



United States
Environmental Protection
Agency

Pesticides and
Toxic Substances
Enforcement Division

Washington, DC
20460

Federal Insecticide, Fungicide, and Rodenticide Act

Compliance/Enforcement Guidance Manual

Policy Compendium

Volume 4: FIFRA Enforcement Response Policies

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Volume 4 of the FIFRA Compliance Enforcement Guidance Manual Policy Compendium contains the Enforcement Response Policies issued by the Office of Compliance Monitoring that are currently in effect. The Table of Contents of the remaining volumes, FIFRA miscellaneous sources, and a list of obsolete documents are contained in the Appendices.

Any questions or comments concerning these documents should be addressed to:

Director, Policy and Grants Division
Office of Compliance Monitoring (EN-342)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Volume 4: Enforcement Response Policies¹

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Enforcement Response Policy for the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA ERP)	07/02/90

¹Note: These documents may also be found in Appendix 6 of the FIFRA Compliance/Enforcement Guidance Manual.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 24 1981

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Status of a State or County Government Agency under Section
14(a)(2) of FIFRA

TO: Regional Enforcement Division Directors
Pesticide Branch Chiefs

Enclosed for your reference is a memorandum prepared by the Legal Section of the Pesticides and Toxic Substances Enforcement Division in response to a question by Region VII concerning the treatment of state or county government pesticide applicators under the FIFRA civil penalty section. The conclusion this memorandum reaches is that under Section 14(a)(2) of FIFRA, state or county government applicators should be treated in the same way as private applicators.

A handwritten signature in black ink, reading "A. E. Conroy II".

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 10 1981

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Status of a State or County Government Agency under Section 14(a)(2) of FIFRA

FROM: Ruthanne Miller, Legal Intern *Resm*
Legal Section

TO: John Ulfelder, Head *JU*
Legal Section

Introduction

Section 14(a) of FIFRA establishes civil penalties for different classes of offenders as follows:

(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, 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.

The problem this memorandum addresses is whether a state or local government agency which applies other than restricted use pesticides is considered under section 14(a)(2) as "any private applicator or other person not included in paragraph (1)" and thus subject to a written warning for a first offense, or considered as "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 thus subject to a penalty of not more than \$500 for the first offense.

While the statutory language of the latter category on its face appears to include a state or local government agency applying non-restricted use pesticides - as an applicator who applies the registered pesticide "only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served"-, the legislative history of this section indicates that Congress did not intend to include a state or county agency in this category. Therefore, such an agency should only be subject to a written warning for a first offense.

Discussion

In the section-by-section analysis of FIFRA by the U.S. Senate the classification of offenders in section 14 is explained as follows:

- (1) Registrants, wholesalers, commercial applicators, dealers, retailers and other distributors who violate FIFRA may be assessed civil penalties of not to exceed \$5,000 for each offense.
- (2) Private applicators and other persons not specifically included above who violate FIFRA will receive a written warning for their first offense, but may be assessed a civil penalty of not to exceed \$1,000 for subsequent offenses.
- (3) Applicators not included in (1) above who are in the business of applying registered pesticides for hire - but who do not deliver any unapplied pesticide to any person served - may be assessed civil penalties of not to exceed \$500 for the first offense and \$1,000 for each subsequent offense. This class of offender will include persons who apply general use pesticides for hire, but not persons who apply restricted use pesticides for hire - who are considered to be "commercial applicators" under section 2(e).

(emphasis added) SENATE COMM. ON AGRICULTURE, NUTRITION, AND FORESTRY, 95TH, CONG., 2D SESS., FEDERAL PESTICIDE ACT OF 1978 (Comm. Print 1979) at 162-63.

In the section-by-section analysis of the Federal Pesticide Act of 1978, the third classification is described in a similar way by the Senate Agriculture Committee:

This amendment establishes a third class of violators and penalties as follows: Applicators for hire who are neither commercial applicators (that is, they apply only general use pesticides) nor distributors (that is, they do not deliver unapplied pesticides to the persons so served)....

(emphasis added) Id. at 78.

In order for a state or county government agency to fall in the third category and be subject to a fine for a first offense, the agency or its employees would, thus, have to be considered "applicators in the business of applying registered pesticides for hire" or "applicators for hire."

The legislative history of the Federal Pesticides Act of 1978 indicates, however, that the phrase "applicator for hire" was directed at the pest control industry. Prior to the 1978 amendments, pest control operators were treated in the same way as "sellers" and "distributors." The former section 14 penalty provision had only two categories of offenders as follows:

(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.

In 1977 the National Pest Control Association lobbied heavily for a statutory distinction between "users" of pesticides and "sellers and distributors" of pesticides in the amended version of FIFRA. On June 8, 1977, Dr. Phillip J. Spear, acting executive director of the National Pest Control Association, testified before the Senate Subcommittee on Agricultural Research and General Legislation in favor of an amendment "to distinguish use from distribution and sale," stating that "[the NCPA] strenuously object[s] to EPA's interpretation that a pest control operator who supplies the pesticides which he applies commercially is not only selling a service - the application - but is also distributing a product - the pesticides." 123 CONG. REC. 25707 (1977). That the lobbying efforts were successful is evidenced by the Committee of Conference's adoption of a modified House amendment distinguishing commercial pest control applicators from sellers and distributors. Section 2(e)(1) was amended to provide that "[a]ny 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."

The Senate had responded by amending FIFRA to establish "professional applicators" as a separate class of persons. This amendment, which was not adopted, is explained in the Joint Explanatory Statement of the Committee of Conference as follows:

29. Professional or Commercial Applicators

A. The Senate bill amends FIFRA to establish "professional applicators" as a class of persons separate from "sellers" and "distributors." (Professional applicators are now considered as sellers or distributors for the purposes of enforcing FIFRA.) Specifically, the Senate bill adds to section 2 of FIFRA a definition of "professional applicator" to mean an applicator who applies pesticide for hire; and amends other sections of FIFRA to make professional applicators subject to the unlawful acts provisions, the stop sale, use, or removal order provisions, and the criminal and civil penalties in FIFRA.

(emphasis added) SENATE COMM. ON AGRICULTURE, NUTRITION, AND FORESTRY, 95th CONG. 2D SESS., FEDERAL PESTICIDE ACT OF 1978 (Comm. Print 1979) at 29. Although the Senate bill provided the distinction in definition, it also provided that this class of "professional applicators" be subject to the same strict penalty and inspection provisions as sellers and distributors. The language of this Senate amendment shows the origin of the phrase "applicator for hire" and shows that this phrase was directed at those persons in the pest control industry.

The amendment which was agreed to in conference established a separate category for this group of offenders, instead of incorporating them with sellers and distributors. The Committee of Conference explained the adopted category as follows:

The conference substitute amends the civil penalties in section 14(b)(2) [sic]. If there is a violation by a person who commercially applies a pesticide registered for general use, or use dilution of such pesticide, a civil penalty of up to \$500 may be imposed for the first offense and up to \$1,000 for each subsequent offense.

(emphasis added) ^{1/}Id. at 30. The use of the word "commercially" in this explanation supports the interpretation that this category of offenders

^{1/} It appears that there is a misprint here. The reference should be to §14(a)(2) - the civil penalty provision, not to §14(b)(2) - the criminal penalty provision.

includes only applicators in the pesticide control industry, and not local or county government agencies.

In addition to the legislative history of section 14(a)(2), case law interpreting the phrase "for hire" as used in other statutes has determined that public officers and public employees who work for a set salary may not be considered "for hire."

In the case of People v. Sturgis, 79 N.Y.S. 969, 78 App. Div. 460 (Sup. Ct. 1903) the New York Supreme Court determined that a city fireman was not included in a labor law which defined the term employee as "a mechanic, workingman or laborer who works for another for hire." (emphasis added) Id. at 969. The court stated its rationale as follows:

It is obvious that the legislature did not intend to include the uniformed members of the fire department within the act, when, in the second section, it limited its application to a mechanic, workingman, or laborer "who works for another for hire." The word "hire" evidently does not relate to public officers or others holding positions under the city, who are included in the classified lists of the civil service law, such as the uniformed members of the fire department who are appointed to a position after rigid examination, and free from competitive lists. No contract of hiring is made with them. They receive annual salaries, not wages, either in the common or legal acceptance of the term.... Under other sections, they are graded in rank, receive salaries according to such rank, and become entitled to pensions under certain conditions. These rights and privileges clearly differentiate them from laborers working for hire.

Id. at 970-71.

In the later case of Aleksich v. Industrial Accident Fund, 151 P. 2d. 1016 (Mont. 1944), the Supreme Court of Montana, in determining whether a policeman was afforded protection under the Workmen's Compensation Act, interpreted in a similar way the word "hire" as used in a section defining "employee" or "workman" as "every person in this state... who is in the service of an employer... under any appointment or contract of hire, expressed or implied, oral or written...." Id. at 1018. The court quoted the Webster's New International Dictionary definition of "hire" as meaning "'to engage or purchase labor or services of (anyone) for compensation or wages; as, to hire a servant, an agent or an advocate.'" Id. The court stated as follows:

The word "hire" denotes the relationship of master and servant arising out of a contract, expressed or implied, and we must assume that the legislature used the word in its ordinary meaning. Officers are not servants.

They are neither hired nor discharged at the will of anyone. Their compensation is a salary fixed by law and can be increased or decreased only by legislative enactment.... Unless the statute specifically includes public officers it is generally held under statutes binding the application to employees under an appointment or contract of hire, a public officer is not included.

Id.

Since case law has determined that public officers and public employees may not generally be considered "for hire" and since the legislative history of FIFRA section 14(a)(2) specifically shows that this phrase was directed at the pest control industry, a state or local government agency which applies an other than restricted use pesticide should not be subject to a fine for a first offense as would an "applicator for hire," but instead should be subject only to a written warning.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 10 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: FIFRA §7(c) Enforcement Response Policy

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring

TO: Addressees

A handwritten signature in black ink, appearing to read "A. E. Conroy II", written over the typed name in the "FROM" field.

Attached is the Enforcement Response Policy for the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 7(c) Pesticide Producing Establishment Reporting Requirement. This policy is immediately effective and supersedes the May 24, 1985 Interim Enforcement Response Policy for the FIFRA §7(c) Pesticide Producing Establishment Reporting Requirement. This policy sets forth the appropriate enforcement action to initiate for FIFRA §7(c) violations. Please refer to Appendix C of the Enforcement Response Policy (the last 2 pages of the document) for a summary chart of the enforcement response policy.

The following changes were made to the final policy in response to comments regarding the April 26, 1985 draft policy.

- o Page 2, Persons Not Required to Report Production. The following sentence was incorporated: "Also, any person who is a producer solely because he produces a custom blended pesticide is not required to report if he meets the requirements set forth in the FIFRA Compliance Program Policy No. 3.4 entitled 'Custom Blenders'."
- o Page 5, Incomplete Reporting - Reporting in a Manner Inconsistent with the Regulations.
 - The timeframe for submitting missing information was changed from 5 days to 10 days.

- The following sentence was incorporated to further explain what is meant by a minor omission of information: "Minor omissions of information are clerical errors and/or the omission of minor amounts of information as to reflect an oversight."
- o Page 5, False Reporting/Major Omissions of Information - Reporting in a Manner Inconsistent with the Regulations. The following example concerning a major omission was incorporated: "An example of a major omission of information would be demonstrated by an establishment that does not report a pesticide which was produced in the preceding year. For instance, an establishment which produced 5 different pesticides, but reported production of only 4 pesticides."
- o Page 6, Administrative Civil Penalty FIFRA §14(a)(1). The timeframe for which civil complaints should be issued was changed from 2 months to 75 days (2.5 months).
- o Page 11, Violations, (3) Nonreporting Violation or Notably Late Reporting - Annual. The following paragraph was incorporated: "Producers of pesticides in bulk form shall be assessed a penalty in accordance with GBP Matrix A for the first nonreporting violation. Subsequent non-reporting violations warrant a penalty assessment from GBP Matrix C."
- o Appendix A, Page A-5. A Model Notice of Termination of Establishment Registration was added.
- o Appendix C. An Appendix C was added to the attached policy. This appendix includes the Enforcement Response Chart and the Civil Penalty Matrix.

Also attached, for your information, is the Office of Compliance Monitoring's response to comments concerning the draft policy.

If you have any questions concerning this enforcement response policy, please contact Claudia Goforth of my staff at FTS 475-6723.

Attachments

COMMENTS REGARDING THE FIFRA §7
ENFORCEMENT RESPONSE POLICY
AND OCM'S RESPONSE

- o One commenter mentioned that the name "bulk producer" should be changed to producers of pesticide in bulk form.

OCM changed the name of bulk producer to "producers of pesticide in bulk form".

- o Many Regions questioned the practicality of issuing civil complaints for violations within 60 days from the due date of the report.

The policy has been changed whereby civil complaints are to be issued within 75 days from the due date of the report

- o Several Regions stated that the good faith adjustment factor constituted a 40% reduction of penalty, not 20% as stated in the policy.

According to 39 FR 27711, 7/31/74, good faith permits a total reduction of 20%.

- o One Region said "The matrix, we firmly believe, should be revised to include lower penalties."

OCM disagrees. The information required under FIFRA §7(c) is used for regulatory purposes of risk assessment as well as for inspection and targetting purposes. OCM considers §7(c) violations to be serious. This is due to the potential impact on the Agency's ability to conduct accurate risk assessments and compliance inspections. Therefore, the penalty matrix has not been changed.

- o One commenter stated that it is unrealistic to expect either a State or Federal inspector to respond by inspecting a terminated pesticide producing establishment.

The timeframe for inspection of a pesticide producing establishment which has had its registration terminated was increased from one month to two months. However, OCM does not believe that the number of establishments which have their registration terminated will increase.

- o One Region stated that the chart on page 10 of the draft policy is unnecessary and cumbersome.

The chart, which is now located in appendix C, is designed for easy access by Regional personnel in determining the enforcement response for a specific violation. The chart will remain in the policy since the majority of Regions agreed that the chart is an effective tool for determining an enforcement response.

- o One Region requested that producers of pesticides in bulk form should receive a lower penalty for a first time non-reporting violation.

OCM agreed and changed the policy to include a lower penalty assessment for the first time nonreporting violation of producers of pesticides in bulk form. This change was incorporated due to the unique factors which are associated with producers of pesticides in bulk form.

- o One Region requested that an example regarding major and minor omissions of information be included.

OCM incorporated examples of major and minor omissions of information.

- o One Region stated that the time period for which a report should be considered late is ten days.

The majority of Regional comment agreed with the timeframe provided in the policy. Therefore, to maintain national consistency, the timeframe for issuing civil enforcement actions for late reporting shall remain as 30 days from the February 1 due date.

- o Some commenters stated that the firm should be granted 10 days instead of 5 to submit the information which was omitted from report.

The timeframe for submitting information was increased to 10 days.

- o One commenter stated that the notably late violation category should be deleted.

OCM disagrees. If a report is received after the civil complaint has been prepared (not issued) for a nonreporting violation, the establishment can no longer be considered nonreporting since the Region now has the report in its possession. Therefore, a notably late reporting category

was incorporated to cover instances such as this. It is important to note that the establishment is subject to the same civil penalty assessment as an establishment which does not report. OCM believes that a cutoff date by which all violators are subject to a penalty irrespective of when a Region issues its complaints is necessary. Otherwise the treatment of a notably late reporter will vary depending on the region in which the establishment is located. For example, if a report is 65 days late and the Region issues its complaint by day 60 and another Region issues its complaints by day 75, the enforcement response will be different for notably late reporting versus nonreporting, although the report is submitted on day 65. In fact, there could be a difference in the enforcement response within the same Region depending on the date an establishment's complaint is sent.

- o One commenter felt a statement was needed which explained that the postmark date of mailed reports will be considered as the submission date.

A statement such as this was included in the draft policy and shall remain in the final policy.

FEB 10 1986

ENFORCEMENT RESPONSE POLICY FOR
FIFRA SECTION 7(c) PESTICIDE PRODUCING
ESTABLISHMENT REPORTING REQUIREMENT

Environmental Protection Agency
Office of Pesticides and Toxic Substances
Office of Compliance Monitoring
Washington, D.C. 20460

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I: INTRODUCTION

Policy Summary

This policy sets forth the procedures which the Environmental Protection Agency will follow in determining what level of action to bring against establishments that violate section 7(c) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (hereafter FIFRA or the Act).

Background

Section 7(c) of FIFRA permits the Administrator to require any producer operating an establishment registered under section 7 to submit a production report within 30 days after notification of registration of his establishment and thereafter on an annual basis. The due date for the annual report is stated in 40 CFR §167.5 as February 1 of every year. Failure to submit a production report is a violation of the requirements set forth in FIFRA §7(c) and violates section 12(a)(2)(L) of the Act.

EPA considers failure to comply with this reporting requirement a serious violation. Violations of the section 7 reporting requirement impacts the Agency's risk assessment capability as well as its ability to effectively target inspections. It is also important to note that this is the major mechanism by which EPA can determine what pesticides an establishment is producing.

Persons Regulated

Any person producing a pesticide or device is subject to section 7 and required to register his establishment with EPA. In addition, section 7(c) requires all registered establishments to submit an annual production report to the Agency. The regulations at 40 CFR §167.2(a) define which producing establishments must report.

