Protection Agency or elsewhere as the Administrator may designate for the purpose of determining from such examinations whether they comply with the requirements of this Act. If it shall appear from any such examination that they fail to comply with the requirements of this Act, the Administrator shall cause notice to be given to the person against whom criminal or civil proceedings are contemplated. Any person so notified shall be given an opportunity to present his views, either orally or in writing, with regard to such contemplated proceedings, and if in the opinion of the Administrator it appears that the provisions of this Act have been violated by such person, then the Administrator shall certify the facts to the Attorney General, with a copy of the results of the analysis or the examination of such pesticide for the institution of a criminal proceeding pursuant to section 14(b) or a civil proceeding under section 14(a), when the Administrator determines that such action will be sufficient to effectuate the purposes of this Act.

7 USC 136i.

"(2) *Notice not required.*—The notice of contemplated proceedings and opportunity to present views set forth in this subsection are not prerequisites to the institution of any proceeding by the Attorney General.

"(3) *Warning notices.*—Nothing in this Act shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

"SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

7 USC 136h

"(a) *In General.*—In submitting data required by this Act, the applicant may (1) clearly mark any portions thereof which in his opinion are trade secrets or commercial or financial information and (2) submit such marked materials separately from other material required to be submitted under this Act.

"(b) *Disclosure.*—Notwithstanding any other provision of this Act, and subject to the limitations in subsections (d) and (e) of this section the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

"(c) *Disputes.*—If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), he shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (b).

"(d) *Limitations.*—

"(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public: *Provided*, That the use of such data for any registration purpose shall be governed by section 3 of this Act: *Provided further*, That this paragraph does not authorize the disclosure of any information that—

P.L. 95-396;  
92 Stat. 830.

Information,  
availability  
to public.

7 USC 136a.

“(A) discloses manufacturing or quality control processes,

“(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

“(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

“(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

“(3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice: *Provided*, That where the Administrator finds that disclosure of information described in clause (A), (B), (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court shall give expedited consideration to any such action. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

“(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

“(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

P.L. 95-396;  
92 Stat. 831.

“(e) *Disclosure to Contractors.*—Information otherwise protected from disclosure to the public subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

P.L. 95-396;  
92 Stat. 831.

“(f) *Penalty for disclosure by Federal Employees.*—

“(1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than \$10,000 or imprisoned for not more than one year, or both. Section 1905 of title 18 of the United States Code shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act. Nothing in this Act shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.

“(2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.

P.L. 95-396;  
92 Stat. 831.

“(g) *Disclosure to Foreign and Multinational Pesticide Producers.*—

“(1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or

in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this Act, which information is relevant to the determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

"(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliation of such persons.

"(3) Section 1001 of title 18 of the United States Code shall apply to any affirmation made under paragraph (1) of this subsection.

Records.

## "SEC. 11. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

7 USC 136i

"(a) *In General.*—No regulations prescribed by the Administrator for carrying out the provisions of this Act shall require any private applicator to maintain any records or file any reports or other documents.

"(b) *Separate Standards.*—When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.

## "SEC. 12. UNLAWFUL ACTS.

7 USC 136j

"(a) *In General.*—

"(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person—

"(A) any pesticide which is not registered under section 3, except as provided by section 6(a)(1);

7 USC 136a, 136d.

"(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3;

"(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 3;

"(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 25(c)(5);

7 USC 136w.

"(E) any pesticide which is adulterated or misbranded; or

"(F) any device which is misbranded.

"(2) It shall be unlawful for any person—

"(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act;

"(B) to refuse to keep any records required pursuant to section 8, or to refuse to allow the inspection of any records or establishment pursuant to section 8 or 9, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 9;

7 USC 136f, 136g.

"(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to his own name and address, the name and address of the person residing in the United States from whom he received the guaranty or undertaking;

"(D) to use for his own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts,

or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this Act which is confidential under this Act;

7 USC 136a.

"(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a produce registered under this Act for restricted use without giving the classification of the product assigned to it under section 3;

7 USC 136a.

P.L. 95-396;  
92 Stat. 832.

"(F) 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 section 3(d) and any regulations thereunder; *Provided*, 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;

"(G) to use any registered pesticide in a manner inconsistent with its labeling;

"(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

7 USC 136k.

"(I) to violate any order issued under section 13;

7 USC 136j.

"(J) to violate any suspension order issued under section 6;

"(K) to violate any cancellation of registration of a pesticide under section 6, except as provided by section 6(a)(1);

7 USC 136c.

"(L) who is a producer to violate any of the provisions of section 7;

7 USC 136e, 136f.

"(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to section 8, any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this act;

"(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this Act;

"(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act; or

"(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.

"(b) *Exemptions.*—The penalties provided for a violation of paragraph (1) of subsection (a) shall not apply to—

"(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom he purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to him, and that it complies with the other requirements of this Act, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this Act;

"(2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

"(3) any public official while engaged in the performance of his official duties;

"(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

"(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

7 USC 136a.

### "SEC. 13. STOP SALE, USE, REMOVAL, AND SEIZURE.

"(a) *Stop Sale, Etc., Orders.*—Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the pro-

visions of this Act, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed 'stop sale, use, or removal' order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

"(b) *Seizure.*—Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

"(1) in the case of a pesticide—

"(A) it is adulterated or misbranded;

"(B) it is not registered pursuant to the provisions of section 3;

"(C) its labeling fails to bear the information required by this Act;

"(D) it is not colored or discolored and such coloring or discoloring is required under this Act; or

"(E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;

"(2) in the case of a device, it is misbranded; or

"(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this Act and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment. In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

"(c) *Disposition After Condemnation.*—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold; *Provided*, That upon payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

"(d) *Court Costs, Etc.*—When a decree of condemnation is entered against the pesticide or device, court costs and fees, storage, and other proper expenses shall be awarded against the person, if any, intervening as claimant of the pesticide or device.

#### "SEC. 14. PENALTIES.

7 USC 136f

"(a) *Civil Penalties.*—

"(1) *In General.*—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than \$5,000 for each offense.

"(2) *Private Applicator.*—Any private applicator or other person not included in paragraph (1) who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than \$1,000 for each offense: *Provided*, That any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or use dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than \$500 for the first offense nor more than \$1,000 for each subsequent offense.

P.L. 95-396;  
92 Stat. 832.

"(3) *Hearing.*—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged.

P.L. 95-306;  
92 Stat. 833

"(4) *Determination of Penalty.*—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty."

"(5) *References to Attorney General.*—In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

"(b) *Criminal Penalties.*—

"(1) *In General.*—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than \$25,000, or imprisoned for not more than one year, or both.

"(2) *Private applicator.*—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than \$1,000, or imprisoned for not more than 30 days, or both.

7 USC 136a

"(3) *Disclosure of information.*—Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than \$10,000, or imprisoned for not more than three years, or both.

"(4) *Acts of officers, agents, etc.*—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

7 USC 136a

"SEC. 15. INDEMNITIES.

"(a) *Requirement.*—If—

"(1) the Administrator notifies a registrant that he has suspended the registration of a pesticide because such action is necessary to prevent an imminent hazard;

"(2) the registration of the pesticide is canceled as a result of a final determination that the use of such pesticide will create an imminent hazard; and

"(3) any person who owned any quantity of such pesticide immediately before the notice to the registrant under paragraph (1) suffered losses by reason of suspension or cancellation of the registration. The Administrator shall make an indemnity payment to such person, unless the Administrator finds that such person (i) had knowledge of facts which, in themselves, would have shown that such pesticide did not meet the requirements of section 3(c)(5) for registration, and (ii) continued thereafter to produce such pesticide without giving timely notice of such facts to the Administrator.

7 USC 136a

"(b) *Amount of Payment.*—

"(1) *In General.*—The amount of the indemnity payment under subsection (a) to any person shall be determined on the basis of the cost of the pesticide owned by such person immediately before the notice to the registrant referred to in subsection (a)(1); except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by such person immediately before the notice referred to in subsection (a)(1).

"(2) *Special rule.*—Notwithstanding any other provision of this Act, the Administrator may provide a reasonable time for use or other disposal of such pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this subsection, proper adjustment shall be made for any pesticide used or otherwise disposed of by such owner.

**"SEC. 16. ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW.**

7 USC 136a

"(a) *District Court Review.*—Except as is otherwise provided in this Act, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts.

"(b) *Review by Court of Appeals.*—In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all cases filed therein pursuant to this section.

72 Stat. 941;  
80 Stat. 1323.

62 Stat. 928

"(c) *Jurisdiction of District Courts.*—The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of this Act.

"(d) *Notice of Judgments.*—The Administrator shall, by publication in such manner as he may prescribe, give notice of all judgments entered in actions instituted under the authority of this Act.

**"SEC. 17. IMPORTS AND EXPORTS.**

7 USC 136a

"(a) *Pesticides and Devices Intended for Export.*—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

P.L. 95-396;  
92 Stat. 833  
(See note below)

"(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1) (A), (C), (D), (E), (G), and (H), 2(q)(2) (A), (B), (C) (i) and (iii), and (D), 7, and 8 of this Act; and

7 USC 136, 136e, 136f.

"(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

7 USC 136a, 136d.

"(b) *Cancellation Notices Furnished to Foreign Governments.*—Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.

P.L. 95-396;  
92 Stat. 833.

Notification.

"(c) *Importation of Pesticides and Devices.*—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon his request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the

Section 18 (b) of the Federal Pesticide Act of 1978 provides, The amendment [to Section 17(a)] made by subsection (a)(1) of this section shall become effective March 29, 1979.

7 USC 136a note.

right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this Act, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond: *And provided further*, That all charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

"(d) *Cooperation in International Efforts*.—The Administrator shall in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

"(e) *Regulations*.—The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (c) of this section.

7 USC 136p

#### "SEC. 18. EXEMPTION OF FEDERAL AGENCIES.

"The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption.

P.L. 94-140;  
89 Stat. 754

"The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination."

7 USC 136q

#### "SEC. 19. DISPOSAL AND TRANSPORTATION.

Regulations.

"(a) *Procedures*.—The Administrator shall, after consultation with other interested Federal agencies, establish procedures and regulations for the disposal or storage of packages and containers of pesticides and for disposal or storage of excess amounts of such pesticides, and accept at convenient locations for safe disposal a pesticide the registration of which is canceled under section 6(c) if requested by the owner of the pesticide.

7 USC 136d

"(b) *Advice to Secretary of Transportation*.—The Administrator shall provide advice and assistance to the Secretary of Transportation with respect to his functions relating to the transportation of hazardous materials under the Department of Transportation Act (49 U.S.C. 1657), the Transportation of Explosives Act (18 U.S.C. 831-835), the Federal Aviation Act of 1958 (49 U.S.C. 1421-1430, 1472 11), and the Hazardous Cargo Act (46 U.S.C. 170, 375, 416).

80 Stat. 944;  
74 Stat. 808;  
79 Stat. 286;  
72 Stat. 775;  
85 Stat. 481;  
Contract  
Authority.P.L. 95-396;  
92 Stat. 833.

"(c) *Provisions for unused quantities*.—Notification of cancellation of any pesticide shall include specific provisions for the disposal of the unused quantities of such pesticide.

7 USC 136r

#### "SEC. 20. RESEARCH AND MONITORING.

"(a) *Research*.—The Administrator shall undertake research, including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this Act, and he shall conduct research into integrated pest management in coordination with the Secretary of Agriculture. The Administrator shall also take care to insure that such research does not duplicate research being undertaken by any other Federal agency.

P.L. 95-396;  
92 Stat. 834.

"(b) *National Monitoring Plan*.—The Administrator shall formulate and periodically revise, in cooperation with other Federal, State, or local agencies, a national plan for monitoring pesticides.



"(c) *Monitoring*.—The Administrator shall undertake such monitoring activities, including, but not limited to, monitoring in air, soil, water, man, plants, and animals, as may be necessary for the implementation of this Act and of the national pesticide monitoring plan. The Administrator shall establish procedures for the monitoring of man and animals and their environment for incidental pesticide exposure, including, but not limited to, the quantification of incidental human and environmental pesticide pollution and the secular trends thereof, and identification of the sources of contamination and their relationship to human and environmental effects. Such activities shall be carried out in cooperation with other Federal, State, and local agencies.

P.L. 95-396;  
92 Stat. 834.

## "SEC. 21. SOLICITATION OF COMMENTS; NOTICE OF PUBLIC HEARINGS.

7 USC 136n

"(a) The Administrator, before publishing regulations under this Act, shall solicit the views of the Secretary of Agriculture in accordance with the procedure described in section 25(a).

P.L. 94-140;  
89 Stat. 752;

"(b) In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at his discretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as he deems proper.

7 USC 136w

"(c) In connection with all public hearings under this Act the Administrator shall publish timely notice of such hearings in the Federal Register.

Publications in  
Federal Register.

## "SEC. 22. DELEGATION AND COOPERATION.

7 USC 136i

"(a) *Delegation*.—All authority vested in the Administrator by virtue of the provisions of this Act may with like force and effect be executed by such employees of the Environmental Protection Agency as the Administrator may designate for the purpose.

"(b) *Cooperation*.—The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this Act, and in securing uniformity of regulations.

## "SEC. 23. STATE COOPERATION, AID, AND TRAINING.

7 USC 136e

"(a) *Cooperative Agreements*.—The Administrator may enter into cooperative agreements with States and Indian tribes—

P.L. 95-396;  
92 Stat. 834.

"(1) to delegate to any State or Indian tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this Act, and to assist States and Indian tribes in implementing cooperative enforcement programs through grants-in-aid; and

"(2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agreements, to train and certify applicators consistent with the standards the Administrator prescribes.

Effective with the fiscal year beginning October 1, 1978, there are authorized to be appropriated annually such funds as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agreements, of conducting training and certification programs during such fiscal year. If funds sufficient to pay 50 percent of the costs for any year are not appropriated, the share of each State and Indian tribe shall be reduced in a like proportion in allocating available funds.

"(b) *Contracts for Training*.—In addition, the Administrator may enter into contracts with Federal, State, or Indian tribal agencies for the purpose of encouraging the training of certified applicators.

"(c) *Information and Education*.—The Administrator shall, in cooperation with the Secretary of Agriculture, use the services of the cooperative State extension services to inform and educate pesticide users about accepted uses and other regulations made under this Act.

7 USC 136.

**"SEC. 24. AUTHORITY OF STATES.**P.L. 95-396;  
92 Stat. 835.

"(a) A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

"(b) Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

7 USC 136a.

"(c)(1) 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 in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or cancelled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State.

"(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

21 USC 301.

"(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act that permits the residues of the pesticide on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

7 USC 136w.

"(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 25 of this Act, that a State is not capable of exercising adequate controls to assure that State registration under this station will be in accord with the purposes of this act or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond."

7 USC 136w

**"SEC. 25. AUTHORITY OF ADMINISTRATOR.**P.L. 94-140;  
89 Stat. 751.

"(a)(1) *Regulations.*—The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

P.L. 94-140;  
89 Stat. 752.

(2) *Procedure.*—

Publications in  
Federal Register.

"(A) *Proposed regulations.*—At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.

P.L. 95-396;  
92 Stat. 836.Publication in  
Federal Register.

"(B) *Final regulations.*—At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register

(with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement.

In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

"(C) *Time requirements.*—The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

"(D) *Publication in the federal register.*—The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register."

"(3) *Congressional Committees.*—At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, he shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture and Forestry of the Senate."

"(4) **RULE AND REGULATION REVIEW.** —

"(A) **CONGRESSIONAL REVIEW.** — Notwithstanding any other provision of this Act, simultaneously with promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. Except as provided in subparagraph (B), the rule or regulation shall not become effective, if within 90 calendar days of continuous session of Congress after the date of promulgation, both Houses of Congress adopt a concurrent resolution, the matter after the resolving clause of which is as follows: 'That Congress disapproves the rule or regulation promulgated by the Administrator of the Environmental Protection Agency dealing with the matter of \_\_\_\_\_, which rule or regulation was transmitted to Congress on \_\_\_\_\_, the blank spaces therein being appropriately filled.

[Added by PL 96-539, Dec. 18, 1980]

"(B) **EFFECTIVE DATE.** — If at the end of 60 calendar days of continuous session of Congress after the date of promulgation of a rule or regulation, no committee of either House of Congress has reported or been discharged from further consideration of a concurrent resolution disapproving the rule or regulation, and neither House has adopted such a resolution, the rule or regulation may go into effect immediately. If, within such 60 calendar days, such a committee has reported or been discharged from further consideration of such a resolution, or either House has adopted such a resolution, the rule or regulation may go into effect not sooner than 90 calendar days of continuous session of Congress after its promulgation unless disapproved as provided in subparagraph (A).

[Added by PL 96-539, Dec. 17, 1980]

"(C) For the purposes of subparagraphs (A) and (B) of this paragraph—

[Added by PL 96-539, Dec. 17, 1980]

"(i) continuity of session is broken only by an adjournment of Congress sine die; and

[Added by PL 96-539, Dec. 17, 1980]

"(ii) the days on which either House is not in session because of an adjournment of more than 3 days to a day certain are excluded in the computation of 60 and 90 calendar days of continuous session of Congress.

[Added by PL 96-539, Dec. 17, 1980]

"(D) **EFFECT OF CONGRESSIONAL INACTION.** — Congressional inaction on or rejection of a resolution of disapproval shall not be deemed an expression of approval of such rule.

[Added by PL 96-539, Dec. 17, 1980]

"(E) **JUDICIAL REVIEW.** —

"(i) Any interested party, including any person who participated in the rulemaking involved, may institute such actions in the appropriate district court of the United States, including actions for declaratory judgment, as may be appropriate to construe the constitutionality of any provision of this paragraph. The district court immediately shall certify all questions of the constitutionality of this paragraph to the United States court of appeals for the circuit involved, which shall hear the matter sitting en banc.

[Added by PL 96-539, Dec. 17, 1980]

P.L. 95-396;  
92 Stat. 836.

Publication in  
Federal Register.

P.L. 94-140;  
89 Stat. 753.

"(ii) Notwithstanding any other provision of law, any decision on a matter certified under clause (i) of this subparagraph shall be reviewable by appeal directly to the Supreme Court of the United States. Such appeal shall be brought not later than 20 days after the decision of the court of appeals.

[Added by PL 96-539, Dec. 17, 1980]

"(iii) It shall be the duty of the court of appeals and of the Supreme Court of the United States to advance on the docket and to expedite to the greatest possible extent the disposition of any matter certified under clause (i) of this subparagraph.

[Added by PL 96-539, Dec. 17, 1980]

"(b) *Exemption of Pesticides.*—The Administrator may exempt from the requirements of this Act by regulation any pesticide which he determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.

"(c) *Other Authority.*—The Administrator, after notice and opportunity for hearing, is authorized—

"(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

"(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

"(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91-601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act;

"(4) to specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) or section 7 of this Act upon his determination that application of such provision is necessary to effectuate the purposes of this Act;

"(5) to prescribe regulations requiring any pesticide to be colored or discolored if he determines that such requirement is feasible and is necessary for the protection of health and the environment; and

"(6) to determine and establish suitable names to be used in the ingredient statement.

"(d) *SCIENTIFIC ADVISORY PANEL.*—The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of seven members appointed by the Administrator from a list of 12 nominees, six nominated by the National Institutes of Health, and six by the National Science Foundation. The Administrator may require such information from the nominees to the advisory panel as he deems necessary, and he shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS-18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The

84 Stat. 1670.  
15 USC 1471 note.

7 USC 136c.

P.L. 94-140  
89 Stat. 753  
7 USC 136d.  
7 USC 136w.

Publication in  
Federal Register.

Publication in  
Federal Register.

Members.

Publications in  
Federal Register.

Compensation.  
5 USC 5332  
note.

P.L. 94-140  
89 Stat. 754

Regulations.

advisory panel established under this subsection shall terminate September 30, 1981. In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

[Amended by PL 96-539, Dec. 17, 1980]

“(e) PEER REVIEW. — The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide: *Provided*, That whenever the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term ‘peer review’ shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines.”

[Added by PL 96-539, Dec. 17, 1980]

[Editor's note: Section 2(b) of PL 96-539 provides:

“(b) The provisions of this section shall become effective upon publication in the Federal Register of final procedures for peer review as provided in this section, but in no event shall such provisions become effective later than one year after the date of enactment of this Act.”]

Advisory panel,  
termination.

42 USC 4365.

7 USC 136d.

7 USC 136d.

Comments.

“Peer review.”  
Publication in  
Federal  
Register.

7 USC 136w note.

## “SEC. 26. STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

“(a) For the purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

“(1) has adopted adequate pesticide use laws and regulations; *Provided*, That the Administrator may not require a State to have pesticide use laws that are more stringent than this Act; .

“(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

“(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

“(b) Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 4 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under Section 4 of this Act in effect on September 30, 1978 not later than March 31, 1979.

“(c) the Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this Act. Notwithstanding the provisions of section 2(e) (1) of this Act, during any period when the Administrator has such enforcement responsibility, section 8(b) of this Act shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or use dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 9(a) of this Act shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

7 USC 136w-1

P.L. 95-396;  
92 Stat. 836.

7 USC 136u

7 USC 136b

7 USC 136

7 USC 136f

7 USC 136g

7 USC 136w-2

P.L. 95-396;  
92 Stat. 837.**"SEC. 27. FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS.**

"(a) Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this Act. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this Act.

"(b) Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of 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.

7 USC 136w-1

"(c) Neither section 26 of this Act nor this section shall limit the authority of the Administrator to enforce this Act, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

7 USC 136w-3

**"SEC. 28. IDENTIFICATION OF PESTS; COOPERATION WITH DEPARTMENT OF AGRICULTURE'S PROGRAM.**P.L. 95-396;  
92 Stat. 838.

"The Administrator, in coordination with the Secretary of Agriculture, shall identify those pests that must be brought under control. The Administrator shall also coordinate and cooperate with the Secretary of Agriculture's research and implementation programs to develop and improve the safe use and effectiveness of chemical, biological, and alternative methods to combat and control pests that reduce the quality and economical production and distribution of agricultural products to domestic and foreign consumers.

7 USC 136w-4

**"SEC. 29. ANNUAL REPORT.**P.L. 95-396;  
92 Stat. 838

7 USC 136a

"The Administrator shall submit an annual report to Congress before February 16 of each year and the first report shall be due February 15, 1979. The report shall include the total number of applications for conditional registration under section 3(c)(7)(B) and 3(c)(7)(C) of this Act that were filed during the immediately preceding fiscal year, and, with respect to those applications approved, the Administrator shall report the Administrator's findings in each case, the conditions imposed and any modification of such conditions in each case, and the quantities produced of such pesticides.

7 USC 136x

**"SEC. 30. SEVERABILITY.**

"If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this Act which can be given effect without regard to the invalid provision or application, and to this end the provisions of this Act are severable.

**"SEC. 31. AUTHORIZATION FOR APPROPRIATIONS.**

"There is authorized to be appropriated such sums as may be necessary to carry out the provisions of this Act for each of the fiscal years ending June 30, 1973, June 30, 1974, and June 30, 1975. The amounts authorized to be appropriated for any fiscal year ending after June 30, 1975, shall be the sums hereafter provided by law."

P.L. 94-51  
89 Stat. 257

"There is hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning July 1, 1975, and ending September 30, 1975, the sum of \$11,967,000.

P.L. 94-109  
89 Stat. 577

There is hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1975, and ending November 15, 1975, the sum of \$5,983,500.

P.L. 94-140  
89 Stat. 782

7 USC 136y.

"There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1975, and ending September 30, 1976, the sum of \$47,868,000, and for the period beginning October 1, 1976, and ending September 30, 1977, the sum of \$46,636,000, and for the period beginning October 1, 1977, and ending September 30, 1978, the sum of \$54,500,000, and for the period beginning October 1, 1978, and ending September 30, 1979, such sums as may be necessary, but not in excess of \$70,000,000.

P.L. 96-539  
94 Stat. 3194

There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1979, and ending September 30, 1980, such sums as may be necessary, but not in excess of \$72,160,000, and for the period beginning October 1, 1980, and ending September 30, 1981, such sums as may be necessary, but not in excess of \$77,500,000."

*Amendments to Other Acts*

Sec. 3. of P.L. 92-516 (1972) states, The following Acts are amended by striking out the terms "economic poisons" and "an economic poison" wherever they appear and inserting in lieu thereof "pesticides" and "a pesticide" respectively:

- (1) The Federal Hazardous Substances Act, as amended (15 U.S.C. 1261 et seq.);
- (2) The Poison Prevention Packaging Act, as amended (15 U.S.C. 1471 et seq.); and
- (3) The Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

74 Stat. 1305

84 Stat. 1670

52 Stat. 1040

*Effective Dates of Provisions of Act*

Sec. 4. of P.L. 92-516 (1972), as amended, states, (a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, and as otherwise provided by this section, the amendments made by this Act shall take effect at the close of the date of the enactment of this Act, provided if regulations are necessary for the implementation of any provision that becomes effective on the date of enactment, such regulations shall be promulgated and shall become effective within 90 days from the date of enactment of this Act.

(b) The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder.

Savings  
provision  
61 Stat. 163.  
7 USC 135 note.

(c)(1) Two years after the enactment of this Act the Administrator shall have promulgated regulations providing for the registration and classification of pesticides under the provisions of this Act and thereafter shall register all new applications under such provisions.

(2) Any requirements that a pesticide be registered for use only by a certified applicator shall not be effective until five years from the date of enactment of this Act.

P.L. 94-140;  
89 Stat. 752.

(3) A period of five years from date of enactment shall be provided for certification of applicators.

P.L. 94-140;  
89 Stat. 753.

(A) One year after the enactment of this Act the Administrator shall have prescribed the standards for the certification of applicators.

(B) Each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).

P.L. 95-396;  
92 Stat. 842.

(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

(4) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.

(e) For purposes of determining any criminal or civil penalty or liability to any third person in respect of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted.

*Legislative History*

Public Law 92-516  
92nd Congress, H. R. 10729  
October 21, 1972

HOUSE REPORTS: No. 92-511 (Comm. on Agriculture) and No. 92-1540 (Comm. of Conference).

SENATE REPORTS: No. 92-838 (Comm. on Agriculture and Forestry) and No. 92-970 (Comm. on Commerce).

## CONGRESSIONAL RECORD:

Vol. 117 (1971): Nov. 8, 9, considered and passed House.  
 Vol. 118 (1972): Sept. 26, considered and passed Senate, amended.  
 Oct. 5, Senate agreed to conference report.  
 Oct. 12, House agreed to conference report.

## WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS:

Vol. 8, No. 44 (1972): Oct. 21, Presidential statement.

Public Law 94-140  
 94th Congress, H. R. 8841  
 November 18, 1975

HOUSE REPORTS: No. 94-497 (Comm. on Agriculture) and NO. 94-668 (Comm. of Conference).

SENATE REPORT No. 94-452 (Comm. on Agriculture and Forestry).

CONGRESSIONAL RECORD: Vol. 121 (1975).

Sept. 26, Oct. 3, 9, considered and passed House.  
 Nov. 12, considered and passed Senate, amended.  
 Nov. 18, House agreed to conference report.  
 Nov. 19, Senate agreed to conference report.

Public Law 95-396  
 95th Congress, S. 1678  
 September 30, 1978

HOUSE REPORTS: No. 95-343 and No. 95-343, Pt. 2, (Comm. on Agriculture) both accompanying H.R. 7073 and No. 95-1560 (Comm. of Conference).

SENATE REPORTS: No. 95-334 (Comm. on Agriculture, Nutrition and Forestry) and 95-1188 (Comm. of Conference).

CONGRESSIONAL RECORD:

Vol. 123 (1977): July 29, considered and passed Senate.  
 Sept. 22, Oct. 31, considered and passed House, amended, in lieu of H.R. 7073.

Vol. 124 (1978): Sept. 18, Senate agreed to conference report.  
 Sept. 19, House agreed to conference report.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS:

Vol. 14, No. 40: Oct. 2, 1978, Presidential statement.

The following is Section 27(a) of P.L. 95-396, the "Federal Pesticide Act of 1978", but is not an amendment to FIFRA.

*Studies*

7 USC 136w-4  
 note.

Report to  
 congressional  
 committee.

Report to  
 congressional  
 committee.

Sec. 27. (a) The Administrator of the Environmental Protection Agency shall perform a study examining the feasibility of assessing and collecting fees from persons applying to register, or amend the registration of, pesticides to cover the costs incurred by the Environmental Protection Agency in processing such applications under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. The Administrator shall complete this study and submit a report setting forth the findings of the study and recommendations for the implementation of these findings to the Senate Committee on Agriculture, Nutrition, and Forestry and the House Committee on Agriculture, not later than June 30, 1979.

(b) The Administrator, in cooperation with the Secretary of Agriculture, and after consultation with appropriate State officials, shall review available scientific information dealing with issues involved in the methods of pesticide application, including, but not limited to, the advisability of ultra-low-volume methods of application, and shall recommend to the Senate Committee on Agriculture, Nutrition, and Forestry and the House Committee on Agriculture such changes as the Administrator may deem necessary in existing law relative to provisions of the Act pertaining to the use of a registered pesticide in a manner inconsistent with its labeling. The report shall be submitted as soon as practicable, but not later than March 31, 1979.

(c) The Administrator shall submit an updated study examining the problems of minor uses of pesticides not specifically permitted by labeling. The Administrator shall complete this study and submit a report setting forth the findings of the study and recommendations for the implementation of these findings to the Senate Committee on Agriculture, Nutrition, and Forestry and the House Committee on Agriculture, not later than June 30, 1979.



## 4 FIFRA Regulatory Elements

FIFRA was enacted by Congress to provide for the pre-market clearance of pesticides and the post-market surveillance of pesticides and pesticidal devices. The following sections of this chapter discuss the primary regulatory means by which the Act is implemented. The primary regulatory elements of FIFRA include:

- Registration of Pesticides;
- Establishment Registration;
- Pesticide Disposal;
- Experimental Use Permits;
- Emergency Exemptions for Federal and State Agencies; and
- State Registration of Pesticides To Meet Local Needs.



## 4a Registration of Pesticides

The basic element of EPA's pesticide regulation program is the registration of pesticides destined for use in the United States. Section 3 of FIFRA and 40 C.F.R. Part 162 provide the basic authority for the registration program.

The objectives of the pesticide registration program are to:

- Bring the product into compliance with Section 3 of the Act;
- Provide users with pesticides that will not cause unreasonable adverse effects to the environment when used as directed;
- Provide users with pesticides that will be effective for the purposes listed on the label;
- Provide users with pesticides that are essentially safe when used as directed;
- Identify the registrant and/or producer responsible for the pesticide; and
- Identify registered pesticides in the event that enforcement action is required.

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### Applicability of Registration Requirements

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The Act requires that all producers (see Glossary) of pesticides have their products registered with EPA.

With few exceptions, it is unlawful for any person in any State to sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver to another person any pesticide that is not registered.

A pesticide may be registered by the Administrator if it is determined that:

- The composition of the product warrants the proposed claims made for it;
- Its labeling and other required material comply with the requirements of the Act;
- The product will perform its intended functions without unreasonable adverse effects to the environment; and
- The product will not generally cause unreasonable adverse effects to the environment when used in accordance with widespread and commonly recognized practices.

Registered pesticides will be classified as either "general" or "restricted," according to use.

#### Pesticides Exempt From Registration Requirements

The following pesticides are exempt from registration requirements under FIFRA [40 C.F.R. §162.5(b)]:

- Pesticide products that are offered solely for human use and are also either a new drug within the meaning of the Federal Food, Drug, and Cosmetic Act or an article determined not to be a new drug by the FDA through a regulation establishing conditions for the article's use;
- Pesticides being transferred from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment;
- Pesticides being transferred for use in accordance with the requirements of an experimental use permit;
- ~~Pesticides whose registration is cancelled under Section 6(c) of the Act and are shipped solely for disposal;~~
- Pesticide products intended for export to any foreign country when prepared or packaged according to the specifications or directions of the foreign purchaser; and
- Pesticides being transferred for use by a Federal or State agency under the provisions of a Section 18 emergency exemption.

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Registration Procedures

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Types of Registration

The following is a brief description and summary of the types of registration and the general requirements for each type.

New Registrations. The following must be filed with the Registration Division:

- Application for Pesticide (EPA Form 8570-1);
- Confidential Statement of Formula (EPA Form 8570-4);
- Five copies of the proposed labeling;
- Supporting data concerning product efficacy, general and environmental chemistry, and hazard, as required by 40 C.F.R. §162.8;
- Offer-To-Pay Statement;
- Certification Statement;
- Statement proposing a classification of general or restricted use for the product;
- Supportive data; and
- Any other information required.

NOTE: Filing an application does not constitute registration. Once a company files an initial application, it is assigned a permanent registrant number. This number, followed by a hyphen and letters is the file symbol. When and if the product is accepted for registration, the file symbol is converted to the product registration number.

Ex. Before Acceptance

File Symbol  
339-R

After Acceptance

EPA Registration Number  
339-1

Amended Registrations. An application for amended registration must be submitted when changes are proposed in the labeling (such as the addition of new uses, change in product name, or request for additional brand names) or when minor changes are proposed in the formulation of the pesticide. The following must be submitted:

- Application for Amended Pesticide Product Registration (EPA Form 8570-11);

- Two draft copies of the proposed changes to the previously approved labeling with supporting data; and
- Five copies of the final printed label in accordance with 40 C.F.R. §162.10, Labeling Requirements. Final printed labeling need not be submitted until after draft copies are approved by EPA.

When a minor change in the product's chemistry is desired, the Confidential Statement of Formula (EPA Form 8570-4) should also be submitted. If the addition of a new use requires data, then two copies of this data should also be submitted.

#### Distribution Under Amended Labeling

After the effective date of a change in labeling or formula (the acceptance date), the product may still be marketed using the previously accepted label during the five-year registration period, unless the Registration Division indicates otherwise.

Supplemental Registrations (Private Labels). A basic registrant's product can be supplementally registered for a distributor, thus allowing the distributor to market the product under his or her own brand name without a separate registration.

Certain conditions are applicable for supplemental registration:

- The distributor's product must have the same composition as the basic registrant's product;
- The distributor's product must be manufactured and packaged by the same person who manufactures and packages the registered basic product;
- The product labeling for the distributor must bear the same claims as the basic product provided; however, specific claims may be deleted if by so doing no other changes are necessary;
- The product must remain in the manufacturer's unbroken container;
- The label must bear the EPA registration number of the basic registered product followed by a hyphen and the distributor's company number; and
- The distributor's product must bear the name and address of the distributor, qualified by such terms as "Packed for...", "Distributed by...", or "Sold by...."

The following should be submitted by the registrant:

- Application for Supplemental Registration of Distributor (EPA Form 8570-5), which includes proof of concurrence by the distributor; and
- Distributor's company number for each proposed distributor.

Renewal Registrations.\* Registration is effective for a period of five years from the date of registration. At the end of the registration period, a notice of intent to cancel will be sent to the registrant at the latest address known to the Registration Division. If a registrant wishes to continue the registration in effect after the expiration of the five-year registration period, a request for renewal registration must be made within 30 days of receipt of a notice of intent to cancel. If a continuance is not requested, cancellation of registration will become effective at the end of the 30-day period following receipt of the notice.

Applications for renewal are subject to certain labeling and data requirements. If the product or its labeling fails to comply with current requirements, the registrant will be afforded an opportunity to make the necessary corrections. Following receipt of a notice of intent to continue registration, the Registration Division may request specific data from the registrant.

Re-registration. FIFRA Section 3(g), as amended in 1978, directs EPA to re-register all currently registered products as expeditiously as possible. Central to the re-registration program is a document called a Registration Standard. Each standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's position and requirements for a company to retain full registration.

Once a standard is published, the Agency will solicit the appropriate registrants to re-register their products. Those registrants who wish to continue to sell or distribute their product in commerce must then meet the conditions and requirements of the standard. Although these requirements may vary from one active ingredient to another, in general they include:

- Submission of needed scientific data that the Agency does not have;
- Compliance with standards of toxicity, composition, labeling, and packaging; and
- Satisfaction of the data compensation provisions.

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\* The five-year renewal program is currently inoperative.

Conditional Registration. FIFRA Section 3(c)(7) authorizes the Administrator to conditionally register a pesticide product even though certain required data may not have been submitted or evaluated by EPA. A conditional registration is a registration for which the submission (or Agency review) has been deferred to a future date.

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### Labeling Requirements

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The registration program is designed to ensure that pesticide products will be safe and effective when used in accordance with statements listed on the label. FIFRA requires every pesticide product to bear a label containing the following:

- Name, brand, or trademark under which the product is sold;
- Name and address of producer, registrant, or person for whom produced;
- Net contents statement;
- Product registration number (EPA Reg. No.);
- Producing establishment number (EPA Est. No.) (This number may be placed on the immediate container instead of the label.);
- Ingredient statement;
- Warning or precautionary statement;
- Directions for use; and
- Use classification.



## 4b Establishment Registration

Establishment registration is accomplished through application by a responsible company official to the Pesticides Group in the appropriate Regional Office of EPA. Registration is a formal procedure, and the firm should make written application to the EPA Regional Office having jurisdiction for the State in which the establishment is located. Foreign companies who wish to register their establishment with EPA should submit an application form to the Headquarters PTSCMS in Washington, D.C. The Regional Office or Headquarters will assign an establishment number.

Each establishment will be assigned only one EPA establishment number. (In rare instances, an exception may be made when two separate corporate entities use the same facilities.) All pesticide products and active ingredients released for shipment in interstate commerce or released for export from or import into the United States must bear the establishment number. The establishment number must appear on the label or immediate container of all pesticide products.

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### Authority

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Section 7 of FIFRA and 40 C.F.R. Part 167 require that establishments be registered with EPA before producing any pesticide product or active ingredient.\*

Section 25(c)(4) of FIFRA gives the Administrator authority "to specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) [misbranding] or section 7 [establishment registration]...."

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\* Proposed rules are under development for incorporating the term "active ingredient" under FIFRA §7 requirements.

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## Objectives

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The objectives of the establishment registration are to:

- Identify the production site at which a pesticide, device, or active ingredient was produced;
- Provide for more efficient production monitoring;
- Identify the producer in the event that enforcement action is required;
- Identify the production site in the event it is necessary to recall or stop sale of pesticides or pesticidal devices due to adverse effects to humans or the environment through accident, willful misuse, mishandling, or other adverse actions; and
- Determine total quantities and types of pesticidal chemicals or devices introduced into the environment.

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## Applicability of Registration Requirements

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All establishments where pesticides, devices, or active ingredients are produced must be registered except for those pesticides or devices not subject to provisions of the Act or those active ingredients that are used to produce pesticides not subject to provisions of the Act. The term "produce" has been defined in the regulations as meaning "to manufacture, prepare, propagate, compound, or process any pesticide...including any pesticide produced for use pursuant to Sections 3, 5, 17, 18, or 24, or any active ingredient used in producing a pesticide or device." The term also means to repackage or otherwise change the container of any pesticide, active ingredient, or device. The following establishments are in this category and must be registered:

- Producers who use active ingredients in making a pesticide;
- Producers of technical material;
- Formulators;
- Repackagers;
- Custom blenders;
- Producers of pesticide products for export;

- Foreign producers who export products to the United States; and
- Producers of pesticides under experimental use permits.

In addition, establishments that produce pesticides for other companies under a contract must also be registered. The establishment number of the actual producer must appear on all products.

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## Registration Procedures

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### Initial Registration

EPA Form 3540-8, Application for Registration of Pesticide-Producing Establishments, must be completed and submitted to the appropriate Regional Office or to Headquarters.

The Pesticides Group in each Regional Office or the Headquarters PTSCMS will review the applications. Applicants will be contacted by these offices when errors or omissions are apparent. Pesticide inspectors will be called upon, as necessary, to verify application information.

### Changes to Existing Registration

Changes in company headquarters, ownership, or address (as identified in Item 2 of EPA Form 3540-8) must be reported within 30 days to the EPA Regional Office having jurisdiction over the State in which the company headquarters is located.

### Cancellation or Revocation of Registration

If a registered establishment no longer produces pesticides, the Regional Office should be notified to request cancellation of the registration, unless the firm intends to re-enter production at a later date.

The registration of an establishment may be revoked for one of the following reasons:

- Company request;
- Failure of company to submit required reports; or
- Registration due to administrative or other error.

An establishment registration may not be revoked or terminated for violations of other requirements under FIFRA. Civil or criminal penalties are applied for other violations and the establishment registration remains in effect.

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Establishment Registration Numbers

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The EPA Regional Office or PTSCMS will assign an establishment number to applicants. The numbering system is based on the company registrant number, the abbreviation for the State in which the establishment is located, and a sequential number for each establishment registered by that company within the State.

Placement on Label or Container

The establishment number preceded by "EPA Est." must appear on all packaging and containers as follows:

Example: EPA Est. 777-KY-3

That number is to be the one assigned to the last establishment at which the product was produced or repackaged. No combinations of product registration and establishment numbers will be permitted. The establishment number may appear anywhere on the pesticide container or on the label. It must also appear on the outside container or wrapper of the package if it cannot be clearly read on the immediate container.

The establishment number is to be used in addition to and not in lieu of the product registration number. Both the establishment number and the product registration number must appear on the product released for shipment. The establishment number may be on either the label or the immediate container, while the product registration number must appear on the label.

Producers may seek approval of various techniques or formats for displaying the establishment number. If the company obtains approval to include more than one establishment number on a label, the producing establishment for the labeled product must be marked, notched, or otherwise clearly noted thereon for identification purposes. Following are examples of approved formats that may be adopted for use by pesticide producers.

- Example 1. The company (registrant) number is 123, and there are three registered establishments--two in Indiana (IN) and one in Massachusetts (MA). The three establishment numbers are printed in full. Those products produced at the second site in Indiana may be identified by a saw-cut, notch, arrow (as shown), or similar indicator.

EPA Est. 123-IN-1  
123-IN-2 <  
123-MA-1

- Example 2. The company (registrant) number is followed by the State abbreviation and the digit(s) of the establishment(s) located in that State. When another State is introduced, the company number need not be repeated. To indicate the actual production site, the establishment digit may be identified by a saw-cut, notch, arrow (as shown), or similar indicator. This example shows a product produced at the second site in Indiana.

EPA Est. 123-IN-1-2<: MA-1.

- Example 3. The producer is adding its own code number to identify the actual production site. Each of the three establishment numbers on the label will be followed by a code; a statement following the numbers will explain that the inspector must look on the bottom of the container to determine the actual producing establishment.

EPA Est. 123-LI-1, 2: MA-1

See last letter on bottom of  
can for actual establishment.

Other variations must be approved by Headquarters PTSCMS. (In no case may the establishment number be combined with the product registration number.)

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#### Establishment Production Reports

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Each producer must submit an annual report of pesticide production to include activities relating to:

- Manufacture;
- Formulation;
- Repackaging;
- Export and import;
- Experimental use;
- Special local needs of States; and
- Federal and State emergency exemptions.

Producers who manufacture their own products and serve as distributors of other products must report only their own production. Distributors and sellers need not report if they are not producers. Also, any person who is a producer solely because he or she produces a custom-blended pesticide need not report.

Each establishment must have its own report and may not be combined in the case of one company having several establishment locations. However, the company headquarters may complete the forms.

### When To Report

Reports from all registered establishments must be submitted annually, by February 1, to the Regional Office having jurisdiction over the State in which the establishment is located. The original and one copy of the form are to be submitted.

When a new establishment is registered, a pesticides report must be submitted to the Regional Office or to Headquarters within 30 days after notification of registration. A pesticides report form (EPA Form 3540-16) will be furnished to the producer with the assignment of the establishment number.

### What To Report

Only those products actually produced at the reporting establishment should be included. Information on products sold or distributed by, but not produced at, the reporting establishment is not to be included in this report.

Products produced under several distributor numbers are to be reported as one product under the basic product number and using the registered product name.

The Annual Production Report Form is used to prepare the annual report. Information required for the report includes:

- Establishment name and address;
- Establishment number;
- Listing of each pesticide product or device produced;
- Pesticide registration number;
- Product name; and
- Chemical formulation, if the product or device:
  - Is not registered with EPA or the State,
  - Does not have registration applied for,
  - Is produced under an experimental use permit, or
  - Is an unregistered technical material shipped under a Section 3b exemption.

Confidentiality

Section 7(d) of FIFRA provides that any information submitted by industry to EPA pursuant to an establishment registration application will be considered confidential and subject to the provisions of Section 10 (Protection of Trade Secrets and Other Information) of the Act.

Section 12(a)(2)(D) of FIFRA provides that it is unlawful for any person "to use for his own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this Act which is confidential under this Act." In addition, Section 10(f) provides that any past or present officer or employee of the United States who willfully discloses confidential information subject to Section 10(b) to any person not entitled to receive such information shall be fined not more than \$10,000, or imprisoned for not more than one year, or both. (See Chapter Eleven for specific information concerning confidentiality procedures.)





### 4c Pesticide Disposal

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#### Authority

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Under Section 19 of FIFRA, the Agency has the authority to issue procedures and regulations for the disposal and storage of excess pesticides, pesticide containers, and pesticide-related wastes. Because of certain information gaps and a nationwide shortage of safe disposal facilities, the Agency has issued guidelines and recommended procedures for the disposal and storage of pesticides as the first step in fulfilling its mandate to regulate the disposal of pesticides (39 Fed. Reg. 15236, 40 C.F.R. Part 165). As a second step, the Agency intends to promulgate a set of regulations that prohibit the "worst acts" of pesticide disposal and storage and, eventually, to promulgate comprehensive regulations for the disposal and storage of pesticides.

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#### Enforcement Actions and Disposal Practices

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##### Section 19 Regulations and Recommended Procedures

The procedures for disposal and storage of excess pesticides, pesticide containers, and pesticide-related wastes, promulgated pursuant to Section 19 (40 C.F.R. §165.7 et seq.), are merely recommended procedures and do not carry the force of law. While all persons or parties should be encouraged to follow the Section 19 guidelines, no enforcement action will be taken against those who do not adhere to the guidelines.

Nonetheless, it is unlawful to dispose of pesticides in a manner inconsistent with the label directions for disposal [Section 12(a)(2)(G)] unless the person is following these Section 19 procedures.

However, pursuant to Executive Order 11752 (38 Fed. Reg. 34793), compliance with the Section 19 recommended procedures for the disposal and storage of pesticides is mandatory for all Federal agencies.

Transportation of Unregistered Pesticides for the Purpose of Disposal

Although the shipment of an unregistered pesticide is an unlawful act pursuant to Section 12(a)(1)(A), the Agency has interpreted Section 19 as authorizing the movement of such pesticides for the specific purposes of disposal or storage (38 Fed. Reg. 15237). Thus civil or criminal penalties will not be imposed upon persons shipping unregistered pesticides to disposal sites.

In the event that there is some question as to whether unregistered pesticides are actually being shipped for disposal, regional enforcement officers should make inquiries to confirm that such shipments are for the purpose of disposal. If satisfactory evidence is not available to show that the unregistered pesticides were actually being shipped for disposal or if routine investigation does not corroborate the owner's claim of shipment for disposal, a civil complaint or a civil penalty warning citation may be issued as appropriate. The person cited may then offer evidence in a settlement conference or plead as an affirmative defense in a civil penalty hearing that the unregistered pesticides were actually being shipped for disposal. The regional enforcement personnel should encourage those persons interested in shipping unregistered pesticides to disposal sites to notify the Regional Office in advance of such shipments.

## 4d Experimental Use Permits

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### Authority

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Section 5 of FIFRA and 40 C.F.R. Part 172 provide the Administrator with the authority to issue an experimental use permit in order for an applicant to accumulate information necessary to register a pesticide under Section 3 or to secure information for a new use of a registered pesticide.

The Administrator may revoke any experimental use permit: (1) if it is found that the terms or conditions are being violated; (2) if its terms or conditions are inadequate to avoid unreasonable adverse effects to the environment; (3) if new evidence is obtained which demonstrates that the tolerance will be inadequate to protect the public health; or (4) for failure to meet any provisions of 40 C.F.R. Part 172.

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### Scope

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The regulatory provisions of FIFRA for experimental use permits do not apply to tests to determine the purpose, toxicity, or properties of a pesticide, where the tester does not expect to receive any benefits from the use of the pesticide.

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### Permit Application Procedures

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An application (EPA Form 8570-17) for an experimental use permit must be submitted in triplicate to the Registration Division of the Office of Pesticide Programs. The contents must include:

- Names and addresses of applicants, participants, and cooperators;
- Registration number of product, if registered;
- Proposed method of storage and disposal;

- Proposed objective and purpose of testing;
- Factors relating to testing program; and
- Tolerance data.

For an unregistered pesticide product, the application must also include:

- Confidential statement of composition;
- Chemical and physical properties of active ingredients;
- Data of the rate of decline of residues on treated crop or environmental site or other data regarding entry into treated areas; and
- Results of toxicity tests.

The permit will be issued upon the determination by the Administrator that the statutory and regulatory provisions of Section 5 have been met. The permit will specify the conditions, duration, and recordkeeping requirements.

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#### Labeling Requirements

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All pesticides shipped or used under an experimental use permit must be labeled with the following (40 C.F.R. §172.6):

- The statement "For Experimental Use Only";
- Permit number;
- The statement "Not for sale to any person other than a participant or cooperator of the EPA-approved experimental use program";
- Name, brand, or trademark;
- Name and address of the permittee, producer, or registrant;
- Net contents;
- Ingredient statement;
- Warning or caution statement;
- Limitations on entry into treated areas;
- Establishment registration number, if appropriate; and
- Directions for use.

## 4e Emergency Exemptions for Federal and State Agencies

Under Section 18 of FIFRA the Administrator has the authority to exempt Federal and State agencies from the requirements of the Act under the following emergency conditions:

- A pest outbreak has or is about to occur and no pesticide registered for the particular use, or alternative method of control, is available;
- Significant economic or health problems would occur without the use of the pesticide; or
- There is insufficient time to register a pesticide before the discovery or prediction of a pest outbreak.

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### Types of Exemptions

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#### Specific Exemption

A specific exemption may be granted to control the outbreak of a pest in the United States and is valid only for the specific situation involved. Exemption conditions may include:

- Limitation on quantity of pesticide used;
- Conditions under which it may be applied;
- Persons who may apply the pesticide;
- Monitoring activities; and
- Duration of exemption (never longer than one year).

Quarantine/Public Health Exemption

A quarantine or public health exemption may be granted to prevent the introduction or spread of a foreign pest into or throughout the United States. Exemption conditions include:

- Duration of exemption (never longer than one year, although the Administrator may renew the exemption); and
- No pesticide may be used that has been suspended by the Administrator.

Crisis Exemption

Crisis exemptions are granted to any Federal or State agency in situations involving the unpredictable outbreak of pests in the United States where the responsible official in authority determines:

- There is no readily available pesticide registered for the particular use; and
- The time element is too critical to request a specific exemption.

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Procedures To Be Followed

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Specific Exemption

Upon approval of a specific exemption, the Federal or State agency must:

- Immediately inform the Administrator in writing of the time and place of pesticide application;
- Inform the Administrator of the location, quantity, and extent of use of the pesticide within 10 days of final application or use;
- Initiate monitoring activities specified by the exemption and report any adverse effects to the Agency; and
- Provide the Administrator with a summary report on the emergency action taken and the outcome of such action within one year of the granting of the exemption.

Quarantine/Public Health Exemption

The Federal or State agency using or applying pesticides under this exemption must:

- Maintain records of all treatments including:
  - Application site,
  - Pesticide used,
  - Rate of application, and
  - Quantity used; and
- Submit to the Administrator and the Hearing Clerk of the Agency, one month after the expiration of the exemption, a report listing:
  - Number of treatments,
  - Pesticides used for each type of treatment, and
  - Steps taken to comply with registration requirements of the Act.

Crisis Exemption

When a Federal or State agency determines that it will avail itself of a crisis exemption, the head of the Federal agency or the Governor of the State or their designees must notify the Administrator by telegram within 36 hours of this determination.

Within 10 days of the application for use of the pesticide, they must file with the Administrator the following certified information:

- The nature and scope of the emergency, including the pest involved;
- That no pesticide registered for the particular use was readily available, and the basis for such determination;
- That the time element was too critical to request a specific or quarantine/public health exemption;
- The location, quantity, method of application, duration of application, and qualifications of personnel involved in the application;
- The steps being taken to reduce adverse effects; and
- Any other information requested by the Administrator.

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Withdrawal of Exemptions

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The Administrator will withdraw an exemption upon determination that:

- An agency is not complying with the requirements of the exemption;  
or
- Such action is necessary to protect humans or the environment.



## 4f State Registration of Pesticides

Under Section 24(c) of FIFRA, a State is authorized to register a new end use product for any use, or additional use of a federally registered pesticide.

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### Conditions for Section 24(c) Registration

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The following conditions must exist before a State can register a pesticide under Section 24(c):

- There is a special local need for the use within the State;
- The pesticide may be distributed and used only within the registering State;
- A State may not register a pesticide for a food or feed use unless tolerances, exemptions, or other clearances have been issued under the Federal Food, Drug, and Cosmetic Act;
- Registration for the same use has not been denied, disapproved, suspended, or cancelled; and
- The registration is in accord with the purposes of FIFRA.

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### Types of Section 24(c) Registrations

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Section 24(c) registrations are issued either as amendments to Federal registrations or as State-issued registrations for new products. Amendments to Federal registrations are based on the following use provisions:

- Any new use of a federally registered pesticide;

- Any use of a federally registered product for which registration of other uses of the product was denied, disapproved, cancelled, or suspended; and
- Any use of a federally registered product for which registration of some or all uses has been voluntarily cancelled by the registrant.

State-issued registrations for new products are based on the following product criteria:

- A product identical in composition to a federally registered product but different in packaging or identity of the formulation;
- A product that contains the same active and inert ingredients as a federally registered product, but in different percentages; and
- A product containing a new combination of active or active and inert ingredients if each active or inert ingredient is contained in a federally registered pesticide.

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### Registration Disapproval/Suspension

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#### General Disapproval

State registrations that do not have a composition and use pattern which is similar to federally registered pesticide products may be disapproved by the Administrator if there are reasonable grounds.

#### Special Disapproval

The Administrator may disapprove any State registration, including a registration for a similar product if it is determined that the use of the product:

- Would constitute an imminent hazard; or
- May result in a residue on food or feed exceeding or not covered by a tolerance, exemption, or other clearance under the Federal Food, Drug, and Cosmetic Act.

#### Suspension

The Administrator may suspend all or any part of a State's authority to register pesticides under Section 24(c) if the State:

- Is not capable of exercising adequate pesticide controls; or
- Has failed to exercise adequate pesticide controls.

## 5 Glossary

ACT -- When used in this manual, "the Act" means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA).

ADMINISTRATIVE LAW JUDGE -- An Administrative Law Judge appointed pursuant to 5 U.S.C. §3105 (see also 5 C.F.R. Part 930, as amended by 37 Fed. Reg. 16789).

ADMINISTRATOR -- The Administrator of the Environmental Protection Agency.

ADULTERATED -- A pesticide is adulterated if:

- Its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;
- Any substance has been substituted wholly or in part for the pesticide; or
- Any valuable constituent of the pesticide has been wholly or in part abstracted.

AFFIDAVIT -- A written statement made on oath before a notary public or other person authorized to administer oaths.

AGENCY -- The United States Environmental Protection Agency (EPA).

BATCH -- A quantity of a pesticide product made in one operation or lot or if made in a continuous or semi-continuous process or cycle, the quantity produced during an interval of time to be determined by the producer.

BIN LABELS -- Stock supply of labels that have not been affixed to the product containers.

BOOKS AND RECORDS -- All records required pursuant to Sections 8 and 9 of the Act and 40 C.F.R. §169.2 and all records in lieu thereof.

CERTIFIED APPLICATOR -- Any individual who is certified under Section 4 as authorized to use or supervise the use of any pesticide that is classified for restricted use.

**CIVIL ADMINISTRATIVE COMPLAINT** — A written communication alleging one or more violations of specific provisions of the Act or regulations promulgated thereunder (40 C.F.R. §22.03). Each complaint shall include: (1) reference to the provisions of the Act alleged to have been violated; (2) a concise factual statement of the violation; (3) the amount of the proposed penalty; (4) a statement of the appropriateness of the penalty; (5) notice of the respondent's rights to an adjudicatory hearing; and (6) a statement reciting the section(s) of the Act authorizing the issuance of the complaint (40 C.F.R. §22.14).

**COMMERCIAL APPLICATOR** — A certified applicator (whether or not he or she is a private applicator with respect to some uses) who uses or supervises the use of any pesticide that is classified for restricted use for any purpose or on any property other than as provided by the definition of "private applicator."

**COMPLAINANT** — Any person authorized to issue a complaint on behalf of the Agency to persons alleged to be in violation of the Act (40 C.F.R. §22.03).

**CONSENT AGREEMENT** — Any written document containing stipulations of fact; conclusions regarding material issues of law, fact, or discretion; and a specified proposed penalty acceptable to both complainant and respondent that results from any settlement conference (40 C.F.R. §22.18).

**COOPERATOR** -- Any person who grants permission to a permittee or a permittee's designated participant for the use of an experimental use pesticide at an application site owned or controlled by the cooperator.

**CUSTOM BLENDED PESTICIDE** -- A pesticide that meets the following conditions:

- The blend contains only registered pesticides, fertilizers, and inert ingredients;
- Each pesticide used in the blend bears end-use labeling directions providing for use of the product in such a blend, or the blend is recommended in writing by an appropriate State or Federal agency official;
- The blend is produced to the order of the user;
- The blend is not held in the inventory; and
- The blend is delivered to the user with a copy of the end-use labeling of the pesticide(s) used in the blend and a statement specifying the composition of the mixture.

**DEFAULT ORDER** -- An order issued pursuant to 40 C.F.R. §22.17 disposing of a matter of controversy between respondent and the Agency upon (1) the failure of respondent to file a timely answer to the complaint; (2) the failure of one of the parties to comply with a prehearing or hearing order of the Presiding Officer, or (3) the failure of one of the parties to appear at a conference or hearing without good cause being shown.

**DEGRADATION PRODUCT** -- A substance resulting from the transformation of a pesticide by physical, chemical, or electromagnetic means.

**DEVICE** -- Any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest or other form of plant or animal life (other than humans and other than bacteria, viruses, or other microorganisms on or in living humans or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

**DISTRICT COURT** -- A United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

**DRIFT** -- Movement of a pesticide through the air (during or immediately after application or use) to a site other than the intended site of application or use.

**EFFICACY** -- The capacity of a pesticide product when used according to label directions to control, kill, or induce the desired action in the target pest.

**ENVIRONMENT** -- Includes water, air, land, and all plants, humans and other animals living therein, and the interrelationships that exist among these.

**ESTABLISHMENT** -- Any place where a pesticide or device is produced or held for distribution or sale.

**FINAL ORDER** -- An order issued by the Administrator after an appeal of an initial decision, accelerated decision, decision to dismiss, or default order disposing of a matter in controversy between the parties or an initial decision under 40 C.F.R. §22.27(c).

**GENERAL USE PESTICIDE** -- A pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment.

**HEARING** -- A hearing open to the public provided in Section 14(a)(3) of the Act and conducted pursuant to the provisions of Chapter 5, Subchapter II of Title 5 of the United States Code, and the rules of practice found at 40 C.F.R. Part 22.

**HEARING CLERK** — The Hearing Clerk, United States Environmental Protection Agency, Washington, D.C. 20460.

**IMMINENT HAZARD** -- A situation that exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior pursuant to the Endangered Species Act of 1973.

**INERT INGREDIENT** — An ingredient that is not active [FIFRA §2(m)]; or, all ingredients that are not active ingredients as defined in 40 C.F.R. §162.3(c), and includes, but is not limited to, the following types of ingredients (except when they have pesticidal efficacy of their own): solvents such as water; baits such as sugar, starches, and meat scraps; dust carriers such as talc and clay; fillers; wetting and spreading agents; propellents in aerosol dispensers; and emulsifiers.

**INITIAL DECISION** — The decision issued by the Administrative Law Judge based upon the record of the hearing out of which the decision arises or upon the rendering of an accelerated decision. The decision is supported by findings of fact and conclusions regarding all material issues of law, fact, or discretion. This decision will become the final decision and order of the Administrator without further proceedings unless the decision is appealed or the Administrator orders a review of the case.

**INSPECTOR** -- Any officer or employee of the Environmental Protection Agency or of any State duly authorized by the Administrator to conduct inspections, make investigations, collect samples, and otherwise carry out the provisions of the Act. Such person may also be known by such designations as Consumer Safety Officer, Pesticide Inspector, Accident Investigation Officer, Compliance Officer, etc.

**JUDICIAL OFFICER** -- An officer or employee of the Agency designated as a judicial officer who shall meet the qualifications and perform functions provided for in 40 C.F.R. §22.04.

**LABEL** — The written, printed, or graphic matter on or attached to the pesticide or device or any of its containers or wrappers.

**LABELING** — All labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time or to which reference is made on the label or in literature accompanying the pesticide or device [See Section 2(p)(2)(B) of the Act for exceptions].

**MARKET PLACE** -- All places other than production sites where pesticides or devices are held for distribution or sale.

**MISBRANDED** — A pesticide is misbranded if:

-- Its labeling bears any statement, design, or graphic representation, relative thereto or to its ingredients, that is false or misleading.

- It is contained in a package or other container or wrapping that does not conform to EPA standards.
  - It is an imitation of, or is offered for sale under the name of, another pesticide.
  - Its label does not bear the establishment registration number.
  - Any required information on the label or labeling is not prominently and conspicuously placed.
  - The accompanying labeling does not contain directions for use that are necessary for effecting the purpose for which the product is intended.
  - The label does not contain a required warning or caution statement.
  - The label does not bear an ingredient statement on that part of the immediate container that is displayed under customary conditions of purchase. The ingredient statement must also appear on any outside container or wrapper that conceals the statement on the immediate container. (The product is not misbranded if its size and form make such placement impracticable and if EPA permits placement elsewhere on the immediate container or outside container or wrapper.)
  - The labeling does not contain a statement of the use classification under which the product is registered.
  - There is no label on the immediate container or concealing wrapper bearing:
    - The name and address of the producer, registrant, or person for whom produced;
    - The name, brand, or trademark under which the pesticide is sold;
    - The net weight or measure of the content; and
    - The required registration number and use classification.
  - The pesticide is highly toxic to humans and the label does not bear:
    - The skull and crossbones;
    - The word "poison" prominently in red on a background of distinctly contrasting color; and
    - A statement of practical treatment (first aid or otherwise) in case of poisoning by the pesticide.
- MISUSE -- Use of registered pesticide in a manner not permitted by its labeling [see Section 2(ee) of the Act for exceptions].

NOTICE OF JUDGMENT -- A written notice of all judgments entered in actions instituted under the authority of the Act and includes civil, criminal, and seizure actions.

PACKAGED, LABELED, AND RELEASED FOR SHIPMENT -- The term, "packaged, labeled, and released for shipment" defines that point in the producing-marketing process of a pesticide when (1) the product has been produced and (2) it is the intent of the producer that such product be introduced into commerce.

At the producer establishment level, such intent to introduce the product into the channels of trade (release for shipment) may be evinced by any of the following factors:

- The producer's assertions that what is being sampled is representative of what is actually sold;
- The storage of the product in areas, such as loading docks, warehouses, or other areas where finished products are held for shipment in the ordinary course of business;
- The custom of the pesticide chemical industry indicates that similarly situated products are intended for release; or
- The custom of the particular producer indicates that similarly situated products have in the past been intended for release.

Although there is a strong presumption in the situation in which a product is "intended for release" that the product has been "released for shipment," it is within the inspector's discretion to entertain a producer's assertion that under the particular circumstances such product was not intended for introduction into commerce.

At the distribution and retail establishment levels, products have been "released for shipment" at an earlier time by the producer establishment and, therefore, are subject to inspection and sampling as finished products.

PARTICIPANT -- Any person acting as a representative of the permittee, and responsible for making available for use, or supervising the use or evaluation of, an experimental use pesticide to be applied at a specific application site.

PARTY -- Any person, group, organization, agency, or department that participates in a hearing as complainant, respondent, or intervenor.

PERMITTEE -- Any applicant to whom an experimental use permit has been granted.

PERSON -- Any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.



PEST -- (1) Any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganism on or in living humans or other living animals) that the Administrator declares to be a pest under Section 25(c)(1) and under 40 C.F.R. §162.14 as being injurious to health or environment.

PESTICIDE -- Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or any substance or mixture of substances intended for use as a plant regulator, defoliant, or dessicant.

PESTICIDE FORMULATION -- The substance or mixture of substances comprised of all active and inert (if any) ingredients of a pesticide product.

PESTICIDE PRODUCT -- A pesticide offered as a commercial product, complete with active and inert (if any) ingredients, in a container having a label, and any labeling.

PETITIONER -- Any person adversely affected by a notice of the Administrator and who requests a public hearing.

PRESIDING OFFICER -- The Administrative Law Judge designated by the Chief Administrative Law Judge to serve as the Presiding Officer of an administrative hearing arising out of the Act.

PRIVATE APPLICATOR -- A certified applicator who uses or supervises the use of any pesticide classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers or agricultural commodities) on the property of another person.

PRODUCE -- To manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced for use pursuant to Sections 3, 5, 17, 18, or 24, or any active ingredient used in producing a pesticide or device. The term also means to repackage or otherwise change the container of any pesticide, active ingredient, or device. "Produce" does not mean to dilute, mix, or blend a registered end-use pesticide for personal use according to label directions, or as allowed by Section 2(ee) of the Act.

PRODUCER -- Any person who produces any pesticide, device, or active ingredient.

PROGRAMMED INSPECTION -- An inspection requiring the selection of a specific program activity that is subject to routine compliance monitoring and results from an enforcement strategy based upon objective selection criteria.

REGIONAL ADMINISTRATOR -- The Administrator (or delegate) of a Regional Office of the Agency.

- REGIONAL HEARING CLERK — An individual duly authorized by the Regional Administrator to serve as hearing clerk for a given Region. Correspondence may be addressed to the Regional Hearing Clerk, United States Environmental Protection Agency (address of Regional Office).
- REGIONAL JUDICIAL OFFICER — An officer or employee of the Agency duly authorized by the Regional Administrator to serve as the Judicial Officer for the Region as provided in the Consolidated Rules of Practice (CROP).
- REGISTRANT — A person who has registered any pesticide pursuant to the provisions of FIFRA.
- RESIDUE — The active ingredient(s), metabolite(s), or degradation product(s) that can be detected in the crops, soil, water, or other component of the environment (including humans), following the use of the pesticide.
- RESPONDENT — Any person proceeded against in a complaint.
- RESTRICTED USE PESTICIDE — A pesticide that when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause without additional regulatory restrictions, unreasonable adverse effects on the environment.
- SPECIAL LOCAL NEED -- A pest problem (existing or imminent within a State) that cannot be effectively controlled because an appropriate EPA-registered pesticide product is not available.
- UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR — Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is responsible for the actions of that person and who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.
- UNPROGRAMMED INSPECTION ("For Cause" Inspection) — An inspection in which probable violations of the Act are observed or brought to the attention of the Agency through, for example, an employee's complaint or a competitor's tip.
- USE -- Any act of handling or release of a pesticide, or exposure of humans or the environment to a pesticide through acts, including but not limited to:
- Application of a pesticide, including mixing and loading and any required supervisory action in or near the area;

- Storage actions for pesticides and pesticide containers; and
- Disposal actions for pesticides and pesticide containers.

Use as defined here incorporates application. However, the certification requirement for certain restricted use pesticides only applies with respect to applications of such pesticides. Many aspects of use do not include application (e.g., storage or transportation), and hence are outside the requirement for certification.



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## Chapter Two

# General Operating Procedures

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# General Operating Procedures

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### Primary Office Responsibilities

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The basic framework setting forth the responsibilities of each EPA office participating in enforcement activities was established by the Administrator's memorandum of July 6, 1982, entitled "General Operating Procedures for the Civil Enforcement Program" (GOP). (See EPA's General Enforcement Policy Compendium.) This chapter describes the respective roles and relationships of the various EPA offices that are involved with FIFRA enforcement.

EPA's enforcement program includes both compliance-oriented and legal-oriented activities. The compliance-oriented activities are primarily the responsibility of EPA's program offices, and the legal-oriented activities are principally charged to the Office of Legal and Enforcement Counsel (OLEC), including the Regional Counsel. Because many enforcement activities involve several aspects, these activities cannot be defined as strictly "compliance" or "legal." Where both elements are present, the EPA attorney must be especially diligent in coordinating the legal aspects with the functions of the other participating offices. The basic relationship between the attorney and the program office is that of attorney-client.

The basic enforcement functions are divided among the participating offices as follows:

#### Regional Administrator

##### Program Office

- Identifies instances of noncompliance;
- Establishes priorities for handling instances of noncompliance;
- Evaluates the technical sufficiency of actions designed to remedy violations;

- Identifies for formal action those cases that cannot be resolved less formally;
- Provides technical support necessary for developing cases and conducting litigation;
- Issues written notices of warning;
- Issues stop sale, use, or removal orders;
- Cooperates with district courts in the disposition of condemned pesticides or devices;\*
- Issues routine civil administrative complaints;
- Evaluates the appropriateness of civil penalties;\* and
- Negotiates and prepares consent agreements memorializing settlements between the Agency and respondents prior to the alleged violator's filing of an answer or failing to file an answer to a complaint.\*

#### Regional Counsel

- Acts as attorney for "client" program offices;
- Assists program office in drafting or reviewing notices of warning, administrative orders, or administrative complaints;
- Ensures consistency of action with OLEC guidance;
- ~~Attends negotiations whenever outside parties are represented by counsel in negotiations;~~
- Serves as lead attorney for the Agency in administrative proceedings originating in the Region; and
- Refers requests for emergency temporary restraining orders to the Department of Justice and the appropriate United States Attorney.\*

#### Headquarters

##### Program Office--PTSCMS

- Manages national program matters;

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\* Consultation with other offices is required.



- Establishes national enforcement compliance priorities;
- Provides overall direction to and accountability measures for the enforcement compliance program;
- Provides technical support (including support for litigation activities);
- Takes lead role in preparing guidance and policy decisions on enforcement compliance issues;
- Consults with the Regions, on enforcement actions at the earliest possible stage in the case development process for the following actions:
  - "Non-routine" cases of first impression or those of national significance,
  - Misuse actions,
  - Proposed civil penalty settlements involving a monetary reduction of greater than 40 percent,
  - Injunctions,
  - Seizures,
  - Recall requests, and
  - Requests to override State enforcement actions; and
- Works with OLEC in preparing joint guidance for areas in which compliance and legal issues overlap.

#### Registration Division

- Determines status of product as a pesticide or device under FIFRA;
- Determines registration status of a pesticide;
- Assesses significance of scientific test results;
- Provides expert witnesses, as appropriate, at legal proceedings; and
- Assists in legal services by:
  - Providing copies of accepted product labels for Regional Office use,
  - Providing Registration Division support for substantive label defect review, and
  - Interpreting label defects.

OLEC

- Provides legal advice regarding enforcement matters to the Assistant Administrator of Pesticides and Toxic Substances;
- Develops legal and enforcement policies and guidance;
- Confers with the Department of Justice on the potential impact of enforcement policy on litigation matters;
- Cooperates with the Assistant Administrator of Pesticides and Toxic Substances in the development of enforcement policies involving both enforcement compliance and enforcement legal activities; and
- Assists and supports the Regional Counsel lead attorneys and Department of Justice attorneys by coordinating legal activity and contributing case information to the development process.

Office of General Counsel

- Provides legal interpretation of applicable statutes and regulations to support the FIFRA enforcement programs;
- Has lead responsibility, in consultation with OLEC, for defensive litigation arising out of enforcement actions (e.g., Federal court challenges to EPA's civil penalty proceedings); and
- Represents the Agency in national suspension and cancellation proceedings.

National Enforcement Investigation Center (NEIC)

NEIC is located in Denver, Colorado, and functions as a national technical resource and investigative unit. NEIC's expertise in investigation and evidence discovery can assist case development and provide litigation support. The OLEC establishes NEIC's priorities and its availability. Regional Administrators and the Assistant Administrator for Pesticides and Toxic Substances are requested to involve NEIC in cases that have precedential implications, national significance, or are multi-regional in nature.

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Concurrence Procedures

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Generally, Headquarters has waived concurrences in routine civil cases. (Criminal cases must be referred to the Criminal Enforcement Division; see Chapter Nine.) However, consultation is required in the following instances:

- Requests to override State enforcement actions;
- Requests for all misuse actions;
- Requests for reduction of civil penalties greater than 40 percent; and
- Requests for recalls, seizures, and injunctions.

The consultation procedures relating to each of the above actions are discussed in the section of the manual pertaining to the individual subject matter.

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State and Federal Interagency Cooperation

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FIFRA charges EPA with the responsibility of protecting public health and the environment from the risks associated with exposure to pesticides. In order to fulfill this responsibility, EPA seeks cooperation with appropriate State and Federal agencies.

State Cooperation

Cooperative Enforcement Agreements. FIFRA Section 23, authorizes EPA to enter into cooperative enforcement agreements with the States (including Indian tribes). Under these agreements, each State conducts compliance monitoring and enforcement activities under State and Federal pesticide control laws. These activities include pesticide producer establishment inspections; marketplace surveillance; pesticide use observations; pesticide misuse investigations; experimental use permit inspections; and certified applicator and restricted use pesticide dealer record inspections.

- Compliance Monitoring Activities. Under the cooperative enforcement agreements, State personnel are responsible for conducting inspections under both FIFRA and the State's pesticide laws. During all inspections and sample collections performed under FIFRA, the State inspectors use the standard Federal forms and procedures outlined in the EPA Pesticides Inspection Manual. However, during all inspections and sample collections performed under authority of State law, State personnel must use State forms and follow State procedures, including those related to chain of custody.

- Enforcement Activities. Under the cooperative enforcement agreements, the State reviews the quality and sufficiency of evidence gathered in the course of all investigative activities. If evidence reveals a violation of only the State's pesticide laws, the State would pursue the appropriate remedy provided by State law. Where evidence reveals a possible violation of only Federal law, the State would forward the information to the EPA Regional Office and prepare testimony and witnesses as necessary.

If evidence reveals a violation of both State and Federal law, the State may bring appropriate enforcement action under State law or refer the case to EPA for action under FIFRA. In the event that a case is referred to EPA for action, the Agency case preparation officer should review the case file to ensure that the State inspection procedures adhere to basic constitutional guarantees. If the State evidence gathered by State inspectors is obtained legally and is within the scope of admissible evidence, EPA should proceed with the case.

Primacy. FIFRA Section 26 provides that a State shall have primary enforcement responsibility for pesticide use violations (primacy) if EPA determines that the State has adopted adequate pesticide use laws and has adequate procedures for implementing these laws. In addition, Section 26 allows a State to obtain primacy if the State has entered into a cooperative enforcement agreement with EPA or has an approved Section 4 certification plan that meets the requirements for adequate laws and procedures.

Under the Final Interpretive Rule governing FIFRA Sections 26 and 27 (40 C.F.R. Part 173), EPA and each State will annually define significant cases to be tracked by EPA after referral to the State.

- Compliance Monitoring Activities. After EPA formally refers a significant case to a State, the Agency will contact the State to learn the results of the inspection and the State's proposed enforcement response to the violation. The Region should determine whether the State has conducted an adequate investigation. An investigation should be considered adequate if the State has (1) followed proper sampling and other evidence gathering techniques; (2) responded expeditiously to the referral; and (3) documented all inculpatory or exculpatory events or information. If the Region cannot negotiate an adequate inspection with the State, the Region may pursue its own investigation after notice to the State. That notice should summarize the facts relating to the State investigation, discuss the reasons for EPA's determination that the action is inadequate, and state that the EPA will initiate its own investigation.
- Enforcement Activities. Under primacy, a State has 30 days following after completion of the investigation to commence an appropriate enforcement action. The Region may extend this period if required by the procedural characteristics of the State's regulatory structure.

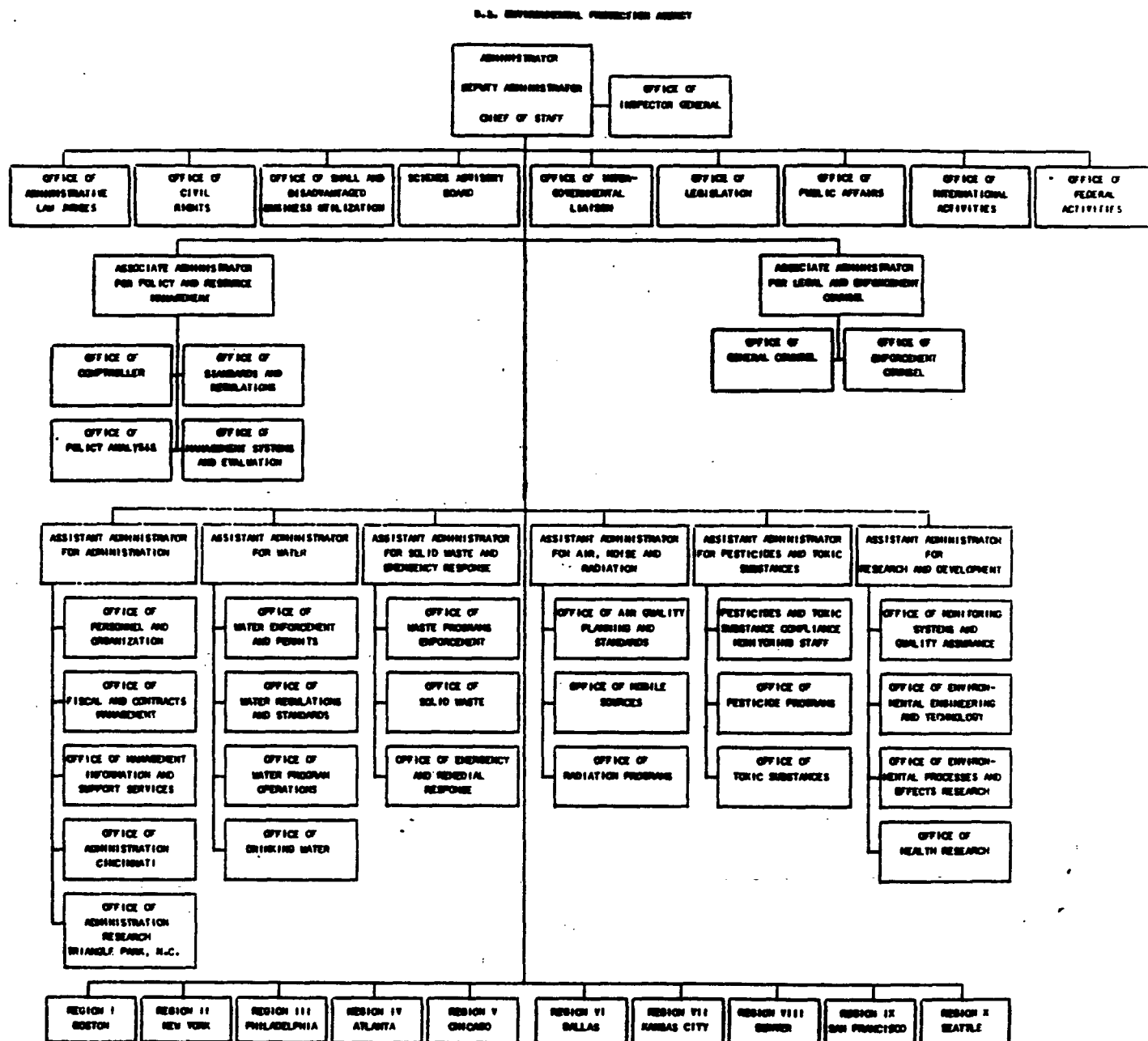
If, after consultation with the State, the Region determines that the State's intended enforcement response to the violation is inappropriate, EPA may bring its own action after notice to the State (see 40 C.F.R. Part 173, Section 5 B for criteria). That notice should summarize the facts relating to the State's enforcement response, discuss the reasons for EPA's determination that the enforcement action is inadequate, and state that EPA will initiate its own enforcement action. However, regional attorneys should not initiate an enforcement action sooner than 30 days after the matter was referred to the State. If a State determines that the most appropriate enforcement action is not available under State law, it may refer the case in writing to EPA for enforcement under FIFRA.