Those producers who must comply with the reporting provision of FIFRA §7 include but are not limited to:

- o Producers of registered pesticides;
- o Producers of technical material;
- o Producers of devices;

- o Producers of pesticide products for export;
- o Reformulators;
- o Repackagers (includes relabelers);
- o Producers of pesticides in bulk form;
- o Foreign producers who export to the United States;
- o Producers of pesticides under an Experimental Use Permit;
- o Establishments which produce pesticides/devices under contract;
- o Producers of active ingredients (will be addressed in future FIFRA §7 regulations); and
- o Custom blenders (see section "Persons Not Required to Report.")

Establishments which did not produce over the past year or years and are still registered with EPA as a producing establishment are subject to this reporting requirement and must file a report stating "zero production". Therefore, any producer operating an establishment registered under FIFRA §7 must file an annual report, even if the registered establishment is not currently producing. Nonproducing registered establishments are also subject to the same remedies as a registered establishment that is actively producing.

Persons Not Required to Report Production

Any person who is a producer solely because he produces a custom blended pesticide is not required to report if he meets the requirements set forth in the FIFRA Compliance Program Policy No. 3.4 entitled "Custom Blenders".

Requirements of FIFRA §7(c)

Initial Report

When a producing establishment is registered, EPA provides the pesticide establishment report form (EPA Form 3540-16) to the producer along with the assigned establishment number. The completed form is to be submitted to EPA within 30 days after the receipt of the written notification of establishment registration. This pesticide establishment report is considered as the initial pesticide establishment report and is to be submitted by the establishment to the appropriate Regional Office.

In the case of foreign producers, their reports must be submitted to the Office of Compliance Monitoring (OCM).

Annual Report

After submitting the initial report, producers are required to submit production reports on an annual basis. The due date, as set forth in 40 CFR §167.5(c), is on or before February 1.

The postmark date on the report shall be considered as the date of submission for reports mailed to the Regional Office.

Request for an Extension

An establishment may request an extension from EPA concerning the due date for the annual production report. EPA may grant an extension if the request is made prior to the expiration of the due date and the producer can present just cause regarding the need for an extension. Granting of the extension will be at the discretion of the Regional Office, or OCM for foreign producers.

Information Required

Only those products produced and/or distributed by the reporting establishment should be included in the report. Information on products sold or distributed by, but not produced at, the reporting establishment are not to be included in the production report. However, if a registered establishment did not produce or distribute any products, an annual report indicating zero production must be submitted.

The pesticide establishment report shall include: the types of pesticides produced; the past year's amount of production and sales and distribution of each product; the amount of current production of each product; and the amount of product which has been sold or distributed in the past calendar year.

Additional information required in the report concerns manufacturing use products, end-use products, repackaged products, exports and imports, section 5 Experimental Use Permits, section 24(c) registrations and section 18 exemptions.

It is important to note that each establishment must have its own report and may not combine a report with any other establishment even if a company has several establishments. However, the company headquarters may complete the report forms for each of its producing establishments.

Violations

There are five types of reporting violations:

- o Late Reporting;
- o Notably Late Reporting;
- o Nonreporting;
- o Incomplete Reporting; and
- o Falsification of Information in the Report.

If a producer fails to submit a complete report by the required due date or falsifies information in the report, he may be charged with a violation under section 12(a)(2)(L), 7 USC §136j(a)(2)(L), and shall be subject to the remedies set forth in this enforcement response policy.

Late Reporting

For the purpose of this enforcement response policy, enforcement action will be initiated if the required production report is not submitted on or before the established due date. A production report submitted within 1 to 30 days after the due date shall be considered as a late report. It is important to note that reports submitted even one day after the due date will be considered as a late report.

Notably Late Reporting and Nonreporting

If a producing establishment does not submit the annual pesticide report within 30 days after the February 1 due date, the establishment will be considered as nonreporting and assessed the appropriate civil penalty.

If a report is submitted after the 30th day past the due date, but prior to the issuance of the civil complaint for nonreporting, the establishment will be considered as filing a notably late report and will be assessed the same civil penalty as a nonreporting violation. (Since the report had been submitted, the violation would no longer be nonreporting.)

Incomplete Reporting - Reporting in a Manner Inconsistent with the Regulations

A report may be technically incomplete. This violation occurs when the producer has failed to submit all required information. The Agency recognizes that not all such omissions are deliberate and its initial response to minor omissions in a report will be to telephone or write the submitter and attempt to obtain the missing information.

EPA considers minor omissions of information to be clerical errors and/or the omission of minor amounts of information as to reflect an oversight. If the submitter fails to provide EPA with the required information within 10 days from the date of the initial request, via letter, the report may then be considered incomplete. Consequently, the Agency shall issue a FIFRA §9(c)(3) notice of warning.

The notice of warning will provide the establishment with 20 calendar days to submit the necessary information. If a producer operating an establishment commits a second or subsequent (within a 3 year timeframe) incomplete reporting violation, he will be subject to a civil penalty.

False Reporting/Major Omissions of Information -
Reporting in a Manner Inconsistent with the Regulations

The submitter who was negligent about consulting records or performing calculations cannot claim to have reported all reasonably ascertainable information. Such negligence may be treated as falsification since the ultimate result of failure to meet the standard was the submission of false information. Furthermore, to knowingly falsify any information contained in the report is an unlawful act under FIFRA §12(a)(2)(M). Knowing or unknowing, major omissions are a violation of FIFRA §12(a)(2)(L).

An example of a major omission of information would be demonstrated by an establishment that does not report a pesticide which was produced in the preceding year, i.e., an establishment which produced 5 different pesticides, but reported production of only 4 pesticides.

II: LEVEL OF ACTION

The available levels of action for violations of the section 7 reporting rule include notices of warning, administrative civil penalties, termination of establishment registrations, and criminal sanctions.

Notice of Warning Under FIFRA §9(c)(3)

The notice of warning is the appropriate enforcement action for the following violations:

- o Nonreporting.- Initial Report.
Failing to submit the initial production report within 30 days after notification of the establishment registration. (Failure to report after the receipt of a FIFRA §9(c)(3) warning will result in termination of the establishment's registration.)

- o Late Reporting - Annual Report.
First offense in filing a late report. (Please note that this refers only to those situations in which the Region has received the report within 30 days after the due date.)

- o Incomplete Reporting - Minor Omissions of Information.

The registrant will be given 20 calendar days to submit the report, or the missing information, after the receipt of a notice of warning. If the Agency does not receive the report within the given timeframe, proceedings to terminate the establishment registration will commence (refer to section entitled Termination of Establishment Registration for further explanation and guidance).

The FIFRA §9(c)(3) notice of warning should be sent via certified mail with return receipt requested. A sample notice of warning for each applicable offense is located in Appendix A.

Administrative Civil Penalty FIFRA §14(a)(1)

Issuance of a civil complaint proposing a penalty is the appropriate enforcement response for the following violations:

- o Late Reporting - Second or Subsequent Violation Within a Three Year Timeframe From the First Violation;
- o Notably Late Reporting;
- o Nonreporting;
- o Incomplete Reporting - Second or Subsequent Violation (within a three year timeframe); and
- o Falsification of Information Contained in the Pesticide Report, or Major Omissions of Information.

The civil complaint should be issued within 75 days (2.5 months) after the February 1 report due date. Civil penalties should be assessed in accordance with the guidelines and procedures established in Part III of this policy. For additional guidance in assessing a civil penalty see the "General FIFRA Compliance/ Enforcement Guidance Manual", 1983, Chapter 7, entitled "Administrative Actions: Civil".

Termination of Establishment Registration

Termination For Cause

The regulations relating to the registration of a pesticide producing establishment (40 CFR §167.3 and 7 USC §136e) state

that an establishment's registration will remain in effect so long as the establishment submits the required production report. If the producing establishment fails to submit a production report within 20 calendar days after the date of receipt of the notice of warning or civil penalty, EPA will initiate procedures to terminate the establishment's registration. This action will be independent of any other enforcement action.

To terminate an establishment's registration, a Notice of Intent to Terminate must first be issued to the producing establishment. This notice will identify the violation and warn the producer that the registration for his establishment will be terminated if the report in question is not received within the next 20 calendar days. The Notice of Intent to Terminate Registration should be sent with the initial enforcement action or, at the latest, by May 1, or 20 days before the designated deadline of termination. (A sample Notice of Intent to Terminate Registration is located in Appendix A, page A-4).

Regions should assure that the establishment's registration is terminated on or before June 1 if the producer has not submitted his annual report within the timeframe set forth by the initial enforcement action (i.e., notice of warning or civil penalty).

Foreign Producers

The Office of Compliance Monitoring will issue a Notice of Intent to Terminate to any foreign producer who fails to submit a report within 30 days from the due date. If the report in question is not received within 30 calendar days from receipt of the Notice of Intent to Terminate, the establishment's registration will be terminated. Regions shall be informed of the termination of foreign establishment's registration (along with the Department of Treasury - U.S. Customs Service). This is to prevent entry of a pesticide product from a foreign establishment which has had its establishment registration terminated.

Inspections

Inspection of the producing establishment, for which registration has been terminated, should be conducted within 2 months following termination of the establishment's registration. This is to ensure adherence to the provisions of FIFRA §7.

Public Notification of Establishments Which Cannot Be Located

By July 1 of each year, all Regional Offices shall submit a listing to the Compliance Division of OCM, which identifies those establishments for which registrations are to be terminated, but have not been notified because the Regions have been unable to locate the establishment.

OCM will subsequently compile a listing of all those establishments which cannot be located and publish the establishment's name and number in the Federal Register for official public notification of the termination of the establishment's registration.

Reregistration After Termination

Producers desiring reregistration of their establishment must apply for establishment registration pursuant to the requirements of 40 CFR §167.2.

Requested Termination

Termination of an establishment registration may also occur upon the request of the establishment or parent company. This typically happens as a result of the establishment: 1) going out of business; 2) no longer producing pesticides or; 3) no longer falling under the purview of FIFRA §7. Termination of an establishment registration in such situations should not be confused with termination for cause.

Criminal Sanctions FIFRA §14(b)(1)

Criminal sanctions pursuant to §14(b)(1) of the Act will be sought in situations that when measured by the nature of the conduct and the compliance history of the subject, reflect the most serious cases of misconduct.

For FIFRA §7, the Agency may consider criminal action for knowing and willful falsification of the information provided to the Agency. Since the Agency may terminate the registration of producers who fail to report, EPA will generally not consider criminal action for nonreporting violations.

PART III: ASSESSING AN ADMINISTRATIVE CIVIL PENALTY

Summary of the Penalty Policy

All civil administrative penalties should be calculated by selecting the appropriate gravity based penalty (GBP) and making appropriate modifications based on application of the adjustment factors in the general FIFRA Civil Penalty System.

CIVIL PENALTY MATRIX

	I	II	III	IV	V
A. Late Reporting Violation -- Subsequent Violation §12(a)(2)(L)	200	400	600	800	1000
B Incomplete Reporting -- Producer Does Not Respond to Notice of Warning. Also Those Producers Who Commit a Subsequent Violation §12(a)(2)(L)	320	800	1760	2720	3200
C. Notably Late Reporting or Nonreporting Violation -- Annual Report §12(a)(2)(L)	320	800	1760	2720	3200
D. Submission of False §7 Report Data §§12(a)(2)(M) & 12(a)(2)(N)	500	1250	2750	4250	5000

Explanation of Penalty Policy

Calculation of the Gravity Based Penalty

The Gravity Based Penalty (GBP), for each type of violation is to be selected from the matrix provided on page 9 of this document.

Violations

1) Subsequent Late Reporting.

This violation concerns the producing establishment which has received a previous FIFRA §9(c)(3) notice of warning for submitting a late report within 3 years from the present reporting year.

Since the actual report is in the possession of the Agency, a lesser penalty is appropriate. Penalties shall be assessed according to Penalty Matrix A.

2) Incomplete Reporting - Second or Subsequent Violation.

When information is omitted from the pesticide report, the Agency will contact the producing establishment and request the information. If the information is not immediately accessible, the producing establishment may then be granted 10 days to submit the necessary information, via letter to the proper EPA Region, (or Headquarters in the case of foreign establishments). If the registrant does not respond by submitting the requested information within 10 days, they will be considered as filing an incomplete report and subject to a civil penalty. In such cases the Region is to assess a penalty in accordance with GBP Matrix B.

3) Notably Late Reporting or Nonreporting Violation - Annual Report.

A production report is considered notably late if the report is submitted to the Agency more than 30 days after the due date, but prior to the issuance of the civil complaint for nonreporting.

Nonreporting results when a producer operating an establishment does not submit a report to the Agency.

Notably late reporting and nonreporting violations receive the same penalty assessment. Penalties shall be assessed in accordance with GBP Matrix C, unless the establishment falls into one of the following categories.

A. Nonreporting by Producers of Pesticides in Bulk Form -

Producers of pesticide in bulk form shall be assessed a penalty in accordance with GBP Matrix A for a first time nonreporting violation. Subsequent nonreporting violations warrant a penalty assessment from GBP Matrix C.

B. Nonreporting by Establishments with Zero Production -

When a nonproducing establishment fails to report, EPA will issue a civil complaint in accordance with GBP Matrix C. If the producer requests termination of his establishment registration within 20 calendar days after the civil complaint has been issued, the civil penalty may be reduced to zero. Please note that reduction of a penalty is at the discretion of EPA.

In the event the producer reregisters his establishment, and commits another nonreporting violation, he will be subject to a civil penalty, without the option of the penalty being reduced to zero.

4) Falsification of Report Data.

When a producer knowingly falsifies any information submitted to EPA pursuant to section 7, the proposed penalty shall be selected from GBP Matrix D. Reporting false information is a serious violation, one which warrants an increased penalty and may subject the producer to criminal proceedings. Please note that submission of a report with major omissions of information which are not "knowingly" omitted is a violation of FIFRA §12(a)(2)(L).

An example of false reporting is an establishment which produces 5 pesticides yet only reports production of 4 pesticides. If the Agency discovers that an establishment actually produced 5 pesticides in the past year, and not 4 as reported, the establishment would be cited for falsification of information.

Adjustment Factors

The FIFRA Civil Penalty Policy specifies that the penalty is to be adjusted by applying appropriate adjustment factors. Several adjustment factors are particularly relevant to violations of this reporting requirement. Adjustment factors are outlined in the General FIFRA Civil Penalty Policy; however the following factors are especially applicable to violations of this reporting requirement:

- o History of prior such violation;
- o Effect on person's ability to continue in business; or
- o Good faith attitude (up to 20% reduction).

Penalty Assessment When Business Size is Unknown

When no information concerning a producing establishment's size of business can be found, the Agency will propose the penalty at the GBP Category V Size of Business Level. The Category V amount shall be the penalty proposed unless the establishment can verify to EPA, at the expense of the establishment, its size of business. The proposed penalty will subsequently be adjusted to reflect the documented information demonstrating the establishment's size of business. (A sample size of business letter which may be used in the aforementioned instance can be found in Appendix B.)

APPENDIX A

Model Notice of Warning

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

EPA Est. 000-00

Establishment's Address

Gentlemen:

NOTICE OF WARNING

FOR FAILING TO FILE INITIAL PESTICIDE ESTABLISHMENT REPORT

This letter constitutes a warning pursuant to section 9(c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (hereafter FIFRA), 7 USC section 136g(c)(3). The Environmental Protection Agency is hereby advising you that you are in violation of section 12(a)(2)(L) of FIFRA, 7 USC §136j(a)(2)(L), by failing to file the initial pesticide production report within thirty (30) calendar days after the receipt of notification of registration for your establishment which included the EPA Production Report Form. The aforementioned information was sent via certified mail to (ESTABLISHMENT'S NAME, ADDRESS) and was received on (DATE OF RETURN RECEIPT).

You are hereby advised to file the initial report with this Regional Office, within twenty (20) calendar days. If you have not filed the initial pesticide production report within the twenty (20) calendar days, you shall be subject to the remedy set forth in Part 40 Code of Federal Regulations §167.5, whereby the registration of this producing establishment shall be terminated.

All necessary measures are taken by the Agency to preclude the issuance of a notice of termination of registration. However, if the report is not received within the given timeframe of this notice, proceedings to terminate your establishment's registration will be pursued.

Please note that according to FIFRA, no person shall produce any pesticide subject to FIFRA in any State unless the establishment in which it is produced is registered with the Administrator.

If you have any questions concerning this matter, please contact (NAME AND PHONE NUMBER).

Sincerely yours,

Signature
(Name and Title)

Model Notice of Warning

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

EPA EST. 000-00

Establishment's Address

Gentlemen:

NOTICE OF WARNING

FOR FILING A LATE ANNUAL PESTICIDE ESTABLISHMENT REPORT

This letter constitutes a warning pursuant to section 9(c)(3) of the Federal Insecticide Fungicide and Rodenticide Act, as amended (FIFRA), 7 USC section 136j(c)(3). The Environmental Protection Agency is hereby advising you that you are in violation of section 12(a)(2)(L) of FIFRA, 7 USC §136j(a)(2)(L), by not filing the annual pesticide report required by FIFRA §7(c), on or before the February 1 due date. The report filed by your producing establishment located at (address) was received by this Office on (DATE).

You are hereby advised to comply with the regulations promulgated at 40 CFR §167.5(c) which states the due date for annual reports as being February 1 of each year. Noncompliance with this reporting requirement in the future may subject your producing establishment to an administrative civil penalty.

If you have any questions concerning this notice of warning, please contact (NAME) at (PHONE NUMBER).

Sincerely yours,

(Signature
Name and Title)

Model Notice of Warning for Failing to File a
Complete Pesticide Report

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

EPA EST. 000-00

Establishment's Address

Gentlemen:

NOTICE OF WARNING

FOR FAILING TO SUBMIT A COMPLETE PESTICIDE REPORT

This letter constitutes a warning pursuant to section 9(c)(3). 7 USC section 136j(c)(3) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, (FIFRA). The Environmental Protection Agency is hereby advising you that you are in violation of section 12(a)(2)(L) of FIFRA, 7 USC section 136(a)(2)(L), by failing to submit the information which was missing from the annual pesticide report received on (DATE). This Office contacted you on (DATE) via (letter or telephone) to request the missing information whereby your establishment was allocated ten (10) days to submit the information to this Office. The information required in the pesticide report may be found at 40 CFR 167.5(a).

You are hereby advised to submit the information requested within twenty (20) calendar days from the receipt of this Notice of Warning. Failure to do so may subject your producing establishment to an administrative civil penalty.

If you have any questions concerning this matter, please contact (NAME) at (PHONE #).

Sincerely yours,

Signature
(Name and Title)

Model Notice of Intent to Terminate Establishment Registration

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

EPA Est. 000-00

Establishment's Address

Gentlemen:

NOTICE OF INTENT TO TERMINATE ESTABLISHMENT REGISTRATION

You are hereby advised of the Environmental Protection Agency intention to terminate the registration of your pesticide producing establishment located in (city and state) pursuant to 40 CFR §167.3 and section 7 of the Federal Insecticide, Fungicide and Rodenticide Act, (FIFRA), as amended, 7 USC §6136, in response to your failure to submit the production report required by section 7(c) of FIFRA and 40 CFR §167.3.

Your failure to file the required report by February 1, 19 ____ has already subjected you to the (NOTICE OF WARNING, CIVIL OR CRIMINAL PENALTY) provision of the Act. Failure to submit the required reports within twenty (20) calendar days from the date this notice will result in the termination of your establishment registration, which shall be effective upon the issuance of a Notice of Termination of Establishment Registration. Submission of the required report within the twenty (20) day time period shall not affect your liability under the provisions of FIFRA, whereby the enforcement action which had previously been initiated against your establishment is still in effect. However, termination of your establishment registration is an enforcement action, independent of any other.

In the event you do not respond to this notice, you should assure yourself that all necessary measures will be taken to preclude any production not in compliance with FIFRA or the regulations.

Sincerely yours,

Signature
(Name and Title)

Model Notice of Termination of
Establishment Registration

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

EPA Est. 000-00

(Company name)
(Address)

Subject: (Establishment registration number)

NOTICE OF TERMINATION OF ESTABLISHMENT REGISTRATION

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, (FIFRA) 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 establishment report(s) together with an application for establishment registration (EPA Form 3540-16).

Please be assured that all necessary measures shall be taken to preclude any action at your establishment which is 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)

APPENDIX B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

(Est. name and address)

Dear ()::

Enclosed is an administrative Civil Complaint alleging violations documented under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA).

In determining the amount of the penalty, the Agency is required to consider 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 violations. The Guidelines for the Assessment of Civil Penalties (39 FR 27712) set forth the following size-of-business gradations, based on gross annual sales:

Category I	Less than \$100,000
Category II	\$100,000 - \$400,000
Category III	\$400,000 - \$700,000
Category IV	\$700,000 - \$1,000,000
Category V	In excess of \$1,000,000

In the absence of specific information on your firm's size of business, as determined by gross annual sales, it has been assumed for purposes of this Complaint that your firm is a Category V size of business.

Please be assured that if your firm has been placed in Category V incorrectly, the proposed penalty will be adjusted upon submittal of reliable financial information indicating another category is appropriate. If you have any questions concerning this matter, please contact (name) at (phone #).

Sincerely yours,

Signature
(Name and Title)

Enclosure

APPENDIX C

SECTION 7(c) ENFORCEMENT RESPONSE CHART

VIOLATION/ UNLAWFUL ACT OF FIFRA	VIOLATION CATEGORY	INITIAL ENFORCEMENT ACTION	FINAL REMEDY/ACTION WHEN NO RESPONSE TO INITIAL ACTION
LATE REPORTING §12(a)(2)(L)	Annual Report-- 1st Violation	§9(c)(3) -- Notice of Warning (Regions must already have the report)	
INCOMPLETE REPORTING §12(a)(2)(L)	Annual Report-- 1st Violation	§9(c)(3) -- Notice of Warning with 20 days Allocated for Response	
NONREPORTING §12(a)(2)(L)	Initial Report-- 1st Violation	§9(c)(3) -- Notice of Warning with 20 days Allocated for Response Plus a Notice of Intent to Terminate	Termination of Establishment's Registration
LATE REPORTING §12(a)(2)(L)	Annual Report-- Subsequent Violation within 3 Years	Civil Penalty (See GBP Matrix A)	
INCOMPLETE REPORTING §12(a)(2)(L)	Annual Report-- Subsequent Violation	Civil Penalty (See GBP Matrix B) -- 20 days Allocated to Submit Missing Information -- Notice of Intent to Terminate Sent Along with Penalty	Termination of Establishment's Registration

SECTION 7(c) ENFORCEMENT RESPONSE CHART (CONTINUED)

VIOLATION/ UNLAWFUL ACT OF FIFRA	VIOLATION CATEGORY	INITIAL ENFORCEMENT ACTION	FINAL REMEDY/ACTION WHEN NO RESPONSE TO INITIAL ACTION
NOTABLY LATE OR NONREPORTING §12(a)(2)(L)	Annual Report-- All Violations	Civil Penalty (See GBP Matrix C, except for producers of pesticides in bulk form - 1st time violation see GBP Matrix A) Notice of Intent to Terminate Sent Along with Penalty	Termination of Establishment's Registration
FALSIFICATION OF INFORMATION §§12(a)(2)(M) & 12(a)(2)(N) MAJOR OMISSIONS OF INFORMATION §12(a)(2)(L)	1st and/or Subsequent Violation	Civil Penalty -- (See GBP Matrix D), Notice of Intent to Terminate Sent Along with Penalty, or May Be Subject to Criminal Action	Termination of Establishment's Registration

CIVIL PENALTY MATRIX FOR SECTION 7(c)

I II III IV V

A	200	400	600	800	1000
B	320	800	1760	2720	3200
C	320	800	1760	2720	3200
D	500	1250	2750	4250	5000

**ENFORCEMENT RESPONSE POLICY
FOR THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)**

**Office of Compliance Monitoring
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency**

July 2, 1990

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07/02/90

ENFORCEMENT RESPONSE POLICY FOR THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

INTRODUCTION

This document sets forth the procedures and criteria that will be used to determine the appropriate enforcement response for violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The FIFRA Enforcement Response Policy (ERP) is designed to provide fair and equitable treatment of the regulated community by ensuring that similar enforcement responses and comparable penalty assessments will be made for comparable violations. The policy is designed to provide for swift resolution of environmental problems and to deter future violations of FIFRA by the respondent as well as other members of the regulated community.

This policy supersedes the previous FIFRA Civil Penalty Assessment Guidelines published in the Federal Register on July 31, 1974 (39 FR 27711). There have been many amendments to the statute, as well as EPA rulemaking, since the 1974 FIFRA Civil Penalty Assessment Guidelines, which are incorporated into this revised FIFRA ERP. Also superseded by this FIFRA ERP are: the 1983 Level of Action Policy published as section 2 of Chapter 5 of the FIFRA Compliance/Enforcement Guidance Manual; the June 8, 1981 Guidance for the Enforcement of the Child-Resistant Packaging Regulation; and the June 11, 1981 FIFRA Enforcement Policy - Interim Penalty Guidelines.

Except for the civil penalty assessment matrix, the February 10, 1986 FIFRA Section 7(c) Enforcement Response Policy remains in effect, and is to be used to determine the appropriate enforcement response for FIFRA section 7(c) violations. The matrix setting forth the penalties in this policy should be used instead of the matrix in the February 10, 1986 policy. Additional supplements to the FIFRA ERP will be forthcoming which will more clearly discuss the appropriate enforcement response for violations of other specific program requirements, such as the FIFRA Good Laboratory Practice (GLP) Standards and the FIFRA section 19 regulations.

OVERVIEW OF THE POLICY

This FIFRA Enforcement Response Policy (ERP) is divided into three main sections. The first section, "Determining the Level of Action," briefly describes the Agency's options for responding to violations of FIFRA. Section 2 of this ERP, "Assessing Administrative Civil Penalties," elaborates on the Agency's policy and procedures for calculating civil penalties to be assessed against persons who violate FIFRA. Section 2 also contains the Agency's policy for negotiating a "settlement with conditions" for civil penalties issued under FIFRA. The third section of this policy contains the appendices necessary for calculating civil penalties. The four appendices to this ERP are: (1) Appendix A - FIFRA Charges and Gravity Levels; (2) Appendix B - Gravity Adjustment Criteria; (3) Appendix C - The Summary of Tables; and, (4) Appendix D - The FIFRA Civil Penalty Calculation Worksheet.

Guidance on the appropriate enforcement response for violations of specific FIFRA programs, such as the FIFRA Good Laboratory Practice Standards,* FIFRA section 19 recall requests,* or FIFRA section 7(c) Pesticide Producing Establishment Reporting Requirements, should be attached as additional appendices, and used in conjunction with the overall FIFRA ERP.

* Enforcement response policies for the Good Laboratory Practice Standards, and the FIFRA section 19 regulations will be forthcoming.

DETERMINING THE LEVEL OF ACTION

Once the documentation of a FIFRA violation is complete, the appropriate level of action called for by the severity of the violation needs to be selected. These levels of response include:

- o Notices of Detention under section 17(c);
- o Notices of Warning under sections 9(c)(3), 14(a)(2), and 14(a)(4);
- o Stop Sale, Use, or Removal Orders under section 13(a);
- o Seizures under section 13(b);
- o Injunctions under section 16(c);
- o Civil administrative penalties under section 14(a);
- o Denials, suspensions, modifications, or revocations of applicator certifications under 40 CFR Part 171;
- o Criminal referrals under section 14(b); and
- o Recalls.

Notices of Detention

A shipment of a pesticide or device being imported into the United States cannot be brought into the country until EPA makes a determination of the admissibility of that shipment. However, under the U.S. Customs' regulations for the enforcement of section 17(c) of FIFRA (19 CFR Part 12.110 - 12.117), subsequent to the receipt of a Notice of Arrival completed by the Administrator, 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. When a shipment of pesticides is released under bond, the shipment may not be used or otherwise disposed of until the Administrator has determined the admissibility of that shipment. Should the shipment subsequently be refused entry and the importer or agent fails to return the pesticide or device, the bond is forfeited.

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. If the consignee has not requested a hearing, or has not exported the pesticide or device within 90 days from the date of the notice, the Customs Service will oversee destruction of the pesticide or device.

Notices of Warning

FIFRA sections 14(a)(2), 14(a)(4), and 9(c)(3) provide EPA with the authority to respond to certain violations of FIFRA with a Notice of Warning to the violator.

Section 14(a)(2) Notices of Warning

Under section 14(a)(2) of FIFRA, a written warning for a violation of FIFRA must be issued to a private applicator or other person not covered by section 14(a)(1) prior to the assessment of a civil penalty. Applicators who apply a registered general use pesticide as a service in controlling pests but who do not deliver any unapplied pesticides ("for hire" applicators), are also included in section 14(a)(2) but are not subject to this limitation. A "for hire" applicator may be assessed a penalty up to \$500 for the first offense.

Sections 9(c)(3) and 14(a)(4)

Section 14(a)(4) of FIFRA states that EPA may choose to issue a Notice of Warning in lieu of a civil penalty if EPA determines that the violation occurred despite the exercise of due care or the violation did not cause significant harm to health or the environment. Section 9(c)(3) also permits the EPA to issue a written Notice of Warning in lieu of instituting a proceeding for minor violations of FIFRA if the Administrator believes that the public interest will be adequately served through this course of action.

Generally, a violation will be considered minor, and a section 9(c)(3) notice of warning may be issued in lieu of a civil complaint if the total "gravity adjustment value", as determined from Appendix B of this ERP, is less than three (see the section of this ERP entitled "Gravity of the Violation" and Appendix B, "Gravity Adjustment Criteria"). A Notice of Warning may also be appropriate for certain first-time record keeping violations as listed in Appendix A of this ERP (e.g., late section 7 reports).

Stop Sale, Use, or Removal Orders (SSURO)

Section 13 of FIFRA provides EPA the authority to issue a Stop Sale, Use, or Removal Order (SSURO) to any person who owns, controls, or has custody of a pesticide or device, whenever EPA has reason to believe on the basis of inspection or tests that: (1) a pesticide or device is in violation of any provision of the Act; (2) a pesticide or device has been or is intended to be distributed in violation of the Act; or, (3) when a registration of a pesticide has been cancelled by a final order or has been suspended. A civil penalty should generally be assessed in addition to the SSURO when a violation of FIFRA has occurred.

A 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: (1) it may be issued whenever EPA has reason to believe that the product is in violation of the Act; (2) it is easier to prepare and issue than a seizure; (3) the SSURO has an effect on all of the product under the ownership, custody, or control of the individual receiving the SSURO regardless of where the product is located; (4) the SSURO can be written so as to include future amounts of the product that may come into custody of the person on whom the SSURO is served; and, (5) it can easily be adapted to particular circumstances.

As per the FIFRA Compliance Program Policy Number 3.9, issued on July 6, 1987, when a SSURO is issued to a basic registrant with regard to a registered pesticide product, the terms of the SSURO are equally applicable to the supplemental registrants of the product.

Mandatory Issuance of a SSURO

A SSURO is to be issued against persons who own, control, or have custody of pesticides in the following categories:

- Pesticides for which there is reason to believe that there is a potential hazard to man or the environment because: (1) they are not registered, or are so over-formulated, underformulated, or adulterated, as to present a serious health hazard; or, (2) 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 followed by a user, is likely to cause a life-endangering health hazard or serious adverse environmental effects (a pesticide lacking a restricted use label is an especially serious labeling violation). This provision includes labeling for products that: (1) are ineffective for the purposes claimed; (2) are so chemically deficient as to affect deleteriously the product's efficacy; or, (3) bear false or misleading safety claims.
- Pesticides or hazardous devices* that are in violation of the Act and are the subject of a recall, but which the responsible party refuses to remove, is recalcitrant in removing, or is unable to remove from the channels of trade.
- 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.
- Pesticides which have been suspended under FIFRA section 6.

* 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 a SSURO. See December 19, 1979 Memorandum: "Enforcement Actions Concerning Nonhazardous Pesticide Devices."

Discretionary Issuance of a SSURO

The EPA may also issue a SSURO in cases where there is reason to believe a product either is in violation of the Act or that the product has been 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. The EPA may also issue a SSURO if a product has been cancelled under any section of the Act, or suspended under FIFRA sections 4 or 3(c)(2)(B), and the existing stock deadlines have occurred at that level of sale, distribution, or use.

Use of a SSURO for Minor Violations

While EPA will usually reserve the use of a SSURO for relatively serious violations, the need to issue a 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 on the label, EPA may decide to issue a SSURO to ensure that the product will be distributed or sold in compliance with the Act.

Seizures

Section 13(b) of FIFRA gives EPA the authority to initiate in rem condemnation proceedings in U.S. District Court. Once a Court grants the Agency's request for authority to conduct a seizure, FIFRA section 9(b)(3) authorizes officers or employees duly designated by the Administrator to obtain and execute warrants for the purpose of seizing any pesticide or device that is in violation of the Act. Seizures may be executed with the assistance of the U.S. Marshal.

Under FIFRA section 13(b), EPA may initiate seizure actions in District Court against 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, if: (1) a pesticide is adulterated or misbranded; (2) a pesticide is unregistered; (3) a pesticide has labeling which does not bear the information required by the Act; (4) a pesticide is not colored or discolored as required; (5) a pesticide bears claims or directions for use that differ from those made in connection with its registration; (6) a device is misbranded; or, (7) a pesticide or device causes unreasonable adverse effects upon the environment, even when used in accordance with the requirements imposed by the Act.

The previous examples are similar to those circumstances that would lead the Agency to issue a SSURO. Because a SSURO can be issued in less time and with less preparation than that required for a seizure, the SSURO is the preferred enforcement remedy in terms of expediency. Nevertheless, the Agency should consider initiating a seizure in the following circumstances:

- o The Agency has issued a SSURO, but the recipient of the order has not complied with it;
- o The Agency has reason to believe that a person, if issued a SSURO, will not comply with it;
- o There exists a pesticide so hazardous that it should be removed from the marketplace, place of storage, or place of use to prevent any chance of harm to human health or the environment;
- o The seizure will be used to support a recall; or
- o It is necessary to dispose of products being held under a SSURO for which the responsible party has taken no corrective action and has expressed an intent not to take corrective action.