### Federal Interagency Cooperation

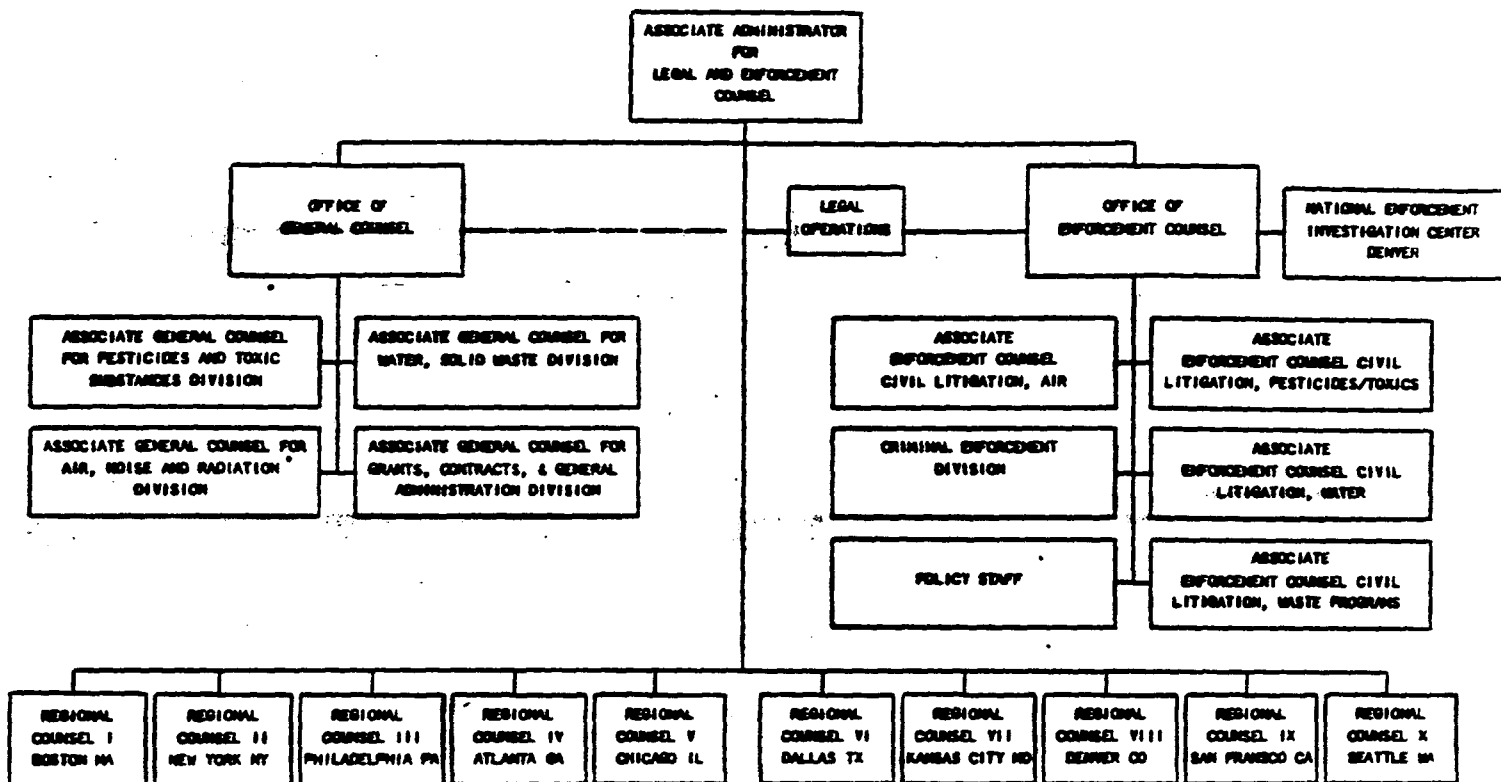
United States Department of Justice (DOJ). EPA's working relationship with the Department of Justice and the United States Attorneys Office continues to be governed by the June 1977 Memorandum of Understanding between the DOJ and EPA. All criminal cases, collection and seizure actions, and warrants for inspections under FIFRA must be filed by the DOJ and United States Attorneys Office. EPA Headquarters and regional components are expected to use their best efforts to insure that a constructive working relationship is maintained with DOJ and to provide assistance to DOJ in the preparation of those actions. (For the procedures for referring actions involving criminal cases, collection, seizure, or warrants, see the individual topics in the manual.)

Food and Drug Administration (FDA). FDA grants tolerances or exemptions on pesticide products that are proposed to be used in a manner that is likely to result in residues in or on food or feed. FDA surveillance programs include the collection and examination of samples and data audits. Upon encountering foodstuffs containing pesticide residues that may have resulted from pesticide misuse, the FDA will notify the appropriate EPA Regional Office. EPA will then proceed with its own investigation.



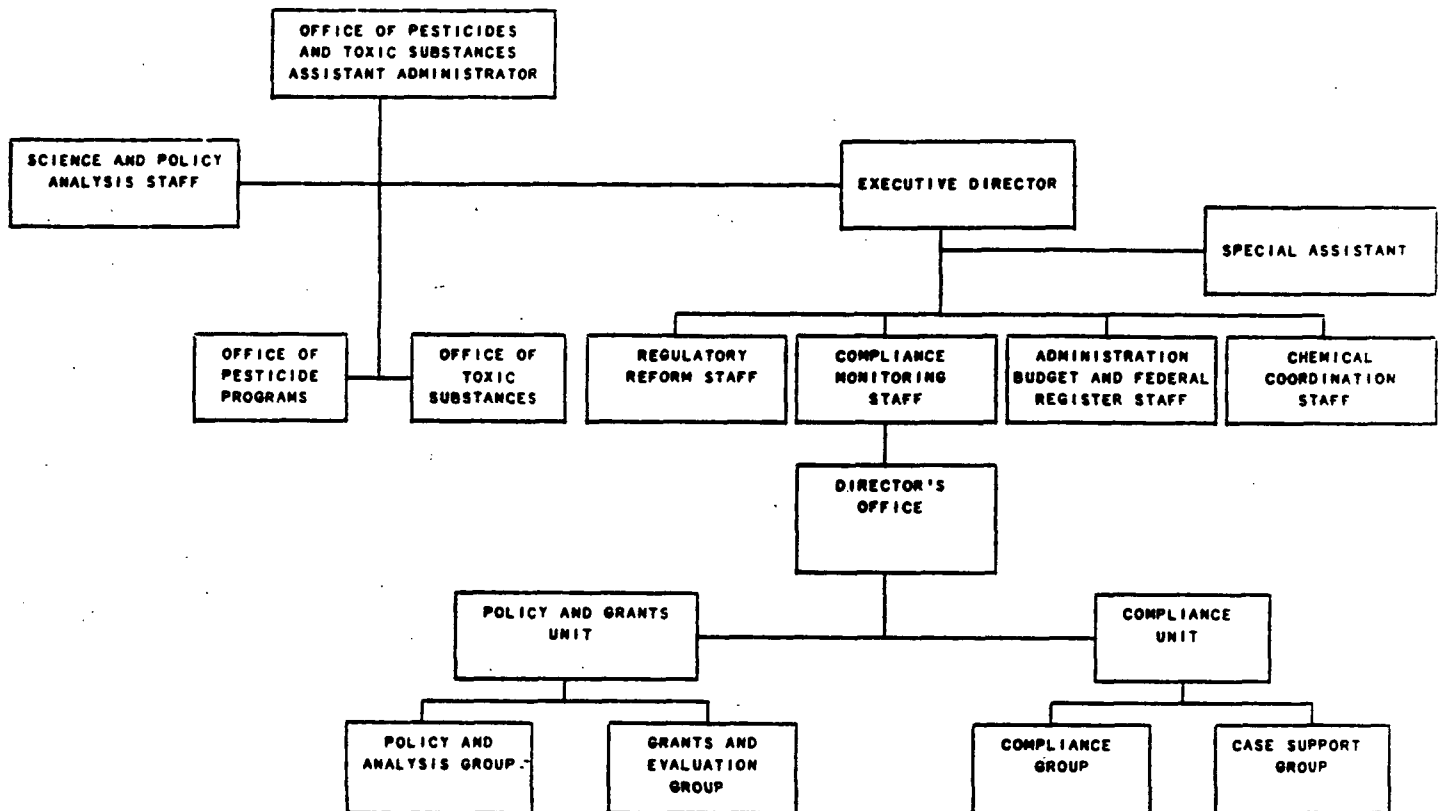


## OFFICE OF LEGAL AND ENFORCEMENT COUNSEL

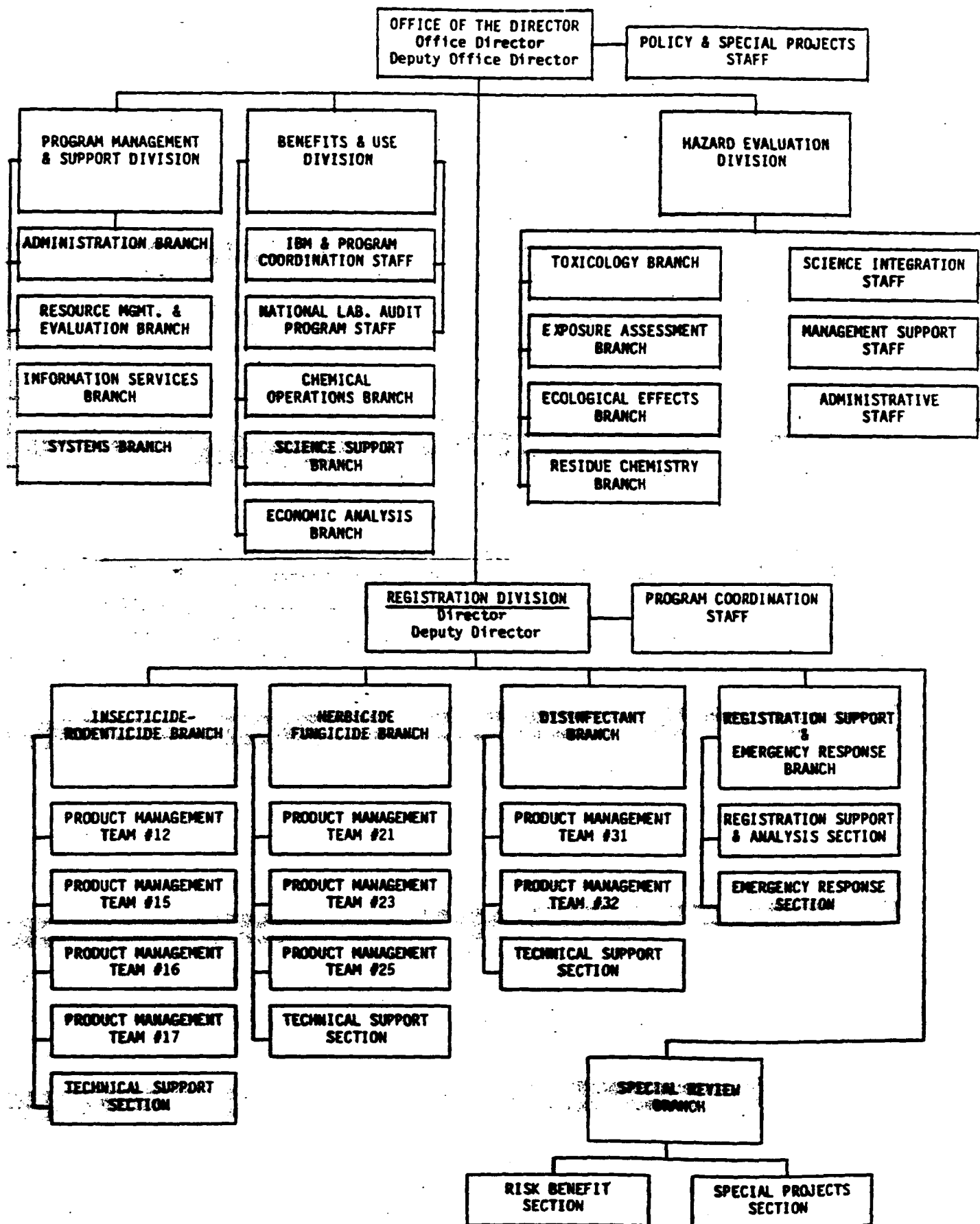


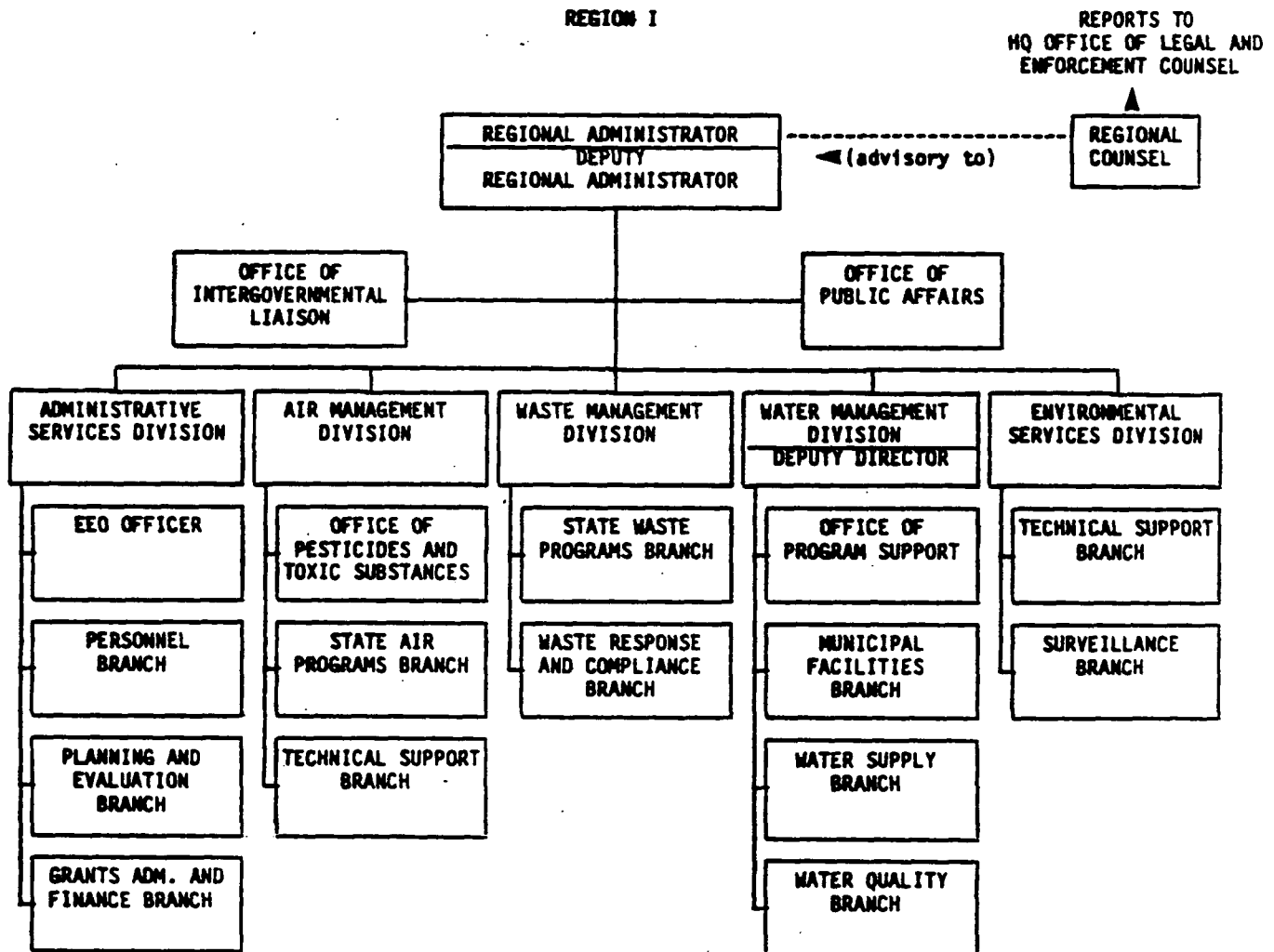


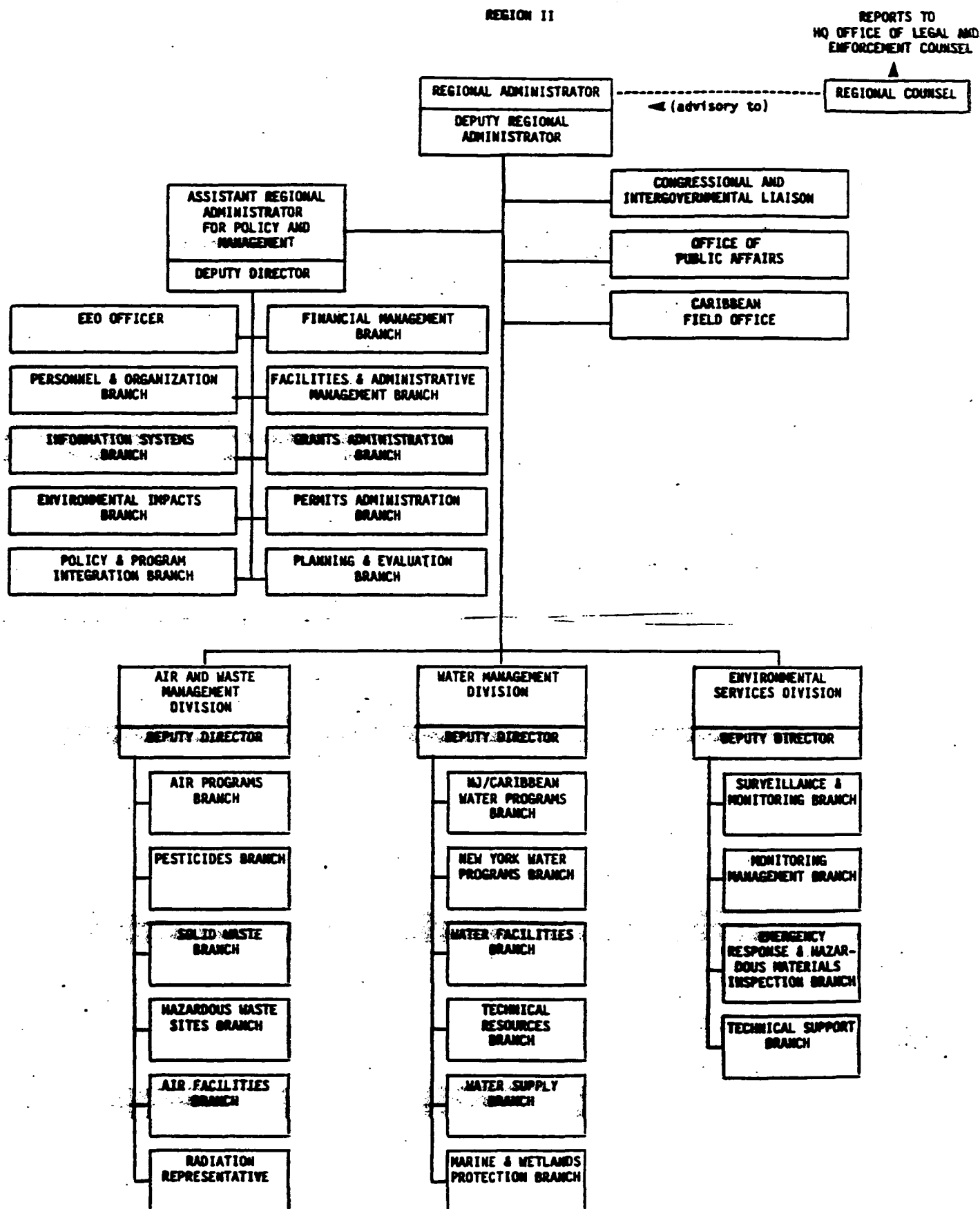
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OFFICE OF THE ASSISTANT ADMINISTRATOR

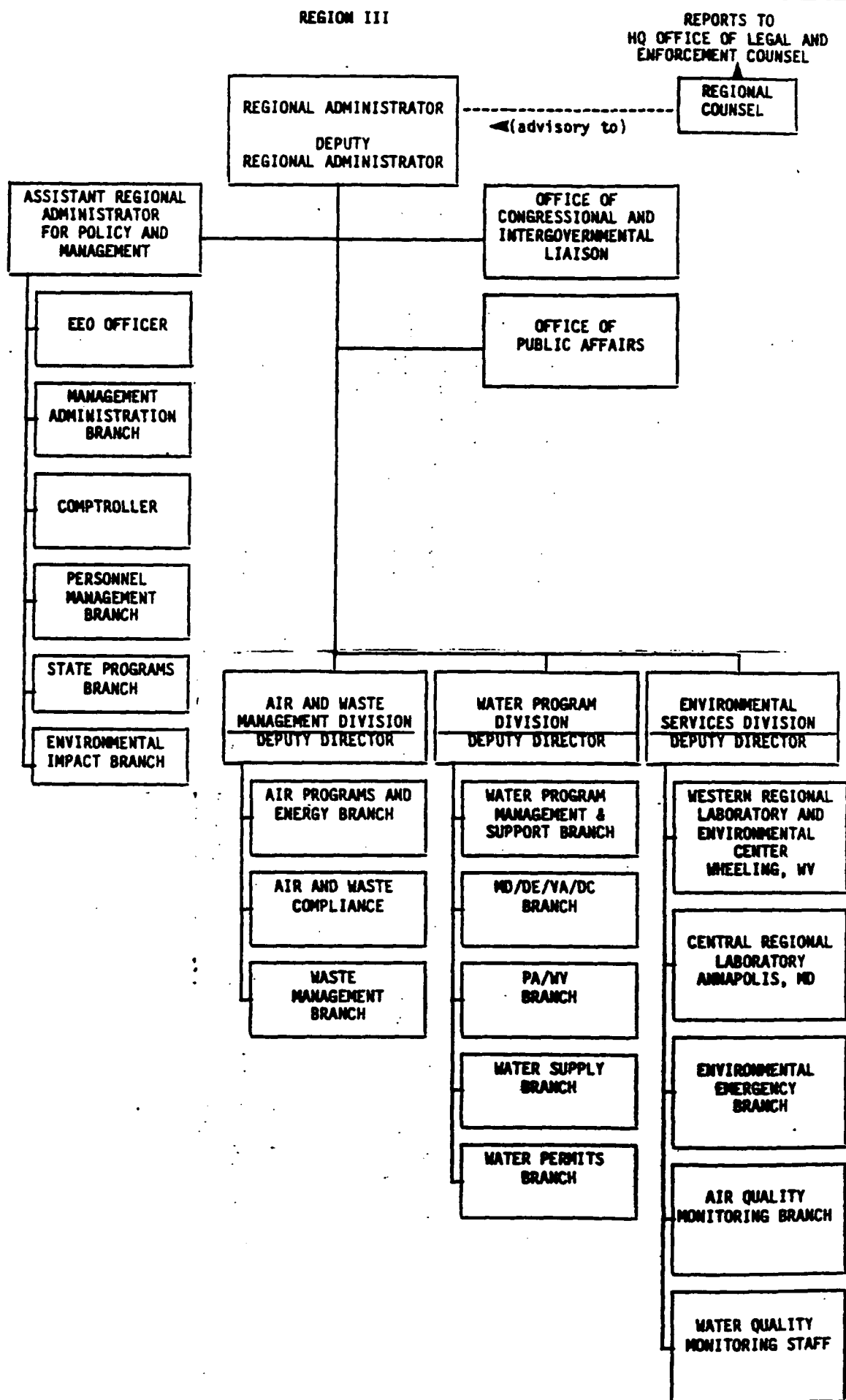


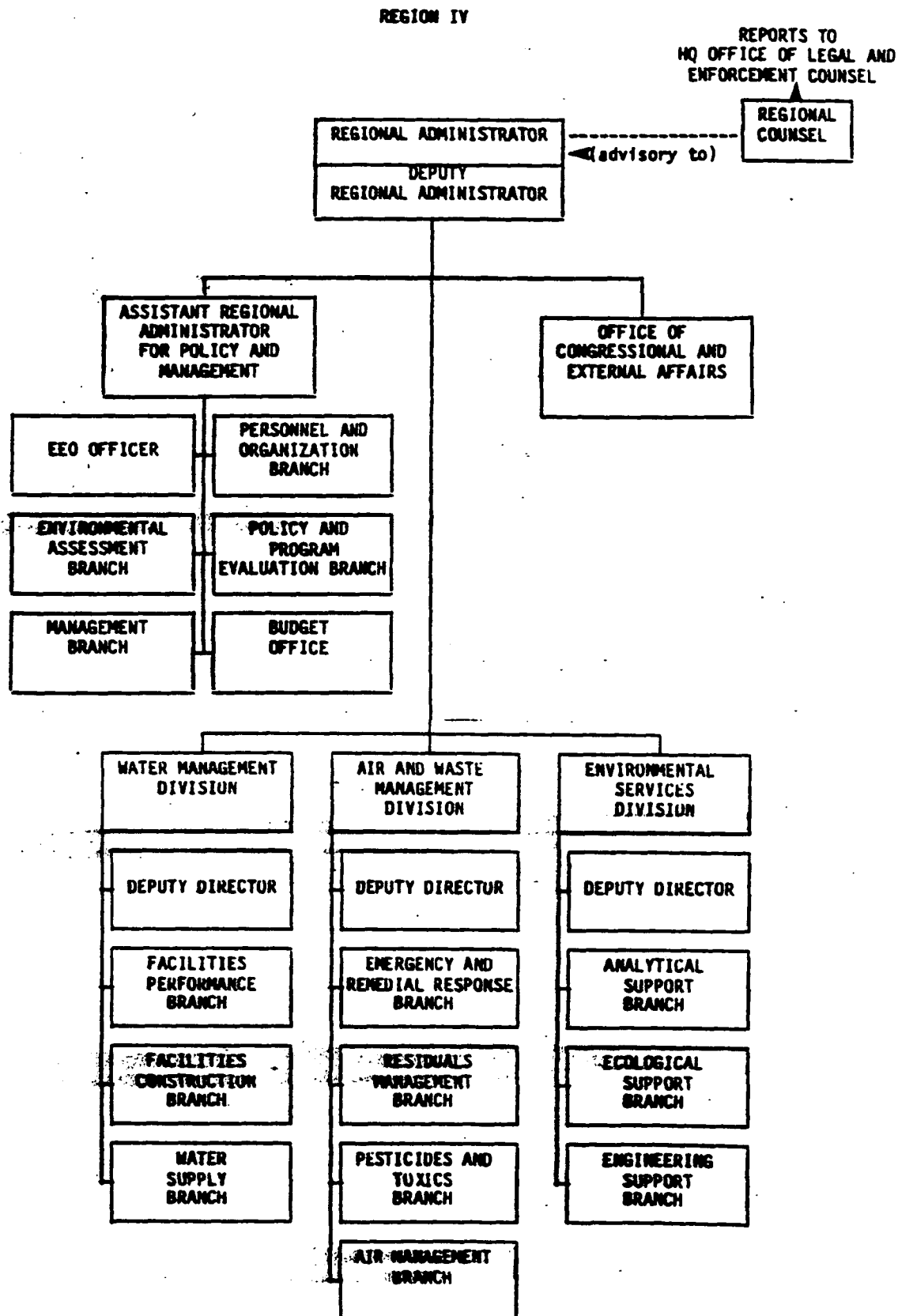
## OFFICE OF PESTICIDE PROGRAMS



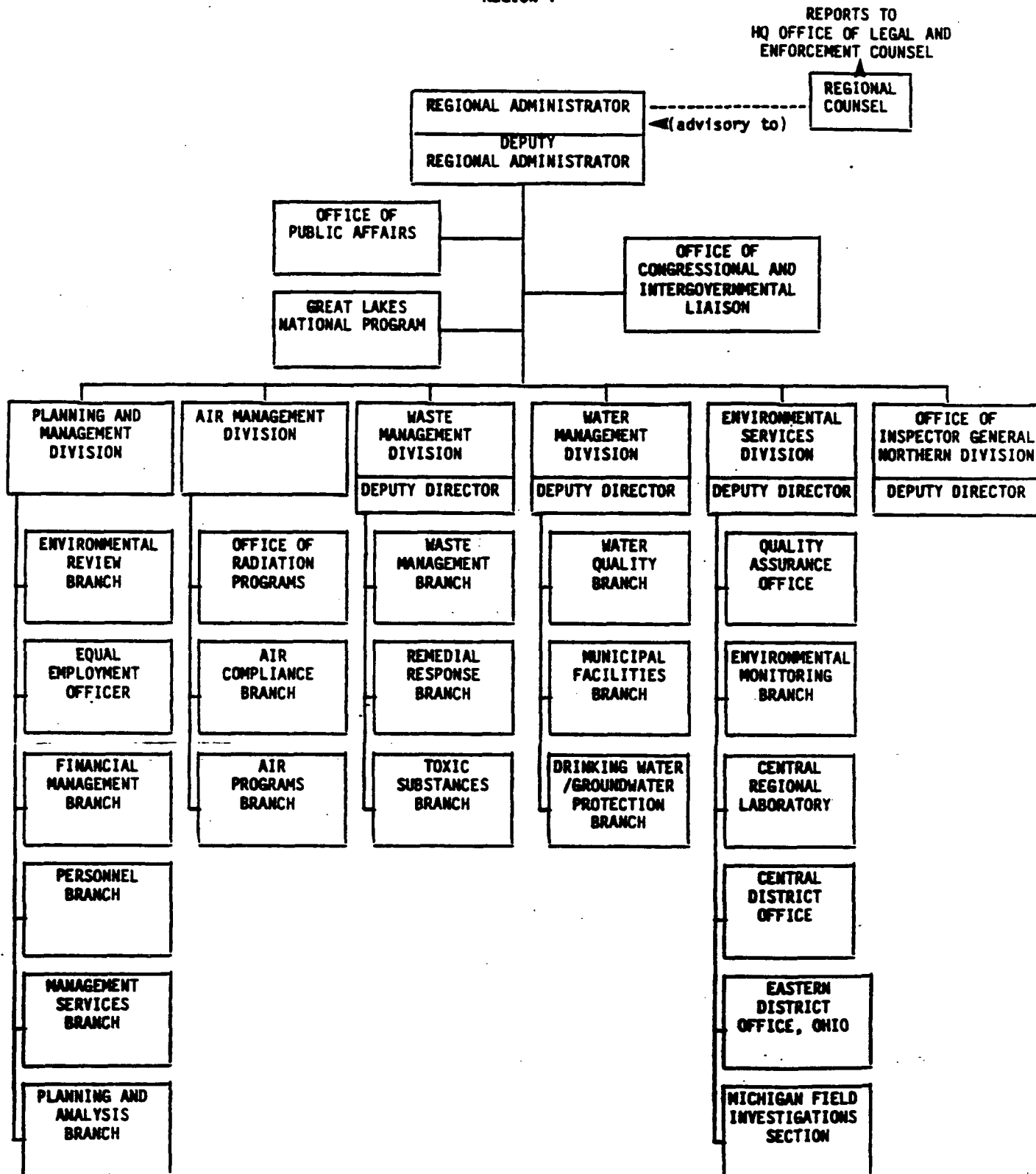


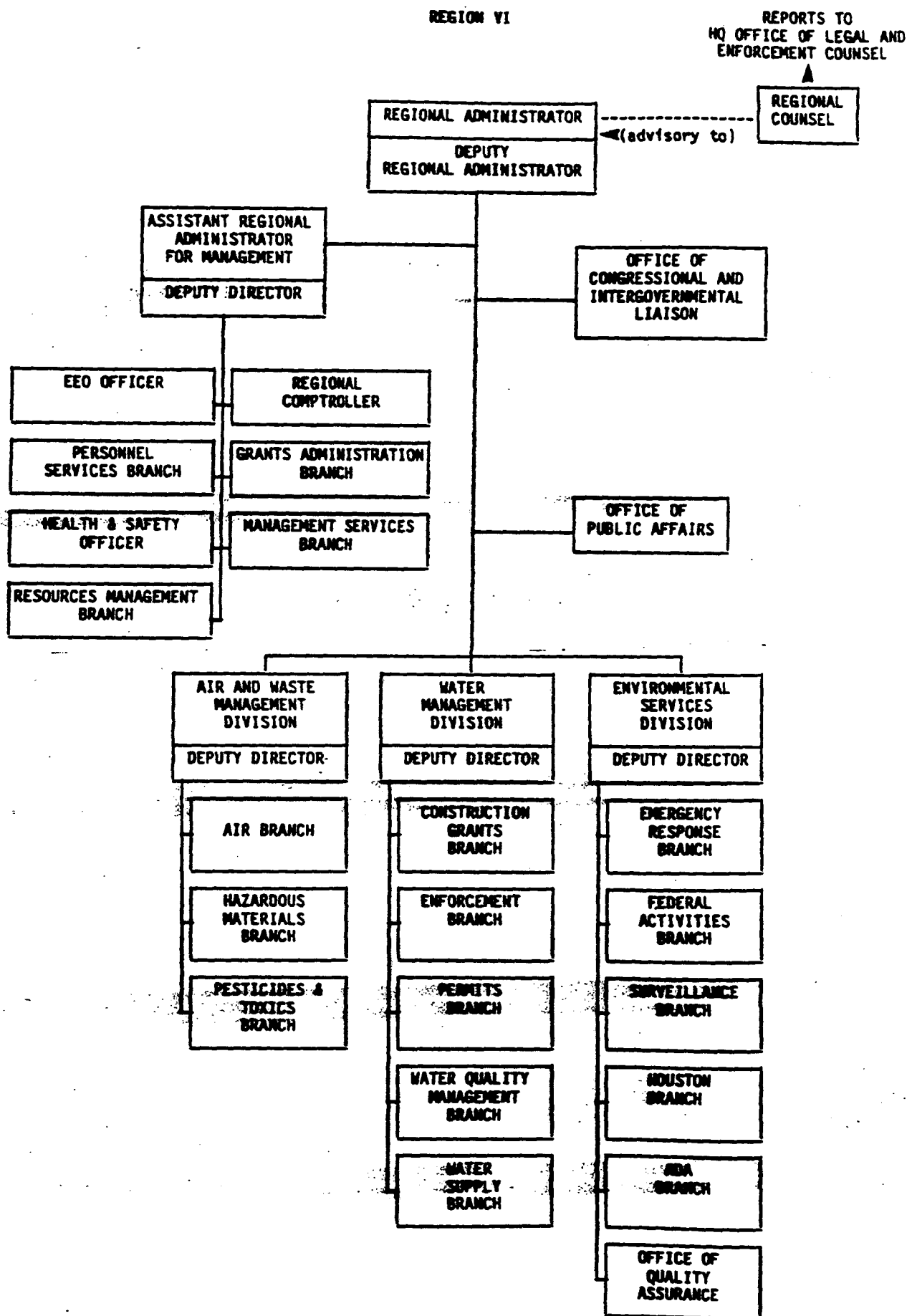




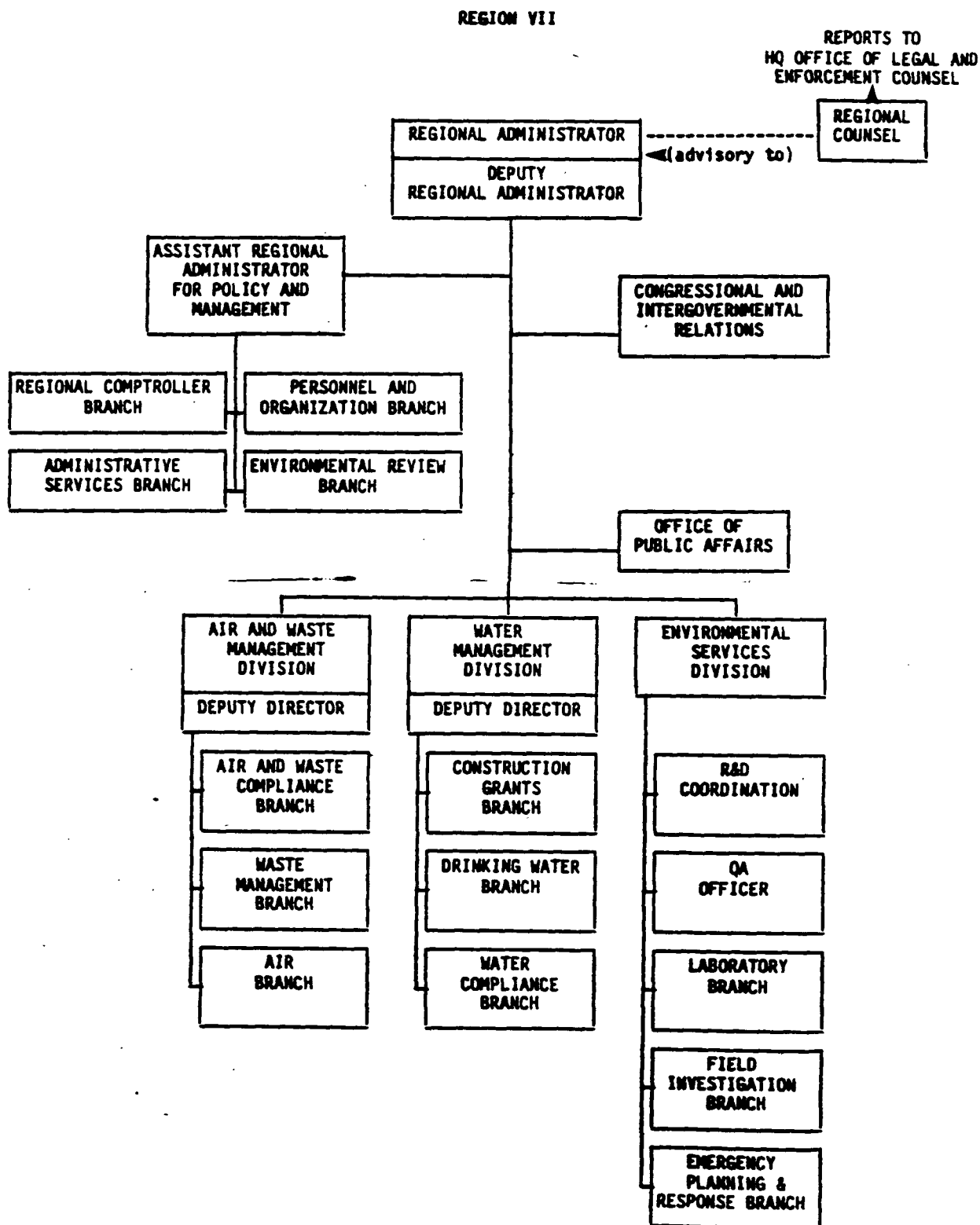


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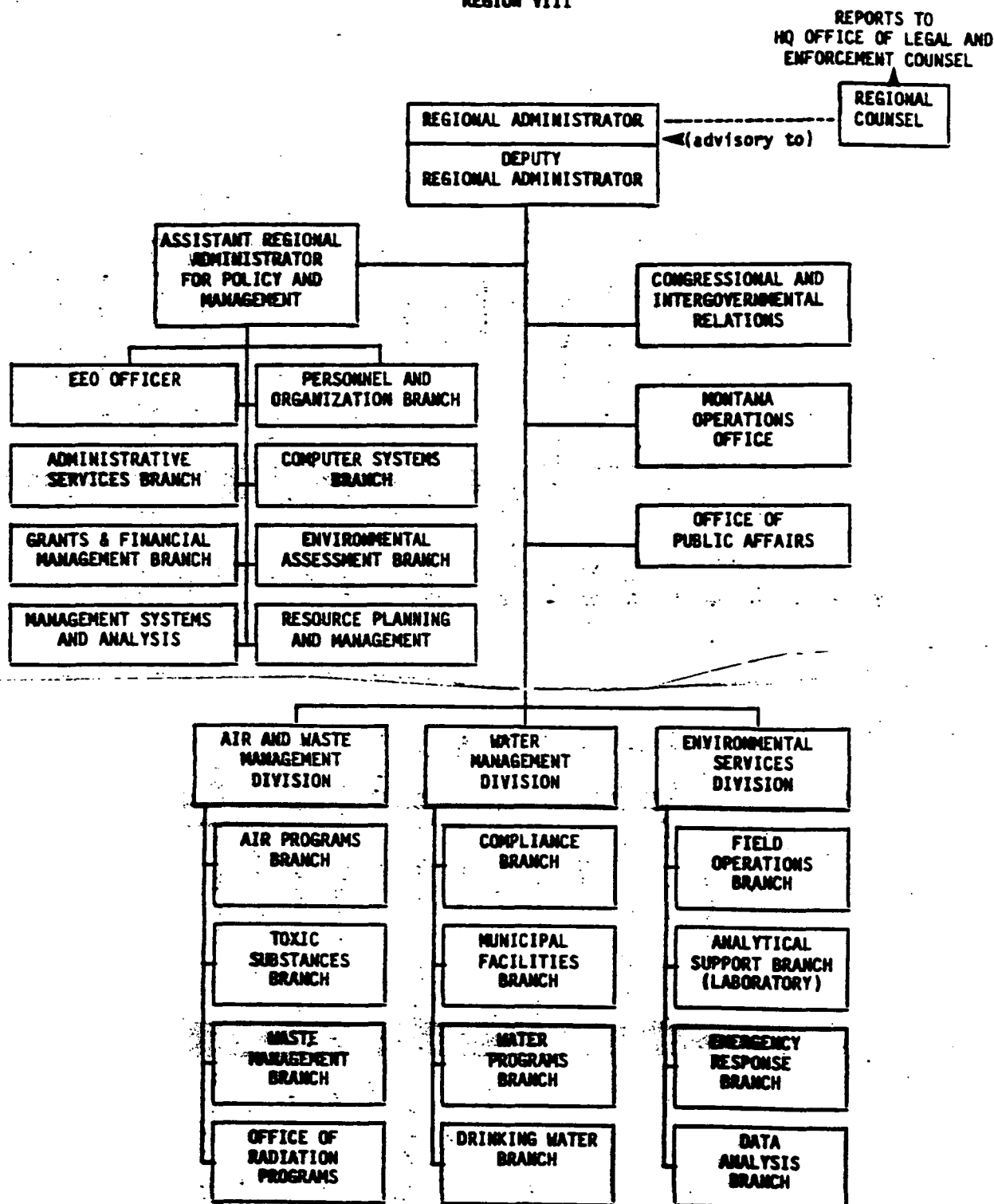


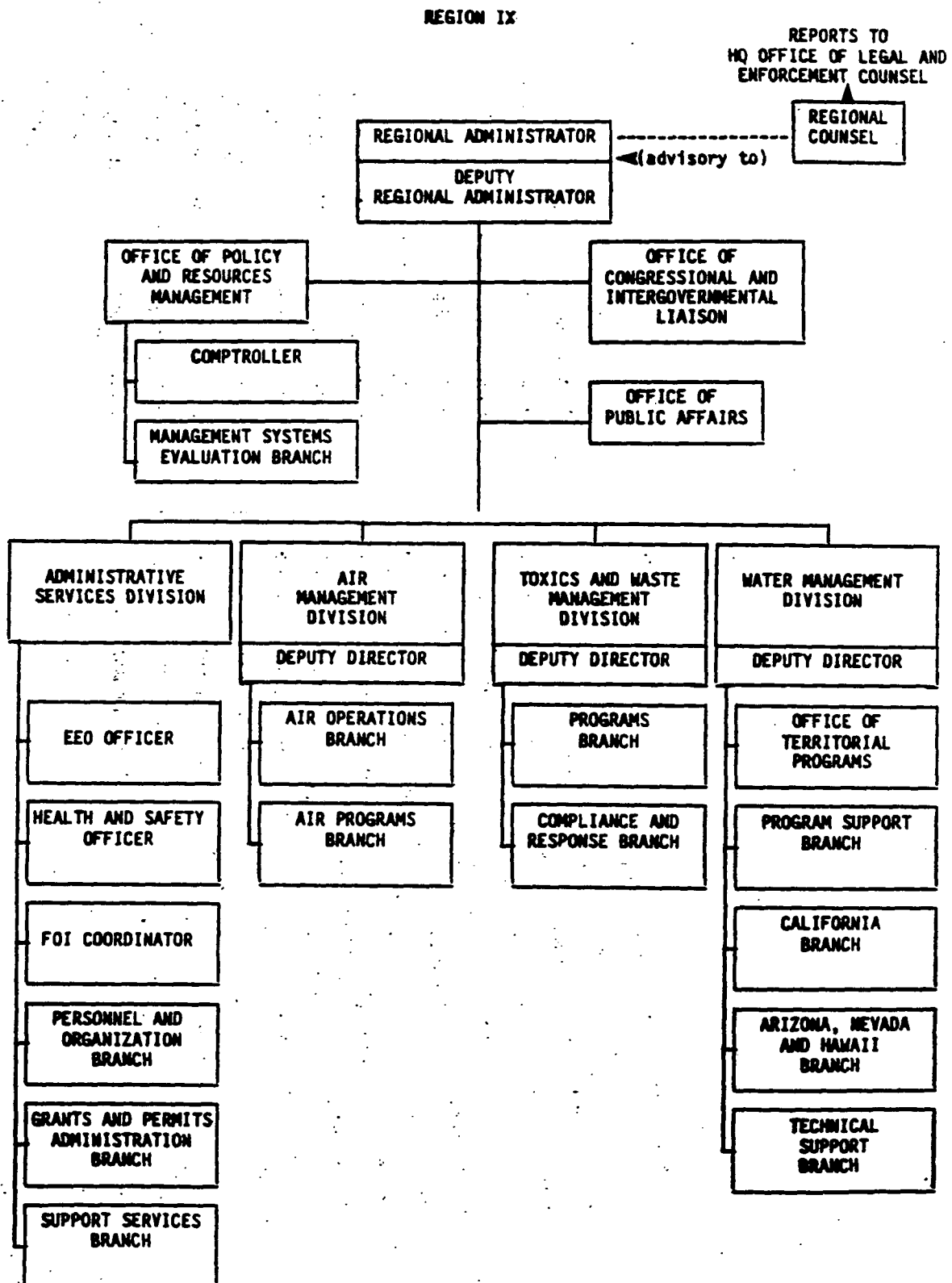


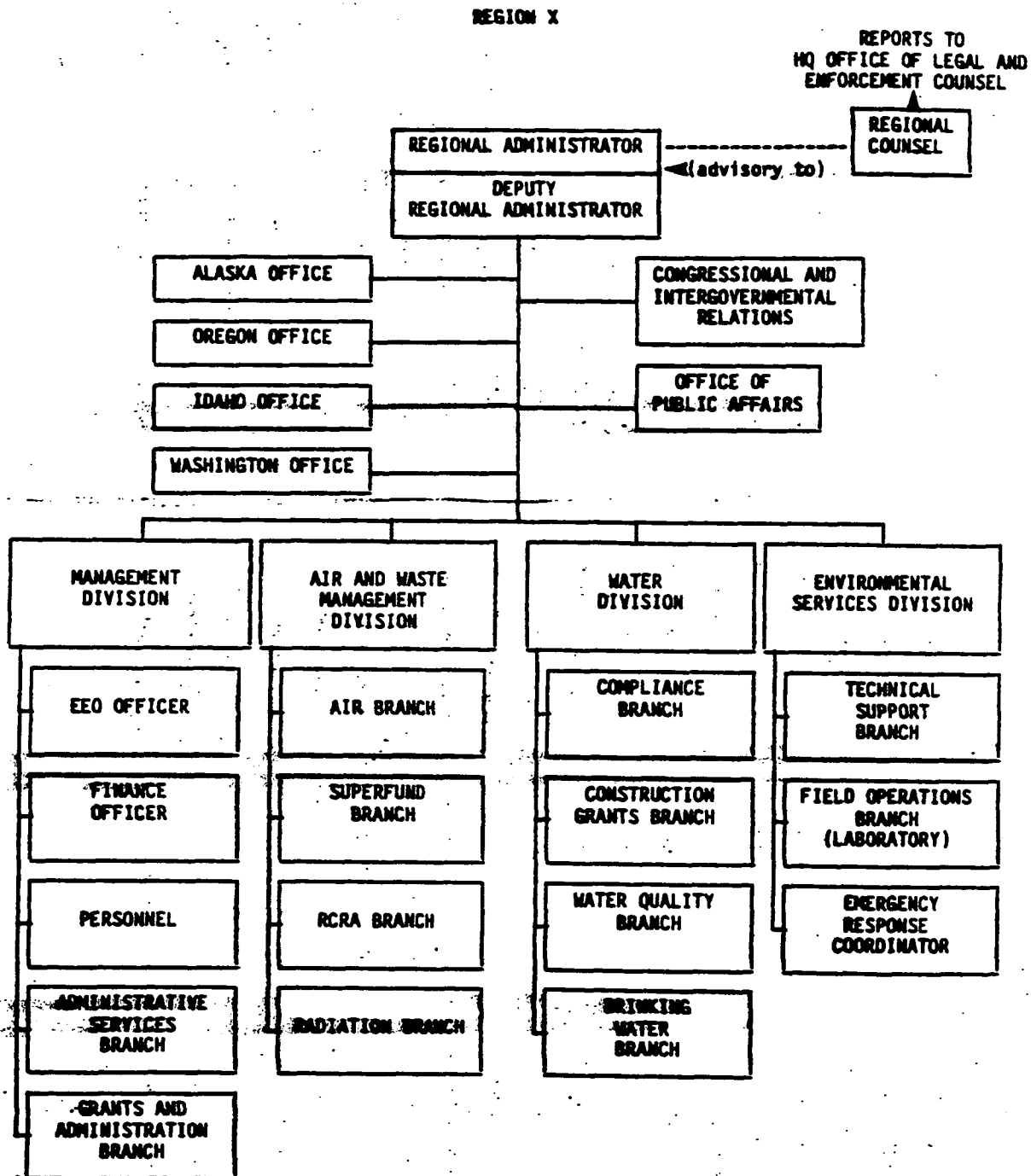




## REGION VIII







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# Chapter Three

## Compliance Monitoring Procedures

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# 1 Introduction

Compliance monitoring is a term used to describe the means by which EPA verifies conformance with statutory and regulatory requirements. In the context of FIFRA, this includes the following types of activities:

- Books and Records Inspections;
- Establishment Inspections; and
- Use/Misuse Investigations.

In the event that an owner or operator of a regulated facility denies an inspector entry to perform any of the above inspections, FIFRA authorizes officers or employees of EPA who have been duly designated by the Administrator to obtain and execute entry and inspection warrants.

This chapter briefly outlines the procedures associated with these FIFRA compliance monitoring activities.





# 2 Inspections

Compliance inspections are the primary enforcement mechanisms used to detect and verify violations. Facilities are selected for inspection either under a neutral administrative inspection scheme or "for cause." (See definition of an unprogrammed inspection in the Glossary.) Selection may be made, depending on the circumstances, by Headquarters or Regional Offices in cooperation with States with EPA enforcement grants.

Evidence obtained during an inspection may result in the Agency taking any of the following enforcement actions:

- Issuance of a notice of warning;
- Request for voluntary recall;
- Issuance of a stop sale, use, or removal order (SSURO);
- Assessment of an administrative civil penalty;
- Institution of a civil court action; and
- Institution of a criminal court action.

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### Custodial Situations

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Compliance inspections conducted by EPA personnel under the authority of FIFRA generally will not involve the need to warn individuals of their rights under the fifth amendment of the United States Constitution. The fifth amendment provides that "No person...shall be compelled in any criminal case to be a witness against himself." Issues concerning this right arise whenever a person is taken into custody or otherwise has his or her freedom restricted by law enforcement officers. Since inspections under FIFRA are generally not conducted by law enforcement officers and do not involve custodial situations, fifth amendment rights are not implicated.

All individuals who conduct such inspections should be aware of what constitutes a custodial situation. When an individual is under arrest, he or she is clearly in custody. However, a custodial situation may also be created when, as a result of the demeanor and authority of the questioner and the physical situation, a reasonable person would not feel free to leave. These types of situations should be avoided during an administrative inspection.

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**Noncustodial Situations**

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Statements made to an inspector during a noncustodial administrative inspection should be given voluntarily. The term voluntary, as used in the judicial sense, relates to the circumstances surrounding the investigation and the taking of statements. Such diverse factors as the following are considered:

- Coercion or threats by the interviewer;
- Overbearing will of the interviewer;
- Promises of benefit by persons in authority;
- Deceit by the interviewer during the interrogation;
- The accused's age, experience, and level of education; and
- The accused's knowledge of his or her constitutional rights.

# 2a Records and Establishment Inspections

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### Authority

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Sections 8(b) and 9(a) of FIFRA authorize any officer or employee of EPA or any State or political subdivision duly designated by the Administrator to enter facilities under the scope of the Act in order to inspect and to copy records, as well as to inspect and to sample pesticides or pesticidal devices that are packaged, labeled, and released for shipment.

Inspections must be conducted in a prescribed manner including the:

- Presentation of credentials to owner, operator, or agent in charge;
- Presentation of a notice of inspection detailing the suspected violation or cause for the inspection;
- Entry at a reasonable time and prompt completion; and
- Issuance of a receipt for samples in the case of an establishment or marketplace inspection.

Section 12(a)(2)(B) of FIFRA makes it unlawful for any person to refuse to allow an EPA officer or employee to take a sample of any pesticide or to inspect records or establishments covered by Sections 8 or 9.

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### Scope

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Inspections conducted under Section 9 of FIFRA extend to the inspection of facilities where pesticides or pesticidal devices are held for distribution or sale. Samples may be taken of pesticides and pesticidal devices released for shipment. Samples may also be taken of any container or label for such pesticides or pesticidal devices.

The scope of establishment inspection does not extend into manufacturing, formulating, repackaging, or technical material storage areas because FIFRA does not provide explicit authority to enter these areas. The inspector does have access to areas (1) where pesticides or devices are packaged, labeled, and released for shipment; (2) where containers and labeling of pesticides or devices are stored; and (3) where books and records, referred to in Sections 8 and 9 of the Act, are kept.

Records inspections conducted under Section 8(b) of FIFRA extend to the inspection and copying of records showing the delivery, movement, or holding of pesticides or pesticidal devices.

FIFRA limits the extent of records inspections by providing that no regulation or inspection may extend to records of:

- Financial data;
- Sales data (other than shipment data);
- Pricing data;
- Personnel data; and
- Research data (other than data relating to registered pesticides or to information on a pesticide for which an application for registration has been made).

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### **Purpose**

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The purpose of an inspection is to ensure compliance with FIFRA and with the rules promulgated under FIFRA. In summary, the inspector's role is:

- To inform the regulated industry of the requirements of the law; and
- To document suspected violations.

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### **Elements of an Inspection**

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The elements of FIFRA facility inspections can be grouped into the following categories: (1) pre-inspection preparation; (2) entry; (3) opening conference; (4) sampling and documentation; (5) closing conference; and (6) report preparation. These elements are common to all inspections, but the emphasis given to the separate elements will vary with the needs of the individual inspection.

### Pre-Inspection Preparation

To ensure effective use of the inspector's time, the following procedures are undertaken before beginning the inspection of a selected facility:

- Establishing inspection objectives;
- Establishing the scope of the inspection;
- Conducting a review of Agency records;
- Preparing necessary documents; and
- Preparing sampling equipment and safety equipment.

### Entry

Entry procedures are followed to obtain actual physical entry into the facility. Entry involves the following steps:

- Introduction;
- Presenting official credentials;
- Presenting the notice of inspection; and
- Managing denial of entry when necessary (see Section 2c of this chapter).

### Opening Conference

After entry, the inspector conducts an opening conference with the facility management. During the opening conference, the inspector is responsible for the following activities:

- Discussing the objectives and scope of the inspection;
- Advising of the availability of duplicate samples;
- Providing information on FIFRA and its rules; and
- Planning meetings with personnel.

### Sampling and Documentation

Reviewing facility records, taking official samples, and preparing documentation are the basic inspection activities. It is these activities that provide the evidentiary support the Agency uses in enforcement actions. The inspector's responsibilities include:

- Targeting facility and locating records;
- Inspecting facility records;
- Preparing documentation of all inspection activities;
- Inspecting conditions and taking photographs, if necessary;
- Taking necessary samples, sealing samples, and establishing "chain of custody"; and
- Operating in a safe and efficient manner.

### Closing Conference

The closing conference with facility officials enables the inspector to prepare receipts, answer questions, and provide information about FIFRA. At the closing conference, the inspector "wraps up" the inspection by:

- Writing necessary receipts;
- Advising that results of analysis of an official sample will be furnished if and when analysis is made; and
- Discussing inspection findings.

### Report Preparation

All evidence must be organized and coordinated in a comprehensive, relevant, and accurate report including:

- Inspection report forms;
- Narrative report; and
- Other documentary support.

Suspected violations are to be documented in the above reports. Compliance proceedings personnel will review the report file to determine the adequacy of the evidence. Any information needing clarification should be reviewed with the inspector.

### 2b Use/Misuse Investigations

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#### General

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Investigations to determine whether pesticides are being properly used can be divided into two categories:

- Use Inspections. This includes routine investigations or observations made on a cross section of pesticide uses during or immediately following application. The purpose of use inspections is to develop data on the common practices of applying pesticides, to encourage the proper use of pesticides, and to determine whether pesticides are being used in accordance with their directions. It is Agency policy to obtain the consent of the owner, operator, or person in charge of the premises for this type of investigation.
- Misuse Investigations. This includes investigations of reported or suspected cases of pesticide misuse. These investigations are conducted to develop evidence in support of enforcement actions arising from the use of a registered pesticide in a manner inconsistent with its labeling. Entry should be on the basis of consent freely given or with a valid search warrant since information gathered to support a subsequent enforcement action must be protected for admission into court as evidence.

Use/Misuse investigations will generally proceed through the same stages as the records and establishment inspections described in this chapter. However, for details on the procedures for entering and conducting a use/misuse investigation, please refer to the FIFRA Inspection Manual, Chapter 6, "Use/Misuse Investigations."

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#### Authority

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Although Section 12(a)(2)(G) of FIFRA makes it clear that the Agency is to enforce against the misuse of pesticides, FIFRA does not provide expressed

authority to conduct use/misuse investigations. Nonetheless, the following statutory and common law doctrines are available to the Agency for conducting these investigations.

#### Statutory Basis

Where there is "probable cause" that a violation of one of the "use" provisions of the Act has occurred, a warrant [FIFRA §9(b)\*] authorizing entry for the purpose of inspecting and sampling may be obtained. (See Section 2c of this chapter.)

Section 9(a) of FIFRA authorizes entry into those places where pesticides are held for distribution and sale for the purpose of inspecting and sampling pesticides that are (or have been) packaged, labeled, and released for shipment. In the context of pesticide use inspections, Section 9(a) permits entry into establishments of those persons who offer "for hire" applicator services. These types of establishments would include the primary place of business of a commercial pesticide applicator or the applicator service vehicle or any other service equipment used to hold the pesticide for distribution or sale.

#### Common Law Basis

If the above statutory authorities do not apply, entry and sampling for purposes of a use/misuse investigation may occur only when one of the following common law doctrines applies:

- Consent. Consent must be given freely and voluntarily (not as a result of duress, misrepresentation, or coercion) by the owner, his or her agent, or the person in charge of the property or premises. For repeated inspections at the same site, it is necessary to obtain consent for each entry and sampling unless prior consent is given to cover all such inspections.

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\* Section 9(b) of FIFRA authorizes employees duly designated by the Administrator to obtain inspection warrants in order to enter a facility for purposes of inspecting and sampling if there is "probable cause" to believe that a violation of FIFRA has occurred. Although the amount of evidence necessary to establish probable cause for an administrative warrant under Section 9(b) of FIFRA is less than that necessary to obtain a criminal search warrant, sufficient evidence must be available to demonstrate that it is reasonable to conclude that specific provisions of FIFRA have been violated.



- Exigent Circumstances. If a serious situation exists, such as the endangerment of human health or public safety occurring on private property, an inspector may enter the property to assist in preventing the harm when:

- There is insufficient time to procure a warrant, and
- Consent cannot be readily obtained.

This doctrine should be used only in rare instances since it places a heavy burden on the Agency to justify its entry without authority.

- Plain View. This doctrine applies in those instances where an inspector has lawfully gained entry onto private property or premises (such as to conduct monitoring or to follow up an accident report) and subsequently encounters a violation in his or her "plain view." The inspector may observe and document the violation so long as he or she stays within the scope of the authorization to enter the property or premises.
- Open Fields. An inspector may observe and document a violation occurring in an open area within his or her view so long as the inspector does not enter the property on which the violation is occurring. For example, an inspector on a country road can observe and prepare evidence on a visible misuse that is occurring in a field adjacent to that road.



### 2c Warrants

A warrant can be used to gain entry into a facility when facility officials have denied entry to an inspector or have withdrawn their consent to inspect during an inspection. In certain circumstances it may be necessary to obtain a warrant prior to an inspection. A warrant is a judicial authorization for an appropriate official (EPA inspector, State inspector, U.S. Marshal, or other authorized officer) to enter a specifically described location and perform clearly defined inspection functions.

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#### Authority

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Section 9(b) of FIFRA authorizes officers or employees duly designated by the Administrator to obtain and execute warrants authorizing:

- "(1) entry for the purpose of this section;
- "(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act 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; and
- "(3) the seizure of any pesticide or device which is in violation of this Act."

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#### Policy

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It is the policy of EPA to obtain a warrant when all other efforts to gain lawful entry have been exhausted. This policy, of course, does not apply to pre-inspection warrants.

Marshall v. Barlow's Inc.

In Marshall v. Barlow's, Inc., 436 U.S. 307 (1978), the Supreme Court addressed the need for an administrative warrant when an Occupational Health and Safety Administration (OSHA) inspector sought entry into a workplace where consent for the inspection was not voluntarily given by the owner. The Court concluded that an administrative warrant was required to conduct such regulatory inspections unless the industry is one with a history of extensive regulation, such as liquor or firearms.

EPA guidance recognizes that inspections conducted pursuant to authority under FIFRA may constitute an exception to the Barlow's decision, due to the long history of Federal regulation of pesticide manufacture. Although the issue has not been tested, as a matter of policy, the Agency will apply the requirements of Barlow's to all FIFRA inspections, including inspections conducted by State personnel.

According to Barlow's, a warrant may be obtained where there is a specific reason to think that a violation has been committed (i.e., where there is probable cause such as an employee's complaint or a competitor's tip). A warrant may also be issued if the Agency can show that the establishment to be inspected has been selected pursuant to a neutral inspection scheme. To meet Barlow's requirements and to carry out its duties under the Act, the Agency has developed criteria to be used in selecting an activity for a programmed (neutral) inspection. (See Appendix 1, Neutral Administrative Inspection Scheme, for details of the criteria.)

Seeking a Warrant Before Inspection

A warrant may be obtained before the inspector sets forth to conduct the inspection. A pre-inspection warrant may be obtained at the discretion of the Regional Office if:

- A violation is suspected and could be covered up within the time needed to secure a warrant;
- Prior correspondence or other contact with the facility to be inspected provides reason to believe that entry will be denied when the inspector arrives; or
- The facility is unusually remote from a magistrate or a district court, and thus obtaining a warrant would require excessive travel time.

Civil Versus Criminal Warrants

If the purpose of the inspection is to discover and correct, through civil procedures, noncompliance with regulatory requirements, a civil warrant should be secured if entry is refused.

If the primary purpose of the inspection is to gather evidence for a criminal prosecution and there is sufficient evidence available to establish probable cause for a criminal warrant, then a civil warrant should not be used to gain entry. Rather, a criminal search warrant must be obtained pursuant to Rule 41 of the Federal Rules of Criminal Procedure (Fed. R. Crim. P.). (See Agency "Guidelines for the Use of Administrative Discovery Devices in the Development of Potential Criminal Cases.")

Evidence obtained during a valid civil inspection is generally admissible in criminal proceedings.

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### Securing and Serving an Administrative Warrant

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The following procedures for obtaining and serving a warrant have been developed in accordance with the Barlow's decision.

#### Important Procedural Considerations

- The application for a warrant should be made as soon as possible after the denial of entry or withdrawal of consent.
- In order to satisfy the requirements of the Barlow's decision, the affidavit in support of the warrant must include a description of the reasons why the establishment has been chosen for inspection. The only acceptable reasons are specific probable cause (e.g., an employee's complaint or competitor's tip) or selection of the establishment for inspection pursuant to a neutral administrative inspection scheme.
- A warrant must be served without undue delay and within the number of days stated (standard is 10 days). The warrant will usually direct that it be served during daylight hours.
- Since the inspection is limited by the terms of the warrant, it is very important to specify to the greatest extent possible the areas intended for inspection, records to be inspected, samples to be taken, etc. A vague, overly broad warrant, probably will not be signed by the magistrate.
- If the owner refuses entry to an inspector holding a warrant but not accompanied by a U.S. Marshal, the inspector should leave the establishment and inform the U.S. Attorney.

#### Procedures for Obtaining a Warrant

1. Contact the Regional Counsel's Office. The inspector should discuss with the Regional Counsel's Office the facts regarding the denial or withdrawal of consent or the circumstances that gave

rise to the need for a pre-inspection warrant. A joint determination will then be made whether or not to seek a warrant.

2. Contact Headquarters Pesticides and Toxic Substances Program Office. The Regional Office should notify Headquarters PTSCMS prior to obtaining a warrant.
3. Contact the United States Attorneys Office. After a decision has been made to obtain a warrant, the designated regional official should contact the U.S. Attorney for the district in which the property is located. The Agency should assist the United States Attorneys Office in the preparation of the warrant and necessary affidavits.
4. Apply for the Warrant. The application for a warrant should identify the statutes and regulations under which the Agency is seeking the warrant. The name and location of the site or establishment to be inspected should be clearly identified, and, if possible, the owner and/or operator should be named. The application can be a one- or two-page document if all factual requirements for seeking the warrant are stated in the affidavit, and the application so states. The application is to be signed by the U.S. Attorney.
5. Prepare the Affidavits. The affidavits in support of the warrant application are crucial documents. Each affidavit should consist of consecutively numbered paragraphs that describe all of the facts in support of warrant issuance. Each affidavit should be signed by a person with first-hand knowledge of all the facts stated, most likely the inspector. An affidavit is a sworn statement that must be notarized or sworn to before the magistrate. (See Exhibit 3-1.)
6. Prepare the Warrant for Signature. The draft should be ready for the magistrate's signature. Once signed, the warrant is an enforceable document. The warrant should contain a "return of service" or "certificate of service" that will indicate upon whom the warrant was served. This part of the warrant is to be dated and signed by the inspector after the warrant is served. (See Exhibit 3-2.)
7. Serve the Warrant. The warrant is served on the facility owner or the agent in charge and the inspection will normally commence or continue. Where there is probability that entry will still be refused, or where there are threats of violence, the inspector should be accompanied by a U.S. Marshal. In this case, the U.S. Marshal is principally charged with executing the warrant, and the inspector should abide by the U.S. Marshal's decisions.
8. Inspecting With the Warrant. The inspection should be conducted strictly in accordance with the warrant. If sampling is authorized, all procedures must be followed carefully, including presentation of receipts for all samples taken. If records or

other property are authorized to be taken, the inspector must issue a receipt for the property and maintain an inventory of anything removed from the premises. This inventory will be examined by the magistrate to ensure that the warrant's authority has not been exceeded.

9. Return the Warrant. After the inspection has been completed, the warrant must be returned to the magistrate. Whoever executes the warrant (i.e., the U.S. Marshal or whoever performs the inspection) must sign the return of service form indicating to whom the warrant was served and the date of service. The executed warrant is then returned to the U.S. Attorney who will formally return it to the issuing magistrate or judge. If anything has been physically taken from the premises, such as records or samples, an inventory of such items must be submitted to the court, and the inspector must be present to certify that the inventory is accurate and complete.

## Model Affidavit in Support of Application for a Warrant

## UNITED STATES DISTRICT COURT

DISTRICT OF \_\_\_\_\_

Docket No. \_\_\_\_\_

Case No. \_\_\_\_\_

In the matter of:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Affidavit in Support of  
Application for a Warrant

State of \_\_\_\_\_:

County of \_\_\_\_\_:

(Name of Affiant) \_\_\_\_\_, being duly sworn upon his  
(her) oath, according to law, deposes and says:

1. I am a 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, 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. This warrant is sought under Section 9 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. §136g), which provides:

"(b) WARRANTS.--For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing--

"(1) entry for the purpose of this section;

"(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act 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; and

"(3) the seizure of any pesticide or device which is in violation of this Act."

3. (Name of establishment, person, or place) is a (describe its business) which 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 specific facts that give use to the probable cause, or the neutral administrative inspection scheme used to select the facility for inspection.)
4. The (inspection, reproduction of records, sampling, or issuance of the stop sale, use, or removal order) 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 [optional, if needed] the issuance of a stop sale, use, or removal order.
7. A return will be made to the court at the completion of the inspection, reproduction of records, sampling, or the issuance of a stop sale, use, or removal order.
8. The authority for the issuance of the inspection warrant is Section 9 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and Marshall v. Barlow's Inc., 436 U.S. 307 (1978).

(Signature of Affiant)

(Title)

(Division)

Region ( )

United States Environmental Protection Agency

Before me, a notary public of the State of \_\_\_\_\_,  
County of \_\_\_\_\_, on this \_\_\_\_\_ day of \_\_\_\_\_,  
19\_\_\_\_, personally appeared \_\_\_\_\_,  
and upon oath stated that the facts set forth in this application are  
true to his(her) knowledge and belief.

(Signature of Notary)

A Notary Public of \_\_\_\_\_

My Commission Expires \_\_\_\_\_

## Model Warrant

## UNITED STATES DISTRICT COURT

\_\_\_\_\_  
DISTRICT OF \_\_\_\_\_

In the matter of:

Docket No. \_\_\_\_\_

Case No. \_\_\_\_\_

Warrant for Inspection, Reproduction of  
Records, Sampling, and Issuing Stop  
Sale, Use, or Removal Order of Pesticides  
or Devices Pursuant to the Federal  
Insecticide, Fungicide, and Rodenticide  
Act, as amended, (7 U.S.C. §§135, 136)

To \_\_\_\_\_ (name), \_\_\_\_\_ (title), \_\_\_\_\_  
(division), Environmental Protection Agency, Region \_\_\_\_\_, and any  
other duly authorized enforcement officer of said division:

Application having been made and probable cause shown, by (name  
of officer) \_\_\_\_\_, for inspection and sampling of packaged, labeled,  
released pesticides or devices, as well as labeling and containers  
found in the establishment described below; and for inspection and  
reproduction of records showing quantity, date of shipment, and the  
name of consignor and consignee of any pesticide or device found in  
said establishment which is adulterated, misbranded, not registered in  
the case of a pesticide or otherwise in violation of the Federal  
Insecticide, Fungicide, and Rodenticide Act, as amended, or should  
such records not be available for inspection, all other available  
records and information relating to such delivery, movement, or holding  
of any pesticide or device that is in violation of the said Act; for  
the issuance or surveillance of any stop sale, use, or removal order  
of any pesticide or device that is in violation of the said Act; all  
within the establishment or place described as:

\_\_\_\_\_  
(Name of establishment or place)\_\_\_\_\_  
(Address)

or

Application having been made and probable cause shown, by (name  
of officer) \_\_\_\_\_, for inspection or sampling of pesticides used in viola-  
tion of the said Act, at the place described as:

\_\_\_\_\_  
(Name of person or property owner)\_\_\_\_\_  
(Address)

Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, by the Federal Environmental Pesticide Control Act of 1972, (hereinafter Federal Insecticide, Fungicide, and Rodenticide Act, as amended), the Federal regulations promulgated thereunder and the decision of the Supreme Court in Marshall v. Barlow's, Inc., 436 U.S. 307 (1978), you are authorized to enter (immediately) the above described premises upon presentation of this warrant and therein to carry out the inspections, sampling, reproduction of records, and/or issuance or surveillance of any stop sale, use, or removal order described above.

(Signature of Magistrate)

(Date)

RETURN OF SERVICE

I hereby certify that a copy of the within warrant was served by presenting a copy of same to (facility owner or agent) on (date) at (location of establishment or place).

(Signature of person making service)

(Official title)

RETURN

Inspection of the establishment described in this warrant was completed on (date).

(Signature of person conducting the inspection)

### 3. Subpoenas

FIFRA does not provide for subpoena authority.\*

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\* Except under FIFRA Section 6(d) where the Administrative Law Judge has subpoena authority to compel testimony or the production of documentation from any person during a cancellation or change of classification proceeding held under FIFRA Section 6(b).



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# Chapter Four

## Documentation of Evidence

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# 1 Introduction

Upon completion of a Section 9 inspection, pesticide enforcement inspectors are required to organize the documentary evidence gathered during this inspection into a file commonly called the ID (or Sample) Jacket. The ID Jacket file includes all the forms, reports, and documentary evidence secured by the inspector relating to an official pesticide or pesticidal device sample. Once compiled, the file is sent to a Regional Case Development Officer (RCDO) who reviews the inspection results for possible enforcement action.



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## Chapter Four

# 2 Inspection File Review

To ensure the validity and quality of documentary evidence for an administrative or judicial enforcement proceeding, the RCDO must review the evidence for objectivity, adequacy, and proper identification. In some instances the RCDO will need an enforcement case review, which could include the verification of the sample's pesticide registration and labeling status, as well as an interpretation of laboratory test results. In all cases, the RCDO must verify that all procedural safeguards were implemented so as not to prejudice a possible enforcement action.

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### Substantiation of Each Violation

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In most cases, a violation will be substantiated through a combination of evidential sources. The RCDO's review must seek to substantiate each possible violation from the evidence supplied by the inspector. Whenever necessary, the RCDO should obtain from the inspector additional evidence or clarification of existing evidence.

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### Controlled Identification of Each Sample

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An important aspect of any review by the RCDO is the determination that all samples were properly collected and accurately and completely identified.

Whenever a sample is taken, the inspector prepares a Collection Report (EPA Form 3540-7), which describes the sample collection process. Information required for the report includes:

- Type of sample;
- Sample number, subsample number;
- Date of collection;
- Collection method;

- Description of sample (including quantity collected, color, texture, viscosity, etc.);
- Duplicate samples (if provided); and
- Description of procedures for sealing sample.

Each ID Jacket will also be identified by a sample number. The RCDO should check the number to see if it corresponds to the ID number on the Collection Report Form.

All samples that are to be used as evidence should be sealed with the official EPA seal (EPA Form 7500-2). The seal is placed on the sample container by the inspector to help preserve the integrity of the sample.

A written receipt (EPA Form 3540-3) describing the sample obtained by the inspector is issued to the appropriate facility representative whenever a sample is taken. The receipt may also be used to verify that a duplicative sample was given the facility. The ID Jacket may not always include a copy of the receipt. If an enforcement action is considered, a copy may be obtained from the Inspection Report that was filed with the Regional Office.

The two types of samples commonly collected are official and investigational.

Official Samples. These include samples or documents of pesticides or devices that, if violative, serve as a basis for legal action. In general, an RCDO should ensure that an official sample:

- Was collected only from material that had been "packaged, labeled, and released for shipment" (see Glossary);
- Was representative of the lot from which it was obtained; and
- Was identified and officially sealed so as to maintain its continuity and integrity as court evidence.

Official samples include:

- Producer/Marketplace Samples. Actual samples of a pesticide or pesticidal device collected by an inspector at the producer, wholesale, or retail level.
- Documentary Samples. Copies of the label and/or labeling and copies of any records showing shipment of the product and the responsible parties.
- Post-Seizure Samples. Actual samples collected from a lot of merchandise that is in the custody of a U.S. court. A court order must be entered before sampling, and these actions must be carried out in accordance with such orders.

- Induced Samples. Actual samples of pesticides or pesticidal devices that are not obtained by EPA official procedures (e.g., notice of inspection, collection report, etc.). These samples are usually requested by mail. An induced sample is the least desirable method of obtaining a sample and should be used only when the other methods have been exhausted.
- Import Samples. Actual samples of pesticides or pesticidal devices that are offered for importation into the United States from a foreign port. Proper documentation for import shipments should include Customs entry papers, foreign invoices, and records showing movement from the port of entry.
- Use Samples. Actual samples of the pesticide that are collected during a use inspection. This type of sample may be field collected from a formulated pesticide, diluted pesticide, or as a residue from plant material, animal tissue, soil, water, etc.

Investigational Samples. These include samples of pesticides or devices collected for special investigation or information purposes. These samples need not be collected from lots or stocks that have been packaged, labeled, and released for shipment. No legal action can be taken on investigational samples.



### 3 Review of Adequacy of Evidence

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#### Initial Review of the ID Jacket

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Once the RCDO has received the ID Jacket, its contents must be reviewed in the context of the following considerations:

- Adequacy of the documentation (see below);
- Significance of violation (see Chapter Five for Level of Action Policy); and
- Violative history of the firm (see Chapter Five for Level of Action Policy). Violative history may be obtained from the FIFRA and TSCA Enforcement System (FATES).

#### Adequacy of the Documentation

The initial phase of the review will focus on two aspects of the documentation:

- That all necessary documentation and samples have been provided; and
- That the documentation is adequate to prove the substance of the violation as indicated by the results of the inspection.

The purpose of the review is to develop a recommendation for action on the violation; either to proceed with an enforcement action or to dismiss the violation as not worthy of prosecution.

In some instances, review will indicate possible violations not documented by the inspection. In these cases, the RCDO should seek to secure the additional documentation for the new violation. For example, this may require further consultation with the inspector or forwarding the file to Headquarters for an enforcement case review. When a violation is discovered that is unrelated to the initial suspected violation, that new violation should be pursued as a new action.

Contents of the ID Jacket

The ID Jacket should normally contain the following items:

Label of a Pesticide or Device. The label should either be an actual copy (or photocopy) or a typewritten copy. The label should be identified by sample number, date of collection, inspector initials, and, if appropriate, subsample numbers.

Notice of Inspection (EPA Form 3540-2) or Warrant. If an enforcement action is being considered, a copy of the notice of inspection or warrant may be obtained from the Establishment Inspection Report. The notice and/or warrant should be reviewed to ensure the inspection adhered to the terms specified in the documents.

Receipt for Sample. The written receipt should describe the sample and verify that a duplicate sample, if requested, was given to the facility official. The RCDO should verify sample identification numbers.