Injunctive Relief

Section 16(c) of FIFRA gives EPA the authority to initiate injunctive actions before the U.S. District Court. These actions may consist of permanent injunctions, preliminary injunctions, or temporary restraining orders.

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: (1) 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; (2) the Agency has already diligently exercised all appropriate administrative remedies (such as SSUROs and civil penalties), yet the violation or threat of a violation continues unabated; or (3) irreparable injury, loss, or damage will result if the relief sought is not granted.

In the case of a preliminary injunction or temporary restraining order, the Agency must additionally demonstrate that: (1) immediate and irreparable injury, loss, or damage will result if the requested relief is not granted; and, (2) there is a likelihood of Agency success at trial, based on the 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:

- o The violation of a section 6 suspension or cancellation order;
- o The violation of a SSURO where a civil penalty or criminal prosecution would not provide a timely or effective remedy to deter further violations;
- o There is continued production (in violation of the FIFRA section 7 requirements), shipment, sale, distribution, or use of an unregistered pesticide after the Agency has taken civil or criminal action;
- o A person continues to sell, distribute, or make available for use a restricted use pesticide (RUP) other than in accordance with FIFRA section 3(d), after the Agency has already exercised an enforcement remedy;
- o A person continues to violate the FIFRA section 17 import or export requirements after the Agency has already exercised an enforcement remedy; and,
- o A person continues to use a pesticide in a manner inconsistent with its labeling, in a manner contrary to an experimental use permit, or repeats any violation of FIFRA, after the Agency has already exercised an enforcement remedy.

Civil Administrative Penalties

FIFRA section 14(a)(1) states that a registrant, commercial applicator, wholesaler, dealer, or other distributor may be assessed a civil penalty of up to \$5,000 for each violation of FIFRA. Section 14(a)(2) allows the Administrator to assess a private applicator or other person up to \$1,000 for each violation of FIFRA, subsequent to receiving a Notice of Warning or a citation for a prior violation (the prior warning or citation may have been for the same or different FIFRA violation). Additionally, section 14(a)(2) states that an applicator who applies a registered general use or unclassified pesticide as a service in controlling pests but does not deliver any

unapplied pesticide (a "for hire applicator") may be assessed a civil penalty of not more than \$500 for the first offense of FIFRA, and \$1,000 for each subsequent offense.*

A civil penalty is the preferred enforcement remedy for most violations. A civil penalty is appropriate where the violation: (1) presents an actual or potential risk of harm to humans or the environment (SSUROs or injunctive relief should be pursued in addition to a civil penalty if the harm is extreme or imminent), or would impede the Agency's ability to fulfill the goals of the statute; (2) was apparently committed as a result of ordinary negligence (as opposed to criminal negligence), inadvertence, or mistake; and the violation either: (a) involves a violation 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, (b) involves a private applicator or other person not listed in above and who has received a prior warning or citation for a FIFRA violation.

Denials, Suspensions, Modifications, or Revocations of Applicator Certifications

The regulations relating to the certification of pesticide applicators (40 CFR Part 171) authorize EPA to deny, suspend, or revoke a federally issued applicator certification if the holder of the certification 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 CFR Section 171.11(f)(5)(i)]. Therefore, EPA will deny, suspend, modify, or revoke a federal certification only in response to serious violations or against persons with a history of noncompliance.

* Any applicator, including a "for hire applicator", who holds or applies an unregistered pesticide to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, will be considered a distributor of pesticides and will be subject to the higher penalties set forth in sections 14(a)(1) and 14(b)(1) of FIFRA.

Any applicator, other than a private applicator, who uses or supervises the use of a restricted use pesticide (RUP), whether or not that applicator is certified, is a commercial applicator and is subject to the higher penalties set forth in sections 14(a)(1) and 14(b)(1) of FIFRA.

Any applicator, including an applicator who is certified, who holds or applies a general use pesticide (GUP) or an unclassified pesticide in violation of FIFRA for that pesticide will be subject to the lower penalties set forth in FIFRA sections 14(a)(2) and 14(b)(2).

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 at least six months following denial or revocation. Therefore, EPA will deny or revoke a certification where: (1) a violation resulted in a fatality or created an imminent danger of a fatality; (2) a violation resulted in severe damage to the environment or created an imminent danger of severe damage to the environment; (3) a misuse violation has resulted in significant contamination of food and water; (4) the violator's certification has been suspended as a result of a previous serious violation; or (5) a person has maintained or submitted fraudulent records or reports.

If EPA pursues an action to deny, revoke, or modify an applicator's certification, EPA will notify the applicant or federal certificate holder of: (1) the ground(s) upon which the denial, revocation, or modification is based; (2) the time period during which the denial, revocation, or modification is effective, whether permanent or otherwise; (3) the conditions, if any, under which the individual may become certified or recertified; and (4) any additional conditions EPA may impose. EPA must also provide the federally certified applicator an opportunity to request a hearing prior to final Agency action to deny, revoke, or modify the certificate.

Suspensions

Generally, the Agency will pursue the less severe alternative of suspending an applicator's federal certification in response to violations by applicators who have previously been issued a civil complaint for a violation of FIFRA. The Agency will suspend an applicator's certification for up to four months for the second independent violation of FIFRA.* For each additional violation, two months may be added to the term of suspension up to a limit of eight months. The exact length of the suspension (within the limits stated above) should result in an economic loss to the applicator of at least the statutory maximum civil penalty that could have been assessed.

* For purposes of this section of the policy, 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.

If EPA decides to suspend certification, it must notify the applicator of the grounds upon which the suspension is based, and 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.

Generally, a suspension is pursued against an individual applicator for a subsequent offense in addition to the issuance of a civil penalty against the employer.

EPA may also suspend certifications of commercial applicators who violate restricted use pesticides recordkeeping requirements [see 40 CFR 171.11(c)(7); 40 CFR 171.11(f)(1)(iii)]. 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.

Criminal Proceedings

Section 12 of FIFRA specifically lists the unlawful acts that are subject, not only to civil and administrative enforcement, but also to criminal investigation and penalties (see Chapter 20, "FIFRA Criminal Enforcement," of the Pesticides Inspection Manual).

Section 14(b) of FIFRA (7 U.S.C 136l) provides the authority to proceed with criminal sanctions against violators of the Act, as follows:

- o A registrant, applicant for a registration, or producer who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$50,000 or imprisonment for up to 1 year, or both.
- o A commercial applicator of a restricted use pesticide, or any other person not described above who distributes or sells pesticides or devices, who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$25,000 or imprisonment for up to 1 year, or both.

- o 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.

In addition, pursuant to the Alternatives Fines Act (18 U.S.C. 3571) the FIFRA criminal fine amounts may be substantially increased if the violation results in death.

All acts of the regulated community exhibiting actual or suspected environmental criminal conduct should be discussed with EPA Regional or Headquarter's Criminal Enforcement Counsel or to the Office of Criminal Investigations for an assessment and possible investigation.

Parallel Criminal and Civil Proceedings

Civil/administrative and criminal enforcement actions may be conducted simultaneously whenever deemed necessary by the EPA Assistant Administrator for the Office of Enforcement in order to seek immediate relief to protect human health or the environment. Simultaneous civil actions and criminal proceedings may be appropriate if the environmental consequences of a violation pose a hazard requiring remedial measures by a defendant.

The State and Federal Roles in Criminal Enforcement of FIFRA

State primacy for pesticide use violations, under FIFRA sections 26 and 27, also applies to criminal FIFRA use violations. States are initially allowed 30 days to commence appropriate enforcement actions for such violations. However, criminal violations which do not constitute pesticide use violations may be investigated and prosecuted on the Federal level without waiting for State authorities to exercise their primary enforcement responsibility. The State should be informed of any criminal investigation being conducted within their State.

Violations of a cancellation or suspension order, an EPA stop sale, use, or removal order (SSURO), fraudulent labeling, advertising, or registration of a pesticide are among those types of FIFRA violations for which States do not have primary enforcement authority. Even where there is a FIFRA pesticide use violation, the States can choose to waive their primary enforcement responsibility to allow Federal criminal enforcement action to be undertaken.

FIFRA's Relationship to Other Federal Criminal Laws

Possible criminal environmental offenses should be brought promptly to the attention of EPA Criminal Enforcement Counsel, Special Agents in the Office of Criminal Investigations, or the appropriate state authorities. This is true even if the suspected criminal activity does not appear to be a violation of FIFRA. The criminal conduct may also be amenable to prosecution under one of the other environmental laws or one of the general criminal laws.

For instance, submission of false registration information may not only constitute a violation of FIFRA, but also the Federal false statement statute and conspiracy laws. The unlawful disposal of pesticides may be a criminal violation of the Resource Recovery and Conservation Act (RCRA) or, if the disposal was into a river, such conduct could be a criminal violation of the Clean Water Act. Which statute to proceed under may not be decided until the investigation is almost complete and may depend on factors such as the evidence available to establish an offense and the different penalty levels of the involved statutes.

Recalls

In general, under FIFRA sections 19(b)(3) and (4), if a registration of a pesticide has been suspended and cancelled, and EPA finds that a recall is necessary to protect public health or the environment, EPA will request that a voluntary or mandatory recall be conducted. Additionally, the EPA will continue its policy of initiating formal and informal recalls in cases where a product is either potentially hazardous when used as directed, ineffective for the purposes claimed, or violative in nature. Formal and informal recalls are not authorized under the statute. Therefore, the effectiveness of a formal or informal recall action is contingent on the cooperation of the company involved.

Voluntary and Mandatory Recalls

A voluntary recall may be appropriate if a product is suspended and cancelled and the voluntary recall will be sufficient to protect human health or the environment. If not, mandatory recall procedures issued as a regulation under FIFRA sections 19(b)(3) and (4) may require registrants, distributors, or sellers of a pesticide to recall the pesticide; to make available storage facilities to accept and store existing stocks of the suspended and cancelled pesticide; to inform the EPA of the location of the storage facility; and to inform the EPA of the progress of the recall. The parties

subject to the recall must also provide transportation of the pesticide, on request; and take reasonable steps to inform holders of the recall and transportation provisions. Persons conducting the recall must comply with transportation, storage and disposal requirements. The criteria for the recall plans will be issued under FIFRA section 19(b) through the 40 CFR Part 165.

Formal and Informal Recalls

The Agency should consider a formal or informal recall of a product when, among other things, its use as directed by the label is likely to result in: (1) injury to the user or handler of the product; (2) injury to domestic animals, fish, wildlife, or plant life; (3) physical or economic injury because of ineffectiveness or due to the presence of actionable residues; or (4) identifiable adverse effects on the environment. A product does not have to be suspended or cancelled in order for EPA to decide that requesting a formal or informal recall is appropriate.

A formal or informal recall must only be requested where the evidence clearly supports the need for 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 analysis, staff evaluations and opinions, and such other information as may be available. All information supporting a recall decision must be included in the official file.

Formal recalls are used for more serious problems and 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.

An informal recall should be used 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.

Press Releases/Advisories, Etc.

Regions may, at their discretion, issue a press release/advisory to notify the public of a person's violation of FIFRA. However, the issuance of press release/advisory must not be an item of negotiation during settlement.

A press release/advisory can be a useful tool to notify the public of a person's noncompliance with FIFRA and to educate the public on the requirements of FIFRA.

ASSESSING ADMINISTRATIVE CIVIL PENALTIES

FIFRA section 14(a)(1) states that a registrant, commercial applicator, wholesaler, dealer, or other distributor may be assessed a civil penalty of up to \$5,000 for each violation of FIFRA. Section 14(a)(2) allows the Administrator to assess a private applicator or other person up to \$1,000 for each violation of FIFRA, subsequent to receiving a Notice of Warning or a citation for a prior violation. Additionally, section 14(a)(2) states that an applicator who applies a registered general use pesticide as a service in controlling pests but does not deliver any unapplied pesticide (a "for hire applicator") may be assessed a civil penalty of not more than \$500 for the first offense of FIFRA, and \$1,000 for each subsequent offense.

Additionally, as the statutory definitions of "distribute or sell" and "commercial applicator" indicate, and as the conference report for the Federal Pesticide Act of 1978 confirms (Senate Report No. 95-1188; September 12, 1978; page 44 and 45), any applicator, including a "for hire" applicator, who holds or applies an unregistered pesticide to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, will be considered a distributor of pesticides and will be subject to the higher penalties set forth in sections 14(a)(1) and 14(b)(1) of FIFRA. Additionally, any applicator, other than a private applicator, who uses or supervises the use of a restricted use pesticide (RUP), whether or not that applicator is certified, is a commercial applicator and is subject to the higher penalties set forth in sections 14(a)(1) and 14(b)(1) of FIFRA. Finally, any applicator, even if that applicator is certified, who holds or applies a general use pesticide (GUP) or an unclassified pesticide in violation of FIFRA will be subject to the lower penalties set forth in FIFRA sections 14(a)(2) and 14(b)(2).

The FIFRA Civil Penalty System - Computation of the Penalty

In determining the amount of the civil penalty, section 14(a)(4) of FIFRA requires the Agency to consider the appropriateness of the penalty to the size of the business of the person charged, the effect of the penalty on the person's ability to continue in business, and the gravity of the violation.

Computation of the penalty amount is determined in a five stage process in consideration of the FIFRA section 14(a)(4) criteria listed above. These steps are: (1) determination of gravity or "level" of the violation using Appendix A of this ERP; (2) determination of the size of business category for the violator, found in Table 2; (3) use of the FIFRA civil penalty matrices found in Table 1 to determine the dollar amount associated with the gravity level of violation and the size of business category of the violator; (4) further gravity adjustments of the base penalty in consideration of the specific characteristics of the pesticide involved, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the culpability of the violator, using the "Gravity Adjustment Criteria" found in Appendix B; and, (5) consideration of the effect that payment of the total civil penalty will have on the violator's ability to continue in business, in accordance with the criteria established in this ERP. A proposed civil penalty may be further modified during the course of settlement negotiations in accordance with the section of this ERP entitled "Adjusting the Proposed Civil Penalty in Settlement."

Use of the FIFRA Civil Penalty Matrix

The gravity of the violation and the size of the business are considered in the FIFRA Civil Penalty Matrices shown in Table 1. Each cell of the matrix represents the Agency's assessment of the appropriate civil penalty, within the statutory maximum, for each gravity level of a violation and for each size of business category. Since FIFRA imposes different statutory ceilings on the maximum civil penalty that may be assessed against persons listed in FIFRA section 14(a)(1) and persons listed in section 14(a)(2), this policy has separate penalty matrices for section 14(a)(1) violators and section 14(a)(2) violators.

The section 14(a)(2) penalty matrix will only be used by the Agency for persons falling under FIFRA section 14(a)(2) who have previously been issued a notice of warning or civil complaint (FIFRA section 14(a)(2) states that private applicators are only subject to civil penalties subsequent to receiving a Notice of Warning or following a citation for a prior violation, and "for hire" applicators are only subject to a maximum \$500 civil penalty for their first offense of FIFRA). The Agency has only included three levels in the section 14(a)(2) Civil Penalty Matrix, rather than the four levels provided in the section 14(a)(1) matrix. This is because the Agency does not believe that the lower base penalty figure that can be obtained from a "level 4" is appropriate for violations of the statute committed after the receipt of a notice of warning or civil complaint.

When a civil penalty is the appropriate response for a first-time violation by a "for hire applicator" who violates any provision of FIFRA while holding or applying a registered general use pesticide or a registered unclassified pesticide, that civil penalty will be the statutory maximum of \$500. Subsequent violations will be assessed using the FIFRA section 14(a)(2) civil penalty matrix below.

TABLE 1

**CIVIL PENALTY MATRIX
FOR FIFRA SECTION 14(a)(1)**

SIZE OF BUSINESS

LEVEL	I	II	III
level 1	5,000	5,000	5,000
level 2	5,000	4,000	3,000
level 3	4,000	3,000	2,000
level 4	3,000	2,000	1,000

**CIVIL PENALTY MATRIX
FOR FIFRA SECTION 14(a)(2) ***

SIZE OF BUSINESS

LEVEL	I	II	III
level 1	1,000	1,000	1,000
level 2	1,000	800	600
level 3	800	600	500

* This 14(a)(2) matrix is only for use in determining civil penalties issued subsequent to a notice of warning or following a citation for a prior violation, or in the case of a "for hire" applicator using a registered general use pesticide, subsequent to the issuance of a civil penalty of \$500.

Size of Business

In order to provide equitable penalties, the civil penalties that will be assessed for violations of FIFRA will generally decrease as the size of the business decreases, and vice versa. Size of business is determined from an individual's or a company's gross revenues from all revenue sources during the prior calendar year. If the revenue data for the previous year appears to be unrepresentative of the general performance of the business or the income of the individual, an average of the gross revenues for the three previous years may be used. Further, the size of business and gross revenue figures are based on the entire corporation rather than a specific subsidiary or division of the company which is involved with the violation (including all sites owned or controlled by the foreign or domestic parent company), unless the subsidiary or division is independently owned.

As shown in the FIFRA Civil Penalty Matrices in Table 1, the appropriateness of the penalty to the size of the business of the person charged is based on three distinct "size of business" categories. Further, because the gross revenues of the persons listed in FIFRA section 14(a)(1) [registrants, commercial applicators, wholesalers, dealers, retailers, or other distributors] will generally be higher than the gross incomes of the persons listed in FIFRA section 14(a)(2) [private applicators and other persons not listed in 14(a)(1)], the policy has separate "size of business" categories for FIFRA section 14(a)(1) persons and section 14(a)(2) persons. The "size of business" categories for FIFRA section 14(a)(1) and section 14(a)(2) violators are listed in Table 2.

TABLE 2

For section 14(a)(1) violators, the size of business categories are:

I	-	over \$1,000,000
II	-	\$300,001 - \$1,000,000
III	-	\$0 - \$300,000

For section 14(a)(2) violators, the categories are:

I	-	over \$200,000
II	-	\$50,001 - \$200,000
III	-	\$0 - \$50,000

When information concerning an alleged violator's size of business is not readily available, the penalty is to be calculated using the Category I size of business. The Category I size of business will remain the base penalty value unless the violator can establish, at their expense and to the Agency's satisfaction, that it should be considered in a smaller size of business category.

Gravity of the Violation

Determination of the gravity of the violation is a two step process: (1) determination of the appropriate "gravity level" that EPA has assigned to the violation, and (2) the adjustment of that base penalty figure, as determined from the gravity level, to consider the actual set of circumstances that are involved in the violation.

The gravity "level" established for each violation of FIFRA is listed in Appendix A of this ERP. The "levels" assigned to each violation of FIFRA represents an assessment of the relative gravity of each violation. The relative gravity of each violation is based on an average set of circumstances which considers the actual or potential harm to human health and/or the environment which could result from the violation, or the importance of the requirement to achieving the goals of the statute. The gravity level, which is determined from the chart in Appendix A, is then used to determine a base penalty figure from the FIFRA Civil Penalty Matrices.

As the actual circumstances of the violation differ from the "average" circumstances assumed in each gravity level of the Civil Penalty Matrices, the dollar amount derived from the matrix should be adjusted upward or downward. The Agency has assigned adjustments, based on the gravity adjustment criteria listed in Appendix B, for each violation relative to the specific characteristics of the pesticide involved, the harm to human health and/or harm to the environment, compliance history of the violator, and the culpability of the violator. Under the FIFRA civil penalty system, the gravity adjustment values from each gravity category listed in Appendix B are to be totaled. The dollar amount found in the matrix will be raised or lowered, within the statutory maximum (\$5,000 for section 14(a)(1) persons and \$1,000 for 14(a)(2) persons), based on the total gravity values in Table 3.

TABLE 3

Total Gravity Value	Enforcement Remedy
3 or below	No action, Notice of Warning, or 50% reduction of matrix value.*
4	Reduce matrix value 40%
5	Reduce matrix value 30%
6	Reduce matrix value 20%
7	Reduce matrix value 10%
8 to 12	Assess matrix value
13	Increase matrix value 10%**
14	Increase matrix value 15%**
15	Increase matrix value 20%**
16	Increase matrix value 25%**
17 or above	Increase matrix value 30%**

* 50% reduction of matrix value is recommended where multiple count violations exist.

** Matrix value can only be increased to the statutory maximum of \$5,000 per offense for persons under FIFRA section 14(a)(1), and \$1,000 for persons under FIFRA section 14(a)(2).

Gravity Adjustments for Recordkeeping and Reporting Violations

The gravity of recordkeeping and reporting violations are already considered in the dollar amounts presented in the FIFRA civil penalty matrices. Further, recordkeeping and reporting violations do not lend themselves to utilizing the gravity adjustments listed in Appendix B. Therefore, first-time civil penalties should be assessed at the matrix value, while subsequent penalties should be increased by an increment of 30% (up to the statutory maximum).

Ability to Continue in Business/Ability to Pay

Section 14(a)(4) of FIFRA requires the Agency to "consider" the effect of the penalty on the person's ability to continue in business when determining the amount of the civil penalty.

EPA will generally not collect a total civil penalty which exceeds a violator's ability to pay. There are three methods that EPA has chosen to determine a violator's ability to pay, depending on the specifics of the case: (1) a detailed tax, accounting, and financial analysis; (2) a guideline of four percent of average gross annual income; or, (3) ABEL (a computer model).^{*} The latter two are described below.

Four percent of gross sales. The average gross income (from all sources of revenue) for the current year and the prior three years will be calculated. Even where the net income is negative, four percent of gross income will be used as the "ability to continue in business/ability to pay" guidance, since companies with a positive gross income will be presumed to have sufficient cash flow to pay penalties even where there have been net losses. For corporations, EPA will consider revenues from the total corporate entity in its determination of ability to pay/ability to continue in business. Total corporate entity refers to all sites owned and controlled by the foreign or domestic parent company.

ABEL. ABEL is an EPA computer model that is designed to assess a for-profit entity's ability to pay. The evaluation is based on the estimated strength of internally-generated cash flows. The program uses standard financial ratios to evaluate a violator's ability to borrow money and pay current and long-term operating expenses. ABEL also projects the probable availability of future internally-generated cash flows to evaluate some of a violator's options for paying a civil penalty. Because the program only focuses on a violator's cash flow, there are other sources of revenue that should also be considered to determine if a firm is unable to pay the full penalty. These include:

- o certificates of deposit, money market funds, or other liquid assets;
- o reduction in business expenses such as advertising, entertainment, or compensation of corporate officers; or,
- o sale or mortgage of non-liquid assets such as company cars, aircraft, or land.

^{*} Other methods for determining a violator's ability to pay may be provided in future guidance.

It can be assumed that the respondent has the ability to pay at the time the complaint is issued if information concerning the alleged violator's ability to pay is not readily available. The respondent will be notified in the civil complaint of their right under the statute to have their ability to continue in business considered in the determination of the amount of the civil penalty. Any alleged violator can raise the issue of ability to pay/ability to continue in business in their answer to the civil complaint, or during the course of settlement negotiations.

If an alleged violator raises the inability to pay as a defense in their answer, or in the course of settlement negotiations, the respondent should be asked to present appropriate documentation, such as tax returns, financial statements, etc. Such records are to be provided to the Agency at the respondent's expense and must conform to generally recognized accounting principles and procedures. If the proposed penalty exceeds the ability to pay guidance, the penalty may be reduced to a level consistent with FIFRA section 14(a)(4).

There may be some cases where a respondent argues that it cannot afford to pay the proposed civil penalty even though the penalty as adjusted does not exceed the ability to pay guidance. In such cases, EPA may consider a delayed payment schedule or a "Settlement with Conditions" agreement (see the "Settlement With Conditions" section of this Enforcement Response Policy). In exceptional circumstances, EPA may also consider further adjustment below the ability to pay guidance.

Finally, it is important that the regulated community not see the violation of FIFRA as a way of aiding financially troubled businesses. Therefore, while EPA will generally not collect a civil penalty which exceeds a violator's ability to pay, EPA reserves the option, in appropriate circumstances, of seeking a penalty that might exceed the ability to pay guidelines, cause bankruptcy, or result in a violator's inability to continue in business. However, if the case is generated out of the EPA Regional Offices, the case file must contain a written explanation, signed by the Regional Program Division Director, which explains the reasons for exceeding the civil penalty "ability to pay" guidelines. If the case is generated out of EPA Headquarters, the case file must contain a written explanation signed by the Director of the Compliance Division. Additionally, to ensure full and consistent consideration of penalties that may cause bankruptcy or closure of a business, the Regions shall consult with the Office of Compliance Monitoring and obtain concurrence before the decision is made to settle the case or proceed to a hearing.

For additional information on the consideration of a violator's ability to continue in business, see the EPA General Enforcement Policy #GM-22, entitled "A Framework for Statute-Specific Approaches to Penalty Assessments," issued on February 16, 1984 as part of the Agency's General Enforcement Policy Compendium.

Independently Assessable Charges

A separate civil penalty, up to the statutory maximum, shall be assessed for each independent violation of the Act. A violation is independent if it results from an act (or failure to act) which is not the result of any other charge for which a civil penalty is to be assessed, or if the elements of proof for the violations are different. Dependent violations may be listed in the complaint, but will not result in separate civil penalties.

Consistent with the above criteria, the Agency considers violations that occur from each shipment of a product (by product registration number, not individual containers), or each sale of a product, or each individual application of a product to be independent offenses of FIFRA.* Each of these independent violations of FIFRA are subject to civil penalties up to the statutory maximum of \$5,000 for section 14(a)(1) and \$1,000 for section 14(a)(2). For example, when the EPA can document that a registrant has distributed a misbranded product (one single EPA product registration number) in four separate shipments (filling four orders), EPA will charge that registrant with four counts of selling or distributing a misbranded product, and assess the registrant civil penalties of up to \$20,000. Similarly, when the EPA can document that a registrant has shipped four separate misbranded products (four separate EPA product registration numbers) in a single shipment, EPA will charge the registrant four counts of selling or distributing a misbranded product, and assess civil penalties of up to \$20,000. A commercial applicator that misuses a restricted use product on three occasions (either three distinct applications or three separate sites) will be charged with three counts of misuse, and assessed civil penalties of up to \$15,000. A dealer that sells a restricted use pesticide (RUP) to six uncertified persons, other than in accordance with FIFRA section 3(d), will be charged with six violations of FIFRA, and assessed civil penalties of up to \$30,000.

* Independent violations which can be documented as both per sale and per shipment are to be calculated only as either per sale or per shipment, whichever is more appropriate based on the supporting documentation, and whichever approach yields the highest civil penalty. For example, if Person A has a violation involving 1 sale and 2 shipments, and Person B has a violation involving 2 sales and 1 shipment, both persons would be charged for 2 violations of FIFRA (Person A is charged for 2 shipments and Person B is charged for 2 sales).

On the other hand, a single event or action (or lack of action) which can be considered as two unlawful acts of FIFRA (section 12) cannot result in a civil penalty greater than the statutory limit for one offense of FIFRA. For instance, a person can be assessed a civil penalty of up to \$5,000 for selling and distributing a product in violation of a cancellation order. However, while the Agency considers a cancelled product to be no longer registered, that same person should not also be assessed an additional civil penalty of up to \$5,000 for sale and distribution of the same unregistered product. In this example the violation of the cancellation order is dependent on the sale and distribution of the unregistered/cancelled product.

Another example of a dependent violation is multiple misbranding on a single product label. If a single product label is misbranded in one way or ten ways, as defined by FIFRA section 2(q), it is still misbranding on a single product label and is considered a single violation of FIFRA section 12(a)(1)(E). As a single violation of FIFRA, the maximum civil penalty that may be assessed is \$5,000. However, EPA may assess a count of misbranding each time that a misbranded product is sold or distributed. For example, a registrant who sells or distributes four distinct shipments of a misbranded pesticide product may be assessed a civil penalty of up to \$20,000.

Voluntary Disclosure

In order to encourage voluntary disclosure of FIFRA violations, the Agency will offer a 40% reduction of the civil penalty if the disclosure was made: (1) by the violator promptly to EPA, or States with cooperative enforcement agreements [within 30 to 60 days of discovery by the violator]; (2) before the violation was discovered by EPA or a State; (3) before an inspection was scheduled by EPA or a State; and, (4) the violator immediately takes all the steps necessary to come into compliance, and steps requested by the Agency to mitigate the violation.

The reduction for voluntary disclosure may be made prior to issuing the civil complaint. The civil complaint should state the original penalty and the reduced penalty and the reason for the reduction.

Adjusting the Proposed Civil Penalty in Settlement

Upon an answer to a civil complaint by the person charged (respondent), the following circumstances may arise which may justify adjustment of the penalty proposed in the civil complaint:

Factual Changes

Recalculation of the proposed penalty is appropriate if the respondent can demonstrate that the size of business category, culpability, or other facts used to derive the gravity adjustment values from Appendix B are inaccurate. Adjustments to the proposed civil penalty may also be appropriate if the respondent can demonstrate an "inability to pay" the civil penalty (See "Ability to Continue in Business/Ability to Pay" section of this policy). Where additional facts indicate to the Agency that the original penalty is not appropriate, a new penalty shall be calculated consistent with the new facts. The burden is on the respondent to raise those factors which may justify the recalculation of the penalty.

Negotiations Involving Only the Amount of the Penalty

In some cases the respondent may admit to all jurisdictional and factual allegations charged in the complaint and may desire a settlement conference limited to the amount of the proposed penalty. In the absence of "special circumstances," (as discussed in the "Special Circumstances" section of this ERP), a settlement conference may be conducted to consider the amount of the proposed penalty.

Good Faith Adjustments

During the course of settlement negotiations, the EPA may consider the respondent's attitude or good faith efforts to comply with FIFRA to reduce the penalty as much as 20 percent below the proposed penalty, if such a reduction would serve the public interest.

In no case is such a reduction mandated, and in no case should such a reduction occur in the absence of an appropriate showing by the respondent and finding by the Agency. Additionally, any reduction on account of the attitude or good faith efforts does not have to extend to the full 20 percent reduction. Further, the total civil penalty may not be reduced by more than 20 percent below the proposed penalty without a showing of "special circumstances" as discussed below.

Special Circumstances/Extraordinary Adjustments

Should a case arise in which EPA determines that there are no grounds for adjustment of the proposed civil penalty based on new financial information or other facts, or on a showing of inability to continue in business, and that equity would not be served by adjusting the proposed penalty by only the allowable 20 percent good faith attitude adjustment, the Regional Program Division Director may approve an extraordinary adjustment to the proposed penalty for up to an additional 20%. This adjustment is only appropriate in extraordinary circumstances and is not to be used routinely. The EPA may also consider a delayed payment schedule or a "Settlement With Conditions" agreement.

If a "special circumstances" reduction of the proposed civil penalty is granted, the case file must include substantive reasons why the extraordinary reduction of the civil penalty was appropriate, including: (1) setting forth the facts of the case; (2) why the penalty provided from the FIFRA civil penalty matrices and gravity adjustment was inequitable; (3) how all other methods for adjusting or revising the proposed penalty would not adequately resolve the inequity; and, (4) the manner in which the extraordinary adjustment of the penalty effectuated the purposes of the Act. The Regional Program Division Director's written concurrence for the extraordinary reduction must be incorporated into the case file. Additionally, a copy of the written justification for the special circumstances reduction must accompany the consent agreement and final order (CAFO), or consent agreement and consent order (CACO) which the Regions send to the Office of Compliance Monitoring.

Settlement With Conditions (SWC)

The Environmental Protection Agency (EPA) may choose to substitute part of a civil penalty assessed for a violation of FIFRA for a specific environmentally beneficial activity that would be performed by the Respondent. The Agency refers to the settlement of a case under terms which commit the respondent to perform specified acts in exchange for reduction of the penalty as "Settlement with Conditions (SWC)."

Under an SWC agreement, in exchange for a specified amount of the proposed civil penalty, the violator agrees to take extensive and specific environmentally beneficial activities, such as pollution prevention projects, risk communication, remedying ground water hazards, clean-up operations, training, etc. These actions must exceed those normally expected under the circumstances (actions in excess of those required to correct the violation for which the violator was charged, and actions in

excess of those already required by Federal/State/local laws), must be taken within a specific time period, and will be strictly monitored by the Agency. It is the responsibility of the Regional Program Office to monitor compliance with the SWC agreement. Follow-up inspections should be conducted, as appropriate. If the Agency is not satisfied that the conditions of the agreement have been met at the end of the term, the full amount of the penalty is due.

A minimum cash penalty should always be collected from the violator regardless of the value of the SWC activities. Further, steps must be taken to prevent a violator from gaining an unwarranted tax advantage through income tax deductions of the cost of the SWC activities. One method to do this is to calculate the net present after tax value of the SWC activities (the Agency's BEN computer model may be used for this purpose), and require that the violator pay a minimum cash penalty equal to that sum of money, in addition to the SWC activities.

Settlements with Conditions should be employed with restraint. The SWCs should not be used in a manner which encourages people to violate FIFRA until they are discovered and then offer to correct actions in hope of a penalty reduction. Further, a violator is not presumed to be entitled to an SWC and such relief is granted at the discretion of the Agency.

Criteria for Choosing an SWC

An SWC should be considered in the following circumstances:

- o Violations have been documented which warrant a civil penalty; and,
- o The violations do not evidence wanton, knowing, or willful disregard for regulatory requirements; and,
- o The violator has exhibited a good-faith attitude toward solving the noncompliance and has no history of non-compliance; and,
- o There are clear public benefits to use of an SWC; and
- o An SWC acceptable to EPA can be negotiated.

An SWC should also be considered where the total proposed civil penalty exceeds the ability to pay guidance, or when nonprofit entities are found to be in violation of FIFRA.

Responses to Noncompliance with the SWC

Penalty Payment

If the respondent fails to adhere to the conditions of the SWC, the uncollected penalty, or the uncollected portion of the penalty is due and payable within 60 days from the date the conditions of the SWC were to be met. If the respondent refuses to pay, the Agency may refer the action to the Department of Justice which may bring a recovery action.