Collection Report. This is the official report of the sample collection. The following should be verified from the report:

- The ID number appearing on the Collection Report should agree with the number on the ID Jacket. For documentary samples, the notation "DOC" will appear after the ID number; for investigational samples, "INV" will appear after the ID number; for post-seizure samples, "P.S." will appear after the ID number; and import samples will be identified by "Import";
- Date of shipment (from transportation records) of the sample;
- Amount of the product before sampling (the amount on hand must be less than or equal to the amount shipped);
- Descriptions indicating number of samples and method of collection;
- Shipper of sample (from transportation records); and
- Reason for collection--either to document a suspected violation, or as part of a "Market Basket Survey" of products without accompanying documentation.

History of Official Sample (EPA Form 3540-17). This document is placed in the ID Jacket by laboratory personnel once the physical sample has been received by the laboratory for analysis. It shows whether the integrity of the sample has been maintained during its stay at the laboratory. Each time the sample seal is broken and resealed, it must be noted on the form.

It is important for the RCDO to demonstrate that none of the samples involved in the case preparation have been tampered with or contaminated during collection, transit, storage, or analysis. An accurate accounting



must be maintained to trace the possession of each sample from the moment of collection to its introduction as evidence. Accountability can be checked by reviewing the following documents:

- Receipt for sample;
- Collection report; and
- History of official sample.

Laboratory Test Methods. Test methods employed in the analysis of pesticide or pesticidal device samples fall into two categories, official and unofficial.

- Official Test Method. Refers to a test method accepted by a recognized standard-setting organization, such as the Association of Official Analytical Chemists (AOAC) or the American Society for Testing and Materials (ASTM).
- Unofficial Test Method. Refers to a method that has not as yet been accepted as a standard method but is employed by EPA in the analysis of a sample because other reliable test methods are not available.

Extreme care and judgment should be exercised in preparing enforcement cases when unofficial test methods are used as the basis for evidence of a violation of the FIFRA. Consultations with Headquarters Case Development Officers (HQCOs) are strongly recommended before proceeding with enforcement actions in these cases.

Laboratory Test Results. Test results are placed in the ID Jacket upon completion of the analysis. Tests include:

- Sample Report of Analysis (EPA Form 3540-5), which shows the chemical composition of the sample collected versus composition guaranteed by the registrant. Usually a cross-contamination will be conducted by the laboratory and the percentage of contaminants, if any, noted; and/or
- Efficacy test, which shows the effectiveness of the product.

Other Evidential Documentation. Suspected violations may also be documented by the inspector using the following support methods:

- Affidavit. Sworn statements taken by the inspector relating to personal first-hand knowledge of a potential violation. The affidavit may be used to substantiate the violation or to set the circumstances surrounding the violation. Careful review should be made of the affidavit for evidence in support of an enforcement action. The person making the affidavit must sign it and be able to personally verify the facts contained in the statement.

The object of an affidavit is to obtain a clear and concise written record of factual information relating to a suspected violation. The oath taken by the person making the affidavit serves to substantiate the truth of the statement. Affidavits may be used to verify the dates obtained from a facility's records (e.g., the date of shipment). Review should emphasize the admissibility of the affidavit in court. This includes determining that the affidavit was properly executed and that it contributes valid evidence to any contemplated proceeding. The affidavit itself should contain the following:

- Identity of the affiant;
- The reason why the affidavit was taken;
- The pertinent facts in a simple narrative style, arranged in chronological order; and
- A concluding paragraph indicating that the affiant read and understood the statement.

In addition, any corrections made to the final copy must be initialed by the affiant.

- Statements. Similar in most respects to an affidavit except that statements are not taken under oath. Although not having the same weight in court, statements are taken for the same reasons and under the same procedures as an affidavit. Statements can be used to verify data collected during an inspection. For example, a statement may be obtained from a facility representative as to a date of shipment. Review should verify the person's identity and the truth of the statement through a signature or some other written or verbal acknowledgment.
- Printed Matter. This includes any brochures, literature, labeling, or any other printed matter providing information concerning a pesticide or pesticidal device including claims, directions for use, contents data, or promotional information. For pesticides, review of the printed matter directly relates to terms and conditions specified in the registration. Printed matter must be identified by inspector's initials, date of collection, and related sample number.
- Photographs. The documentary value of photographs ranks high as admissible evidence. Clear photographs of a relevant subject, taken in proper light and at proper lens setting provides an objective record of conditions at the time of inspection. Review must ensure that the photographs are clear, objective, and properly identified. The photographs should be identified by location, purpose, date, time, inspector's initials, and related sample number. This information should be recorded on the photographs, or in the inspector's field notebook, or both.

- Drawings and Maps. Schematic drawings, maps, charts, and other graphic records can be useful in supporting violation documentation. They can provide graphic clarification of site location relative to height and size of objects, and other information that, in combination with samples, photographs, and other documentation, can produce an accurate, complete evidence package.

Review should ensure that drawings and maps are simple and free of extraneous details. Basic measurements and compass points should be included to provide a scale for interpretation.

- Mechanical Recording. Records produced by an electronic or mechanical apparatus can be entered as evidence. Review of charts, graphs, and other "hard copy" should ensure relevance and identity. The data collected should be identified by date of collection, inspector's initials, and related sample number.

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#### Further Processing of the ID Jacket—Enforcement Case Review

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Once the ID Jacket has been initially reviewed by the RCDO, further development of the case may be required at Headquarters. If so, the ID Jacket should be sent to the appropriate HQCDO who serves as coordinator for the enforcement case review process. Aspects of the case that may require further processing include:

Product Registration Status. The status of a pesticide (registered or not registered) is determined by the Registration Division after a search of their files. In some instances the Region may also wish to know whether a pesticide registration is suspended or cancelled.

Pesticide or Device Determination. When a suspected pesticide is not registered or is not under a Section 5 experimental use permit, then a determination is made by the appropriate Registration Division official of whether the product is a pesticide. Devices are reviewed to determine if they are pesticidal in nature and if so whether or not they are exempt from EPA regulation.

Labeling Review. Copies of all pesticide labels collected as part of an inspection should be compared with the latest EPA-accepted label for that pesticide and any major discrepancies noted. If the latest accepted label is not present at the Regional Office, it should either be requested from Headquarters or the corresponding ID Jacket should be sent to Headquarters for review. In addition, questionable interpretations of label statements should be classified by the Registration Division before the Regional Office proceeds with any enforcement action.

Scientific Review. If product defects are noted as a result of laboratory tests, the ID Jacket should be sent by the RCDO to Headquarters. A review will be conducted by Registration Division personnel to determine the significance of the discrepancy as it relates to the sample's chemical composition, efficacy, or toxicity.

The Registration Division will enter the registration status and pesticide determination on the Enforcement Case Review Form (EPA Form 8500-7). This form will also include the product's accepted name and the name and address of the registrant. Written comments as to labeling discrepancies and significance of test results are placed on EPA Form 8500-7A. Copies of the above forms are placed by the Registration Division into the appropriate ID Jacket and, along with testimony from the responsible Registration Division official, may serve as evidence in court.

For any violations noted during an enforcement case review, the RCDO should consult the Level of Action Policy section of this manual (Chapter Five) for guidance as to the appropriate enforcement response.

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#### Additional Sources of Documentation

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Frequently, additional information will be needed in order to complete the review of the ID Jacket. In some cases this information will be provided by subsequent reports. If not, the RCDO should seek to obtain the additional information or elaboration from the most knowledgeable source. Additional sources of documentation include:

- Establishment Inspection Report;
- Inspector's Narrative Report; and
- Inspector's Field Notebook.

#### Shipping Documentation

Section 8(b) of FIFRA provides authority to inspect and copy all records showing the delivery, movements, or holding of a pesticide or pesticidal device. This documentation, which is often done as a part of a Section 9 inspection, identifies the responsible party within the stream of commerce who is suspected of a FIFRA violation.

Information that might be obtained from shipping records includes:

- Identity of pesticide or device;
- Quantity sold, received, shipped, or stored;
- Dates sold, received, or shipped;

- Sources of the pesticide or device; and
- Transporter of the pesticide or device.

Records providing this information include:

- Bill of Lading;
- Freight Bill;
- Parcel Post Cancellation Stamp;
- Invoice;
- Packing Slip;
- Purchase Order; and
- Receiving Report.





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## Chapter Four

### 1 Introduction

Upon completion of a Section 9 inspection, pesticide enforcement inspectors are required to organize the documentary evidence gathered during this inspection into a file commonly called the ID (or Sample) Jacket. The ID Jacket file includes all the forms, reports, and documentary evidence secured by the inspector relating to an official pesticide or pesticidal device sample. Once compiled, the file is sent to a Regional Case Development Officer (RCDO) who reviews the inspection results for possible enforcement action.





# 2 Inspection File Review

To ensure the validity and quality of documentary evidence for an administrative or judicial enforcement proceeding, the RCDO must review the evidence for objectivity, adequacy, and proper identification. In some instances the RCDO will need an enforcement case review, which could include the verification of the sample's pesticide registration and labeling status, as well as an interpretation of laboratory test results. In all cases, the RCDO must verify that all procedural safeguards were implemented so as not to prejudice a possible enforcement action.

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### Substantiation of Each Violation

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In most cases, a violation will be substantiated through a combination of evidential sources. The RCDO's review must seek to substantiate each possible violation from the evidence supplied by the inspector. Whenever necessary, the RCDO should obtain from the inspector additional evidence or clarification of existing evidence.

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### Controlled Identification of Each Sample

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An important aspect of any review by the RCDO is the determination that all samples were properly collected and accurately and completely identified.

Whenever a sample is taken, the inspector prepares a Collection Report (EPA Form 3540-7), which describes the sample collection process. Information required for the report includes:

- Type of sample;
- Sample number, subsample number;
- Date of collection;
- Collection method;

- Description of sample (including quantity collected, color, texture, viscosity, etc.);
- Duplicate samples (if provided); and
- Description of procedures for sealing sample.

Each ID Jacket will also be identified by a sample number. The RCDO should check the number to see if it corresponds to the ID number on the Collection Report Form.

All samples that are to be used as evidence should be sealed with the official EPA seal (EPA Form 7500-2). The seal is placed on the sample container by the inspector to help preserve the integrity of the sample.

A written receipt (EPA Form 3540-3) describing the sample obtained by the inspector is issued to the appropriate facility representative whenever a sample is taken. The receipt may also be used to verify that a duplicative sample was given the facility. The ID Jacket may not always include a copy of the receipt. If an enforcement action is considered, a copy may be obtained from the Inspection Report that was filed with the Regional Office.

The two types of samples commonly collected are official and investigational.

Official Samples. These include samples or documents of pesticides or devices that, if violative, serve as a basis for legal action. In general, an RCDO should ensure that an official sample:

- Was collected only from material that had been "packaged, labeled, and released for shipment" (see Glossary);
- Was representative of the lot from which it was obtained; and
- Was identified and officially sealed so as to maintain its continuity and integrity as court evidence.

Official samples include:

- Producer/Marketplace Samples. Actual samples of a pesticide or pesticidal device collected by an inspector at the producer, wholesale, or retail level.
- Documentary Samples. Copies of the label and/or labeling and copies of any records showing shipment of the product and the responsible parties.
- Post-Seizure Samples. Actual samples collected from a lot of merchandise that is in the custody of a U.S. court. A court order must be entered before sampling, and these actions must be carried out in accordance with such orders.

- Induced Samples. Actual samples of pesticides or pesticidal devices that are not obtained by EPA official procedures (e.g., notice of inspection, collection report, etc.). These samples are usually requested by mail. An induced sample is the least desirable method of obtaining a sample and should be used only when the other methods have been exhausted.
- Import Samples. Actual samples of pesticides or pesticidal devices that are offered for importation into the United States from a foreign port. Proper documentation for import shipments should include Customs entry papers, foreign invoices, and records showing movement from the port of entry.
- Use Samples. Actual samples of the pesticide that are collected during a use inspection. This type of sample may be field collected from a formulated pesticide, diluted pesticide, or as a residue from plant material, animal tissue, soil, water, etc.

Investigational Samples. These include samples of pesticides or devices collected for special investigation or information purposes. These samples need not be collected from lots or stocks that have been packaged, labeled, and released for shipment. No legal action can be taken on investigational samples.



### 3 Review of Adequacy of Evidence

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#### Initial Review of the ID Jacket

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Once the RCDO has received the ID Jacket, its contents must be reviewed in the context of the following considerations:

- Adequacy of the documentation (see below);
- Significance of violation (see Chapter Five for Level of Action Policy); and
- Violative history of the firm (see Chapter Five for Level of Action Policy). Violative history may be obtained from the FIFRA and TSCA Enforcement System (FATES).

#### Adequacy of the Documentation

The initial phase of the review will focus on two aspects of the documentation:

- That all necessary documentation and samples have been provided; and
- That the documentation is adequate to prove the substance of the violation as indicated by the results of the inspection.

The purpose of the review is to develop a recommendation for action on the violation; either to proceed with an enforcement action or to dismiss the violation as not worthy of prosecution.

In some instances, review will indicate possible violations not documented by the inspection. In these cases, the RCDO should seek to secure the additional documentation for the new violation. For example, this may require further consultation with the inspector or forwarding the file to Headquarters for an enforcement case review. When a violation is discovered that is unrelated to the initial suspected violation, that new violation should be pursued as a new action.

Contents of the ID Jacket

The ID Jacket should normally contain the following items:

Label of a Pesticide or Device. The label should either be an actual copy (or photocopy) or a typewritten copy. The label should be identified by sample number, date of collection, inspector initials, and, if appropriate, subsample numbers.

Notice of Inspection (EPA Form 3540-2) or Warrant. If an enforcement action is being considered, a copy of the notice of inspection or warrant may be obtained from the Establishment Inspection Report. The notice and/or warrant should be reviewed to ensure the inspection adhered to the terms specified in the documents.

Receipt for Sample. The written receipt should describe the sample and verify that a duplicate sample, if requested, was given to the facility official. The RCDO should verify sample identification numbers.

Collection Report. This is the official report of the sample collection. The following should be verified from the report:

- The ID number appearing on the Collection Report should agree with the number on the ID Jacket. For documentary samples, the notation "DOC" will appear after the ID number; for investigational samples, "INV" will appear after the ID number; for post-seizure samples, "P.S." will appear after the ID number; and import samples will be identified by "Import";
- Date of shipment (from transportation records) of the sample;
- Amount of the product before sampling (the amount on hand must be less than or equal to the amount shipped);
- Descriptions indicating number of samples and method of collection;
- Shipper of sample (from transportation records); and
- Reason for collection--either to document a suspected violation, or as part of a "Market Basket Survey" of products without accompanying documentation.

History of Official Sample (EPA Form 3540-17). This document is placed in the ID Jacket by laboratory personnel once the physical sample has been received by the laboratory for analysis. It shows whether the integrity of the sample has been maintained during its stay at the laboratory. Each time the sample seal is broken and resealed, it must be noted on the form.

It is important for the RCDO to demonstrate that none of the samples involved in the case preparation have been tampered with or contaminated during collection, transit, storage, or analysis. An accurate accounting

must be maintained to trace the possession of each sample from the moment of collection to its introduction as evidence. Accountability can be checked by reviewing the following documents:

- Receipt for sample;
- Collection report; and
- History of official sample.

Laboratory Test Methods. Test methods employed in the analysis of pesticide or pesticidal device samples fall into two categories, official and unofficial.

- Official Test Method. Refers to a test method accepted by a recognized standard-setting organization, such as the Association of Official Analytical Chemists (AOAC) or the American Society for Testing and Materials (ASTM).
- Unofficial Test Method. Refers to a method that has not as yet been accepted as a standard method but is employed by EPA in the analysis of a sample because other reliable test methods are not available.

Extreme care and judgment should be exercised in preparing enforcement cases when unofficial test methods are used as the basis for evidence of a violation of the FIFRA. Consultations with Headquarters Case Development Officers (HQCDOs) are strongly recommended before proceeding with enforcement actions in these cases.

Laboratory Test Results. Test results are placed in the ID Jacket upon completion of the analysis. Tests include:

- Sample Report of Analysis (EPA Form 3540-5), which shows the chemical composition of the sample collected versus composition guaranteed by the registrant. Usually a cross-contamination will be conducted by the laboratory and the percentage of contaminants, if any, noted; and/or
- Efficacy test, which shows the effectiveness of the product.

Other Evidential Documentation. Suspected violations may also be documented by the inspector using the following support methods:

- Affidavit. Sworn statements taken by the inspector relating to personal first-hand knowledge of a potential violation. The affidavit may be used to substantiate the violation or to set the circumstances surrounding the violation. Careful review should be made of the affidavit for evidence in support of an enforcement action. The person making the affidavit must sign it and be able to personally verify the facts contained in the statement.



The object of an affidavit is to obtain a clear and concise written record of factual information relating to a suspected violation. The oath taken by the person making the affidavit serves to substantiate the truth of the statement. Affidavits may be used to verify the dates obtained from a facility's records (e.g., the date of shipment). Review should emphasize the admissibility of the affidavit in court. This includes determining that the affidavit was properly executed and that it contributes valid evidence to any contemplated proceeding. The affidavit itself should contain the following:

- Identity of the affiant;
- The reason why the affidavit was taken;
- The pertinent facts in a simple narrative style, arranged in chronological order; and
- A concluding paragraph indicating that the affiant read and understood the statement.

In addition, any corrections made to the final copy must be initialed by the affiant.

- Statements. Similar in most respects to an affidavit except that statements are not taken under oath. Although not having the same weight in court, statements are taken for the same reasons and under the same procedures as an affidavit. Statements can be used to verify data collected during an inspection. For example, a statement may be obtained from a facility representative as to a date of shipment. Review should verify the person's identity and the truth of the statement through a signature or some other written or verbal acknowledgment.
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- Photographs. The documentary value of photographs ranks high as admissible evidence. Clear photographs of a relevant subject, taken in proper light and at proper lens setting provides an objective record of conditions at the time of inspection. Review must ensure that the photographs are clear, objective, and properly identified. The photographs should be identified by location, purpose, date, time, inspector's initials, and related sample number. This information should be recorded on the photographs, or in the inspector's field notebook, or both.

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#### Further Processing of the ID Jacket—Enforcement Case Review

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Once the ID Jacket has been initially reviewed by the RCDO, further development of the case may be required at Headquarters. If so, the ID Jacket should be sent to the appropriate HQCDO who serves as coordinator for the enforcement case review process. Aspects of the case that may require further processing include:

Product Registration Status. The status of a pesticide (registered or not registered) is determined by the Registration Division after a search of their files. In some instances the Region may also wish to know whether a pesticide registration is suspended or cancelled.

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Labeling Review. Copies of all pesticide labels collected as part of an inspection should be compared with the latest EPA-accepted label for that pesticide and any major discrepancies noted. If the latest accepted label is not present at the Regional Office, it should either be requested from Headquarters or the corresponding ID Jacket should be sent to Headquarters for review. In addition, questionable interpretations of label statements should be classified by the Registration Division before the Regional Office proceeds with any enforcement action.

Scientific Review. If product defects are noted as a result of laboratory tests, the ID Jacket should be sent by the RCDO to Headquarters. A review will be conducted by Registration Division personnel to determine the significance of the discrepancy as it relates to the sample's chemical composition, efficacy, or toxicity.

The Registration Division will enter the registration status and pesticide determination on the Enforcement Case Review Form (EPA Form 8500-7). This form will also include the product's accepted name and the name and address of the registrant. Written comments as to labeling discrepancies and significance of test results are placed on EPA Form 8500-7A. Copies of the above forms are placed by the Registration Division into the appropriate ID Jacket and, along with testimony from the responsible Registration Division official, may serve as evidence in court.

For any violations noted during an enforcement case review, the RCDO should consult the Level of Action Policy section of this manual (Chapter Five) for guidance as to the appropriate enforcement response.

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#### Additional Sources of Documentation

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Frequently, additional information will be needed in order to complete the review of the ID Jacket. In some cases this information will be provided by subsequent reports. If not, the RCDO should seek to obtain the additional information or elaboration from the most knowledgeable source. Additional sources of documentation include:

- Establishment Inspection Report;
- Inspector's Narrative Report; and
- Inspector's Field Notebook.

#### Shipping Documentation

Section 8(b) of FIFRA provides authority to inspect and copy all records showing the delivery, movements, or holding of a pesticide or pesticidal device. This documentation, which is often done as a part of a Section 9 inspection, identifies the responsible party within the stream of commerce who is suspected of a FIFRA violation.

Information that might be obtained from shipping records includes:

- Identity of pesticide or device;
- Quantity sold, received, shipped, or stored;
- Dates sold, received, or shipped;

- Sources of the pesticide or device; and
- Transporter of the pesticide or device.

Records providing this information include:

- Bill of Lading;
- Freight Bill;
- Parcel Post Cancellation Stamp;
- Invoice;
- Packing Slip;
- Purchase Order; and
- Receiving Report.



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# Chapter Five

## Determination of Appropriate Enforcement Response

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# 1 Introduction

Once the documentation of a violation is complete and EPA personnel have determined that an enforcement action is warranted, EPA must decide upon the appropriate level of action called for by the severity of the violation. There are two categories of action—administrative and judicial. Generally, the Agency uses administrative actions for violations of a lesser nature, for first-time violators, or to obtain relief on short notice, as in the case of stop sale, use, and removal orders. The Agency reserves judicial actions for use in violations of an especially egregious nature that result in serious harm to human health or the environment, and for willful or repeated violations.

Administrative levels of action include the following:

- Advertising letters;
- Notices of detention under Section 17(c);
- Notices of warning under Sections 9(c)(3) and 14(a)(2);
- ~~Terminations of establishment registrations under 40 C.F.R. §167.3;~~
- Denials, suspensions, modifications, or revocations of applicator certifications under 40 C.F.R. §171.11;
- Recall requests;
- Stop sale, use, or removal orders under Section 13(a); and
- ~~Civil administrative penalties under Section 14(a).~~

The criteria for the use of each of the above levels of action are discussed later in this chapter. Specific procedures for preparing and issuing these actions are found in Chapter Six, "Administrative Enforcement Actions: Notices of Violation and Administrative Orders," and Chapter Seven, "Administrative Enforcement Actions: Civil Penalty Proceedings."



Judicial actions may involve either civil or criminal proceedings. Civil proceedings include:

- Injunctions under Section 16(c); and
- Seizures under Section 13(b).

Criminal proceedings are authorized under Section 14(b). The criteria for the use of judicial actions are also found later in this chapter. Chapter Eight, "Judicial Enforcement: Civil Actions," and Chapter Nine, "Judicial Enforcement: Criminal Actions," discuss procedures for civil and criminal judicial proceedings.

In addition, Exhibit 5-1 contains level of action guidance applicable to efficacy standards for hospital or medical use disinfectants and rodenticides.

## 2 Level of Action Policy

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### Advertising Letters

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An advertising letter is a letter issued by EPA as notice to a company that collateral literature concerning a product (i.e., literature or advertising that does not accompany the product) bears unaccepted pesticide statements or pesticide or device claims. An advertising letter may be issued by the Agency upon receipt of or knowledge of such literature and without EPA having in its possession an official sample of the pesticide or device accompanied by the literature. An advertising letter should identify:

- The literature; and
- The unaccepted statements (if related to a registered product), the pesticide claims (if related to an unregistered pesticide), or the device claims (if related to a device).

In addition, the advertising letter should request a written response from the recipient informing the Agency of whatever action the company plans to take in response to the concerns expressed by EPA. The Agency will take no further action\* (even when the company fails to respond to the letter) until and unless EPA collects an official product sample with the offending literature. At that time, EPA may issue a notice of warning or civil complaint, as warranted by the circumstances.

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\* The Agency may, however, refer a case of unacceptable advertising to the Federal Trade Commission for action.

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Notices of Detention

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Section 17 of FIFRA authorizes EPA to refuse admission of a pesticide or device being imported into the United States if EPA determines that such pesticide or device violates any provisions of the Act. This refusal is known as a Notice of Detention and Hearing. Upon receiving a copy of the notice, the Department of the Treasury, through the Customs Service, will refuse delivery to the consignee and will oversee destruction of any pesticide or device refused delivery that is not exported by the consignee within 90 days from the date of the notice. However, under the Customs regulations for the enforcement of Section 17(c) of FIFRA, the District Director of Customs may release a shipment to the importer or the importer's agent before an EPA inspection of the shipment. Such a release occurs only upon execution of a bond in the amount of the value of the pesticide or device, plus duty. Should the shipment subsequently be refused entry and the importer or agent fails to return the pesticide or device, the bond is forfeited. A shipment released to the importer cannot be used or otherwise disposed of until EPA makes a determination of the admissibility of that shipment.

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Notices of Warning

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Section 14(a)(2) Notices of Warning

Section 14(a)(2) of FIFRA requires EPA to use a notice of warning in response to the first civil offense committed by a private applicator or other person not covered under Section 14(a)(1). Section 14(a)(1) covers registrants, commercial applicators, "for hire" applicators, wholesalers, dealers, retailers, and other distributors. "For hire" applicators are applicators who apply general use pesticides as a service in controlling pests but who do not deliver any unapplied pesticides.

Section 9(c)(3) Notices of Warning

Since the Agency is attempting to concentrate its pesticides enforcement resources on serious violations and repeat offenders, EPA may also issue notices of warning under Section 9(c)(3) of FIFRA in response to first-time violations committed by those persons covered by Section 14(a)(1), with the following exceptions:

- The Agency should pursue a remedy more severe than a warning in response to first offenses that result in (1) a real risk to humans or the environment or (2) any actual harm stemming from the violator's failure to exercise due care (i.e., the degree of care a reasonably prudent person would exercise in similar circumstances); and

- The Agency should apply a remedy other than a notice of warning in the case of a violation by a person who has already been placed on notice of the existence of FIFRA or its requirements. (EPA will consider a person to have been placed on notice if that person has been subject to a formal inspection by EPA personnel or has interacted with the Agency by obtaining a product registration, an establishment registration, or any other similar license, permit, or certification.)

The Agency, in its discretion, may decide to issue a Section 9(c)(3) warning notice against persons included in the latter exception or against a repeat violator whose second violation is an extremely minor one, if EPA enforcement officials believe that justice will be served by employing such a remedy.

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#### Termination of Establishment Registration

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The regulations related to the registration of pesticide-producing establishments (40 C.F.R. §167.3) state that an establishment registration will remain in effect so long as the establishment continues to submit annual pesticides reports. If the establishment fails to submit a report in any year, the Agency may issue either a notice of warning or a civil penalty, based on the provisions of FIFRA Sections 7(c)(1) and 12(a)(2)(L).<sup>\*</sup> A notice of warning would be the typical action for a newly registered establishment that failed to submit its initial pesticides report. The Agency should initiate a civil penalty in response to the failure to file a pesticides report on the part of an establishment that previously filed at least one annual report and is thus on notice as to its continuing responsibility to submit annual reports. If the establishment does not submit an annual pesticides report within 20 days after the date of receipt of the notice of warning or civil penalty, EPA will initiate procedures to terminate the establishment registration, independent of the other action.

#### Non-Enforcement Termination

Termination of establishment registration may also occur upon request of the establishment or parent company, typically because the establishment has gone or will go out of business, no longer produces pesticides, or otherwise no longer falls under the purview of FIFRA Section 7. In such cases the procedures for terminating establishment registration are

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- Newly registered establishments must submit reports within 30 days of notification of establishment registration; subsequent reports are due by February 1 of each year. The Agency may, however, grant discretionary extensions of up to 30 days for filing a report before the report is considered delinquent.

strictly technical and are based on the operating procedures of the FIFRA and TSCA Enforcement System (FATES). Termination of establishment registration in such situations should not be confused with termination for cause.

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#### Denials, Suspensions, Modifications, or Revocations of Applicator Certifications

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The regulations relating to the certification of pesticide applicators (40 C.F.R. Part 171) authorize EPA to deny, suspend, modify, or revoke federally issued applicator certifications if the certificate holder violates FIFRA or its regulations. The Agency views an enforcement action affecting certification status as a very strong measure, to be taken only when the "public health, interest or welfare warrants immediate action" [40 C.F.R. §171.11 (f)(5)(i)]. Therefore, EPA will deny, suspend, modify, or revoke a certification only in response to serious violations or against persons with a history of noncompliance. The Agency may take any of these actions if it determines that an applicant for or holder of a certification has:

- Been convicted under Section 14(b) of FIFRA;
- Been subject to a final order imposing a civil penalty under Section 14(a);
- Misused a pesticide;
- Made available for use, or used, a registered pesticide classified for restricted use other than in accordance with Section 3(d);
- Refused to keep and maintain records required by 40 C.F.R. Part 171;
- Made false or fraudulent records, invoices, or reports;
- Failed to comply with any limitations or restrictions on or in a previously issued certificate; or
- Violated any other provision of FIFRA or its regulations.

#### Denial/Revocations

The denial or revocation of a certification not only deprives an applicator of the authority to apply restricted use pesticides but also, as compared to suspension of a certification, forces the applicator to take additional steps to acquire or re-acquire certification. In addition, the Agency will not consider an application to acquire or re-acquire certification for a period of not less than six months following denial or revocation. Thus EPA will deny or revoke a certification only where a violation has resulted

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in a fatality or created an imminent danger of a fatality, where the violator's certification has been suspended as a result of a previous violation, or where a person has made fraudulent records or reports.

### Suspensions

When considering invoking the less severe alternative of suspending a certification, EPA personnel must determine whether it is appropriate to pursue a suspension and for how long such suspension should be in effect. These determinations will depend upon the gravity of the violation in question.

Suspension (Misuse Violation). In suspending a certification due to an incident of misuse, EPA will refer to criteria for assessing the gravity of a use violation (see Exhibit 5-2). The gravity of a use violation is a function of:

- The risk of harm posed to human health and the environment by the violation; and
- The degree of misconduct exhibited by the violator.

The Agency will assign weightings, based on the gravity criteria, for each use violation relative to the pesticide involved, the harm to human health and/or to the environment, the history of noncompliance, and the culpability of the violator. (For purposes of this section of the manual, EPA will not distinguish between commercial and private applicators. Consideration of applicator status is inherent in the policy in that suspensions have a more substantial impact on commercial applicators, affecting their primary business activity.) The Agency will use the gravity value thus obtained to decide whether and for how long to suspend a certification, in accordance with the following table:

Total Gravity Value	Enforcement Remedy
4 or below	No action or Notice of Warning
5 to 8	Suspension of up to 2 months
9 to 12	Suspension of between 2 and 4 months
13 or above	Suspension of between 4 and 6 months

To determine whether the term of a suspension should be at the higher or lower end of the given ranges, EPA will consider any gravity-related factors not accounted for in the gravity criteria. In addition, EPA will consider the degree to which the suspension will have an adverse economic impact on the applicator. Applicators who would be minimally affected by a suspension, such as those who apply restricted use pesticides infrequently, should receive longer suspensions than applicators whose day-to-day

business activities would be severely disrupted by the loss of their certifications.

Suspensions should generally be pursued against individual applicators in lieu of a Section 14(a) civil administrative penalty. This, however, does not preclude EPA from issuing both a suspension as well as issuing a warning letter or from assessing a civil penalty against the employer of the applicator in addition to suspending the certification of the applicator.

Suspension (Recordkeeping Violation). EPA may also suspend certifications of commercial applicators who violate restricted use pesticides recordkeeping requirements [see 40 C.F.R. §171.11(c)(7); 40 C.F.R. §171.11(f)(1)(iii)]. These violations do not lend themselves to analysis utilizing gravity of harm criteria. Consequently, EPA will suspend the certifications of persons who fail to maintain restricted use pesticides records based solely on gravity of misconduct considerations. The Agency will assess suspensions of up to two months for the second independent violation resulting from the failure to maintain restricted use pesticides records. For each additional violation, two months may be added to the term of the suspension up to a limit of six months. In cases where the violation involved keeping fraudulent records (i.e., where the violator intentionally concealed or misrepresented the true circumstances and the extent of the use of restricted use pesticides), EPA may revoke the violator's certification in response to the initial infraction.

If EPA decides to suspend certification, it must notify the applicator of the time period during which the suspension will be in effect. In order for the suspension to function as a deterrent, the suspension should take effect during the time when the applicator is most likely to be applying restricted use pesticides.

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### Recall Requests

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No explicit authority exists in FIFRA for the recall of products. The effectiveness of a recall action, therefore, is contingent on the cooperation of the involved company.

Recalls should be initiated by EPA in all cases where available information indicates that the product is either potentially hazardous when used as directed or ineffective for the purposes claimed. The Agency should consider a recall of a product when, among other things, its use as directed is likely to result in:

- Injury to the user or handler of the product;
- Injury to domestic animals, fish, wildlife, or plant life;

- Physical or economic injury because of ineffectiveness or due to the presence of actionable residues; or
- Identifiable adverse effect on the environment.

EPA personnel must view a request for recall as a serious and extraordinary matter and must make a request for recall of a product only in those cases where the evidence clearly supports such action. The initial decision that a product should be withdrawn from the market will be based on information in the sample file including laboratory analyses, staff evaluations and opinions, and such other information as may be available and relevant. All information supporting a recall decision must be included in the official file.

#### Formal and Informal Recalls

There are two types of recalls—formal and informal. Formal recalls are used for more serious problems when it is essential that EPA regional personnel follow up the recall with a visit to the company. Formal recall involves EPA monitoring, detailed reporting by the company involved, and notification to State officials. This type of recall is normally accompanied by another enforcement action, generally a civil penalty.

The Agency uses informal recalls in cases where a recall is necessary but the level of potential hazard is not great or when it is unlikely that significant amounts of the defective product remain in the marketplace. An informal recall is conducted entirely by the company involved with no monitoring by EPA or State officials.

#### Level of Recall Determination

The level of recall is 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 following recall levels should be considered:

- Wholesale or First Point of Distribution. This will normally include all informal recalls and those formal recalls in which the product distribution is limited and consequently the potential danger is low.
- Retail Level. This will be the normal level for most formal recalls.
- User Level. This level will be requested only in cases in which there is a known serious hazard to human health or the environment.



### Scope of the Recall

EPA must also consider the scope of the recall (i.e., the amount of the product that the recall will cover). In the case of labeling violations, the recall should include all of the product bearing the unacceptable labeling. For chemical violations, the recall should include all of the product bearing the same batch code(s) as the sample(s) found in violation. If the product is uncoded, EPA will determine the scope of the recall after contacting the responsible company. After reviewing the firm's manufacturing and shipping records, EPA personnel should be able to determine a range of manufacturing dates to include in the recall.

The recall of a defective product by the manufacturer or distributor is the most effective and efficient means of removing such a product from the market. However, since it is strictly voluntary, the success of the recall program depends on the industry's knowledge that:

- EPA will make a recall request only in those cases where there is a likelihood of physical or economic injury from the use of a product according to label directions;
- The Agency will use all legal means available to it to support or supplement any recall request, including stop sale, use, or removal orders, seizures, and civil penalties; and
- State officials will cooperate with the Agency in the removal of such products.

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### Stop Sale, Use, or Removal Orders

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A stop sale, use, or removal order (SSURO) should be issued by EPA if the violation is of an ongoing nature and threatens to cause serious or widespread harm. This remedy is not designed to prevent future violations, but rather is intended to limit the amount of harm that might result from a violation. In order to preserve the hearing rights of the recipient of an SSURO, EPA should supplement the order with a civil penalty assessment.

An SSURO is among the most expedient and effective remedies available to EPA in its efforts to prevent illegal sale, distribution, and use of pesticides. Its advantages over other actions (such as seizures) are that:

- It may be issued without prior adjudication of the violative character of the product (i.e., EPA may issue an SSURO simply when it has reason to believe that the product is in violation of the Act);
- It is easier to prepare and issue than a seizure;

- It can be written so as to include future amounts of the product that may come into the custody of the person on whom the SSURO is served; and
- It can be easily adapted to particular circumstances.

#### Criteria for Use

The language of Section 13(a) confers broad authority upon EPA to issue SSUROs. The Agency may issue an SSURO when any one of three situations exists:

- If, upon inspection or testing, EPA believes a product is in violation of the Act;
- If EPA believes that a product has been or is intended to be distributed or sold in violation of the Act; or
- If EPA has cancelled or suspended the registration of a product.

An SSURO is ordinarily issued by EPA without prior notice to the person served. Because an order is issued without notice, the actual or potential danger to human health or the environment posed by the violative product or situation must be both serious and imminent. In addition, the danger must require such urgent relief that there is no time to seek other remedies or that other administrative remedies would be inappropriate. Accordingly, EPA officials must observe stringent guidelines in determining whether issuance of an SSURO is appropriate, as outlined below.

Mandatory Issuance of an SSURO. The Agency must issue an SSURO against persons who own, control, or have custody of pesticides in the following categories:

- Pesticides whose registrations have been cancelled or suspended by EPA, except cases in which the Agency has permitted the use of existing stocks, or where continued marketing presents no human health or environmental hazard;
- Pesticides for which there is reason to believe present a potential hazard to man or the environment because:
  - They are not registered, or are so grossly overformulated or adulterated, as to present a serious health hazard, or
  - They are packaged in improper or damaged containers, or are so inadequately labeled, as to make safe or effective use unlikely or impossible;

- Pesticides or devices with labeling that is materially misleading or fraudulent and, if observed by a user, is likely to cause a life-endangering health hazard or serious adverse environmental condition. (A pesticide lacking a restricted use label is an especially serious labeling violation.) This provision includes labeling for products that:
  - Are ineffective for the purposes claimed,
  - Are so chemically deficient as to affect deleteriously the product's efficacy, as determined by laboratory test results, or
  - Bear false or misleading safety claims;
- Pesticides or hazardous devices\* that are in violation of the Act and are the subject of a voluntary recall, but which the responsible party refuses to remove, is recalcitrant in removing, or is unable to remove from channels of trade; and
- Pesticides or hazardous devices that are in violation of the Act and for which a civil penalty has been issued but which have not been brought into compliance.

Discretionary Issuance of an SSURO. EPA may exercise its discretion in issuing an SSURO in cases where a product either is in violation of the Act or is intended to be distributed or sold in violation of the Act, and the gravity of the violation is less than that required for issuance of a mandatory SSURO. In addition to an analysis of the relative severity of the violation (or lack thereof), the following factors should be considered:

- Whether the violation is another in a series of violations by the producer or distributor. In cases of recidivism, of uncorrected violations previously brought to the individual's attention, or of repeated negligent conduct, an SSURO may be appropriate where other enforcement remedies have failed to bring about corrective action or where it is deemed necessary to prevent continued marketing of the violative product;
- Whether the violation is easily corrected. If it appears that the individual is cooperative and can easily remedy the violation, an SSURO may be unnecessary; and

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\* A hazardous device is one presenting a direct threat to human health or the environment by its use (e.g., a water treatment device whose labeling makes false, misleading, or fraudulent claims to purify raw well water or other untreated water supplies). For nonhazardous devices (e.g., an electromagnetic rodent repelling device) that are misbranded, Agency policy is to complete civil penalty proceedings before issuing an SSURO. See December 19, 1979 Memorandum: "Enforcement Actions Concerning Nonhazardous Pesticide Devices."

- Who has custody of the product. An SSURO may be more appropriate, and a violation more immediately cured, if the violative product is found at the producer level rather than at the retail level.

In all other cases, EPA should consider an alternative enforcement remedy available under FIFRA.

#### Use of SSURO for Minor Violations

While EPA will usually reserve the use of an SSURO to relatively serious violations, the need to issue an SSURO may arise in certain cases involving minor violations. For example, in the face of continued and repeated minor violations, or when several minor violations appear together on a label, EPA may decide to issue an SSURO to ensure that the product will be distributed only in compliance with the Act.

#### Alternative Approaches

Even in cases where the existence of a serious violation would justify the issuance of an SSURO, the Agency may consider the use of alternative approaches to achieve compliance. For example, certain pesticide labeling violations can be rectified through a voluntary recall by the manufacturer, and this may be the most expeditious way to prevent any harm to human health or the environment. Thus, in certain cases that could legitimately call for the issuance of an SSURO, particularly those concerned with labeling violations, EPA might first consider contacting the appropriate responsible party and negotiating a voluntary recall.

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#### Civil Administrative Penalties

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A civil penalty, as authorized by Section 14(a) of FIFRA, is the remedy of choice for most violations. A civil penalty should be proposed where the violation presents (a real but not an extreme and unreasonable) risk to humans or the environment; is likely to be an isolated occurrence; was apparently committed as a result of ordinary negligence, inadvertence, or mistake; and either:

- Involves a first offense under the Act by any registrant, commercial applicator, "for hire" applicator, wholesaler, dealer, retailer, or other distributor (no prior warning is required by FIFRA for violators in this category); or
- Involves a private applicator or other person, other than any party specified in the first category, who has received a prior warning or citation for a violation of FIFRA. (The prior warning or citation may have been for the same or a different FIFRA violation.)

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## Injunctions

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Section 16(c) of FIFRA gives EPA the authority to initiate injunctive actions before district courts.\* Because an injunction is an extraordinary form of relief, the Agency's arguments must be clear and compelling. In initiating a permanent injunction action, EPA must indicate to the court that:

- The Agency's administrative or other judicial enforcement remedies would be inadequate either at restraining the violation or at preventing unreasonable risk to human health or the environment;
- The Agency has, in fact, already diligently exercised all appropriate administrative remedies (such as SSUROs and civil penalties), yet the violation continues unabated; and
- Irreparable injury, loss, or damage will result if relief is not granted.

In the case of a preliminary injunction or temporary restraining order, the Agency must additionally demonstrate that:

- Immediate and irreparable injury, loss, or damage will result if relief is not granted; and
- There is a likelihood of success at trial, based on facts before the court.

Under FIFRA, there are a number of specific circumstances that may justify injunctive relief. These include but are not limited to:

- The violation of a Section 6 suspension order;
- The violation of an SSURO where a civil penalty or criminal prosecution would not provide a timely or effective remedy to deter further violations;
- There is continued production, shipment, sale, or use of an unregistered pesticide after the Agency has taken civil or criminal action; and

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\* These actions may consist of permanent injunctions, preliminary injunctions, or temporary restraining orders. These types of injunctions are discussed in more detail in Section 4 of Chapter Eight.

- The Agency has exercised an enforcement remedy and a person continues to make available for use a restricted use pesticide other than in accordance with FIFRA Section 3(d), or continues to use a pesticide in a manner inconsistent with its labeling or in a manner contrary to an experimental use permit.

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### Seizures

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Section 13(b) of FIFRA gives EPA the authority to initiate in rem condemnation proceedings in district court. Once a court grants the Agency's request for authority to conduct a seizure, FIFRA Section 9(b) authorizes duly designated Agency employees to obtain and execute warrants for the purpose of seizing any pesticide or device that is in violation of the Act.

Since seizures are judicial actions directed against violative products rather than against individuals, EPA may initiate actions in court against:

- A pesticide that is adulterated, misbranded, unregistered, not colored or discolored as required, or bears claims or directions for use that differ from those made in connection with its registration;
- A device that is misbranded; or
- A pesticide or device that causes unreasonable adverse effects upon the environment, even when used in accordance with requirements imposed by the Act.

The above examples are similar to those that would lead the Agency to initiate an SSURO. Because an SSURO can be effected in less time and with less preparation than that required for a seizure, it is the preferred remedy in terms of expediency. Nevertheless, the Agency should consider initiating a seizure in the following circumstances:

- The Agency has issued an SSURO, but the recipient of the order has not complied with it;
- The Agency has reason to believe that a person, if issued an SSURO, will not comply with it;
- There exists a pesticide so hazardous that it should be removed from the marketplace or place of use;
- The seizure will be used to support a recall; or
- It is necessary to dispose of products being held under an SSURO for which the responsible party has taken no corrective action and has expressed an intent not to take corrective action.

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Criminal Proceedings

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Section 14(b) of FIFRA provides EPA with the authority to proceed with criminal sanctions against violators of the Act, subject to the following distinctions:

- A registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$25,000, or imprisonment for not more than one year, or both.
- A private applicator or other person not included above who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$1,000, or imprisonment for not more than 30 days, or both.

The Agency may initiate criminal proceedings in every case in which EPA can meet the stringent requirements of evidence and proof leading to a conviction. However, Agency policy, as well as pragmatic resource considerations, argues against the use of criminal sanctions in any but the most serious instances of environmental misconduct, as determined by the nature of the violation, the history of compliance on the part of the responsible person, or the seriousness of the environmental consequences.

Considerations

There are a number of specific factors that the Agency must carefully consider before proceeding with a criminal prosecution. (Chapter Nine, "Judicial Enforcement: Criminal Actions," addresses these considerations in much greater detail.)

Knowledge. The Agency must determine that the violator in question knowingly violated the statute. That is, there must be evidence of intent in the commission of the violative act, rather than it merely being the result of accident or mistake.

Seriousness. Criminal actions should be considered for the most serious types of environmental misconduct. This consideration will be judged by reviewing the extent of environmental harm or human health hazard that resulted from, or was threatened by, the prohibited conduct. Factors such as the duration of the conduct and the toxicity of the pollutants are considered. Also of significance in assessing the seriousness of the conduct is the impact—real or potential—upon EPA's regulatory function.

Deterrence. The Agency must consider the importance of and need for deterrence of criminal conduct, either on the part of a specific person, or on the part of the larger community. In the case of a serious and willful violation, the interests of deterrence may well best be served by the imposition of criminal sanctions.

Compliance History. The compliance history of the person who is the subject of possible criminal proceedings will enter into the Agency's deliberations. While a history of noncompliance is not requisite for pursuing criminal sanctions, certainly criminal prosecution becomes more appropriate when a history of noncompliance exists.

Simultaneous Actions. The Agency may consider whether there is a need for criminal enforcement proceedings contemporaneous with a civil or administrative enforcement action, or whether one type of action alone will serve the situation in question. While simultaneous proceedings are permissible, and there may be very compelling reasons for pursuing both, the legal and practical difficulties inherent in so doing argue against such an approach except in the most extraordinary circumstances.

#### Use of Criminal Proceedings

The Agency has identified a number of specific situations that may be considered of such a serious nature that criminal prosecution is particularly appropriate. To list these situations, however, should not be viewed as precluding criminal prosecution in circumstances not included below:

- Failure to report information on the unreasonable adverse effects of a registered pesticide;
- Falsification of records;
- Violation of an order suspending or cancelling a product registration;
- Violation of an SSURO;
- Unlawful uses of pesticides; and
- Illegal distribution of unregistered pesticides.



**Efficacy Standards and Level of Action Guidance  
for Disinfectants and Rodenticides**

Efficacy standards have been developed and are being utilized by the Agency for hospital or medical use disinfectant products and rodenticides. The efficacy standards and level of action guidance for these two types of pesticides are summarized below. However, for the complete disinfectants laboratory testing procedures and level of action guidance, refer to December 17, 1980 Memorandum: "Regulation of Public Health Related Disinfectant Products." Additionally, for both disinfectants and rodenticides, consult the civil penalty matrix in Appendix 6 for the appropriate civil penalty calculations.

**Disinfectants**

Only hospital or medical use products that make claims for Salmonella choleraesius, Staphylococcus aureus, or Pseudomonas aeruginosa\* are tested.

**Level I Testing**

In Level I testing, 60 carriers must be tested against each of the above organisms with each of three samples, representing three different batches. This amounts to 180 carriers per sample; a total of 540 carriers.

• **Disinfectant Sample(s)**

**Performance Standard:** A sample is determined to fail efficacy testing if organisms on 2 or more of the 60 carriers are not destroyed.

**Level of Action:** For each sample that fails the above standard, an SSURO is issued on the batch from which the sample was collected and a civil penalty is issued for failure of the batch to meet the efficacy requirements.

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\* Failure of a product to destroy Pseudomonas aeruginosa is considered equal to failure of a product to destroy Staphylococcus aureus or Salmonella choleraesius.

- Disinfectant Product(s)

Performance Standard: A product provisionally fails efficacy testing if two or more of the three samples fail to destroy any test organism.

Level of Action: Level II testing is initiated for each product that fails the above standard.

### Level II Testing

If a product fails Level I testing, five additional samples representing five different batches are collected for testing at Level II. Sixty carriers are tested for each organism that the product fails to destroy in Level I.

- Disinfectant Sample(s)

Performance Standard: A sample is determined to fail efficacy requirements if organisms on 2 or more of the 60 carriers are not destroyed.

Level of Action: For each sample that fails the above standards, an SSURO is issued on the batch from which the sample was collected, and a civil penalty is issued for failure of the batch to meet the efficacy requirements.

- Disinfectant Product(s)

Performance Standard: A product is determined to fail efficacy testing if three or more of the five samples fail to destroy any organism.\*

Level of Action: Initiation of cancellation proceedings.

### Rodenticides

Both single dose (acute) and multiple dose rodenticides that make claims for commensal rodents are tested for efficacy.

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\* Level II product failures are based on the upper bounds of the 95 percent confidence level. Consequently, a sample must fail 5 out of 60 carriers (not 2 out of 60 as in Level I tests) to count as a failure.

- Acute or Single Dose

Performance Standard: The minimum standard is 90 percent rodent mortality after eight days of testing for the product to be effective in commensal rodent control.

Level of Action: A civil penalty is issued for failure of the batch to meet the above efficacy requirements.

- Multiple Dose

- Cereal or water baits

Performance Standard: The minimum standard is 33 1/3 percent bait acceptance and 90 percent mortality in order for the product to be considered effective in a commensal rodent population.

Level of Action: A civil penalty is issued for failure of the batch to meet the above efficacy requirements.

- Paraffin blocks

Performance Standard: The minimum standard is 25 percent bait acceptance and 80 percent mortality in order for the product to be considered effective in a commensal rodent population.

Level of Action: A civil penalty is issued for failure of the batch to meet the above efficacy requirements.

**Criteria for Determining the Gravity of a Use Violation  
for Purposes of a Certification Action**

Violation	Weighting	Activity
<b>GRAVITY OF HARM</b>		
Pesticide	2	Toxicity—Category I pesticides, restricted use pesticides, or pesticides that are associated with chronic health effects (mutagenicity, oncogenicity, teratogenicity, etc.)
	1	Toxicity—Categories II through IV, no known chronic effects
Harm to Human Health	5	Serious or widespread actual harm to human health
	3	Serious or widespread potential harm to human health
	1	Minor potential or actual harm to human health, neither serious nor widespread
Environmental Harm	5	Substantial or widespread actual harm to the environment (e.g., crops, water, livestock, wildlife, wilderness, or other sensitive natural areas)
	3	Substantial or widespread potential harm to the environment
	1	Minor potential or actual harm to the environment, neither widespread nor substantial

Violation	Weighting	Activity
GRAVITY OF MISCONDUCT		
Noncompliance History	4	More than one prior violation of FIFRA by the applicator
	2	One prior violation
	0	No prior violations
Culpability	4	Knowing or willful violation
	2	Violation resulting from negligence
	0	Violation was neither knowing nor willful and did not result from negligence; good faith efforts made to comply with the law

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# Chapter Five

## Determination of Appropriate Enforcement Response

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# 1 Introduction

Once the documentation of a violation is complete and EPA personnel have determined that an enforcement action is warranted, EPA must decide upon the appropriate level of action called for by the severity of the violation. There are two categories of action—administrative and judicial. Generally, the Agency uses administrative actions for violations of a lesser nature, for first-time violators, or to obtain relief on short notice, as in the case of stop sale, use, and removal orders. The Agency reserves judicial actions for use in violations of an especially egregious nature that result in serious harm to human health or the environment, and for willful or repeated violations.

Administrative levels of action include the following:

- Advertising letters;
- Notices of detention under Section 17(c);
- Notices of warning under Sections 9(c)(3) and 14(a)(2);
- ~~Terminations of establishment registrations~~ under 40 C.F.R. §167.3;
- Denials, suspensions, modifications, or revocations of applicator certifications under 40 C.F.R. §171.11;
- Recall requests;
- Stop sale, use, or removal orders under Section 13(a); and
- ~~Civil administrative penalties~~ under Section 14(a).

The criteria for the use of each of the above levels of action are discussed later in this chapter. Specific procedures for preparing and issuing these actions are found in Chapter Six, "Administrative Enforcement Actions: Notices of Violation and Administrative Orders," and Chapter Seven, "Administrative Enforcement Actions: Civil Penalty Proceedings."



Judicial actions may involve either civil or criminal proceedings. Civil proceedings include:

- Injunctions under Section 16(c); and
- Seizures under Section 13(b).

Criminal proceedings are authorized under Section 14(b). The criteria for the use of judicial actions are also found later in this chapter. Chapter Eight, "Judicial Enforcement: Civil Actions," and Chapter Nine, "Judicial Enforcement: Criminal Actions," discuss procedures for civil and criminal judicial proceedings.

In addition, Exhibit 5-1 contains level of action guidance applicable to efficacy standards for hospital or medical use disinfectants and rodenticides.

## 2 Level of Action Policy

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### Advertising Letters

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An advertising letter is a letter issued by EPA as notice to a company that collateral literature concerning a product (i.e., literature or advertising that does not accompany the product) bears unaccepted pesticide statements or pesticide or device claims. An advertising letter may be issued by the Agency upon receipt of or knowledge of such literature and without EPA having in its possession an official sample of the pesticide or device accompanied by the literature. An advertising letter should identify:

- The literature; and
- The unaccepted statements (if related to a registered product), the pesticide claims (if related to an unregistered pesticide), or the device claims (if related to a device).

In addition, the advertising letter should request a written response from the recipient informing the Agency of whatever action the company plans to take in response to the concerns expressed by EPA. The Agency will take no further action\* (even when the company fails to respond to the letter) until and unless EPA collects an official product sample with the offending literature. At that time, EPA may issue a notice of warning or civil complaint, as warranted by the circumstances.

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\* The Agency may, however, refer a case of unacceptable advertising to the Federal Trade Commission for action.

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Notices of Detention

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Section 17 of FIFRA authorizes EPA to refuse admission of a pesticide or device being imported into the United States if EPA determines that such pesticide or device violates any provisions of the Act. This refusal is known as a Notice of Detention and Hearing. Upon receiving a copy of the notice, the Department of the Treasury, through the Customs Service, will refuse delivery to the consignee and will oversee destruction of any pesticide or device refused delivery that is not exported by the consignee within 90 days from the date of the notice. However, under the Customs regulations for the enforcement of Section 17(c) of FIFRA, the District Director of Customs may release a shipment to the importer or the importer's agent before an EPA inspection of the shipment. Such a release occurs only upon execution of a bond in the amount of the value of the pesticide or device, plus duty. Should the shipment subsequently be refused entry and the importer or agent fails to return the pesticide or device, the bond is forfeited. A shipment released to the importer cannot be used or otherwise disposed of until EPA makes a determination of the admissibility of that shipment.

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Notices of Warning

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Section 14(a)(2) Notices of Warning

Section 14(a)(2) of FIFRA requires EPA to use a notice of warning in response to the first civil offense committed by a private applicator or other person not covered under Section 14(a)(1). Section 14(a)(1) covers registrants, commercial applicators, "for hire" applicators, wholesalers, dealers, retailers, and other distributors. "For hire" applicators are applicators who apply general use pesticides as a service in controlling pests but who do not deliver any unapplied pesticides.

Section 9(c)(3) Notices of Warning

Since the Agency is attempting to concentrate its pesticides enforcement resources on serious violations and repeat offenders, EPA may also issue notices of warning under Section 9(c)(3) of FIFRA in response to first-time violations committed by those persons covered by Section 14(a)(1), with the following exceptions:

- The Agency should pursue a remedy more severe than a warning in response to first offenses that result in (1) a real risk to humans or the environment or (2) any actual harm stemming from the violator's failure to exercise due care (i.e., the degree of care a reasonably prudent person would exercise in similar circumstances); and

- The Agency should apply a remedy other than a notice of warning in the case of a violation by a person who has already been placed on notice of the existence of FIFRA or its requirements. (EPA will consider a person to have been placed on notice if that person has been subject to a formal inspection by EPA personnel or has interacted with the Agency by obtaining a product registration, an establishment registration, or any other similar license, permit, or certification.)

The Agency, in its discretion, may decide to issue a Section 9(c)(3) warning notice against persons included in the latter exception or against a repeat violator whose second violation is an extremely minor one, if EPA enforcement officials believe that justice will be served by employing such a remedy.

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#### Termination of Establishment Registration

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The regulations related to the registration of pesticide-producing establishments (40 C.F.R. §167.3) state that an establishment registration will remain in effect so long as the establishment continues to submit annual pesticides reports. If the establishment fails to submit a report in any year, the Agency may issue either a notice of warning or a civil penalty, based on the provisions of FIFRA Sections 7(c)(1) and 12(a)(2)(L).<sup>\*</sup> A notice of warning would be the typical action for a newly registered establishment that failed to submit its initial pesticides report. The Agency should initiate a civil penalty in response to the failure to file a pesticides report on the part of an establishment that previously filed at least one annual report and is thus on notice as to its continuing responsibility to submit annual reports. If the establishment does not submit an annual pesticides report within 20 days after the date of receipt of the notice of warning or civil penalty, EPA will initiate procedures to terminate the establishment registration, independent of the other action.

#### Non-Enforcement Termination

Termination of establishment registration may also occur upon request of the establishment or parent company, typically because the establishment has gone or will go out of business, no longer produces pesticides, or otherwise no longer falls under the purview of FIFRA Section 7. In such cases the procedures for terminating establishment registration are

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- \* Newly registered establishments must submit reports within 30 days of notification of establishment registration; subsequent reports are due by February 1 of each year. The Agency may, however, grant discretionary extensions of up to 30 days for filing a report before the report is considered delinquent.

strictly technical and are based on the operating procedures of the FIFRA and TSCA Enforcement System (FATES). Termination of establishment registration in such situations should not be confused with termination for cause.

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#### Denials, Suspensions, Modifications, or Revocations of Applicator Certifications

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The regulations relating to the certification of pesticide applicators (40 C.F.R. Part 171) authorize EPA to deny, suspend, modify, or revoke federally issued applicator certifications if the certificate holder violates FIFRA or its regulations. The Agency views an enforcement action affecting certification status as a very strong measure, to be taken only when the "public health, interest or welfare warrants immediate action" [40 C.F.R. §171.11 (f)(5)(1)]. Therefore, EPA will deny, suspend, modify, or revoke a certification only in response to serious violations or against persons with a history of noncompliance. The Agency may take any of these actions if it determines that an applicant for or holder of a certification has:

- Been convicted under Section 14(b) of FIFRA;
- Been subject to a final order imposing a civil penalty under Section 14(a);
- Misused a pesticide;
- Made available for use, or used, a registered pesticide classified for restricted use other than in accordance with Section 3(d);
- Refused to keep and maintain records required by 40 C.F.R. Part 171;
- Made false or fraudulent records, invoices, or reports;
- Failed to comply with any limitations or restrictions on or in a previously issued certificate; or
- Violated any other provision of FIFRA or its regulations.

#### Denial/Revocations

The denial or revocation of a certification not only deprives an applicator of the authority to apply restricted use pesticides but also, as compared to suspension of a certification, forces the applicator to take additional steps to acquire or re-acquire certification. In addition, the Agency will not consider an application to acquire or re-acquire certification for a period of not less than six months following denial or revocation. Thus EPA will deny or revoke a certification only where a violation has resulted

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in a fatality or created an imminent danger of a fatality, where the violator's certification has been suspended as a result of a previous violation, or where a person has made fraudulent records or reports.

### Suspensions

When considering invoking the less severe alternative of suspending a certification, EPA personnel must determine whether it is appropriate to pursue a suspension and for how long such suspension should be in effect. These determinations will depend upon the gravity of the violation in question.

Suspension (Misuse Violation). In suspending a certification due to an incident of misuse, EPA will refer to criteria for assessing the gravity of a use violation (see Exhibit 5-2). The gravity of a use violation is a function of:

- The risk of harm posed to human health and the environment by the violation; and
- The degree of misconduct exhibited by the violator.

The Agency will assign weightings, based on the gravity criteria, for each use violation relative to the pesticide involved, the harm to human health and/or to the environment, the history of noncompliance, and the culpability of the violator. (For purposes of this section of the manual, EPA will not distinguish between commercial and private applicators. Consideration of applicator status is inherent in the policy in that suspensions have a more substantial impact on commercial applicators, affecting their primary business activity.) The Agency will use the gravity value thus obtained to decide whether and for how long to suspend a certification, in accordance with the following table:

Total Gravity Value	Enforcement Remedy
4 or below	No action or Notice of Warning
5 to 8	Suspension of up to 2 months
9 to 12	Suspension of between 2 and 4 months
13 or above	Suspension of between 4 and 6 months

To determine whether the term of a suspension should be at the higher or lower end of the given ranges, EPA will consider any gravity-related factors not accounted for in the gravity criteria. In addition, EPA will consider the degree to which the suspension will have an adverse economic impact on the applicator. Applicators who would be minimally affected by a suspension, such as those who apply restricted use pesticides infrequently, should receive longer suspensions than applicators whose day-to-day

business activities would be severely disrupted by the loss of their certifications.

Suspensions should generally be pursued against individual applicators in lieu of a Section 14(a) civil administrative penalty. This, however, does not preclude EPA from issuing both a suspension as well as issuing a warning letter or from assessing a civil penalty against the employer of the applicator in addition to suspending the certification of the applicator.

Suspension (Recordkeeping Violation). EPA may also suspend certifications of commercial applicators who violate restricted use pesticides recordkeeping requirements [see 40 C.F.R. §171.11(c)(7); 40 C.F.R. §171.11(f)(1)(iii)]. These violations do not lend themselves to analysis utilizing gravity of harm criteria. Consequently, EPA will suspend the certifications of persons who fail to maintain restricted use pesticides records based solely on gravity of misconduct considerations. The Agency will assess suspensions of up to two months for the second independent violation resulting from the failure to maintain restricted use pesticides records. For each additional violation, two months may be added to the term of the suspension up to a limit of six months. In cases where the violation involved keeping fraudulent records (i.e., where the violator intentionally concealed or misrepresented the true circumstances and the extent of the use of restricted use pesticides), EPA may revoke the violator's certification in response to the initial infraction.

If EPA decides to suspend certification, it must notify the applicator of the time period during which the suspension will be in effect. In order for the suspension to function as a deterrent, the suspension should take effect during the time when the applicator is most likely to be applying restricted use pesticides.

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### Recall Requests

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No explicit authority exists in FIFRA for the recall of products. The effectiveness of a recall action, therefore, is contingent on the cooperation of the involved company.

Recalls should be initiated by EPA in all cases where available information indicates that the product is either potentially hazardous when used as directed or ineffective for the purposes claimed. The Agency should consider a recall of a product when, among other things, its use as directed is likely to result in:

- Injury to the user or handler of the product;
- Injury to domestic animals, fish, wildlife, or plant life;

- Physical or economic injury because of ineffectiveness or due to the presence of actionable residues; or
- Identifiable adverse effect on the environment.

EPA personnel must view a request for recall as a serious and extraordinary matter and must make a request for recall of a product only in those cases where the evidence clearly supports such action. The initial decision that a product should be withdrawn from the market will be based on information in the sample file including laboratory analyses, staff evaluations and opinions, and such other information as may be available and relevant. All information supporting a recall decision must be included in the official file.

#### Formal and Informal Recalls

There are two types of recalls—formal and informal. Formal recalls are used for more serious problems when it is essential that EPA regional personnel follow up the recall with a visit to the company. Formal recall involves EPA monitoring, detailed reporting by the company involved, and notification to State officials. This type of recall is normally accompanied by another enforcement action, generally a civil penalty.

The Agency uses informal recalls in cases where a recall is necessary but the level of potential hazard is not great or when it is unlikely that significant amounts of the defective product remain in the marketplace. An informal recall is conducted entirely by the company involved with no monitoring by EPA or State officials.

#### Level of Recall Determination

The level of recall is 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 following recall levels should be considered:

- Wholesale or First Point of Distribution. This will normally include all informal recalls and those formal recalls in which the product distribution is limited and consequently the potential danger is low.
- Retail Level. This will be the normal level for most formal recalls.
- User Level. This level will be requested only in cases in which there is a known serious hazard to human health or the environment.



### Scope of the Recall

EPA must also consider the scope of the recall (i.e., the amount of the product that the recall will cover). In the case of labeling violations, the recall should include all of the product bearing the unacceptable labeling. For chemical violations, the recall should include all of the product bearing the same batch code(s) as the sample(s) found in violation. If the product is uncoded, EPA will determine the scope of the recall after contacting the responsible company. After reviewing the firm's manufacturing and shipping records, EPA personnel should be able to determine a range of manufacturing dates to include in the recall.

The recall of a defective product by the manufacturer or distributor is the most effective and efficient means of removing such a product from the market. However, since it is strictly voluntary, the success of the recall program depends on the industry's knowledge that:

- EPA will make a recall request only in those cases where there is a likelihood of physical or economic injury from the use of a product according to label directions;
- The Agency will use all legal means available to it to support or supplement any recall request, including stop sale, use, or removal orders, seizures, and civil penalties; and
- State officials will cooperate with the Agency in the removal of such products.

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### Stop Sale, Use, or Removal Orders

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A stop sale, use, or removal order (SSURO) should be issued by EPA if the violation is of an ongoing nature and threatens to cause serious or widespread harm. This remedy is not designed to prevent future violations, but rather is intended to limit the amount of harm that might result from a violation. In order to preserve the hearing rights of the recipient of an SSURO, EPA should supplement the order with a civil penalty assessment.

An SSURO is among the most expedient and effective remedies available to EPA in its efforts to prevent illegal sale, distribution, and use of pesticides. Its advantages over other actions (such as seizures) are that:

- It may be issued without prior adjudication of the violative character of the product (i.e., EPA may issue an SSURO simply when it has reason to believe that the product is in violation of the Act);
- It is easier to prepare and issue than a seizure;

- It can be written so as to include future amounts of the product that may come into the custody of the person on whom the SSURO is served; and
- It can be easily adapted to particular circumstances.

#### Criteria for Use

The language of Section 13(a) confers broad authority upon EPA to issue SSUROs. The Agency may issue an SSURO when any one of three situations exists:

- If, upon inspection or testing, EPA believes a product is in violation of the Act;
- If EPA believes that a product has been or is intended to be distributed or sold in violation of the Act; or
- If EPA has cancelled or suspended the registration of a product.

An SSURO is ordinarily issued by EPA without prior notice to the person served. Because an order is issued without notice, the actual or potential danger to human health or the environment posed by the violative product or situation must be both serious and imminent. In addition, the danger must require such urgent relief that there is no time to seek other remedies or that other administrative remedies would be inappropriate. Accordingly, EPA officials must observe stringent guidelines in determining whether issuance of an SSURO is appropriate, as outlined below.

Mandatory Issuance of an SSURO. The Agency must issue an SSURO against persons who own, control, or have custody of pesticides in the following categories:

- Pesticides whose registrations have been cancelled or suspended by EPA, except cases in which the Agency has permitted the use of existing stocks, or where continued marketing presents no human health or environmental hazard;
- Pesticides for which there is reason to believe present a potential hazard to man or the environment because:
  - They are not registered, or are so grossly overformulated or adulterated, as to present a serious health hazard, or
  - They are packaged in improper or damaged containers, or are so inadequately labeled, as to make safe or effective use unlikely or impossible;

- Pesticides or devices with labeling that is materially misleading or fraudulent and, if observed by a user, is likely to cause a life-endangering health hazard or serious adverse environmental condition. (A pesticide lacking a restricted use label is an especially serious labeling violation.) This provision includes labeling for products that:
  - Are ineffective for the purposes claimed,
  - Are so chemically deficient as to affect deleteriously the product's efficacy, as determined by laboratory test results, or
  - Bear false or misleading safety claims;
- Pesticides or hazardous devices\* that are in violation of the Act and are the subject of a voluntary recall, but which the responsible party refuses to remove, is recalcitrant in removing, or is unable to remove from channels of trade; and
- Pesticides or hazardous devices that are in violation of the Act and for which a civil penalty has been issued but which have not been brought into compliance.

Discretionary Issuance of an SSURO. EPA may exercise its discretion in issuing an SSURO in cases where a product either is in violation of the Act or is intended to be distributed or sold in violation of the Act, and the gravity of the violation is less than that required for issuance of a mandatory SSURO. In addition to an analysis of the relative severity of the violation (or lack thereof), the following factors should be considered:

- Whether the violation is another in a series of violations by the producer or distributor. In cases of recidivism, of uncorrected violations previously brought to the individual's attention, or of repeated negligent conduct, an SSURO may be appropriate where other enforcement remedies have failed to bring about corrective action or where it is deemed necessary to prevent continued marketing of the violative product;
- Whether the violation is easily corrected. If it appears that the individual is cooperative and can easily remedy the violation, an SSURO may be unnecessary; and

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\* A hazardous device is one presenting a direct threat to human health or the environment by its use (e.g., a water treatment device whose labeling makes false, misleading, or fraudulent claims to purify raw well water or other untreated water supplies). For nonhazardous devices (e.g., an electromagnetic rodent repelling device) that are misbranded, Agency policy is to complete civil penalty proceedings before issuing an SSURO. See December 19, 1979 Memorandum: "Enforcement Actions Concerning Nonhazardous Pesticide Devices."

- Who has custody of the product. An SSURO may be more appropriate, and a violation more immediately cured, if the violative product is found at the producer level rather than at the retail level.

In all other cases, EPA should consider an alternative enforcement remedy available under FIFRA.

#### Use of SSURO for Minor Violations

While EPA will usually reserve the use of an SSURO to relatively serious violations, the need to issue an SSURO may arise in certain cases involving minor violations. For example, in the face of continued and repeated minor violations, or when several minor violations appear together on a label, EPA may decide to issue an SSURO to ensure that the product will be distributed only in compliance with the Act.

#### Alternative Approaches

Even in cases where the existence of a serious violation would justify the issuance of an SSURO, the Agency may consider the use of alternative approaches to achieve compliance. For example, certain pesticide labeling violations can be rectified through a voluntary recall by the manufacturer, and this may be the most expeditious way to prevent any harm to human health or the environment. Thus, in certain cases that could legitimately call for the issuance of an SSURO, particularly those concerned with labeling violations, EPA might first consider contacting the appropriate responsible party and negotiating a voluntary recall.

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#### Civil Administrative Penalties

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A civil penalty, as authorized by Section 14(a) of FIFRA, is the remedy of choice for most violations. A civil penalty should be proposed where the violation presents (a real but not an extreme and unreasonable) risk to humans or the environment; is likely to be an isolated occurrence; was apparently committed as a result of ordinary negligence, inadvertence, or mistake; and either:

- Involves a first offense under the Act by any registrant, commercial applicator, "for hire" applicator, wholesaler, dealer, retailer, or other distributor (no prior warning is required by FIFRA for violators in this category); or
- Involves a private applicator or other person, other than any party specified in the first category, who has received a prior warning or citation for a violation of FIFRA. (The prior warning or citation may have been for the same or a different FIFRA violation.)

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## Injunctions

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Section 16(c) of FIFRA gives EPA the authority to initiate injunctive actions before district courts.\* Because an injunction is an extraordinary form of relief, the Agency's arguments must be clear and compelling. In initiating a permanent injunction action, EPA must indicate to the court that:

- The Agency's administrative or other judicial enforcement remedies would be inadequate either at restraining the violation or at preventing unreasonable risk to human health or the environment;
- The Agency has, in fact, already diligently exercised all appropriate administrative remedies (such as SSUROs and civil penalties), yet the violation continues unabated; and
- Irreparable injury, loss, or damage will result if relief is not granted.

In the case of a preliminary injunction or temporary restraining order, the Agency must additionally demonstrate that:

- Immediate and irreparable injury, loss, or damage will result if relief is not granted; and
- There is a likelihood of success at trial, based on facts before the court.

Under FIFRA, there are a number of specific circumstances that may justify injunctive relief. These include but are not limited to:

- The violation of a Section 6 suspension order;
- The violation of an SSURO where a civil penalty or criminal prosecution would not provide a timely or effective remedy to deter further violations;
- There is continued production, shipment, sale, or use of an unregistered pesticide after the Agency has taken civil or criminal action; and

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\* These actions may consist of permanent injunctions, preliminary injunctions, or temporary restraining orders. These types of injunctions are discussed in more detail in Section 4 of Chapter Eight.

- The Agency has exercised an enforcement remedy and a person continues to make available for use a restricted use pesticide other than in accordance with FIFRA Section 3(d), or continues to use a pesticide in a manner inconsistent with its labeling or in a manner contrary to an experimental use permit.

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### Seizures

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Section 13(b) of FIFRA gives EPA the authority to initiate in rem condemnation proceedings in district court. Once a court grants the Agency's request for authority to conduct a seizure, FIFRA Section 9(b) authorizes duly designated Agency employees to obtain and execute warrants for the purpose of seizing any pesticide or device that is in violation of the Act.

Since seizures are judicial actions directed against violative products rather than against individuals, EPA may initiate actions in court against:

- A pesticide that is adulterated, misbranded, unregistered, not colored or discolored as required, or bears claims or directions for use that differ from those made in connection with its registration;
- A device that is misbranded; or
- A pesticide or device that causes unreasonable adverse effects upon the environment, even when used in accordance with requirements imposed by the Act.

The above examples are similar to those that would lead the Agency to initiate an SSURO. Because an SSURO can be effected in less time and with less preparation than that required for a seizure, it is the preferred remedy in terms of expediency. Nevertheless, the Agency should consider initiating a seizure in the following circumstances:

- The Agency has issued an SSURO, but the recipient of the order has not complied with it;
- The Agency has reason to believe that a person, if issued an SSURO, will not comply with it;
- There exists a pesticide so hazardous that it should be removed from the marketplace or place of use;
- The seizure will be used to support a recall; or
- It is necessary to dispose of products being held under an SSURO for which the responsible party has taken no corrective action and has expressed an intent not to take corrective action.

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Criminal Proceedings

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Section 14(b) of FIFRA provides EPA with the authority to proceed with criminal sanctions against violators of the Act, subject to the following distinctions:

- A registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$25,000, or imprisonment for not more than one year, or both.
- A private applicator or other person not included above who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$1,000, or imprisonment for not more than 30 days, or both.

The Agency may initiate criminal proceedings in every case in which EPA can meet the stringent requirements of evidence and proof leading to a conviction. However, Agency policy, as well as pragmatic resource considerations, argues against the use of criminal sanctions in any but the most serious instances of environmental misconduct, as determined by the nature of the violation, the history of compliance on the part of the responsible person, or the seriousness of the environmental consequences.

Considerations

There are a number of specific factors that the Agency must carefully consider before proceeding with a criminal prosecution. (Chapter Nine, "Judicial Enforcement: Criminal Actions," addresses these considerations in much greater detail.)

Knowledge. The Agency must determine that the violator in question knowingly violated the statute. That is, there must be evidence of intent in the commission of the violative act, rather than it merely being the result of accident or mistake.

Seriousness. Criminal actions should be considered for the most serious types of environmental misconduct. This consideration will be judged by reviewing the extent of environmental harm or human health hazard that resulted from, or was threatened by, the prohibited conduct. Factors such as the duration of the conduct and the toxicity of the pollutants are considered. Also of significance in assessing the seriousness of the conduct is the impact—real or potential—upon EPA's regulatory function.

Deterrence. The Agency must consider the importance of and need for deterrence of criminal conduct, either on the part of a specific person, or on the part of the larger community. In the case of a serious and willful violation, the interests of deterrence may well best be served by the imposition of criminal sanctions.

Compliance History. The compliance history of the person who is the subject of possible criminal proceedings will enter into the Agency's deliberations. While a history of noncompliance is not requisite for pursuing criminal sanctions, certainly criminal prosecution becomes more appropriate when a history of noncompliance exists.

Simultaneous Actions. The Agency may consider whether there is a need for criminal enforcement proceedings contemporaneous with a civil or administrative enforcement action, or whether one type of action alone will serve the situation in question. While simultaneous proceedings are permissible, and there may be very compelling reasons for pursuing both, the legal and practical difficulties inherent in so doing argue against such an approach except in the most extraordinary circumstances.

#### Use of Criminal Proceedings

The Agency has identified a number of specific situations that may be considered of such a serious nature that criminal prosecution is particularly appropriate. To list these situations, however, should not be viewed as precluding criminal prosecution in circumstances not included below:

- Failure to report information on the unreasonable adverse effects of a registered pesticide;
- Falsification of records;
- Violation of an order suspending or cancelling a product registration;
- Violation of an SSURO;
- Unlawful uses of pesticides; and
- Illegal distribution of unregistered pesticides.



**Efficacy Standards and Level of Action Guidance  
for Disinfectants and Rodenticides**

Efficacy standards have been developed and are being utilized by the Agency for hospital or medical use disinfectant products and rodenticides. The efficacy standards and level of action guidance for these two types of pesticides are summarized below. However, for the complete disinfectants laboratory testing procedures and level of action guidance, refer to December 17, 1980 Memorandum: "Regulation of Public Health Related Disinfectant Products." Additionally, for both disinfectants and rodenticides, consult the civil penalty matrix in Appendix 6 for the appropriate civil penalty calculations.

**Disinfectants**

Only hospital or medical use products that make claims for Salmonella choleraesius, Staphylococcus aureus, or Pseudomonas aeruginosa\* are tested.

**Level I Testing**

In Level I testing, 60 carriers must be tested against each of the above organisms with each of three samples, representing three different batches. This amounts to 180 carriers per sample; a total of 540 carriers.

• **Disinfectant Sample(s)**

Performance Standard: A sample is determined to fail efficacy testing if organisms on 2 or more of the 60 carriers are not destroyed.

Level of Action: For each sample that fails the above standard, an SSURO is issued on the batch from which the sample was collected and a civil penalty is issued for failure of the batch to meet the efficacy requirements.

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\* Failure of a product to destroy Pseudomonas aeruginosa is considered equal to failure of a product to destroy Staphylococcus aureus or Salmonella choleraesius.

- Disinfectant Product(s)

Performance Standard: A product provisionally fails efficacy testing if two or more of the three samples fail to destroy any test organism.

Level of Action: Level II testing is initiated for each product that fails the above standard.

### Level II Testing

If a product fails Level I testing, five additional samples representing five different batches are collected for testing at Level II. Sixty carriers are tested for each organism that the product fails to destroy in Level I.

- Disinfectant Sample(s)

Performance Standard: A sample is determined to fail efficacy requirements if organisms on 2 or more of the 60 carriers are not destroyed.

Level of Action: For each sample that fails the above standards, an SSURO is issued on the batch from which the sample was collected, and a civil penalty is issued for failure of the batch to meet the efficacy requirements.

- Disinfectant Product(s)

Performance Standard: A product is determined to fail efficacy testing if three or more of the five samples fail to destroy any organism.\*

Level of Action: Initiation of cancellation proceedings.

### Rodenticides

Both single dose (acute) and multiple dose rodenticides that make claims for commensal rodents are tested for efficacy.

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\* Level II product failures are based on the upper bounds of the 95 percent confidence level. Consequently, a sample must fail 5 out of 60 carriers (not 2 out of 60 as in Level I tests) to count as a failure.

- Acute or Single Dose

Performance Standard: The minimum standard is 90 percent rodent mortality after eight days of testing for the product to be effective in commensal rodent control.

Level of Action: A civil penalty is issued for failure of the batch to meet the above efficacy requirements.

- Multiple Dose

- Cereal or water baits

Performance Standard: The minimum standard is 33 1/3 percent bait acceptance and 90 percent mortality in order for the product to be considered effective in a commensal rodent population.

Level of Action: A civil penalty is issued for failure of the batch to meet the above efficacy requirements.

- Paraffin blocks

Performance Standard: The minimum standard is 25 percent bait acceptance and 80 percent mortality in order for the product to be considered effective in a commensal rodent population.