Reinspection and Additional Enforcement Action

Once the EPA determines that the conditions of the SWC have not been fulfilled and so notifies the respondent, the EPA should reinspect the facility to document any additional violations. When considering additional enforcement actions in response to any violations discovered upon reinspection, the Agency may give consideration to pursuing injunctive action. Clearly, in cases of serious violations where administrative enforcement action cannot be expected to achieve compliance, an injunction may be a desirable enforcement response.

Elements of an SWC

The Agency is examining the procedures for issuing SWC agreements and the necessary contents of those agreements. When final guidance is available, we will incorporate these guidelines into the FIFRA ERP. In the interim, the procedures provided below should be followed:

An SWC, like any FIFRA settlement, consists of: (1) a complaint and (2) a consent agreement and final order (CAFO), or consent agreement and consent order (CACO). It also includes: (3) a Penalty Mitigation Agreement and (4) a Penalty Mitigation Order.

A civil complaint alleging violations of FIFRA and proposing a civil penalty must be issued to establish the Agency's allegations that violations have occurred and to initiate any SWC negotiations. The complaint should be issued in the same format as in any FIFRA administrative civil penalty action.

The CAFO/CACO assesses a total civil penalty and disposes of the administrative proceeding. In the CAFO/CACO, the respondent (1) admits the jurisdictional allegations of the complaint, (2) admits the facts stipulated in the consent agreement or neither admits nor denies specific factual allegations, (3) consents to the assessment of a stated administrative civil penalty, and (4) waives its right to a hearing and consents to the issuance of a final order which requires a payment of a civil penalty.

The Penalty Mitigation Agreement sets forth the Compliance Program and Schedule (CPS). Under this agreement and CPS, the respondent agrees to perform specific remedial actions by specific dates. If the respondent successfully meets the conditions of the penalty mitigation agreement, the EPA will not collect a specified portion of the civil penalty.

The Penalty Mitigation Order formally mitigates a portion of the penalty and is executed when the Agency is satisfied that the respondent has met the conditions outlined in the CPS. If the respondent has not satisfied the conditions, the order informs him that the payment of the previously assessed penalty is due.

APPENDIX A

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(1)(A)	1AA	Sold or distributed a pesticide NOT REGISTERED under section 3 or was CANCELLED or SUSPENDED, which was not authorized by the Administrator.	2
12(a)(1)(A)	1AB	Registrant, wholesaler, dealer, retailer, or other distributor ADVERTISED or otherwise "offered for sale," in any medium, a pesticide that was NOT REGISTERED under section 3 or was CANCELLED or SUSPENDED, other than in accordance with Agency policy.	2
12(a)(1)(B)	1BA	CLAIMS made for a pesticide as part of sale or distribution differed substantially from those accepted in connection with registration.	2
12(a)(1)(B)	1BB	Registrant, wholesaler, dealer, retailer, or other distributor ADVERTISED, or otherwise "offered for for sale" in any medium, a REGISTERED PESTICIDE product for an UNREGISTERED USE, other than in accordance with Agency policy.	2
12(a)(1)(C)	1CA	Sold or distributed a pesticide whose COMPOSITION DIFFERED from the composition represented in the registration.	2
12(a)(1)(D)	1DA	Sold or distributed a pesticide which has not been COLORED or DISCOLORED pursuant to section 25(c)(5).	2
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(A)	1EA	Sold or distributed a pesticide or device which is MISBRANDED in that the label has a statement, design, or graphic representation which is false or misleading.	2
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(B)	1EB	Sold or distributed a pesticide or device which is MISBRANDED in that the pesticide is not contained in a package or other container or wrapping which conforms to the standards established pursuant to section 25(c)(3) (e.g., not contained in child-resistant packaging or safety containers).	2

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(C)	1EC	Sold or distributed a pesticide or device which is MISBRANDED in that it is an imitation of, or is offered for sale under the name of, another pesticide.	2
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(D)	1ED	Sold or distributed a pesticide or device which is MISBRANDED in that the label did not bear the registration number assigned under section 7.	4
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(E)	1EE	Sold or distributed a pesticide or device which is MISBRANDED in that any words, statements, or other information required by the Act were not prominently placed on the label in such a way as to make it readable or understandable.	3
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(F)	1EF	Sold or distributed a pesticide or device which is MISBRANDED in that the label did not contain directions for use necessary to make the product effective and to adequately protect health and the environment.	2
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(G)	1EG	Sold or distributed a pesticide or device which is MISBRANDED in that the label did not contain a warning or caution statement adequate to protect health and the environment.	2
12(a)(1)(E) 2(q)(1)(H)	1EH	Sold or distributed a non-registered pesticide intended for export which is MISBRANDED in that the label did not have a prominently displayed, "Not Registered for Use in the United States of America."	4
12(a)(1)(E) 2(q)(2)(A)	1EI	Sold or distributed a pesticide which is MISBRANDED in that the label did not bear an ingredient statement on the immediate container which is presented or displayed under customary conditions of purchase.	4
12(a)(1)(E) 2(q)(2)(B)	1EJ	Sold or distributed a pesticide which is MISBRANDED in that the labeling does not contain a statement of the use classification for which the product was registered.	3

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(1)(E) 2(q)(2)(C)	1EK	Sold or distributed a pesticide which is MISBRANDED in that there is not a label affixed to the pesticide container, and to the outside wrapper of the retail package if the required information on the immediate container cannot be clearly read, a label bearing all of the following information: (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; and, when required by regulation, (iv) the registration number assigned to the pesticide and the use classification.	4
12(a)(1)(E) 2(q)(2)(D)	1EL	Sold or distributed a pesticide which is MISBRANDED in that the pesticide is sold in quantities highly toxic to man and the label failed to bear a skull and crossbones, and the word "poison" prominently in red on a contrasting background color, and/or the label did not bear a statement of practical treatment.	1
12(a)(1)(E) 2(c)(1) - (3)	1EM	Sold or distributed a pesticide which is ADULTERATED in that: (i) the strength or purity falls below the professed standard of quality expressed on the labeling; (2) any substance has been substituted wholly or in part abstracted; or, (3) any valuable constituent of the pesticide has been wholly or in part abstracted.	2
12(a)(2)(A)	2AA	Person DETACHED, ALTERED, DEFACED, or DESTROYED, in whole or in part, any LABELING required under the Act.	2
12(a)(2)(B)(i)	2BA	Person refused to PREPARE, MAINTAIN, or SUBMIT <u>any</u> RECORDS required under sections 5, 7, 8, 11, or 19.	2
12(a)(2)(B)(ii)	2BB	Person refused to SUBMIT any REPORTS required by or under section 5, 6, 7, 8, 11 or 19.	2

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(2)(B)(ii)	2BC	A registrant refused to submit REPORTS under section 6(a)(2) regarding UNREASONABLE ADVERSE EFFECTS of their pesticide.	1
12(a)(2)(B)(iii)	2BD	Person refused to allow entry, INSPECTION, copying of records, or sampling authorized by this Act.	2
12(a)(2)(C)	2CA	Person gave a GUARANTY or undertaking provided for in section 12(b) which was FALSE in any particular.	2
12(a)(2)(D)	2DA	Person used to their personal advantage or revealed to persons other than those authorized by the Act any INFORMATION acquired under the Act which is CONFIDENTIAL.	3
12(a)(2)(E)	2EA	Registrant, wholesaler, dealer, retailer, or other distributor ADVERTISED a RESTRICTED USE PESTICIDE without indicating that the product was restricted.	2
12(a)(2)(F)	2FA	Person DISTRIBUTED, SOLD, MADE AVAILABLE FOR USE, or USED a RESTRICTED USE PESTICIDE for a purpose other than in accordance with section 3(d) or regulations issued.	2
12(a)(2)(F)	2FB	Person distributed, sold, or made available for use, or used, a RESTRICTED USE PESTICIDE without maintaining the RECORDS required by regulations (A Notice of Warning should be issued for first-time "partial" violations. Violations continuing subsequent to the issuance of a civil complaint are to result in a suspension - see "Denials, Suspensions, Modifications, or Revocations of Applicator Certifications" section of this ERP).	2
12(a)(2)(G)	2GA	Person USED a registered pesticide in a manner inconsistent with its labeling.	2
12(a)(2)(H)	2HA	Person USED a pesticide which was under an EXPERIMENTAL USE PERMIT contrary to the provisions of the permit.	2

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(2)(I)	2IA	Person violated any order issued under section 13 (e.g., STOP SALE, USE OR REMOVAL ORDER or SEIZURE).	1
12(a)(2)(J)	2JA	Person violated any SUSPENSION ORDER issued under section 6.	1
12(a)(2)(J)	2JB	Person violated any SUSPENSION ORDER issued under section 3(c)(2)(B) or 4.	2
12(a)(2)(K)	2KA	Person violated any CANCELLATION ORDER issued under the Act on the grounds of UNREASONABLE ADVERSE EFFECTS.	1
12(a)(2)(K)	2KB	Person violated any CANCELLATION ORDER issued under the Act on grounds OTHER THAN UNREASONABLE ADVERSE EFFECTS.	2
12(a)(2)(K)	2KC	Person failed to submit a SECTION 6(g) NOTICE when required.	2
12(a)(2)(K)	2KD	Person submitted a NOTABLY LATE SECTION 6(g) NOTICE.	3
12(a)(2)(K)	2KE	Person submitted an INCOMPLETE or INCORRECT SECTION 6(g) NOTICE.	3
12(a)(2)(L) 7(a)	2LA	PRODUCED a pesticide or active ingredient subject to the Act in an UNREGISTERED ESTABLISHMENT.	2
12(a)(2)(L) 7(c)(1)	2LB	Producer FAILED TO SUBMIT, or submitted NOTABLY LATE, a REPORT to the Administrator, under SECTION 7, which indicates the types and amounts of pesticides or active ingredients which they are currently producing, which they produced during the past year, and which they sold or distributed during the past year.	2

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(2)(L) 7(c)(1)	2LC	Producer submitted a LATE REPORT to the Administrator, under SECTION 7, which indicates the types and amounts of pesticides or active ingredients which they are currently producing, which they produced during the past year, and which they sold or distributed during the past year (civil complaint issued only if the producer does not respond to a Notice of Warning or there is a subsequent violation within a three year timeframe from the first violation).	4
12(a)(2)(L) 7(c)(1)	2LD	Producer submitted an INCOMPLETE SECTION 7 REPORT with MINOR OMISSIONS of the required information (civil complaint issued only if the producer does not respond to a Notice of Warning or there is a subsequent violation within a three year timeframe from the first violation).	3
12(a)(2)(L) 7(c)(1)	2LE	Producer submitted an INCOMPLETE or a FALSE SECTION 7 REPORT with MAJOR OMISSIONS or ERRORS of the required information.	2
12(a)(2)(L) 7(c)(2)	2LF	Upon request of the Administrator for the purposes of the issuance of section 13 Stop Sale Orders, a PRODUCER FAILED TO PROVIDE the names and addresses of the recipients of the pesticides produced in any of his registered establishments.	1
12(a)(2)(M)	2MA	Person KNOWINGLY FALSIFIED all or any part of an application for registration, application for an experimental use permit, any information submitted under section 7, <u>any</u> records required to be maintained by the Act, <u>any</u> report filed under the Act, or any information marked as confidential and submitted to the Administrator under <u>any</u> provision of the Act.	1
12(a)(2)(N)	2NA	A registrant, wholesaler, dealer, retailer, or other distributor FAILED TO FILE REPORTS required by the Act.	2

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(2)(O)	2OA	Person ADDED A SUBSTANCE TO, or TOOK a substance from a pesticide in a manner that may defeat the purpose of this Act.	2
12(a)(2)(P)	2PA	Person USED a pesticide in TESTS ON HUMAN BEINGS in violation of the conditions specified by the Act.	1
12(a)(2)(Q)	2QA	Person FALSIFIED INFORMATION RELATING to the TESTING of any pesticide (or any of its ingredients, metabolites, or degradation products) for which the person knows will be furnished to the Administrator, or will become a part of any records required to be maintained by this Act.	1
12(a)(2)(Q)	2QB	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a HIGH LEVEL GLP violation.	2
12(a)(2)(Q)	2QC	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a MIDDLE LEVEL GLP violation.	3
12(a)(2)(Q)	2QD	14(a)(1) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP violation.	4
12(a)(2)(Q)	2QE	14(a)(2) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP violation.	3
12(a)(2)(R)	2RA	Person submitted DATA KNOWN TO BE FALSE in support of a registration.	1
12(a)(2)(S)	2SA	Person sold, distributed, or used an UNREGISTERED pesticide in violation of a REGULATION ISSUED UNDER SECTION 3(a).	*
12(a)(2)(S)	2SB	Person violated any REGULATION ISSUED UNDER SECTION 19.	*

* Gravity levels for these violations will be assigned in subsequent ERPs.

APPENDIX B

GRAVITY ADJUSTMENT CRITERIA

APPENDIX B
GRAVITY ADJUSTMENT CRITERIA ¹

VIOLATION	VALUE	CIRCUMSTANCES
GRAVITY OF HARM Pesticide Harm to Human Health Environmental Harm	2	Toxicity - Category I pesticides, Signal Word "Danger", restricted use pesticides (RUPs), pesticides with flammable or explosive characteristics (i.e., signal words "Extremely Flammable" or "Flammable"), or pesticides that are associated with chronic health effects (mutagenicity, oncogenicity, teratogenicity, etc.).
	1	Toxicity - Categories II through IV, signal word "Warning" and "Caution," no known chronic effects.
	5	Actual serious or widespread ² harm to human health.
	3	Potential serious or widespread ² harm to human health.
	3	Harm to human health is unknown.
	1	Minor ³ potential or actual harm to human health, neither serious nor widespread.
	5	Actual serious or widespread ² harm to the environment (e.g., crops, water, livestock, wildlife, wilderness, or other sensitive natural areas).
	3	Potential serious or widespread ² harm to the environment.
	3	Harm to the environment is unknown.
	1	Minor ³ potential or actual harm to the environment, neither widespread nor substantial.

VIOLATION	VALUE	CIRCUMSTANCES
GRAVITY OF MISCONDUCT		
Compliance⁴ History	5	If a violator is a 14(a)(1) person with more than one prior violation of FIFRA, and at least one prior violation was a level 1 violation. If a violator is a 14(a)(2) person with more than two prior FIFRA violations, and at least one prior violation was a level 1 violation.
	4	If a violator is a 14(a)(1) person with more than one prior violation of FIFRA, and no prior level 1 violations. If a violator is a 14(a)(2) person with more than two prior FIFRA violations, and no prior level 1 violations.
	2	If a 14(a)(1) person, one prior violation of FIFRA. If a 14(a)(2) person, two prior FIFRA violations.
	0	No prior FIFRA violations.
Culpability⁵	4	Knowing or willful violation of the statute. ⁶ Knowledge of the general hazardousness of the action.
	2	Culpability unknown.
	2	Violation resulting from negligence.
	0	Violation was neither knowing nor willful and did not result from negligence. Violator instituted steps to correct the violation immediately after discovery of the violation.

APPENDIX B FOOTNOTES

- ¹ The gravity adjustment criteria in Appendix B should not be used for recordkeeping and reporting violations. Therefore, first-time civil penalties for recordkeeping or reporting violations should be assessed at the matrix value, while subsequent penalties should be increased by an increment of 30% (up to the statutory maximum).
- ² For the purposes of this ERP, serious or widespread harm refers to actual or potential harm which does not meet the parameters of minor harm, as described below.
- ³ For the purposes of this ERP, minor harm refers to actual or potential harm which is, or would be of short duration, no lasting effects or permanent damage, effects are easily reversible, and harm does not, or would not result in significant monetary loss.
- ⁴ The following considerations apply when evaluating compliance history for the purposes of Appendix B:
 - (a) In order to constitute a prior violation, the prior violation must have resulted in: (1) a final order, either as a result of an uncontested complaint, or as a result of a contested complaint which is finally resolved against the violator; (2) a consent order, resolving a contested or uncontested complaint by the execution of a consent agreement; (3) the payment of a civil penalty by the alleged violator in response to the complaint, whether or not the violator admits to the allegations of the complaint; or (4) conviction under the FIFRA's criminal provisions.

A notice of warning (NOW) will not be considered a prior violation for the purposes of the gravity adjustment criteria, since no opportunity has been given to contest the notice. Additionally, a stop sale, use, or removal order (SSURO) issued under FIFRA section 13 will not be considered as compliance history.
 - (b) To be considered a compliance history for the purposes of Appendix B, the violation must have occurred within five years of the present violation. This five-year period begins on the date of a final order, consent order, or payment of a civil penalty.
 - (c) Generally, companies with multiple establishments are considered as one when determining compliance history. If one establishment of a company commits a FIFRA violation, it counts as history when another establishment of the same company, anywhere in the country, commits another FIFRA violation.
- ⁵ EPA enforcement officials are not required to determine culpability at the time the complaint is issued (especially if this information is not readily available). EPA enforcement officials may instead assign a weighting factor of 2 (culpability unknown), at the time of the issuance of the complaint. Culpability adjustments may be reconsidered during settlement negotiations.
- ⁶ The Agency may also consider criminal proceedings for "knowing and willful" violations. See the "Criminal Proceedings" section of this ERP.

APPENDIX C

SUMMARY OF TABLES

SUMMARY OF TABLES

TABLE 1

FIFRA CIVIL PENALTY MATRICES

FIFRA SECTION 14(a)(1)

SIZE OF BUSINESS

LEVEL	I	II	III
level 1	5,000	5,000	5,000
level 2	5,000	4,000	3,000
level 3	4,000	3,000	2,000
level 4	3,000	2,000	1,000

FIFRA SECTION 14(a)(2)*

SIZE OF BUSINESS

LEVEL	I	II	III
level 1	1,000	1,000	1,000
level 2	1,000	800	600
level 3	800	600	500

* This matrix is only for use in determining civil penalties issued subsequent to a notice of warning or in the case of a "for hire applicator", subsequent to the issuance of a civil penalty of \$500.

TABLE 2

SIZE OF BUSINESS CATEGORIES

Section 14(a)(1) violators:

I	-	over \$1,000,000
II	-	\$300,001 - \$1,000,000
III	-	\$0 - \$300,000

Section 14(a)(2) violators:

I	-	over \$200,000
II	-	\$50,001 - \$200,000
III	-	\$0 - \$50,000

TABLE 3

GRAVITY ADJUSTMENT CRITERIA

Total Gravity Value*	Enforcement Remedy
3 or below	No action, Notice of Warning, or 50% reduction of matrix value.**
4	Reduce matrix value 40%
5	Reduce matrix value 30%
6	Reduce matrix value 20%
7	Reduce matrix value 10%
8 to 12	Assess matrix value
13	Increase matrix value 10%***
14	Increase matrix value 15%***
15	Increase matrix value 20%***
16	Increase matrix value 25%***
17 or above	Increase matrix value 30%***

* Use Appendix B to determine Gravity Values.

** 50% reduction of matrix value is recommended where multiple count violations exist.

*** Matrix value can only be increased to the statutory maximum.

APPENDIX D

**FIFRA CIVIL PENALTY CALCULATION
WORKSHEET**

FIFRA CIVIL PENALTY CALCULATION WORKSHEET

RESPONDENT _____
 ADDRESS _____

DOCKET NO. _____
 DATE _____

PREPARED BY _____

	count 1	count 2	count 3	count 4
Appendix A				
1. Statutory Violation				
2. FTTS Code				
3. Violation Level				
Table 2				
4. Violator Category - §14(a)(1) or §14(a)(2)				
5. Size of Business Category				
Table 1				
6. Base Penalty				
Appendix B				
7. Gravity Adjustments:				
a. Pesticide Toxicity				
b. Human Harm				
c. Environmental Harm				
d. Compliance History				
e. Culpability				
f. Total Gravity Adjustment Value (add items 7a - 7e)				
Table 3				
g. Percent Adjustment				
h. Dollar Adjustment				
8. Final Penalty* (item 7h from item 6)				
9. Combined Total Penalty (total of all Columns for line 8, above)				

* NOTE: The final penalty in each column of line 8 cannot exceed the statutory maximum.

FIFRA CIVIL PENALTY CALCULATION WORKSHEET (cont.)

	count _	count _	count _	count _
<u>Appendix A</u>				
1. Statutory Violation				
2. FTTs Code				
3. Violation Level				
<u>Table 2</u>				
4. Violator Category - §14(a)(1) or §14(a)(2)				
5. Size of Business Category				
<u>Table 1</u>				
6. Base Penalty				
<u>Appendix B</u>				
7. Gravity Adjustments:				
a. Pesticide Toxicity				
b. Human Harm				
c. Environmental Harm				
d. Compliance History				
e. Culpability				
f. Total Gravity Adjustment Value (add items 7a - 7e)				
<u>Table 3</u>				
g. Percent Adjustment				
h. Dollar Adjustment				
8. Final Penalty* (item 7h from item 6)				

PAGE _____ OF _____.

* NOTE: The final penalty in each column of line 8 cannot exceed the statutory maximum.

**ENFORCEMENT RESPONSE POLICY
FOR THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
GOOD LABORATORY PRACTICE (GLP) REGULATIONS**

**Office of Compliance Monitoring
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency**

September 30, 1991

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9/30/91

**ENFORCEMENT RESPONSE POLICY FOR THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
GOOD LABORATORY PRACTICE (GLP) REGULATIONS**

INTRODUCTION

This policy sets forth the procedures that will be used to determine the appropriate enforcement response for violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPs) found at 40 CFR Part 160. This policy is a supplement to the July 2, 1990 FIFRA Enforcement Response Policy (ERP) and is to be used in conjunction with the policies and matrices found in that ERP.

The EPA relies on data submitted by registrants as the basis for the Agency's regulatory decisions involving pesticide product registrations, tolerances, experimental use permits, special local needs registrations, emergency exemptions, or any other research or marketing permit for a pesticide (hereafter referred to as "research or marketing permits"). In conjunction with the EPA's data audit program, the FIFRA GLPs are intended to ensure the quality and integrity of this data.

Violations of the FIFRA GLPs may impact: (1) the reliability or scientific merits of test data; (2) the ability of the EPA to validate or reconstruct test results; (3) the ability of the Agency to make sound and timely regulatory decisions regarding a pesticide; and, (4) the EPA's administration of the GLP inspection and enforcement program. Therefore, noncompliance with the FIFRA GLP regulations may result in very serious harm to the EPA's regulatory mission and, ultimately, human health and the environment.

Violations of the FIFRA GLPs may involve violations of FIFRA sections 12(a)(2)(B)(i), 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R). Appropriate enforcement responses for violations of the FIFRA GLPs include notices of warning, civil penalties of up to \$5,000 per offense, and criminal penalties. In addition to these enforcement responses, the EPA may take regulatory action for violations of the GLPs, including: rejection of studies which do not comply with the FIFRA GLPs; cancellation, suspension, or modification of a pesticides research or marketing permit; or denial or disapproval of an application for such a permit. Further, in order to help assure that the Federal Government is dealing with responsible contractors, and for the purposes of the Federal Government's protection, pesticide testing facilities responsible for significant or major GLP violations may also be suspended or debarred from Government contracts or subcontracts. To address these types of actions, this policy includes a section on referrals to other EPA offices.

REQUIREMENTS OF THE FIFRA GLPS

The FIFRA GLP standards, found at 40 CFR Part 160, prescribe the minimum requirements that a pesticide testing facility (i.e., the laboratory, field site, etc.) and the sponsor must fulfill in the following areas:

1. Organization and personnel.
2. Facilities.
3. Equipment.
4. Testing facilities operation.
5. Test, control, and reference substances.
6. Protocol for and conduct of a study.
7. Records and reports.

Regulated Community

Any person, including a sponsor, pesticide testing facility, or registrant, who conducts, initiates, or supports a study required by the Agency under FIFRA sections 3, 4, 5, 18, or 24(c), or sections 408 or 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Liability

The EPA may pursue enforcement actions for violations of the FIFRA GLPS against any of the persons listed above depending on the specific facts of the case. Generally, the EPA will pursue separate civil administrative enforcement actions against the study sponsor, applicant for the research or marketing permit, and the pesticide testing facility since each of these parties have affirmative obligations to assure a study complies with the GLP regulations. If the sponsor, applicant for the research or marketing permit, or the pesticide testing facility are the same entity, the EPA will generally pursue a single enforcement action against that single entity. The signers of the GLP compliance statement may also be liable as individuals if the compliance statement required by 40 CFR 160.12 is false. However, in most cases, EPA will pursue enforcement actions against the company for which those individuals are employees or Agents.

Studies Covered Under the FIFRA GLPs

The FIFRA GLPs, as published in the Federal Register on November 29, 1983 (48 FR 53946), apply to all studies performed to determine the toxicity, metabolism, or other effects in humans and domestic animals which were conducted, initiated, or supported on or after May 2, 1984.¹ The FIFRA GLPs, as amended (August 17, 1989; 54 FR 34052), also apply to all studies performed to determine the effects, metabolism, product performance (with the exception of certain efficacy studies), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media, conducted, initiated, or supported on or after October 16, 1989.¹

As per the scope of the GLP regulations found at 40 CFR 160.1 and the definition of a "research or marketing permit" found in 40 CFR 160.3, the FIFRA GLP standards apply to all studies as defined above which are performed to support: (1) an application for registration, amended registration, or re-registration of a pesticide product under FIFRA sections 3, 4, or 24(c); (2) an application for an experimental use permit under FIFRA section 5; (3) an application for an emergency exemption under FIFRA section 18; (4) a petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408; (5) a petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409; (6) a submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B); or (7) any other application, petition, or submission sent to EPA intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.

Violations

Violations of the FIFRA GLP Standards will be charged as unlawful acts of FIFRA under sections 12(a)(2)(B)(i), 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R). The determination of the appropriate unlawful act to charge a violator will depend on the specific facts of the case, based on the following guidance.

¹ The term "supported" includes studies which have been submitted to the EPA after the effective date of the GLP regulations. Therefore, studies which have been conducted or initiated before the effective date, but have been submitted to the EPA in support of a pesticide product research or marketing permit after the effective date, must be submitted with the GLP Compliance Statement required by 40 CFR 160.12.

Violations of the GLPs Related to a False GLP Compliance Statement -
FIFRA §§ 12(a)(2)(M) and 12(a)(2)(Q)

Under 40 CFR 160.12, any person who submits to EPA data from a study which falls under the scope of the GLPs must submit a statement, signed by the applicant of the pesticide product research or marketing permit, the sponsor, and the study director, that: (1) the study complies with the GLP requirements; (2) describes the differences between the practices used in the study and those required by the FIFRA GLPs; or (3) the person was not the sponsor of the study, did not conduct the study, and does not know whether the study complies with the FIFRA GLP requirements. If a study is submitted to EPA with a GLP compliance statement which states that the study complies with the GLP requirements, and GLP violations have occurred, then EPA will consider that compliance statement to be false. Similarly, if a study is submitted to EPA with a GLP compliance statement which incorrectly describes the differences between the practices used in the study and those required by the GLPs, then EPA will also consider the compliance statement to be false.

Submission of a false compliance statement is a violation of FIFRA section 12(a)(2)(M) or FIFRA section 12(a)(2)(Q). If the statement was *knowingly* falsified, EPA may issue a civil penalty for a violation of FIFRA section 12(a)(2)(M) or pursue a criminal action. Otherwise, submission of a false GLP compliance statement will be pursued as a violation of FIFRA section 12(a)(2)(Q), as either a "high level," "middle level," or "low level" GLP violation (see Appendix GLP-A for gravity levels and Appendix GLP-B for guidance for determining whether to assess the violation as a high, middle, or low level violation).

Each independent violation of the GLP regulations which causes the GLP compliance statement to be false may be assessed as a separate violation of either FIFRA section 12(a)(2)(M) or 12(a)(2)(Q), as appropriate. See the "Multiple Violations" section of this ERP for a further discussion. Also see the July 2, 1990 FIFRA ERP, page 25, for a discussion of independently assessable charges.

Violations of the GLPs Not Related to the GLP Compliance Statement

Certain violations of the GLPs may result in an unlawful act under FIFRA section 12 irrespective and independent of the truthfulness of the GLP compliance statement required by 40 CFR Part 160.12. These unlawful acts include FIFRA sections 12(a)(2)(B)(i); 12(a)(2)(M); 12(a)(2)(Q); and, 12(a)(2)(R).

FIFRA Section 12(a)(2)(B)(i)

Section 12(a)(2)(B)(i) of FIFRA states that it shall be unlawful for any person to refuse to prepare, maintain, or submit any records required under sections 5, 7, 8, 11, or 19. The FIFRA GLP records which registrants, applicants for registration, and producers are required to maintain are, in part, required under the authority of FIFRA section 8. Therefore, failure by a registrant, applicant for registration, or producer to prepare, maintain, or submit any of the records required by the GLPs, including those required under 40 CFR 169.2(k), may be charged as a violation of FIFRA section 12(a)(2)(B)(i).

While almost all of the requirements under the GLPs provide in part for the production and retention of certain records, violations by a registrant, applicant for registration, or producer of the requirements under 40 CFR Part 160.190 - Storage and retrieval of records and data, and Part 160.195 - Retention of records, are particularly associated with recordkeeping and should be assessed as a violation of FIFRA section 12(a)(2)(B)(i). However, in cases where the raw data or other records are retained, but not according to the requirements in the GLP standards, unlawful acts under FIFRA sections 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R) should be charged, rather than FIFRA section 12(a)(2)(B)(i).

Because FIFRA section 8 does not currently authorize EPA to require pesticide testing facilities to maintain records, recordkeeping violations by a pesticide testing facility should not be assessed as a violation of FIFRA section 12(a)(2)(B)(i), unless the study is being submitted under FIFRA section 5 for an experimental use permit, or under section 19. Instead, most GLP related recordkeeping or reporting violations by a pesticide testing facility will be charged through enforcement of the truthfulness of the GLP compliance statement [FIFRA sections 12(a)(2)(M) or 12(a)(2)(Q)] or through FIFRA section 12(a)(2)(R).

An unlawful act under FIFRA section 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R) may be charged in addition to the recordkeeping violation charged under FIFRA section 12(a)(2)(B)(i), if the recordkeeping violation also results in the submission of a false GLP compliance statement [§§12(a)(2)(M) or 12(a)(2)(Q)] or the knowing submission of false data [§12(a)(2)(R)]. The EPA considers these unlawful acts to be independently assessable because it is possible to be in violation of the recordkeeping requirements of the GLPs and still submit a true and correct GLP compliance statement which indicates that the required records have not been maintained. It is also possible to maintain the required records, and therefore comply with section 12(a)(2)(B)(i), but to have maintained false records or to knowingly submit false data to the Agency.

FIFRA Section 12(a)(2)(M)

Section 12(a)(2)(M) of FIFRA states that it shall be unlawful for any person to *knowingly* falsify all or any part of an application for registration, application for an experimental use permit, any information submitted under section 7, any records required to be maintained by the Act, any report filed under the Act, or any information marked as confidential and submitted to the Administrator under any provision of the Act. Compliance with the GLPs is required as part of an application for registration or an application for an experimental use permit, and GLP compliance entails the maintenance of records (personnel records, Quality Assurance Unit (QAU) records and reports to management, etc.) and filing of reports (final study reports, including the submission of a GLP compliance statement, QAU reports, etc.). "*Knowing* falsification" of the GLP records or reports as related to these provisions constitutes a violation of FIFRA section 12(a)(2)(M).

FIFRA Section 12(a)(2)(Q)

Section 12(a)(2)(Q) of FIFRA states that it is unlawful for any person to falsify all or part of any information relating to the testing of any pesticide (or any of its ingredients, metabolites, or degradation products) which the person knows will be furnished to the Administrator, or will become a part of any records required to be maintained by this Act.

Regardless of the truthfulness of the GLP compliance statement, through this unlawful act, EPA may pursue an enforcement action for a violation of any requirement of the GLPs which involves the falsification of testing information which was submitted to the EPA, or for which a testing facility or sponsor knows will eventually be submitted to the Agency, or will be required to be maintained as a record under the GLPs or 40 CFR Part 169. The EPA is not required to assert that the falsification was "knowing," only that the information was "false".

Additionally, under this unlawful act, EPA may pursue an enforcement action for a GLP violation for an ongoing study for which no final report has been submitted to the Administrator and for which no compliance statement under 40 CFR 160.12 has yet been signed, provided the EPA can document that information which was required to be documented as the study proceeded was false, and the pesticide testing facility knew that the information was being generated with the intention of being submitted to the EPA (note the requirement in 40 CFR 160.10).² The language of FIFRA section 12(a)(2)(Q) provides this authority since the unlawful act applies to the falsification of information relating to the testing of a pesticide "... that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act."

² The appropriate enforcement response for GLP violations in on-going studies will generally be a notice of warning (NOW), unless the violation involves a "knowing" violation. Further, if the violation for which an NOW was issued is not corrected by the time the study is submitted to the Agency, the EPA will pursue a civil or criminal action.

FIFRA Section 12(a)(2)(R)

Section 12(a)(2)(R) of FIFRA states that it is a violation of FIFRA to submit data known to be false in support of a registration. Studies required under FIFRA sections 3, 4, and 24(c) are clearly required to support a pesticide registration. Additionally, studies conducted under FIFRA section 5 and 18 may be used to support a pesticide product registration at some time. Therefore, *knowing* submission of false data, including false records/reports required under the FIFRA GLPs will constitute a violation of this provision of FIFRA. Unlike FIFRA section 12(a)(2)(Q), the applicability of this unlawful act is dependent on a finding that the data submitted was "*known*" to be false by the violator.

Multiple Violations

A statement, under 40 CFR 160.12, which certifies that a study complies with the GLPs is a statement that all requirements listed in 40 CFR Part 160 have been met. If requirements of the GLPs have not been met, then the GLP compliance statement is false. Each independent requirement of the GLPs which has been violated, but has been represented through the statement as in compliance, may be considered a separate count of FIFRA section 12(a)(2)(M) or 12(a)(2)(Q), as appropriate, and each count assessed a civil penalty up to the statutory maximum (see the July 2, 1990 FIFRA ERP, page 25, for a discussion of independently assessable charges). For example, a sponsor could be assessed a civil penalty for up to \$15,000 because that sponsor submitted a study with a GLP compliance statement which failed to truthfully state that the pesticide testing facility: (1) failed to maintain personnel records; (2) failed to designate a study director; and, (3) failed to record raw data.