Level of Action: A civil penalty is issued for failure of the batch to meet the above efficacy requirements.

**Criteria for Determining the Gravity of a Use Violation  
for Purposes of a Certification Action**

Violation	Weighting	Activity
GRAVITY OF HARM		
	Pesticide	2
		Toxicity—Category I pesticides, restricted use pesticides, or pesticides that are associated with chronic health effects (mutagenicity, oncogenicity, teratogenicity, etc.)
		1
		Toxicity—Categories II through IV, no known chronic effects
	Harm to Human Health	5
		Serious or widespread actual harm to human health
		3
		Serious or widespread potential harm to human health
		1
		Minor potential or actual harm to human health, neither serious nor widespread
Environmental Harm		5
		Substantial or widespread actual harm to the environment (e.g., crops, water, livestock, wildlife, wilderness, or other sensitive natural areas)
		3
		Substantial or widespread potential harm to the environment
		1
		Minor potential or actual harm to the environment, neither widespread nor substantial

Violation	Weighting	Activity
GRAVITY OF MISCONDUCT		
	4	More than one prior violation of FIFRA by the applicator
	2	One prior violation
	0	No prior violations
	4	Knowing or willful violation
	2	Violation resulting from negligence
Culpability	0	Violation was neither knowing nor willful and did not result from negligence; good faith efforts made to comply with the law

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# Chapter Six

## Administrative Enforcement Actions: Notices of Violation and Administrative Orders

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# 1 Introduction

This chapter outlines the specific procedures that EPA should follow in initiating and processing administrative enforcement actions, once the Agency has determined that an administrative enforcement response is appropriate for a detected violation. These actions include the following:

- Advertising letters;
- Notices of detention under Section 17(c);
- Notices of warning under Sections 9(c)(3) and 14(a)(2);
- Terminations of establishment registrations under 40 C.F.R. §167.3;
- Denials, suspensions, modifications, or revocations of applicator certifications under 40 C.F.R. §171.11;
- Recall requests; and
- Stop sale, use, or removal orders under Section 13(a).

One or more examples of each type of action, in its proper format, appear as exhibits at the end of this chapter.

Civil administrative penalties are not covered in this chapter. However, civil administrative penalty procedures are outlined in detail in Chapter Seven, "Administrative Enforcement Actions: Civil Penalty Proceedings." Appendix 6, "Penalty Policies," also contains useful procedural information for civil penalty actions. In addition, Chapter Five, "Determination of Appropriate Enforcement Response," discusses the criteria the Agency uses in deciding when and what type of enforcement actions to issue.





## 2 Administrative Enforcement Procedures

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### Advertising Letters

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An advertising letter is a letter issued by EPA as notice to a company that collateral literature concerning a pesticide or device bears unaccepted pesticide statements or pesticide or device claims. Since FIFRA does not contain a specific provision for advertising letters, it is not an enforcement action in an official sense. Rather, it indicates Agency concern regarding the statements or claims found in the advertising or literature related to a product and encourages voluntary correction on the part of the responsible party. It does not imply any further enforcement action, although the Agency may take further action if EPA subsequently collects an official sample and finds that the company has not taken corrective steps.

### Content Requirements

An advertising letter consists of three parts (see Exhibit 6-1):

- An identification of the collateral literature;
- An identification of the unaccepted statements (if related to a registered pesticide), the pesticide claims (if related to an unregistered pesticide), or the device claims (if related to a device); and
- A request to the recipient to respond to EPA with an indication of how the company will make changes or corrections in the literature, typically by deleting, qualifying, or justifying the statements or claims.

### Service

The Agency should issue an advertising letter by certified mail, return receipt requested.

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Notices of Detention

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Section 17 of FIFRA authorizes EPA to refuse admission of a pesticide or device being imported into the United States if EPA determines that such product violates any provisions of the Act. This refusal is known as a Notice of Detention and Hearing (see Exhibit 6-2).

Procedures

When, on the basis of available information or actual inspection, the Agency determines that an imported shipment should be detained, EPA should prepare and issue to the importer a Notice of Detention and Hearing. The Agency should also send a copy of the notice to the District Director of Customs at the port of entry. For this reason, the EPA Regional Offices should have on file the names and addresses of the District Directors, plus the customs compliance officers or commodity specialists who deal with EPA for each port of entry within the Region's jurisdiction.

Release Notice. If, through examination of the product or other means, EPA can determine that the product has been brought into compliance with FIFRA, EPA should issue a Release Notice (see Exhibit 6-3) to the importer with a copy to the District Director of Customs of the port of entry.

Refusal of Admission. If the product has not been brought into compliance with the Act, EPA should issue a Notice of Refusal of Admission (see Exhibit 6-4) to the importer with a copy to the District Director of Customs at the port of entry. The District Director will refuse entry of the product and will cause destruction of the product if the importer does not export it within 90 days from the date of such Notice of Refusal of Admission.

Release of Product Under Bond. If the District Director of Customs has already released the product to the importer under bond, the District Director will take action to enforce the terms of the bond. If the District Director finds it necessary to request forfeiture of an importer's bond because the importer did not hold the shipment intact as required, the District Director may ask EPA to determine the amount to be levied against the importer's bond. The Agency should determine penalties according to the severity of the violations and the reasons why the product was not available for redelivery.

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Notices of Warning

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Section 14(a)(2) of FIFRA requires EPA to use a notice of warning in response to the first civil offense committed by private applicators or other persons not covered under Section 14(a)(1). The Agency may also issue notices of warning under Section 9(c)(3) of FIFRA in response to

first-time violations committed by any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor, "for-hire" applicator—that is, those persons covered by Section 14(a)(1)—if, in EPA's judgment, justice will be served by employing that remedy rather than a civil penalty or other action.

#### Content Requirements

A notice of warning is a letter to the responsible party and consists of three parts (see Exhibit 6-5):

- Identification of the violative product or action;
- Identification, citation, and explanation of the violation; and
- A closing paragraph indicating the expected response from the recipient, if any.

If the Agency does not receive the requested response from the recipient, indicating what action that party has taken to correct the violation, the Agency will not initiate any further enforcement action. However, EPA may wish to schedule a follow-up inspection to determine whether the violation has been corrected. If EPA finds, upon reinspection, that the responsible party has not corrected the violation, the Agency should proceed with a civil penalty.

#### Service

The Agency should issue a notice of warning by certified mail, return receipt requested.

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#### Terminations of Establishment Registrations

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The regulations related to the registration of pesticide-producing establishments, at 40 C.F.R. §167.3, state that the registration of an establishment will remain in effect so long as the establishment continues to submit annual pesticides reports. If the establishment fails to submit a report in any year, EPA may issue either a notice of warning or a civil penalty, based on the provisions of FIFRA Sections 7(c)(1) and 12(a)(2)(L). A notice of warning is the appropriate action for a newly registered establishment that fails to submit its initial pesticides report. The Agency should initiate a civil penalty in response to the failure to file a pesticides report on the part of an establishment that previously filed at least one annual report and is thus on notice as to its continuing responsibility to submit annual reports.

### Procedures

If the establishment does not submit a report within 20 days after the date of receipt of a notice of warning or civil penalty, EPA should issue a Notice of Intent to Terminate Establishment Registration (see Exhibit 6-6). This notice informs the establishment of the violation of failure to report and warns the establishment of impending termination of registration if EPA does not receive the delinquent report in an additional 20 days. The notice also reminds the establishment of the potential violation of producing pesticides, active ingredients, or devices in an unregistered establishment.

Termination of Registration. If the Agency does not receive the delinquent report in the 20-day period following its issuance of a Notice of Intent to Terminate Establishment Registration, EPA should then issue a Notice of Termination of Establishment Registration (see Exhibit 6-7). This notice revokes the registration, effective as of the date of issuance, and contains a warning against producing pesticides, active ingredients, or devices in an unregistered establishment, as well as instructions for obtaining reinstatement of registration. The Agency should send the notice by certified mail, return receipt requested. The Agency may proceed with both the Notice of Intent To Terminate Establishment Registration and the Notice of Termination of Establishment Registration independently of any other action, such as a civil penalty.

Reinstatement of Registration. It is Agency policy to reinstate terminated establishment registration, provided that the company submits all reports due and submits a completed Application for Registration of Pesticide-Producing Establishment (EPA Form 3540-8). The Agency will issue the same establishment registration number to the re-registered establishment. The submission of delinquent reports and of an application for establishment registration, however, does not preclude the Agency from proceeding with a civil penalty action for failure to submit reports.

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### Denials, Suspensions, Modifications, or Revocations of Applicator Certifications

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The regulations relating to the certification of pesticide applicators (40 C.F.R. Part 171) authorize EPA to deny, suspend, modify, or revoke federally issued applicator certifications if the certificate holder violates FIFRA or its regulations. The regulations also specify the procedures that EPA must follow in denying, suspending, modifying, or revoking a certification.

The Agency may suspend any part or all of a certification immediately and without provision for a hearing upon determining that such action is warranted by "the public health, interest, or welfare" [40 C.F.R. §171.11(f)(5)(1)]. The Agency may deny issuance of a certificate, or modify or revoke an existing certificate, after providing opportunity for a hearing.

Content Requirements

Suspension. If EPA decides to suspend a certification, the Agency must notify the certificate holder of:

- The grounds for suspension;
- The time period during which the suspension will be effective; and
- The Agency's intent to revoke or modify the certificate, as appropriate. A notice to revoke or modify may be issued before or at the same time as the notice to suspend.

Denial. If the Agency decides to deny the issuance of a certificate to an applicant, or to modify or revoke a previously issued certificate, it must notify the applicant or certificate holder of:

- The grounds for such action;
- The time period for which such action will be effective and whether the action will be permanent or temporary;
- The conditions, if any, under which the person may become certified or recertified; and
- Any additional conditions that EPA may impose.

Hearings

At the same time, the Agency must also provide the affected person with the opportunity to request a hearing prior to final Agency action on its proposed denial, revocation, or modification. If the person requests such a hearing, EPA must:

- Notify the person of the assertions and facts upon which EPA has based its decision;
- Provide the person opportunity to offer written statements, explanations, comments, and arguments relevant to the proposed action;
- Provide the person such other procedural opportunities as may be appropriate to ensure a fair and impartial hearing; and
- Appoint an EPA attorney, who has no prior connection with the case at hand, as Presiding Officer to conduct the hearing.

The Presiding Officer must promptly conduct a hearing. He or she must consider all evidence, explanations, comments, and arguments submitted by both EPA and the affected person and render a decision and order as soon as possible. Such an order is a final Agency decision, subject to judicial review under FIFRA Section 16.

### Considerations

As noted above, a suspension, because of the extraordinary circumstances implicit in such an action, becomes effective immediately, and there is no opportunity for review or appeal. However, since a notice to suspend must include or be preceded by a notice to deny, modify, or revoke a certificate, and since a denial, modification, or revocation must include opportunity to request a hearing prior to final Agency action, the affected person retains the right to a hearing.

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### Recall Requests

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A recall is a request from the Agency to the party responsible for a violative product to voluntarily withdraw that product from the marketplace. Because FIFRA contains no explicit authority for recalls, the effectiveness of such an action is dependent on the cooperation of the involved company.

The Headquarters PTSCMS and the Registration Division of the Office of Pesticide Programs jointly will make the determination for a formal recall involving a product whose registration EPA has suspended or cancelled. In all other cases, the Region in which a violative product was produced will make the decision to initiate a recall and whether the recall should be formal or informal. A Region initiating a recall must consult with the Headquarters PTSCMS. Consultation with the Registration Division is also required for all formal recalls.

### Procedures

When consulting with PTSCMS, the initiating Region should forward a Proposal for Recall Form (see Exhibit 6-8) to PTSCMS by telecopier, along with adequate documentation by which to judge the recall decision. If PTSCMS agrees with a recall (along with the Registration Division, if necessary), the Region would receive initial notification of the decision by telephone. PTSCMS would then return the Proposal for Recall Form by mail, signed by a PTSCMS official (and a Registration Division official, if necessary). Should PTSCMS (and/or the Registration Division) object to the decision to recall, the form would be returned with the reasons for the objection noted in writing.

The Agency should request a recall in the form of a letter to the responsible company. It is important that recall letters be as complete and informative as possible. Whenever possible, the letter should clearly express the expected level and scope of the recall.

Content Requirements

A formal recall request in connection with a suspension or cancellation should contain the following (see Exhibit 6-9):

- The reason for recall;
- The identity of the product to be recalled;
- The procedures to be followed; and
- The EPA personnel who will supervise the action and who may be contacted by the company in regard to the recall.

A formal recall request for any other reason should include (see Exhibit 6-10):

- The reason for the recall, citing the violation;
- The shipment or producer establishment involved;
- The identity of the product to be recalled, including batch codes if the recall involves an ineffective or misformulated product;
- The procedures to be followed; and
- The EPA personnel who will supervise the recall and whom the company may contact in regard to the recall.

An informal recall usually accompanies another enforcement action, such as a civil penalty or a stop sale, use, or removal order (SSURO). The informal recall request should contain (see Exhibit 6-11):

- The reason for recall, citing the violation; and
- The identity of the product to be recalled, including batch codes if the recall involves an ineffective or misformulated product.

The Headquarters PTSCMS should prepare all formal recall letters involving product registration suspension or cancellation. The Regional Offices should prepare all other types of recall letters. In either case, the initiating office should mail the recall letter by certified mail, return receipt requested. The initiating office should also distribute copies of the recall letter to the other Regional Offices and to the Headquarters PTSCMS for their use in monitoring the recall.



An SSURO may apply prospectively to amounts of the named product that may come into the person's ownership, control, or custody.

### Procedures

**Service.** The Agency should serve a written or printed SSURO to the person who owns, controls, or has custody of the violative product. An authorized Agency employee should serve the original copy (i.e., deliver by hand) and acknowledge the service by signing the order in the space provided and entering his or her title and the time and date of service. Where it is highly impractical to deliver an SSURO by hand, EPA may instead serve it by certified mail, return receipt requested. The person served should acknowledge receipt of the order by signing the order in the space provided, entering his or her title, and returning a copy to the person serving the order (if it is served in person) or to the issuing EPA office (if served by certified mail). A failure or refusal on the part of the person served to acknowledge receipt does not invalidate either the order or its service, but the EPA official or office serving the order should note in the file such a failure or refusal.

**Marking.** Wherever practical, a sticker should be placed on the material covered by the order to indicate to all persons coming in contact with the product that it is under such an order. The sticker must be placed so as not to obscure or destroy the product labeling when removed. If the order is served in person, the EPA official making the service should post the sticker. If the order is served by mail, the order should instruct the person served to clearly identify to his or her employees the product that is under order. The issuing EPA office may also wish to include with the order a sticker for the receiving person to post with the product or an illustrative example of how the product covered by the order should be identified.

### Monitoring the SSURO

As long as an SSURO remains in effect, the issuing EPA office should monitor periodically the order to determine that its terms are being observed. Similarly, EPA should check for compliance with the order before terminating it. Documentation of such monitoring should be noted in the official file.

### Disposing of the Product

Since any product under an SSURO cannot be disposed of in any manner contrary to the terms of the order, the Agency must determine the proper disposition for the product in each case. Acceptable disposition can usually be accomplished through one or a combination of the following:

- Obtaining product registration;

- Reconditioning by relabeling, reformulation, and/or repackaging so as to bring into compliance with FIFRA;
- Relabeling so as to remove from the purview of FIFRA;
- Designating for institutional uses that do not constitute use violations;
- Detoxifying;
- Distributing for sale and use for lawfully registered uses;
- Relabeling or repackaging for export in conformance with Sections 3, 17, and 19 of FIFRA;
- Obtaining for distribution and use a valid experimental use permit; or
- Destroying.

#### Terminating the SSURO

When EPA determines that the responsible party has taken appropriate steps to accomplish proper disposition, EPA should record the method of disposition and the amount of the pesticide or device involved and issue a letter terminating the SSURO (see Exhibit 6-13). In cases of disposition requiring movement of the product under the SSURO, EPA must first amend the order in writing to allow such movement. Therefore, EPA should terminate an order only after completion of the disposition.

If EPA terminates an SSURO on the basis of the responsible person's attestations that the product has been brought into compliance with FIFRA but without benefit of an actual inspection by the Agency, EPA should draft the letter terminating the order so that such termination is conditional upon the product being in compliance with the Act. The Agency might otherwise find itself in a situation in which the SSURO is terminated although, through mistake or fraud, the product is still not in compliance with FIFRA.

#### Violations of the SSURO

Any violation of an SSURO is a violation of FIFRA Section 12(a)(2)(I) and is considered a very serious violation warranting either a civil or criminal penalty. The Agency may proceed directly to a civil or criminal penalty, as appropriate, if the violator is a "registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor." In those instances in which a private applicator or other person not included under Section 14(a)(1) violates an SSURO, Sections 14(a)(2) or 14(b)(2) govern the violation. Since Section 14(a)(2) requires a written warning for first-time offenders, EPA should consider exercising either a Section 14(b)(2) criminal prosecution for private applicators or other persons

covered by Section 14(a)(2) who violate an SSURO, or issue a notice of warning and, should the violation of the SSURO continue, proceed with a civil penalty. In addition to taking a civil penalty or criminal action in response to the violation of an SSURO, EPA should also institute Section 13(b) seizure proceedings to prevent any continued violations of the order. Should both a seizure and a Section 14 penalty be ineffective in preventing violation of an SSURO, the Agency may seek injunctive relief under Section 16(c).

## Model Advertising Letter

(Company name)  
(Address)

Subject:

Gentlemen:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, the Environmental Protection Agency has obtained copies of (title or description of collateral literature).

This literature makes statements regarding the product, (name of product), such as (quote improper or unacceptable statements or claims). These statements identify the product as a pesticide within the meaning of the Act. Refer to Section 3 of the Act, a copy of which is enclosed. The use of these statements in connection with the distribution and sale of the product would constitute a violation of the Act. Therefore, you should delete these statements or submit an application for the registration of the product.

Please inform us of the action you will take in this matter.

Sincerely yours,

(Signature, name, and title)

Enclosure

Note: This is a general example only and does not represent the only appropriate format. Additional or different paragraphs may be included as necessary to fully explain or describe the unaccepted statements or claims and the response that the Agency expects from the responsible party.

## Model Notice of Detention and Hearing

(Company name)(Address)Subject: (Sample number)

Gentlemen:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, the 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 hold the merchandise 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) days after your receipt of this notice. Should you desire to present your views orally, in addition to filing a written reply, you should so advise us in your answer in order that we may set a date for such presentation, which would be held in this office.

Sample No(s).

Product Name(s)

Date of Importation

Consignee

Shipper/Manufacturer

Entry No.

Date

Port of Entry

Upon examination, it appears that the product(s) failed to comply with the provisions of the Act in that (describe violation). A copy of the Act is enclosed for your reference.

Sincerely yours,

(Signature, name, and title)

Enclosure

## Model Release Notice

(Company name)  
(Address)

Subject: (Sample number)

Gentlemen:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, the Environmental Protection Agency has completed its consideration of the following shipment. Based 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 No(s).

Product Name(s)

Date of Importation

Consignee

Shipper/Manufacturer

Entry No.

Date

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 violative.

Sincerely yours,

(Signature, name, and title)

## Model Notice of Refusal of Admission

(Company name)(Address)Subject: (Sample number)

Gentlemen:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, the Environmental Protection Agency has examined samples or other evidence with respect to the following shipment and has granted to you an opportunity for a hearing.

Sample No(s).

Product Name(s)

Date of Importation

Consignee

Shipper/Manufacturer

Entry No.

Date

Port of Entry

It appears that the product(s) is(are) not in compliance with the Act and is(are) subject to refusal of admission due to the following violation(s):

(Described violations)

The Agency hereby notifies you that it refused admission of the merchandise. You must export this merchandise, under supervision of the Customs Service, within ninety (90) days from the date of this notice or within such additional time as the District Director of Customs 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 yours,

(Signature, name, and title)

## Model Notice of Warning

(Company name)

(Address)

Subject: (Sample number)

Gentlemen:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, the Environmental Protection Agency has under consideration a sample of (name of product), which the Agency obtained on (date of inspection). This product had been released for shipment by your producing establishment in (city and state).

The product did not comply with the provisions of the Act in that (describe violations).

You should make all necessary corrections to assure yourself that any further marketing of this product is in full compliance with the provisions of the Act. The Agency will include in the file regarding this matter any additional information that you wish to submit.

Sincerely yours,

(Signature, name, and title)

Note: This is a general example only and does not represent the only appropriate format. Additional or different paragraphs may be include as necessary to fully explain or describe violations and the response that the Agency expects from the responsible party.



**Model Notice of Intent to Terminate  
Establishment Registration**

(Company name)  
(Address)

**Subject:** (Establishment registration number)

**Gentlemen:**

The Environmental Protection Agency hereby informs you of the Agency's intention to terminate the registration of your establishment, located in (city and state), pursuant to Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, and 40 C.F.R. §167.3. The Agency intends to take this action based on your failure to submit reports required by Section 7(c) of the Act and by 40 C.F.R. §167.5.

Your failure to file the required reports by (due date) has already subjected you to civil or criminal penalties under the Act. Your failure to submit the required reports within twenty (20) days of your receipt of this notice will result in the termination of your establishment registration, effective upon the date of the Agency's issuance of a Notice of Termination of Establishment Registration. Your submission of the required reports within the twenty (20) day time period shall not affect your liability under the civil and criminal penalty provisions of the Act.

You should take all necessary measures to preclude any production at your establishment not in compliance with the Act. Production of pesticides, active ingredients, or devices in an unregistered establishment or in an establishment whose registration has been terminated is an unlawful action subject to the civil and criminal penalty provisions of the Act.

**Sincerely yours,**

(Signature, name, and title)

**Model Notice of Termination of  
Establishment Registration**

(Company name)

(Address)

Subject: (Establishment registration number)

Gentlemen:

The Environmental Protection Agency hereby informs you that the Agency has terminated the registration of your establishment, located in (city and state), pursuant to Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136 and 40 C.F.R. §167.3. The Agency has taken this action based on your failure to submit reports required by Section 7(c) of the Act and by 40 C.F.R. §167.5.

You may apply for reinstatement of your establishment registration at any time subsequent to the termination of your establishment registration. However, the reinstatement of your establishment registration will be expressly conditional upon the Agency's receipt of your delinquent pesticide report(s) together with an application for establishment registration (EPA Form 3540-8).

You should take all necessary measures to preclude any production at your establishment not in compliance with the Act. Production of pesticides, active ingredients, or devices in an unregistered establishment or in an establishment whose registration has been terminated is an unlawful action subject to the civil and criminal penalty provisions of the Act.

Sincerely yours,

(Signature, name, and title)

## Proposal for Recall Form

☐ Formal Recall☐ Informal Recall

Region \_\_\_\_\_ has decided to recall the product (name of product) for the following reasons: (reasons for recall)

Region \_\_\_\_\_ requests that the Compliance Monitoring Staff (and the Registration Division, in the case of formal recalls) review this proposed action, based upon the following evidence, copies of which are attached:

☐ Collection Report☐ Scientific Review☐ Analytical Reports☐ Other - Specify☐ Labels

Regional Office \_\_\_\_\_

(Sign and Date)

Agreement with this recall action should be indicated with signature and date below. If there is objection to this action, the reason should be specified.

Compliance Monitoring Staff \_\_\_\_\_

(Sign and Date)

Registration Division \_\_\_\_\_

(Sign and Date)

**Model Formal Recall Request in Connection with  
Suspension or Cancellation**

(Company name)

(Address)

Subject: (Name of product and registration number)

Gentlemen:

On (date) the Environmental Protection Agency sent a letter to you notifying you that registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, for (name of product) is (suspended/cancelled).

As set forth in the letter of (suspension/cancellation), the Agency has determined that (general reason for suspension or cancellation). Therefore, the Agency requests that your company take immediate action to withdraw this product from the market. Specifically, the Agency requests:

1. That your company initiate procedures to determine the locations of all quantities of this product and the amount of such product at each location;
2. That the product be returned to your company from all such locations; and
3. That you inform us of (a) all steps your company has taken in connection with the recall of this product, and (b) the completeness of the recall action.

The Agency will supervise this action through the office of (name, title, address, and telephone number of supervising EPA official). Mr./Ms. (name), or a representative of his/her office will contact you on this matter.

Thank you for your cooperation.

Sincerely yours,

(Signature, name, and title)

**Model Formal Recall Request in Connection  
with Sample Collections**

(Company name)  
(Address)

Subject: (Sample number)

Gentlemen:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136, the Environmental Protection Agency has obtained and tested a sample of the product (name of the product). The Agency obtained this sample on (date of inspection) from your producing establishment located in (city and state).

Tests of the product coded (indicate code) showed the product to be (results of tests and their implications for use of the product).

In view of the intended uses of this product, the Agency requests that your company take immediate action to withdraw this product from the market. Specifically, the Agency requests:

1. That your company initiate procedures to identify the consignees of the product;
2. That your company request that the consignees return this product to your company; and
3. That you inform us of (a) all steps your company has taken in connection with the recall of this product, and (b) the completeness of the recall action.

The Agency will supervise this action through the office of (name, title, address, and telephone number of supervising EPA official). Mr./Ms. (name) or a representative of his/her office will contact you regarding this matter.

Thank you for your cooperation.

Sincerely yours,

(Signature, name, and title)

**Model Informal Recall Request**

The Agency requests that you take steps to determine whether any additional amounts of this product remain in channels of trade. If so, the Agency further requests that you remove all such lots of the product, coded (indicate code), from the market.

**Note:** For an informal recall request, the above paragraph is inserted into the documents that are prepared in connection with other enforcement actions (e.g., civil penalty, stop sale, use, or removal order, etc.).

## Model Stop Sale, Use, or Removal Order

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## STOP SALE, USE, OR REMOVAL ORDER

(Date) \_\_\_\_\_

(Name of persons ordered) \_\_\_\_\_

Sample No(s). \_\_\_\_\_

(Name of company) \_\_\_\_\_

(Address) \_\_\_\_\_

By the authority vested in me pursuant to Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136k, I hereby order you not to sell, use, or remove the pesticide or device (name of product, batch codes, and other identification).

Based upon inspection or tests, the Environmental Protection Agency has reason to believe that the pesticide or device is in violation of the provisions of Section \_\_\_\_\_ of the Act in that the pesticide or device (specify violations).

This order shall pertain to all quantities of the above-named pesticide or device within the ownership, control, or custody of the above-named person, wherever located. Said pesticide shall not be sold, used, or removed other than in accordance with the provisions of this order or of such further orders as may be issued in connection with this pesticide or device.

Any person violating the terms or provisions of this order shall be subject to the penalties described in Section 14 of the Act, 7 U.S.C. §136l.

(Signature, name, and title) \_\_\_\_\_

Order served by: (Signature and title of EPA employee, time and date) \_\_\_\_\_

Order received by: (Signature and title of person named above) \_\_\_\_\_

For information concerning this Stop Sale, Use, or Removal Order, contact: (Name and title, address and phone number of Regional Office)

## Model Termination of Stop Sale, Use, or Removal Order

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

TERMINATION OF STOP SALE, USE, OR REMOVAL ORDER

(Date)(Name of person ordered)Sample No(s).                     (Name of company)(Address)

The Environmental Protection Agency has determined that (state amount) of the pesticide or device named in the Stop Sale, Use, or Removal Order dated (date of order) has been (method of approved disposal; e.g., registered, relabeled, destroyed, etc.) as of (date of disposition). Therefore, the Stop Sale, Use, or Removal Order is terminated concerning the amount of the pesticide or device stated above. Any other amounts of the pesticide or device affected by the order shall remain under the effect of the order until disposed of in the manner described above.

(Signature, name, and title)



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# Chapter Seven

## Administrative Enforcement Actions: Civil Penalty Proceedings

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## Chapter Seven

# 1 Introduction

In most instances, the Regional Office determines those violations that warrant the imposition of an administrative civil penalty. Many violations fall into this category. However, if the violation is sufficiently minor, a notice of warning may be appropriate (see Chapter Six, "Administrative Enforcement Actions: Notices of Warning and Administrative Orders"). Conversely, if the violation is committed knowingly, criminal prosecution may be more appropriate (see Chapter Nine, "Judicial Enforcement: Criminal Actions"). Chapter Five contains a general discussion of appropriate enforcement responses.

This chapter focuses on FIFRA civil penalty actions and the procedures for litigating administratively assessed penalties.

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### Consolidated Rules of Practice

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The Consolidated Rules of Practice (CROP, promulgated on April 9, 1980, 45 Fed. Reg. 24360, codified at 40 C.F.R. §22.01 et seq.) govern all adjudicatory proceedings for the assessment of civil penalties under FIFRA.\* They replaced the rules previously promulgated under Section 14 of FIFRA. The CROP are chiefly distinguished from the former rules by a shift in administrative appellate jurisdiction from the Regional Administrator to the Administrator.

### Regional Versus National Actions

The preappellate stage of most administrative proceedings generally occurs at the regional level. Therefore, the CROP discuss these stages only in the context of regional actions. However, if the violation is not Region-specific, the entire administrative proceeding may take place at the national level.

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\* The citations in the text in bold type are references to the 40 C.F.R. Part 22.

In order to apply to national actions, the CROP require the following substitutions of Agency officials:

<u>Regional</u>	<u>National</u>
Regional Hearing Clerk	Hearing Clerk
Regional Administrator	Administrator
Regional Judicial Officer	Judicial Officer

Substitutions between regional and national officials may also occur if an official is disqualified pursuant to the CROP. 22.04(d) Certain filing and service requirements specified by the CROP are also altered if the actions are conducted at the national level. For example, the Regional Hearing Clerk must forward a record of the proceeding to the Hearing Clerk when an initial decision is issued in a regional proceeding. Such a transfer is unnecessary if the proceeding was conducted at the national level. 22.27(a)

## 2 Elements of a Violation: Administrative

Under Section 14 of FIFRA, the Agency may issue administrative civil complaints to persons who violate Section 12 of the Act. In order to establish a prima facie administrative case against a respondent, the Agency must establish, by proper evidence, each element of the violation charged. The following charts list each violation that may occur under FIFRA, the related elements of proof that are necessary to bring the violation to court, and the means by which the element of proof is established.

## Section 12 (a)(1)(A)

Any pesticide not registered under Section 3.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the pesticide is not registered.</li> <li>4. Determination that the continued sale and use of existing stocks is not permitted under §6(a)(1) <u>if</u> the product has been cancelled.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or Registration Division (RD) personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel determine registration status after a search of their files. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>4. Same as No. 3, above.</li> </ol>

## Section 12 (a)(1)(B)

Any registered pesticide for which any claims made for it as part of its distribution or sale differed substantially from the claims made in connection with its registration.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a registered pesticide.</li> <li>3. Claims made for a registered pesticide as part of its distribution or sale differ substantially from the claims made in connection with its registration.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel determine registration status after a search of their files. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Compare copy of pesticide label, collected as part of the inspection, with registered label. For significance of claimed label discrepancies, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Section 12 (a)(1)(C)

Any registered pesticide whose composition differed at the time of its distribution or sale from the composition described in connection with its registration.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a registered pesticide.</li> <li>3. Determination that the composition of a pesticide sold or distributed in commerce differs from the composition under which it is registered.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel determine registration status after a search of their files. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Chemistry tests determine the composition of a pesticide sample picked up in commerce. These tests are compared with registrant's claimed composition for discrepancies. See "Laboratory Test Results" under "Initial Review of the ID Jacket" (Chapter 4). Appropriate RD personnel determine the significance of any discrepancy. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> </ol>



## Section 12 (a)(1)(D)

Any pesticide that has not been colored or discolored pursuant to the provisions of Section 25(c)(5).

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the pesticide has not been colored or discolored pursuant to the provisions of Section 25 (c)(5).</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Consult 40 C.F.R. §162.13 for requirements imposed on registrants to color or discolor pesticides.</li> </ol>

## Section 12 (a)(1)(E); 2(q)(1)(A)

Any pesticide or device that was misbranded in that the labeling bore a statement, design, or graphic representation that was false or misleading.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, received and (having so received) delivered or offered to deliver a pesticide or device.</li> <li>2. Determination that the product is a pesticide or device.</li> <li>3. Determination that the pesticide or device was misbranded in that its labeling bore a statement or graphic representation that was false or misleading, i.e.: <ul style="list-style-type: none"> <li>• A false or misleading statement concerning the composition of the product;</li> <li>• A false or misleading statement concerning the effectiveness of the product as a pesticide or device;</li> <li>• A false or misleading statement concerning the value of the product for purposes other than as a pesticide or a device;</li> <li>• A false or misleading comparison with other pesticides or devices;</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Consult 40 C.F.R §162.10(a)(5) for requirements imposed on products to prevent misbranding. Compare copy of pesticide label collected as a part of inspection with registered label. If available, RD will review efficacy data for the product. For the significance of misbranding, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ul style="list-style-type: none"> <li>● Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal government;</li> <li>● The name of a pesticide containing two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients, even though the names of the other ingredients are stated elsewhere in the labeling.</li> <li>● A true statement used in such a way as to give a false or misleading impression to the purchaser;</li> <li>● Label disclaimers that negate or detract from labeling statements required under the Act and implementing regulations;</li> <li>● <del>Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "non-injurious," "harmless," or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and</del></li> <li>● Non-numerical and/or comparative statements on the safety of the product, including but not limited to: <ul style="list-style-type: none"> <li>- <del>"Contains all natural ingredients,"</del></li> <li>- "Among the least toxic chemicals known," or</li> <li>- "Pollution approved."</li> </ul> </li> </ul>	

## Sections 12(a)(1)(E); 2(q)(1)(B)

Any pesticide or device that was misbranded in that it was contained in a package or other container or wrapping which did not conform to the standards established by Section 25(c)(3).

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, received and (having so received) delivered or offered to deliver a pesticide or device.</li> <li>2. Determination that the product is a pesticide or device.</li> <li>3. Determination that the pesticide or device has not been properly packaged.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Consult 40 C.F.R. §162.16 for the requirements imposed on registrants to package pesticide products or devices in a manner that prevents injury or illness. Also see Child-Resistant Packaging Guidelines issued by PTSCMS. If determination cannot be made, refer to RD personnel. For the significance of deficiencies, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(1)(C)

Any pesticide or device that was misbranded in that it was an imitation of, or was offered for sale under the name of, another pesticide or device.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, received and (having so received) delivered or offered to deliver a pesticide or device.</li> <li>2. Determination that the product is a pesticide or device.</li> <li>3. Determination that the pesticide or device was misbranded in that it was offered for sale under the name of another pesticide or device, i.e.: <ul style="list-style-type: none"> <li>• A manufacturer duplicated the composition of another pesticide and offered it for sale under the name of that pesticide.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel determine that manufacturer of product is not the producer registered to manufacture that product. See "Scientific Review" under "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> </ol>

## Sections 12(a)(1)(E); 2(q)(1)(D)

Any pesticide or device that was misbranded in that its label did not bear the assigned registration number of the establishment in which it was produced.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide or device.</li> <li>2. Determination that the product is a pesticide or device.</li> <li>3. Determination that the label of the pesticide or device did not bear the assigned registration number of the establishment in which it was produced.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or PTSCMS personnel review product labeling to determine whether the appropriate establishment registration number appears on the label collected during the inspection. Consult 40 C.F.R. §162.10(e) for requirements. For the significance of the omission, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(1)(E)

Any pesticide or device that was misbranded in that words, statements, or other information that is required to appear on the label or labeling was not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide or device.</li> <li>2. Determination that the product is a pesticide or device.</li> <li>3. Determination that the label or labeling of the pesticide or device does not conform to the format required by the product's registration.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review product labeling to determine conformance with the label accepted in conjunction with the registration. Consult 40 C.F.R. §162.10(a)(2) for "Prominence and Legibility" requirements. For the significance of the discrepancies, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(1)(F)

Any pesticide or device that was misbranded in that the labeling accompanying it did not contain the directions for use that are necessary for effecting the purpose for which the product is intended, and if complied with together with any requirements imposed under Section 3(d) of the Act, are adequate to protect human health and the environment.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide or device.</li> <li>2. Determination that the product is a pesticide or device.</li> <li>3. Determination that the directions for use did not meet the requirements imposed for the protection of health and the environment by the Act and implementing regulations.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review product labeling to determine whether the label obtained during inspection conforms to the label accepted in conjunction with the product's application for registration. Consult 40 C.F.R. §162.10(i) for requirements. For the significance of the discrepancies, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>



## Sections 12(a)(1)(E); 2(q)(1)(G)

Any pesticide or device that was misbranded in that the label did not contain a warning or caution statement which is necessary, and if complied with, together with any requirements imposed under Section 3(d) of the Act, is adequate to protect human health and the environment.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, received and (having so received) delivered or offered to deliver a pesticide or device.</li> <li>2. Determination that the product is a pesticide or device.</li> <li>3. Determination that the warning or caution statements did not meet requirements of the Act and/or implementing regulations.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review product labeling to determine whether the label obtained during the inspection conforms to the label accepted in conjunction with the product's application for registration. Consult 40 C.F.R. §162.10(h) for requirements. For the significance of the discrepancies, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(1)(H)

Any nonregistered pesticide intended for export that was misbranded in that the statement, "Not registered for use in the United States," was not prominently placed on the label.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the product is not registered.</li> <li>4. Determination that the required statement was not prominently placed on the label.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel determine registration status after a search of their files. See "Further Processing of ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>4. Appropriate regional or RD personnel review pesticide label to determine whether the required statement was prominently placed. For the significance of its omission, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(2)(A)

Any pesticide that was misbranded in that the label did not bear an ingredient statement on that part of the immediate container that is presented or displayed under customary conditions of purchase, or on another part of the immediate container, or on the outside container or wrapper, as permitted by the Administrator.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the product label bears the ingredient statement in the appropriate position except where: <ul style="list-style-type: none"> <li>• The size or form of the product container makes it impracticable to place the statement on the part of the label displayed to purchasers; and</li> <li>• The statement appears prominently in another position as permitted.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review the product labeling to determine whether the label obtained during inspection conforms to the label accepted in conjunction with the product's application for registration. Consult 40 C.F.R. §162.10(g)(2) for the requirements. For the significance of the discrepancies, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(2)(B)

Any pesticide that was misbranded in that the labeling did not contain a statement of the use classification under which the product was registered.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the product label does not bear the required statement of use classification, or does not bear the appropriate statement in the proper position or size.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review product label to determine whether the label obtained at the inspection conforms to the label accepted in conjunction with the product's registration application. Consult 40 C.F.R. §162.10(j) for the requirements. For the significance of the discrepancies, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(2)(C)

Any pesticide that was misbranded in that there was not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing the required information.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the product label does not bear the following required information: <ul style="list-style-type: none"> <li>• The name and address of the producer, registrant, or person for whom the pesticide was produced;</li> <li>• The name, brand, or trademark under which the pesticide is sold;</li> <li>• The net weight or measure of the contents, unless an exemption is granted by the Administrator; and</li> <li>• The registration number assigned to the pesticide and the use classification.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review product labeling to determine if the label obtained in the inspection conforms to the label accepted in conjunction with the product's application for registration. For the significance of the omissions, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(q)(2)(D)

Any pesticide that was misbranded in that it contained a substance or substances highly toxic to humans and its label failed to bear:

- The skull and crossbones;
- The word "Poison" in red on a distinctly contrasting background; and
- A statement of practical treatment (first aid or otherwise) in case of poisoning.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the product label does not bear the required statements or designs.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review the product labeling to determine whether the label obtained during inspection conforms to the label accepted in conjunction with the product's registration application. Consult 40 C.F.R. §162.10(h) for the requirements. For the significance of the omission, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(1)(E); 2(c)

Any pesticide that was adulterated in that:

- Its strength or purity fell below the professed standard of quality under which it was sold;
- Another substance had been substituted wholly or in part for the pesticide; or
- A valuable constituent of the pesticide had been wholly or in part abstracted.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver a pesticide.</li> <li>2. Determination that the product is a pesticide.</li> <li>3. Determination that the product was adulterated in a manner described by the Act.</li> </ol>	<ol style="list-style-type: none"> <li>1. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>3. Appropriate regional or RD personnel review chemistry laboratory tests to determine whether the product composition conforms to the composition accepted in conjunction with the application for registration. See "Scientific Review" under "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4). For the significance of the adulteration, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Section 12(a)(2)(A)

A person detached, altered, defaced, or destroyed, in whole or in part, labeling required under the Act.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that the sampled label had been detached, altered, defaced, or destroyed, in whole or in part.</p>	<p>1. Review documentation of the violation to determine the extent of the violation. See "Other Evidential Documentation" under "Initial Review of the ID Jacket" and "Labeling Review" under "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4). For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>



## Section 12(a)(2)(B)

A person refused to keep records required by Section 8 or by 40 C.F.R. Part 169.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that pesticide or device producer did not maintain the following records:</p> <ul style="list-style-type: none"> <li>● Records showing: <ul style="list-style-type: none"> <li>- Product name</li> <li>- EPA registration number</li> <li>- Experimental permit number (if applicable)</li> <li>- Batch amounts</li> <li>- Batch identification</li> <li>- Production control records</li> <li>- Complete formula if required</li> </ul> </li> <li>● Brand names and quantities of pesticides or devices produced. Records of producer receipts of pesticides, devices, active ingredients used in producing pesticides. <ul style="list-style-type: none"> <li>- Brand name/common or chemical name</li> <li>- Name and address of shipper</li> <li>- Name of transporter</li> <li>- Date received</li> <li>- Quantities received</li> </ul> </li> <li>● Records regarding shipment of pesticides, devices, and active ingredients. <ul style="list-style-type: none"> <li>- Brand name/common or chemical name</li> <li>- Name and address of consignee</li> </ul> </li> </ul>	<p>1. Regional personnel review copies of records obtained during inspection to determine whether the records are maintained. See "Other Evidential Documentation" under "Initial Review of the ID Jacket" (Chapter 4). Consult 40 C.F.R. Part 169 for the requirements. For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ul style="list-style-type: none"> <li>- Name of originating carrier</li> <li>- Date shipped or delivered for shipment</li> <li>- Quantities shipped or delivered for shipment</li> <li>- Distribution information required for pesticides produced pursuant to an experimental use permit, a special exemption, or a special local need</li> <li>• Inventory records of items produced. <ul style="list-style-type: none"> <li>- Types</li> <li>- Amounts of pesticides or active ingredients</li> <li>- Quantities of devices</li> </ul> </li> <li>• Copies of all domestic advertising of restricted uses.</li> <li>• Copies of all guarantees.</li> <li>• For items intended solely for export <ul style="list-style-type: none"> <li>- Copies of foreign purchaser's specifications or directions for production</li> <li>- Copies of labels or labeling</li> <li>- Copies of statement signed by foreign purchaser acknowledging that the item is not registered for use and cannot be sold for use in the U.S. (Must be obtained for the first shipment of a particular product to a particular purchaser each year.)</li> </ul> </li> </ul>	

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ul style="list-style-type: none"> <li>● Records on disposal <ul style="list-style-type: none"> <li>- Method</li> <li>- Dates</li> <li>- Sites</li> <li>- Types of pesticides</li> <li>- Amounts</li> </ul> </li> <li>● Records of tests on humans. The following records of tests on human beings must be maintained for 20 years or sent to EPA after 3 years <ul style="list-style-type: none"> <li>- Name and address of subject</li> <li>- Test dates</li> <li>- Test types</li> <li>- Written consent of subject</li> <li>- All information and instructions given to subject</li> <li>- Any adverse effects of tests on subjects</li> </ul> </li> <li>● Research data records <ul style="list-style-type: none"> <li>- Test reports sent to EPA in support of: <ul style="list-style-type: none"> <li>● Registration</li> <li>● Tolerance petition</li> <li>● All underlying raw data with their interpretations and evaluations</li> </ul> </li> </ul> </li> </ul>	

## Section 12(a)(2)(B)

A person refused to allow the inspection of any records or of an establishment pursuant to Section 8 or 9.\*

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that the agent in charge of a FIFRA-regulated establishment did not allow the inspector entry for purposes of conducting an inspection or examination of records.</p>	<p>1. Review inspector's documentation that he or she was denied entry into the establishment for purposes of conducting an inspection or examination of records. Documentation should include the name and position of the company official who refused entrance or records examination, a summary of the conversation or events, and the date and time of the denial.</p>
<p>* In <u>N. Jonas and Company Inc.</u>, I.F.&amp;R. Docket No. III-121C (July 27, 1978), an Administrative Law Judge held that, even after the Supreme Court's decision in <u>Marshall v. Barlow's Inc.</u>, 436 U.S. 307 (1978) [see Three Warrants in Chapter Three], the refusal to allow a warrantless inspection of a FIFRA-regulated establishment properly subjected the owner to an administratively assessed civil penalty.</p>	

## Section 12(a)(2)(B)

A person refused to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to Section 9.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that the agent in charge of the establishment did not allow the inspector to take a sample of a pesticide.</p>	<p>1. Review inspector's documentation that he or she was denied the right to take a pesticide sample. Documentation should include the name and position of the company official who disallowed the inspector to take a sample of the pesticide, a summary of the conversation or events, and the date and time of the denial.</p>

## Section 12(a)(2)(C)

A person gave a guaranty or undertaking provided for in Section 12(b) that was false in any particular.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that guaranty of registration and compliance with the Act meet the requirements of the Act and implementing regulation.</p>	<p>1. Consult 40 C.F.R. §162.12 for regulatory requirements and sample guaranty. Review copies of guaranty obtained during inspection. See "Other Evidential Documentation" under "Initial Review of the ID Jacket" (Chapter 4). For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>

## Section 12(a)(2)(D)

A person used to personal advantage or revealed to persons other than those authorized by the Act any confidential information acquired under the Act.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that confidential information was used for personal advantage.</p>	<p>1. Conduct investigation to determine whether respondent had access to confidential information and whether such information was revealed to unauthorized personnel for respondent's personal advantage. Investigation should include:</p> <ul style="list-style-type: none"> <li>• Interviews (affidavits) with the party suspected of releasing the information;</li> <li>• The party(ies) suspected of receiving the confidential information; and</li> <li>• Any other individual with knowledge of the incident.</li> </ul> <p>For significance of the alleged disclosure, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>

## Section 12(a)(2)(E)

A person advertised, in his or her capacity as a registrant, wholesaler, dealer, retailer, or other distributor, a pesticide registered for restricted use without giving the classification assigned under Section 3 of the Act.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that the product is a pesticide registered for restricted use.</li> <li>2. Determination that a restricted use pesticide was advertised for sale without its appropriate use classification.</li> </ol>	<ol style="list-style-type: none"> <li>1. Appropriate regional or RD personnel determine registration status after a search of their files. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>2. Review product advertising to determine whether the use classification is included. For list of restricted use pesticides, see 40 C.F.R. §162.31. See "Labeling Review" under "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4). Appropriate regional RD personnel determine product classification status. For the significance of the omission, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>



## Section 12(a)(2)(F)

A person made available for use or used a restricted use pesticide for any purpose other than in accordance with Section 3(d) and any regulations thereunder.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that the product is a pesticide.</li> <li>2. Determination that a restricted use pesticide was made available for use or used in a manner not in accordance with the uses allowed for the product's registration.</li> </ol>	<ol style="list-style-type: none"> <li>1. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>2. Consult 40 C.F.R. §162.31 to determine whether the product contains an active ingredient that requires a restricted use classification. Review inspector's report to determine whether dealer sold restricted use pesticide to inappropriate, person or, if appropriate whether pesticide was improperly used. Review product label to determine use classification. See "Labeling Review" under "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4). For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Section 12(a)(2)(G)

A person used a registered pesticide in a manner inconsistent with its labeling.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that the product is a registered pesticide.</li> <li>2. Determination that the product was used in a manner inconsistent with its labeling.</li> </ol>	<ol style="list-style-type: none"> <li>1. Regional personnel ensure that product is registered through regional files or RD review. Review accepted label to determine acceptable uses. See "Labeling Review" under "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>2. Review documentation to determine whether the actions of the respondent (use of the pesticide) were inconsistent with the product's label. For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Section 12(a)(2)(H)

A person used a pesticide that was under an experimental use permit contrary to the provisions of the permit.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that pesticide is under an experimental use permit.</li> <li>2. Determination that use of the pesticide violated the terms of the permit. The permit will specify the following: <ul style="list-style-type: none"> <li>• Duration of the permit;</li> <li>• Limitations and uses;</li> <li>• Additions;</li> <li>• Records maintenance requirements;</li> <li>• Labeling requirements; and</li> <li>• Reporting requirements.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Appropriate RD personnel verify that pesticide is under a permit.</li> <li>2. Consult permit issued by RD and 40 C.F.R. Part 172 for terms and conditions of permit. Compare with inspection documentation to determine nature of alleged violation. See "Other Evidential Documentation" under "Initial Review of the ID Jacket" (Chapter 4). For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Section 12(a)(2)(I)

A person violated an order issued under Section 13.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that the person who owns, controls, or has custody of a pesticide or device has violated the terms of a stop sale, use, or removal order (SSURO) in that any person having received the SSURO may not sell, use, or remove the pesticide or device</p>	<p>1. Consult the order to determine the terms and conditions of the order. Verify that the order has not been vacated but is still valid. Review inspection documentation to determine whether the pesticide or device was distributed in commerce. See "Additional Sources of Documentation" (Chapter 4).</p>

## Section 12(a)(2)(J)

A person violated a suspension order issued under Section 6.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that the product has had its registration suspended by order of the Administrator.</li> <li>2. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, received and (having so received) delivered or offered to deliver a pesticide in violation of the suspension order.</li> <li>3. Determination as to whether existing stocks of the product may be distributed in commerce.</li> </ol>	<ol style="list-style-type: none"> <li>1. Appropriate PTSCMS and/or RD personnel advise regional staff of order. (Notice of Suspension published in <u>Federal Register</u>; also on file with RD.)</li> <li>2. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>3. Consult order and PTSCMS policy guidance on case of existing stocks, remaining uses, and time frames for use. For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Section 12(a)(2)(K)

A person violated cancellation of registration issued under Section 6.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that the registration of a pesticide has been cancelled.</li> <li>2. Respondent (person) distributed, sold, offered for sale, held for sale, shipped, received and (having so received) delivered or offered to deliver a pesticide product whose registration has been cancelled.</li> <li>3. Determination as to whether existing stocks of the product may be distributed in commerce.</li> </ol>	<ol style="list-style-type: none"> <li>1. Appropriate PTSCMS and/or RD personnel advise regional staff of product registration cancellation. (Published in the <u>Federal Register</u>.)</li> <li>2. Identification of the responsible party for suspected violation in commerce. See "Additional Sources of Documentation" (Chapter 4).</li> <li>3. Consult order to determine appropriate terms and conditions. Check to see if there is any PTSCMS policy guidance on use of existing stocks and time frames for use. For the significance of the alleged violations, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(2)(L); 7(a)

A person violated Section 7 by failing to register his or her producing establishments.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that a pesticide, active ingredient of a pesticide, or device was produced (see definition, Section 2(w) of the Act).</li> <li>2. Determination that the producer of a pesticide, active ingredient, or device subject to the Act has failed to register his or her production establishment.</li> </ol>	<ol style="list-style-type: none"> <li>1. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide, active ingredient, or device. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>2. Appropriate regional or PTSCMS personnel determine establishment registration status. For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Sections 12(a)(2)(L); 7(c)(1)

A person violated Section 7 by failing to provide, in either an annual or initial report, the types and amounts of pesticides or devices he or she is currently producing, has produced during the past year, or has distributed during the past year.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that producer has failed to submit the required information or failed to submit the information in a timely manner.</p>	<p>1. Appropriate regional or PTSCMS personnel determine if report was submitted, and if so, review initial or annual report to determine whether the required information is included and has been filed in a timely manner. Consult 40 C.F.R. §167.5 for requirements. For the significance of the violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>



## Sections 12)(a)(2)(L); 7(c)(2)

A person violated Section 7 by failing to provide the names and addresses of recipients of pesticides or devices produced at his or her registered establishment pursuant to the Administrator's request for purposes of issuing a stop sale, use, or removal order pursuant to Section 13.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that the required information will not be supplied by the producer or is not maintained.</p>	<p>1. Review the request for the information to determine adequacy of notice. For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>

## Sections 12(a)(2)(M); 14(a)

Any person who knowingly falsified all or part of any:

- Application for registration (40 C.F.R. Part 162);
- Application for an experimental use permit (40 C.F.R. Part 172);
- Information submitted under Section 7 (40 C.F.R. Part 167);
- Information marked as confidential and submitted under any provision of the Act;
- Records required to be maintained by Section 8 (40 C.F.R. Part 169);
- Records, reports, or invoices required by 40 C.F.R. §171.11(c)(7); or
- Reports required to be filed by the Act.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination that required information has been falsified.</p>	<p>1. Review the data submitted to meet regulatory requirements. Compare with records obtained during the inspection of the facility to determine whether discrepancies exist. For the significance of the violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>

## Section 12(a)(2)(N)

Any person who failed, in his or her capacity as a registrant, wholesaler, dealer, retailer, or other distributor, to file reports required by the Act.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<p>1. Determination of person's status and failure to file the required report.</p>	<p>1. Consult applicable regulation to determine reporting requirements. For the significance of the violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</p>

## Section 12(a)(2)(0)

Any person who added a substance to, or took a substance from, a pesticide in a manner that may defeat the purpose of the Act.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that the product is a pesticide.</li> <li>2. Determination that a person altered the composition of a pesticide in order to defeat the purpose of the Act.</li> </ol>	<ol style="list-style-type: none"> <li>1. Appropriate regional or RD personnel review product labeling claims to determine whether the product is a pesticide. See "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4).</li> <li>2. Appropriate regional or RD personnel review laboratory tests to determine whether the pesticide has been altered. See "Scientific Review" under "Initial Review of the ID Jacket" (Chapter 4) and "Laboratory Test Results" under "Further Processing of the ID Jacket—Enforcement Case Review" (Chapter 4). For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>

## Section 12(a)(F)

Any person who used a pesticide in tests on human beings in violation of conditions specified by the Act.

ELEMENTS OF THE VIOLATION	ESTABLISHING THE VIOLATION
<ol style="list-style-type: none"> <li>1. Determination that the test subject was not fully informed of:               <ul style="list-style-type: none"> <li>• The nature and purpose of the test; and</li> <li>• Any foreseeable physical and mental health consequences.</li> </ul> </li> <li>2. Determination that the test subject did not freely volunteer to participate in the test.</li> </ol>	<ol style="list-style-type: none"> <li>1. Conduct investigation, then interview test subject. Review testing agreement to determine the degree of disclosure made to the test subject concerning the risks of the test.</li> <li>2. Interview test subject. Review scientific review of the test to verify nature and purpose of test. For the significance of the alleged violation, see "Level of Action Policy" (Chapter 5) and for the penalty amount, see Appendix 6.</li> </ol>



### 3 Complaint Preparation and Filing

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#### Civil Penalty Complaint Criteria

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As was previously discussed in Chapter Five, a civil penalty action is warranted when the violation presents a real (but not an extreme and unreasonable) risk to humans or the environment; is likely to be an isolated occurrence; is apparently the result of ordinary negligence, inadvertence, or mistake; and either:

- Involves a first offense under the Act by any registrant, commercial applicator, "for-hire" applicator, wholesaler, dealer, retailer, or other distributor (no prior warning is required by the Act); or
- Involves a private applicator or other person (other than any party specified above), who has received a prior warning or citation for a violation of the Act. (The prior warning or citation may have been for the same or a different FIFRA violation.)

Issuance of a complaint initiates a FIFRA Section 14(a) administrative penalty action.\*

#### Involvement of Multiple Respondents in a Single Violation

Frequently, the distribution of pesticides or devices in commerce will involve more than one party before the product is ultimately purchased for use. These multiple-party relationships are known as "distribution chains." Some examples of distribution chains include:

- A distributor who is also the registrant of a pesticide and the company that produces the pesticide for this distributor/registrant; and

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\* The complaint also serves to satisfy the notice and opportunity to be heard requirement for those actions subject to Section 9(c)(1) of FIFRA.

- A producer who holds a registration for a pesticide and a retailer who sells the producer/registrant's pesticide.

Under certain circumstances, more than one party in a distribution chain may be legally responsible for the same product violation. Pesticide enforcement officials may cite multiple respondents in administrative cases for an identical violation where it is determined that:

- The distributor/registrant and/or producer has no mechanism and has made no effort to determine the reliability of its supplier or packager;
- The violative product bears the name of a registered distributor even when no physical contribution was made to a processing or packaging error and there was no knowledge of the violation; or
- The violative product bears the name of a distributor who is not the distributor/registrant but whose name provides a basis for consumer reliance.

Nonregistered retailers (functioning as "mere conduits" standing next to the ultimate consumer in the chain of distribution) may, at the complainant's discretion, be spared a civil penalty action in favor of a Section 9(c)(3) notice of warning or an enforcement correspondence if:

- The violative product does not bear the retailer's name; or
- The violative product bears the retailer's name but the name does not provide the basis for consumer reliance.

A producer who is not a registrant but who functions as an agent of the registrant, and whose liability is based solely on the legal relation with the registrant may, at the complainant's discretion be similarly treated.

In the case of a single violation involving multiple respondents from multiple Regions, designation of regional jurisdiction over the cases or consolidation of cases thus arising will be determined jointly by the involved Regions and Headquarters PTSCMS on a case-by-case basis.

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### Delegated Authority

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#### Regional Administrator

The Regional Administrator is to exercise all powers and duties as prescribed or delegated under the Act and the CROP. In addition, the



Regional Administrator\* has been delegated the authority to:

- Issue administrative complaints;
- Evaluate the appropriateness of civil penalties; and
- Negotiate and sign consent agreements memorializing settlements between the Agency and respondent prior to the alleged violator's filing of an answer or failure to file an answer to a complaint.

The Regional Administrator, however, must consult with the Regional Counsel's office before exercising any of the above authorities. In addition, the Regional Administrator must consult (verbally or in writing) with Headquarters PTSCMS in the following instances:

- Routine misuse cases (verbal),
- Exceptional misuse cases of first impression or of unusual national importance (written), and
- ~~Settlement reductions of more than 40 percent of the penalty amount originally proposed (written).~~

In every proceeding, the Regional Administrator will rule on all motions filed or made before an answer to the complaint is filed. 22.16(c)

#### Regional Judicial Officer

A Regional Administrator may delegate all or part of his or her authority to act in a given proceeding to a Regional Judicial Officer. Any such delegation is to be performed in accordance with the CROP.

~~A Regional Judicial Officer may exercise any authority delegated to him or her by the Regional Administrator, or the Regional Judicial Officer may refer any case or motion to the Regional Administrator when such referral is appropriate. 22.04(b)(3)~~

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\* The Assistant Administrator for Pesticides and Toxic Substances may also exercise these authorities in multi-regional cases or cases of national significance. However, he or she must consult in advance with the Associate Administrator for OLEC or his or her designee and must notify any affected Regional Administrators or their designees when exercising ~~any of the above authorities. These authorizations are redelegable to the Division Director level.~~

Presiding Officer

The Presiding Officer is to conduct a fair and impartial proceeding, ensure that the facts are fully elicited, adjudicate all issues, and avoid delay. The Presiding Officer has the authority, under 22.04(c), to:

- Conduct administrative hearings under these rules of practice;
- Rule upon motions, requests, and offers of proof; dispose of procedural requests; and issue all necessary orders;
- Administer oaths and affirmations and take affidavits;
- Examine witnesses and receive documentary or other evidence;
- For good cause, upon motion by a party or sua sponte (i.e., upon his own motion), order a party or an officer or agent thereof to produce testimony, documents, or other nonprivileged evidence and, failing the production thereof without good cause being shown, draw adverse inferences against that party;
- Admit or exclude evidence;
- Hear and decide questions of facts, law, or discretion;
- Require parties to attend conferences for the settlement or simplification of the issues, or the expedition of the proceedings; and
- Do all other acts and take all measures necessary for the maintenance of order and for the efficient, fair, and impartial adjudication of issues arising in proceedings governed by the CROP.

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FIFRA Penalty Assessment Considerations

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Factors for Determining Penalty Amount

Section 14(a)(4) of FIFRA requires that the Agency consider the following factors in determining the initial penalty amount. Information impacting on this determination may be obtained from financial reports (e.g., Dun and Bradstreet), corporate reports, and reports filed with other government agencies such as the Securities and Exchange Commission.

- The Size of the Business of the Person Charged. As applied to violators subject to Section 14(a)(1) of the Act and "for hire" applicators under Section 14(a)(2), size of business should be interpreted to include total business revenues from total business operations of the business entity to which that product in violation is attributable.

Where a subsidiary company is validly separable as an entity discrete from its parent, it should be considered alone. Where pesticide production is a constituent part of a total business operation involving numerous nonpesticide products, size of business shall be based on total revenues. This determination should be based on acceptable accounting procedures.

The proportion of the pesticide's component to the total diversified activities of the respondent, profit versus loss, etc., may be considered for purposes of mitigation, but should not be entered at the outset when initial penalty assessment is determined based on consideration of the size of the business.

- The Effect on the Defendant's Ability To Continue in Business. Should there be evidence at the outset that the proposed penalty will affect the respondent's ability to continue in business, the initial assessment should reflect this consideration and such mitigation as is appropriate.

Should it be clear at the outset that the respondent will be unable to pay the proposed penalty (evidence of bankruptcy or business loss available in rare circumstances when the violation is discovered), a penalty complaint should be filed nonetheless noting the absence of any assessment based on inability to pay and follow through to an appropriate final order. In such case, respondent retains the right to contest such complaint and allegation of violation. (In no other situation should "zero" penalty occur.)

In the absence of information about respondent's inability to pay, the initial presumption will be that the assessment of the proposed penalty will not affect respondent's ability to continue in business.

In no case should a threat by respondent to go out of business voluntarily if a penalty is assessed be considered as evidence of inability to pay.

- The Gravity of the Violation. The gravity of any violation is a function of the following factors [see Amvac Chemical Corporation I.F.R. No. IX-4C(1974)]:
  - The potential to injure humans or the environment,
  - The severity of the potential injury,
  - The scale and type of product use anticipated,
  - The identity of the persons exposed to the risk of injury,
  - The extent to which the applicable provisions of the Act were in fact violated,
  - ~~The violator's history of compliance and actual knowledge of the Act, and~~
  - Any evidence of good faith.

History of compliance and good faith may be considered to include activities under FIFRA as amended in 1972, 1975, 1978, and under the 1947 FIFRA, provided that such history does not include any complaint or notice to which respondent made answer or explanation and which was not further pursued by the complainant [see In Re Beaulieu I.F.&R. No. IX-10C(1974)]. A prior notice without any further action may be considered by the complainant in determining the issue of respondent's prior knowledge of the Act.

### Penalty Assessment Guidelines

EPA has established a penalty assessment system that initially assesses a penalty amount based on the nature and extent of the violation and then adjusts this amount in consideration of mitigating or exacerbating factors. The guidelines for assessing civil penalties are provided in Appendix 6 of this manual.

### Independently Assessible Charges

A separate civil penalty should be assessed for each violation of the Act that results from an independent act (or failure to act) by the respondent and is substantially distinguishable from any other charge in the complaint for which a civil penalty is to be assessed. A given charge is independent of, and substantially distinguishable from, any other charge when it requires an element of proof not needed by the others. (See Elements of a Violation: Administrative in Section 2 of this chapter.) Not every charge that appears in a complaint can be separately assessed. Where a charge derives primarily from or merely restates another charge, a separate assessment is not warranted. Charges that do not support a separate assessment are to be indicated in the complaint as "lesser included charges."\*

### Multiple Misbranding

Multiple instances of pesticide and device misbranding, however, are not independently assessible when there is a shipment of a single pesticide

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\* See In the Matter of Pearson & Company, I.D. Nos. 88176, 88468, 90943, Initial Decision by ALJ Bernard D. Levinson, May 31, 1974; and In Re: Chapman Chemical Company, I.D. No. 104559, amended Final Order by R. A. Jack E. Ravan, July 29, 1975. See also Blockburger v. United States, 284 U.S. 299 (1932); and Tesciona v. Hunter, 151 F.2d 589 (10th Cir. 1945).

product.\* Multiple misbrandings must appear either:

- As lesser included charges to accompany a count of misbranding; or
- As allegations in a single count.

In either case, only a single civil penalty should be assessed. The gravity of the single violation involving several label deficiencies, however, may be determined to be greater than that of a violation involving only one misbranding. Thus it may support a higher penalty than that proposed for a single misbranding. A proposed penalty may be derived by locating on the penalty matrix a figure for one of the misbranding violations and increasing that figure up to as much as \$5,000. The increase would depend on the number and/or seriousness of the additional misbrandings, as well as whether they are cited as primary or lesser included charges.

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### Complaint Preparation

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Since the complaint initiates an administrative civil penalty action and is the focal point for all subsequent proceedings, it must be as complete as possible. Failure to file a complaint that meets the standards and procedures outlined in this chapter may:

- Cause a delay in the proceedings;
- Prevent the complainant from being granted a motion for default under Section 22.17 of the CROP; and
- Make the complainant subject to adverse motions by other parties to the proceedings.

### Checklist of Complaint Requirements 22.14(a) \*\*

The following elements are considered necessary to establish the legal sufficiency of a civil penalty complaint:

1. Statement reciting the section(s) of the Act authorizing the issuance of the complaint;

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\* See In the Matter of Hawk Industries, Inc., I.F.&R. Docket No. II-120-C, issued by ALJ Bernard D. Levinson, December 21, 1976.

\*\* The numbers to the left of each of the following items correspond to numbers in Exhibit 7-1, which shows a sample complaint. The numbers in the exhibit identify examples of each kind of information.

2. Specific reference to each provision of the Act and to the regulations that the respondent is alleged to have violated;
3. Concise statement of the factual basis for alleging the violation;
4. Statement explaining the proposed penalty;
5. Copy of the Agency's "Guidelines for the Assessment Section 14(a); Citation Charges for Violations," 39 Fed. Reg. 27711 (1974);
6. Proposed amount of civil penalty to be assessed;
7. Notice of respondent's right to request a hearing on any material fact contained in the complaint or on the appropriateness of the amount of the proposed penalty;
8. Copy of the Consolidated Rules of Practice (CROP);
9. Notice of opportunity for an informal settlement conference; and
10. Date and signature with notation of title of a duly authorized official of the Agency.

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### Elements of the Complaint

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The discussion under each element of the complaint gives the purpose of the element and in some cases the reason for its particular place in the complaint.

### Caption

- Identification of Respondents (A).\* Respondents, or those against whom the complaint is filed, are to be accurately and individually identified on the left side of the caption.
- Docket Number and Subjects of the Complaint (B). The I.F.&R. Docket Number and matters addressed in the complaint are to be properly identified on the right side of the caption. Docket numbers are assigned by the Regional Hearing Clerk. The docket number designates the Region involved in Roman numerals followed by the case number (e.g., I.F.&R. Docket No. IX-10C). The docket number must be accurately reflected in the caption, because it is the identifying number for all subsequent documents filed in the proceedings.

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\* The letters in parentheses to the right of each element correspond to the letters in Exhibit 7-1.

Jurisdictional Authority (C)

The complaint must contain a statement of jurisdictional authority that informs the Presiding Officer and the respondent of the statutory authority under which the complaint is issued. This statement should be in the beginning of the complaint and should be as specific and precise as possible.

22.14(a)(1)

Factual Allegations (D)

In this section of the complaint, the specific facts of a particular violation are tied to the statute, rule, regulation, and/or order that allegedly has been violated.

The goal of this section is to adequately inform the Presiding Officer of the alleged violations and to inform the respondent of the charges so that an adequate response can be prepared.

Violations are identified by the particular sample (ID) number.

In the event of a complaint containing multiple sample (ID) numbers, the discussion of each separate sample (ID) should contain an enumeration of the facts and circumstances of each separate violation related to that sample. The proposed penalty assessment should include an enumeration of the dollar amount proposed for each violation charged with respect to that sample or an indication that a particular charge is "lesser included" and bears no penalty assessment. The factual allegations of the complaint, including multiple samples, should be separated into paragraphs.

In making factual allegations, the key word is "concise." "Conciseness" means that all material facts necessary to establish the factual basis for each violation are specified, while extraneous or irrelevant information is omitted. Although the purpose of this section is only to inform the respondent and Presiding Officer of the facts that the alleged violation is based on, all relevant facts should be included rather than risk failure to meet the requirements set forth in the CROP. For instance, even though the respondent may have been present when certain facts were ascertained, those facts must still be included to inform the respondent and the Presiding Officer of their legal significance.

22.14(a)(3)

Citation of Legal Requirements Violated (E)

The citation of the particular provision of the statute, regulation, rule, or order that allegedly has been violated must be as specific as possible. For example, if the complaint alleges a violation of Section 12 of FIFRA, the specific subsection under Section 12 that is the basis of the violation must be cited [e.g., misuse of pesticide 12(a)(2)(G)].

22.14(a)(2)

Amount of Civil Penalty and Rationale (F, G)

This section of the complaint is intended to:

- Explain the reason for the proposed penalty (F) in a manner that reflects the fact that the Agency has considered the penalty assessment factors specified by Section 14(a)(4) of FIFRA. Every detail of the Agency's reasoning process need not be reflected; however, the section should state that the FIFRA criteria were considered in assessing the penalty. In order to help meet the statutory requirement without unnecessary elaboration, a copy of the Agency's policy in assessing FIFRA civil penalties should be attached to the complaint; and  
22.14(a)(5)
- Specifically identify the proposed penalty amount (G).  
22.14(a)(4)

Right to Request a Hearing (H)

The respondent must be informed of the right to request a hearing concerning any material fact contained in the complaint or concerning the appropriateness of the amount of the proposed penalty. The respondent should be referred to a copy of the CROP, which is attached to the complaint, for information concerning the request for a hearing and the consequences of failing to request a hearing.  
22.14(a)(6)

Notice of Opportunity for an Informal Settlement Conference (I)

The Agency encourages all parties against whom a civil penalty proceeding has been initiated to pursue the possibility of settlement through informal conferences with the Agency. Therefore, the respondent should be informed that, regardless of whether a hearing is requested, a request for informal settlement conference may be made. The respondent should be cautioned, however, that a request for an informal conference does not stay the running of the 20-day time period for requesting a hearing and filing an answer.

Signature Block (J)

The complaint must be dated and signed (with notation of title) by a duly authorized official of the Agency.



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Service of the Complaint

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The respondent is served with a copy of the complaint in either of the following manners:

22.05(b)

- Personal service. The complaint and accompanying documents are left with the respondent or an authorized representative; or
- Service by certified mail, return receipt requested. The complaint and accompanying documents are mailed to the respondent or an authorized representative.

Personal Service

~~For personal service on an individual at a business address, the complaint is left with the respondent or a person who is in charge of the office, such as an office manager, or a person who is responsible for the respondent's administrative affairs, such as a personal secretary.~~

For personal service on a corporation, company, or association, the complaint is left with an officer, partner, managing or general agent, or any other person authorized by appointment or by Federal or State law to receive service of process.

For personal service on a named individual at a residential address, the complaint is left with any person of suitable age and discretion who resides there.

Service by Mail

If the complaint is addressed to an individual person, it should be mailed to the last known business address by certified mail, return receipt requested.

~~If the complaint is addressed to a corporation, company, or association, it should be mailed, return receipt requested, to the last known address of an officer, partner, managing or general agent, or any other person authorized by appointment or by Federal or State law to receive service of process.~~

The return receipt establishes that the complaint was received on a particular date.

~~The receipt should be attached to the original complaint, which is retained by the Agency. If no return receipt is obtained, another letter should be sent. If no receipt is again obtained, personal service may be necessary.~~

**Service Upon U.S. Government Officials or Agencies**

Service upon an officer or agency of the United States must be made by delivering a copy of the complaint to the officer or agency, or in the manner prescribed by applicable regulations. If the agency is a corporation, service may be either personal or by certified mail directed to an officer, partner, managing or general agent, or any other person authorized by appointment or law to receive service of process.

22.05(b)(1)(iii)

**Service on State or Local Government Entities or Officials**

Service upon a State or local unit of government, or a State or local officer, agency, department, corporation, or other instrumentality must either be made in the manner prescribed by State law or upon the chief executive officer of the governmental unit or the State or local officer.

22.05(b)(1)(iv)

**Certificates of Service**

Proof of service must be made either by a properly executed affidavit of service (Exhibit 7-3) for personal service, or by a properly executed return receipt, for service by mail. A certificate of service must be filed with the original complaint.

22.05(b)(1)(v)

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**Filing the Complaint**

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The original and one copy of the complaint (with proof of service) must be filed with the Regional Hearing Clerk.

22.05(a)(1)

## Sample Complaint

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE ADMINISTRATOR

In re:	(A)	)	I.F.&R. Docket No. 1-420C	(B)
		)		
		)		
Firetog Industries, Inc.		)	COMPLAINT	
36 Sunshine Drive,		)	AND	
Clark, MA 02856		)	NOTICE OF OPPORTUNITY	
		)	FOR HEARING	
Respondent		)		
		)		
		)		

COMPLAINT

1. (C)

This civil penalty action is instituted pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by Section 14 [7 U.S.C. §1361] of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (hereinafter referred to as FIFRA). The complainant in this action is John Doe, Division Director, Enforcement Division, Region I, United States Environmental Protection Agency, who has been duly authorized to institute this action. The respondent in this action is Firetog Industries, Inc.

2. Allegations or Counts (D)

This is to notify you that there is reason to believe respondent has violated Section 12 [7 U.S.C. §136j] of FIFRA. The pesticide listed below is not in compliance with provisions of FIFRA as specified.

3. (E)

I.D. No. 152049 - MOLD STOP (EPA Registration No. 3681-3), which was being held for sale or distribution by your establishment in Clark, Massachusetts, on January 29, 1983, was:

1. Misbranded in that the label stated, in part:

\*\* \* \*

MOLD

STOP

\* \* \*

ACTIVE INGREDIENTS: 25% Propionic Acid

\* \* \*

whereas, when tested, the product did not contain 25% Propionic Acid. [FIFRA §12(a)(1)(E), 7 U.S.C. §136j(a)(1)(E); FIFRA §2(q)(1)(A), 7 U.S.C. §136(q)(1)(A)]

2. Adulterated in that its strength or purity fell below the professed standard or quality under which it was being held for sale. [FIFRA §12(a)(1)(E), 7 U.S.C. §136j(a)(1)(E); FIFRA §2(c)(1), 7 U.S.C. §136(c)(1)]

(When analyzed, the product was found to contain only 13.81% and 14.23% Propionic Acid in two separate tests.)

4. Proposed Civil Penalty (F)

In arriving at the assessment of the penalty specified below, the Environmental Protection Agency, as required by Section 14(a)(4) of FIFRA [7 U.S.C. §136l(a)(4)], has taken into consideration the following factors concerning the respondent:

- The size of respondent's business;
- The respondent's ability to continue in business, in light of the proposed penalty; and
- The gravity of the alleged violation.

5. Agency policy with respect to assessment is governed by the Environmental Protection Agency's "Guidelines for the Assessment Section 14(a); Citation Charges for Violations" [39 Fed. Reg. 27711 (1974)], a copy of which is attached to this complaint.

6. (G)  
Based on the above considerations, the Environmental Protection Agency proposes to assess a civil penalty in the amount of three thousand, seven hundred and forty dollars (\$3,740) against Firetogg Industries, Inc.

7. Notice of Opportunity To Request a Hearing (H)

8. This administrative civil penalty proceeding will be conducted pursuant to the Consolidated Rules of Practice (CROP) [40 C.F.R. §22.01 et seq.], a copy of which accompanies this complaint. Pursuant to the CROP, you have the right to request a hearing to contest any factual allegation set forth in the complaint or the appropriateness of the proposed penalty. In the event that you wish to request a hearing and to avoid having the above penalty assessed without further proceedings, you must file a written answer to this complaint with the Regional Hearing Clerk, United States Environmental Protection Agency, Region 1, John F. Kennedy Federal Building, Boston, Massachusetts 02203.

If you do not request a hearing or file a written answer within twenty (20) days of receipt of this complaint, the above penalty will be assessed without further proceedings, and you will be so notified.

9.

Settlement Conference

(I)

The Environmental Protection Agency encourages all parties against whom a civil penalty is proposed to pursue the possibility of settlement as a result of informal conferences. Therefore, whether or not you request a hearing, you may confer informally with the Agency concerning (1) whether the alleged violation in fact occurred as set forth above, or (2) the appropriateness of the proposed penalty in relation to the size of your business, the gravity of the violation, and the effect of the proposed penalty on your ability to continue in business. The request for an informal conference does not stay the running of the twenty (20) day time period for requesting a hearing and filing an answer. To explore the possibility of settlement in this matter, contact Ms. Kate Smith, Enforcement Division, United States Environmental Protection Agency, Region 1, John F. Kennedy Federal Building, Boston Massachusetts 02203, telephone (312) 989-9876.

10.

(J)

\_\_\_\_\_  
John Doe  
Director, Enforcement Division

Date: \_\_\_\_\_ At: \_\_\_\_\_

Enclosures: FIFRA, as amended  
Guidelines for the Assessment Section 14(a); Citation  
Charges for Violations  
Consolidated Rules of Practice (CROP)

## Sample Cover Letter

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
Region I  
John F. Kennedy Federal Building  
Boston, MA 02203

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

G.B. Stubbs, Registered Agent  
Firetog Industries, Inc.  
36 Sunshine Drive,  
Clark, MA 02856

Dear Mr. Stubbs:

As the enclosed complaint and notice of opportunity for hearing indicates, the United States Environmental Protection Agency has initiated an administrative civil penalty proceeding against Firetog Industries, Inc., for violations of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. §136 et seq.).

It is suggested that you carefully read and analyze the complaint and the enclosed Consolidated Rules of Practice (40 C.F.R. §22.01 et seq.) so that you are fully apprised of the alternatives offered to you in considering the alleged violation, proposed penalty, and opportunity for a hearing. You will note that you have only twenty (20) days from your receipt of this notice within which to file an answer to the enclosed complaint with the Regional Hearing Clerk, United States Environmental Protection Agency, Region I, John F. Kennedy Federal Building, Boston, Massachusetts 02203. Failure to file a timely answer, in writing, will result in a default order being entered against you for the full amount of the assessed penalty.

The Agency encourages all parties against whom a civil penalty proceeding has been initiated to pursue the possibility of settlement through informal conferences with the Agency. Therefore, regardless of whether you request a hearing, you are extended the opportunity to request an informal settlement conference. To request a conference, please write to Ms. Kate Smith, United States Environmental Protection Agency, Region I, John F. Kennedy Federal Building, Boston, Massachusetts 02203, or telephone Ms. Smith at (312) 989-9876. Any discussion you may have with Ms. Smith will not affect the time period in which you are permitted to request a hearing or file an answer to the complaint.

Sincerely,

John Doe  
Director, Enforcement Division

Enclosure

## Model Affidavit of Service

AFFIDAVIT OF SERVICE  
UNITED STATES OF AMERICA  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

I hereby certify that being a person over 18 years of age, I served a copy of the within complaint

- (check one) ( ) in person  
( ) by registered mail, return receipt requested  
( ) by leaving the copy at principal place of business,  
which is

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- ( ) (write in other method, such as leaving it at dwelling,  
serving registered agent of corporation, etc.)

on the person named in the complaint on (month, day, and year).

(Signature of person making service)

(Name of person making service)

(Title, if any)





## 4 Prehearing Stage

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### Intervenors and Amicus Curiae

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~~An individual may make a motion to become an intervenor in any proceeding conducted under the CROP. To intervene, the individual's motion must reflect that:~~

- The individual has a certain interest in the proceeding that is not adequately represented by the original parties;
- The individual's presence will not unduly prolong or otherwise prejudice the adjudication of original parties' rights; and
- The individual will be affected adversely by a final order.

~~A motion to become an intervenor is ordinarily made before the first prehearing conference. However, the motion may be made after that time if good cause is shown for the failure to file in a timely manner. A party objecting to the intervention may make an answer to the motion to intervene within 10 days following service of the motion. Once an individual is permitted to intervene, that individual becomes a full party to the proceeding.~~

~~22.11(a), 22.11(b), 22.11(c), 22.03(a)~~

~~An individual may make a motion to file an amicus curiae brief. The motion must identify the interest of the applicant and the desirability of the proposed amicus brief. If the motion is granted, the Agency official granting the motion specifies the time for filing the brief. Once the motion is granted, the individual, while not considered a full party, is permitted to file amicus briefs in all subsequent briefings during the proceeding and is served with copies of all documents relating to such briefings.~~

~~22.11(d)~~

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Agency Files

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The Agency must maintain at least two files—one that is initiated by the Regional Hearing Clerk and one that is initiated by the Presiding Officer upon assignment to a case. In addition, an enforcement official bringing the action must maintain a separate file with duplicates of all documents filed in the proceeding. (See Regional Pesticides Enforcement Case File in this section.)

22.05(a)(1), 22.05(a)(2)

If the action is initiated at the national instead of the regional level, certain terms should be substituted for the terms set forth below. (See Regional Versus National Actions in Section 1 of this chapter.)

Files of Regional Hearing Clerk and Presiding Officer

All substantive documents served in the proceeding must be filed with the Regional Hearing Clerk. The Regional Hearing Clerk initiates this file after receiving the original and one copy of the complaint and the accompanying certificate of service. All original copies of filings and communications from Agency officials, including those from the Presiding Officer, are to be maintained in the Regional Hearing Clerk's file.

The Presiding Officer's file contains copies of all correspondence, except for correspondence from the parties to the Presiding Officer. Originals of such correspondence are kept by the Presiding Officer.

The documents that are filed with the Regional Hearing Clerk include:

22.05(a)

- Original and one copy of the complaint;
- Originals and copies of certificates of service;
- Original filings of any intervenors;
- Original answer received from the respondent;
- Original and one copy of rulings, orders, decisions, and other documents that are issued by the Regional Administrator, Regional Judicial Officer, or Presiding Officer;

22.06

- Originals of direct correspondence from the Presiding Officer to the parties; and
- Copies of direct correspondence from the parties to the Presiding Officer.

Copies of the above documents must be maintained in the Presiding Officer's file, except for correspondence from the parties to the Presiding Officer. The originals of such correspondence are kept by the Presiding Officer.

#### Regional Pesticides Enforcement Case File

The Agency enforcement official initiating a complaint maintains a separate file containing duplicates of all documents filed in the proceeding, as well as other enforcement documents relating to the case. Documents in this file include:

- Copies of all documents filed with the Regional Hearing Clerk or Presiding Officer;
- Any internal EPA documents used in generating the enforcement action (e.g., concurrence documents, checklists, etc.);
- EPA investigative records such as laboratory reports and copies of ~~business records~~;
- Original Penalty Assessment Worksheet(s);
- All correspondence between the respondent and other EPA parties; and
- All correspondence between EPA and other Federal or State agencies (e.g., the Department of Justice).

This file shall be retained for a minimum of five years in the Region after termination of the case, after which time it should be transferred to ~~Records Control Center~~.

#### Filing Requirements

A document is considered sufficient for filing if:

- It contains, on the first page of the document, a caption that identifies the respondent and the docket number assigned for the proceeding:  
22.05(c)(2)
- It bears the signature of the filing party, counsel, or other representative (except for exhibits); and  
22.05(c)(3)
- It bears the name, address, and telephone number of the person filing the document if it is the initial document filed by that person. Any changes in this information must be sent to the Hearing Clerk, Presiding Officer, and all other parties to the

proceeding. If a party fails to provide or, when appropriate, amend this information, the right to notice and service is waived.  
22.05(c)(4)

The Agency official with jurisdiction over the proceeding may prescribe additional requirements for the form of documents.

22.05(c)(1)

If the applicable requirements are not met, the Agency official receiving the filing may refuse to accept it until it is properly amended. Permission to amend is granted only upon motion to the Administrator, Regional Administrator, or Presiding Officer who refused to file the defective document.

22.05(c)(5)

Also, any party filing a document after the complaint has been issued must certify that copies of the document have been sent to other parties, appropriate Agency officials, and any amicus curiae. While the CROP do not give explicit sanctions for failure to provide an appropriate certificate of service, failure to serve copies of documents on individuals who have a right to notice may delay the proceeding and, in some cases, may even result in an otherwise entirely correct proceeding being dismissed by the Presiding Officer or being overturned on appeal.

22.05(a)(2)

#### Public Access to Documents Filed

Subject to any confidentiality requirements specified by law, the documents filed in the proceeding must be made available by the Regional Hearing Clerk for public inspection during business hours.

22.09(a)

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#### Prohibition of Ex Parte Discussion

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After a complaint has been issued, certain Agency officials are prohibited from discussing ex parte (i.e., without notice to all parties) the merits of the proceeding with individuals or their representatives who have an interest in the proceeding.

22.08

Although ex parte discussion about the merits of a proceeding is prohibited, if such communication occurs, it is regarded as argument, and a copy of the ex parte communication is served on all other parties in the proceeding. Those other parties are then afforded an opportunity to reply.

Failure to comply with these provisions of the CROP can taint an otherwise entirely correct proceeding and may result in its dismissal by the Presiding Officer or in the action being overturned on appeal.

The Agency officials subject to ex parte prohibitions are:

- Administrator;
- Regional Administrator;
- Judicial Officer;
- Regional Judicial Officer;
- Presiding Officer; and
- Any other person who is likely to advise these officials (e.g., the Associate Administrator for OLEC and the Assistant Administrator for Pesticides and Toxic Substances).

The Agency officials listed above are prohibited from participating in ex parte discussions with the following individuals:

- ~~An Agency official who performs a prosecutorial or investigative function in the proceeding or a factually related proceeding;~~
- Any person outside the Agency who has an interest in the proceeding; and
- Any representative of the persons identified above.

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#### Answer to the Complaint

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~~The respondent must respond to the allegations in the complaint within 20 days after service of the complaint.\* The response is in the form of an answer. In the answer, the respondent must admit, deny, or explain each of the factual allegations contained in the complaint. Where the respondent has no knowledge of the allegations and makes a statement to that effect, the allegations are considered denied. 22.15(b) Failure to admit, deny, or explain any material factual allegation contained in the complaint constitutes an admission of that allegation.~~

~~22.15(d)~~

#### Procedural Considerations

Before the answer is filed, all motions are made to the Administrator or Regional Administrator, or the Judicial Officer or Regional Judicial

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\* Service of the complaint is complete when the return receipt is signed (if the complaint was mailed) or when personal service is effectuated.

Officer, as appropriate. After the answer is filed, a Presiding Officer is designated, and all motions are made to that official.

22.16(c)

Filing a timely answer precludes the complainant from seeking a motion for default based on the failure to file a timely answer.

22.17(a)(1)

Filing a timely answer lessens complainant's opportunity to amend since, as a matter of right, the complainant may amend the complaint once before the answer is filed. Otherwise, a motion must be made to and approved by the Presiding Officer.

22.14(d)

The complainant may withdraw the complaint, all or in part, without prejudice one time before the answer has been filed. After one withdrawal before the filing of an answer or after the filing of an answer, the complaint may be withdrawn only upon motion granted by the Presiding Officer or Regional Administrator.

22.14(e)

#### Sufficiency of Answer

The answer must meet the following requirements:

- Filing the original of the answer with the Regional Hearing Clerk; and
- Complying with the general filing, service, and content requirements specified by the CROP.

22.05

The contents of the answer must include:

- Clear and direct admissions, denials, or explanations of each factual allegation contained in the complaint of which the respondent has any knowledge. If the respondent has no knowledge of a particular factual allegation and makes a statement to that effect, the allegations are considered denied. All allegations should be addressed in some manner;
- Grounds for defense;
- Facts that the respondent will put in issue; and
- Any request for a hearing.

22.15(b)

Evaluation of Answer

Upon receiving a copy of the answer, the complainant should immediately review it for any deficiencies and also check with the Regional Hearing Clerk to ensure that the requirements concerning timely filing and the general filing requirements have been met. Review of the answer might also indicate that a motion to amend the complaint is warranted (i.e., if proposed penalties should be reduced or increased).

Consequences of Deficient Answer

If the form requirements specified by Section 22.05(c) of the CROP are not complied with, the Regional Hearing Clerk can refuse to file the answer.  
22.05(c)(5)

If the requirements specified by Section 22.15(b) of the CROP are not complied with, the insufficient answer may be regarded as an admission of the matter(s) not sufficiently discussed.

22.15(d)

If the answer is not filed within the time requirement (20 days), the complainant can seek a default order.

22.17(a)(1)

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Prehearing Motions

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Motions may be made by the parties before a hearing is convened. Before the filing of an answer, motions are filed with the Regional Administrator. After the filing of an answer, motions are filed with the Presiding Officer.

22.16(c)

Written Motions

All motions made during the proceeding, except those made orally on the record during a hearing must:

22.05(a)(2), 22.05(b)(2), 22.16(a)

- Be in writing;
- Specifically state the grounds or basis for the motion;
- Specifically identify the action(s) that the motion seeks;

- Be accompanied by any evidence that is being relied upon by the movant (e.g., affidavits and legal memoranda); and
- Be served upon the parties.

A written motion must also comply with the general filing and service provisions of Section 22.05 of the CROP (i.e., it must be properly signed, accompanied by appropriate certificates of service, and bear an appropriate docket number).

Since a transcript is required only in a hearing and may be used in prehearing conferences at the discretion of the Presiding Officer, most motions made before the hearing will probably have to be in writing and conform with the requirements specified by Section 22.16(a) of the CROP. 22.19(c)

#### Reply to Motion

A party's response to any written motion must be filed with the Regional Hearing Clerk within 10 days after service of such motion, except in the case of a motion for a default order, which specifies a 20-day period for replies. Like all documents filed in the proceeding, replies to motions must bear the docket number and comply with the filing and service requirements specified by Section 22.05 of the CROP. 22.16(b), 22.17(a)

If a response is not filed within the time specified by Section 22.07 of the CROP, any objection to the motion is considered waived, and the motion may be granted without further argument. 22.16(b)

The Administrator, Regional Administrator, and Presiding Officer, as appropriate, may set a shorter time than 10 days for the response, and may also permit oral argument concerning motions. 22.16(b)

#### Examples of Prehearing Motions

The following types of motions might be made during the prehearing stage of the proceeding. Some motions must be made during the prehearing stage, but most may be made at other stages of the proceeding as well:

- Motion for default for failure to file a timely answer;  
22.17(a)(1)
- Motion to intervene;  
22.11(a)
- Motion to file amicus curiae brief;  
22.11(d)



- Motion for default for failure to comply with a prehearing order of the Presiding Officer;  
22.17(a)(2)
- Motion for default for failure to appear at a conference or hearing convened by the Presiding Officer pursuant to Section 22.19 of the CROP;  
22.17(a)(3)
- Motion for consolidation or severance; and  
22.12(a), 22.12(b)
- Motion for postponement of hearing.  
22.21(c)

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### Default Orders

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Default orders may be issued in three circumstances:

- Against the respondent for failure to file a timely answer to the complaint; 22.17(a)(1)
- Against a complainant or respondent for failure to obey a prehearing or hearing order that has been issued by the Presiding Officer; and 22.17(a)(2)
- Against a complainant or respondent for failure to attend a conference or hearing without good cause being shown. 22.17(a)(3)

Motions for default are made either to the Regional Administrator or Regional Judicial Officer in the first circumstance, or to the Presiding Officer in the second and third circumstances.

A motion for default may be made by any person who is a party to the proceeding [as defined by Section 22.03(a) of the CROP] at the time the motion is made. ("Any person" apparently includes intervenors.) In addition, the Presiding Officer is permitted to issue a default order sua sponte in the latter two default circumstances.  
22.17(a)

### Procedures

The party making a motion for default must include with the motion a proposed default order (see Exhibit 7-4). The motion for default must be served on all parties and otherwise conform with the filing and service requirements specified by Section 22.05 of the CROP.

The alleged defaulting party has 20 days from service of the motion for default to reply to the motion.

This time period is 10 days longer than that generally specified for replies to motions (Section 22.16(b) of the CROP).

#### Default Order as Initial Decision

A default order at the time it is issued by the Presiding Officer (Regional Administrator or the Regional Judicial Officer, if a timely answer is not filed) constitutes an initial decision of the proceeding. As such, it must:

##### 22.17(b)

- Contain findings of fact, conclusions regarding material issues of law or discretion, and the recommended penalty; and

##### 22.17(c)

- Be filed with the Regional Hearing Clerk.

##### 22.17(b)

The Regional Hearing Clerk must serve copies of the initial decision on all parties to the proceeding and otherwise comply with Section 22.27 of the CROP, which addresses transfer of the proceeding's record to the Hearing Clerk. The default order becomes the final order of the Administrator within 45 days after its service upon the parties unless (1) the default order is appealed or (2) the Administrator elects, sua sponte, to review the default order.

#### Appeal

A default order may first be appealed by a motion to set aside the default order made to the Agency official who issued the default order. Any further appeal of the default order must be made directly to the Administrator pursuant to Section 22.30 of the CROP.

##### 22.17(d), 22.29(a)

#### Consequences of Final Default Order

When the Administrator issues a final order upon default against the respondent, respondent is subject to the following consequences:

- The respondent has essentially "admitted" to all facts alleged in the complaint and the right to a hearing is waived; and
- The penalty proposed in the complaint will become due and payable within 60 days after the final order is issued. 22.17(a)

The admission of factual allegations and waiver of hearing applies only to the immediate civil penalty proceeding and does not affect any other proceedings. In addition, the 60-day period for payment of the penalty begins only after the Administrator has issued a final order upon default, not after the Presiding Officer issues the initial default order.

When the Administrator issues a final order upon default against the complainant, the complaint is dismissed with prejudice. If the complaint is dismissed with prejudice, the complainant cannot reinstitute a civil penalty proceeding that is based on the allegations in the dismissed complaint.

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### Settlement

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EPA encourages settlement of a civil penalty proceeding, if the settlement is consistent with the provisions and objectives of FIFRA and its applicable regulations.

22.18(a)

### Procedures

A settlement conference can be requested at any time. The parties may confer on settlement whether or not the respondent has requested a hearing. Before an answer is filed and a Presiding Officer is appointed, settlement conferences can be convened by consent of the parties. After a Presiding Officer has been appointed, settlement conferences are subject to the jurisdiction of the Presiding Officer who may order a prehearing conference settlement. As an alternative, the parties may be directed to correspond with the Presiding Officer concerning settlement.

22.18, 22.19

### Consent Agreement and Proposed Consent Order

If a settlement is reached by the parties, they must forward a written consent agreement (see Exhibit 7-5) and a proposed consent order to the Regional Administrator. In addition, they must serve copies of these documents on the Presiding Officer if one has been appointed. The consent agreement must contain the following information before the Regional Administrator can approve it:

22.18(b)

- The signature of all parties or their representatives in the proceeding (e.g., complainant, respondent, and any intervenors);
- A statement in which the respondent admits that the Agency has jurisdictional authority to bring the complaint;
- A statement in which the respondent admits facts stipulated in the consent agreement or neither admits nor denies facts alleged in the complaint; and
- A statement in which the respondent consents to the assessment of the stated civil penalty that is reflected in the consent agreement and proposed consent order.

Also, the consent agreement must include any and all terms of the agreement among the parties. Consequently, any terms to which the parties have agreed in reaching a settlement must be reflected in the consent agreement (e.g., agreement not to pursue criminal penalties, agreement by intervenor not to pursue private damage remedies, agreement by the respondent to take actions that minimize the effect of the violation, etc.).

Partial settlement of the proceedings is permitted and, in many cases, is likely. Settlement agreements and proposed consent orders must be very carefully drawn and completely understood before signatures are obtained so that the parties understand precisely what elements of the matter are not disposed of by the consent agreement and consent order.

The consent agreement becomes final and binding on the parties only after the Regional Administrator has signed the consent order. The consent order disposes of only those elements of the proceeding that are specifically addressed by that order and the consent agreement.

The proposed consent order must be prepared for the Regional Administrator's signature. It need not restate all the terms of the consent agreement, but it must at least explicitly incorporate by reference the consent agreement as being the basis for the consent order.

#### 22.18(c)

The Regional Administrator, in deciding whether to issue a final consent order, may require parties to the settlement to appear in person to answer questions relating to the proposed consent agreement or order.

### Filing of Consent Agreement and Order

The consent agreement and the final consent order constitute important documents that affect the substantive and procedural rights of the parties. Consequently, the originals of these documents must be placed in the Regional Hearing Clerk's file, and copies must be served as required by Section 22.06 of the CROP.

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### Prehearing Conference

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When a hearing is ordered, the Presiding Officer also convenes a prehearing conference, unless it appears unnecessary. Prehearing conferences are intended to facilitate and expedite a hearing proceeding. These conferences encourage informal, frank discussions among the parties on any matter that could expedite the hearing. Any anticipated problems should be discussed at this time. The prehearing conference may involve:

#### 22.19(a)

- Settling the case;

- Attempting to simplify the proceeding through consolidation of issues and stipulation by the parties;
- Amending the pleadings;
- Exchanging information concerning evidence to be presented (e.g., identities of expert witnesses and summaries of their testimony and exchange of exhibits, documents, and prepared testimony);
- Limiting the number of witnesses;
- Setting a time and place for the hearing; and
- Attending to any matter that may expedite the disposition of the proceeding.

#### Exchange of Information

The CROP generally require that the parties exchange witness lists, brief descriptions of witness testimony, and copies of all documents and physical evidence that will be introduced into evidence. This requirement supports the accepted manner of hearings—one that is forthright and avoids surprise. 22.19(b)

#### Failure To Exchange Information

If the party does not exchange information before the hearing and desires to introduce a document or a witness during the hearing, that party must request the permission of the Presiding Officer. Additionally, if such permission is granted, the Presiding Officer must first allow other parties a reasonable time to review the newly introduced evidence.

#### Protection of Evidence Sources

Certain unusual circumstances may justify not following the policy of early information exchange. One such example is a reasonable belief that witnesses might be subject to physical or economic intimidation. Another circumstance is a reasonable belief that the nature of the documentary or physical evidence would permit the respondent to intimidate witnesses, destroy evidence, or otherwise improperly interfere with the enforcement efforts of the Agency. In such situations, the Presiding Officer should be fully informed of the reasons for withholding evidence or the identity of a particular witness.

#### Role of Discovery

The CROP state that evidence that is not subject to the mandatory exchange of witness lists and documents in the prehearing conference, shall be subject to discovery only upon determination by the Presiding Officer.

This provision is primarily intended to address discovery by deposition. To obtain such discovery, a party must make a motion for discovery to the Presiding Officer, which demonstrates that the:

22.19(f)

- Proceeding will not be unreasonably delayed by discovery;
- Information sought cannot be obtained through alternative means;  
and
- Information sought is of significant probative value.

22.19(f)(1)

If the discovery involves oral depositions, then a party must also show that the evidence will not be preserved for presentation by a witness.

22.19(f)(2)

The difference between evidence that is subject to mandatory exchange requirements and evidence that may be discovered must be carefully understood. If the evidence being sought should normally be exchanged under Section 22.19(b) and for some reason is being withheld, then a motion to the Presiding Officer to enforce the requirements of the CROP must be made, not a motion for discovery.

If an order for discovery issued by the Presiding Officer is not obeyed, the inference may be drawn that revealing the withheld information would adversely affect the party withholding it. Also, an order for default may be issued based on a failure to comply with a prehearing or hearing order.

22.19(f)(4), 22.17(a)

An order for discovery is an important document that affects the procedural rights of the parties. It must, therefore, be included in the Regional Hearing Clerk's file, and copies must be served in accordance with requirements of Section 22.06 of the CROP.

#### Record of Prehearing Conference

The record of a prehearing conference generally consists of a summary prepared by the Presiding Officer that incorporates all rulings or orders containing directions to parties and any written stipulations or agreements of the parties. Except for those portions of a prehearing conference that relate to settlements, a transcript of the prehearing conference may be made. The transcript is ordered by the Presiding Officer upon motion of a party or sua sponte.

22.19(c)

Settlement conferences, however, are not recorded in order to ensure that the parties are able to negotiate freely and compromise without fear that such agreements will be subsequently revealed.

The transcript or written summary of the prehearing conference must be filed with the Regional Hearing Clerk for inclusion in the Regional Hearing Clerk's file.

#### 22.06

If a transcript is taken, motions made during the hearing may be oral. However, if no transcript is taken, any motions made must be in writing and must otherwise conform with the requirements of Section 22.16 of the CROP and the filing, service, and content requirements specified by Section 22.05.

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### Motion for Accelerated Decisions and Dismissals

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#### Motion for Accelerated Decision

The Presiding Officer may issue an accelerated decision either sua sponte or upon motion by the respondent or complainant. The accelerated decision may involve a particular issue or the entire case, and may be issued at any time during the proceeding if the Presiding Officer finds that:

#### 22.20

- No genuine issue of material fact exists between respondent and complainant; and
- The complainant or respondent is entitled to a judgment as a matter of law. "Entitled to a judgment as a matter of law" means that the movant has established by undisputed or undisputable (not reasonably challenged) evidence that all technical and legal elements in a violation did occur and that, consequently, the Presiding Officer must decide a particular issue or the entire case in the movant's favor at that time. Because there is nothing to adjudicate, there is no need for a hearing.

A discussion of all of the relevant precedents and considerations that apply to a motion for an accelerated decision is not feasible in the space allowed. However, some general principles can be discussed.

Nature of Motion. A motion for an accelerated decision challenges the essential position of the other party's case. The motion asserts that, under the facts and law of the case, the adverse party's position is entirely without merit. In this sense, it is not merely a technical motion—that is, one which seeks to establish that the manner or form of the other party's pleadings is technically insufficient to establish a defense or a claim. It would not, for example, seek to establish that the respondent's defense pleadings lack discussion of an essential element of the defense. Instead, the motion seeks to undermine the adverse party's pleadings by demonstrating that, irrespective of those pleadings, the facts and law of the case require a judgment in favor of the moving party.

**Facts.** By requiring that no genuine material issue of fact exists between the parties, the standard for an accelerated decision does not mean that the parties must agree on all material facts. Instead, the material facts may be either undisputed, or undisputable, that is, not reasonably challenged.

**Affirmative Defenses.** The complainant must demonstrate entitlement to a judgment as a matter of law. The complainant is required not only to prove the elements of the violation by undisputed or undisputable evidence, but also to address any affirmative defenses raised by the respondent with undisputed or undisputable evidence (e.g., an argument that the respondent relied on Agency advice in violating applicable regulations).

**Evidence and Burden.** The Presiding Officer will probably rely on affidavits and counteraffidavits in reaching a decision on the motion for an accelerated decision. However, the Presiding Officer may consider any admissible evidence, including stipulations, admissions, expert witness testimony, deposition testimony, and officially noticed evidence.

22.20(a)

In deciding whether to grant the motion for an accelerated decision, the Presiding Officer generally gives the party against whom the motion is made every benefit of the doubt.

#### Motion To Dismiss

In addition to a motion for an accelerated decision, the respondent can make a motion to dismiss for:

- Failure of the complainant to establish a prima facie case; and
- Other grounds that show that the complainant has no right to relief. 22.20(a)

To find useful precedent and argument for these standards, the following sources may be helpful:

- For the first standard, Rule 41(b) of the Federal Rules of Civil Procedure (Fed. R. Civ. P.), Involuntary Dismissals, and any Federal decisions on this rule; and
- For the second standard:
  - Agency decisions—in which FIFRA standards for an accelerated decision were applied—that relate to failure to state adequate claim or in which the result was required by justice, and
  - Federal decisions [involving Fed. R. Civ. P. 12(b) which relates to motions to dismiss] that were based on lack of jurisdiction, insufficient process, or failure to state a claim upon which relief can be granted.



Partial Decision

A decision that grants a motion for an accelerated decision or a motion to dismiss need not dispose of all issues in the proceeding. If such a partial order is issued, the Presiding Officer must also determine which issues remain in controversy between the parties. To do so, the Presiding Officer must issue an interlocutory order that specifies the issues disposed of by the accelerated decision or dismissal order, and those issues that remain in controversy.

22.20(b)(2)

Initial Decision

If an accelerated decision or dismissal order is issued to dispose of all issues in the proceeding, such orders are treated as initial decisions and may be appealed to the Administrator under Section 22.30 of the CROP.  
22.20(b)(1) If a partial decision is rendered, the objecting party, before appealing, must await the issuance of a final initial decision or obtain certification to appeal an interlocutory decision.

22.20(b)(2), 22.29

An initial decision must comply with the requirements of Section 22.27(a) on content, filing, service, and transfer requirements.



# 5 Hearing Stage

The Presiding Officer convenes a hearing on request by the respondent or, if appropriate, sua sponte—if the matter has not yet been disposed of by a default order, accelerated decision, dismissal order, or consent order. The Chief Administrative Law Judge appoints a Presiding Officer as soon as the respondent files an answer.

22.21

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### Notice of Hearing and Venue

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The Presiding Officer must issue a notice of hearing to all parties, identifying the time, date, and place for the hearing, at least 20 days before the date set for the hearing. 22.21(b) The hearing is generally held in the county, parish, or incorporated city where the respondent resides unless otherwise agreed to in writing by all parties.

22.35(b)

Any party may make a motion for change of venue.

22.19(d), 22.21(d)

In addition, a party may make a motion for postponement of the hearing but must demonstrate good cause for the request.

22.21(c)

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### Presentation of Evidence

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As is true for all Agency administrative proceedings, the complainant is the first to present evidence. The complainant must establish a prima facie case; that is, the complainant must submit evidence that the events ~~alleged in the complaint did occur, that the events constitute a violation~~ of the Act, and that the proposed civil penalty is appropriate. After the complainant has established a prima facie case, the respondent must then present any defense to the allegations that are contained in the complaint and any affirmative defenses that are raised by the answer.

22.24

"Burden of Presentation" and "Burden of Persuasion" are used in the CROP to describe the burden of proof that is placed on the parties in the hearing.

22.24 The definitions are as follows:

- Burden of Presentation (Burden of Going Forward With the Evidence)—A party must introduce evidence on the claims or defenses raised in the complaint or answer.
- Burden of Persuasion—Each party must convince the Presiding Officer of the affirmative allegations in his or her pleading.

The complainant is alleging that a violation has in fact occurred and, therefore, has the burden of presentation. The complainant also has the burden of persuasion. Once the complainant has established a prima facie case, the burden of presentation shifts to the respondent, who must then introduce sufficient evidence to rebut or outweigh the evidence presented by the complainant. The burden of persuasion never shifts, but remains with the complainant throughout the proceeding; that is, the complainant always has the obligation of convincing the Presiding Officer, by a preponderance of the evidence, of the allegations contained in the complaint.

The respondent has the burden of persuasion with respect to any affirmative defenses raised in the answer—for example, a reliance argument based on Agency advice. The Burden of Presentation initially rests with the respondent but shifts, once the respondent has introduced sufficient evidence to support a favorable finding.

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### Preponderance of Evidence

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Each matter contested in the hearing is determined by the Presiding Officer on the basis of a preponderance of the evidence. To prevail, a party must convince the Presiding Officer that, on balance, his or her allegations appear more likely or probable than the other party's allegations. This standard, is different from a criminal standard, which requires a decision based on "evidence beyond a reasonable doubt" or "evidence excluding a reasonable doubt."

22.24

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### Default Orders and Accelerated Decisions

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During the hearing, the complainant should keep in mind that a motion for default order (except one based on failure to file a timely answer) or a motion for an accelerated decision may be appropriate despite the advanced stage of the proceeding.

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Hearing Rules of Evidence

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Under the CROP, the Presiding Officer must admit evidence unless it falls in one of the following categories:

- Irrelevant;
  - Immaterial;
  - Unduly repetitious;
  - Unreliable; and
  - Of little probative value.
- 22.2(a)

When in doubt, the Presiding Officer will most likely admit, not exclude, evidence.

Confidential Information

The CROP state that, from the outset, confidential information can be introduced as evidence. The Presiding Officer may make such orders as may be necessary to consider such evidence in camera, including the preparation of a supplemental initial decision to address questions of law, fact, or discretion arising out of that portion of the evidence that is confidential or includes trade secrets.

22.22(a)

~~Unless otherwise permitted by the Presiding Officer, such a supplemental decision, if issued before the final initial decision, is to be treated like a partial decision and is not appealable until the final initial decision is issued or certification to appeal an interlocutory decision is obtained.~~

22.29(a)

For confidential commercial information, the complainant should be aware that 5 U.S.C. §1901 prohibits the disclosure of such information by a government official. (See also Chapter Eleven.)

Materiality and Relevancy

Two standards described in the CROP concern materiality and relevancy. Materiality and relevancy are legal terms of art, and previous cases should be consulted to determine how they have been treated by the Agency. Federal case law should also be consulted.

22.22(a)

- Materiality. Material evidence is evidence that is pertinent to or has a legitimate and effective bearing on the case. For example, the evidence relating to the status of an officer within a corporation may be material to proving that he or she knowingly violated FIFRA by manufacturing a certain pesticide. The officer's status within the local church, however, is not likely to be material.
- Relevancy. Evidence that is material may or may not be relevant. Relevant evidence is evidence that has a tendency to make a fact in issue more probable or less probable. The emphasis here is on the probative value of the evidence. The probative value of offered evidence must be assessed in light of the facts in issue. For example, to prove that a reporting violation has occurred, evidence demonstrating that a particular EPA report was prepared but not sent would surely be relevant. In contrast, evidence that the firm generally failed to maintain good business records might still be considered material but is less likely to be considered relevant or probative.

Although materiality and relevancy have technical distinctions, in general, both standards can be viewed in terms of probative value of evidence. If an item of evidence has probative value (i.e., tends to prove or disprove a particular proposition) to the issue for which it is introduced, then both criteria are satisfied.

#### Evidence Relating to Settlement

Any evidence relating to settlement that would be excluded under Rule 408 of the Federal Rules of Evidence (Fed. R. Evid.) is also excluded under the CROP. Rule 408 of the Fed. R. Evid. generally excludes evidence of settlement or attempted settlement when it is offered as proof of an admission of liability. However, this evidence may be admitted for another purpose, such as proving bias of a witness or disproving a contention of undue delay. When such evidence is offered for these purposes, it may still be excluded if the Presiding Officer determines that its probative value is outweighed by confusion of issues, undue delay, etc.

#### Testimony of Witnesses

Witnesses are generally examined orally upon oath or affirmation. The Presiding Officer, however, may allow certain exceptions to this rule (e.g., an affidavit from a dying witness). Any witness appearing at the hearing may be cross-examined if the cross-examination is not unduly repetitious.

22.22(b), 22.22(d)

Verified Statements in Lieu of Direct Testimony

In lieu of direct testimony, a party may desire that a witness admit into the record previously prepared statements of fact or opinion. Such a request may be appropriate when the testimony is technical or academic and does not lend itself to a clear, cohesive presentation through direct questions. This type of evidence can be admitted only upon the approval of the Presiding Officer.

A copy of the written statement must be submitted to the Presiding Officer, reporter, and opposing counsel before it is delivered. The evidence contained in the statement is subject to the same rules of testimonial evidence that apply to oral testimony (e.g., the witness must swear to or affirm the statement and is subject to oral cross-examination concerning the statement).

22.22(c)

Affidavits in Lieu of Direct Testimony

When a witness is "unavailable," as defined by Rule 804(a) of the Fed. R. Evid., an affidavit may be admitted into evidence in lieu of oral testimony. Under Rule 804(a), witnesses are deemed unavailable if they are exempt by a court order, refuse to testify in spite of a court order, claim lack of memory, are dying or physically impaired, or are absent despite efforts to secure their attendance.

22.22(d)

Exhibits and Physical Evidence

If exhibits are introduced, the original and one copy must be filed with the Presiding Officer where practicable. A true copy of any exhibit may be substituted for the original if submitting the original is not possible. Copies must also be furnished to each party.

22.22(e)

Official Notice

The Presiding Officer may take official notice of any matter judicially noticed in the Federal courts, of matters permitted under Rule 201 of the Fed. R. Evid., and of other facts that are within the specialized knowledge and experience of the Agency. Official notice may be sua sponte or upon motion by one of the parties.

22.22(f)

Official notice under Rule 201 of the Fed. R. Evid. is limited to adjudicative facts that are not subject to reasonable dispute and that are:

- Generally known within the territorial jurisdiction of the proceeding; or

- Capable of accurate and ready determination.

"Adjudicative facts" directly concern the immediate parties in the proceeding—who did what, when, where, how, and with what motive or intent. These facts relate to the occurrence(s) alleged by the pleadings, which must be adjudicated to decide the case.

The official notice that the Presiding Officer may employ as a result of the special expertise of the Agency is broader than that permitted by Rule 201 of the Fed. R. Evid. Consequently, official notice extends to all matters about which the Agency is presumed expert. For example, the experience and knowledge of the Agency in an environmental area might justify official notice that, statistically, a physical event always occurs under a certain set of environmental circumstances.

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### Objections and Rulings

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Objections about the conduct of the hearing, such as evidentiary and procedural objections, may be stated orally or in writing. The form of the objection depends on the circumstances. In general, however, if the objection involves a relatively complicated argument and if time permits, it should be written. If it is written, it must comply with the service, filing, and content requirements specified by Section 22.05 of the CROP. 22.23(a)

### Rulings and Exceptions to Rulings

The Presiding Officer must rule on all objections and provide reasons for the rulings, which will become part of the record. Copies of the ruling must be served on the parties by the Presiding Officer and the original entered into the Regional Hearing Clerk's file in accordance with Section 22.06 of the CROP. The CROP also state that to take specific exception to each overruled objection is not necessary. The exception to an overruled objection is automatic and is not waived by further participation in the hearing. 22.23(a)

### Appeal of Ruling

A ruling on an objection is not subject to an automatic interlocutory appeal to the Administrator. A party wishing to appeal the ruling immediately, must make a motion in writing within six days of notice of the ruling to the Presiding Officer to certify such a ruling to the Administrator. (See also "Appeals of Interlocutory Orders or Rulings" in this section.)



Unlike other motions made during a hearing, a request for certification may not be made orally, but must be in writing.

22.29(a)

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### Offers of Proof

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If evidence is found immaterial, irrelevant, etc. and cannot be introduced, the party seeking to introduce it may not only object to its exclusion, but may also make an offer of proof. An offer of proof places the evidence into the official record, and the Administrator on appeal can use such evidence to reopen the hearing. This offer consists of:

- One copy of the documentary or physical evidence; or
- A brief written summary, if the evidence is testamentary.

Such offers of proof are not mandatory, and the right to appeal the exclusion of evidence is preserved under Section 22.23(a). Nonetheless, offers of proof should generally be made whenever evidence is excluded.

22.23(b)

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### Transcript of Hearing

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A hearing must be transcribed verbatim, and the reporter must send the original and copies of the transcript to the Regional Hearing Clerk for filing. A copy must also be sent to the Presiding Officer. The Regional Hearing Clerk must notify all parties of the availability of the transcript and permit them to obtain a copy upon payment of a reproduction fee. Payment may be waived if a party can show that the cost is unduly burdensome. A certificate of service should accompany each copy of the transcript. Persons not a party to the proceeding may receive a copy of the transcript (except for confidential portions of the transcript) upon payment of a reproduction fee.

22.25

The transcript of the hearing is an important document because:

- Many objections and motions made during the hearing are oral and are thus reflected only in the transcript; and
- The transcript is used by the parties to draft the proposed findings of fact, conclusions of law, and orders, which are then submitted to the Presiding Officer for consideration in issuing the initial decision.

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Proposed Findings, Conclusions, and Orders

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At the conclusion of the hearing, parties may submit proposed findings of fact, conclusions of law, and orders to the Presiding Officer for consideration in issuing the initial decision.

The purpose of the proposals and supporting briefs is to advocate positions of the submitting party and to persuade the Presiding Officer to adopt that party's proposals.

Procedures

The proposed findings of fact, conclusions of law, and orders, together with supporting briefs, may be submitted to the Presiding Officer for consideration within 20 days of notice of the transcript's availability. The proposals and briefs must be served on the other parties. Although the Presiding Officer must permit reply briefs, the timing of such briefs can be specified. The proposals and all briefs must be in writing and must contain adequate references to the record and authorities relied on.

22.26

Preparation

In preparing the proposals, the focus should be on issues that the Presiding Officer must address in the initial decision.

The importance of the proposals and briefs cannot be overemphasized. Through these materials, the position of the submitting party can be detailed, and the Presiding Officer can view in depth the merits of the party's position.

Initial Decision

The Presiding Officer must issue an initial decision as soon as is "practicable" after the period specified for filing reply briefs to the proposed findings, conclusions of law, and orders.

The initial decision should contain the Presiding Officer's:

- Findings of fact and conclusions for all material issues of law or discretion;
- Reasons for those findings and conclusions;
- Recommended civil penalty; and
- Proposed final order.

In determining the dollar amount of the recommended civil penalty assessed in the initial decision, the Presiding Officer must consider, in addition to the criteria listed in Section 14(a)(3) of FIFRA, the following:

- Respondent's history of compliance with the Act or its predecessor statute; and
- Any evidence of good faith or lack thereof.

The Presiding Officer must also consider the guidelines for the assessment of civil penalties under FIFRA [39 Fed. Reg. 27711 (1974)].

#### 22.35(c)

Specific reasons must be set forth in the initial decision if the Presiding Officer increases or decreases the amount of penalty from that originally assessed in the complaint. The Presiding Officer, however, cannot increase the amount of penalty from that which was recommended in the complaint if the respondent has defaulted.

#### Challenge to Initial Decision

The initial decision becomes a final order within 45 days after it is served unless:

- A party files a motion to reopen the hearing, which stops the 45-day period until the motion is denied or the reopened hearing is concluded; or

22.28

- A party makes an appeal to the Administrator, or the Administrator determines sua sponte that a review of the initial decision is appropriate.

22.27

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#### Motion To Reopen a Hearing

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If a party believes that additional evidence should be introduced into the record, that party may make a motion to reopen the hearing. Such a motion must be made no later than 20 days after service of the initial decision on the parties. The motion to reopen the hearing must state the specific grounds upon which relief is sought, state the nature and purpose of the evidence to be adduced, and show that the evidence is not merely cumulative. The party must also demonstrate why the evidence was not introduced at the hearing. The motion must be written and must comply with the requirements specified for such motions and the filing, service, and content requirements for submitting documents.

22.28(a)

Replies from other parties must be made within 10 days after the motion is served. The Presiding Officer must render a decision on the motion as soon as is practicable after the filing of replies.

22.28(b)

Filing a motion to reopen a hearing shall automatically stay the running of all time periods (e.g., appeals) until such time as the motion is denied or the reopened hearing is concluded.

22.28(b)

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### Appeals of Interlocutory Orders or Rulings

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#### Immediately Appealable Orders

The only orders or rulings that may be appealed to the Administrator as a matter of right are:

- Accelerated decisions that decide the entire case;  
22.20, 22.29
- Dismissal Orders;  
22.20, 22.29
- Default orders; and  
22.17, 22.29
- Initial decisions rendered after an evidentiary hearing.  
22.27, 22.29

All other orders or rulings issued by an Agency official during the prehearing and hearing proceedings are considered interlocutory. As such, they must await the issuance of an initial decision before they can be appealed, unless the Agency official issuing such orders or rulings certifies them to the Administrator on appeal.

22.29

#### Procedures and Standards for Interlocutory Orders

A motion for interlocutory appeal of an order or ruling must be filed in writing within six days of notice of such ruling or order.

22.29

Besides stating the grounds for appeal, the moving party must demonstrate, to the appropriate Agency official, that:

- The order or ruling involves important legal or policy issues concerning which there is substantial grounds for difference of opinion; and

- Immediate appeal will materially advance the proceeding or that waiting for normal review will be ineffective or inadequate.  
22.29(b)

The motion must also comply with requirements for filing, service, and content requirements specified in the CROP.

If the Presiding Officer does not certify the interlocutory appeal, a party may make a motion to the Administrator within six days of service to reverse that decision on the grounds that it is contrary to the public interest. This motion must also comply with the requirements of Section 22.16 and 22.05 of the CROP, except that the appropriate Agency officials receiving the motion are the Regional Hearing Clerk and the Administrator.  
22.29(c)

#### Actions by the Administrator

If the Presiding Officer certifies the interlocutory appeal, the Administrator may:  
22.29(c)

- Deny the certification as improvidently granted;
- Take no action within 30 days and thereby dismiss the certification; or
- Grant the certification, review the interlocutory appeal, and grant or deny the appeal on its merits.

Ordinarily, the interlocutory appeal will be decided on the basis of the submissions made by the Presiding Officer. The Administrator may, however, allow further briefs and oral argument.  
22.29(c)

#### Request for Stay

The motion for interlocutory appeal may include a request for stay of the proceeding pending the Administrator's decision on the certification and interlocutory appeal. The request must demonstrate that extraordinary circumstances exist to justify granting the stay. If the Presiding Officer grants a request for stay of over 30 days, it must be separately approved by the Administrator.  
22.29(d)

## Sample Default Order

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
 REGION III  
 6TH AND WALNUT STREETS  
 PHILADELPHIA, PENNSYLVANIA 19106

In re:	)	I.F.&R. Docket No. III-54C
	)	
W.G. Neudecker and Sons	)	
1215 Madison Avenue, N.E.	)	
Washington, D.C. 20019	)	DEFAULT ORDER
Respondent	)	

Preliminary Statement

This civil proceeding for the assessment of a penalty was initiated pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136 et seq., (hereinafter referred to as FIFRA) charging that the unregistered pesticide, "Adcide for Algae Control," was shipped from Washington, D.C., to Rockville, Maryland, on September 11, 1982, in violation of Section 12(a)(1)(A) of FIFRA [7 U.S.C. §136j(a)(1)(A)]. It is hereby determined that an appropriate default order shall be issued based on the findings of fact and conclusions of law as set forth below.

Findings of Fact

1. Two cases, each bearing four one-gallon bottles of the product, "Adcide for Algae Control," were shipped by W.G. Neudecker and Sons (respondent) from 1215 Madison Avenue, N.E., Washington, D.C., to Water Way Inc., 5544 Sycamore Lane, Rockville, Maryland, on or about September 11, 1982 (Shipping Order No. 45643). A sample from said shipment was obtained subsequently by representatives of the Environmental Protection Agency (EPA), Region III.
2. At the time of said shipment, the product sample bore a label that it was intended for the prevention of algae and slime.
3. At the time of the said shipment, said product was not registered as a pesticide with EPA.
4. On July 16, 1983, the Enforcement Division, EPA, Region III (the complainant), issued a complaint and notice of opportunity for hearing to respondent, pursuant to Section 14(a) of FIFRA [7 U.S.C. §136l(a)], alleging that respondent had violated Section 12(a)(1)(A) of FIFRA by shipping an unregistered pesticide in interstate commerce [7 U.S.C. §136j(a)(1)(A)]. (A copy of the complaint is annexed hereto as Attachment A.)

5. In the complaint, a civil penalty of \$2,300 was proposed against respondent. Said penalty was proposed on the basis of its appropriateness to the size of respondent's business, the effect on respondent's ability to stay in business, and the gravity of the violation as calculated by reference to the EPA "Guidelines for the Assessment Section 14(a); Citation Charges for Violations" [39 Fed. Reg. 27711 (1974)]. For purposes of assessing said penalty, respondent's gross annual sales were determined to be between \$200,000 and \$1 million during the previous year. Based on prior information communicated to complainant by the president of respondent, respondent was considered to have had knowledge of the registration requirement. Accordingly, the proposed penalty was assessed at \$2,300. Furthermore, based on a comparison of respondent's gross annual sales with the amount of the proposed penalty, it was determined that said penalty would have no substantial effect on respondent's ability to continue in business.

6. The complaint in the instant case set forth respondent's right to request a hearing within twenty (20) days of receipt of the complaint, the requirement of a written answer to the complaint, and the consequences of failure to answer the complaint. Furthermore, a copy of the Consolidated Rules of Practice (CROP), 40 C.F.R. §22.01 et seq., was enclosed with the complaint.

7. Said complaint was mailed to respondent on July 16, 1983, via certified mail. Receipt No. 202684 was returned to complainant, stamped July 17, 1983, and bearing the signature "Betty Wilson" as signer for the addressee. (Copy enclosed as Attachment B.)

8. As of this date, respondent has failed either to respond to the complaint, request a formal hearing, or file an answer to the complaint pursuant to the CROP.

#### Conclusions of Law

1. At the time of above shipment, said product was a pesticide within the meaning of Section 2(u) of FIFRA by virtue of its label claim of use against algae, a pest within the meaning of Section 2(t) of FIFRA. [7 U.S.C. §§136(u), 136(t)]

2. By reason of the facts as set out in the findings of fact, respondent violated Section 12(a)(1)(A) of FIFRA by shipping an unregistered pesticide in interstate commerce. [7 U.S.C. §136j(a)(1)(A)]

3. By failing to file a timely answer to the complaint and to request a formal hearing, respondent has admitted the facts alleged in the complaint and has waived its right to a hearing. Accordingly, respondent is in default and the proposed civil penalty is therefore due and payable. [CROP, 40 C.F.R. §22.17]

4. It is further concluded that by reason of the facts as set out in paragraph five (5) of the findings of fact, the amount of the proposed penalty is appropriate pursuant to Section 14(a)(4) of FIFRA [7 U.S.C. §1361(a)(4)] for the following reasons:

- a. The penalty is appropriate to the size of the business;
- b. The size of the penalty would have no significant effect on respondent's ability to continue in business; and
- c. The violation involves the extremely grave charge of interstate shipment of an unregistered pesticide.

#### Order

Respondent shall within sixty (60) days of receipt of this default order pay by cashier's or certified check a civil penalty in the amount of two thousand three hundred dollars (\$2,300) to the Treasurer, United States of America. Such remittance may be sent by messenger or certified mail to the Pesticides Hearing Clerk, U.S. Environmental Protection Agency, Region III, Curtis Building, 6th & Walnut Streets, Philadelphia, Pa. 19106. In the event of failure of respondent to make said payment within sixty (60) days of receipt of this default order, the matter shall be referred to the United States Attorney for the District of Columbia pursuant to Section 14(a)(5) of FIFRA [7 U.S.C. §1361(a)(5)] for recovery by appropriate action in United States District Court.

AND NOW, THIS DAY OF October 4, 1983 the foregoing order is hereby issued under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Consolidated Rules of Practice adopted pursuant thereto. [7 U.S.C. §1361(a)(1)-(4); 40 C.F.R. §22.01 et seq.]

Regional Administrator



## Model Consent Agreement and Final Order

Environmental Protection Agency	)	I.F.&R. Docket No. III-54C
	)	
In re:	)	
	)	
W.G. Neudecker and Sons	)	CONSENT AGREEMENT AND
1215 Madison Avenue, N.E.,	)	FINAL ORDER
Washington, D.C. 20019	)	
Respondent	)	

Preliminary Statement

1. This civil proceeding for the assessment of a penalty was initiated pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, ~~as amended~~. [7 U.S.C. §136 et seq. (hereinafter FIFRA).] The action was instituted by a complaint and notice of opportunity for hearing, filed upon respondent pursuant to FIFRA, charging violations of (cite specific sections of the Act)

2. Respondent filed an answer admitting the jurisdictional allegations of the complaint, admits (facts admitted), and explains (neither admits nor denies) (facts explained).

3. Respondent hereby explicitly waives the right to request a hearing on any issue consented to herein.

4. ~~Respondent consents to the issuance of the order hereinafter recited,~~ with the stipulations and admission of facts and conclusions of law for the purposes of this proceeding only. Respondent consents to the payment of a civil penalty of the amount set out in the order.

Findings of Fact

[The "Findings of Fact" section shall state with particularity all findings of fact with respect to each material allegation noted in the complaint.]

Conclusions of Law

By reason of the facts set forth in the "Findings of Fact," it is concluded that respondent has violated Section(s)        of FIFRA.

Respondent hereby consents to the issuance of the following order. The (title of the Regional Office) EPA Region        hereby recommends that the Regional Administrator issue the following order:

Order

Respondent shall within sixty (60) days of receipt of this consent agreement and final order, pay by cashier's or certified check a civil penalty in the amount of (\$ ) dollars, payable to the Treasurer United States of America. Such payment shall be remitted to the Hearing Clerk, EPA Region , (address) . Failure to remit such payment will result in the referral of this matter to the United States Attorney General for collection pursuant to Section 14(a)(5) of FIFRA, as amended.

[Alternative Order]

Based on a finding that the payment of any or all of the penalty hereinbefore addressed would materially affect respondent's ability to continue in business, respondent, having duly stipulated to the violations as charged, is excused from payment in accordance with the terms of Section 14(a)(4) of FIFRA, as amended.

(Signature of respondent)

(Signature of complainant)

Date: \_\_\_\_\_ At: \_\_\_\_\_

It is so ordered. This order shall become effective immediately.

(Signature of Regional Administrator)  
Regional Administrator, EPA Region \_\_\_\_\_

(Title)

EPA Region \_\_\_\_\_

Date: \_\_\_\_\_ At: \_\_\_\_\_

## 6 Post-Hearing Stage

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### Appeal of Initial Decision

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#### Jurisdiction of Administrator

The Administrator assumes full jurisdiction of the case immediately after the Presiding Officer issues an initial decision. The Administrator assumes jurisdiction regardless of whether or not a party appeals the initial decision. If, however, a party files a motion to reopen a hearing, the Presiding Officer may rule on that motion.

22.27(c)

Once the initial decision is issued, the Regional Hearing Clerk's File, which now includes the original initial decision, is forwarded to the Hearing Clerk. Consequently, the appellant must send any notice of appeal and accompanying appellate brief to the Hearing Clerk. A motion to reopen a hearing, however, is to be filed with the Regional Hearing Clerk.

22.27(a), 22.30(a)

#### Notice of Appeal and Appellate Brief

The notice of appeal and appellate brief must comply with the general filing, service, and form requirements of the CROP where appropriate. The ~~notice of appeal and the appellate brief must be filed with the Hearing Clerk within 20 days after the initial decision is served on the parties.~~

22.30(a)(1)

The notice of appeal must address the disputed findings of fact and conclusions of law contained in the initial decision. Specifically, it must contain:

• ~~Alternative findings of fact;~~

• Alternative conclusions regarding issues of law or discretion;

• A proposed order that reflects the conclusions and findings desired by the appellant; and

- Relevant references to the record and the initial decision.  
22.30(a)(1)

The appellate brief is intended to present the appellant's arguments as to why the appeal should be granted. As such, it must include:

- A statement of issues presented for review;
- A statement of the nature of the case;
- Identification of the facts that are relevant to the issues presented for review;
- Specific arguments on the issues presented;
- A short conclusion that includes the precise relief being sought; and
- Appropriate references to the record and the initial decision.

#### Party's Reply

Any other party or amicus curiae may file a reply brief with the Hearing Clerk within 15 days of service of a notice of appeal and appellate brief. The reply brief is specifically intended to address only the appellate brief and should be so limited. Therefore, it should respond to the argument raised by the appellant, together with references to the relevant portions of the record, initial decision, or appellate brief. The reply brief must also comply with service, filing, and content requirements specified by the CROP.

22.30(a)(2)

#### Administrator's Actions

Even if the initial decision is not formally appealed, the Administrator may determine sua sponte that a review of the initial decision is necessary. The Administrator, however, has only 45 days after service of the initial decision to review the initial decision sua sponte. Otherwise, the initial decision of the Presiding Officer becomes the final order of the Administrator. 22.27(c), 22.30(b) If the Administrator determines to review the initial decision sua sponte, the Hearing Clerk shall serve notice of such intention upon the parties. The notice will include a statement of issues to be briefed by the parties and a time schedule for the service and filing of briefs.

22.30(b)

Scope of Review

The appeal of the initial decision must concern only those issues raised by the parties in the previous proceeding.

22.30(c)

Oral Argument on Appeal

Oral argument on appeal is not automatic and may be granted only if a party makes a request to the Administrator or the Administrator orders it sua sponte. In assigning a time and place for oral argument, the Administrator must consider the convenience of the parties. There are no standards specified in the CROP for deciding whether oral argument should be heard.

22.30(d)

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Final Order

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Timing and Content

The Administrator is required to issue a final order as soon as is practicable after the final action of the appeal process—either after filing of appellate briefs, filing of subsequent briefs if ordered by the Administrator, or oral argument, whichever occurs last.

22.31

The Administrator may, in the final order:

- ~~Adopt, modify, or set aside all or some of the findings and~~ conclusions contained in the initial decision or order; and
- Increase or decrease the recommended penalty unless the initial decision is a default order (in which case the Administrator may not increase the recommended penalty).

The CROP requires the final order to contain the reasons for any decision ~~that the Administrator makes.~~

Motion To Reconsider and Stay Request

A party may file a motion to reconsider a final order within 10 days after service of the final order. A motion to reconsider must set forth the matters claimed to have been erroneously decided and the nature of the ~~alleged errors. The motion may also include a request that the final order~~ be stayed pending a resolution of the motion to reconsider. Unless such a request for stay is granted, however, the effective date of the final order is the date on which it was issued, unless otherwise ordered by the Administrator.

22.32

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Appeal From Final Order

A party may appeal the findings of the final order to a United States court of appeals pursuant to the provisions of Section 16(b) of FIFRA. The obligation to pay the civil penalty does not become due until the party has exhausted all appeals.

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Notice of Judgment

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Upon signature of the final order by the Regional Administrator, the case will be closed and a notice of judgment prepared and sent to Headquarters for publication in accordance with the requirements under Section 16(d) of the Act. (See Appendix 2, Notices of Judgment.)

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Payment of Penalty

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The payment of the civil penalty specified in a final order of the Administrator is due and payable in full within 60 days after the respondent receives the final order, unless otherwise agreed by the parties.

22.31(b)

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# Chapter Eight

## Judicial Enforcement: Civil Actions

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# 1 Introduction

Under FIFRA, regulatory remedies are initially and primarily handled through the use of administrative actions. However, in those instances where EPA is unable to obtain compliance with administrative actions, the Act authorizes EPA to seek relief through civil court injunctive and in rem (seizure) proceedings.

An injunction is a writ issued by a court forbidding or commanding a person to perform a particular act. Injunctions involve the equity powers of Federal courts and are generally viewed as an extraordinary form of relief. Consequently, they are not readily granted and a party seeking injunctive relief has a heavy burden in demonstrating the need for such action.

In rem (seizure) proceedings signify acts against things rather than individuals. Therefore, a proceeding "in rem" is one taken against property and has for its object the disposition of the property.



## 2 Elements of a Violation: Civil

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### Evidence in Support of Civil Actions

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Civil actions require supportive evidence that goes beyond the prima facie evidence necessary to establish administrative violations of FIFRA. In some instances, this may require the use of expert witnesses to establish certain elements of proof (e.g., immediate and irreparable injury). Below follows a list of additional evidentiary showings that should be met before undertaking an injunctive or in rem action.

#### Injunctive Actions\*

Traditionally, courts have required the petitioner or plaintiff to make the following showings before a permanent injunction would be issued:

- There is an inadequate remedy at law;
- The applicable administrative remedies have been exhausted; and
- Irreparable injury, loss, or damage will result if the relief is not granted.

Issuance of a preliminary injunction or temporary restraining order would require the following additional showings:

- Immediate and irreparable injury, loss, or damage will result if the relief is not granted; and

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\* These actions may consist of permanent injunctions, preliminary injunctions, or temporary restraining orders. These types of injunctions are discussed in more detail in Section 4 of this chapter.

- There is a likelihood of success at trial, based on facts before the court.

The above criteria are not, however, uniformly applied by the various judicial districts. While some jurisdictions emphasize different aspects of the criteria, other courts have developed alternative tests that use some, but not all, of the elements listed above. For this reason, an attorney considering this type of civil action should research recent trends in the jurisdiction in which the injunction is being sought.

#### In Rem (Seizure) Actions

For a pesticide or pesticidal device, the Act specifies that the following jurisdictional conditions be met before initiating an in rem (seizure) proceeding:

- The pesticide or device is found and seized within the jurisdiction of the district court that will hear the action; and
- The pesticide or device is being transported or, having been transported, remains unsold or in original unbroken packages; or
- The pesticide or device is sold or offered for sale in any State; or
- The pesticide or device is imported from a foreign country.

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#### Use of Expert Witnesses

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As in the case of administrative actions, civil judicial enforcement proceedings generally require the presentation of expert testimony by EPA personnel appearing as witnesses. Such testimony is used to establish certain elements of proof that justify the relief sought (e.g., the showing of immediate and irreparable injury for obtaining an injunction). Witnesses should be selected for their direct knowledge of the circumstances surrounding the suspected violation, because the witnesses will be required to relate any such knowledge to the court. (See Appendix 5, "Expert Witnesses.")

### 3 Procedures for Filing Actions

Requests for FIFRA civil court actions are referred to the Department of Justice or the appropriate United States Attorneys Office by the Associate Administrator for OLEC (or the Associate Administrator's designee).<sup>\*</sup> In most instances, the Regional Office will initiate the request for an injunction or an in rem action and will designate the lead Agency attorney.<sup>\*\*</sup> The lead attorney is responsible for preparing the "referral package," which, upon completion, is sent from the Regional Office to OLEC. A copy of the package should also be forwarded to PTSCMS.

A referral package contains:

- Referral Memorandum. A referral memorandum identifies the primary elements of the proposed litigation. Specifically, the memorandum, at a minimum, should include:
  - Identification of the potential defendants;
  - Brief factual summary of the case;
  - Identification of the major issues (including potential problems that may exist with the case);

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<sup>\*</sup> The Regional Office has independent authority to refer requests for emergency temporary restraining orders under FIFRA to the Department of Justice and the appropriate United States Attorneys Office. When exercising this authority, however, the Regional Administrator must notify the Associate Administrator for OLEC and the Assistant Administrator for Pesticides and Toxic Substances (or their designees).

<sup>\*\*</sup> Headquarters program and Enforcement Counsel staff may participate more actively in the case development process if precedential or nationally significant issues are involved.

- Status of past Agency enforcement efforts; and
- Names of Agency and Department of Justice attorneys who are involved in the case, including the lead attorney.
- Civil Litigation Report. In addition to the referral memorandum, the referral package must contain a litigation report, prepared by the designated lead EPA attorney. (For a complete outline and guide to preparing the report, see Exhibit 8-1.) The report must include a synopsis of the facts and history of the violation, including past violations by the potential defendant. The report must cite the specific sections of FIFRA and its regulations that have been violated.

The report must show that all elements of the violation have been satisfied. For each element, the report should indicate the available supporting evidence. A copy of the necessary documentary evidence and summary of the expected expert testimony should be attached to the litigation report.

The lead attorney should include a statement regarding the specific relief to be sought (e.g., injunctive or in rem action). The report should also include a list of any equities that may weigh against granting the relief sought by EPA; any expected defenses by the violator (and how they will be countered); and any past, anticipated, or pending State or Federal actions (administrative or judicial) against the violator. Where an injunction is requested, the report should discuss the likelihood that the violator would comply without the imposition of an injunction.

Once the referral package is received by Headquarters, Enforcement Counsel attorneys will conduct a limited final legal review to ensure completeness and consistency in application of enforcement policy. The case will then be transmitted to the Department of Justice or the appropriate United States Attorneys Office. OLEC will notify the Regional Administrator and the Assistant Administrator for Pesticides and Toxic Substances (or their designees) upon the transmittal of the civil referral.

Following the referral of a case, the lead EPA attorney will be responsible for coordinating responses to all requests for supplemental information by the Department of Justice or the United States Attorneys Office. The lead Agency attorney also will be responsible for keeping program officials and other previously involved Agency attorneys apprised of case developments after referral.

Agency employees who are involved in the investigation and referral to the Department of Justice of civil FIFRA actions should familiarize themselves with the Agency documents listed below. These documents are contained in EPA's General Enforcement Policy Compendium.

- Memorandum of Understanding Between the Department of Justice and the Environmental Protection Agency (6/15/77);

- Quantico Guidelines for Enforcement Litigation (4/8/82);
- General Operating Procedures for EPA's Civil Enforcement Program (7/6/82); and
- Case Referrals for Civil Litigation (9/7/82).

### Model Civil Litigation Report Outline and Guide\*

#### Title Page

- A. Identify the facility by name and location and indicate the parent company if different from the facility name.
- B. Identify who prepared the report (both legal and technical personnel) indicating addresses and telephone numbers.
- C. Show the date of completion/submission of the report.

#### Table of Contents (Standardized Example)

I.	Information Identifying the Defendant(s)	Page ____
II.	Synopsis of the Case	Page ____
III.	Statutory Authority	Page ____
IV.	Description of Defendant's Business and Technical Description of the Pollution Source	Page ____
	A. Facility Description	Page ____
	B. Source of Pollution	Page ____
	C. Pollutants Involved; Environmental Harm (Where Appropriate)	Page ____
	D. Available Control Technology and/or Remedial Action	Page ____

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\* The Model Civil Litigation Report Outline and Guide is to be used for all Agency civil referrals to the Department of Justice. Civil litigation reports, however, are most frequently used in referring civil court actions under statutes other than FIFRA. Therefore, certain sections of the report would not need to be as detailed as those prepared for referrals involving non-FIFRA violations. For example, since FIFRA referrals involve only requests for injunctive or in rem relief, civil penalties would not need to be discussed in Section VII of the report (Relief Requested).



V.	Administrative and Enforcement History	Page ____
VI.	Required Elements of Proof and Evidence	Page ____
	A. Elements of Proof	Page ____
	B. Evidence of Violation	Page ____
	C. Evidence of Environmental Harm (Where Appropriate)	Page ____
	D. Discovery	Page ____
	E. Evidence Favorable to Violator	Page ____
	F. Government Witnesses	Page ____
	G. Defense Witnesses	Page ____
	H. Resource Needs	Page ____
VII.	Relief Requested	Page ____
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	B. Standards To Be Met	Page ____
	C. Compliance Schedule	Page ____
	D. Stipulated Contempt Fines	Page ____
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	F. Necessary Bonds	Page ____
VIII.	Anticipated Issues	Page ____
	A. Possible Defenses	Page ____
	B. Equitable Arguments	Page ____
	C. Pending Related Administrative or Court Action	Page ____
	D. Other Issues	Page ____
	E. Discussion of Any Potential Practical Problem With the Case	Page ____
IX.	Litigation Strategy	Page ____
	A. Need for Preliminary Injunction	Page ____

B. Potential for Summary Judgment	Page ____
C. Settlement Potential	Page ____
D. Other Potential Defendants	Page ____
X. Index of Attachments	Page ____
XI. Attachments	Page ____
<ul style="list-style-type: none"><li>• Copies of correspondence</li><li>• Copies of relevant regulated submissions</li><li>• Copies of relevant policy memos, regulations, interpretations</li></ul>	

### Body of the Report

- I. Information Identifying the Defendant(s)
  - A. Legal name of company
  - B. Address: Corporate headquarters
  - C. Name of facility (if different from "A")
  - D. Address of facility (if different from "B")
  - E. SIC code
  - F. State of incorporation
  - G. Registered agent for service
  - H. Legal counsel (name, address, telephone number)
  - I. Judicial district in which violator is located

### II. Synopsis of the Case

This section should be a one-or two-page articulation of the heart of the case. It should describe both the violation and the proposed relief. It should not describe statutory authority or intricate legal issues in detail.

This succinct statement of the case will provide the reader a framework in which to fit the details developed and presented in the body of the litigation report.

The factual basis of the case should be touched upon. Purely conclusory characterization of the case is not as useful as showing the facts of a violation and requested relief. For example, it is better to say a violator discharged or emitted X quantity of Y pollutant for Z days, than to simply say that the violator did not comply with the terms of a permit, State Implementation Plan (SIP), or statute.

The environmental seriousness of the violation, its ongoing nature, and a violator's recalcitrance may be touched upon in this section (but will also be developed later in paragraph IV(C)).

### III. Statutory Authority

- A. Present the substantive requirements of the law and applicable regulations. Reference all federal statutes by U.S.C. citation as well as by the section of the pertinent Act. Summarize the enforcement authority, jurisdiction, and venue. Specific elements of proof are to be addressed in paragraph VI.
- B. Lengthy dissertation on the law is unnecessary. However, in the instance of State Implementation Plans under the Clean Air Act, or Water Quality Standards under the Clean Water Act, or involvement of any other state law or regulation, a more extensive explanation of the law or regulation may be necessary. Pertinent excerpts from any applicable state laws or regulations should be identified and attached to the litigation report.
- C. Any prior interpretation of pertinent state laws or regulations which are germane to the case should be referenced when identifying the law violated. If a state's interpretation of the law has been different from ours, the issue should be discussed with the state and fully explained in this section of the litigation report. (This section may then be referenced when discussing potential defenses, etc., in paragraph VIII.)
- D. List any other possible theories of violation under federal, state, or common law.

### IV. Description of the Defendant's Business and Technical Description of the Pollution Source

- A. Describe the violating corporation and the particular division or facility in question. Any interesting corporate interrelationships or subsidiaries should be noted.

- B. Discuss the business of the corporation and/or division, providing details about the facility in question, what is produced, and what causes the pollution. Emphasis should be on the particular process that is causing the problem. Plant and process should be thoroughly explained, including those outfalls or emission points not subject to this enforcement action. Diagrams should be referenced and attached to, or included in, the litigation report. Photographs of the source may be helpful.
- C. Discuss the types of pollutants being discharged, and potential health and environmental effects. Although the seriousness of the violation is not technically a requirement of proof in enforcement of certain statutes, it is sometimes relevant to the assessment of penalties and equitable relief. For this reason, it should be discussed in the report although it will not be the sole determinant of whether a case has prosecutorial merit. The Department of Justice has suggested the following considerations in assessing the seriousness of the violation:
- The discharge of toxics or mutagens or carcinogens is more serious than the discharge of conventional pollutants;
  - The discharge of large quantities of pollutants is more important than the discharge of small quantities;
  - Bioaccumulative wastes posing long-term threats are more serious than biodegradable wastes;
  - The discharge of pollutants in an area not attaining primary ambient air quality standards is more important than discharges in an area not meeting secondary standards;
  - The discharge of pollutants that directly and demonstrably affect health or the environment is more than those that have no direct or obvious effect;
  - Ongoing present violations that the Government seeks to stop are more important than episodic violations which have ceased; and
  - A defendant with a history of violations is more worthy of attention than a first offender.

If a case does not present obvious "serious" health effects or environmental harm, but is compelling for some other reason (e.g., deterrence of continued, blatant violations of the law), this should be indicated.

- D. Discuss available methods of controlling the problem. Specify technology(s) that will achieve the imposed limits, and indicate the time requirements for a schedule of compliance which considers time necessary for design, contracting, construction, and startup. (This is not inconsistent with EPA policy of not prescribing specific compliance technologies. This information may be necessary in court to illustrate technical feasibility if requested by the judge.)

Cost estimates should be included, to the extent known. Indicate the reliability of the estimates. (Reference paragraph VII(E) as appropriate.)

V. Chronological Administrative History and/or Earlier Enforcement Actions (State and Federal)

- A. ~~Show all attempts to exact compliance or impose sanctions~~ administratively or judicially that have been considered or taken. A full historical chronology should be presented.
- B. Indicate whether necessary notice pursuant to the statutory requirements has been given to the violator prior to initiation of court action.

VI. Required Elements of Proof and Evidence

- A. List the necessary elements of proof to establish the ~~violation under each statute involved.~~
- B. Present a detailed, objective, factual analysis of all real, documentary, and testimonial evidence corresponding to each necessary element of proof in paragraph VI(A) above.

Indicate the location of all real evidence.

Reference each item of documentary evidence as an attachment, ~~except where it is too voluminous (in which case indicate its present location).~~

Identify all witnesses by name (indicating whether lay or expert), when indicating the import and substance of their testimony. Complete addresses and phone numbers of witnesses will be listed in paragraph VII(E) below.

- ~~C. Discovery. Where evidence may be made available by~~ discovery, indicate:

1. The type of evidence anticipated;

2. The person or organization currently having the evidence; and
3. The type of discovery to be used.

Assess the quality of the evidence. Be objective. Any facts or circumstances that affect the strength of the Agency's proof should be explicitly set forth. The newness or oldness of evidence is relevant; the dependability of testing techniques is important. Any assumptions, and the reasons for them, should be spelled out.

- D. If establishing environmental harm is important to the case, set forth the evidence of harm (as done in paragraph VI(B) for elements of substantive violation).
- E. List all evidence favorable to the violator, including test results that differ from EPA's. Any relevant fact that may bear adversely on the Government's contentions should be highlighted. Defense witnesses, to the extent they can be anticipated, should be listed in paragraph VI(G).
- F. List all government witnesses alphabetically with business address, and telephone number and home phone number. Qualifications of experts should be given.

All witnesses listed should have been consulted and thoroughly interviewed. Paragraph VI(B) should set out in succinct fashion the actual facts and opinions to be included in the testimony.

- G. List all defense witnesses anticipated, identifying their employment, expertise, etc. The likely content of their testimony should be set out in paragraph VI(E).
- H. Indicate projected resource needs (e.g., experts, money, etc.).

## VII. Relief Requested

This paragraph should include a comprehensive "bottom-line" settlement position on all items of relief necessary, including those set forth below. If there are policy questions or conflicts associated with any requested relief, discuss them. This section should be carefully detailed. It will be relied upon in determining the acceptability of any settlement offers/proposed consent decrees.

- A. Preliminary injunction.
- B. Standards to be met (interim and final).

- C. Compliance schedule for available technology with phasing, duration, etc. (Reference paragraph IV(D), as appropriate.)
- D. Stipulated contempt fines in conjunction with compliance schedule.
- E. Civil Penalties.
  - 1. Economic savings realized by the violator should be analyzed. The EPA Civil Penalty Evaluation form should be completed, discussed, and attached. Calculations should be included as attachments. This section should include discussion of all elements developed under EPA's civil penalty policy, including ability of the company to pay and recalcitrance.
  - 2. Comment on types of credits possible (or proposed by the violator), as well as credits considered and/or allowed for other similar violators (including municipal POTWs).
  - 3. If economic savings is not a relevant measure of penalty assessment, explain what basis should be used.
- F. Necessary bonds.

Witnesses necessary to establish the relief requested should be identified by name, address and telephone number, with a brief summary of the subject of their testimony.

#### **VIII. Anticipated Issues**

##### **A. Possible defenses.**

(Analyze only defenses that are likely to be presented; fanciful theories can be ignored.)

- 1. Outline legal issues. Attach legal memoranda on threshold legal issues (e.g., Chapter 11 Reorganization) or collateral legal action asserted as a bar to enforcement litigation.
- 2. Outline factual issues.

##### **B. Equitable arguments by the violator.**

(e.g., EPA delay in promulgating guidelines; installation of equipment that did not work; in compliance at its other facilities; emission standard to be revised; inability to finance; economic constraints, etc.)

Any past action, or inaction, (not necessarily judicial or administrative) by a state or any EPA office that the company may use as an excuse, or cite for reliance. (e.g., promises of less stringent limits; agreement not to sue, etc.).

- C. Pendency of any action involving the violator or EPA on related issues in any court or administrative forum. (Reference paragraph V(A), as necessary.)
- D. Other possible issues that might arise at trial.
- E. Discuss any potential practical problems with the case.

#### IX. Litigation Strategy

- A. Need for preliminary injunction.
- B. Potential for summary judgment.
- C. Settlement potential.
  - 1. Past contacts by EPA, the Department of Justice or the United States Attorneys Office.
  - 2. Present negotiating posture and assessment of potential for settlement. Include comparison of posture with "bottom-line" settlement position from paragraph VII.
- D. Other potential defendants.
- E. Other pending actions against violator.

#### X. Index of Attachments

#### XI. Attachments



## 4 Injunctive Actions

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### Statutory Authority

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EPA has the authority to initiate injunctive actions under Section 16(c) of FIFRA, which states that the "district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of this Act."

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### Justification for Seeking Injunctive Relief

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~~The courts are generally reluctant to issue mandatory injunctions or to~~ issue injunctions that will alter the status quo except in the most compelling instances. Consequently, the Agency's need for injunctive relief should be clear and unmistakable. A permanent injunction should be considered when:

- The Agency's administrative or other judicial enforcement remedies would be inadequate either at restraining the violation or at ~~preventing unreasonable risk to humans or the environment;~~
- The Agency has, in fact, already diligently exercised all appropriate administrative remedies, yet the violation continues unabated. For FIFRA, this would include remedies such as stop sale, use, or removal orders (SSUROs), negotiations, hearings, fines, etc., which fail to prevent or stop the violation; and
- ~~Irreparable injury, loss, or damage will result if relief is not~~ granted. "Irreparable" means that the damage cannot be undone once it takes place.

A preliminary injunction or temporary restraining order should be considered when the following additional elements are present:

- Immediate and irreparable injury, loss, or damage will result if relief is not granted. "Immediate" is self-explanatory and is interpreted strictly; and
- There is likelihood of success at trial based on facts before the court (i.e., more than a 50 percent chance of winning at a trial based on facts before the court at the time of application).

Modern court trends have been to relax the requirement of irreparable injury. In particular, where a statute prohibits certain conduct, many courts will presume the conduct to be injurious thus warranting an injunction without requiring a showing of irreparable injury. This doctrine has been applied to violations of the Federal Food, Drug, and Cosmetics Act [U.S. v. Diapulse Corp. of America, 457 F.2d 25 (2nd Cir. 1972)]. It is reasonable to expect that the doctrine can be extended to apply to violations of FIFRA. For instance, where there is a real possibility of an "imminent hazard" to human health or the environment, irreparable injury may not need to be shown.

#### Conditions That May Justify Injunctive Relief

Injunctive relief may be justified when:

- There is a violation of a Section 6 suspension order;
- There is a violation of an SSURO, where a civil penalty or criminal prosecution would not provide a timely and effective enforcement remedy to deter further violations;
- There is continued production, shipment, sale, or use of an unregistered pesticide after the Agency has taken civil or criminal action; or
- The Agency has exercised an enforcement remedy and a person continues to make available for use a restricted use pesticide other than in accordance with Section 3(d), or continues to use a pesticide in a manner inconsistent with its labeling or in a manner contrary to an experimental use permit.

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#### Procedures for Seeking Injunctive Relief

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##### 1. Determine the Necessity for Injunctive Relief

- Regional Initiation. The Regions generally make the initial determination that an injunction is necessary to restrain

violations of FIFRA or to prevent harm to humans and the environment. The regional determination must be based on a careful weighing of the facts of the violation, of the evidence available to document the severity of the violation, and of the justifications discussed above.

- Headquarters Initiation. In some instances, Headquarters may be the initiating party when noncompliance with the terms of the statute exists on a national level or the Registration Division has alerted PTSCMS to a situation that warrants an injunction.

#### Determine Type of Injunction To Be Sought

- Temporary Restraining Order (Exhibit 8-2). A temporary restraining order (TRO), sometimes known as a provisional injunction, is limited and will expire in 10 days (but can be extended an additional 10 days by the court). It is used when it can be shown by ~~affidavit or verified complaint that immediate and irreparable~~ injury, loss, or damage will occur before the time that the adverse party can present its case. The purpose of the TRO is to preserve the status quo until a motion for a preliminary injunction can be heard. Its advantage is that it is the most expediently obtained form of injunctive relief.

Rule 65(b) of the Federal Rules of Civil Procedure (Fed. R. Civ. P.) controls the procedural steps for obtaining a TRO. Generally the attorney for the adverse party, if known (or if not known, the adverse party itself), must be given oral or written notice of the request for a TRO. However, this requirement is suspended if (1) ~~it is shown by specific facts that immediate and irreparable harm will occur before the adverse party can be heard and~~ (2) if the government attorney certifies in writing the efforts, if any, taken to provide notice to the adverse party and the reasons supporting the claim that notice should not be required. The facts demonstrating immediate and/or irreparable injury, loss, or damage, may appear either in a verified complaint or in a separate affidavit signed by an EPA employee other than the attorney for the case. Along with the motion for a TRO, a copy of the suggested TRO ~~should be filed.~~

When a TRO is granted without notice (i.e., ex parte), the motion for a preliminary injunction must be set for hearing at the earliest possible time. The party who obtained the TRO must then proceed with the application for a preliminary injunction and if the party does not do so, the TRO will be dissolved by the court. If a defendant moves to modify or dissolve a TRO, there must be a ~~hearing and the Agency must be informed at least two days before~~ the hearing.

- Preliminary Injunction (Exhibit 8-3). A preliminary injunction by its very nature is interlocutory, provisional, or temporary. It is intended to preserve the status quo pending final determination of the action after a full hearing on the merits. It is different from a TRO in that a preliminary injunction requires advance notice to the adverse party, and it can last longer than 10 days.

Notice presumes a hearing and an opportunity to contest the motion for an injunction. The applicant has the burden of establishing the right to injunctive relief. To do so, it is advisable to rely on more than affidavits (Exhibit 8-4) whenever possible. Oral testimony should be available when and if necessary to substantiate the Agency's contentions.

At the hearing on the application for preliminary injunction, the court may order an advancement and the consolidation of the trial on the merits. Consequently, the government attorney should be prepared to go forward with the prosecution of the case when seeking a preliminary injunction.

- Permanent Injunction (Exhibit 8-5). A permanent injunction, also called a final or perpetual injunction, is generally unlimited in duration. It is usually granted only after a full trial on the merits. Consequently, the judgment granting a permanent injunction constitutes final disposition of the suit, although the judgment may be appealed to a circuit court.

Mere passage of time will not dissolve a permanent injunction, unless the judgment itself so provides. However, the prospective features of a final injunctive decree are subject to termination or modification by the court when warranted by changed conditions.

### 3. Determine the Appropriate District Court Having Jurisdiction

The Regional Office must determine which is the appropriate district court having jurisdiction over the violator. An injunction operates in personam (meaning "against the particular person"), so that the district court in which the motion is filed must have in personam jurisdiction over the party against whom the injunction is sought. Usually this means that the person or corporation who is the defendant must live or have a place of business within that State. Service of process, or the delivery of written notice, in a district court is subject to the territorial limits of the State in which the court is located. However, in some instances, an injunction may have an in rem ("against the world at large") effect on property or items that are the subject of the suit or that are within the court's in rem jurisdiction. In rem jurisdiction may have a broader reach for serving process than does in personam—it is easier to get "the thing" than it is "the person." These possibilities should be explored informally with the appropriate U.S. Attorney before formal referral of the case file.

#### 4. Prepare the Referral Package

See discussion in "Procedures for Filing Actions" (Section 3) in this chapter.