Unlawful acts under FIFRA sections 12(a)(2)(B)(i); 12(a)(2)(M); 12(a)(2)(Q); and, 12(a)(2)(R) may be assessed in addition to those violations assessed as a false compliance statement, provided that these additional unlawful acts are independent of the counts charged as a falsification of the GLP compliance statement.

Generally, GLP violations will be assessed on a per study basis. Therefore, multiple violations of the same requirement in separate studies will be considered as separate offenses. These violations are independent violations, and therefore, each violation should be assessed a separate civil penalty of up to the statutory maximum. However, as a matter of policy, multiple violations of the same GLP requirement in a *single* study will not be assessed as separate offense each time the specific requirement is violated in that study. Rather, multiple violations of the same requirement in a single study will be considered as a single offense which may be raised from a low level to a middle level, or a middle level to a high level GLP violation, depending on the significance and frequency of the violation in a single study (see Appendix GLP-B-2). The Agency has taken this approach for this ERP because many of the GLP requirements which require repetitious compliance throughout the life of the study (such as failing to initial data entries (40 CFR 160.130(e)), can occur unchecked in a single study for an undefined period of time, and penalties for violations of a single repetitive requirement could accumulate to inappropriate or unrealistic levels.

LEVELS OF ACTION

The levels of enforcement action for violations of the FIFRA GLPs include notices of warning, administrative civil penalties, and criminal proceedings. Additionally, in accordance with the July 2, 1990 FIFRA ERP, press releases should be issued in conjunction with most enforcement responses (except notices of warning).

Notices of Warning (NOW)

Notices of Warning (NOW) are the appropriate enforcement response in the following circumstances:

- o First-time violations by an independent pesticide testing facility which has been contracted by a study sponsor to conduct testing which falls under the scope of the GLPs.³ Under FIFRA section 14, any person not listed in section 14(a)(1), who is not a "for-hire applicator", may only receive a civil penalty subsequent to receiving a written notice of warning from the Administrator (see page 4 of the July 2, 1990 FIFRA ERP). Pesticide testing facilities are not included under FIFRA section 14(a)(1) and, therefore, fall under the category of persons under FIFRA section 14(a)(2) who must receive an NOW prior to being assessed a civil penalty for violations of FIFRA.
- o First-time "low level" GLP violations assessed as violations of FIFRA section 12(a)(2)(Q) (see Appendix GLP-B).

³ Pesticide testing facilities which are owned or operated by the registrant may be charged a civil penalty of up to \$5,000 per offense for the first violation of the GLPs under FIFRA section 14(a)(1).

- o GLP violations assessed as violations of FIFRA sections 12(a)(2)(B)(i), or 12(a)(2)(R) which are clerical or technical violations which either separately or collectively have a relatively minor impact on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make a regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results or reconstruct the study; and, (4) the EPA's administration of the GLP inspection and enforcement program (i.e., impairment of the Agency's inspection targeting ability or the efficiency of the GLP compliance inspections or data audits, etc.).⁴
- o Falsification of records required to be maintained in an ongoing study for which no final report has been submitted to the Administrator and for which no compliance statement under 40 CFR 160.12 has yet been signed.

Generally, a notice of warning will not be appropriate if the violator has previously violated the GLP regulations (criteria for establishing "compliance history" may be found in the July 2, 1990 FIFRA ERP, Appendix B, page B-3, footnote number 4) or the violator has received a notice of warning for a previous GLP related violation.

Civil Administrative Penalties

Civil penalties assessed for violations of the FIFRA GLPs are to be calculated according to the procedures and matrices provided in the July 2, 1990 FIFRA Enforcement Response Policy. The gravity levels established for each violation on the FIFRA GLPs are listed in Appendix GLP-A of this ERP and in Appendix A of the July 2, 1990 FIFRA ERP.

Civil penalties may be assessed against both the study sponsor and the pesticide testing facility. A registrant (usually the study sponsor), or pesticide testing facility owned by a registrant, will be assessed civil penalties of up to \$5,000 per offense under FIFRA section 14(a)(1). An independent pesticide testing facility who was contracted by the study sponsor will be assessed civil penalties of up to \$1,000 per offense, subsequent to a written notice of warning, under section 14(a)(2).

⁴ An example of a clerical or technical violation which has a relatively minor impact on the criteria listed above is a one-time failure to fulfill one of the GLP repetitive requirements, such as, failure to sign or initial, and date a data entry [160.130(e)]. Another example is a transcription error which can be verified or corrected by other means and which did not result in an erroneous conclusion for the overall study.

A civil administrative penalty will be issued for all violations of the FIFRA GLPs which do not qualify for a notice of warning and have an impact on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make a regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results, i.e., reconstruct study, verify results; or, (4) the EPA's administration of the GLP inspection and enforcement program (i.e., targeting of inspections, delay in an the Agency's inspection activities or data audit because standard GLP procedures or formats are not followed, etc.). In addition, a civil administrative penalty will be issued for repeat violations of the GLP regulations.

Most violations of FIFRA GLP Standards are considered as recordkeeping or reporting violations. As noted in the July 2, 1990 FIFRA ERP, the gravity of recordkeeping and reporting violations are already considered in the dollar amounts presented in the FIFRA civil penalty matrices. Further, recordkeeping and reporting violations do not lend themselves to utilizing the gravity adjustments listed in Appendix B of the July 2, 1990 FIFRA ERP. Therefore, first-time civil penalties are to be assessed at the matrix value, while subsequent civil penalties should be increased by an increment of 30% (up to the statutory maximum). Please note, repeat violations of the identical GLP requirement may indicate a "knowing or willful" violation, and therefore, the need to pursue criminal proceedings.

Criminal Proceedings

Criminal proceedings may be initiated against an applicant for registration, or study sponsor who is a registrant, applicant for registration, or pesticide producer, for knowing and willful violations of the FIFRA GLPs, under FIFRA section 14(b)(1)(A) for criminal penalties of up to \$50,000 and/or imprisonment for up to one year. Any commercial applicator of a restricted use pesticide, or any person not described in FIFRA section 14(b)(1)(A) who distributes or sells pesticides or devices, who knowingly violates any provision of FIFRA shall be fined up to \$25,000 and/or imprisoned for up to one year. The EPA may also pursue criminal proceedings against the pesticide testing facility, or other person for knowing and willful violations of the GLPs under FIFRA section 14(b)(2) for criminal penalties of up to \$1,000 and/or imprisonment for up to 30 days. Additionally, criminal proceedings may be pursued against the registrant, pesticide testing facility, or other person for violating Title 18 of the U.S. Code.

REFERRALS

In addition to the levels of enforcement action listed in the previous section, the EPA may take regulatory action for violations of the GLPs, including: rejection of studies which do not comply with the FIFRA GLPs; cancellation, suspension, or modification of a pesticides research or marketing permit; or denial or disapproval of an application for such a permit. Further, in order to help assure that the Federal Government deals with responsible contractors, and for the purposes of the Federal Government's protection, pesticide testing facilities responsible for significant or major GLP violations may also be suspended or debarred from Government contracts or subcontracts. Until further guidance is issued, the Agency's regulatory response for violations of the GLPs will be addressed on a case-by-case basis and, therefore, will not be addressed in detail in this policy.

Office of Pesticide Programs

If the Agency discovers any significant or major GLP violations or data concerns in the course of a facility inspection or study audit, the Office of Compliance Monitoring will notify the Office of Pesticide Programs so that Office may consider if any regulatory action would be appropriate. These regulatory actions include: (1) rejection of studies which do not comply with the FIFRA GLPs; (2) cancellation, suspension, or modification of a pesticide's research or marketing permit; or, (3) denial or disapproval of an application for such a permit.

Pursuit of an enforcement action by the EPA, such as the issuance of a civil or criminal complaint, does not obligate the Agency to pursue a regulatory response, such as study rejection or cancellation/suspension of a pesticides research or marketing permit. Similarly, a regulatory response by the Agency does not obligate the Agency to pursue an enforcement action. The EPA's decision to pursue an enforcement response and/or regulatory response to a GLP violation will, by administrative necessity, occur on different tracks and will be based on the individual merits of each approach on a case-by-case basis.

Office of Administration

Pesticide testing facilities responsible for significant or major GLP violations may be suspended or debarred from Government contracts, subcontracts, and assistance loan and benefit programs. This action is not for the punishment of the violator nor is it an enforcement tool, but rather it is for the protection of the Federal Government by assuring that the Government will be dealing with responsible contractors.

The Office of Compliance Monitoring will notify the Compliance Branch of the Grants and Administration Division, Office of Administration of the identity of pesticide testing facilities which are responsible for a significant or major GLP violation and have been assessed a civil penalty through a final order or when there is evidence of a criminal offense for violations of the FIFRA GLPs, so that Office may decide whether they wish to pursue suspension or debarment proceedings in accordance with the Federal Acquisition Regulations (FAR) at 48 CFR Subpart 9.4, and the EPA Suspension and Debarment regulations found at 40 CFR Part 32.

APPENDIX GLP - A

**FIFRA CHARGES AND GRAVITY LEVELS
FOR CIVIL PENALTIES ASSESSED FOR VIOLATIONS OF THE
FIFRA GOOD LABORATORY PRACTICE STANDARDS**

GLP-A-1

APPENDIX GLP-A FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FTTS CODE	VIOLATION	LEVEL
12(a)(2)(B)(i)	2BA	Person refused to PREPARE, MAINTAIN, or SUBMIT <u>any</u> RECORDS required under sections 5, 7, 8, 11 or 19.	2
12(a)(2)(M)	2MA	Person KNOWINGLY FALSIFIED all or any part of an application for registration, application for an experimental use permit, any information submitted under section 7, <u>any</u> records required to be maintained by the Act, <u>any</u> report filed under the Act, or any information marked as confidential and submitted to the Administrator under <u>any</u> provision of the Act.	1
12(a)(2)(Q)	2QA	Person FALSIFIED INFORMATION RELATING to the TESTING of any pesticide (or any of its ingredients, metabolites, or degradation products) for which the person knows will be furnished to the Administrator, or will become a part of any records required to be maintained by this Act.	1
12(a)(2)(Q)	2QB	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a HIGH LEVEL GLP* violation.	2
12(a)(2)(Q)	2QC	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a MIDDLE LEVEL GLP* violation.	3
12(a)(2)(Q)	2QD	14(a)(1) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP* violation.	4
12(a)(2)(Q)	2QE	14(a)(2) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP* violation.	3**
12(a)(2)(R)	2RA	Person submitted DATA KNOWN TO BE FALSE in support of a registration.	1

* Guidance on the parameters for determining whether a GLP violation assessed as an unlawful act under FIFRA section 12(a)(2)(Q) is a HIGH, MIDDLE, or LOW LEVEL violation is found in Appendix GLP-B.

** A higher level has been assigned for FIFRA section 14(a)(2) persons because a civil penalty which is assessed under this provision represents the second violation of that person. Violators who fall under the category of persons listed in FIFRA section 14(a)(2) must receive a Notice of Warning for the first GLP violation.

APPENDIX GLP - B

GUIDANCE FOR DETERMINING WHETHER TO ASSESS A GLP VIOLATION UNDER FIFRA SECTION 12(a)(2)(Q) AS A HIGH, MIDDLE, OR LOW LEVEL VIOLATION

GLP-B-1

APPENDIX GLP-B GUIDANCE FOR DETERMINING WHETHER TO ASSESS A GLP VIOLATION UNDER FIFRA SECTION 12(a)(2)(Q) AS A HIGH, MIDDLE, OR LOW LEVEL VIOLATION

When assessing a civil penalty for violations of FIFRA section 12(a)(2)(Q) for submission of a false compliance statement (FTTS codes 2QB, 2QC, 2QD, and 2QE, as listed in Appendix GLP-A of this ERP and Appendix A of the July 2, 1990 FIFRA ERP), the parameters listed in this appendix will be used to determine whether a GLP violation is a "high", "middle", or "low level" GLP violation. Because of the expertise that is necessary to make an assessment of the impact of a GLP violation, the determination of whether a violation will be considered as a high, middle, or low level will be made at EPA Headquarters by the Office of Compliance Monitoring with input from the Office of Pesticide Programs and the Office of Enforcement based on the criteria listed in this appendix. A brief summary of the rationale for the categorization of the impact of the GLP violation should be included as part of the civil complaint sent to the respondent.

High Level GLP Violations

A "high level" violation of the FIFRA GLPs involves a substantial failure to comply with the regulations. "High level" GLP violations will have a substantial impact on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make a regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results, i.e., reconstruct the study, verify results; or (4) the EPA's administration of the GLP inspection and enforcement program (i.e., impairment of the Agency's inspection targeting ability or the efficiency of the GLP compliance inspections or data audits, etc.). Violations which will be considered as "high level" based on the above criteria include, but are not limited to:

- 1) Failure to notify a person performing under contract of the applicability of GLPs - §160.10.
- 2) Failure to keep personnel records - §160.29.
- 3) Falsification of personnel records - §160.29.
- 4) Failure to designate a study director - §160.31.
- 5) Failure to assure the existence of a Quality Assurance Unit (QAU) - §160.31.
- 6) Failure of the QAU to conduct any inspections or maintain any records - §160.31.

GLP-B-2

- 7) Failure to maintain Standard Operating Procedures - §160.81.
- 8) Failure to follow laboratory SOPs without documentation in the raw data and/or written authorization from management - §160.81(a).
- 9) Failure to isolate all newly received animals from outside sources until their health status has been evaluated - §160.90(b).
- 10) Failure to characterize the test, control, or reference substances - §160.105.
- 11) Failure to have a protocol - §160.120.
- 12) Deviation from the protocol without documentation and/or study director written signoff - §160.120(b).
- 13) Failure to record raw data - §160.130.
- 14) Falsification of raw data - §160.130.
- 15) Failure to retain raw data and specimens - §160.51, §160.190, and §160.195.

Partial compliance with a "high level" GLP violation, such as the examples listed above, may justify considering the violations as "middle level" GLP violations.

Middle Level GLP Violations

All violations of GLPs which are not considered "high level" violations are considered to be "middle level" GLP violations **UNLESS** the violation is determined to be a "low level" violation (see the subsequent section for the criteria for determining a "low level" violation).

Partial compliance with any of the violations which could be considered as a "high level" GLP violation (such as the violations listed in the "High Level GLP Violation" section above), may qualify for consideration as a "middle level" GLP violation. For example, a pesticide testing facility may be charged a "middle level" GLP violation rather than a "high level" GLP violation for failure to maintain personnel records, provided that the personnel records for that facility are mostly complete.

GLP-B-3

Low Level GLP Violations

A GLP violation will be considered "low level" in cases where the violative act was purely clerical or technical in nature with relatively minor impacts on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make a regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results, i.e., reconstruct the study, verify results; or, (4) the EPA's administration of the GLP inspection and enforcement program (i.e., targeting of inspections, delay in the Agency's inspection or data audit activities because standard GLP procedures or formats are not followed, etc.). "Low level" violations are appropriate where there is a general program in place by a violator to comply with the GLPs, but instances of noncompliance occur anyway due to apparent inadvertent error, equipment failures, or other similar occurrences. Violations which will be considered as "low level" based on the above criteria include, but are not limited to:

- 1) A facility generally maintained a current summary of training and experience and job description for each individual engaged in the study but failed to do so for one or two individuals - §160.29(b).
- 2) A facility generally maintained records which documented equipment inspection, maintenance, testing, calibrating, and/or standardizing operations, but failed to document these operations in one instance - §160.63(c).
- 3) A facility maintained all revisions to the standard operating procedures (SOPs) but failed to note the date of the revision in one or two instances - §160.81(d).
- 4) A reagent or solution which is documented not to degrade does not have an expiration date on the label - §160.83.
- 5) One-time failure to fulfill one of the GLPs repetitive requirements, such as failure to sign or initial, and date a data entry - §160.130(e).
- 6) A clerical error or transposition of numbers in the final study report which can be verified or corrected by other means and which did not result in an erroneous conclusion for the overall study - §160.185 or §160.195.

If the EPA believes that justice may be served, EPA may issue a Notice of Warning under FIFRA section 9(c)(3) for first-time "low level" GLP violations. However, subsequent "low level" violations will result in the assessment of a level 4 civil penalty for a FIFRA section 14(a)(1) violator and a level 3 civil penalty for a FIFRA section 14(a)(2) violator.

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The documents in this index are referenced by the Compendium subject/volume abbreviation and the date of the document. However, FIFRA Compliance Program Policy Compendium documents are referenced by the subject/volume abbreviation and the document number. The abbreviations for the subject/volumes in this index are as follows:

- TG -- Technical Guidance (Volume 1);
- SRG -- State-Related Guidance (Volume 2);
- ES -- Enforcement Strategies (Volume 3);
- ERP -- Enforcement Response Policies (Volume 4); and
- FCPP -- FIFRA Compliance Program Policy Compendium (Volume 5)

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