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#### Court Actions on Motions for Injunctive Relief

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If an injunction is granted, the following actions should ensue:

- Preparation for the Next Stage of the Proceeding. If the court grants a motion for a preliminary injunction or TRO, the regional attorney in conjunction with the U.S. Attorney must begin preparation for the next stage in the proceeding, whether that be a full trial on the merits or a more extensive and permanent type of injunction.
- Monitoring the Injunction. Although it is the court's responsibility to monitor any equitable decree, including an injunction, the courts have limited resources and often encounter practical difficulties in monitoring compliance. If the court does not ask the Agency to monitor the injunction, the Region should offer to assist the court in monitoring the injunction and to report any violations of the injunction. A violation of an injunction will subject the party to a charge of contempt of court.

If an injunction is denied, the Agency may either:

- Appeal the denial; or
- ~~Accept the denial and pursue other legal remedies.~~

In both instances, the Headquarters Case Development Officer (HQCDO) should be consulted by the Regional Office to determine which course of action to take.

## Model Motion for Temporary Restraining Order

United States District Court

\_\_\_\_ District of \_\_\_\_\_

(Title of Action)

Civil Action No. \_\_\_\_\_

Motion for Temporary Restraining  
Order [With or Without Notice]

Plaintiff, the United States of America, herewith moves this court to grant [\* (1) forthwith and without notice to defendant for his attorney] a temporary restraining order restraining defendant, his agents, and employees from (set forth acts sought to be enjoined) pending a hearing and disposition of plaintiff's motion for a preliminary injunction on the grounds that immediate and irreparable loss, damage, or injury will result to [\* (2) plaintiff, the public, the environment] as set forth in the attached verified complaint and affidavits of (name of affiant) [\* (3) before notice can be given] and before defendant or his attorney can be heard in opposition [\* (4) as appears more fully in the attached certificate of the undersigned showing that all reasonable effort has been made to notify the (defendant and/or his attorney) of this motion].

(Signature of U.S. Attorney)  
United States Attorney for the

\_\_\_\_ District of \_\_\_\_\_

Date \_\_\_\_\_

- \* (1),(3),(4) - These statements are optional depending upon whether or not the defendant or his attorney receives advance notice of the request for a TRO.
- \* (2) - The victim of the alleged injury can be best determined from the actual facts of the case at hand.

## Model Motion for Preliminary Injunction

United States District Court

\_\_\_\_ District of \_\_\_\_

(Title of Action)

Civil Action No. \_\_\_\_\_

## Motion for Preliminary Injunction

Plaintiff moves the court for a preliminary injunction enjoining the defendant (name of defendant), his agents, servants, employees, and attorneys and all persons in active concert and participation with him, pending the final hearing and determination of this action, from (set forth act or acts sought to be enjoined) on the grounds that:

- (1) ~~Unless restrained by this court defendant will perform the acts referred to;~~
- (2) Such action by the defendant will result in immediate and irreparable injury, loss, or damage to (the plaintiff, the public interest, or the environment), as appears in the verified complaint and the affidavit of (name of affiant), attached hereto; and
- (3) The issuance of a preliminary injunction herein will not cause undue inconvenience or loss to defendant, but will prevent ~~immediate and irreparable injury to the plaintiff.~~

(Signature of U.S. Attorney)

United States Attorney for the

\_\_\_\_ District of \_\_\_\_

Date \_\_\_\_\_

**Model Affidavit in Support of Motion for Preliminary Injunction**

United States District Court

\_\_\_\_ District of \_\_\_\_\_

(Title of Action)

Civil Action No. \_\_\_\_\_

Affidavit in Support of Motion for  
Preliminary Injunction(Name of Affiant) , being duly sworn, deposes and says:

- (1) It [the United States] is the plaintiff in the above-entitled action; and that it makes this affidavit in support of plaintiff's motion for a preliminary injunction herein.
- (2) This is an action [to enjoin defendant from engaging in any violation of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136 et seq.].
- (3) [Statement of facts to support the motion].

\_\_\_\_\_  
(Signature of Affiant)(other than EPA attorney)

Subscribed and sworn to and before me at (City and State)

\_\_\_\_ this \_\_\_\_ day of \_\_\_\_\_, 19\_\_.

\_\_\_\_\_  
(Signature of Attesting Official)(other than EPA attorney)



## Model Motion for Permanent Injunction

United States District Court

\_\_\_\_ District of \_\_\_\_\_

(Title of Action)

Civil Action No. \_\_\_\_\_

## Motion for Permanent Injunction

Plaintiff, the United States of America, herewith moves the court to make permanent the preliminary injunction issued herein on (date). In support, plaintiff submits (the opinion of the court of \_\_\_\_\_) which is conclusive to the effect that the (behavior or activity of the defendant) is unlawful and no additional evidence could alter that result.

[optional: (1) Counsel may also want to include a paragraph moving the court to enter the mandate of a higher court, if the grant of injunction has been unsuccessfully appealed.]

[optional: (2) Counsel may also find it necessary to include a motion either for the dismissal of defendant's counterclaim or for the grant of summary judgment as to the counterclaim.]

(Signature of U.S. AttorneyUnited States Attorney for the

\_\_\_\_ District of \_\_\_\_\_

Date \_\_\_\_\_



## 5 In Rem (Seizure) Actions

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### Statutory Authority

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Section 13(b) of FIFRA authorizes the seizure, through an in rem condemnation proceeding in district court, of:

- Any pesticide that is adulterated, misbranded, unregistered, not colored or discolored as required, or bears claims or directions for use that differ from those made in connection with its registration;
- Any pesticidal device that is misbranded; and
- ~~Any pesticide or pesticidal device that causes unreasonable adverse effects upon the environment, even when used in accordance with the requirements imposed under the Act.~~

Section 9(b) authorizes duly designated Agency employees to obtain and execute warrants for the purpose of seizing any pesticide or pesticidal device that is in violation of the Act.

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### Enforcement Criteria

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Seizure of a pesticide or device is effectuated through an in rem condemnation proceeding conducted according to Rule 9(h) of the Federal Rules of Civil Procedure (Fed. R. Civ. P.) and the Supplementary Rules for ~~Certain Admiralty and Maritime Claims~~ [Title 28 U.S.C.]. The procedure to initiate this judicial action requires more preparation and time than that necessary to issue an SSURO.

Therefore, the SSURO is the preferred remedy in terms of expediency. A seizure, nonetheless, should be considered when:

- An SSURO has been issued and is not being complied with;
- There is reason to believe that an SSURO, if issued, would not be complied with;
- A pesticide is so hazardous that it should be removed from the marketplace or its place of use;
- It is necessary to support a recall; or
- It is necessary to dispose of products that remain under an SSURO without corrective action and for which there is an expressed intent not to take corrective action by the person holding the violative product.

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### In Rem Procedures

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#### 1. Prepare the Referral Package

Upon determining that a pesticide or device is in violation of the Act and that a seizure is the appropriate level of enforcement action, the Regional Office should prepare a civil litigation referral package (see Section 3 of this chapter). The package may include a proposed complaint in rem (Exhibit 8-6), which is prepared in accordance with Rule C of the Supplemental Rules for Certain Admiralty and Maritime Claims that accompany the Fed. R. Civ. P. The necessary elements of the complaint in rem are that:

- It be verified by oath or affirmation;
- It describe with reasonable particularity the property that is the subject of the action;
- It state that the property to be seized is (or will be during the pendency of the action) within the jurisdiction of the district court that will hear the action;
- It state the place of seizure; and
- It state the allegations of the violations, as required by the statute, with sufficient particularity that the defendant/respondent can frame responsive pleadings and investigate the facts without moving for a more definite statement.

## 2. Execute the Warrant

Once the complaint in rem is filed with the court, an "arrest" warrant (i.e., a warrant for the arrest of the property that is the subject of the action) will be issued. According to Rule C(3) of the Supplemental Rules, the warrant is delivered to a U.S. Marshal for execution. However, Section 9(b) of the Act provides that duly designated EPA employees are authorized to obtain and execute warrants for the purpose of effecting a Section 13(b) seizure. It is the Agency's view that a seizure warrant may be served by either a U.S. Marshal or an EPA employee. These possibilities should be brought to the U.S. Attorney's attention, and the Region should make known its preference. However, the Region should abide by the wishes of the U.S. Attorney if it is preferred that the U.S. Marshal serve the warrant.

## 3. Notify Other Regions

The Region should notify other Regions of its actions if there is reason to believe that the violative product is also in those Regions.

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## Compliance With a Seizure

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The violation of a court-ordered seizure or decree of condemnation constitutes contempt of court. When any such violation is found, it should be reported promptly to the U.S. Attorney who filed the seizure action.

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## Disposition of a Seizure

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While pesticides or pesticidal devices under seizure are in the control of the court, the Regional Office will usually be called upon to recommend or approve the method of disposition and may be directed to supervise the court-ordered action in decrees of condemnation. When agreeable to the U.S. Attorney, the Regional Office should prepare the proposed consent or default decree to be filed by the U.S. Attorney.

## Reconditioning

Where disposition is achieved by reconditioning, the person supervising the reconditioning under a consent decree should report the method of reconditioning, what examinations or tests were made, and whether the pesticide or pesticidal device is now in compliance with the provisions of the Act (Exhibit 8-7).

Agency Reimbursement

Because the Agency will be reimbursed by the claimant for expenses incurred in the seizure, the Region should keep a record of all expenses incurred in connection with the supervision and disposition of the seized products. The schedule of expenses should be attached to the report of supervision and presented to the U.S. Attorney for collection concurrent with the payment of court costs (Exhibit 8-8).

Model Complaint In Rem

IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF \_\_\_\_\_

United States of America

v.

Complaint In Rem

TO THE HONORABLE JUDGE OF SAID COURT:

This is a complaint in rem filed in behalf of the United States of America by the United States Attorney for this District, who represents as follows:

I

This is an action in rem instituted pursuant to Section 13(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136k(b), for the seizure for confiscation by a process in rem for condemnation of (name of the product in the caption), a product offered for sale, sold, transported or imported as a (pesticide or device) within the meaning of Section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136. Authority to bring this action is vested in the United States Attorney by 28 U.S.C. §547(2).

II

This court has jurisdiction of the subject matter of this action pursuant to 7 U.S.C. §136k(b) and 7 U.S.C. §136n(c).

## III

On or about \_\_\_\_\_, 19\_\_\_\_,  
the product was (transported, imported, sold, offered for sale) by \_\_\_\_\_  
from \_\_\_\_\_  
to \_\_\_\_\_

and the product remains unsold or in the original unbroken packages and  
is now in the possession of (person in possession and exact location)

or elsewhere within the jurisdiction of this Honorable Court.

## IV

The product is labeled, marked, and branded (in part) as follows:

The product is in violation of the Act as follows:

(State allegation with specific reference to unlawful acts)



WHEREFORE, in consideration of the premises, the complainant, United States of America, prays:

(a) That the pesticide/device, \_\_\_\_\_ be proceeded against and seized for condemnation and confiscation, and that it be disposed of as the Court may direct in accordance with the provisions of Section 13(b) of the Act [7 U.S.C. §136k(b)] and in conformity with the practice of this Court, and that the parties specified in paragraph II of this complaint and any and all other persons having or pretending to have any right, title, or interest in and to the product be notified to appear herein in order that they may answer all and singular the allegations herein set forth.

(b) That this Honorable Court may enter all such orders, decrees, and judgments as may be necessary in the premises to grant further relief to your complainant and for the costs of this proceeding should such costs not be satisfied out of the proceeds of the sale of the product, if this Honorable Court should decree the same to be sold.

(c) That your complainant may have such other and further relief as the nature of the case may require.

(Signature of U.S. Attorney  
United States Attorney for the

\_\_\_\_\_ District of \_\_\_\_\_

#### VERIFICATION

I have read the foregoing pleading and know its contents; which is true and correct of my own knowledge, except as to matters therein stated upon my information and belief, and as to such matters I believe it to be true.

Executed on this \_\_\_\_\_ day of (date) \_\_\_\_\_

(location) \_\_\_\_\_

\_\_\_\_\_  
United States Attorney

## Model Report of Supervision of Disposition

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REPORT OF SUPERVISION OF DISPOSITION OF PESTICIDE OR DEVICE	
Pesticide or Device Detained Under	
(Stop Sale, Etc., Order, Seizure by Marshal)	
(EPA Seizure (warrant); Voluntary Recall; Give Place and Date of	
Detention)	
Sample No., I.F.&R. No., Court No. _____	
Name of Pesticide or Device _____	
Nature of Violation _____	
_____	
Type of Disposition Order or Agreement _____	
(Consent Decree; Voluntary	
Reconditioning; Court-Ordered Destruction; Etc.)	
Method of Disposition _____	
(Reformulate; Relabel; Destroy; Etc.)	
_____	
Results of Disposition Action _____	
(In Compliance - Relabeled; Etc.)	
(Not in Compliance - Ineffective by Test; Etc., Give Test Results, Etc.)	
Further Action Required _____	
(None or, Further Reformulation; Relabeling; Etc.)	
_____	
Remarks _____	
_____	
_____	
(Signature and Title of EPA Employee)	
_____	
(Place and Date)	

# Model Expenditure Report Form

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**CHARGES FOR SUPERVISION OF DISPOSITION OF PESTICIDE OR DEVICE**  
**(Attached to Report of Supervision)**

Sample No., I.F.&R. No., Court No. \_\_\_\_\_

Name of Pesticide or Device \_\_\_\_\_

Amount of Pesticide or Device

Method of Disposition

Types of Charges	Unit			Charge	Total
	Hours	Days	Miles		

Inspector Time

Analyst Time

**Inspector Per Diem**

**Analyst Per Diem** \_\_\_\_\_

**Inspector Automobile Use**

### Analyst Automobile Use

Other Transportation or  
Miscellaneous Expenses  
(itemize)

### Sub-Totals

**Grand-Total**

**Remarks:**

(Signature of Inspector or Analyst)



## 6 Settlement Agreements

By their very nature, FIFRA civil actions do not involve settlement agreements. Nonetheless, an injunction or in rem (seizure) action that is granted to EPA by a district court is also usually monitored for compliance by the Agency. The violation of either type of civil action will subject the responsible party to a charge of contempt of court.



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## Chapter Nine

# Judicial Enforcement: Criminal Actions

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## Judicial Enforcement: Criminal Actions

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### Statutory Authority

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Section 14(b) of FIFRA provides the following criminal penalties for the "knowing violation" of any provision of the Act:

- (1) In General.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than \$25,000, or imprisoned for not more than one year, or both.
- (2) Private applicator.—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall be guilty of a ~~misdemeanor and shall on conviction be fined not more than \$1,000, or imprisoned for not more than 30 days,~~ or both.

Section 12 of FIFRA enumerates those acts considered unlawful under the Act (see Chapter Seven for a complete listing.)

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### Basic Enforcement Policy

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The objective of the pesticides enforcement program is to ensure compliance with the terms and provisions of FIFRA. The Act provides the Agency with a variety of administrative, civil, and criminal enforcement options to accomplish this goal. A broad range of potential overlap exists among ~~these various options. Theoretically at least, the Agency is free to~~

pursue criminal sanctions in every situation presenting evidence supporting the requisite elements of proof.\*

As a matter of enforcement policy and resource allocation, such an unrestrained use of criminal sanctions is neither warranted nor practical. The commitment of investigative and technical resources necessary for the successful prosecution of a criminal case is high. More importantly, a criminal referral for investigation or prosecution can entail profound consequences for the subject of the referral. Accordingly, criminal referrals should be confined to situations that reflect the most serious cases of environmental misconduct--when measured by the nature of the conduct, the compliance history of the subject, or the gravity of the environmental consequences.

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### Criteria for Identification of a Potential Criminal Action

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This section discusses the considerations that should be examined in determining whether to proceed with a criminal vis-a-vis administrative/civil action.

#### The Scienter Requirement

An individual who engages in conduct prohibited by statute or regulation can be prosecuted civilly or administratively without regard to the mental state that accompanied the conduct. Criminal sanctions, on the other hand, will be limited ordinarily to cases in which the prohibited conduct is accompanied by evidence of a "guilty knowledge" or intent on the part of the prospective defendant. Referred to as the scienter requirement, this element of proof exists under virtually every environmental statute enforced by the Agency.\*\*

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\* Pesticide use of FIFRA violations are an exception to this general statement. Sections 26 and 27 of FIFRA establish standards and procedures for according to the States the primary enforcement responsibility (primacy) for pesticide use violations. Where a State has primacy, the Agency will not bring an enforcement action unless the State is unwilling or unable to address the situation. If the State has referred the matter to the Agency, the Agency will proceed as with any other case under FIFRA.

\*\* One exception to this general rule is the Refuse Act, 33 U.S.C. §407, which has generally been interpreted as a "strict liability" statute. [See, e.g., United States v. White Fuel Corporation, 498 F.2d 619 (1st Cir. 1974).] In addition, a prosecution for illegal discharges under the Clean Water Act can be based on negligent or willful conduct, 33 U.S.C. §1319(c)(1). "Negligence" is not, strictly speaking, a form of scienter.

Under FIFRA, criminal penalties are imposed only for "knowing" violations of the Act. The term "knowing" has been used in a number of other criminal provisions and has been interpreted to mean that the violative act must be done intentionally and not as a result of accident or mistake.

To date, only one case has addressed the meaning of the word "knowing" as it is used in FIFRA. In United States v. Corbin Farm Services, 444 F. Supp. 510 (E.D. CA. 1978), the defendants were charged with the knowing use of a registered pesticide in a manner inconsistent with its labeling. The label on the pesticide in question stated: "For water fowl protection do not apply...on fields where water fowl are known to repeatedly feed." The defendants had applied this pesticide to a field containing evidence of bird activity, which resulted in the death of migratory birds. The court found that in order to prove knowing activity, the government must show a general intent on the part of the defendants to do the act in question (i.e., the government was required to show that the defendant knew that he was using a pesticide when he sprayed the field). Proof of intent to violate FIFRA was not necessary.

The requirement to prove a culpable mental state, as well as a prohibited act, is certainly the clearest distinction between criminal and administrative/civil enforcement actions.

#### The Nature and Seriousness of the Offense

As a matter of enforcement policy and resource allocation, EPA will investigate and refer only the most serious forms of environmental misconduct for criminal prosecution.

Of primary importance to this assessment is the extent of environmental ~~contamination or human health hazard that has resulted from, or was~~ threatened by, the prohibited conduct. In general, this determination will depend upon considerations such as the duration of the conduct; the toxicity of the pollutants involved; the proximity of population centers; the quality of the receiving land, air, or water; the amount of Federal, State, or local cleanup expenditures; and public sentiment supporting strong enforcement action in response to a specific situation.

~~Also of significance in assessing the seriousness of the illegal conduct is the impact—real or potential—on EPA's regulatory functions.~~ This factor is of particular importance in cases of the falsification or concealment of records, reports, or other information. For example, even if a technical falsification case can be made, criminal sanctions may not be appropriate if the distortion of information could not reasonably have been expected to have a significant impact on EPA's regulatory or decisionmaking process. However, where the impact is material, as in the case where the ~~falsification activity might cause EPA to register a pesticide with~~ demonstrated carcinogenic potential, the need for criminal sanctions should be considered.

### The Need for Deterrence

Deterrence of criminal conduct by a specific individual (individual deterrence) or by the community at large (general deterrence) has always been one of the primary goals of criminal law. Where the offense is deliberate and results in serious environmental contamination or human health hazard, the need to achieve deterrence through the application of strong punitive sanctions will almost always exist.

The goal of deterrence may, on occasion, justify a criminal referral for an offense that appears relatively minor. This would be true, for example, for offenses that—while of limited importance by themselves—would have a substantial cumulative impact if commonly committed. This might also be true when addressing violations by an individual with an extended history of recalcitrance and noncompliance.

### The Compliance History of the Subject(s)

The compliance history of the subject of a potential criminal referral also should be considered in determining the appropriateness of criminal sanctions. As a general rule, criminal sanctions become more appropriate as the incidents of noncompliance increase. The occurrence of past enforcement actions against a company or the failure of administrative/civil enforcement, is certainly not a prerequisite to a criminal referral. However, a history of environmental noncompliance will often indicate the need for criminal sanctions to achieve effective individual deterrence.

### The Need for Simultaneous Administrative/Civil or Enforcement Action

Simultaneous administrative/civil and criminal enforcement proceedings are legally permissible, United States v. Kordel, 397 U.S. 1, 11 (1970), and on occasion are clearly warranted. However, separate litigation staffs would need to be appointed on initiation of a grand jury investigation, if not before. Furthermore, the pursuit of simultaneous proceedings would provide fertile grounds for legal challenges to one or both proceedings that, even if unsuccessful, would consume additional time and resources. Thus, parallel proceedings should be avoided except where clearly justified.

In this regard, it should be noted that some of the goals of a criminal prosecution, including deterrence, can be achieved through an administrative or civil action that secures substantial civil penalties in addition to injunctive relief. Moreover, recent experience indicates that while some cases may result in periods of incarceration, criminal sentences will often be limited to monetary fines and a probationary period. In light of this reality, the use of the additional time and resources necessary to pursue a criminal investigation is often not justified.

Criminal Enforcement Priorities

The Criminal Enforcement Division, in conjunction with the Agency program offices, has developed investigative priorities in each of the Agency's program areas. The purpose of this effort is to focus the limited investigative resources of the Agency on the most serious cases of environmental misconduct. These priorities are fluid and will be modified to reflect additional regulatory programs in the Agency as they develop. In addition, the creation of these priorities does not preclude the possibility of criminal referral for conduct not falling within these investigative priorities.

The order of listing is random. It is not intended to create a ranking within the priorities for a statute. Nor is any statute given higher priority than another. The priorities for FIFRA are listed below.

Failure To Report Information on the Unreasonable Adverse Effects of a Registered Pesticide. Section 14(b) of FIFRA, 7 U.S.C. §1361(b), ~~establishes misdemeanor penalties for the knowing violation of any provision of the Act. Section 12(a)(2)(N) provides that it is unlawful to fail to submit information required by Section 6(a)(2). This section requires a registrant to report to EPA any information that the registrant obtains after the pesticide is registered regarding unreasonable adverse effects of the pesticide on the environment. A high investigative priority will be placed on knowing violations of this reporting requirement.~~

Falsification of FIFRA Records. Sections 12(a)(2)(M) and 14(b) of FIFRA, 7 U.S.C. §§136j(a)(2)(M) and 1361(b), establish misdemeanor penalties for the knowing falsification of specified records maintained or filed under FIFRA, including registration data. A high investigative priority will be placed ~~on falsification activity that has—or could reasonably be expected to have—a significant impact on EPA's regulatory or decisionmaking process.~~

Violation of Suspension or Cancellation Orders. Sections 12(a)(2)(J), 12(a)(2)(K) and 14(b) of FIFRA, 7 U.S.C. §§136j(a)(2)(J), 136j(a)(2)(K) and 1361(b), establish misdemeanor penalties for knowing violations of the terms of cancellation and suspension orders issued under Section 6 of FIFRA. A high investigative priority will be placed on knowing violations that result in, or threaten, significant environmental contamination or ~~human health hazard.~~

Violation of Stop Sale, Use, or Removal Orders. Sections 12(a)(2)(I) and 14(b) of FIFRA, 7 U.S.C. §§136j(a)(2)(I) and 1361(b), establish misdemeanor penalties for knowing violations of the terms of stop sale, use, or removal orders under Section 13(a). A high investigative priority will be placed on knowing violations that result in, or threaten, significant environmental contamination or human health hazard.

Unlawful Uses of Pesticides. Sections 12(a)(2)(G) and 14(b) of FIFRA, 7 U.S.C. §§136j(a)(2)(G) and 1361(b), establish misdemeanor penalties for the knowing use of a pesticide in a manner inconsistent with its labeling. If

referred by a State with primary use enforcement responsibilities, a high investigative priority will be assigned to misuse cases that result in, or threaten, significant environmental contamination or human health hazard.

Illegal Distribution of Unregistered Pesticides. Sections 12(a)(1)(A) and 14(b) of FIFRA, 7 U.S.C. §§136j(a)(1)(A) and 136l(b), establish misdemeanor penalties for the knowing distribution, receipt, etc. of an unregistered pesticide. The pesticide registration process outlined in Section 3 of FIFRA, 7 U.S.C. §136a, is the cornerstone of EPA's program to monitor and regulate the safety of pesticides. A high investigative priority will be placed on illegal transactions involving unregistered pesticides that result in, or threaten, significant environmental contamination or human health hazard.

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### Procedures for the Investigation and Referral of a Criminal Case

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#### Investigation

The Criminal Enforcement Division maintains the primary role in the investigation and referral to the Justice Department of allegations of criminal misconduct. The division is staffed by experienced criminal investigators located in each of five area offices and EPA Headquarters. (Exhibit 9-1 contains a list of the division's area offices and their scope of responsibility.)

An initial "lead" or allegation of potential criminal activity may come to the Agency from any of several sources, including State agencies, routine compliance inspections, disgruntled plant employees, or citizen groups. Regardless of its source, it should be transmitted immediately to the Special-Agent-In-Charge of the responsible field office, who will open a case file\* and assign a criminal investigator (known as a Special Agent) to the lead for follow-up.

If the reliability of the lead is unclear, the Special Agent will conduct a preliminary inquiry solely to determine the credibility of the allegation and to make an initial assessment of the need for more thorough investigation. This initial inquiry will be brief and will not involve extensive commitment of resources or time. Its sole purpose is to reach an initial determination on the need for a complete investigation.

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\* The opening of a case file does not commit the Agency to proceed with a criminal referral at the culmination of the investigation; nor does it reflect an Agency decision that criminal conduct has occurred. All enforcement options remain open and should be considered until referral to the Justice Department.

Once a determination has been made by the Criminal Enforcement Division that a thorough investigation is warranted, the Special Agent will immediately contact the Regional Counsel in the Region where the investigation is to be conducted. The Regional Counsel will ensure that no civil enforcement action is pending or contemplated against the investigative target and will assign an attorney to work with the investigator during the case development process. The regional attorney and Special Agent will also contact the appropriate regional program office to ensure that no administrative enforcement action is pending or contemplated. In addition, where the need for technical support during the investigation is contemplated, the regional program office will be asked to assess the availability of technical resources and, when appropriate, to designate a specific individual to work with the Special Agent during the course of the investigation.

While simultaneous administrative/civil and criminal enforcement actions are legally permissible, they will be the exception, rather than the rule. As a general rule, an administrative or civil proceeding will be held in abeyance pending the resolution of the criminal investigation. One exception to this general rule will be those situations in which emergency remedial response is mandated. In these situations, however, the criminal investigation will not be initiated without the prior approval of the appropriate Regional Counsel and Enforcement Counsel.

Management of the investigation will be the primary responsibility of the Special Agent, acting under the supervision of the Field Office Special-Agent-In-Charge. The Special Agent will be responsible for determining the basic investigation approach and will take the lead in conducting interviews; assembling and reviewing records; planning and executing surveillances; coordinating with State, Federal, and local law enforcement agencies; planning and executing searches; developing informants; and performing other investigative matters. A technical person will work with the Special Agent during those portions of an investigation requiring technical expertise.

#### Notice of Contemplated Proceedings

Section 9(c)(1) of FIFRA requires the Agency to give notice and an opportunity to be heard to those persons\* against whom enforcement proceedings, which arise as a result of establishment inspections conducted under authority of Section 9(a), are contemplated. It should be noted, however, that Section 9(c)(2) clearly specifies that such notice is not a prerequisite to the initiation of criminal proceedings by the Department of Justice.

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\* Section 2(s) of FIFRA defines person to mean any "individual, partnership, association, corporation, or any organized group of persons whether incorporated or not" [7 U.S.C. §136(s)].

### Referral

A referral recommendation will be developed when the independent field investigation has been exhausted, or when it can or should proceed no further without the initiation of a grand jury investigation by the Justice Department. Where a referral is made for further investigation by a grand jury, the task of creating a complete referral package is difficult since the case has not yet been completely developed. Therefore, a streamlined referral process has been initiated for these cases to eliminate inefficiency and to provide for the more natural development of criminal cases. See Exhibit 9-2 for a copy of these procedures. At this point, the results of the investigation will be assembled in a referral package. The preparation of the overall referral package will be the responsibility of the regional attorney assigned to the investigation, working in conjunction with the Special Agent.

Once the package is prepared, it will be reviewed by the Special-Agent-In-Charge and the Regional Counsel, who will act as joint signatories. Technical portions of the package will also be reviewed by the regional or Headquarters program office, or the NEIC—depending on the source of technical support. During this technical review, the availability of technical resources to support litigation should also be reviewed and specifically confirmed by the appropriate technical office.

Following completion of the referral package and concurrence in the referral recommendation by the Special-Agent-In-Charge and the Regional Counsel, three copies of the referral package and all exhibits should be directed to the Associate Enforcement Counsel for Criminal Enforcement, Criminal Enforcement Division (LE-134E), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington D.C. 20460. No copies of the referral package will be sent to the local United States Attorneys Office or the Justice Department until Headquarters has reviewed and approved the referral.

If either the Special-Agent-In-Charge or the Regional Counsel believe the referral should not be made, that official will include a statement of the reasons underlying this position and make an alternative recommendation (i.e., close out investigation, change to civil referral, change to administrative action, etc.). The package will, nevertheless, be directed to the Criminal Enforcement Division for review; a final referral decision will be made by the Associate Administrator for OLEC (or the Associate Administrators designee).

The Headquarters review will focus on the adequacy of case development; adherence to the criminal enforcement priorities of the Agency; legal issues of first impression; consistency with related program office policy; and general prosecutorial merit. In cases involving particularly complex issues of law, the Criminal Enforcement Division will also consult with General Counsel attorneys. If, following this review process, the referral recommendation is accepted, referral packages will be directed simultaneously to the Justice Department and the appropriate United States Attorneys Office. Appropriate cover letters will be drafted by the Criminal Enforcement Division.



Referral Package Format

Referral packages should be prepared in accordance with the Uniform Criminal Referral Package Format effective on January 1, 1982. (See Exhibit 9-3.). However, referral packages prepared for those cases referred for further investigation by a grand jury should be prepared in accordance with the May 9, 1983 guidance concerning referral procedure for criminal cases (see Exhibit 9-2).

References

Agency employees who are involved in the investigation and referral to the Department of Justice of allegations of criminal violations of FIFRA should familiarize themselves with the Agency documents listed below. Although a digested form of some of this material is contained in this section, most of the items are not covered in detail. The documents are contained in the General Enforcement Policy Compendium, or copies of the documents may be obtained by contacting the Criminal Enforcement Division, EPA Headquarters.

- General Operating Procedures for the Criminal Enforcement Program (October 31, 1982);
- Criminal Enforcement Priorities;
- Agency Guidelines for Participation in Grand Jury Investigations;
- Agency Guidelines for the Use of Administrative Discovery Devices in the Development of Potential Criminal Cases;
- ~~Guidelines on Press Relations on Matters Pertaining to EPA's Criminal Enforcement Program; and~~
- Policy and Procedures on Parallel Proceedings at the EPA.

## Criminal Enforcement Divisions: Field Offices

Philadelphia Field Office  
(Regions I, II and III)

Special-Agent-In-Charge  
Criminal Enforcement Division  
EPA - Region III  
Curtis Building  
6th & Walnut Streets  
Philadelphia, PA 19106  
FTS 597-1949

Seattle Field Office  
(Regions IX and X)

Special-Agent-In-Charge  
Criminal Enforcement Division  
EPA - Region X  
1200 6th Avenue  
Seattle, WA 98101  
FTS 399-9874

Atlanta Field Office  
(Regions IV and VI)

Special-Agent-In-Charge  
Criminal Enforcement Division  
EPA - Region IV  
345 Courtland Street, N.E.  
Atlanta, GA 30365  
FTS 257-4885

Denver Field Office  
(Region VIII)\*

Special-Agent-In-Charge  
Criminal Enforcement Division  
National Enforcement Investigations  
Center  
Box 25227  
Denver Federal Center  
Denver, CO 80225  
FTS 234-2158

Chicago Field Office  
(Regions V and VII)

Special-Agent-In-Charge  
Criminal Enforcement Division  
EPA - Region V  
230 South Dearborn Street  
Chicago, IL 60604  
FTS 886-9874

\* The Denver Field Office is located at the National Enforcement Investigations Center. In addition to Region VIII cases, its responsibilities include cases that overlap the jurisdiction of field offices. Assignment of these cases will be the responsibility of EPA Headquarters.

## Referral Procedure for Criminal Cases



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

MAY 9 1983

OFFICE OF  
LEGAL AND ENFORCEMENT COUNSEL

MEMORANDUM

SUBJECT: Referral Procedure for Criminal Cases

FROM: Courtney M. Price *Courtney M. Price*  
Acting Associate Administrator  
and General Counsel

TO: Regional Counsels, Regions I-X  
All SAICs, Criminal Enforcement Division

Under the current General Operating Procedures, a criminal referral to the Justice Department may be made for one of two reasons: for prosecution (where the investigative effort is complete and we believe the crime is capable of being proved); and for further investigation in conjunction with the Justice Department.

In the latter situation—"referrals for further investigation"—the scope of the ultimate prosecution, and even the identity of defendants, may well not be known. The purpose of the referral is to facilitate further development of the case rather than to incorporate final Agency decisions on the viability or advisability of a prosecution. As such, it can and often does occur at an early stage in the case development process.

In these situations, the task of creating a complete referral package is difficult—in light of the fact that the case has not yet been completely developed. It is also time consuming, and thus can prejudice the investigation. The time spent in attempting to prepare a complete referral package, and in processing the package through the Regional and the Headquarters review system, can cause delays in the development of the case while not providing the countervailing benefits normally realized in the referral process, i.e. close scrutiny of the evidence prior to filing or a final assessment of the merits of criminal prosecution.

**Referral Procedure for Criminal Cases**

-2-

To eliminate this inefficiency, and provide for the more natural development of criminal cases, a shortened referral package will be used where the purpose of the referral is for further investigation in conjunction with the Justice Department, rather than to incorporate a complete investigative package. (The format appears as Attachment A.)

This package will provide a basis on which to make the best possible assessment both at the Regional level and at EPA Headquarters on the merits of the potential case. At the same time, it will provide a vehicle for the more rapid transmission of our investigative work product to prosecutors with the Justice Department, who will then become part of the criminal case development team.

The modified referral package will normally be prepared by the Special Agent assigned to the investigation, who will be most familiar with investigative activity to date. The package must be prepared in close coordination with Regional legal and technical personnel assigned to the investigation. As under existing procedures, the referral will be approved by both the Special-Agent-in-Charge and the Regional Counsel before transmission to EPA Headquarters for approval. Cover letters to the appropriate United States Attorney and to the Land and Natural Resources Division will be drafted at EPA Headquarters for the signature of the Associate Administrator.

Questions on this procedure should be directed to Peter Beeson (382-4543). It is our hope that these modified procedures will ensure the most efficient possible development of our criminal cases.

**Attachments**

## Referral Procedure for Criminal Cases

ATTACHMENT AMEMORANDUM

SUBJECT: Criminal Referral

FROM: Special-Agent-in-Charge \_\_\_\_\_  
Field Office  
Criminal Enforcement DivisionRegional Counsel  
Region \_\_\_\_\_THRU: Associate Enforcement Counsel  
Criminal Enforcement Division

Enforcement Counsel

TO: Associate Administrator and General Counsel

Attached for your consideration are materials assembled by this Agency in a criminal investigation against \_\_\_\_\_. It is the opinion of our offices that further development of this case should proceed in close coordination with the Justice Department. An overview of the nature of this investigation is provided below for your information. We recommend immediate referral to the (U.S. Attorney/Federal District) and to the Land and Natural Resources Division for further development.

## Referral Procedure for Criminal Cases

REFERRAL PACKAGE  
(Name of Case)  
(Name of District)

I. Identity of Subject(s) of Investigation:

Individual(s):

1. Name
2. Title
3. Age
4. Home/work address
5. Current employment
6. Criminal record, if any
7. Prior EPA enforcement action
8. Other pertinent information

Corporation(s):

1. Name and nature of business
2. Parent company
3. Subsidiaries
4. Address of facility(ies) associated with offenses
5. State of incorporation
6. Size of company
7. Prior EPA enforcement action
8. Other pertinent information

II. Nature of Activity under Investigation

1. Location and duration
2. Venue
3. Significance of Activity (A brief statement of reasons underlying the need to address the misconduct with criminal sanctions.)

**Referral Procedure for Criminal Cases**

-2-

**III. Statutory Offenses**

1. Applicable Statutes: (A summary of Federal environmental and related laws potentially violated by the activity, accompanied by pertinent citations to the United States Code and the Code of Federal Regulations)
2. Evidence Gathered to Date: (A brief summary of available evidence, accompanied by copies of selected investigative reports prepared within the Criminal Enforcement Division that reflect this evidence (for example, surveillance reports or interview summaries.)

**IV. Personnel Assigned**

1. Special Agent
2. Regional Attorney
3. Technical Staff

	Page
VI. Legal Issues .....	
VII. Environmental Impact .....	
VIII. Recommendation .....	
Appendix A. List of Witnesses.....	
Appendix B. List of Exhibits .....	
Appendix C. Exhibits .....	

A discussion of each individual section follows.

### Body of the Report

Section I—Introduction. The introduction will provide a synopsis of the investigation to orient the reader. It should be brief. A detailed discussion of the evidence will be provided in a subsequent section of the report.

Within the introduction, the following areas should be addressed:

- The identity of the corporate and individual subject(s) of the investigation;
- A brief description of the nature and duration of the criminal activity under investigation;
- Venue (i.e., the Federal district(s) in which the offense occurred). If venue lies in more than one district, an explanation should be included for the Region's choice of one Federal district over another for referral; and
- The regional recommendation underlying the referral.

Section II—Statutory Authority. This section should include the statutory provisions that provide the basis for the referral. Pertinent portions of each statute should be quoted in full, followed by a listing of the elements of each offense that must be provided in a subsequent prosecution.

Section III—Subjects of the Investigation. This section will be used to provide pertinent background data on the subjects of the referral. For each individual subject, the following minimum information should be included:

- Name and title;
- Approximate age;
- Home and work addresses;
- Nature of current employment; and
- Criminal record, if known.



For each corporate subject, include:

- Name of company and parent corporation, if appropriate;
- Complete address of company;
- Complete address of facility associated with offenses;
- State of incorporation of corporate subjects;
- Registered agent for service; and
- A brief statement of the business, profits, and size of the company.

Section IV—Enforcement and Regulatory History. This section should include a description of all known enforcement activity (State and Federal) relating to environmental matters taken against the subject in the past. In addition, any previous efforts by EPA to remedy the present problem through informal, administrative, or civil means should be discussed.\*

Finally, if the Region is recommending that the criminal referral be pursued simultaneously with a parallel civil/regulatory proceeding against the subject(s), this fact should be highlighted. The steps taken in the Region to ensure proper coordination and separation of the parallel proceedings should also be described.

Section V—Description of the Evidence. This section will constitute the major portion of the report. Its function is to present the results of the Region's investigative activity and to demonstrate how the criminal conduct uncovered in that investigation will be proved at trial.

Background. There is no one proper way to present the evidence. Any method that is clear and organized is acceptable. A chronological approach is recommended, however, both because it is simple to follow and because prosecutors often present their evidence before the grand jury and at trial within a chronological framework.

Regardless of the organization chosen, all substantial facts detailed in this section should be supported by some item of evidence—a witness interview, a letter from EPA correspondence files, an NPDES permit, results from a compliance inspection, technical analysis of a

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\* Care should be taken while writing this report to avoid duplication.

If facts relating to past regulatory or enforcement activity are discussed in subsequent sections (e.g., as evidence of a "willfull" or "knowing" violation), only a brief summary should be included in this section.

pollutant sample, a photograph, etc. Copies of these items of evidence should be included, in turn, as exhibits to the litigation report, for easy reference by the reviewing personnel at EPA Headquarters, the Justice Department and the United States Attorneys Office.\* The existence of evidentiary support for the factual allegations contained in the referral is crucial. The end goal of the referral process is a successful prosecution. The question is not, ultimately, what happened but whether it can be proved at trial.

Required Information. In completing Section V, the following items should be included (although not necessarily in separate portions of the section):

- A detailed review of all facts constituting the alleged criminal behavior. Speculation should be avoided. If the evidence currently available does not support one or more elements of the offense(s) under investigation, this should be highlighted, since this will assist in focusing future investigation by grand jury or otherwise;
- Any statements by the subject(s) of the investigation pertaining to the subject matter of the investigation. Written, as well as oral, statements should be included;
- Evidence indicating willful or knowing behavior by the investigative targets;

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\* The following paragraph is an example of the chronological presentation of evidence supported by exhibits:

On May 1, an NPDES permit was issued to Company X that contained the following provisions...(see Exhibit 1, NPDES permit). On May 5, the plant's waste treatment system ceased operation. (See Exhibit 2, Interview Report of Informant A.) At that time, Company X faced several imminent production deadlines. (See Exhibit 3, Sales Contract Between Company X and Company Y.) Production continued, resulting in the discharge of raw sewage between May 5 and July 5. (See Exhibit 4, Analytical Reports Provided by Former Chemist of Company X.) Discharge monitoring reports submitted by Company X for this period nevertheless falsely reported compliance. (See Exhibit 5, Company X DMRs.) Moreover, in response to an EPA inquiry, Company X reported the successful operation of its waste treatment system on July 1, almost two months after the breakdown. (See Exhibit 6, Letter, Company X to EPA.)

- Any facts that bear on the reliability of the available evidence. This might include, for example, equipment breakdowns during technical sampling, or prior inconsistent statements of a government witness. Ultimate conclusions should not be made on the reliability of a particular witness or piece of evidence in the report; rather, simply include all facts relevant in assessing the reliability; and
- A complete chronology of contacts between EPA and the subject(s) concerning the environmental problem underlying the referral.

Section VI—Legal Issues. In preparing a case for trial, the Justice Department's prosecutor will want to consider both the weaknesses in the government's case and the affirmative defenses available to the defendants. In completing this portion of the referral package, consider:

- Legal Defenses. This might include, for example, arguments that a discharge of pollution was not into a navigable water for the United States and therefore not regulated under the Clean Water Act; or that dumping activity did not involve a "hazardous waste" identified or listed under the Resource Conservation and Recovery Act.
- Evidentiary Challenges. This might include, for example, challenges to the methods used to obtain evidence, or to the government's ability to authenticate evidence due to a break in the chain of custody.
- Equitable Defenses. This might include, for example, EPA's vacillation of regulatory standards, the cost of compliance, labor difficulties at the facility, etc.

In completing this section, speculation should be avoided. Potential defenses should not be included unless there is some basis for their assertion under the facts of the case.

Section VII—Environmental Impact. This section should provide an assessment of the significance of the environmental harm or human health hazard resulting from the conduct under investigation.

Precise statements in this area are not essential elements of most criminal offenses and will often be difficult to support scientifically. When the investigation focuses on historical rather than ongoing conduct, or involves falsified technical documents, the task becomes even more difficult. Normally, however, an educated estimate—based on the type of pollutant involved, the location, and normal operating capacity of the facility—can be made. Where this is possible, the information will provide one significant basis for assessing the gravity of the misconduct.

**Section VIII—Recommendation.** The report should conclude with a specific recommendation for the appropriate future course of the case. Normally, one of two recommendations will be made:

- **Further Investigation.** Where the use of an investigative grand jury is contemplated (for example when witnesses are not talking and compulsory process is required), the referral will recommend further investigation. In this situation, an additional recommendation for prosecution may or may not be appropriate. If the evidence in hand provides an adequate basis on which to base such a judgment, a recommendation for prosecution under specific statutory provisions should be included. If the available evidence is not sufficient, a prosecutorial recommendation should be withheld pending completion of the grand jury work and consideration of the results.
- **Prosecution.** If the field investigation is complete, the conduct has been documented, and grand jury work is required—if at all—only to present the evidence and secure an indictment, the referral should include a recommendation for prosecution under specific statutory provisions.

Following the specific recommendation, the report should include the best available projection of resources necessary to bring the case to resolution. This projection should discuss investigative, technical, and legal resources and should indicate the Regional Office's ability to provide these resources.

**Appendix A—List of Witnesses.** This section is particularly useful to prosecutors supervising the case and will frequently be used in issuing subpoenas, planning a grand jury presentation, and estimating the scope of the prosecution. For each witness, the writer should provide all available background data (e.g., name, residence, work address, telephone numbers, etc.) and a brief summary (one paragraph) of the matters on which testimony is anticipated. This section should include not only the key substantive witnesses, but also those who will establish the appropriate foundation for documentary or physical evidence (e.g., photographers, chain of custody witnesses, record custodians, etc.). Confidential informants should not be identified in this list.

**Appendices B and C—List of Exhibits and Exhibits.** Copies of every substantial piece of documentary evidence in the case should be included as an exhibit to the report\* and should be indexed to allow

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\* Exceptions will be made if the exhibit is too bulky or otherwise inappropriate for inclusion in the report. Pollution samples, for example, will remain with the regional offices; however, copies of reports reflecting their analysis should be included where possible.

for easy reference in the main body of the report. Original exhibits or documents should not be included in the referral package if this can be avoided. They will normally be used as evidence in trial, and should be retained in the Regional Office until other arrangements are made with the Justice Department prosecutor supervising the case.

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# Chapter Ten

## Post-Settlement Enforcement

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Enforcement of Settlement Agreements	10-1



## Post-Settlement Enforcement

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### Monitoring Settlement Agreements

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The Agency often settles an administrative civil penalty action with a violator prior to the actual hearing, thus obviating the need for costly litigation. Such settlements under FIFRA take the form of consent agreements and consent orders.

Consent agreement negotiations focus primarily on the appropriate size of the penalty to be imposed on the violator. Adjustments to the penalty are made by considering such factors as the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. However, remedial performance as a means of remitting a civil penalty assessment is generally not used in FIFRA consent agreements and consent orders.

In order to ensure continued compliance with FIFRA as well as with the terms of the consent agreement and order, the Agency performs post-settlement monitoring, which includes:

- Follow-up inspections by EPA or State personnel (depending upon whether the State has primacy or a cooperative agreement, or both) as a part of routine assignments under a neutral inspection scheme; and
- Ensuring that the violator has paid the stipulated civil penalty.

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### Enforcement of Settlement Agreements

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Collecting fines that have been imposed under the terms of a consent agreement and consent order should be followed up on a timely basis by government personnel. The procedures and policies for collection action referrals to the United States Attorneys Office are set forth in Appendix 4.



Follow-up inspections that reveal continuing violations of a settlement agreement could subject the violator to additional civil penalty actions or, in fact, subject the person(s) to possible criminal sanctions under Section 14(b) of FIFRA. (Consult Chapter Five for the level of action guidance appropriate in these situations.)

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# Chapter Eleven

## Special Considerations

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## Special Considerations

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### FIFRA Section 7 Confidential Information\*

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Under FIFRA Section 7 and its implementing regulations, persons who produce pesticides or active ingredients used in producing pesticides must register their establishment with and submit annual data to EPA. Failure to do so is a violation of Section 12(a)(2)(L). Because some of the data submitted in connection with Section 7 is confidential and may be used as part of an active enforcement case, the following section on confidentiality and disclosure of information is included in this manual.

#### Authority

Section 7(d) of FIFRA states: "Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 10."

Section 10(b) of FIFRA states: "...[T]he Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential...."

Section 12(a)(2)(D) of FIFRA makes it unlawful for any person "to use for his own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other

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\* Confidential information submitted pursuant to Section 3 of FIFRA is rarely used in case development work. If the need to use Section 3 data arises, EPA's FIFRA Confidential Business Information Security Manual should be consulted.

Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this Act which is confidential under this Act."

### Penalties

FIFRA Section 10(f) states that any officer or employee of the United States or former officer or employee of the United States who willfully discloses information subject to Section 10(b) is subject to a \$10,000 penalty, or imprisonment for not more than one year, or both. Contractors who are furnished confidential information as authorized by Section 10(e) are considered employees and are subject to these penalties.

### Document Control

Chapter 12 of the EPA Securities Manual is applicable to FIFRA privileged information and should be referenced in matters pertaining to document control. The chapter describes the policies, procedures, and responsibilities regarding physical control of privileged information received by an officer or employee of EPA under a pledge of confidence from a person, firm, partnership, corporation, or association.

### Section 7 Information

Procedures for Determining Confidentiality. Under EPA's Freedom of Information Act (FOIA) regulations in 40 C.F.R. Part 2 Subpart B, a procedure has been set up for determining whether information is confidential or nonconfidential.

Under this procedure, if information submitted to EPA has been claimed as confidential, the information may not be disclosed to the public until a determination has been made that the information is not confidential, the affected business has been given 30 days' notice of the determination, and the affected business has been given an opportunity to challenge the determination. Final FIFRA determinations are made by the Office of General Counsel. However, program offices may make initial determinations (see 40 C.F.R. §2.204). If the program office makes the determination that the information may be entitled to confidential treatment, the office must:

- Deny any FOIA request for the information;
- Write to the affected business asking it to substantiate its claim; and
- Refer the matter to the EPA legal office for a final confidentiality determination.

If the program office determines that the information in question is clearly not entitled to confidential treatment, the program office must give notice of the decision to the affected business and, after the notice period ends, disclose the information to the requestor.

Confidential Versus Nonconfidential Information. Agency determinations as to the confidential nature of Section 7 data are as follows:

- Confidential Information. Information submitted to the Agency by a producer operating an establishment and deemed confidential under Section 7 includes the amounts of a pesticide, or if applicable, active ingredients used in producing pesticides that:
  - Are currently being produced,
  - Were produced during the past year, and
  - Were sold or distributed during the past year.
- Nonconfidential Information. Information submitted to the Agency by a producer operating an establishment and deemed nonconfidential under Section 7 includes the names of the pesticides or active ingredients used in producing pesticides sold or distributed at an establishment. In addition, the following Section 7 information is available on pesticide labels (which are available to the public) and, at the discretion of PTSCMS, is not considered confidential:
  - The establishment name, number, and address, and
  - For each pesticide or active ingredient used in producing pesticides, the product number (if any), the product classification (if known), the market the product was produced for (if known), and the use classification (if known).

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#### Disclosure of Confidential Information

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EPA may disclose FIFRA confidential information under specific circumstances and to specified persons. Among these disclosures are disclosures to Congress or the Comptroller General [40 C.F.R. §2.209(b)]; disclosures to other Federal agencies [40 C.F.R. §2.209(c)]; disclosures to Federal courts [40 C.F.R. §2.209(d)]; disclosures to physicians, pharmacists, health officials, etc. when necessary to treat illness or injury or to prevent imminent harm to health, property, or the environment [40 C.F.R. §2.307(h)(2)]; and disclosures to contractors [40 C.F.R. §2.307(h)(3)].

The Associate General Counsel has ruled that EPA may not disclose to States (or their employees or representatives) confidential information obtained by EPA pursuant to Section 7(c) of FIFRA.



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# Appendices

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# 1 Neutral Administrative Inspection Scheme

The following appendix outlines example criteria that may be applied by EPA Headquarters and Regional Offices (in cooperation with those States that have EPA Enforcement Grants) in selecting an activity for a programmed inspection. Other acceptable criteria may be used in lieu of those examples listed below. "For cause" or unprogrammed inspections, however, are not subject to neutral inspection scheme requirements. (See Glossary for definitions of programmed and unprogrammed inspections.)

All programmed inspections are conducted within the guidelines and priorities set forth in the Pesticides and Toxic Substances Enforcement Division's FIFRA Inspection Manual.

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## Producer Establishments

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~~Producer establishments are inspected at least once every two years.~~  
However, where violations of the Act have been observed during a programmed inspection, a follow-up inspection is to take place within six months after the programmed inspection. These follow-up inspections continue at six-month intervals until the violations have ceased.

Each Regional Office should have the following lists for each State under its jurisdiction:

- ~~Category I—a list of those producer establishments that have been inspected during the past two years;~~
- Category II—a list of those producer establishments that have not been inspected during the past two years; and
- Category III—a list of those producer establishments that have been inspected and where violations of the Act have been found.

Each list contains both the name and EPA establishment number of the producer. Producer establishments in Categories I and II are arranged according to the numerical sequence of their establishment numbers. Selection of an establishment for inspection is based upon the sequence contained in the Category II list.

When a Category II establishment is inspected and found in compliance, it is placed on the Category I list in numerical sequence according to its establishment number. However, a Category II establishment may be scheduled for a follow-up inspection and placed on the Category III list if a programmed inspection uncovers a violation of the Act. Such a follow-up inspection is to take place within six months after the programmed inspection. Follow-up inspections may continue at six-month intervals until no further violations are found. Once found in compliance with the Act, the Category III establishment is placed on the appropriate Category I list. Placement of an establishment on the Category I list, however, does not preclude the Agency from conducting a subsequent unprogrammed inspection of that establishment under the provisions of the warrants section, FIFRA §9(b), when a violation of the Act is later suspected.

Ordinarily, the scheduling of inspections is carried out in accordance with the numerical scheme of the Category II list. Nonetheless, in recognition of the need to efficiently utilize Regional Office resources, the following adjustment factors may be employed to modify the selection:

- Location of the establishment. For example, two establishments located in the same geographic area may be inspected at the same time despite their numerical position in the Category II list so long as one of the establishments has been scheduled according to the numerical scheme;
- Seasonal nature of operations at the establishment;
- Size of the establishment, number of employees, and probable length of time required for inspection. For example, if only two days are available to conduct a programmed inspection, then an inspection requiring more than two days should not be scheduled at that time; and
- Specific special circumstances. For example, inspection of a plant that is not operating normally because of a strike, should not be scheduled at that time.

Any Category II establishment that is not scheduled for inspection because of the application of an adjustment factor retains the same priority on the list that it would have had but for the adjustment.

The above adjustment factors are designed to promote the most efficient use of compliance personnel and resources and may affect the scheduling of an establishment inspection at any step in the selection process.

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**Marketplace Inspections**

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It is the Agency's intention to conduct a regular inspection at each marketplace establishment at least once every four years. However, where violations of the Act have been found during a programmed inspection, a follow-up inspection is to take place within six months of the programmed inspection. Follow-up inspections continue at six-month intervals until the violations have ceased.

Each Regional Office should have the following lists for each State under its jurisdiction:

- Category I—a list of those marketplace establishments that have been inspected during the past four years; and
- Category II—a list of those marketplace establishments that have been inspected during the past four years and where violations of the Act (which were the responsibility of the establishment) were found.

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**Restricted Use Pesticides**

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It is EPA's intention to conduct an inspection at least once every two years at each pesticide dealer establishment where restricted use pesticides are sold. However, where violations of the Act have been found during a programmed inspection, a follow-up inspection is to take place within six months of the programmed inspection. Follow-up inspections continue at six-month intervals until the violations have ceased.

Each Regional Office should have the following lists for each State under its jurisdiction:

- Category I—a list of those dealer establishments that sell restricted use pesticides and that have been inspected during the past two years; and
- Category II\*—a list of those dealer establishments that have been inspected during the past two years and where violations of State or Federal pesticide laws have been found.

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\* The initial Category II list should also indicate whether any follow-up inspections were conducted, the date(s) of any such follow-up inspection(s), and whether or not any further violations were found.

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**Experimental Use Permit**

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The Regional Office is responsible, on a selected basis, for supervision of the experimental uses conducted within its Region. Supervision is for the purposes of observing and reporting whether the terms and conditions of the permit are being met and to determine whether the terms and conditions are adequate to avoid unreasonable adverse effects on the environment.

Each Regional Office should establish its own supervision schedule based on the following list of priorities:

- Permits for pesticides that are completely new classes of compounds (e.g., juvenile hormones);
- Permits for chemicals with special potential hazard to man or the environment, such as:
  - Highly toxic products,
  - Products with a propensity to drift,
  - Products with high terrestrial or aquatic mobility, and
  - Products of a particularly persistent nature;
- Permits for chemicals with previously registered uses that were subject to adverse action on the Agency's part;
- Permits for those companies that have a history of noncompliance, inadequate supervision, or other indications of an uncooperative attitude;
- Permits for those chemicals that may ultimately have a widespread major use (e.g., chemicals that will replace a major pesticide that has been cancelled by the Agency); and
- Any other permits for which the Registration Division requests special information.

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**Books and Records Inspections**

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As a practical matter, the books and records inspection program should be an integral part of the establishment inspection program. Books and records should be examined whenever a producer establishment inspection is made; but, such an examination should not be limited to only those inspections. For instance, books and records inspections may be made upon a specific request for certain information, or as a follow-up to an Agency stop sale, use, or removal order.

## 2 Notices of Judgment

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### Authority

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Under Section 16(d) of FIFRA, the Administrator of EPA is required to give notice by publication of all judgments entered in actions instituted under the Act. The purpose of this publication is to make available to the public the results of court decisions and civil penalty proceedings involving pesticidal products and devices. A notice of judgment contains the following information:

- Responsible party;
- Specific violations;
- Dates and nature of the legal action; and
- Penalty imposed for the violation.

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### Agency Policy

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The Agency publishes a notice of judgment for each seizure, criminal prosecution, and civil complaint action completed. A notice of judgment will not be published in the following instances:

- Seizures. When no product is available for seizure;
- Criminal Cases. When cases are declined for prosecution by the U.S. Attorney; and
- Civil Complaints. When civil complaints are withdrawn by the Agency before the respondent files an answer.

In civil penalty cases involving a hearing before an Administrative Law Judge, the entire initial decision will be published in the notice of judgment.

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## Responsibility

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The Assistant Administrator for Pesticides and Toxic Substances has been delegated, by the Administrator, the authority to give notice by publication of all judgments entered in actions instituted. Within the Office of Pesticides and Toxic Substances, PTSCMS is responsible for preparing the notices of judgment.

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## Procedures

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### Regional Office

Each EPA Region will maintain a record of all seizure and criminal referral actions and all civil penalty complaints issued. Each case will be reviewed after its conclusion to determine whether all necessary information is present in the file. Once an action has been completed, the Region will prepare a draft notice of judgment and forward it to the Headquarters Case Development Officer (HQCDO). To ensure completeness and uniformity of reporting, information for notices of judgment should be submitted in the format shown in Exhibits A-1, A-2, and A-3, as appropriate.

The draft notices must be complete, accurate, and legible to avoid any misinterpretation of spelling, citations, etc. The proper and complete name of the firm and product involved must be used. Because of the wide distribution of notices of judgment, including some to the respondents and defendants, it is important that the information reported for inclusion in the publications be factual.

The statutory references and charges to be included for publication in a notice of judgment include all the charges made in the indictment or civil complaint. If any of those charges are dismissed, withdrawn, or dropped, the information should be included in the concluding paragraph of the notice that summarizes the final results of the action. The Regions will promptly inform the appropriate HQCDO of the termination of each seizure, criminal action, and civil proceeding. It is important that information be furnished on each case to which an I.F.&R. Docket Number has been assigned. If the case is withdrawn before the answer is filed, a negative report should be submitted to account for all I.F.&R. Docket Numbers.

### PTSCMS

The HQCDO will review the draft notices of judgment submitted by the Regions for completeness and accuracy. Notices of judgment will be printed at reasonable intervals, in groups of 50 or more.

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**Distribution**

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Distribution of notices of judgment will be made by PTSCMS, who regularly compile a mailing list of recipients of the notices. Such recipients include libraries, universities, civic groups, pesticide producers, and private citizens. Other distribution may be made by special request.



## Notice of Judgment After Seizure

United States of America v. 40 one-gallon jugs,  
(Amount)

more or less, of a product labeled in part "HELENA BRAND PRO-LIN  
WEED KILLER".

U.S. District Court, District of New Mexico, November 29, 1972.  
(Judicial District) (Date of Final Decree)

(I.F.&R. No. VI-17 I.D. No(s). 90829.)

This was a seizure action charging the product with being in violation of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.

§136k(b)  
(Statutory References)

The action pertained to (complete a. or b.)

a. A shipment(s) made

on May 2, 1972,  
by Helena Chemical Company,  
from Lubbock, Texas,  
to Dexter, New Mexico.

b. A product(s) held for distribution or sale

on \_\_\_\_\_,  
(Date of Inspection)  
at \_\_\_\_\_,  
(Name of Producer Establishment)  
\_\_\_\_\_  
(City and State)

Charges included nonregistration.

(Type of Final Decree and Disposition of Product)

The Judgment Decree of Condemnation ordered destruction of the product.

## Notice of Judgment of Criminal Proceeding

United States v. Sterling Drug, Inc.,  
(Name of Defendant)

U.S. District Court, Northern District of Ohio,  
(Judicial District)

Criminal No. CR 73-135, July 26, 1974.  
(Date of Final Decision)

(I.F.&R. No. 1363, I.D. No(s). 72760, 73184, 73706, & 78835.)

This was a criminal action prepared by EPA Region V charging the defendant in a(n) five count information (indictment) with violating the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§136j(a)(1)(B); 136j(a)(1)(E); 136(q)(1)(A); and 136(q)(1)(G)

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(Statutory References)

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The action pertained to (complete a. or b.)

a. A shipment(s) made

on October 2 and 25, 1968; December 16, 1968; and July 21, 1969,  
from Toledo, Ohio,  
to Buffalo, New York; Pocatello, Idaho; Omaha, Nebraska; and  
Vancouver, Washington.

b. A product(s) held for distribution or sale

on \_\_\_\_\_,  
(Date of Inspection)

at \_\_\_\_\_,  
(Name of Producer Establishment)

\_\_\_\_\_  
(City and State)

The pesticide(s) involved was(were) ROCALL BRAND SANITIZING AGENT and BARRAGE CONCENTRATED BOWL CLEANSER; charges include: claims differed from those made in connection with registration, and misbranding—product was not effective when used as directed—and lack of adequate warning statements on labels.

The defendant entered plea of nolo contendere to counts 1 and 2.  
(Give plea and list all counts.) The remaining counts were dismissed.

A fine of \$ 500.00 was levied.  
(Give explanation of decision.)

## Notice of Judgment of Civil Penalty Proceeding

In Re: Steelcote Manufacturing Company,  
(Name of Respondent)

EPA Region VII, September 3, 1974.  
(Date of Final Order)

(I.F.&R. No. VII-46C, I.D. No(s). 91563.)

This was a civil action charging the respondent with violating the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. \_\_\_\_\_

§§136j(a)(1)(E); 136(q)(1)(A); 136(q)(1)(F); 136(q)(1)(G); and

136(q)(2)(C)(iv)

(Statutory References)

The action pertained to (complete a. or b.)

a. A shipment(s) made

on \_\_\_\_\_,

from \_\_\_\_\_,

to \_\_\_\_\_,

b. A product(s) held for distribution or sale

on September 7, 1973,  
(Date of Inspection)

at Steelcote Manufacturing Company,  
(Name of Producer Establishment)

St. Louis, Missouri.  
(City and State)

The pesticide(s) involved was(were) DAMP-TEX A & A SEALER;

charges include: lack of adequate warning or caution statement on labels, lack of adequate directions for use on labels, lack of assigned registration number on labels, and labels bore false or misleading safety claims.

(Complete summary of final results including hearing, default, accelerated decision, consent agreement, final order, and amount of assessment. If withdrawn after answer, explain.)

The respondent signed a consent agreement. The final order assessed a civil penalty of \$1,200.

### 3 Sample Record Status and Permanent Abeyance Procedures

The purpose of this section is to set forth guidelines for placing sample records in different categories of activity. It also gives guidance on retiring inactive records.

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#### Sample Record Status

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For record management purposes, sample record cases are placed in the following categories:

- Active. A sample record file is considered active throughout the testing and review period until it is officially determined in writing that no enforcement action is indicated or until all enforcement actions and correspondence have been concluded.
- Abeyance. After it has been determined that no enforcement action is indicated or after all enforcement actions and correspondence have been concluded, but the file needs to be retained for reference, the sample record is considered to be in abeyance status.
- Permanent Abeyance (PA). When correspondence is no longer being carried on with the firm, no further action is expected or possible, and the case is closed, the case is placed in permanent abeyance. In the instance of notice of warning letters, if no reply from the firm is received within 90 days, the sample record should be removed from active status and permanent abeyance procedures initiated.

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Permanent Abeyance (PA) Procedures

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Types of PA

PA Without Action. Refers to placing a sample record in permanent abeyance because the sample is chemically and biologically satisfactory and meets all the labeling requirements of the Act.

PA With Action. Refers to placing a sample record in permanent abeyance after the enforcement action has been concluded.

PA Procedure

PA Without Action. If examination of the sample record reveals that no enforcement action is warranted:

- Mark "PA" and the date on the face of the sample record jacket; and
- On a monthly basis, the Regional Offices will notify the appropriate laboratories of the sample(s) that was(were) placed into permanent abeyance. THIS IS IMPORTANT—It notifies the respective laboratories that the file has been closed and that the sample can be disposed of in accordance with the appropriate disposal method.

PA With Action. When it is determined that no further action is necessary after an enforcement action and subsequent follow-up, then follow the above steps under "PA Without Action."

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Records Retirement and Retrieval

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The EPA records disposition program is designed to provide for the regular removal from valuable office space of all records and nonrecord materials no longer essential for current operations, and for the systematic release of filing equipment for reuse. At regular intervals PA sample records should be transferred to the appropriate Federal records center.

## 4 Collection of Civil Penalty Assessments

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### Authority

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Upon nonpayment of a civil penalty within the prescribed time periods, ~~Section 14(a)(5) of the Act specifies that the matter be referred to the~~ Attorney General for collection: "In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court."

However, before any referral to the Attorney General, the Agency must satisfy the directives and standards for collection set forth in the Federal Claims Collection Act (31 U.S.C. §§951-953) and the Federal Claims Collection Standards (FCCS, 4 C.F.R. §§101-105 Exhibit A-4).

~~In general, the procedures in the FCCS are mandatory, but the failure of the Agency to comply with any provision of the standards will not be~~ available as a defense to any party in a subsequent action for collection.

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### Policy

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~~Under the FCCS, the Agency is held to a policy standard of aggressive collection action, on a timely basis, and with effective follow-up of all civil penalty assessments.~~

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### Collection Procedures

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#### Written Demands for Payment

The FCCS requires that the Agency make three written demands, at 30-day intervals, on the respondent in terms that inform the debtor of the consequences of failing to cooperate.

The Agency's policy is to initiate the written demands concurrent with the issuance of a final order so that the third and final demand will be made on the same day the payment period elapses (i.e., 60 days after issuance of a final order).

Upon the Issuance of the Final Order. At the time that a final order is issued and served on the respondent, he or she should receive a written demand for any payment of such penalty and the length of time in which he or she has to pay it. Such notice should also inform the respondent of the consequences of failing to cooperate.

Thirty Days After Issuance of the Final Order. After 30 days have elapsed, even though the payment period has not expired, the Agency will again serve on the respondent a demand for the payment and again warn the respondent of the consequences of failing to pay (Exhibit A-5). Given the possibility that the payment may be in the mail when this second warning is sent, the Agency should also make a brief apologetic statement informing respondent to disregard the warning if the payment has been sent.

Sixty Days After the Issuance of the Final Order. The respondent must pay the civil penalty 60 days after the service of a final order unless a motion to reconsider has been made or judicial review of the final order has been sought. Subject to those two exceptions, if payment of the penalty has not been tendered at the end of the 60-day period, the Agency will send a final demand to the respondent for payment of the delinquent civil penalty assessment. This letter should be written to inform the respondent that unless payment is tendered within 15 days, the penalty will be referred to the United States Department of Justice or the United States Attorneys Office for collection in a district court. The letter should state that such action is routinely accomplished through a motion for summary judgment in favor of the United States and that the respondent will be barred from raising any issues as to fact or law that should have been raised in the administrative proceeding (Exhibit A-6).

#### Follow-up to Final Demand for Payment

Section 102.6 of the FCCS dictates that the Agency undertake personal interviews with the debtors when it is feasible, having regard for the amounts involved and the proximity of Agency representatives to such debtors.

It is PTSCMS policy to arrange personal interviews if it is feasible and convenient for the regional officials involved in the case. In the absence of a personal interview, the Regional Office should at least establish telephone contact with the respondent to urge prompt payment of the claim and to personally warn the respondent of the consequences of failing to pay the penalty.

Good faith inability to arrange a personal interview or to establish telephone contact with the respondent should not deter the Regional Office from referring claims to the United States Attorneys Office for collection.

Documentation of Collection Efforts

The Agency should record and maintain a file of all collection efforts and activities prior to referral.

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Types and Methods of Payment

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Full Payment

The most preferable method of collection is a check for the full amount owed, payable to the United States of America. Such payment should be delivered to the Regional Hearing Clerk for the Region in which the final order was issued.

Collection Installments

Section 102.10 of the FCCS provides for installment payments. This type of payment should be used when the respondent has demonstrated and documented an inability to pay the penalty in a lump sum.

In that Section 14(a)(4) of FIFRA requires a consideration of ability to continue in business in assessing the penalty, this installment provision should rarely be needed as the issue will have been previously resolved.

In the event that installment payments are justified and allowed, such payments shall:

- Be on a regular basis;
- Bear a reasonable relation to the size of the debt and the debtor's ability to pay;
- Be sufficient in size and frequency to liquidate the claim in not more than three years; and
- Be no less than \$10 except under the most unusual circumstances.

In allowing a respondent to pay by installment, the regional attorney should attempt to obtain an executed confess-judgment note, comparable to the Department of Justice Form USA-70a.

The Agency may accept installment payments notwithstanding the refusal of the respondent to execute a confess-judgment note.

Compromise of the Penalty

The FCCS provide for compromising claims when it can be assured that the respondent's financial ability will not permit payment of the claim in full



or when the litigative risks or the costs of litigation dictate such action.

It is the express policy of PTSCMS that penalty assessments in final orders shall not be subject to compromise except under the most unusual circumstances. For the most part, FIFRA requires that ability to pay be considered before a civil penalty is imposed; therefore, the inability to pay the penalty should not be an issue in the post-final order stage of the civil penalty proceeding. However, inability to pay should be considered where:

- The civil penalty was assessed by default, so that the respondent's ability to pay was never confirmed by the respondent in determining the amount of the penalty; or
- The respondent's financial condition has deteriorated dramatically since the time the penalty was assessed. The Agency should be alert to the possibility that assets have been fraudulently concealed or improperly transferred. The burden falls upon the respondent to affirmatively demonstrate and document any such inability.

Section 103.5 of the FCCS provides that, where an enforcement policy is concerned, a penalty should only be compromised if the sum to be agreed upon will adequately serve the Agency's enforcement policy in terms of deterrence and securing compliance.

For this reason, and for the reason that a respondent usually has already had an opportunity for settlement, the compromise provision should be rarely exercised.

In the event such a compromise is effected, it must be authorized by the Regional Administrator for it has the effect of altering the final order.

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### Suspension or Termination of Collection Activity

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#### Suspension

The Agency may temporarily suspend collection action for payment of a penalty when the respondent cannot be located after a diligent search and/or when future collection prospects seem more promising than present actions.

Section 104.2 of the FCCS provides a partial listing of sources that may be helpful in locating missing respondents. Efforts should be made to avoid any applicable statute of limitations.

### Termination

Collection action may be terminated and the Agency's file on the penalty closed under the following conditions:

- Inability to collect any substantial amount;
- Inability to locate debtor;
- Cost will exceed recovery;
- Claim legally is without merit; or
- Claim cannot be substantiated by evidence.

Section 104.3 of the FCCS provides further information on termination of claims.

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## Referrals Procedures

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### General

Claims on which aggressive collection action has been taken and that cannot be compromised will be referred to the Department of Justice or the United States Attorneys Office. Such referrals should be made as early as possible consistent with the aggressive Agency collection action and the standards for collection set forth in the FCCS.

### Referral Parties and Minimum Amounts

Department of Justice. All penalty assessments in the amount of \$10,000 or greater should be referred to the Department of Justice.

United States Attorneys Office. All penalty claims in amounts less than \$10,000 should be referred to the appropriate United States Attorneys Office.

When referring a claim of less than \$600 for collection, the Regional Office must emphasize to the U.S. Attorney that the referral is important to a significant enforcement policy.

### Procedures for a Proper Referral

~~The regional attorney should prepare the Claims Collection Litigation Report (CCLR) for the U.S. Attorney consistent with the form and instructions in Exhibit A-7.~~

## CHAPTER II—FEDERAL CLAIMS COLLECTION STANDARDS (GENERAL ACCOUNTING OFFICE—DEPARTMENT OF JUSTICE)

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## § 101.1

## Title 4—Accounts

## PART 101—SCOPE OF STANDARDS

## Sec.

101.1 Prescription of standards.

101.2 Omissions not a defense.

101.3 Fraud, antitrust, and tax claims excluded.

101.4 Compromise, waiver, or disposition under other statutes not precluded.

101.5 Conversion claims.

101.6 Subdivision of claims not authorized.

101.7 Required administrative proceedings.

101.8 Referral for litigation.

AUTHORITY: Sec. 2, 80 Stat. 309; 31 U.S.C. 962.

SOURCE: 31 FR 13381, Oct. 15, 1966, unless otherwise noted.

## § 101.1 Prescription of standards.

The regulations in this chapter, issued jointly by the Comptroller General of the United States and the Attorney General of the United States under section 3 of the Federal Claims Collection Act of 1966, 80 Stat. 309, prescribe standards for the administrative collection, compromise, termination of agency collection, and the referral to the General Accounting Office, and to the Department of Justice for litigation, of civil claims by the Federal Government for money or property. Additional guidance is contained in Title 4 of the General Accounting Office Manual for Guidance of Federal Agencies. Regulations prescribed by the head of an agency pursuant to section 3 of the Federal Claims Collection Act of 1966 will be reviewed by the General Accounting Office as a part of its audit of the agency's activities.

[44 FR 22701, Apr. 17, 1979]

## § 101.2 Omissions not a defense.

The standards set forth in this chapter shall apply to the administrative handling of civil claims of the Federal Government for money or property but the failure of an agency to comply with any provision of this chapter shall not be available as a defense to any debtor.

## § 101.3 Fraud, antitrust, and tax claims excluded.

The standards set forth in this chapter do not apply to the handling of any claim as to which there is an indi-

cation of fraud, the presentation of a false claim, or misrepresentation on the part of the debtor or any other party having an interest in the claim, or to any claim based in whole or in part on conduct in violation of the antitrust laws. Only the Department of Justice has authority to compromise or terminate collection action on such claims. However, matters submitted to the Department of Justice for consideration without compliance with the regulations in this chapter because there is an indication of fraud, the presentation of a false claim, or misrepresentation on the part of the debtor or any other party having an interest in the claim, may be returned to the agency forwarding them for further handling in accordance with the regulations in this chapter if it is determined that action based upon the alleged fraud, false claim, or misrepresentation is not warranted. Tax claims, as to which differing exemptions, administrative consideration, enforcement considerations, and statutes apply, are also excluded from the coverage of this chapter.

## § 101.4 Compromise, waiver, or disposition under other statutes not precluded.

Nothing contained in this chapter is intended to preclude agency disposition of any claim under statutes other than the Federal Claims Collection Act of 1966, 80 Stat. 308, providing for the compromise, termination of collection action, or waiver in whole or in part of such a claim. See, e.g., "The Federal Medical Care Recovery Act," 38 Stat. 593, 42 U.S.C. 2651, et seq., and applicable regulations, 28 CFR 43.1, et seq. The standards set forth in this chapter should be followed in the disposition of civil claims by the Federal Government by compromise or termination of collection action (other than by waiver pursuant to statutory authority) under statutes other than the Federal Claims Collection Act of 1966, 80 Stat. 308, to the extent such other statutes or authorized regulations issued pursuant thereto do not establish standards governing such matters.

**Chapter II—Federal Claims Collection Standards****§ 102.2****§ 101.5 Conversion claims.**

The instructions contained in this chapter are directed primarily to the recovery of money on behalf of the Government and the circumstances in which Government claims may be disposed of for less than the full amount claimed. Nothing contained in this chapter is intended, however, to deter an agency from demanding the return of specific property or from demanding, in the alternative, either the return of property or the payment of its value.

**§ 101.6 Subdivision of claims not authorized.**

A debtor's liability arising from a particular transaction or contract shall be considered as a single claim in determining whether the claim is one of less than \$20,000, exclusive of interest, for the purpose of compromise or termination of collection action. Such a claim may not be subdivided to avoid the monetary ceiling established by the Federal Claims Collection Act of 1966, 80 Stat. 308.

**§ 101.7 Required administrative proceedings.**

Nothing contained in this chapter is intended to require an agency to omit or foreclose administrative proceedings required by contract or by law.

**§ 101.8 Referral for litigation.**

As used in this chapter referral for litigation means referral to the Department of Justice for appropriate legal proceedings, unless the agency concerned has statutory authority for handling its own litigation.

**PART 102—STANDARDS FOR THE ADMINISTRATIVE COLLECTION OF CLAIMS**

**Sec.**

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**AUTHORITY:** Sec. 3, 80 Stat. 309; 31 U.S.C. 962.

**§ 102.1 Aggressive agency collection action.**

The head of an agency or his designee shall take aggressive action, on a timely basis with effective followup, to collect all claims of the United States for money or property arising out of the activities of, or referred to, his agency in accordance with the standards set forth in this chapter. However, nothing contained in this chapter is intended to require the General Accounting Office or the Department of Justice to duplicate collection actions previously undertaken by any other agency.

[31 FR 13381, Oct. 15, 1966]

**§ 102.2 Demand for payment.**

Appropriate written demands shall be made upon a debtor of the United States in terms which inform the debtor of the consequences of his failure to cooperate. In the initial notification, the debtor should be informed of the basis for the indebtedness, the applicable requirements or policies for charging interest and reporting delinquent debts to commercial credit bureaus, and the date by which the payment is to be made (date due). The date due should be specified and, normally, should be not more than 30 days from the date of the initial notification. Three progressively stronger written demands at not more than 30-day intervals will normally be made unless a response to the first or second demand indicates that further demand would be futile and the debtor's response does not require rebuttal. Further exceptions may be made where it

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is necessary to protect the Government's interests (e.g., the statute of limitations (28 U.S.C. 2415)). Agencies should respond promptly to communications from the debtor. Agencies should advise debtors who dispute the debt to furnish available evidence to support their contentions.

[44 FR 32702, Apr. 17, 1979]

## § 102.3 Collection by offset.

(a) Collections by offset will be undertaken administratively in accordance with these standards and implementing regulations established by the head of each agency on claims which are liquidated or certain in amount in every instance in which this is feasible. Collections by offset from persons receiving pay or compensation from the Federal Government shall be effected over a period not greater than the period during which such pay or compensation is to be received. See 5 U.S.C 5514.

(b) When the head of an agency, or his designee, pursuant to 5 U.S.C. 5514, 5522, 5705, 5724(f), or other statutory authority, seeks to collect a debt by offset against accrued pay, compensation, accrued benefits derived from Federal service or amount of retirement credit due to a present or former Government employee, a member of the armed forces, a Reserve of the armed forces, or a present or former employee of the U.S. Postal Service, the agency to which the debt allegedly is owed will accord such debtor an opportunity for a pre-offset oral hearing when:

(1) The debtor requests waiver of the indebtedness and the waiver determination turns on an issue of credibility or veracity or (2) when the individual requests reconsideration of the debt and the head of the agency or his designee determines that the question of the indebtedness cannot be resolved by review of the documentary evidence, for example, when the validity of the debt turns on an issue of credibility or veracity. *Provided that*, where the employment or active duty status of a debtor entitled to a hearing under paragraph (b)(1) or (b)(2) of this section terminates, and the creditor agency determines that:

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(i) Amounts accruing to the debtor upon such termination are available for offset in satisfaction of the alleged indebtedness, (ii) such amounts would not be available for offset subsequent to termination and (iii) the time prior to termination does not permit a pre-offset hearing, the agency may withhold from amounts accruing to the individual upon termination, a sum not greater than that of the alleged indebtedness and, subsequent to termination, promptly provide an opportunity for an oral hearing to resolve the issue of indebtedness or waiver. Amounts withheld but later determined not owing to the Government shall be promptly refunded.

(c) Except for debt collection systems in which determinations of indebtedness or waiver rarely involve issues of credibility or veracity, or when employment or military status is about to terminate as described in the proviso of paragraph (b) of this section, prior to collecting any indebtedness by offset the head of the agency to which the debt allegedly is owed or his designee shall provide the debtor a written demand containing the notices prescribed in § 102.2 of this part and include therein:

(1) Notice of the agency's intention to collect by offset; (2) an opportunity to request reconsideration of the debt, or if provided for by statute, waiver of the debt, and (3) an explanation of the debtor's rights pursuant to this section.

(d) Collection by offset against a judgment obtained by the debtor against the United States shall be accomplished in accordance with the Act of March 2, 1875, 18 Stat. 481, as amended, 31 U.S.C. 377.

(e) Appropriate use should be made of the cooperative efforts of other agencies in effecting collections by offset, including utilization of the Army Holdup List, and all agencies are enjoined to cooperate in this endeavor.

[46 FR 39113, July 31, 1981]

## § 102.4 Reporting delinquent debts to commercial credit bureaus.

Agencies shall develop and implement procedures for reporting delinquent debts to commercial credit bu-

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## § 102.8

reus. In the absence of a different rule prescribed by statute, contract, or regulation, a debt is considered delinquent if not paid by the date due specified in the initial notification, unless satisfactory payment arrangements are made by the date due. Agency procedures for reporting delinquent debts to credit bureaus must give due regard to compliance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a, which includes the following requirements:

(a) Promulgate a "routine use" for the disclosure; (b) keep an accounting for disclosures and make them available to the debtor; (c) provide the credit bureaus with corrections and notations of disagreement by the debtor; and (d) make reasonable efforts to assure that the information to be reported is accurate, complete, timely, and relevant. Prior to exercising the option of reporting delinquent debts to commercial credit bureaus, agencies should send a demand letter advising the debtor that such reporting will take place within a specified period of time unless the debtor makes satisfactory payment arrangements or demonstrates some basis on which the debt is legitimately disputed.

[44 FR 22702, Apr. 17, 1979]

## § 102.5 Contracting for collection services.

Agencies should consider contracting for collection services. Contracts may be entered into for this purpose when they meet the following conditions:

(a) The service must supplement, but not replace, the basic collection program of the agency; (b) the authority to resolve disputes, compromise claims, terminate collection action, and initiate legal action must be retained by the agency and; (c) the contractor shall be subject to the Privacy Act of 1974, as amended, 5 U.S.C. 552a, and, when applicable, to Federal and State laws and regulations pertaining to debt collection practices such as the Fair Debt Collection Practices Act, 15 U.S.C. 1692.

[46 FR 22353, Apr. 20, 1981]

## § 102.6 Personal interview with debtor.

Agencies will undertake personal interviews with their debtors when this is feasible, having regard for the

amounts involved and the proximity of agency representatives to such debtors.

[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

## § 102.7 Contact with debtor's employing agency.

When a debtor is employed by the Federal Government or is a member of the military establishment or the Coast Guard, and collection by offset cannot be accomplished in accordance with 5 U.S.C. 5514, the employing agency will be contacted for the purpose of arranging with the debtor for payment of the indebtedness by allotment or otherwise in accordance with section 206 of Executive Order 11222 of May 8, 1965, 3 CFR, 1965 Supp., p. 130 (30 FR 6469).

[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

## § 102.8 Suspension or revocation of license or eligibility.

Agencies seeking the collection of statutory penalties, forfeitures, or debts provided for as an enforcement aid or for compelling compliance will give serious consideration to the suspension or revocation of licenses or other privileges for any inexcusable, prolonged or repeated failure of a debtor to pay such a claim and the debtor will be so advised. Any agency making, guaranteeing, insuring, acquiring, or participating in loans will give serious consideration to suspending or disqualifying any lender, contractor, broker, borrower or other debtor from doing further business with it or engaging in programs sponsored by it if such a debtor fails to pay its debts to the Government within a reasonable time and the debtor will be so advised. The failure of any surety to honor its obligations in accordance with 6 U.S.C. 11 is to be reported to the Treasury Department at once. Notification that a surety's certificate of authority to do business with the Federal Government has been revoked or forfeited by the Treasury Department will be forwarded by that Department to all interested agencies.

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[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

**§ 102.9 Liquidation of collateral.**

Agencies holding security or collateral which may be liquidated and the proceeds applied on debts due it through the exercise of a power of sale in the security instrument or a non-judicial foreclosure should do so by such procedures if the debtor fails to pay his debt within a reasonable time after demand, unless the cost of disposing of the collateral will be disproportionate to its value or special circumstances require judicial foreclosure. Collection from other sources, including liquidation of security or collateral, is not a prerequisite to requiring payment by a surety or insurance concern unless such action is expressly required by statute or contract.

[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

**§ 102.10 Collection in installments.**

Claims, with interest in accordance with § 102.10 should be collected in full in one lump sum whenever this is possible. However, if the debtor is financially unable to pay the indebtedness in one lump sum, payment may be accepted in regular installments. The size and frequency of such installment payments should bear a reasonable relation to the size of the debt and the debtor's ability to pay. If possible the installment payments should be sufficient in size and frequency to liquidate the Government's claim in not more than 3 years. Installment payments of less than \$10 per month should be accepted in only the most unusual circumstances. An agency holding an unsecured claim for administrative collection should attempt to obtain an executed confess-judgment note, comparable to the Department of Justice form USA-70a, from a debtor when the total amount of the deferred installments will exceed \$750. Such notes may be sought when an unsecured obligation of a lesser amount is involved. Security for deferred payments, other than a confess-judgment note, may be accepted in appropriate cases. An agency may accept

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installment payments notwithstanding the refusal of a debtor to execute a confess-judgment note or to give other security, at the agency's option.

[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

**§ 102.11 Exploration of compromise.**

Agencies will attempt to effect compromises (preferably during the course of personal interviews), of claims of \$20,000 or less exclusive of interest, in accordance with the standards set forth in Part 103 of this chapter in all cases in which it can be ascertained that the debtor's financial ability will not permit payment of the claim in full, or in which the litigative risks or the costs of litigation dictate such action.

[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

**§ 102.12 Interest.**

In the absence of a different rule prescribed by statute, contract, or regulation, interest should be charged on delinquent debts and debts being paid in installments in conformity with the Treasury Fiscal Requirements Manual. When a debt is paid in installments, the installment payments will first be applied to the payment of accrued interest and then to principal, in accordance with the so-called "U.S. Rule," unless a different rule is prescribed by statute, contract, or regulation. Prejudgment interest should not be demanded or collected on civil penalty and forfeiture claims unless the statute under which the claim arises authorizes the collection of such interest. See *Rodgers v. United States*, 332 U.S. 371.

[44 FR 22702, Apr. 17, 1979. Redesignated at 46 FR 22353, Apr. 20, 1981]

**§ 102.13 Analysis of costs.**

Agency collection procedures should provide for periodic comparison of costs incurred and amounts collected. Data on costs and corresponding recovery rates for debts of different types and in various dollar ranges should be used to compare the cost ef-



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fectiveness of alternative collection techniques, establish guidelines with respect to the points at which costs of further collection efforts are likely to exceed recoveries, assist in evaluating offers in compromise, and establish minimum debt amounts below which collection efforts need not be taken. Cost and recovery data should also be useful in justifying adequate resources for an effective collection program.

[44 FR 22702, Apr. 17, 1979. Redesignated at 46 FR 22353, Apr. 20, 1981]

## § 102.14 Documentation of administrative collection action.

All administrative collection action should be documented and the bases for compromise, or for termination or suspension of collection action, should be set out in detail. Such documentation should be retained in the appropriate claims file.

[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

## § 102.15 Automation.

Agencies should automate their debt collection operations to the extent it is cost effective and feasible.

[44 FR 22702, Apr. 17, 1979. Redesignated at 46 FR 22353, Apr. 20, 1981]

## § 102.16 Prevention of overpayments, delinquencies, and defaults.

Agencies should establish procedures to identify the causes of overpayments, delinquencies, and defaults and the corrective actions needed. One action that should be considered is the reporting of debts or loans, when first established, to commercial credit bureaus.

[44 FR 22702, Apr. 17, 1979. Redesignated at 46 FR 22353, Apr. 20, 1981]

## § 102.17 Additional administrative collection action.

Nothing contained in this chapter is intended to preclude the utilization of any other administrative remedy which may be available.

[31 FR 13381, Oct. 15, 1966. Redesignated at 44 FR 22702, Apr. 17, 1979 and 46 FR 22353, Apr. 20, 1981]

## PART 103—STANDARDS FOR THE COMPROMISE OF CLAIMS

## Sec.

- 103.1 Scope and application.
- 103.2 Inability to pay.
- 103.3 Litigative probabilities.
- 103.4 Cost of collecting claim.
- 103.5 Enforcement policy.
- 103.6 Joint and several liability.
- 103.7 Settlement for a combination of reasons.
- 103.8 Further review of compromise offers.
- 103.9 Restrictions.

AUTHORITY: Sec. 3, 80 Stat. 309; 31 U.S.C. 952.

SOURCE: 31 FR 15382, Oct. 15, 1966, unless otherwise noted.

## § 103.1 Scope and application.

The standards set forth in this part apply to the compromise of claims, pursuant to section 3(b) of the Federal Claims Collection Act of 1966, 80 Stat. 309, which do not exceed \$20,000 exclusive of interest. The head of an agency or his designee may exercise such compromise authority with respect to claims for money or property arising out of the activities of his agency prior to the referral of such claims to the General Accounting Office or to the Department of Justice for litigation. The Comptroller General or his designee may exercise such compromise authority with respect to claims referred to the General Accounting Office prior to their further referral for litigation. Only the Comptroller General or his designee may effect the compromise of a claim that arises out of an exception made by the General Accounting Office in the account of an accountable officer, including a claim against the payee, prior to its referral by that Office for litigation.

## § 103.2 Inability to pay.

A claim may be compromised pursuant to this part if the Government cannot collect the full amount because of (a) the debtor's inability to pay the full amount within a reasonable time, or (b) the refusal of the debtor to pay the claim in full and the Government's inability to enforce collection in full within a reasonable time by enforced collection proceedings. In deter-

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mining the debtor's inability to pay the following factors, among others, may be considered:

Age and health of the debtor; present and potential income; inheritance prospects; the possibility that assets have been concealed or improperly transferred by the debtor; the availability of assets or income which may be realized upon by enforced collection proceedings. The agency will give consideration to the applicable exemptions available to the debtor under State and Federal law in determining the Government's ability to enforce collection. Uncertainty as to the price which collateral or other property will bring at forced sale may properly be considered in determining the Government's ability to enforce collection. A compromise effected under this section should be for an amount which bears a reasonable relation to the amount which can be recovered by enforced collection procedures, having regard for the exemptions available to the debtor and the time which collection will take. Compromises payable in installments are to be discouraged. However, if payment of a compromise by installments is necessary, an agreement for the reinstatement of the prior indebtedness less sums paid thereon and acceleration of the balance due upon default in the payment of any installment should be obtained, together with security in the manner set forth in § 102.8 of this chapter, in every case in which this is possible. If the agency's files do not contain reasonably up-to-date credit information as a basis for assessing a compromise proposal such information may be obtained from the individual debtor by obtaining a statement executed under penalty of perjury showing the debtor's assets and liabilities, income and expense. Forms such as Department of Justice form DJ-35 may be used for this purpose. Similar data may be obtained from corporate debtors by resort to balance sheets and such additional data as seems required.

**§ 103.3 Litigative probabilities.**

A claim may be compromised pursuant to this part if there is a real doubt concerning the Government's ability to prove its case in court for the full

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amount claimed either because of the legal issues involved or a bona fide dispute as to the facts. The amount accepted in compromise in such cases should fairly reflect the probability of prevailing on the legal question involved, the probabilities with respect to full or partial recovery of a judgment having due regard to the availability of witnesses and other evidentiary support for the Government claim, and related pragmatic considerations. Proportionate weight should be given to the probable amount of court costs which may be assessed against the Government if it is unsuccessful in litigation, having regard for the litigative risks involved. Cf. 28 U.S.C. 2412, as amended by Pub. L. 89-507, 80 Stat. 308.

**§ 103.4 Cost of collecting claim.**

A claim may be compromised pursuant to this part if the cost of collecting the claim does not justify the enforced collection of the full amount. The amount accepted in compromise in such cases may reflect an appropriate discount for the administrative and litigative costs of collection having regard for the time which it will take to effect collection. Cost of collecting may be a substantial factor in the settlement of small claims. The cost of collecting claims normally will not carry great weight in the settlement of large claims.

**§ 103.5 Enforcement policy.**

Statutory penalties, forfeitures, or debts established as an aid to enforcement and to compel compliance may be compromised pursuant to this part if the agency's enforcement policy in terms of deterrence and securing compliance, both present and future, will be adequately served by acceptance of the sum to be agreed upon. Mere accidental or technical violations may be dealt with less severely than willful and substantial violations.

**§ 103.6 Joint and several liability.**

When two or more debtors are jointly and severally liable collection action will not be withheld against one such debtor until the other or others pay their proportionate share. The agency

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should not attempt to allocate the burden of paying such claims as between the debtors but should proceed to liquidate the indebtedness as quickly as possible. Care should be taken that compromise with one such debtor does not release the agency's claim against the remaining debtors. The amount of a compromise with one such debtor shall not be considered a precedent or as morally binding in determining the amount which will be required from other debtors jointly and severally liable on the claim.

## § 103.7 Settlement for a combination of reasons.

A claim may be compromised for one or for more than one of the reasons authorized in this part.

## § 103.8 Further review of compromise offers.

If an agency holds a debtor's firm written offer of compromise which is substantial in amount and the agency is uncertain as to whether the offer should be accepted, it may refer the offer, the supporting data, and particulars concerning the claim to the General Accounting Office or to the Department of Justice. The General Accounting Office or the Department of Justice may act upon such an offer or return it to the agency with instructions or advice.

## § 103.9 Restrictions.

Neither a percentage of a debtor's profits nor stock in a debtor corporation will be accepted in compromise of a claim. In negotiating a compromise with a business concern consideration should be given to requiring a waiver of the tax-loss-carry-forward and tax-loss-carry-back rights of the debtor.

## PART 104—STANDARDS FOR SUSPENDING OR TERMINATING COLLECTION ACTION

## Sec.

- 104.1 Scope and application.
- 104.2 Suspension of collection activity.
- 104.3 Termination of collection activity.
- 104.4 Transfer of claims.

AUTHORITY: Sec. 3, 80 Stat. 309; 31 U.S.C. 952.

SOURCE: 31 FR 13383, Oct. 15, 1966, unless otherwise noted.

## § 104.1 Scope and application.

The standards set forth in this part apply to the suspension or termination of collection action pursuant to section 3(b) of the Federal Claims Collection Act of 1966, 80 Stat. 309, on claims which do not exceed \$20,000 exclusive of interest. The head of an agency or his designee may suspend or terminate collection action under this part with respect to claims for money or property arising out of activities of his agency prior to the referral of such claims to the General Accounting Office or to the Department of Justice for litigation. The Comptroller General or his designee may exercise such authority with respect to claims referred to the General Accounting Office prior to their further referral for litigation.

## § 104.2 Suspension of collection activity.

Collection action may be suspended temporarily on a claim when the debtor cannot be located after diligent effort and there is reason to believe that future collection action may be sufficiently productive to justify periodic review and action on the claim having consideration for its size and the amount which may be realized thereon. The following sources may be of assistance in locating missing debtors: Telephone directories; city directories; postmasters; drivers' license records; automobile title and license records; state and local governmental agencies; district directors of Internal Revenue; other Federal agencies; employers, relatives, friends; credit agency skip locate reports and credit bureaus. Suspension as to a particular debtor should not defer the early liquidation of security for the debt. Every reasonable effort should be made to locate missing debtors sufficiently in advance of the bar of the applicable statute of limitations, such as Pub. L. 89-505, 80 Stat. 304, to permit the timely filing of suit if such action is warranted. If the missing debtor has signed a confess-judgment note and is in default, referral of the note for the entry of judgment should not be delayed because of his missing status.

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Collection action may be suspended temporarily on a claim when the debtor owns no substantial equity in realty and is unable to make payments on the Government's claim or effect a compromise thereof, at the time but his future prospects justify retentions of the claim for periodic review and action and:

(a) The applicable statute of limitations has been tolled or started running anew or (b) future collection can be effected by offset notwithstanding the statute of limitations.

[31 FR 13381, Oct. 15, 1966, as amended at 44 FR 22702, Apr. 17, 1979]

## § 104.3 Termination of collection activity.

The head of an agency or his designee may terminate collection activity and consider the agency's file on the claim closed under the following standards:

(a) *Inability to collect any substantial amount.* Collection action may be terminated on a claim when it becomes clear that the Government cannot collect or enforce collection of any significant sum from the debtor having due regard for the judicial remedies available to the Government, the debtor's future financial prospects, and the exemptions available to the debtor under State and Federal law. In determining the debtor's inability to pay the following factors, among others, may be considered: Age and health of the debtor; present and potential income; inheritance prospects; the possibility that assets have been concealed or improperly transferred by the debtor; the availability of assets or income which may be realized upon by enforced collection proceedings.

(b) *Debtor's location.* Collection action may be terminated on a claim when the debtor cannot be located, there is no security remaining to be liquidated, the applicable statute of limitations has run, and the prospects of collecting by offset notwithstanding the bar of the statute of limitations is too remote to justify retention of the claim.

(c) *Cost and amount recovery.* Collection action may be terminated on a claim when it is likely that the cost of further collection action will exceed the amount recoverable thereby.

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(d) *Claim legally without merit.* Collection action should be terminated on a claim whenever it is determined that the claim is legally without merit.

(e) *Claim cannot be substantiated by evidence.* Collection action should be terminated when it is determined that the evidence necessary to prove the claim cannot be produced or the necessary witnesses are unavailable and efforts to induce voluntary payment are unavailing.

## § 104.4 Transfer of claims.

When an agency has doubt as to whether collection action should be suspended or terminated on a claim it may refer the claim to the General Accounting Office for advice. When a significant enforcement policy is involved in reducing a statutory penalty or forfeiture to judgment, or recovery of a judgment is a prerequisite to the imposition of administrative sanctions, such as the suspension or revocation of a license or the privilege of participating in a Government sponsored program, an agency may refer such a claim for litigation even though termination of collection activity might otherwise be given consideration under § 104.3 (a) or (c). Claims on which an agency holds a judgment by assignment or otherwise will be referred to the Department of Justice for further action if renewal of the judgment lien or enforced collection proceedings are justified under the criteria discussed in this part, unless the agency concerned has statutory authority for handling its own litigation.

## PART 105—REFERRALS TO GAO OR FOR LITIGATION

## Sec.

105.1 Prompt referral.

105.2 Current address of debtor.

105.3 Credit data.

105.4 Report of prior collection actions.

105.5 Preservation of evidence.

105.6 Minimum amount of referrals to the Department of Justice.

105.7 Referrals to GAO.

Authority: Sec. 3, 50 Stat. 309; 31 U.S.C. 952.

Source: 31 FR 13384, Oct. 15, 1966, unless otherwise noted.

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## § 105.1 Prompt referral.

Claims on which collection action has been taken in accordance with Part 102 of this chapter and which cannot be compromised, or on which collection action cannot be suspended or terminated, in accordance with Parts 103 and 104 of this chapter, will be referred to the General Accounting Office in accordance with R.S. 236, as amended, 31 U.S.C. 71, or to the Department of Justice, if the agency concerned has been granted an exception from referrals to the General Accounting Office. Such referrals should be made as early as possible consistent with aggressive agency collection action and the observance of the regulations contained in this chapter and in any event well within the time limited for bringing a timely suit against the debtor.

## § 105.2 Current address of debtor.

Referrals to the General Accounting Office, and to the Department of Justice for litigation, will be accompanied by the current address of the debtor or the name and address of the agent for a corporation upon whom service may be made. Reasonable and appropriate steps will be taken to locate missing parties in all cases. Referrals to the General Accounting Office, and referrals to the Department of Justice for the institution of foreclosure or other proceedings, in which the current address of any party is unknown will be accompanied by a listing of the prior known addresses of such a party and a statement of the steps taken to locate him.

## § 105.3 Credit data.

(a) Claims referred to the General Accounting Office, and to the Department of Justice for litigation, will be accompanied by reasonably current credit data indicating that there is a reasonable prospect of effecting enforced collections from the debtor, having due regard for the exemptions available to the debtor under State and Federal law and the judicial remedies available to the Government.

(b) Such credit data may take the form of: (1) A commercial credit report, (2) an agency investigative report showing the debtor's assets and

liabilities and his income and expenses, (3) the individual debtor's own financial statement executed under penalty of perjury reflecting his assets and liabilities and his income and expenses, or (4) an audited balance sheet of a corporate debtor.

(c) Such credit data may be omitted if: (1) A surety bond is available in an amount sufficient to satisfy the claim in full, (2) the forced sale value of the security available for application to the Government's claim is sufficient to satisfy its claim in full, (3) the referring agency wishes to liquidate loan collateral through judicial foreclosure but does not desire a deficiency judgment, (4) the debtor is in bankruptcy or receivership, or (5) the debtor's liability to the Government is fully covered by insurance, in which case the agency will furnish such information as it can develop concerning the identity and address of the insurer and the type and amount of insurance coverage.

## § 105.4 Report of prior collection actions.

A checklist or brief summary of the actions previously taken to collect or compromise a claim will be forwarded with the claim upon its referral to the General Accounting Office or to the Department of Justice. If any of the administrative collection actions enumerated in Part 102 of this chapter have been omitted, the reason for their omission will be given with the referral. The General Accounting Office and the Department of Justice may return or retain claims at their option when there is insufficient justification for the omission of one or more of the administrative collection actions enumerated in Part 102 of this chapter.

## § 105.5 Preservation of evidence.

Care will be taken to preserve all files, records and exhibits on claims referred or to be referred to the General Accounting Office, or to the Department of Justice for litigation.

## § 105.6 Minimum amount of referrals to the Department of Justice.

Agencies will not refer claims of less than \$600, exclusive of interest for liti-

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gation unless: (a) Referral is important to a significant enforcement policy or (b) the debtor has not only the clear ability to pay the claim but the Government can effectively enforce payment having due regard to the exemptions available to the debtor under State or Federal Law and the judicial remedies available to the Government.

[42 FR 38891, Aug. 1, 1977]

**Title 4—Accounts****§ 105.7 Referrals to GAO.**

Referrals of claims to the General Accounting Office will be in accordance with instructions, including monetary limitations, contained in the General Accounting Office Policy and Procedures Manual for the Guidance of Federal Agencies.

## Model Demand for Payment Letter

Name:

Date:

Address:

I.F.&amp;R. No.:

## Demand for Payment of Civil Penalty - Warning For Failure to Pay

Dear Sir/Madam:

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. §136 et seq.), you are hereby given notice that your penalty payment of \$ \_\_\_\_\_ is due within thirty (30) days and that we expect payment in full before the expiration of the sixty (60) day payment period that started on \_\_\_\_\_ and ends on \_\_\_\_\_

If payment is not received by the expiration of the payment period, this matter shall be referred to the (United States Attorneys Office/Department of Justice) which shall recover such amount by civil action in the nature of a debt owed to the United States government.

In the event that you have already submitted your payment or that it is currently in transit, please disregard this notice and accept our apologies for any inconvenience it may cause you.

\_\_\_\_\_  
Title

EPA Region \_\_\_\_\_

\_\_\_\_\_  
Date

At \_\_\_\_\_

## Model Final Demand for Payment Letter

Name:  
Address:  
I.F.&R. No.:

Date:

Final Demand for Payment of Civil Penalty - Notice of Referral  
to the U.S. Attorney

Dear Sir/Madam:

This letter is to inform you that your penalty payment of \$ \_\_\_\_\_ is past due and to demand immediate payment of the above-mentioned sum. The penalty was imposed by a (Final Order, Consent Decree, or Default Order) signed by the Regional Administrator of Region \_\_\_\_\_ on \_\_\_\_\_ (date) \_\_\_\_\_. You were notified of your obligation to pay upon receipt of the Regional Administrator's order on \_\_\_\_\_ and you were again informed of your obligation to pay on \_\_\_\_\_ (date second demand was sent) \_\_\_\_.

You are hereby notified that unless the payment of the penalty is received in the Regional Office within fifteen (15) days of the date of this notice, this matter will be referred to a U.S. Attorney who shall recover such amount in a civil action in the appropriate United States district court. Such action is routinely accomplished through a motion for summary judgment in favor of the United States. In this proceeding, you will be barred from raising any issues of fact or of law that should have been raised in the administrative proceeding.

\_\_\_\_\_  
Title

EPA Region \_\_\_\_\_

\_\_\_\_\_  
Date

At \_\_\_\_\_



## Claims Collection Litigation Report

### An Overview

The Federal Claims Collection Standards (4 C.F.R. §§101-105) prescribe regulations for the administrative collection, compromise and termination of agency claims, and for the referral of administratively uncollectible claims to the General Accounting Office or to the Department of Justice for litigation. The Standards require that certain information be provided to the Department of Justice when an agency refers a claim for litigation and enforced collection (4 C.F.R. §105.1 et seq.). In cooperation with the General Accounting Office, the attached Claims Collection Litigation Report (CCLR) has been developed by the Debt Collection Section of the Executive Office for United States Attorneys, Department of Justice, as the standard report to provide this information when claims are referred to Justice for litigation and enforced collection. All claims referred to Justice should be accompanied by a completed report.

The CCLR is provided in three different formats: letter (Exhibit 1), memorandum (Exhibit 2), and standard form (Exhibit 3). Each agency may choose the format it prefers to use. Duplicate copies of each format which include bracketed explanatory text are also provided (Exhibits 4, 5 and 6).<sup>\*</sup> In addition, an Item Explanation (Exhibit 7) is provided to assist and direct agencies on the specific information required in each item on the report.

Uniform use of the CCLR by all agencies will serve a number of purposes. First, it will provide Justice with all the information it must have to effectively litigate the claim and enforce collection. The CCLR will provide this essential information "on top and up front" so that no time will be lost searching the client agency's file for the necessary information. This will increase the speed at which claims received from agencies are taken to judgment, or otherwise converted to paying status, and, as a result, should increase the amount of money collected by Justice and returned to the agencies.

Second, the CCLR should improve the quality of claim referrals to Justice by prompting agencies to take more aggressive administrative action to collect claims. Such aggressive collection action is required by the Federal Standards (4 C.F.R. §102.7 et seq.) but has often been overlooked or ignored. In this respect, the CCLR will also serve as a checklist and as a reminder to all persons who deal with these matters of the importance of the Federal requirements. Furthermore, both aggressive action by the agency to collect and prompt referral to Justice of claims which are accompanied by current, accurate and complete information, directly affect Justice's success in the enforced collection of claims. Therefore, we hope that each agency will establish the goal that all of its referable claims be referred to Justice not later than six months after

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<sup>\*</sup> The Pesticides and Toxic Substances Offices have adopted the memorandum format. Therefore, Exhibit 5 (the memorandum format that includes bracketed explanatory text) is included in this appendix. Exhibits 1, 2, and 3 (blank forms) and Exhibits 4 and six, which pertain to other formats, are not included.

the agency's final determination of the amount of the claim. If, as stated in the Item Explanation, preparation of the CCLR is made an integral and contemporaneous function of aggressive collection efforts by all agencies, the CCLR will be completed as and when the agency completes administrative collection action, thus, allowing agencies to promptly refer claims to Justice.

Finally, the CCLR will provide the information needed by Justice from all agencies in the same order and sequence. This will enable Justice personnel to design procedures around the report which will permit better utilization of the modern word and data processing equipment which many law offices now have. Once the information is received in the same sequence, then prerecorded programs will enable such equipment to "read" each "debtor file" to "automatically" produce the documents essential to litigation, for example, the demand letter, complaint, summons and judgment, which relate to a claim. Such automated collections systems will improve the efficiency and speed with which claims are handled and, as a result, Justice should be able to better serve its client agencies.

Because of the uniform order and sequence of this standard report, it will be possible, if an agency so chooses, to provide merely the answers to Items 1 through 51 of the report seriatim. This means that instead of inserting answers to Items 1 through 51 on the actual CCLR form, an agency may follow the standard format of the report, as illustrated in the attached Exhibits 1 through 6, down to Item 1 of the report, and then at that point merely provide a running list of only the Item numbers and corresponding answers for Items 1 through 51. The actual CCLR form and the accompanying Item Explanation would then be used by the agency as its pattern, guide, or key for providing the answers in the running list. When a running list is provided in lieu of inserting the answers onto the actual report form, however, great care should be taken by the agency to assure that the Item numbers and answers provided in the running list correspond to the Item numbers on the report. This method of providing information should both simplify and expedite the agency's preparation of the CCLR. In addition, it should allow for better utilization of available word and data processing equipment to prepare the report.

As both the CCLR and the Item Explanation state, all documentation which supports the claim or, where appropriate, the agency's debtor file should be attached to the report. In addition, the following materials should be prepared and included in the CCLR package:

- 1) A Certificate of Indebtedness which will provide the United States Attorney with a complete statement of how the claim arose (including the statutory, regulatory, or other authority from which the claim arose, a summary statement or resume of the factual basis for the claim, an

itemization of the dates and amounts of any payments made by the debtor to the agency or any credits made by the agency to the debtor, and an itemization of the amount due and owing) and which may be offered by the United States Attorney into evidence to prove the claim;

- 2) A Department of Justice Demand Letter (Exhibit 8) which will be used by the United States Attorney to notify the debtor that the Department of Justice has received the claim for litigation and suit will be brought unless full payment is made within 10 days (please note that this letter need only be prepared and included in the CCLR package for those United States Attorneys' offices listed on the Attachment to Exhibit 8);
- 3) A Department of Justice Acknowledgment ("Comeback Letter") (Exhibit 9) which will be used by the United States Attorney to officially notify the agency that the claim which was referred has been received and will give the referring agency the United States Attorney's claim number; and
- 4) A Department of Justice Deficiency or Declination Letter ("Sendback Letter") (Exhibit 10) which will be used by the United States Attorney to send deficient claims, or claims which the United States Attorney declines to litigate, back to the agency.

The letters should be prepared in the same format reflected in the exhibits.

The Department of Justice solicited comments on the use, content and format of the report from divers Federal agencies. These comments expressed almost universal support for the concept of the report. To the extent possible, all agency suggestions for changes to the report, or that additional items be included in the report, were incorporated. Several agencies were concerned that some of the items of information requested on the report may be superfluous to their particular claims or impossible to obtain. Inability to obtain all information required by the report should not be viewed as a bar to referral of claims to Justice. However, information requested in the litigation report should be provided to the extent feasible. Questions of feasibility should be answered on the basis of and with a clear understanding of the fact that claims referred to Justice are for litigation following aggressive administrative collection action by the referring agency, and that on the basis of the information contained in the CCLR, including the agency's determination of the debtor's ability to pay, and the accompanying supporting documentation or agency debtor file, Justice should be able to successfully prosecute the claims referred to it to judgment and enforce collection of a substantial sum. Any omissions should be explained in the appropriate item on the face of the report.

We realize that as agencies gain experience using the CCLR, problems may arise which could not be foreseen while the report was being developed. Although completion of the report is required, its content and format may be modified in the future based upon any comments or suggestions from agencies using the report. Comments should be brought to the attention of Mr. Edward B. Funston, Assistant Director, Debt Collection Section, Executive Office for U. S. Attorneys, Suite 803, 5205 Leesburg Pike, Falls Church, Virginia 22041. In the near future, the General Accounting Office will incorporate the CCLR and accompanying materials in Title 4 of the General Accounting Office Policy and Procedures Manual for the Guidance of Federal Agencies.

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**CLAIMS COLLECTION LITIGATION REPORT**  
(on memorandum of referring agency)

&gt;(Date) ↑

To: >United States Attorney ↑↑  
>(Judicial District) of (State)  
>(City, State, Zip Code)

Re: >(Name)  
>(Title)  
>(Mailing address if not shown above)  
>  
>  
>(FTS Phone number)

**Attention Claims Collection Unit**

Re: >(Debtor's full name (LAST, First, Middle))  
>(Debtor's mailing address)  
>  
>

>(Debtor's file or reference number)  
>\$(Amount) is the total principal due.  
>\$(Amount) is the total interest due.  
>\$(Amount) is the total administrative charges due.  
>\$(Amount) is the total penalty charges due.  
>\$(Amount) is the total amount due.  
>(Rate) % is the annual interest rate.  
>(Date) is the SOL date.

This claim is referred to you for suit and such other action as you deem appropriate to enforce collection. The prior action taken by this agency and the information provided you complies fully with Federal Claims Collection Standards (4 CFR Parts 101-105). The documentation required by 4 CFR Parts 101-105 is attached and the information you have requested follows.

**THE DEBTOR**

- |   |  |
|---|--|
| 1. Date of Birth: _____   | 2. Social Security Number: _____                                       |
| 3. Also known as:<br>[List aliases of debtor, if known.] _____  | 4. Name used on note/application: _____                                |
| 5. Present residence:<br>[Show actual place of residence, not merely the debtor's mailing address.] _____ | 6. Residence verified by/when:<br>[From what source and when?] _____   |
| 7. Phone number verified by/when:<br>[From what source and when?] _____                                   | 8. Debtor's present phone numbers: _____                               |
| 9. Debtor's last known address:<br>[From what source and when?] _____                                     | 10. Debtor's last known address:<br>[From what source and when?] _____ |

**THE CLAIM**

10. Basis of claim or cause of action: [Briefly describe the claim, e.g.,  
benefit overpayment, loan default, bankruptcy, etc.] \_\_\_\_\_

-1-  
(Memo)

[EXHIBIT 51]

11. Statute of limitations (SOL) runs on:  
[Date?]  
[12, cont'd.]
12. Basis for SOL date:  
[E.g., default date, last payment date]
13. First demand for payment made on:  
[Date?]
14. First demand made by:  
[Who, i.e., agent, official, office?]
15. Method of first demand:  
[E.g., letter, mailgram?]
16. Last demand for payment made on:  
[Date?]
17. Last demand made by:  
[Who, i.e., agent, official, office?]
18. Method of last demand:  
[E.g., letter, phone, personal contact?]
19. Debtor's response:  
[When and how did debtor respond?]  
[20, cont'd.) to the claim, if known.]
20. Does debtor dispute claim:  
[Explain debtor's position with regard
21. Response, if any, to debtor's dispute:  
[Agency response to debtor's dispute,]  
[22, cont'd.) available to debtor, how debtor was advised of them, and debtor's action with regard thereto, if any.]
22. Exhaustion of administrative remedies:  
[Describe administrative remedies
23. Compromise offered or elicited:  
\$(Amount?)  
[24, cont'd.) the debtor or offered the debtor by the claimant agency? Was a basis for compromise offer given; if yes, what was the basis?]
24. Basis for compromise:  
[Was a compromise offer elicited from
25. Response by agency or debtor:  
[if any, by who and what response?]
26. Others legally responsible for debt:  
[E.g., beneficiaries, conservators.]
27. Basis of liability by other parties:  
[Is liability joint or several? Action, if any, taken against other parties? If none, why not? If yes, what action and what amount recovered? Give other relevant details.]

## ACCOUNT INFORMATION

28. Certification of indebtedness: \$(Amount?) as of (Date of determination.) _____	29. Original principal owed by debtor: \$(Amount?) _____
30. Total number/amount of payments made/credits: _____	31. Amount applied to principal: \$ _____
32. Amount applied to charges assessed, penalties and interest: \$ _____	33. Balance due on principal: \$ _____
34. Balance due on charges assessed, penalties and accrued interest: \$ _____ (35. cont'd.) debtor are to be applied.) _____	35. Explain application of payments: <u>[Explain how payments received from the</u> _____
36. Debtor's last payment: \$(Amount and date?) _____	37. Interest accrual date: (The date from which interest is due.) _____

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## DEBTOR'S EMPLOYMENT

38. Present employment:  
 [Employer's name?]  
 [Employer's address; street and number,  
 City, State and ZIP Code?]  
 [Employer's phone number?]
39. Employment verified:  
 [From what source and when?]
40. Debtor's salary:  
 \$[Amount and whether weekly or monthly  
 and whether gross or net?]
41. Salary verified:  
 [From what source and when?]
42. Spouse's employment:  
 [Employer's name?]  
 [Employer's address; street and number,  
 City, State, ZIP Code?]  
 [Employer's phone number?]
43. Spouse's employment verified:  
 [From what source and when?]

## DEBTOR'S ABILITY TO PAY

44. Having due regard for the exemptions to which the debtor is entitled under state and Federal law, the debtor's age and health, present and potential income, inheritance prospects, and the possibility that assets have been concealed or improperly transferred; the current credit report or financial statement attached (or other information found in the attached file) discloses the present or likely future availability of assets or income from which a substantial sum may be obtained by enforced collection proceedings:  
 [Explain.]
45. The following information will assist you in locating property in which the United States has a secured interest: [Describe and attach security agreements and describe and give last known location of property in which the United States has a secured interest. Give asset or fair market value of security (which?).]
46. The following information will assist you in locating other assets of the debtor: [Describe and give the location of real and personal property of the debtor which is or may be vulnerable to attachment or levy (non-exempt assets). Give asset or fair market value of property listed (which?).]

## VALUE OF CLAIM

47. If discounted or sold in commerce, the fair market or asset value of this claim would be: \$[Amount? Explain basis for fair market or asset valuation given, if any.]
48. With due regard to the debtor's ability to pay, as defined by question 44, above, a reasonable and acceptable compromise offer by the debtor would be: \$[Amount? What is basis for amount shown? Explain in relationship to the debtor's assets and income which can be reached by garnishment, levy, or attachment.]

## TRANSFER OR DIRECT DEPOSIT OF FUNDS

49. Accounting officer:  
 [Name, title, agency, mailing address,]  
 \_\_\_\_\_  
 \_\_\_\_\_  
 [FIS phone number.]
50. Agency accounting/dispersing officer  
 code/symbol/number:  
 \_\_\_\_\_
51. Treasury designated appropriation  
 symbol:  
 \_\_\_\_\_

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If I can be of any further assistance in this matter, please do not hesitate to call me at the number given above.

**Agency Employee Responsible for Handling the Claim:**

>(Name)  
>(Title)  
>(Mailing address if not shown above)  
>  
>  
>(FTS Phone number)

Attachments as listed:

† The symbols, the brackets, the boxes, or the text within either of the letter will not appear on the final typed or printed report, but have been included here to explain or clarify the questions/items. The margin and tab settings are indicated on the first line. Once set, they need not be changed to complete the entire report. This report is designed to be typed and printed here or prepared on word processing equipment with either "tab-to-eject" or "margin/tab/indent" commands, i.e., margin-variable-text with pattern ("set") text and print.

†† The address on the first page is the "inside address" but the envelope or "outside address" will have to be more complete. (See Exhibit 11 for appropriate envelope or "outside address.") The judicial district may be written, "Southern District of Iowa," or "District of Kansas," as appropriate. The State can be the accepted two capital letter abbreviation.

(Name)



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## SUPPLEMENTAL SHEET FOR DETAILED ANSWERS

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Indicate line numbers to which the answers apply.

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If more space is required, use full sheets of paper the same size as this page. Attach all sheets behind page 3.

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-3-  
(Name)

## CLAIMS COLLECTION LITIGATION REPORT

Item Explanation

The Claims Collection Litigation Report (CCLR) will provide the Department of Justice with the essential information required for litigation and enforced collection of a substantial sum on an agency claim. As you know, the Federal Claims Collection Standards (4 C.F.R. §§101-105) require that this information be forwarded to the United States Attorney with each claim. The following explanations are provided to assist and direct you on the specific information required in each item on the report. Careful review of and frequent reference to these item explanations throughout the course of agency collections endeavors will facilitate the final preparation of the CCLR and accompanying claim package. If preparation of the CCLR is made an integral and contemporaneous function of aggressive collection efforts by the Department's client agencies, the CCLR will be completed as and when the agency completes administrative collection action.

When the space provided on the face of the CCLR is not adequate for your responses, continuation of the responses should be made on the supplemental sheet attached to the report. When this is done, appropriate notations indicating that additional information is attached should be included at the related items on the face of the CCLR. The supplemental sheet should also be used to provide the same information required in "The Debtor," "Debtor's Employment," and "Debtor's Ability to Pay" sections of the report for the additional debtors on a multiple debtor claim. In addition, the supplemental sheet should be used to provide the same information required in "The Claim" and "Account Information" sections of the report for any additional debts of a single debtor. Again, appropriate notations indicating that additional information is attached should be included at the related sections on the face of the report. All information requested in the report should be provided to the extent feasible. Questions of feasibility should be answered on the basis of and with a clear understanding of the fact that claims referred to the Department of Justice are for litigation following aggressive administrative collection action by the referring agency, and that, on the basis of the information contained in the report, including the agency's determination of the debtor's ability to pay, the Department should be able to successfully prosecute the claims referred to it to judgment and enforce collection of a substantial sum. Therefore, any omissions should be explained in the appropriate items on the report.

As stated in the cover "Overview" to this package, the CCLR is a standard litigation report which will provide Justice with the information on all agency claim referrals in the same order or sequence. Because of the uniform order and sequence of this standard report, it will be possible, if an agency so chooses, to provide easily the answers to Items 1 through 51 of the report en bloc. This means that instead of inserting answers to Items 1 through 51 on the actual CCLR form, an agency may follow the standard format of the report, as illustrated in the attached Exhibits 1 through 6, down to Item 1 of the report, and then at that point merely provide a running list of only the item numbers and corresponding answers for Items 1 through 51. The actual CCLR form and the accompanying Item Explanation would then be used by the agency as its pattern, guide, or key for providing the answers in the running list. When a running list is provided in

EXHIBIT 71

lieu of inserting the answers onto the actual report form, however, great care should be taken by the agency to assure that the Item numbers and answers provided in the running list correspond to the Item numbers on the report. This method of providing information should both simplify and expedite the agency's preparation of the OCLR. In addition, it should allow for better utilization of available word and data processing equipment to prepare the report.

As both the OCLR and the following explanations state, all documentation which supports the claim or, where appropriate, the agency's debtor file should be attached to the report. In addition, the following materials should be prepared and included in the OCLR package:

- 1) A Certificate of Indebtedness which will provide the United States Attorney with a complete statement of how the claim arose (including the statutory, regulatory, or other authority from which the claim arose, a summary statement or resume of the factual basis for the claim, an itemization of the dates and amounts of any payments made by the debtor to the agency or any credits made by the agency to the debtor, and an itemization of the amount due and owing) and which may be offered by the United States Attorney into evidence to prove the claim;
- 2) A Department of Justice Demand Letter (Exhibit 8) which will be used by the United States Attorney to notify the debtor that the Department of Justice has received the claim for litigation and suit will be brought unless full payment is made within 10 days (please note that this letter need only be prepared and included in the OCLR package for those United States Attorneys' offices listed on the Attachment to Exhibit 8);
- 3) A Department of Justice Acknowledgment ("Comeback Letter") (Exhibit 9) which will be used by the United States Attorney to officially notify the agency that the claim which was referred has been received and give the referring agency the United States Attorney's claim number; and
- 4) A Department of Justice Deficiency or Declination Letter (Exhibit 10) which will be used by the United States Attorney to send deficient claims, or claims which the United States Attorney declines to litigate, back to the agency.

The letters should be prepared in the same format reflected in the exhibits.

#### TOP PORTION

Date:  
Inside Address  
or "To" Block:

Show the date that the OCLR is signed.

Simply show "United States Attorney," the Federal judicial district, and the city, state and zip code. The judicial district may be written, "Southern District of Iowa," or "District of Kansas," as appropriate. The state can be the accepted two capital

	letter abbreviation. A complete mailing address for the United States Attorney should be provided on the mailing envelope. (Exhibit 11 provides current mailing addresses for United States Attorneys.)
"From" Block:	[When using the "Memorandum" or "Form" format] Show the name, title, complete mailing address and FTS telephone number of the agency official who will sign the report.
Debtor's Full Name:	Show the last, first and full middle name or middle initial of the debtor. Where appropriate, indicate whether debtor is a "Sr.," "Jr.," "II," etc.
Debtor's Mailing Address:	Show the complete mailing address for the debtor which has been verified by the agency within the past six months.
Debtor's File or Reference Number:	Show the agency's debtor file or reference number.
Total Principal Due:	Show the amount of principal due on the claim. Where fees and costs advanced are to be recovered from the debtor, include them in the principal. The Certification of Indebtedness which you attach should include an explanation and itemization when the total principal due is a cumulative total and combines separate items (e.g., recoverable fees and costs advanced, promissory notes of different dates or amounts).
Total Interest Due:	Show the total amount of interest due through the date of the Certification of Indebtedness. The Certification of Indebtedness which you attach should include an itemization and explanation of interest charges and when, for example, the total interest due includes separate items such as interest due on more than one promissory note or a series of discrete claims, each interest charge should be itemized and explained.
Total Administrative Charges Due:	Show the total amount, through the date of the Certification of Indebtedness, of any administrative charges which may have been assessed by the agency to cover the costs of processing and handling the claim pursuant to the Debt Collection Act of 1982, P.L. 97-365, §11(e)(2). The Certification of Indebtedness which you attach should include an itemization and explanation of such charges.

Total Penalty Charges Due:	Show the total amount, through the date of the Certification of Indebtedness, of any penalty charges which may have been assessed by the agency for debtor's failure to pay any portion of a debt more than ninety (90) days past due pursuant to the Debt Collection Act of 1982, P.L. 97-365 §11(e)(2). The Certification of Indebtedness which you attach should include an itemization and explanation of such penalty charges.
Total Amount Due:	Show the total (Grand Total) amount due on the claim through the date of the Certification of Indebtedness.
Annual Interest Rate:	Show the rate of annual interest charged by the agency on the debt.
SOL (Statute of Limitations) Date:	Show the same statute of limitations date which is to be entered at Item 11 of the CCLR.

## THE DEBTOR

ITEM 1:	Show the debtor's date of birth. In the case of a non-beneficiary debtor (e.g., a representative payee) and the date of birth of the debtor is unknown, show "Unknown." In the event that the debtor is a corporation or partnership, show "Not applicable [corporate/partnership] debtor."
ITEM 2:	Show the debtor's social security number. In the case of a non-beneficiary and the debtor's social security number is unknown, show "Unknown."  In the event that the debtor is a corporation or a partnership, show the tax identification number of the corporation. If the tax identification number of the corporate or partnership debtor is unknown, show "Unknown."
ITEM 3:	Show any other name(s) (alias(es)) used by the debtor. If the debtor is a sole proprietor, show the name under which the sole proprietor conducts business (e.g., d/b/a (doing business as) Smith's Sundries). If no aliases, corporate, partnership, or sole proprietorship names are used by the debtor, or known, show "Not applicable" or "Unknown."

- ITEM 4: Show the name(s) the debtor used on the initial instrument (e.g., application for benefits or loan application) which gave rise to the indebtedness.
- ITEM 5: Show the debtor's complete present residence address, i.e., address of dwelling in which the debtor lives so that he or she may be found for personal service of legal process (complaint and summons). Do not provide a Post Office Box address as the residence address. [The U.S. Postal Service will convert a Post Office Box address to a residence street address upon written request.] It is necessary for the United States Attorney to have current residence information in order to make prompt and effective service of process upon the debtor. If available, also show the name of the county in which the debtor resides. In the case of a corporate debtor, the address should be the debtor corporation's principal place of business and the name and address of the corporation's agent for service of process.
- ITEM 6: Show the name of the person or the source that verified the debtor's present residence address (e.g., the document which verifies or the method used to make the verification) and the most recent date within the last six months that the debtor's residence address was verified.
- ITEM 7: Show the debtor's present telephone number.
- ITEM 8: Show the name of the person or the source that verified the debtor's present telephone number (e.g., the document which verifies or the method used to make the verification) and the most recent date within the last six months that the debtor's present telephone number was verified.
- ITEM 9: Show any information which will assist the United States Attorney in relocating the debtor if he or she moves from the residence given at Item 5. Such information may include, for example, the names, addresses, and telephone numbers of relatives who may know of the debtor's whereabouts, a forwarding address which the debtor left with neighbors or an employer, or the debtor's drivers license number. If the agency reported the debt to a commercial credit

bureau, include the date the debt was reported and the name, address and telephone number of the commercial credit bureau to which reported.

[Stamping "Address Correction Requested" under the return address block on envelopes mailed to the debtor will alert the U.S. Postal Service to inform the creditor agency of changes in the debtor's address. Registered mail with forwarding and return-receipt requested is also an effective way to locate debtors. In addition, the U.S. Postal Service retains change of address notices for one year after they have been filed by a patron.]

In the case of a corporate debtor, include the current residence address of the principal officers of the corporation. Where there is a legal successor in interest to the corporate debtor, the same information requested in Item 5, above, and this item, should be provided for the successor party or corporation.

#### THE CLAIM

ITEM 10:

Briefly describe or characterize the claim or cause of action (e.g., "Social Security Administration benefit overpayment under U.S.C. § \_\_\_\_"). Describe in particularity the nature and type of benefit overpayment, loan default, or other action by the debtor which gave rise to the claim. As shown in the parenthetical example above, be sure to identify the statutory, regulatory, or other authority from which the claim arose. In the event the debtor has filed a bankruptcy petition, include bankruptcy related information in the description of the claim or cause of action. Attach a copy of the initial notice to the debtor of the benefit overpayment, loan default, etc.

ITEM 11:

Show the last date (month, day, year) on which suit can be brought to recover the claim or debt, i.e., the statute of limitations (SOL) date.

ITEM 12:

Show the basis for SOL (statute of limitations) date, e.g., the default date, date of last payment. As a general rule, unless

the debtor made a partial payment on the debt, the statute of limitations date would be based upon the date the agency first became aware of the debt. In the event a partial payment was made by the debtor, the statute of limitations date would be based upon the date of the debtor's last payment. (See 28 U.S.C. §2415 which provides, in part, that "... every action for money damages brought by the United States ... shall be barred unless the complaint is filed within six years after the right of action accrues ... [however] in the event of later partial payment or written acknowledgment of debt, the right of action shall be deemed to accrue again at the time of each such payment or acknowledgment . . . .")

- ITEM 13: Show the date (month, day, year) on which the first agency demand for payment was made on the debtor.
- ITEM 14: Show the name of the agency official, agent, or office that made the first demand for payment on the debtor.
- ITEM 15: Show how the first agency demand for payment was communicated to the debtor (e.g., by letter, mailgram).
- ITEM 16: Show the date (month, day, year) on which the last agency demand for payment was made on the debtor.
- ITEM 17: Show the name of the agency official, agent or office that made the last demand for payment on the debtor.
- ITEM 18: Show how the last agency demand for payment was communicated to the debtor (e.g., by letter, telephone, personal contact with the debtor).
- ITEM 19: Briefly explain the debtor's response, if any, to the agency's demands for payment, the date(s) (month, day, year) of any responses, and the manner in which such responses were communicated to the agency (e.g., by letter, telephone, personal contact). If the debtor did not respond to the agency's demands for payment, show "No response."



## ITEM 20:

If the debtor denied the claim, in whole or in part, give the date (month, day, year) of such denial and explain how the debtor's denial of the claim was made known to the agency (e.g., letter, telephone call, personal interview). Briefly explain the debtor's position with respect to the claim, if known. Explain any defenses that the debtor raised or can be expected to raise with respect to the claim and the merits of such defenses. Attach copies of any agency records documenting the debtor's denial. If the debtor did not dispute the claim, in whole or in part, show "Claim not disputed by debtor."

## ITEM 21:

Briefly explain any agency response to the debtor's denial of the claim. Attach copies of any agency response to the debtor's denial, in whole or in part, of the claim. Otherwise, show "No agency response." If the claim was not disputed by the debtor, show "Not applicable."

## ITEM 22:

Briefly describe any administrative remedies and/or rights available to the debtor (e.g., application for waiver, request for reconsideration, appeal, etc.). Explain how the debtor was apprised of the availability of those remedies and/or rights, and what action was taken by the debtor with regard thereto. Show the date (month, day, year) of any such application for waiver, request for reconsideration, or appeal. Attach copies of any documents evidencing such debtor's application for waiver, request for reconsideration, or appeal. Explain what agency action was taken in response to the debtor's exercise of or attempts to exercise rights to administrative remedies. Show the date (month, day, year) of any such "agency action" and attach copies of documents evidencing the same. Explain any "technical defenses" (procedural deficiencies) that the debtor has raised or can be expected to raise with respect to the claim and the merits of such defenses. (Defenses to the merits of the claim, as distinguished from "technical defenses," are to be discussed under Items 20 and 21.)

Describe and discuss the merits of any counterclaim by the debtor against the United States, as well as any claim for offset which the debtor may assert.

- ITEM 23: Show the amount and date (month, day, year) of any compromise offer made by the agency or elicited from the debtor.
- ITEM 24: Briefly explain whether the compromise offer was elicited from the debtor or offered to the debtor by the agency. Explain the basis of or reason for the amount of the compromise offer, if known.
- ITEM 25: Show the agency or debtor's response (specify which) to the compromise offer and the reason for the acceptance or rejection of the offer in compromise (e.g., "the debtor asserted that he had no funds with which to pay the compromise offered by the agency" or, "the agency rejected the debtor's compromise offer because the debtor's known discretionary expenditures are 10 times the amount of the compromise offer").
- ITEM 26: Show the name(s) and present residence address(es) of any other person(s) liable for repayment of the debt (e.g., beneficiaries, guarantors, assumptors, conservators, corporate officers). The present residence address provided should be that of the dwelling in which the person lives so that he or she may be personally served with legal process (complaint and summons). If no other person is legally responsible for the debt, show "None."
- ITEM 27: Briefly explain the basis of liability of other parties. Explain whether such liability is joint or several, or both. Provide details of any action taken by the agency against the other parties including, for example, the amount of any recovery from other parties. If no action was taken against the other parties legally responsible, explain why.

**ACCOUNT INFORMATION**

- ITEM 28: Show the total amount of the debt (principal, costs and fees advanced, accrued interest, administrative charges, penalty charges) as of the date (month, day, year) of determination (settlement) as reflected on the Certificate of Indebtedness. The Certificate of Indebtedness should provide the United States Attorney with a complete statement of

how the claim arose (including the statutory, regulatory, or other authority from which the claim arose, a summary statement or resume of the factual basis for the claim, an itemization of the dates and amounts of any payments made by the debtor to the agency or any credits made by the agency to the debtor, and an itemization of the amount due and owing) and should be for the full amount of the debt shown on the first page of the report. Attach the Certificate of Indebtedness to the report. In the event that the debtor has filed a bankruptcy petition and if the nature of the security agreement and the property in which the United States has a security interest is such that the debtor can reaffirm the debt, then list the number, dates and amounts of payments to which the debtor is in arrears.

ITEM 29: Show the original amount owed by the debtor. Although there may be many exceptions, this amount will usually be the principal amount of the indebtedness before the accrual of interest and before the debtor has made any payments.

ITEM 30: Show the total number and amount of any payments made by the debtor to the agency or the agency's assignor, or any credits made by the agency to the debtor. For example, if 5 payments of \$25.00 each, show "5 payments/\$125"; if 2 credits of \$30.00 each, show "2 credits/\$60." Indicate the nature of such payments or credits, i.e., whether they were, for example, by offset, lump sum or installment. If no payments or credits were made, show "None."

ITEM 31: If payments or credits were made, show the amount which was applied to the principal of the debt. Otherwise, show "Not applicable."

ITEM 32: Show the total amount which was applied to any administrative charges assessed by the agency, any penalty charges assessed by the agency, and the interest due on the principal amount of the debt, if applicable. If not, show "Not applicable."

ITEM 33: Show the remaining balance due on the principal amount of the debt. In the event that the debtor has filed a bankruptcy petition, show the balance due on the principal as of the date the petition was filed.

- ITEM 34: Show the balance due on any administrative charges assessed by the agency, any penalty charges assessed by the agency, and the accrued interest on the principal amount of the debt, if applicable. If not, show "Not applicable." In the event that the debtor has filed a bankruptcy petition, show the interest due to the date the petition was filed and daily accrual of interest thereafter.
- ITEM 35: Explain how payments received from the debtor are to be applied. Normally, when a debt is paid in partial or installment payments, amounts received by the agency should be applied first to any outstanding administrative charges which have been assessed by the agency pursuant to the Debt Collection Act of 1982, P.L. 97-365, §11(e)(2); second, to any outstanding penalty charges which have been assessed by the agency for debtor's failure to pay any portion of a debt more than ninety (90) days past due pursuant to the Debt Collection Act of 1982, P.L. 97-365, §11(e)(2); third, to accrued interest; and fourth, to outstanding principal.
- ITEM 36: Show the amount and date (month, day, year) of the last payment which the debtor made to the agency or the agency's assignor.
- ITEM 37: Show the interest computation or interest accrual date (i.e., the date from which interest is due), if applicable. If not, show "Not applicable."

## DEBTOR'S EMPLOYMENT

- ITEM 38: Show the name, complete address and telephone number of the debtor's present employer. If the debtor's actual place of work is different from the employer's address and is known, provide the address and telephone number of the debtor's work place. This information will assist the United States Attorney in making prompt service of process upon the debtor in the event the debtor cannot be found for service of process at his or her residence address.
- ITEM 39: Show the date (month, day, year) the debtor's employment was verified by the agency within the past six months, and the source of that verification (e.g., the debtor, debtor's employer, current documentation).

- ITEM 40: Show the debtor's weekly or monthly salary and indicate whether the amount shown is gross or net salary. For example, show "\$350/weekly/gross."
- ITEM 41: Show the date (month, day, year) the salary was verified by the agency within the past six months, and the source of that verification (e.g., the debtor, debtor's employer, current documentation).
- ITEM 42: If applicable and known, show the name, address and telephone number of the spouse's employer. If none of the information is available, show "Not available."
- ITEM 43: If applicable, show the date (month, day, year) the spouse's employment was verified by the agency within the past six months, and the source of that verification (e.g., spouse's employer, current documentation). If none of the information is available, show "Not available."

#### DEBTOR'S ABILITY TO PAY

- ITEM 44: Explain the evidence that discloses and the basis for the agency's determination that, given the debtor's present or likely future availability of assets or income, a substantial sum may be obtained by enforced collection proceedings against the debtor. The agency's determination should take into account any exemptions to which the debtor is entitled under state and Federal law, the debtor's age and health, the debtor's education, present and potential income, number of dependents, inheritance prospects, and the possibility that assets have been concealed or improperly transferred. Also, provide information concerning any legal proceedings, such as proceedings in bankruptcy, that may affect the government's ability to collect the debt. Attach to the report all supporting documentation including, for example, a current credit report or financial statement. In the event of a corporate debtor, an audited balance sheet of the corporate debtor may be attached.

Note: A realistic determination of a debtor's financial ability to pay is essential to enforced collection, particularly with regard to small, unsecured claims. The financial evidence which is provided to the United States Attorney must be current and complete and must disclose that the debtor has sufficient income to pay the debt, or unencumbered non-exempt assets, real or personal, which can be used to liquidate the debt. Generally, if there is insufficient income or unencumbered assets to meet the debtor's day-to-day "necessaries" (i.e., indispensable things, or things proper and useful, for day-to-day living, such as food, clothing, medical attention, and a suitable place of residence), the claim should not be referred to the United States Attorney for litigation and enforced collection. A good rule of thumb for determining whether there is a reasonable prospect for enforced collection of a substantial sum on a small, unsecured claim is that such a claim should not be referred unless the evidence provided discloses that the debtor has sufficient income to pay for "necessaries" and at least \$1800 over a 3-year period, or that the debtor has unencumbered non-exempt assets or property which is at least 10 times greater in value than the amount of the obligation.

## ITEM 45:

Provide any information which will assist the United States Attorney in locating real or personal property in which the United States has or may have a security interest. Describe and give the last known location of such property. Describe and attach security agreements or real estate or chattel mortgages which give the United States a security interest (e.g., papers in the agency's file which describe or show what property was pledged). Show the asset or fair market value of any such real or personal property (or chose in action), and information concerning any prior liens, mortgages, etc., on the pledged real or personal property listed. In the event the debtor is a corporation, provide any information which will assist the United States Attorney in locating the assets of the corporation.

ITEM 46: Provide any information which will assist the United States Attorney in locating other assets of the debtor (i.e., assets other than pledged property shown in Item 45). Particular care should be given to identifying non-exempt assets of the debtor (e.g., real estate which is not the homestead of the debtor, a second vehicle, recreational vessels, etc.). In the event of a corporate debtor, provide any information which will assist the United States Attorney in locating other assets of the corporation. If this information is unknown, show "Unknown."

#### VALUE OF CLAIM

ITEM 47: Show and explain the fair market or asset value of the claim, i.e., the amount of cash which may be realized as a result of litigation of the claim. Explain the basis for the value given. The agency's determination of the value of the claim should be based in part upon the ratio which the amount of the claim or debt bears to the amount of the debtor's assets and income which can be realized by enforced collection and upon the unencumbered value (after prior liens have been satisfied) of any property of the debtor in which the United States has a secured interest. The information provided should reflect the true value of the claim and, thus, enable the United States Attorney to more accurately determine the amount which the government is likely to recover by enforced collection. See the rule of thumb in the Note at Item 44, above, for determining whether there is a reasonable prospect for enforced collection of a substantial sum.

ITEM 48: With due regard to the debtor's ability to pay as defined by Item 44, above, show the agency's recommendation on the amount for which the claim can reasonably be settled or compromised. Explain the basis for the amount shown. This amount should bear a direct relationship to the debtor's assets and income which can be reached by garnishment, levy, or attachment. The agency's recommendation will provide the United States Attorney with the necessary

information and guidance for an informed consideration of any compromise offer or settlement the debtor may make. Furthermore, having such information beforehand will eliminate the delay and expense which would otherwise be necessary for the United States Attorney to obtain the agency's assessment of a debtor's compromise offer made after the claim has been referred to the United States Attorney.

#### TRANSFER OR DIRECT DEPOSIT OF FUNDS

ITEM 49: Show the name, title, complete mailing address and FTS telephone number of the agency official at the accounting code location, as set forth in Item 50 below, who is responsible for resolving any accounting problems which may arise with respect to the individual claim.

ITEMS 50 and 51: In the near future, monies collected by United States Attorneys will be deposited directly to the Treasury or to banks designated by the Treasury to receive such deposits. Under the system being developed, monies will be deposited to a Department of Justice Suspense Account and then, on a regular basis, funds will be transferred to the referring agencies. United States Attorneys' offices will provide on a regular basis accountings of the amounts of payments received from each debtor to the individuals within the agencies responsible for handling debtor claims.

To accommodate these inter-agency fund transfers (in accordance with the Treasury Fiscal Requirements Manual) the information requested in Items 50 and 51 is needed. Therefore, at Item 50 show the agency accounting location code/dispersing officer code/symbol/number to which the accounting documents on recovery from the debtor on referred claims should be initially forwarded. (Show the agency accounting location code/symbol/number where appropriate. If your agency does not have an accounting location code, show the dispersing office code/symbol/number.) At Item 51 show the Treasury appropriation/suspense account/fund account number (whichever is appropriate) to which any recovery from the debtor should be



"Complimentary  
Closing" Block:

credited. (Be sure to include the appropriate agency prefix.) [Note: Please remember that the amount of recovery representing court costs should always be deposited into Treasury Miscellaneous Receipts Account No. 003099, substituting your agency prefix for the two zeros in this symbol.]

[When using the "Letter" format] Show the name, title, complete mailing address, and FTS telephone number of the agency official who will sign the report.

"Agency Employee  
Responsible for  
Handling the  
Claim" Block:

Show the name, title, complete mailing address and FTS telephone number of the agency employee who is most knowledgeable of the history, facts and details of the individual claim and who is responsible for answering any questions or resolving any problems which may arise with respect to the individual claim.

"Attachments as  
Listed" Block:

List all supporting documentation which is included in the OCLR package. All documents provided should be legible.

## Department of Justice Demand Letter

U.S. DEPARTMENT OF JUSTICE  
UNITED STATES ATTORNEY

>[Debtor's full name]  
>[Debtor's mailing address]  
>  
>

>Re: [Name of Agency] Indebtedness  
>[Amount of claim]  
>[Type of overpayment]

Dear>[Mr./Mrs./Ms.]>[Debtor's surname]:

The [Name of Agency] claims that you are indebted to the United States for the amount shown above. The basis for the claim is set forth on the enclosed Certificate of Indebtedness. It is the responsibility of this office to file suit to collect debts owed to the United States after all efforts by the [Name of Agency] to collect have failed.

Unless payment in full is received within the next ten (10) days, we will be compelled to file suit against you in United States District Court to recover the full amount of the claim. In the latter event, court costs, United States Marshal's fees and interest will be added to the amount you now owe. Enforced collection can then be made by the United States Marshal who may be ordered to attach and sell any non-exempt property you have now or may acquire in the future.

Your check or money order for the amount shown above should be made payable to "Treasurer of the United States" and mailed to us in the enclosed self-addressed envelope within ten (10) days.

Only your full cooperation and prompt payment of the amount of the claim will make suit and enforced collection unnecessary.

Very truly yours,

>[Name]  
United States Attorney

Enclosure

[EXHIBIT 3]

United States Attorneys' Offices For Which a  
Department of Justice Demand Letter Should  
be Prepared and Included in the CCLR Package

Judicial District

Alabama, Middle  
Alabama, Southern  
Alaska  
Arkansas, Eastern  
Arkansas, Western  
California, Northern  
Connecticut  
Delaware  
Florida, Northern  
Georgia, Middle  
Hawaii  
Iowa, Northern  
Kansas  
Louisiana, Middle  
Mississippi, Southern  
Missouri, Eastern  
Missouri, Western  
Nebraska  
Nevada  
New Hampshire  
New York, Eastern  
New York, Southern  
New York, Western  
North Carolina, Middle  
North Carolina, Western  
Oregon  
Pennsylvania, Middle  
Puerto Rico  
Rhode Island  
South Carolina  
Tennessee, Middle  
Texas, Western  
Vermont  
Virginia, Western  
West Virginia, Northern

City of Headquarters Office

Montgomery  
Mobile  
Anchorage  
Little Rock  
Fort Smith  
San Francisco  
New Haven  
Wilmington  
Pensacola  
Macon  
Honolulu  
Cedar Rapids  
Topeka  
Baton Rouge  
Jackson  
St. Louis  
Kansas City  
Omaha  
Las Vegas  
Concord  
Brooklyn  
New York  
Buffalo  
Greensboro  
Asheville  
Portland  
Scranton  
Hato Rey  
Providence  
Columbia  
Nashville  
San Antonio  
Burlington  
Roanoke  
Wheeling

[Attachment to Exhibit 8]

## Department of Justice Acknowledgment "Comeback Letter"

U.S. DEPARTMENT OF JUSTICE  
UNITED STATES ATTORNEY

>[Name]  
>[Title]  
>[Agency]  
>[Mailing address]  
>

Re: Receipt of [Name of Agency] Claim  
>[Debtor's full name; LAST NAME, first name, middle name]  
>[Agency's file or claim identification number]  
United States Attorney's claim number:

Dear>

This is to acknowledge receipt of the above-referenced claim which was sent to this office for enforced collection. You will be advised of the success of our efforts in this regard in due course. If your future correspondence or other communication with this office relative to this matter references the debtor's full name and our civil claim number above, we will be able to respond more quickly. Please annotate your file accordingly.

Very truly yours,

>[Name]  
United States Attorney

[EXHIBIT 9]

## Department of Justice Deficiency or Declination Letter

U.S. DEPARTMENT OF JUSTICE  
UNITED STATES ATTORNEY

>[Name]  
>[Title]  
>[Agency]  
>[Mailing address]  
>

Re: [Name of Agency] Claim  
>[Debtor's full name; LAST NAME, first name, middle name]  
>[Agency's file or claim identification number]

Dear>

Our initial review of the above-captioned claim which you recently referred to this office for enforced collection revealed that the claim, as forwarded, does not meet the minimum standards for referral of such claims to the United States Attorney for litigation. As you know, the Federal Claims Collection Standards (4 C.F.R. §§101-105) require that certain information be forwarded to United States Attorneys with each claim.

The reason(s) why we consider this claim to be deficient and we presently decline to enforce collection of the claim through litigation is (are) indicated below.

- \_\_\_\_\_ Claim was not referred well within the time limited for bringing a timely suit against the debtor.
- \_\_\_\_\_ Claim was less than \$600.
- \_\_\_\_\_ Claim did not include the debtor's current residence address for service of complaint and summons.
- \_\_\_\_\_ Claim was not accompanied by credit data obtained within the last six months indicating the present or likely future availability of assets or income from which a substantial sum may be obtained by enforced collection proceedings.

[EXHIBIT 10]

\_\_\_\_\_ Claim was not accompanied by a summary and supporting documentation of the actions previously taken to collect (including agency demands for payment, personal interview with debtor) or compromise the claim.

\_\_\_\_\_ Claims Collection Litigation Report not adequately completed. See Item(s) \_\_\_\_\_. Please provide requested information or an explanation of why you cannot.

\_\_\_\_\_ Other.

If you are able to provide us with the above-indicated information as required by the Federal Claims Collection Standards, then you should resubmit the claim to us for appropriate action.

Very truly yours,

>[Name]  
United States Attorney

## U. S. ATTORNEYS' MAILING ADDRESS LIST

<u>JUDICIAL DISTRICT</u>	<u>HEADQUARTERS OFFICE</u>
Alabama - Northern	200 Federal Building 1800 Fifth Avenue North Birmingham, AL 35203
Alabama - Middle	Post Office Box 197 Montgomery, AL 36101
Alabama - Southern	Post Office Drawer E Mobile, AL 36601
Alaska	Federal Building & U.S. Courthouse 701 C Street, Room C-252 Mail Box 9 Anchorage, AK 99513
Arizona	4000 U.S. Courthouse 230 North First Avenue Phoenix, AZ 85025
Arkansas - Eastern	Post Office Box 1229 Little Rock, AR 72203
Arkansas - Western	Post Office Box 1524 Fort Smith, AR 72901
California - Northern	450 Golden Gate Avenue San Francisco, CA 94102
California - Eastern	3305 Federal Building 650 Capitol Mall Sacramento, CA 95814
California - Central	312 North Spring Street Los Angeles, CA 90012
California - Southern	940 Front Street Room 5-N-19, U.S. Courthouse San Diego, CA 92189
Colorado	1961 Stout Street Suite 1200 Federal Office Building Drawer 3615 Denver, CO 80294
Connecticut	Post Office Box 1824 New Haven, CT 06508

[EXHIBIT 11]

JUDICIAL DISTRICTHEADQUARTERS OFFICE

Delaware	J. Caleb Boggs Federal Building 844 King Street, Room 5001 Wilmington, DE 19801
District of Columbia	Room 2800 U. S. Courthouse 3rd & Constitution Avenue, N.W. Washington, DC 20001
Florida - Northern	100 North Palafox Street Room 307 Pensacola, FL 32581
Florida - Middle	Robert Timberlake Building 500 Jack Street, Room 410 Tampa, FL 33602
Florida - Southern	155 South Miami Avenue Miami, FL 33130
Georgia - Northern	Richard Russell Building Room 1800 75 Spring Street, S.W. Atlanta, GA 30335
Georgia - Middle	Post Office Box U Macon, GA 31202
Georgia - Southern	Post Office Box 8999 Savannah, GA 31412
Guam	Suite 502-A, PNH Building 238 O'Hara Street Agana, GU 96910
Hawaii	Room C-242 PJKK Federal Building Box 50183 300 Ala Moana Boulevard Honolulu, HI 96850
Idaho	Room 693, Federal Building 550 W. Fort Street, Box 037 Boise, ID 83724
Illinois - Northern	Everett McKinley Dirksen Building, Room 1500 S 219 S. Dearborn Street Chicago, IL 60604



JUDICIAL DISTRICTHEADQUARTERS OFFICE

Illinois - Southern

Room 330  
750 Missouri Avenue  
East St. Louis, IL 62202

Illinois - Central

Post Office Box 375  
Springfield, IL 62705

Indiana - Northern

Federal Building, Room 312  
507 State Street  
Hammond, IN 46320

Indiana - Southern

274 U. S. Courthouse  
46 East Ohio Street  
Indianapolis, IN 46204

Iowa - Northern

Post Office Box 4710  
Cedar Rapids, IA 52407

Iowa - Southern

122 U. S. Courthouse  
E 1st and Walnut Street  
Des Moines, IA 50309

Kansas

444 Quincy Street  
Topeka, KS 66683

Kentucky - Eastern

Post Office Box 1490  
Lexington, KY 40501

Kentucky - Western

USPO & Courthouse, Room 211  
601 West Broadway  
Louisville, KY 40202

Louisiana - Eastern

Hale Boggs Federal Building  
500 Camp Street  
New Orleans, LA 70130

Louisiana - Middle

352 Florida Street  
Baton Rouge, LA 70801

Louisiana - Western

Room 3B12  
Federal Building  
Shreveport, LA 71161

Maine

P. O. Box 1588  
Portland, ME 04104

Maryland

8th Floor, U. S. Courthouse  
101 W. Lombard Street  
Baltimore, MD 21201

JUDICIAL DISTRICTHEADQUARTERS OFFICE

Massachusetts

1107 John W. McCormack Fed. Bldg.  
USPO & Courthouse  
Boston, MA 02109

Michigan - Eastern

817 Federal Building  
231 W. Lafayette  
Detroit, MI 48226

Michigan - Western

399 Federal Building  
Grand Rapids, MI 49503

Minnesota

234 U. S. Courthouse  
110 South 4th Street  
Minneapolis, MN 55401

Mississippi - Northern

Post Office Drawer 886  
Oxford, MS 38655

Mississippi - Southern

Post Office Box 2091  
Jackson, MS 39205

Missouri - Eastern

U.S. Court & Custom House  
1114 Market Street, Room 414  
St. Louis, MO 63101

Missouri - Western

549 U. S. Courthouse  
811 Grand Avenue  
Kansas City, MO 64106

Montana

Post Office Box 1478  
Billings, MT 59103

Nebraska

Post Office Box 1228, DTS  
Omaha, NE 68101

Nevada

Box 16030  
Las Vegas, NV 89101

New Hampshire

Federal Building  
Concord, NH 03301

New Jersey

Federal Building  
Room 502  
970 Broad Street  
Newark, NJ 07102

New Mexico

Post Office Box 607  
Albuquerque, NM 87103

<u>JUDICIAL DISTRICT</u>	<u>HEADQUARTERS OFFICE</u>
New York - Northern	Post Office Box 1258 Federal Building Syracuse, NY 13201
New York - Southern	One St. Andrews Plaza New York, NY 10007
New York - Eastern	U. S. Courthouse 225 Cadman Plaza East Brooklyn, NY 11201
New York - Western	502 U. S. Courthouse Court & Franklin Streets Buffalo, NY 14202
North Carolina - Eastern	Post Office Box 26897 Raleigh, NC 27611
North Carolina - Middle	Post Office Box 1858 Greensboro, NC 27402
North Carolina - Western	Post Office Box 132 Asheville, NC 28802
North Dakota	Post Office Box 2505 Fargo, ND 58108
Ohio - Northern	Suite 500 1404 East Ninth Street Cleveland, OH 44114
Ohio - Southern	220 USPO & Courthouse 5th & Walnut Streets Cincinnati, OH 45202
Oklahoma - Northern	Room 460 U. S. Courthouse 333 West Fourth Street Tulsa, OK 74103
Oklahoma - Eastern	Post Office Box 1009 Muskogee, OK 74401
Oklahoma - Western	Room 4434 U. S. Courthouse & Federal Office Building Oklahoma City, OK 73102
Oregon	312 U. S. Courthouse 620 S.W. Main Street Portland, OR 97205

JUDICIAL DISTRICTHEADQUARTERS OFFICE

Pennsylvania - Eastern

3310 U.S. Courthouse  
601 Market Street  
Independence Mall West  
Philadelphia, PA 19106

Pennsylvania - Middle

Post Office Box 309  
Scranton, PA 18501

Pennsylvania - Western

633 USPO & Courthouse  
7th Avenue & Grant Street  
Pittsburgh, PA 15219

Puerto Rico

Federal Office Building  
Room 101  
Carlos E. Chardon Street  
Hato Rey, PR 00918

Rhode Island

Post Office Box 1401  
Providence, RI 02901

South Carolina

Post Office Box 2266  
Columbia, SC 29202

South Dakota

Post Office Box 1073  
Federal Building & Courthouse  
400 South Phillips Avenue  
Sioux Falls, SD 57102

Tennessee - Eastern

Post Office Box 872  
Knoxville, TN 37901

Tennessee - Middle

U. S. Courthouse  
801 Broadway, Room 879  
Nashville, TN 37203

Tennessee - Western

1026 Federal Office Building  
167 North Main Street  
Memphis, TN 38103

Texas - Northern

310 U. S. Courthouse  
10th & Lamar Streets  
Fort Worth, TX 76102

Texas - Southern

Post Office Box 61129  
Houston, TX 77208

Texas - Eastern

Post Office Box 1510  
Beaumont, TX 77704

JUDICIAL DISTRICTHEADQUARTERS OFFICE

Texas - Western

John H. Wood, Jr. Federal Bldg.  
655 East Durango Boulevard  
San Antonio, TX 78206

Utah

200 Post Office & Cthse. Bldg.  
350 South Main Street  
Salt Lake City, UT 84101

Vermont

Post Office Box 570  
Federal Building  
Burlington, VT 05402

Virgin Islands

Post Office Box 1440  
St. Thomas, VI 00801-1440

Virginia - Eastern

2nd Floor  
701 Prince Street  
Alexandria, VA 22314

Virginia - Western

Post Office Box 1709  
Roanoke, VA 24008

Washington - Eastern

Post Office Box 1494  
Spokane, WA 99210

Washington - Western

3600 Seafirst 5th Avenue Plaza  
800 Fifth Avenue  
Seattle, WA 98104

West Virginia - Northern

Post Office Box 591  
Wheeling, WV 26003

West Virginia - Southern

Post Office Box 3234  
Charleston, WV 25332

Wisconsin - Eastern

330 Federal Building  
517 East Wisconsin Avenue  
Milwaukee, WI 53202

Wisconsin - Western

Post Office Box 112  
Madison, WI 53701

Wyoming

Post Office Box 668  
Cheyenne, WY 82003

N. Mariana Islands

c/o U.S. Attorney's Office  
Post Office Box 2  
Agana, GU 96910

## 5 Expert Witnesses

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### Selection of Witnesses

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Administrative, civil, and criminal enforcement actions sometimes require the presentation of expert testimony on behalf of the Agency. Witnesses should be chosen for their direct knowledge of the circumstances surrounding the suspected violation. Below follows some guidelines to aid the EPA attorney in choosing witnesses for judicial proceedings.

#### Headquarters Witnesses

Many of the records pertaining to, and technical experts with knowledge of, regulations concerning pesticide products are located within the Registration Division at Headquarters. Witnesses from the Registration Division are available to testify on:

- The registration status of a pesticide;
- Whether a product is a pesticide or a device subject to FIFRA;
- Agency interpretations of labeling statements, directions for use, etc.; and
- The significance of a discrepancy as it relates to the sample's chemical composition, efficacy, or toxicity.

#### Regional Witnesses

Technical experts in the Regions will generally testify as to:

- Inspection procedures and the facts and findings surrounding an investigation; and
- Programmatic procedures such as inspection schemes, penalty calculations, FIFRA violations, etc.

Other Government Witnesses

EPA personnel often work with other Federal government personnel in developing casework, either through interagency agreements (IAGs) or memorandums of understanding (MOUs). Other government employees of agencies such as the Food and Drug Administration, the U.S. Department of Agriculture, or the Fish and Wildlife Service may be called upon to testify concerning:

- Test procedures, findings, and conclusions related to pesticide or device studies; and
- Information collected during an investigation but referred to EPA for enforcement.

Contractor Witnesses

Expert witnesses will occasionally have to be utilized under contract to testify as to:

- Test procedures, findings, and conclusions related to pesticide or device studies they have conducted; and
- Technical matters for which there are no Agency experts available for testimony.

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Procedures for Requesting Witnesses

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All requests for witnesses who are not regional personnel should be made in writing to the appropriate HQCDO. The HQCDO will, in turn, arrange for the proper witness to represent the Agency in court and will provide a status of the witness's availability to the requesting Region.

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Appearing as a Witness

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Vigorous enforcement programs will increase the probability that an inspector will be called upon to testify in court. By the time a case has entered the judicial system, inspectors and case proceedings personnel will have invested many hours in developing a sound program for prosecution. When a witness is called to testify, it is imperative that quality testimony is provided and a professional image is projected in the courtroom.

A witness, to be effective, must make statements that are understandable and must have them accepted as truth by the judge or jury. In addition to being truthful and honest, a witness' principal aim should be to make a favorable impression on the court. The guidelines presented in this section will help prepare the witness to be effective and credible.

### Personal Appearance and Conduct

Dress is important. A well-groomed, neatly attired witness makes a more favorable impression in the courtroom. Conduct should reflect the solemn nature of the judicial proceedings. In order that a witness presents the appropriate image, the following considerations should be kept in mind at all times.

Come to the courtroom prepared. Be thoroughly familiar with your facts. Pertinent time and dates should be checked. Order all documents and exhibits so that testimony will be presented without fumbling. Be on time when court opens and be available immediately when called to testify.

Try to avoid:

- Doing anything that may attract attention to you. Make yourself as inconspicuous as possible;
- Sitting in groups with more than two or three colleagues. Spread out in the courtroom;
- Whispering or talking to another person or causing any disturbance in the courtroom;
- Showing incredulity or surprise at any testimony given from the witness stand or at statements made by the defense attorney. Avoid expressing approval or disapproval of any testimony by nod, glance, or other gesture;
- Having anything in your mouth (such as gum, toothpick, tobacco, candy, or food);
- ~~Sitting within the enclosure unless instructed to do so;~~
- Discussing the case with the defendant or the defending attorney;
- Talking to the jurors or discussing the case within their hearing;
- Consulting with case personnel while court is in session, unless ~~directed to do so; and~~
- Holding conversations with principals or witnesses for the opposing side. If conversations are unavoidable, confine remarks to matters other than the trial.



Witness Stand Technique

When called to the witness stand, unless previously sworn, go directly to the desk of the Clerk of the Court to be sworn. Take the oath in a solemn manner. Then proceed to the witness chair. If you have a long or unusual name, give a card or paper with the correct spelling to the court stenographer. Assume and maintain proper posture, bearing, and demeanor. Sit erect, but do not appear stiff or tense. Attempt to project an image of poise and self-control.

Speaking. Speak in a clear, distinct, and well-modulated voice. When addressing a jury, look at and speak distinctly to them. Speak loud enough so that the farthest juror can hear you.

Use simple language. If the subject is technical or scientific, reduce the terminology to an understandable level or give definitions of terms used. Avoid idioms or language particular to your profession or to the Agency.

Notes. You may bring notes with you to the witness stand. However, do not bring your field notebook or any other documents you do not want the opposing side to examine. They have a right to see any notes you bring to the witness stand.

Do not hesitate to ask permission to refer to your notes when testifying, provided your notes were made at the time of, or immediately after, the event about which you are testifying. You should not be embarrassed if you cannot recall exact details without referring to your notes. Try not read long passages verbatim from your notes.

Answering Questions. Wait until a question is asked in its entirety before beginning to answer. Never attempt to answer a question you do not fully understand. Ask that the question be repeated or rephrased if its meaning is not clear. If you do not know the answer to a question, say so. Do not try to cover up a lack of knowledge of a particular subject.

Questions should be answered verbally—do not nod assent or shake your head. Answer only what is asked fully and to the point without volunteering information. Do not "spar" or attempt to match wits with the questioning attorney.

Be truthful, and answer all questions frankly, factually, and confidently. Try to limit your testimony to those facts about which you have first-hand knowledge. Anything else may be considered hearsay. Do not exaggerate; state the facts accurately.

Do not express opinions or conclusions unless you are testifying as an expert witness. You cannot assume expert knowledge in a field unless you are an expert by reason of your training and experience. If questioned on a subject beyond your scope, admit that the subject is outside your field or knowledge.

Try not to become listless or "dead pan" in your effort to appear impartial and unbiased. Be natural, candid, frank, and "alive." Conversely, you should not appear impatient or overly anxious to testify. Attempt to minimize nervous tendencies, such as arranging clothes, notes, etc.

Do not speak to the judge unless he or she asks you a question.

### Testifying Under Direct Examination

In a proceeding arising out of an Agency judicial enforcement action, direct or re-direct examinations will generally be conducted by an EPA attorney or a U.S. Attorney. The initial questions he or she will ask will seek to establish:

- Your identity, occupation, and qualifications; and
- The relevancy of your testimony to the proceedings.

Subsequent questions will allow you to relate your testimony to the court. In order to facilitate this questioning, you should:

- Try to give testimony in chronological order. Reveal your first connection with the case. Then give facts in the order they occurred. Your testimony should be memorized, if possible.
- If the opposing attorney objects to a question, do not try to get in an answer before the judge has ruled whether the question is proper.
- Do not try unnecessarily to help the questioning attorney. He will ask additional questions to bring out further details to complete your testimony.
- Be able to identify the defendant.

### Testifying Under Cross Examination

Cross examination is the questioning of witnesses by attorneys representing the opposing side. Under cross examination you may be subjected to vigorous questioning.

Do not be afraid to admit that you discussed your testimony with government attorneys. There is nothing improper in a practical discussion of your testimony with the attorneys.

The opposing counsel may attempt to intimidate you by attacking your veracity and integrity, by making uncomplimentary references to your qualifications or length of service, or by emphasizing errors you have made. Remain calm and answer any question asked unless an objection is raised and sustained. If the opposing counsel attempts to confuse you with rapid questions, answer the questions deliberately and at a comfortable

pace. Ask the attorney to repeat or rephrase any question that is unclear or confusing. If asked a double or "two-pronged" question, ask the attorney to restate it, or carefully answer each part separately.

Wait several seconds before you answer a question put to you in cross examination in order to give the U.S. Attorney an opportunity to object. Avoid, however, undue delays in answering. If an objection has been raised, do not answer any questions until a ruling on the objection has been made.

Do not lose your patience or temper while testifying. A cross-examining attorney often deliberately baits an irascible witness to anger the witness. Try to remain calm and unruffled. Do not become argumentative with the cross-examiner if your testimony is interrupted or for any other reason. Beware of questions to which the cross-examiner demands a "Yes" or "No" answer if such an answer will not reveal the entire truth. These are often leading questions. If a simple yes or no does not properly answer the question, inform the cross-examiner that the question cannot be so answered. If the cross examiner should misquote any of your earlier testimony, you may correct the misquote 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, discuss the matter with the U.S. Attorney.

You may be asked whether you regard certain persons in the field about which you are testifying as recognized authorities. This is often preparatory to asking you whether you agree with certain statements that those authorities have made. If your answer is no, that you do not recognize them as authorities, that line of cross-examination cannot be pursued. Unless you definitely have heard of the named persons and are familiar with their works and do recognize them as authorities, do not expose yourself by saying that you so recognize them.

#### Proper Conduct During Recess and After the Trial

During recess, continue to maintain the same demeanor as in the courtroom. Do not engage in loud conversation or joking, especially about the proceedings. Be as discreet as possible when making any comments that might be overheard.

After the trial, continue to conduct yourself in a manner that will bring credit to you and to the Agency. Make no public display of elation or disappointment over the outcome of the trial. If there is occasion to speak to the defendants, be courteous regardless of their demeanor.

## 6 Penalty Policies

The following items are used by the Agency in establishing its penalty policy guidelines:

- Guidelines for the Assessment of Section 14(a); Citation Charges for Violations
- Guidelines for Enforcing the Child-Resistant Packaging Regulation
- Memorandum (22 Apr 1975)—Interim Deviation From Civil Penalty Assessment Schedule
- Memorandum (11 Jun 1981)—FIFRA Enforcement Policy; Interim Penalty Guidelines



## ENVIRONMENTAL PROTECTION AGENCY

[FRL 243-3]

### CIVIL PENALTIES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RO- DENTICIDE ACT, AS AMENDED

#### Guidelines for the Assessment Section 14(a); Citation Charges for Violations

Final rules of practice governing proceedings conducted in the assessment of civil penalties under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) are being published today in the *Federal Register* at 39 FR 27656. The Environmental Protection Agency is publishing in conjunction with these final rules of practice two intra-Agency documents which are designed to instruct Agency personnel in the procedures to be followed in the assessment of civil penalties against violators of FIFRA.

These documents are (1) Guidelines for the Assessment of Civil Penalties Under Section 14(a) of FIFRA, and (2) Citation Charges for Violations of FIFRA.

As intra-Agency procedural documents, they are not required to be proposed and promulgated (5 U.S.C. 553(b) (A)). In the interest of the open administration of its regulatory authority, however, the Agency has determined to publish these procedural documents.

The Guidelines for the Assessment of Civil Penalties Under Section 14(a) of FIFRA appears in four sections. Section I, Application of the Civil Penalty Assessment Schedule, explains the derivation of the dollar penalty which is considered a base figure to be proposed for particular violations. It also provides a mechanism whereby Agency personnel may, within specified boundaries, exercise discretion in negotiating consent agreements and otherwise adapt the proposed penalty to the exigencies of special circumstances.

Section II, the Civil Penalty Assessment Schedule, lists violations of the Act, classified by the risk that each violation poses to man and the environment, i.e., by the gravity of each violation. Each of these violation classifications is divided into five size-of-business categories. Thus, the Assessment Schedule is a matrix consisting of gravity-of-violation/size-of-business cells. Within each cell is a dollar penalty which may be proposed to be assessed against a person of a given business size who violates the Act in the specified manner.

Section III, the Civil Penalty Assessment Worksheet, is to be used by Agency

personnel in the preparation of the complaint. This Worksheet is to be prepared and retained as an on-going office record of the proceeding, and as a memorandum of the complainant's deliberations concerning the violations cited.

Section IV consists of an item-by-item explanation to Agency personnel regarding procedure for completing and maintaining the Worksheet.

The Citation Charges for Violations of FIFRA is a listing of the citation charges (and code) utilized by the Agency to translate violations of the Act into formal charges against the alleged violator. The charges refer to the specific sections of the Act (or of prior legislation), which are alleged to have been violated. From time to time, as circumstances dictate, these statutory references will be amended.

JOHN QUAKLES,  
Acting Administrator.

JULY 12, 1974.

GUIDELINES FOR THE ASSESSMENT OF CIVIL  
PENALTIES UNDER SECTION 14(A) OF THE  
FEDERAL INSECTICIDE, FUNGICIDE, AND RO-  
DENTICIDE ACT, AS AMENDED

[7 U.S.C. 136 i(a)]

#### SECTION I: APPLICATION OF CIVIL PENALTY ASSESSMENT SCHEDULE

A. Purpose. These Guidelines provide direction to Agency personnel assessing civil penalties under section 14(a) (3) of the Act. That section provides:

In determining the amount of the penalty the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business and the gravity of the violation.

These Guidelines are designed to insure to the extent practicable, that generally comparable penalties will be assessed in different regions for similar violations.

B. Determination to apply the civil penalty remedy. (1) Threshold decision and complaint. Prior to the application of the Civil Penalty Assessment Schedule, (section II of this document), complainant must determine from section 6 of the Pesticides Enforcement Division Case Proceedings Manual, entitled "Enforcement Criteria," whether the violation which is alleged to have been committed would, standing alone, warrant a civil penalty assessment. Where a penalty assessment is warranted, complainant must then identify the alleged violation in the listing of precise citation charges as set forth in the Appendix to the Case Proceedings Manual. This charge code has been revised and retitled "Citation Charges for Violations of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended [7 U.S.C. 136 et seq.]" (This citation charge code is published hereinafter as Appendix II.) The complainant must then prepare a complaint setting forth such charges with specificity

and proposing to assess a civil penalty which is the sum of the independently assessable charges contained in the complaint.

(2) *What constitutes an independently assessable charge.* A separate civil penalty shall be assessed for each violation of the Act which results from an independent act (or failure to act) of the respondent and which is substantially distinguishable from any other charge in the complaint for which a civil penalty is to be assessed. In determining whether a given charge is independent of and substantially distinguishable from any other charge for purposes of assessing separate penalties, complainant must consider whether each provision requires an element of proof not required by the other. Thus, not every charge which may appear in the complaint shall be separately assessed. Where a charge derives primarily from another charge cited in the complaint for which a penalty is proposed to be assessed, the subsequent charge may not warrant a separate assessment. The complaint will propose to assess an appropriate civil penalty for each independent and substantially distinguishable charge.

(3) *Use of notice of warning and civil penalty warning citation.* (a) *Notice of warning.* A written notice of warning pursuant to section 9(c)(3) of the Act may be issued by complainant in the event of a minor violation of the Act which, standing alone, would not warrant a civil penalty assessment, where it appears to the Agency that the public interest would be adequately served thereby. In determining whether a notice of warning adequately serves the public interest, the Agency may consider the history of compliance and evidence of good faith of the person charged.

(b) *Civil penalty warning citation.* In accordance with section 14(a)(3) of the Act, a civil penalty warning citation shall be issued to any private applicator or to any other person (not including registrants, commercial applicators, wholesalers, retailers or other distributors) who has never before received a civil penalty warning citation from complainant, and who has never before been issued a complaint for any prior violation of the Act.

C. *Proposing the amount of the civil penalty in the complaint.* For the purpose of determining the amount of a proposed civil penalty for specification in the complaint, complainant will consult the Civil Penalty Assessment Schedule (section II of this document). This Assessment Schedule categorizes potential violations on the basis of (1) the gravity of the violation and (2) the size of business of the person charged.<sup>1</sup> Graduated penalties are set out in a matrix which anticipates various combinations of these two factors. Each intersection of violation gravity and business size constitutes a cell of the matrix. Within each cell is a dollar amount representing the penalty base figure. This base figure constitutes the dollar amount from which the civil penalty pro-

<sup>1</sup> This penalty schedule does not apply to private applicators and users (not including registrants, commercial applicators, wholesalers, retailers, or other distributors.)

posed for each independently assessable charge may be computed.

(1) *Factors considered in determining the proposed civil penalty.* (a) *Gravity of violation.* One determinant of the amount of a proposed civil penalty is the gravity of the violation. The gravity of any violation is a function of (1) the potential that the act committed has to injure man or the environment; (2) the severity of such potential injury; (3) the scale and type of use anticipated; (4) the identity of the persons exposed to a risk of injury; (5) the extent to which the applicable provisions of the Act were in fact violated; (6) the particular person's history of compliance and actual knowledge of the Act; and (7) evidence of good faith in the instant circumstance.

(b) *Size of business.* The appropriateness of a given penalty is also a function of the size of the business of the person alleged to have violated the Act. Five size gradations of the person are utilized in the Civil Penalty Assessment Schedule. Category I encompasses all firms whose gross sales (total business revenues from all business operations) for the prior fiscal year were less than \$100,000. Category II encompasses all firms whose gross sales for the prior fiscal year were between \$100,000 and \$400,000. Category III encompasses all firms whose gross sales for the prior fiscal year were between \$400,000 and \$700,000. Category IV encompasses all firms whose gross sales for the prior fiscal year were between \$700,000 and \$1,000,000. Category V encompasses all firms whose gross sales exceeded \$1,000,000. [If the data for the last fiscal year is demonstrably unrepresentative of the general performance of the business, gross operating revenues for the three previous years may be analyzed in determining which size category is appropriate.]

(c) *Inability to continue in business.* The Act requires the Agency to consider the effect of the proposed penalty upon the ability of the person charged to continue in business. It shall be presumed initially that assessment of a civil penalty will not affect the ability of the person charged to continue in business. The person charged is notified in the complaint of his right under the statute to consideration of his financial condition in mitigation of the penalty proposed. He may submit financial information indicating the adverse effect of the proposed penalty upon his ability to continue in business. Such information, if bona fide shall be considered in reducing the penalty proposed insofar as is necessary to permit the person charged to continue in business.

(2) *Using the civil penalty assessment schedule to arrive at the proposed civil penalty.* Violations, ordered according to their gravity, are listed along the vertical axis of the Civil Penalty Assessment Schedule. The coded citation charges which correspond to specific violations of the Act (as set forth in the Appendix to the Case Proceedings Manual and published herein as Appendix II) are also enumerated along the vertical axis. The size-of-business gradations run along the horizontal axis. Each independently assessable charge is translated into a dollar

penalty assessment by (1) locating the appropriate charge on the charge code of the Assessment Schedule, and then (2) following that charge across the row of business size until reaching the appropriate business size entry. Each cell in the Assessment Schedule corresponds to a given level of gravity for the exact violation alleged to have been committed and to a given size-of-business category.

Within each gravity/size-of-business cell, there is a dollar amount representing the penalty base figure. In arriving at a civil penalty proposed to be assessed for a given charge, complainant may deviate as much as ten per cent (10%) above or below this base figure. In determining whether to assess the proposed penalty above or below the base figure, complainant shall consider those criteria outlined in section I(C)(1)(a) above. For example, if the product involved is a highly toxic pesticide, or if the person charged has actual knowledge of the Act, has a history of non-compliance, and has not evidenced good faith in his dealings with the Agency arising out of the current alleged violation, the proposed civil penalty should be assessed above the base figure.<sup>2</sup>

D. *Adjusting the proposed civil penalty.* Upon an answer by the person charged (respondent) to a civil complaint, it is foreseeable that circumstances may arise which will necessitate adjustment of the proposed civil penalty.

(1) *Negotiations involving only the amount of penalty.* In some cases respondent may admit to all jurisdictional and factual allegations charged in the complaint and may, in lieu of a public hearing, desire a settlement conference limited to the amount of the proposed penalty. In the absence of "special circumstances" (see section I(D)(3) below), a settlement conference may be conducted to consider the amount of the proposed penalty. In such event, the burden is on respondent to raise at such conference factors which may cause the Agency to mitigate the proposed penalty. If, in the Agency's judgment, such mitigating factors are produced and such reduction would serve the public interest, the Agency may lower the proposed penalty as much as forty percent (40%).

In no case is such reduction mandated, nor should such reduction occur in the absence of an appropriate showing by respondent. Likewise, reduction of the final penalty need not extend to the full amount of forty percent (40%) below the proposed penalty. The total final penalty may not be reduced by more than forty percent (40%) below the civil proposed penalty without a showing of "special circumstances" under section I(D)(3) below.

(2) *Factual changes.* (a) *New non-factual information.* Upon presentation by respondent of facts and circumstances relating to the gravity of the violation which were unknown to complainant at the time the complaint was issued, a new penalty base figure may be proposed. Where these additional

facts indicate that the original charges are not appropriate, new charges shall be made as required by the circumstances. A new penalty shall be calculated by reference to the cells in the matrix which correspond to the new charges.

(b) *Change in size of business.* Upon presentation by respondent of reliable data demonstrating that his business size is other than that employed by complainant in computing the proposed civil penalty, new base penalty figures shall be calculated by reference to the cells in the matrix which correspond to the new size-of-business designation.

(c) *Inability to continue in business.* An unlimited adjustment may be made in the proposed civil penalty upon a showing by respondent that the proposed penalty will have a significant adverse effect upon his ability to continue in business. The burden of providing the information supporting the contention that the proposed penalty will have such adverse effect rests upon respondent. A determination of such adverse effect shall be made only upon an analysis by complainant of certified financial records of all business operations of respondent. Such records shall be provided to the Agency at respondent's expense and shall conform to generally recognized accounting procedures.

(3) *Special circumstances.* Should a case arise in which complainant determines that there are no grounds for adjustment of the proposed penalty based on either new financial or other facts or on a showing of inability to continue in business, and that equity cannot be served by adjusting the proposed penalty the allowable forty percent (40%), the Regional Director of Enforcement may seek concurrence by the Director of the Pesticides Enforcement Division in making an extraordinary adjustment in the proposed penalty. In such case, a "special circumstances" statement shall be sent to the Director of the Pesticides Enforcement Division setting forth with particularity (1) the facts of the case involved; (2) why the penalty provided by the Assessment Schedule would be inequitable; (3) how all methods for adjusting or revising the unadjusted penalty will not adequately resolve the inequity; and (4) the manner in which such an extraordinary adjustment in the penalty will effectuate the purposes of the Act. Concurrence may be written or oral. All documentation of adjustment in such a case should be retained in the Regional Office.

E. *Computation of the civil penalty.* The Civil Penalty Assessment Worksheet (see Section III) shall be used to compute the final proposed civil penalty and to record any subsequent adjustment to that proposed amount in accordance with section I (D). The Worksheet serves as a guide to complainant in arriving at a final civil penalty, as an office record of the on-going case, and as a memorandum of complainant's deliberations concerning the violations cited. The Worksheet need not be sent to the respondent as part of the complaint but should be made available to him upon request. Detailed instructions for completing the proposed penalty and adjusting the Worksheet appear in section IV.

<sup>2</sup> In no case may the proposed penalty be an independently assessable charge under 95.000.



## SECTION III: CIVIL PENALTY ASSESSMENT GUIDELINES

GRAVITY OF VIOLATION

SIZE OF BUSINESS

CHARGE  
CODE

REGISTRATION VIOLATIONS					
<u>Section One: Registration.</u>					
E1	1. Non-Registered.				
	A. No Knowledge	I	II	III	IV
	B. Knowledge/No Application Submitted	220	350	1210	1870
	C. Application Pending	220	800	1780	2720
	D. Registration Denied or Cancelled	220	700	1840	2480
	E. Registration Suspended	500	1250	2730	4290
E15	2. Imitation Product.				
	Product is an imitation of or offered for sale under the name of another pesticide.	I	II	III	IV
		500	1250	2730	4290
LABELING VIOLATIONS					
<u>Section One: Precautionary Statements.</u>					
E2	1. Deficient Precautionary Statements: Lacks Signal Word and/or Caution: Keep Out of Reach of Children.				
	A. Toxicity Level: Danger	I	II	III	IV
	B. Toxicity Level: Warning	280	700	1840	2480
	C. Toxicity Level: Caution	220	500	1780	2720
	D. Toxicity Level: Caution	120	300	940	1020
	(The severity of this violation is based on the level of toxicity of the material.)				
E3	2. Deficient Precautionary Statements: Lacks Required Precautionary Labeling.				
	A. Adverse Effects Highly Probable	I	II	III	IV
	B. Adverse Effects Unknown	500	1250	2730	4290
	C. Adverse Effects Not Probable	280	700	1840	2480
	D. Adverse Effects Not Probable	120	300	940	1020
	(The severity of this violation is based on the level of toxicity of the material.)				
E16	3. Deficient Precautionary Statements: Lacks Symbols and/or Statements.				
	Highly Toxic Material (Can only be considered severe)	I	II	III	IV
		5000	5000	5000	5000
E14	4. Deficient Precautionary Statements: Precautionary Labeling not Prominently or Conspicuously Displayed.				
	A. Toxicity Level: Danger	I	II	III	IV
	B. Toxicity Level: Warning	280	700	1840	2480
	C. Toxicity Level: Caution	220	500	1780	2720
	D. Toxicity Level: Caution	120	300	940	1020
	(The severity of this violation is based on the level of toxicity of the material.)				

## Section Two: Unwarranted Statements with Respect to Product Safety.

E13

## 1. False or Misleading Safety Claim.

	I	II	III	IV	V
A. Adverse Effects Highly Probable	800	1250	2750	4250	5000
B. Adverse Effects Unknown	280	700	1540	2380	2800
C. Adverse Effects Not Probable	120	300	660	1020	1200

E17

## 2. Claims Differ from Those Accepted in Connection with Product's Registration.

	I	II	III	IV	V
A. Claims Unacceptable					
1. Adverse Effects Highly Probable	800	1250	2750	4250	5000
2. Adverse Effects Unknown	280	700	1540	2380	2800
3. Adverse Effects Not Probable	120	300	660	1020	1200
B. Claims Would Be Acceptable	100	250	550	850	1000
C. Economic Fraud	280	700	1540	2380	2800

## Section Three: Directions for Use.

E6

## 1. Inadequate Directions for Use.

	I	II	III	IV	V
A. Likely to Result in Mishandling or Misuse	800	1250	2750	4250	5000
B. Likelihood of Mishandling or Misuse Unknown	280	700	1540	2380	2800
C. Not Likely to Result in Mishandling or Misuse	120	300	660	1020	1200
D. Result in Illegal Residues					
1. Probable	800	1250	2750	4250	5000
2. Not Probable	280	700	1540	2380	2800
E. Inefficacious (Economic Fraud)					
1. Total	800	1250	2750	4250	5000
2. Partial	280	700	1540	2380	2800

E17

## 2. Directions for Use Differ from Those Accepted in Connection with Product's Registration.

	I	II	III	IV	V
A. Directions Unacceptable					
1. Likely to Result in Mishandling or Misuse	800	1250	2750	4250	5000
2. Likelihood of Mishandling or Misuse Unknown	280	700	1540	2380	2800
3. Not Likely to Result in Mishandling or Misuse	120	300	660	1020	1200
B. Directions Would Be Acceptable	100	250	550	850	1000
C. Inefficacious (Economic Fraud)					
1. Total	800	1250	2750	4250	5000
2. Partial	280	700	1540	2380	2800

## Section Four: Defective Ingredient Statement.

E6

	I	II	III	IV	V
A. Totally Lacking					
1. Toxicity Level Danger	800	1250	2750	4250	5000
2. Toxicity Level Warning	280	700	1540	2380	2800
3. Toxicity Level Caution	120	300	660	1020	1200
B. Formulation Differs (Supported by Chemical Analysis)					
1. Adverse Effects Highly Probable	800	1250	2750	4250	5000
2. Adverse Effects Unknown	280	700	1540	2380	2800
3. Adverse Effects Not Probable	120	300	660	1020	1200
C. Formulation Differs	120	300	660	1020	1200

Section Five: Failure to Bear Net Weight Statement.

	I	II	III	IV	V
Failure to bear required statement of net weight or content	120	300	600	1020	1200

Section Six: Failure to Bear Name and Address.

	I	II	III	IV	V
Lacks name and address of producer, registrant or person for whom manufactured	120	300	600	1020	1200

Section Seven: Detached, Altered, Defaced, or Destroyed Labeling.

1. Labeling is Detached, Altered, Defaced or Destroyed

	I	II	III	IV	V
A. Adverse Effects Highly Probable	300	1250	2750	4250	5000
B. Adverse Effects Unknown	280	700	1540	2380	2800
C. Adverse Effects Not Probable	120	300	600	1020	1200

(The severity of this violation is based upon the level of toxicity of the material, as well as upon the nature of the required labeling which was knowingly detached, altered, defaced or destroyed.)

2. Coloration

	I	II	III	IV	V
Not Colored or Discolored as Required	300	1250	2750	4250	5000

ANALYTICAL TEST RESULTS: FORMULATION VIOLATIONS

1. Chemical Defectiveness

	I	II	III	IV	V
A. Adverse Effects Highly Probable	500	1250	2750	4250	5000
B. Adverse Effects Unknown	340	850	1870	2890	3400
C. Adverse Effects Not Probable	180	450	990	1530	1800
D. Inefficacious					
1. Total	500	1250	2750	4250	5000
2. Partial	280	700	1540	2380	2800

2. Net Weight Deficiency

	I	II	III	IV	V
Net Weight Less Than Stated on Label	180	450	990	1530	1800

3. Chemical Contamination

	I	II	III	IV	V
A. Significant Levels	500	1250	2750	4250	5000
B. Trace Levels	280	700	1540	2380	2800

4. Highly Overformulated

	I	II	III	IV	V
A. Adverse Effects Highly Probable	500	1250	2750	4250	5000
B. Adverse Effects Unknown	280	700	1540	2380	2800
C. Adverse Effects Not Probable	120	300	600	1020	1200
D. Inefficacious					
1. Total	500	1250	2750	4250	5000
2. Partial	280	700	1540	2380	2800

## EFFICACY VIOLATIONS

## Section One: Disinfectants

## Ineffective Disinfectants

	I	II	III	IV	V
A. Hospital Use					
1. Kills neither <i>S. aureus</i> nor <i>S. choleraesuis</i>	5000	5000	5000	5000	5000
2. Kills only one of the above listed organisms	4000	4000	4000	4000	4000
B. Non-Hospital Use					
1. Kills neither of the above listed organisms	500	1250	2750	4250	5000
2. Kills only one of the above listed organisms	250	625	1375	2125	2500
C. Fails to kill <i>Trichophyton interdigitale</i>	280	700	1540	2380	2800

## Section Two: Rodenticides

## Ineffective Rodenticides

	I	II	III	IV	V
A. Completely Ineffective	500	1250	2750	4250	5000
B. Partially Effective	280	700	1540	2380	2800

## USE VIOLATIONS

## 1. Use or Disposal of a Pesticide in a Manner Inconsistent with its Labeling

	I	II	III	IV	V
A. Adverse Effects Highly Probable	500	1250	2750	4250	5000
B. Adverse Effects Unknown	280	700	1540	2380	2800
C. Adverse Effects Not Probable	120	300	660	1020	1200

## 2. Use or Disposal Contrary to the Provisions of an Experimental Use Permit

	I	II	III	IV	V
A. Knowledge (of the experimental use permit)	500	1250	2750	4250	5000
B. No Knowledge (of the experimental use permit)	100	250	550	850	1000
C. Shipments made after the expiration of experimental use permit	5000	5000	5000	5000	5000

(Action may always be taken against the holder of the experimental use permit.)

2. Stop Sale, Use or Removal Order					
	I	II	III	IV	V
E19	A. Violation of a Stop Sale, Use or Removal Order	5000	5000	5000	5000
	B. Failure to provide names and addresses of recipients of products believed to be in violation of the Act for purposes of issuing a Stop Sale, Use or Removal Order	500	1250	2750	4250
					5000
4. Violation of a Suspension Order					
E31		I	II	III	IV
	A. Knowledge of the Order	5000	5000	5000	5000
	B. No Knowledge of the Order	120	300	660	1020
					1200
5. Violation of a Cancellation Order					
E32		I	II	III	IV
	A. Knowledge of the Order	500	1250	2750	4250
	B. No Knowledge of the Order	100	250	550	850
					1000
6. Tests on Human Beings					
E36		I	II	III	IV
	Use of pesticide in tests on human beings in violation of the Act	5000	5000	5000	5000
					5000
MISCELLANEOUS VIOLATIONS					
1. Books and Records					
E39		I	II	III	IV
	A. Failure to maintain books and records as required under section 8(a)	420	1050	2310	3570
E25					
	B. Failure to allow inspection of books and records required to be maintained	420	1050	2310	3570
					4200
2. Production and Distribution Data					
E37		I	II	III	IV
	Failure to submit required reports of production or distribution data required under section 7(c)	500	1250	2750	4250
					5000
3. Inspection of Establishments; Sample Collection					
E26		I	II	III	IV
	Failure to allow inspection of an establishment or refusal to allow sampling of a pesticide	500	1250	2750	4250
					5000
4. Failure to Register Producer Establishment					
E33		I	II	III	IV
	A. Knowledge of Registration Requirement	420	1050	2310	3570
	B. No Knowledge of the Registration Requirement	180	450	990	1530
					1800

E34

## 5. Falsified All or Part of an Application

	I	II	III	IV	V
A. Registration Application	500	1250	2750	4250	5000
B. Experimental Use Permit Application	500	1250	2750	4250	5000
C. Confidentiality Status	500	1250	2750	4250	5000
D. Submitted False Production Data	500	1250	2750	4250	5000

E27

## 6. False Guarantee

	I	II	III	IV	V
Manufacturer Gave a False Guarantee	500	1250	2750	4250	5000

## MINOR VIOLATIONS

There are a number of minor violations which may be deemed not serious enough, standing alone, to warrant the assessment of any civil penalty. In the following instances, provided the public interest would be served thereby, the Agency may determine not to assess a civil penalty:

E6

1. Ingredient statement did not appear on the front panel of the immediate container.

E7

2. The term "Inert Ingredient" was less prominently displayed than the term "Active Ingredient".

E9

3. Label failed to bear registration number.

E10

4. Label failed to bear the required statement of net weight.

E12

5. Label failed to bear name, brand, or trademark under which the product was sold.

	I	II	III	IV	V
Where charge number 3(E9) appears in combination with any two of the other above charges.	120	300	660	1020	1200

## WORKSHEET (Reverse side)

## Deriving the Modified Penalty Base Figure

## (7) Modification of the Penalty Base Figure (under Item (6))

Date of Modification \_\_\_\_\_

Reasons for Modification \_\_\_\_\_

## Adjusting the Proposed Civil Penalty

## (11) Negotiation of Penalty Amount

Date of Conference \_\_\_\_\_

Amount Offered by Respondent \$ \_\_\_\_\_

Data Offered by Respondent in Support of  
Reduction \_\_\_\_\_

Total Final Penalty Assessed \$ \_\_\_\_\_

Substantiation \_\_\_\_\_

## (15) Factual Changes

Date of Conference \_\_\_\_\_

New Facts:

Nature \_\_\_\_\_

Substantiation \_\_\_\_\_

☐ A Determination of New Charges or of New  
Size-of-Business Designation  
(new worksheet)☐ B Determination of Special CircumstancesDate of Memorandum \_\_\_\_\_  
(attach)

Total Recommended Penalty \$ \_\_\_\_\_

Date of Concurrence \_\_\_\_\_

Total Final Penalty  
Assessed \$ \_\_\_\_\_

## (16) Inability to Pay

Date of Conference \_\_\_\_\_

Amount Offered by Respondent \$ \_\_\_\_\_

Financial Data Offered by Respondent in  
(source and summary) \_\_\_\_\_

Total Final Penalty Assessed \$ \_\_\_\_\_

Prepared by \_\_\_\_\_

Date \_\_\_\_\_

**SECTION III: CIVIL PENALTY ASSESSMENT WORKSHEET**

Name of Respondent \_\_\_\_\_ 1. Complaint I.D. No. \_\_\_\_\_ 6. Date Final Order Sent \_\_\_\_\_  
 Address of Respondent \_\_\_\_\_ 2. Date Complaint Issued \_\_\_\_\_ 7. Date Remittance Rec'd \_\_\_\_\_  
 \_\_\_\_\_ 3. Date Answer Rec'd \_\_\_\_\_ 8. History of Compliance  
 4. Date Default Order Sent \_\_\_\_\_ a. Prior Action # \_\_\_\_\_  
 5. Date Consent Agreement Signed \_\_\_\_\_ b. Knowledge: Yes \_\_\_\_\_ No \_\_\_\_\_  
 c. Good Faith: Yes \_\_\_\_\_ No \_\_\_\_\_

		Proposed Penalty				Adjusted Penalty			Final Penalty
(1) Charge Code Number	(2) Primary Charge(s)	(4) Penalty Base Figure (\$ amount in matrix cell)	(5) Percentage (%) Increase or Decrease (not to exceed 10% if applied)	(6) Modified Penalty Base Figure (\$ reflecting % increase or decrease if applied)	(8) Proposed Penalty	(10) Minimum Negotiable Penalty (\$ reflecting 40% of proposed penalty)	(12) Percentage (%) Decrease (not to exceed 40% if applied)	(13) Negotiated Penalty Amount (\$ reflecting % decrease if applied)	(14) Final Civil Penalty Amount (\$)
	(3) Lesser Included Charge(s)								

Prepared by \_\_\_\_\_

Concurrence by \_\_\_\_\_

(9) Total Proposed Penalty \$ \_\_\_\_\_

(17) Total Final Civil Penalty Assessed \$ \_\_\_\_\_

(18) Total Final Civil Penalty Imposed \$ \_\_\_\_\_





Guidance for Enforcement  
of the  
Child-Resistant Packaging Regulation

The Child-Resistant Packaging (CRP) regulation<sup>1</sup> (44 Federal Register 13019) was promulgated March 9, 1979 pursuant to Section 25(c)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Since the Enforcement Criteria of the FIFRA Case Proceedings Manual, the Citation Charges for Violations of the FIFRA, As Amended (39 Federal Register 27721) and the Guidelines for the Assessment of Civil Penalties Under Section 14(a) of the FIFRA (39 Federal Register 27711) were written prior to the CRP regulation, they do not incorporate guidance for the enforcement of the CRP regulation.

The Pesticides and Toxic Substances Enforcement Division (PTSED) is issuing this guidance outlining additions and modifications to the above documents to facilitate enforcement of the CRP regulation by the Regions.

Part I of this guidance deals with new enforcement criteria to be added to the Case Proceedings Manual.

Part II of this guidance deals with other changes to be made to the Citation Charges in the Case Proceedings Manual, and to the Guidelines for the Assessment of Civil Penalties Under Section 14(a) of the FIFRA, also found in the Case Proceedings Manual. One charge is added and another expanded, and several penalty matrices are added.

1. A summary of the requirements of the CRP regulation may be found in the document, "Strategy for the Enforcement of the Child-Resistant Packaging Regulation Pursuant to FIFRA."

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Part I: Use of New Enforcement CriteriaExplanation of Mitigating Circumstances in Enforcement Criteria

Enforcement criteria in the Case Proceedings Manual indicate the appropriate level of enforcement action for particular violations of FIFRA. Until December 31, 1981, PTSED's policy regarding the appropriate level of enforcement action for violations of the CRP regulation will take into account the following two mitigating circumstances:

- Registrant's lack of knowledge of the CRP requirements.
- Registrant's good faith efforts prior to March 9, 1981 to comply with the CRP requirements.

After December 31, 1981, registrants can reasonably be expected to have knowledge of the CRP requirements, and can reasonably be expected to have products in CRP despite delays or problems.

The PTSED recognizes the following circumstances as evidence of knowledge of the CRP requirements:

- Some, but not all, products are in CRP.
- Registrant commented on CRP proposed regulations.
- Registrant contacted EPA regarding CRP requirements.
- Registrant filed for an exemption.
- Registrant contracted with packaging manufacturer for CRP closures or packages.
- Registrant contracted or began actual testing of toxicity or package effectiveness.

The PTSED recognizes that the following circumstances could be evidence of good faith efforts on the part of a registrant to comply:

- Registrant contracted with packaging manufacturer for CRP closures or packages prior to March 9, 1981.
- Registrant contracted or began actual testing of toxicity or package effectiveness prior to March 9, 1981.

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Use of Enforcement Criteria

If a registrant subject to the CRP regulation is found to be in violation, Regional enforcement personnel should determine if either of the above mitigating circumstances exists. After determining the applicability of mitigating circumstances, Regional enforcement personnel should refer to the Enforcement Criteria (See p.5) for the appropriate level of enforcement action.

When either of the mitigating circumstances apply, Regional enforcement personnel shall exercise prosecutorial discretion that is conditional upon submission and approval of a Compliance Schedule. Regional enforcement personnel shall issue a Notice of Warning (See Appendix 1), requiring the registrant to submit a Compliance Schedule within twenty (20) days of the Notice of Warning.

When neither mitigating circumstance applies, Regional enforcement personnel shall assess a civil penalty, but shall also exercise prosecutorial discretion by not issuing a Stop Sale, Use, or Removal Order. This exercise of prosecutorial discretion is conditional upon submission and approval of a Compliance Schedule. Regional enforcement personnel shall explain in the letter accompanying the Notice of Civil Complaint and Notice of Opportunity for Hearing that the registrant must submit a Compliance Schedule within twenty (20) days of the letter.

Explanation of Compliance Schedule

Regional enforcement personnel shall negotiate a Compliance Schedule with the registrant, and shall approve or disapprove the Schedule within 45 days of the date of the Notice of Warning. Enforcement personnel shall notify the registrant that the Compliance Schedule has been received, and shall request further information if needed. Registrants should respond to requests for information as soon as possible to meet the 45 day deadline. Additionally, Regional enforcement personnel may wish to contact the Registration Division's packaging expert, Rosalind Gross at 8-557-7780, for assistance in determining a time frame for compliance in the case of uncertainty or dispute with the company. After enforcement personnel approve a Compliance Schedule, they shall forward a copy of the Schedule to the Compliance Monitoring Branch of PTSED.

1. Regional enforcement personnel are expected to handle case development and legal matters. States, who are conducting compliance monitoring activities, in most cases do not currently regulate child-resistant packaging of pesticides.

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The Compliance Schedule should show a timetable for achieving compliance within, at most, 6 months of the date of the Notice of Warning. However, compliance should be achieved no later than December 31, 1981, even if this requires a timetable of less than 6 months. Additionally, the Compliance Schedule should list names of companies or organizations that will be assisting the registrant in testing toxicity or package effectiveness.

When registrants fail to negotiate a Compliance Schedule, or fail to meet their Compliance Schedule, Regional enforcement personnel will no longer exercise prosecutorial discretion. Such registrants are still in violation of the CRP regulation if they continue to release for shipment products which require CRP but are not in CRP. Without the exercise of prosecutorial discretion, such violations are subject to a civil penalty assessment and Stop Sale, Use, or Removal Order (See Part II: Violation 1: Misbranding, p.7, for an explanation of the misbranding violation).

Regional enforcement personnel may grant extensions to Compliance Schedules if the registrant can present a reasonable explanation of problems or delays arising in efforts to comply. No extension shall be granted to a Compliance Schedule allowing noncompliance to continue past December 31, 1981, unless approved by PTSED. Requests for extensions past December 31, 1981, with a detailed explanation of the need for the extension, must be made to the Director of PTSED.

#### Exception to Enforcement Criteria

Prior to inspection, a registrant may volunteer the information that its product, which is subject to CRP, is not in compliance. If the registrant made a good faith effort to comply prior to March 9, 1981, the Region should require the registrant to submit a Compliance Schedule.<sup>1</sup>

If the registrant did not make a good faith effort to comply prior to March 9, 1981, the Region should assess a civil penalty and require the registrant to submit a Compliance Schedule.<sup>2</sup>

If however, the registrant fails to negotiate or fails to meet a Compliance Schedule, the appropriate civil penalty and Stop Sale, Use, or Removal Order shall be issued if they are releasing for shipment products that require CRP but which are not in CRP.

1. The circumstances are similar to those described in enforcement Criterion B, so a similar level of enforcement action is taken. However, the Notice of Warning is not issued.
2. The circumstances are similar to those described in enforcement Criterion C, so a similar level of enforcement action is taken.

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List of Enforcement Criteria

The following Enforcement Criteria are in force prior to December 31, 1981.

- A. Registrant did not know of the CRP regulation.

Level of Action: Notice of Warning and Establishment of a Compliance Schedule.

- B. Registrant knew of the CRP regulation, did not comply with the CRP regulation prior to the March 9, 1981 compliance date, but made a good faith effort as of March 9, 1981 to comply.

Level of Action: Notice of Warning and Establishment of a Compliance Schedule.

- C. Registrant knew of the CRP regulation, did not comply with the CRP regulation as of the March 9, 1981 compliance date, and did not make a good faith effort as of March 9, 1981 to comply.

Level of Action: Notice of Civil Complaint and Notice of Opportunity for Hearing (Refer to the Civil Penalty Assessment Schedule in Part II of this document) and Establishment of a Compliance Schedule.

- D. Registrant failed to meet Compliance Schedule established pursuant to Enforcement Criteria A, B, or C.

Level of Action: Notice of Civil Complaint and Notice of Opportunity for Hearing (Refer to the Civil Penalty Assessment Schedule in Part II of this document) with a Stop Sale, Use, or Removal Order.

1. A Stop Sale, Use, or Removal Order shall apply to products in violation and to all products released for shipment until compliance is achieved.

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After December 31, 1981, all registrants whose pesticide products are subject to the CRP regulation must be in compliance. Only one level of enforcement action will be appropriate.

The following Enforcement Criterion is in force after December 31, 1981:

Registrant did not comply with the CRP regulation.

Level of Action. Notice of Civil Complaint and Notice of Opportunity for Hearing (Refer to Civil Penalty Assessment Schedule in Part II of this document) with a Stop Sale, Use, or Removal Order.

Multiple Assessment

Regional enforcement personnel shall issue a civil complaint containing civil penalty assessments for each registered pesticide product found to be in violation. For instance, one registrant may manufacture seven products, five of which are subject to the CRP requirements. If all five subject products are not in CRP, then a civil complaint with five counts of misbranding shall be issued, each being assessed a penalty.

Additionally, there are several requirements under the CRP regulation. Each requirement that a registrant fails to comply with will be assessed a penalty. (See Hypothetical Case 2, p.16).

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Part II: Citation Charges and  
the Civil Penalty Assessment Schedule

The violations of the Child-Resistant Packaging (CRP) regulation fall into the following five categories:

1. Misbranding (Not in CRP).
2. Failure to file amended registration and certification.
3. Failure to maintain records of toxicity and package testing data.
4. Failure to submit records upon request to EPA.
5. Falsification of amended registration, certification, toxicity testing data, and/or package testing data.

This part of the guidance takes each violation category and explains the changes or additions that must be made to the charges cited in a complaint and to the Civil Penalty Assessment Schedule.

Violation 1: Misbranding

A. Modifications of Charges

The FIFRA §2(q)(1)(B) states that a pesticide product is misbranded if:

"...it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to FIFRA §25(c)(3)."

The distribution of products subject to the CRP requirement in packaging that is not child-resistant after March 9, 1981 constitutes misbranding under FIFRA §12(a)(1)(E). The current list of charges does not cite this specific misbranding violation.



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A new charge is therefore added to the document, Citation Charges for Violations of FIFRA, as follows:

PERSON FAILED TO COMPLY WITH THE PROVISIONS OF THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT IN THAT THE PESTICIDE WAS:

E41. Misbranded in that it was contained in a package or other container or wrapping which did not conform to the standards established by the Administrator pursuant to Section 25(c)(3), i.e. was not in child-resistant packaging.  
 12(a)(1)(E), 7 U.S.C. §136j(a)(1)(E);  
 2(q)(1)(B), 7 U.S.C. §136(q)(1)(B)).

#### B. Modifications of the Civil Penalty Assessment Schedule

A matrix to facilitate calculation of a penalty for a misbranding violation is added to the Civil Penalty Assessment Schedule as follows:

#### SPECIAL PACKAGING VIOLATIONS

##### Section One: Misbranding

1. Pesticide product contained in a package or other container or wrapping which did not conform to the standards established by the Administrator pursuant to Section 25(c)(3), i.e., was not in child-resistant packaging.

		I	II	III	IV	V
E41	A. Toxicity Level Danger	500	1250	2750	4250	5000
	B. Toxicity Level Warning	250	700	1540	2380	2800
	C. Toxicity Level Caution	120	300	660	1020	1200

1. It is anticipated that almost all products subject to CRP are in Toxicity Categories I (Danger) and II (Warning).

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Violation 2: Failure to File Amended Registration and Certification

## A. Modifications of Charges

The failure to file amended registration and certification should be charged under Charge E40, which states as follows:

E40. Failed to file reports required by the Act.  
[12(a)(2)(N), 7 U.S.C. 136j(a)(2)(N)]

## B. Modifications of the Civil Penalty Assessment Schedule

A matrix for Charge E40 was not originally included in the Civil Penalty Assessment Schedule. MISCELLANEOUS VIOLATIONS, p. 27717-18, is revised to include a Section 7, entitled: Failure to File Reports, as follows:

7. Failure to File Reports<sup>1</sup>

	I	II	III	IV	V
A. Knowledge of Report Filing Requirement	420	1050	2310	3570	4200
B. No Knowledge of Report Filing Requirement	180	450	990	1530	1800

\* \* \*

1. Prior to December 31, 1981, the Enforcement Criteria provide that registrants with no knowledge of the CRP requirements (including the report filing requirement) will not immediately be assessed a penalty (See Enforcement Criterion A, p. 4). However, if the registrant fails to negotiate or meet a Compliance Schedule, the knowledge/no knowledge criteria in the above matrix shall apply. Additionally, after December 31, 1981, the above criteria shall apply.

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Violation 3: Failure to Maintain Records of Toxicity and Package Testing Data

The violation, failure to maintain records of toxicity and package testing data, is covered under existing materials, Charge E39 of the Citation Charges and Section 1: A and B, in MISCELLANEOUS VIOLATIONS, p. 27717 of the Schedule. The charge and pertinent sections of the Civil Penalty Assessment Schedule are reproduced here for ease of use.

## A. Charge

E39. Refused to keep any records required pursuant to Section 8 of the Act [7 U.S.C. 136f] and any regulations promulgated thereto [40 CFR 169.2; 12(a)(2)(B), 7 U.S.C. 136j(a)(2)(B)]

## B. Civil Penalty Assessment Schedule

## 1. Books and Records

	I	II	III	IV	V
A. Failure to maintain books and records as required under §8(a)	420	1050	2310	3570	4200

\* \* \*

Violation 4: Failure to Submit Records Upon Request to EPA<sup>2</sup>

## A. Modifications to Charges

The failure to submit records upon request to EPA is a

1. The registrant may not have actual data on file if the company did not perform the testing but, instead, relied on verification from others such as the company which produces the packaging. The registrant should have a letter or literature verifying that the packaging has been tested and met the CRP standards.

2. The CRP regulation at 44 FR 13023 states, "These records shall be available, upon request, for inspection and copying purposes or for submission to EPA."

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violation under FIFRA §12(a)(2)(N), which states

"It shall be unlawful for any person -- ...  
(N) who is a registrant, wholesaler, dealer,  
retailer, or other distributor to fail to  
file reports required by this Act."

The failure to submit records when requested should be charged under Charge E40, which states as follows:

E40. Failed to file reports required by the Act  
[12(a)(2)(N), 7 U.S.C. 136j(a)(2)(N)]

B. Modifications to the Civil Penalty Assessment Schedule

The matrix to be used with Citation Charge E40 is set up in this guidance under Violation 2: Failure to File Amended Registration and Certification. (See p. 9)

Violation 5: Falsification of Amended Registration, Certification, Toxicity Testing Data, and/or Package Testing Data

A. Modifications of Citation Charges

The falsification of amended registration, certification, toxicity testing data, and/or package testing data is a violation under FIFRA §12(a)(2)(M).<sup>1</sup>

As currently worded, Citation Charge E34, which is the charge currently used to cite violations of FIFRA §12(a)(2)(M), cannot be used to cite violators who knowingly falsify CRP material. Therefore the charge is re-worded to incorporate the complete language of Section 12(a)(2)(M), as follows:

E34. Knowingly falsified all or part of the application for registration, an application for experimental use permit, any information submitted to the Administrator pursuant to Section 7, any records required to be maintained pursuant to Section 8, any report filed under this act, or any information marked as confidential and submitted to the Administrator under any provision of this Act.

T. Criminal sanctions may be sought under FIFRA §14(b) for knowing violations of this requirement.

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## B. Modifications of the Civil Penalty Assessment Schedule

Section 5: Falsified All or Part of an Application, under MISCELLANEOUS VIOLATIONS, p. 27718 in the Schedule, is revised to include a fifth gravity factor entitled E: Any Report Filed Under This Act. The fines along the horizontal axis are identical to the fines for the other violations of Section 5. The matrix is revised as follows:

## 5. Falsified All or Part of an Application

	I	II	III	IV	V
A. Registration Application	500	1250	2750	4250	5000
B. Experimental Use Permit Application	500	1250	2750	4250	5000
C. Confidentiality Status	500	1250	2750	4250	5000
D. Submitted False Production Data	500	1250	2750	4250	5000
E. Any Report Filed Under This Act	500	1250	2750	4250	5000

## APPENDIX I

## NOTICE OF WARNING - CHILD-RESISTANT PACKAGING VIOLATION

COMPANY  
STREET  
CITY, STATE, ZIP

Dear

This letter is a Notice of Warning issued pursuant to §9(c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (FIFRA) informing you that an inspection at your facility:

(Name)  
(Address)  
(Establishment Registration #)

has shown violation(s) of the child-resistant packaging regulation issued pursuant to §25(c)(3) of the FIFRA.

The EPA promulgated a final rule (44 Federal Register 13019 March 9, 1979; 40 CFR 162.16) requiring all pesticide products meeting certain criteria to be contained in child-resistant packaging. The regulation requires child-resistant packaging for any pesticide product released for shipment after March 9, 1981, if (1) its labeling allows for residential use, (2) it has not been classified for restricted use, and (3) it meets certain toxicity criteria.

An EPA inspection showed that your product(s):

(Product Name)  
(Registration #)

did not comply with the above requirements of the FIFRA, in that:

(Cite alleged Violations)

Our enforcement personnel have determined that the following mitigating circumstances exist:

We find that these circumstances justify a conditional exercise of prosecutorial discretion. To avoid civil enforcement action by the Agency, you must send this office a Compliance Schedule within 20 days of the date of this Notice of Warning, listing the name(s) and address(es) of any companies with which you will deal for packaging and/or testing of the violative products.

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The Compliance Schedule must also show a timetable setting dates for achieving toxicity testing, packaging testing, and full compliance with the child-resistant packaging regulation. You must achieve full compliance within six (6) months of the date of this letter, or no later than December 31, 1981, whichever comes first.

This office will notify you as soon as your Compliance Schedule is received. Regional enforcement personnel shall approve or disapprove the Compliance Schedule within 45 days of this letter. This office will notify you of any further information required. Failure to furnish such requested information will result in failure to negotiate a Compliance Schedule within 45 days.

If you do not submit a Compliance Schedule within 20 days of the date of the Notice of Warning, or if a Compliance Schedule acceptable to this office is not negotiated within 45 days of the Notice of Warning, this office shall assess a civil penalty, and issue a Stop Sale, Use or Removal Order affecting all current and future products cited in this notice which are released for shipment. Should you have any questions in regard to this Compliance Schedule, please contact \_\_\_\_\_ at \_\_\_\_\_.

Sincerely,

Name  
Title  
Regional Office

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## APPENDIX 2: HYPOTHETICAL CASES

## Hypothetical Case 1:

XYZ Pesticide Company manufactures and distributes a pesticide containing 65% Calcium hypochlorite for use as a swimming pool disinfectant. In the course of a routine inspection, the State pesticides inspector notes that the product is not in child-resistant packaging. The inspector believes that this particular product should be in CRP because the product is listed in EPA's Phase I list of generic products for which an unqualified assumption can be made that they require CRP if used for residential use.

In discussions with the plant manager, the inspector is informed that XYZ had contracted with a company to design and test a package for their product but that the company had gone out of business. XYZ immediately contracted with another company prior to March 9, 1981 but the delay caused them to be in noncompliance as of the March 9, 1981 effective date.

The state pesticides office refers the case to Region Z personnel, because the state law does not include a requirement for child-resistant packaging. Region Z enforcement personnel determine that XYZ made a good faith effort. Therefore Region Z issues a Notice of Warning, requiring XYZ to submit a Compliance Schedule.

XYZ submits a Compliance Schedule showing full compliance is to be achieved by December 1, 1981. Region Z enforcement personnel approve the Compliance Schedule, forwarding a copy of the approved Schedule to Headquarters. A second inspection in December 1981 shows XYZ to be in compliance. No further enforcement action is required.



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## Hypothetical Case 2.

The John Doe Pesticide Company (JDP Co.) manufactures and distributes two pesticide products subject to the CRP regulation. However, during a January 1982 inspection, a State pesticides inspector finds that neither product is in CRP.

The plant manager says that the JDP Co. negotiated and signed a contract to obtain child-resistant packaging on December 31, 1981.

The State pesticides office refers the inspection results to the Regional office. Regional enforcement personnel, following the enforcement criterion in effect after December 31, 1981, issue a civil complaint (containing charges for each pesticide) and two stop sale, use or removal orders (for each type of pesticide) affecting all current and future products released for shipment. PTSED concurs with these enforcement actions. The charges and penalties are assessed as follows: (Note: The size of the JDP Co. was determined to be Category I.)

<u>Charge</u>	<u>Product 1</u>	<u>Product 2</u>
Misbranding	500 (Toxicity Level: Danger)	280 (Toxicity Level: Warning)
Failure to File Amended Registration and Certification	420	420
Failure to Maintain Records of Toxicity and Package Testing	420	420
	<u>1,340</u>	<u>1,120</u>

TOTAL: \$ 2,460

Summary of Action Taken: Civil Complaint citing charges  
E41 (p.8), E40 (p.9), and E39 (p.10)  
Stop Sale, Use or Removal Order  
Civil Penalty of \$2,460 (p.8, p.9,  
and p.10)

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## Hypothetical Case 3.

Several cases of children being poisoned by a pesticide product in alleged child-resistant packaging come to the EPA's attention. None of the incidents are fatal.

EPA Headquarters alerts the Regions where the pesticide is manufactured. Regional enforcement personnel request the State pesticides office in the state of manufacture to conduct an inspection.

State pesticides inspectors examine the files kept by the pesticide company. The inspectors contact the company cited in the pesticides company file as having performed package effectiveness testing for the pesticide company. The inspectors find that the package testing company denies having done the testing. The pesticide company claims that an employee, who was fired for other transgressions, was responsible for the falsification.

After these results are referred to the Regional Office, Regional Enforcement personnel determine that the charge, falsification of an amended registration, certification (E34), toxicity testing data, and/or package testing data shall be cited. The company discontinues production and recalls all products released for shipment.

A civil penalty of \$2,750 is assessed (the company is size III) and a Compliance Schedule is negotiated. A criminal sanction is not taken because: 1) there were no fatalities; 2) the company claims the data was falsified by a terminated employee; and 3) the company cooperated to the fullest extent.

The company meets its Compliance Schedule, so no further enforcement action is taken.

Summary of Action Taken: Civil Complaint citing charge E34  
(See p. 11)  
Civil Penalty of \$2,750 (See p. 12)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

22 APR 1975

OFFICE OF ENFORCEMENT

To: Enforcement Division Directors  
Hazardous Materials Control Branch Chiefs

From: A. E. Conroy II  
Director, Pesticides Enforcement Division

*A.E. Conroy II*

Subject: Interim Deviation from Civil Penalty Assessment Schedule

A review of the Civil Penalty Assessment Schedule as published July 31, 1974 (39 F.R. 27656) has resulted in a determination that the proposed penalty amounts assigned for a violation involving failure to submit required reports of production or distribution data required under Section 7(c) of amended FIFRA (Miscellaneous Violations, Part 2, 39 F.R. at 27717) are excessive when considered within the context of the gravity of harm and misconduct reasonably to be associated with the violation. Thus for immediate use until the Assessment Schedule is revised and republished, the penalty for a violation of the Section 7 reporting requirement for the five size-of-business categories is revised as follows:

I	II	III	IV	V
320	800	1760	2720	3200

This revised penalty may be adopted to apply to any cases currently in progress in so far as deemed practicable and fair.

In accordance with the procedures as set out in Section 3 of the Case Proceedings Manual, "Establishment Registration Enforcement Policy", at 4, following the expiration of twenty (20) days after the failure to file an initial report or for failure to file by February 1 a first annual report, or following failure to file by February 1 any

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annual reports subsequent to the first annual report, a civil complaint may be issued. This policy is modified by the Memorandum of the Director of April 10, 1975, entitled "Late Submission of Pesticides Reports", which provides that an application for an extension of time in the event of unforeseen circumstances filed on or before the due date will relax the deadline for filing the report the 30 additional calendar days. In the event the region determines to respond with a civil complaint (as opposed to some other enforcement option) to the failure to file after the tolling of any of the above-enumerated deadlines, the complaint should propose to assess the full amount of the appropriate penalty by size-of-business in accordance with the revised schedule specified herein. Should the report be filed within the pendency of a civil proceeding, the proposed penalty may be mitigated as much as forty per cent if the region feels such action is warranted based on the facts of the case.

This policy represents an effort to establish a penalty which recognizes at once the lesser value of a Section 7 related offense when compared to other violations which have inherently more direct environmental harm, and the need for reasonable assurance of future compliance with Section 7 requirements. Since a warning and time-extension provision is a condition precedent to the application of sanctions for Section 7 violations and since an additional 30-day extension is available to a producer for good cause, it should never be argued that penalties for Section 7 violations are excessive because of lack of notice or experience by producers in the requirements of this section. Further, the more experience a producer has demonstrated with Section 7 requirements, the less available any mitigation should be in cases of violation.

Attachment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



June 11, 1981

OFFICE OF ENFORCEMENT

**MEMORANDUM**

**SUBJECT: FIFRA Enforcement Policy - Interim Penalty Guidelines**

**TO: Regional Enforcement Division Directors  
Pesticide Branch Chiefs**

The Pesticides and Toxic Substances Enforcement Division is in the process of updating the current penalty guidelines under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Before final revisions can be completed, however, there is a need to develop interim guidelines governing the use of remedies and the response to violations which were not in existence at the time the current guidelines were published.

The Interim Guidelines, attached to this memorandum, address three areas which are not covered in the present guidance and under which cases are currently arising:

- 1) The use of EPA's authority to revoke or suspend federally issued applicator certifications;
- 2) The penalties which should be assessed against persons who fail to maintain records concerning their use of restricted use pesticides (RUPs); and
- 3) The penalties which should be assessed against persons who use, or make available for use, any RUPs other than in accordance with section 3(d) of FIFRA.

The Interim Guidelines do not represent a major departure from the current system of determining appropriate penalties. The Guidelines build upon existing standards for determining the dollar amounts of civil penalties to be assessed against

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violators of RUP-related requirements. In addition, the criteria for deciding whether to revoke or suspend a certificate affect only those cases arising in States with federally operated certification programs.



A. E. Conroy II, Director  
Pesticides and Toxic Substances  
Enforcement Division

Attachment

FIFRA ENFORCEMENT POLICY  
INTERIM PENALTY GUIDELINES

Sections Affected:

FIFRA §§4 and 14  
40 CFR Part 171.11

Issues:

- 1) When, and for how long, should Federal applicator certifications be suspended or revoked?
- 2) What is the appropriate penalty to assess against certified commercial applicators who fail to maintain records concerning their use of restricted use pesticides (RUPs)?
- 3) What is the appropriate penalty to assess against persons who use, or make available for use, any RUP other than in accordance with Section 3(d) of FIFRA?

Policy and Discussion

1) Suspending or Revoking Certifications

(a) Generally.

FIFRA certification regulations (40 CFR Part 171.11) authorize EPA to suspend, revoke, or modify federally issued applicator ~~certifications if the certificate holder violates FIFRA or regulations promulgated thereunder.~~

The Office of Enforcement views an enforcement action affecting certification as a strong measure, to be taken when the "public health, interest or welfare warrants immediate action" (40 CFR Part 171.11(f)(5)(i)). Therefore, this policy statement directs that actions to revoke or suspend certifications only be taken in response to serious violations or against persons with a history of noncompliance.

(b) Revocation.

The revocation of a certification not only deprives an

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applicator of the authority to apply restricted use pesticides for an indefinite period, but also, as opposed to suspension actions, forces the applicator to take additional steps to reacquire the certificate. Thus Regional personnel should only revoke a certification where the violation has resulted in a fatality or created an imminent danger of a fatality, where the violator's certification has previously been suspended, or where a person has made fraudulent records or reports, (40 CFR Part 171.11(f)(1)(iv)). The term of a revocation should be not less than six months.

(c) Suspension.

A Region considering invoking the less severe suspension alternative must determine whether it is appropriate to pursue a suspension action and for how long such suspension should be in effect. The answers to these questions will depend upon the gravity of the violation.

The appendix to this policy statement contains criteria for ~~assessing the gravity of a use violation.~~<sup>1</sup> The gravity of a use violation is a function of (1) the risk of harm posed to human health and the environment by the violation, (2) and the degree of misconduct exhibited by the violator. (See Section 7C 1.b.(2)(a) of the FIFRA Case Proceedings Manual for background information on analyzing gravity.) The Region should assign weightings, based on the gravity criteria in the appendix, for each use violation relative to the pesticide involved, the harm to human health and/or the harm to the environment, the history of noncompliance,

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1. For purposes of this policy, a use violation means any of the acts described in 40 CFR Part 171.11(f)(1)(i), (ii), and (v).



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and the culpability of the violator. The total gravity value thus obtained will be used to decide whether and for how long to suspend a certification, in accordance with the following table:<sup>2</sup>

<u>Total Gravity Value</u>	<u>Enforcement Remedy</u>
4 or below	No action or Warning Citation
5-8	Suspension of up to 2 months
9-12	Suspension of between 2 and 4 months
13 or above	Suspension of between 4 and 6 months

To determine whether the term of a suspension should be at the higher end or at the lower end of the given ranges, the Regions should consider any gravity-related factors not accounted for in the appended gravity criteria. In addition, the Regions should consider the degree to which the suspension will have an adverse economic impact on the applicator. Applicators who will be minimally ~~affected by a suspension, such as those who normally apply very little restricted-use pesticides,~~ should receive longer suspensions than applicators whose day-to-day business activities would be severely disrupted by the loss of their certifications.

Suspension actions should generally be pursued against individual applicators in lieu of Section 14(a) administrative money penalties. This policy, however, does not preclude a Region from

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2. The Office of Enforcement has decided not to distinguish between commercial and private applicators for purposes of this policy. Consideration of applicator status is inherent in the policy in that suspensions have a more substantial impact on commercial applicators, affecting their primary business activity.

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foregoing a suspension action against the applicator in favor of issuing a warning letter or assessing a monetary or criminal penalty, or from assessing a monetary penalty against the firm employing the applicator in addition to suspending the certification of the applicator himself.

It is possible for commercial applicators to violate RUP recordkeeping requirements in addition to use restrictions. (See 40 CFR Part 171.11(c)(7); 40 CFR Part 171.11(f)(1)(iii).) These violations do not lend themselves to analysis utilizing gravity of harm criteria. Consequently, OE's interim policy is to base decisions to suspend the certifications of persons who fail to maintain RUP records solely on gravity of conduct considerations. Up to two month certification suspensions may be assessed for the second independent violation resulting from the failure to maintain RUP records. For each additional violation, two months may be added to the term of the suspension up to a limit of six months. As noted in Part 1(b) above, in cases where the violation resulted from the keeping of fraudulent records, i.e., where the violator intentionally concealed or misrepresented the true circumstances and extent of RUP use, the violator's certification may be revoked in response to the initial infraction.

If EPA decides to suspend a certification, the applicator must be notified of the time period during which the suspension will be effective. In order for the suspension to function as a deterrent, the suspension should take effect during the time

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when the applicator is most likely to be applying restricted use pesticides.<sup>3</sup>

## 2) Failing to Maintain RUP Records

The Office of Enforcement has not yet developed a final civil penalty policy governing the failure to keep RUP records as required in 40 CFR Part 171.11(c)(7), (a violation of Part 171.11(f)(1)(ii)). As interim guidance, Regional personnel should utilize the matrix for Section 8(a) recordkeeping violations found in the current penalty guidelines (Charge Code E39). This matrix is as follows:<sup>4</sup>

	Size of Business Category				
	I	II	III	IV	V
Penalty Amount	450	1050	2310	3570	4200

Restricted use pesticide recordkeeping violations may result from the failure to maintain some or all of the information required by Part 171.11(c)(7). Warning Citations should be issued in response to first-time "partial" recordkeeping offenses. Failure to maintain any of the required RUP records, and "partial" recordkeeping violations following a warning, should result in assessment of a civil penalty. Continued violations may be addressed by a suspension action in accordance with the policy set forth above.

3. EPA may take actions affecting certification other than revocations and total suspensions. Enforcement policy on the use of such actions (i.e., modifications, partial suspensions, and denials of certificates), will be contained in later guidance.
4. Only one matrix is needed since this violation, by definition, implicates only commercial applicators.

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The Agency views the making of fraudulent records, as defined above, to be a more serious violation than the failure to maintain RUP information. Therefore, when assessing a monetary penalty for a violation of Part 171.11(f)(1)(iv), the Regions should utilize the following matrix:

	Size of Business Category				
	I	II	III	IV	V
Penalty Amount	1250	1850	3110	4370	5000

3) Using RUPs, Or Making RUPs Available For Use, Other Than In Accordance With Section 3(d) of FIFRA

Section 12(a)(2)(F) of FIFRA provides that "it shall be unlawful for any person 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 Section 3(d)." Section 3(d) prohibits the use of RUPs by non-certified applicators. In addition, with certain exceptions,<sup>5</sup> persons who make RUPs ~~available for use by non-certified applicators~~ are subject to penalties under Section 12.

As interim policy, we will make use of the existing matrix governing another type of use violation, i.e., use inconsistent with labelling (Section 12(a)(2)(G)). The Section 12(a)(2)(G) matrix (charge code E28) in the current penalty guidelines is divided into three levels, depending on the adverse effects likely to result from the violation. Since Section 12(a)(2)(F)

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5. See the Proviso in Section 12(a)(2)(F) and the preamble to the RUP classification regulations, Part IX, 43 FR 5783, February 9, 1978. To date, no States have issued regulations which would enable persons to sell RUPs under this Proviso.

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RUP violations necessarily involve pesticides which may cause "unreasonable adverse effects on the environment" (Section 3(d)(1)(B),(C)), we will utilize the uppermost level of the matrix, which reads as follows:<sup>6</sup>

	Size of Business Category				
	I	II	III	IV	V
Penalty Amount	500	1250	2750	4250	5000

Thus in determining whether to assess a penalty for Section 12(a)(2)(F) violations, and the amount of such penalty, the Regions should consult existing guidelines governing Section 12(a)(2)(G) violations.

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6. As is the case with RUP recordkeeping violations, only one matrix is needed since this type of violation involves only commercial applicators.

A. E. Conroy II, Director  
Pesticides and Toxic Substances  
Enforcement Division

APPENDIXCriteria For Determining The Gravity Of A Use  
Violation For Purposes Of A Certification Action

## I. GRAVITY OF HARM

	<u>Weighting</u>	<u>Activity</u>
A. Pesticide		
	2	Toxicity category I pesticides, restricted use pesticides, or pesticides that have been demonstrated to be associated with chronic health effects (mutagenicity, oncogenicity, teratogenicity, etc.)
	1	Toxicity categories II-IV, no known chronic effects
B. Harm to Human Health		
	5	Serious or widespread actual harm to human health
	3	Serious or widespread potential harm to human health
	1	Minor potential or actual harm to human health, neither serious nor widespread
C. Environmental Harm		
	5	Substantial or widespread actual <del>harm to the environment, i.e.,</del> crops, water, livestock, wildlife, wilderness, or other sensitive natural areas
	3	Substantial or widespread potential harm to the environment
	1	Minor harm to the environment, neither widespread nor substantial

## II. GRAVITY OF CONDUCT

A. Noncompliance History		
	4	More than one prior violation of FIFRA by the applicator
	2	One prior violation
	0	No prior violations

## A-2

B. Culpability	4	Knowing or willful violation
	2	Violation resulted from negligence
	0	Violation was not knowing or willful and did not result from negligence; good faith efforts made to comply with the law





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## Appendix

# 7 Additional Sources of Compliance/ Enforcement Information

The following is a listing of all FIFRA compliance/enforcement related policies and guidances (other than those contained in this manual) that are currently in effect. Copies of these documents may be obtained from Headquarters PTSCMS or the Office of Legal and Enforcement Policy.

<u>TITLE OF DOCUMENT</u>	<u>DATE OF DOCUMENT</u>
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### Enforcement Actions

"Routine Use of SEC '10-K' Statements in TSCA and FIFRA Civil Penalty Actions"	10/17/80
FIFRA Case Digest (Draft)	1983 (Draft)

### Compliance Monitoring

Pesticides Inspection Manual	1975 Edition
"Enforcement Policy Applicable to Bulk Shipments of Pesticides"	7/11/77
"Request Procedures for Pesticide Samples and Followup on Pesticide Complaints"	7/30/80
"Appropriate Documents to be Presented by State Inspectors Conducting Pesticide Use Inspections in States Having Primacy"	12/18/80

### Technical Guidance

<del>Institution of Pesticides Enforcement Policy</del> Statements (PEPS) [40 FR 19526]	5/5/75
"Water Purifiers"	8/30/75

"Guidance for Enforcement Actions Involving Water Purifier Products"	3/15/76
PEPS #3: Certain Enforcement Policies to be Followed During the Phased Implementation of FIFRA Section 3 [41 FR 13984]	4/1/76
PEPS #4: Preventive Pest Control Treatments In the Absence of Target Pests [41 FR 28005]	7/8/76
Pest Control Devices and Device Producers [41 FR 51065]	11/19/76
"Enforcement Priorities in Structural Pest Control"	1/24/77
a) Establishment Inspections of Pest Control Firms	
b) Pesticides Use Inspections	
c) Prosecutorial Discretion in Pesticide Use Enforcement"	
"Federal Pesticide Act of 1978"	8/22/78
"Primary Use Enforcement Responsibility"	1/4/79
"Review of State Certification Plans Pursuant to FIFRA Section 26"	3/14/79
Notice of Rescission of Pesticide Enforcement Policy Statements (PEPS) Nos. 1,2,5,6,7 [44 FR 33151]	6/8/79
Enforcement Policy Regarding Failures to Report Information Under §6(a)(2) of FIFRA [44 FR 40716]	7/12/79
Agency Interpretation of Requirement Imposed on Registrants by §6(a)(2) of FIFRA [43 FR 37611]	8/23/78
Suspended and Cancelled Pesticides (Booklet)	10/79 (2nd Revision)
Pesticide Use and Production by Veterinarians; Statement of Policy on the Applicability of the Federal Insecticide, Fungicide, and Rodenticide Act to Veterinarians [44 FR 62940]	11/1/79
"Enforcement Actions Concerning Nonhazardous Pesticides Devices"	12/19/79
"Federal Facilities Compliance"	1/16/80

"Clarification of Primary Use Enforcement Responsibility Guidance"	3/4/80
Statement of Policy on the Labeling Requirements for Exported Pesticides, Devices, and Pesticide Active Ingredients and the Procedures for Exporting Unregistered Pesticides [45 FR 50274]	7/28/80
"Enforcement Facts and Strategy; Compliance Monitoring Procedures; Water Purification Devices"	10/80
"Regulation of Public Health Related Disinfectant Products"	12/17/80
Pesticide Registration, Reregistration, and Classification Procedure; Clarification of Policy Issues on Special Packaging [46 FR 15104]	3/3/81
"Strategy for the Enforcement of the Child-Resistant Packaging Regulation under FIFRA"	6/8/81
Federal Insecticide, Fungicide, and Rodenticide Act, State Primary Enforcement Responsibilities [48 FR 404]	1/5/83
"General Compliance Strategy for Products Subject to the FIFRA Label Improvement Program"	4/21/83

Operating Guidance

"Final FY84 Cooperative Agreement Program Guidance"	4/21/83
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Cancellation-Suspension Enforcement StrategiesAldrin Dieldrin

"Continuing State Registration of Products Containing Aldrin and Dieldrin for Which Uses Have Been Suspended"	1/10/75
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Chlordane-Heptachlor

"Enforcement of Administrator's Decision and Order Suspending Most Uses of Heptachlor and Chlordane"	1/15/76
"Clarification of Heptachlor/Chlordane Suspension Order"	1/22/76
"Status Report on Heptachlor/Chlordane Suspension"	2/19/76
"Heptachlor/Chlordane Suspension Order Enforcement Strategy"	3/23/76

"Heptachlor/Chlordane Suspension Order  
Enforcement Strategy—CORN USE" 8/27/76

"Continued Enforcement of Suspension of  
Registration for Certain Products Containing  
Heptachlor and Chlordane" 11/23/76

#### Mercury

"Conclusion of Mercury Cancellation Proceeding" 10/28/76

"Enforcement of Mercury Settlement" 1/6/77

#### 2,4,5-T and Silvex

"Enforcement of Administrator's Emergency  
Orders Suspending 2,4,5-T and Silvex  
Registrations" 3/7/79

"Further Guidance Concerning Enforcement of the  
Administrator's Emergency Orders Suspending 2,4,5-T  
and Silvex Registrations" 4/5/79

"Further Guidance on the Cancellation and Suspension  
of 2,4,5-T and Silvex" 8/20/79

#### Other

"DBCP Suspension Order Enforcement Strategy" 11/7/79

"General Compliance Strategy for Products  
Suspended Under §3(c)(2)(B) of FIFRA" 7/2/82

"Toxaphene Cancellation Compliance" 1/1/83

#### Compendiums

FIFRA Compliance Program Policy Compendium 5/10/82

Compendium Index:

#### Title

Use Recommendations  
Labeling of Outer Containers  
Shipment Prior to Registration  
Distributor Registrations  
Fumigation of Truck Vans on Flatbed Rail Cars  
Custom Blenders  
Production of Pesticides for Personal Use  
Contract Manufacturing

Release of Pesticide Production Data  
Using Registered or Experimental Use Permit  
Pesticides in a Manner Not Included on the Label or Permit  
Closed Application Systems  
Authority for Use Inspections  
Pesticide Processing in Foreign-Trade Zones  
Waiver of Notice of Arrival Requirements  
Special Local Needs Labeling  
Transfer of Use Enforcement Primacy to the States  
Referral of State Misuse Cases to EPA

General Enforcement Policy Compendium

3/3/83

## Compendium Index:

Title

"Visitor's Releases and Hold Harmless Agreements as a Condition to Entry to EPA Employees on Industrial Facilities"	11/8/72
"Professional Obligations of Government Attorneys"	4/19/76
"Memorandum of Understanding Between the Department of Justice and the Environmental Protection Agency"	6/16/77
"'Ex Parte' Rules Covering Communications Which are the Subject of Formal Adjudicatory Hearings"	12/10/81
"Quantico Guidelines for Enforcement Litigation"	4/8/82
"Agency Guidelines for Participation in Grand Jury Investigations"	4/30/82
"Reorganization of the Office of Regional Counsel (includes Administrator's Memorandum of September 15, 1981)"	5/7/82
"Coordination of Policy Development and Review"	6/23/82
"General Operating Procedures for EPA's Civil Enforcement Program"	7/6/82
"Case Referrals for Civil Litigation"	9/7/82
"Criminal Enforcement Priorities for the Environmental Protection Agency"	10/12/82
"General Operating Procedures for the Criminal Enforcement Program"	10/27/82

"Regional Counsel Reporting Relationship"

8/3/83

Additional Sources of FIFRA Compliance Enforcement Information

EPA Delegations of Authority

EPA Manual of Pesticide Misuse Review Committee Policy,  
Procedures, Cases, and Advisory Opinions

EPA Security Manual

Notices of Judgment

Office of Pesticide Programs Policy and Criterial Notice Manual

SFIREG Charter