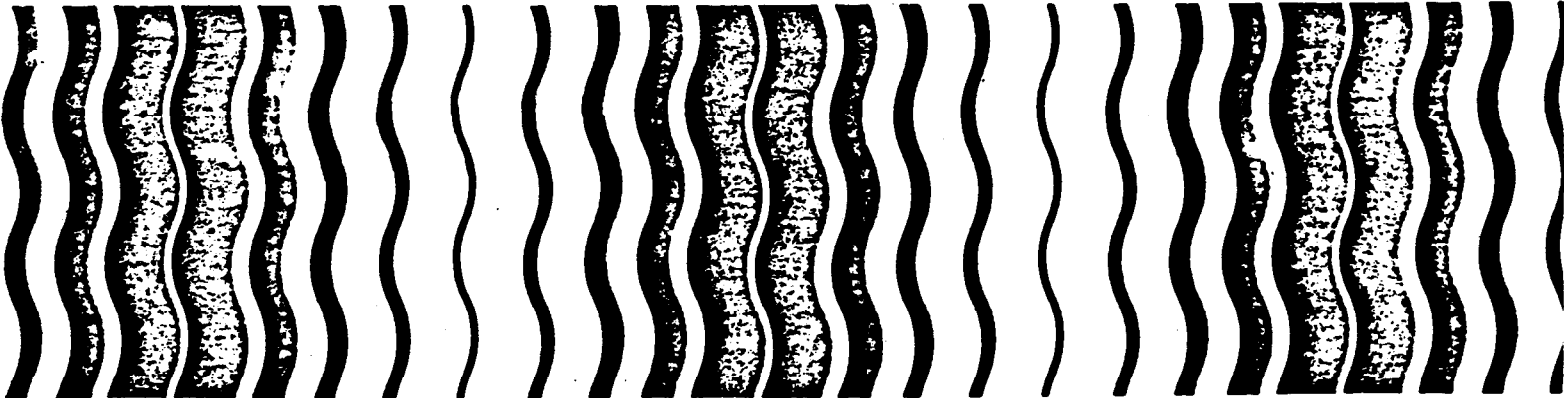
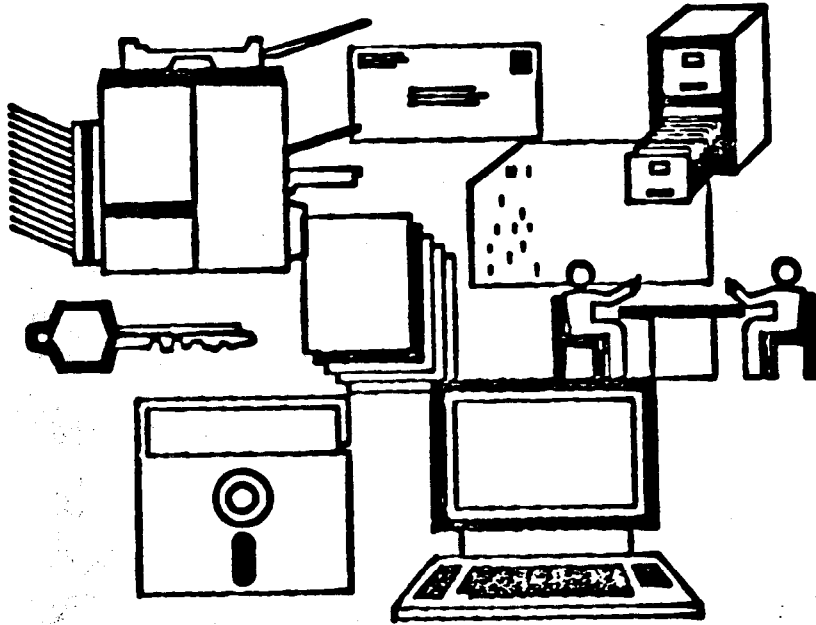




FIFRA

Information Security Manual

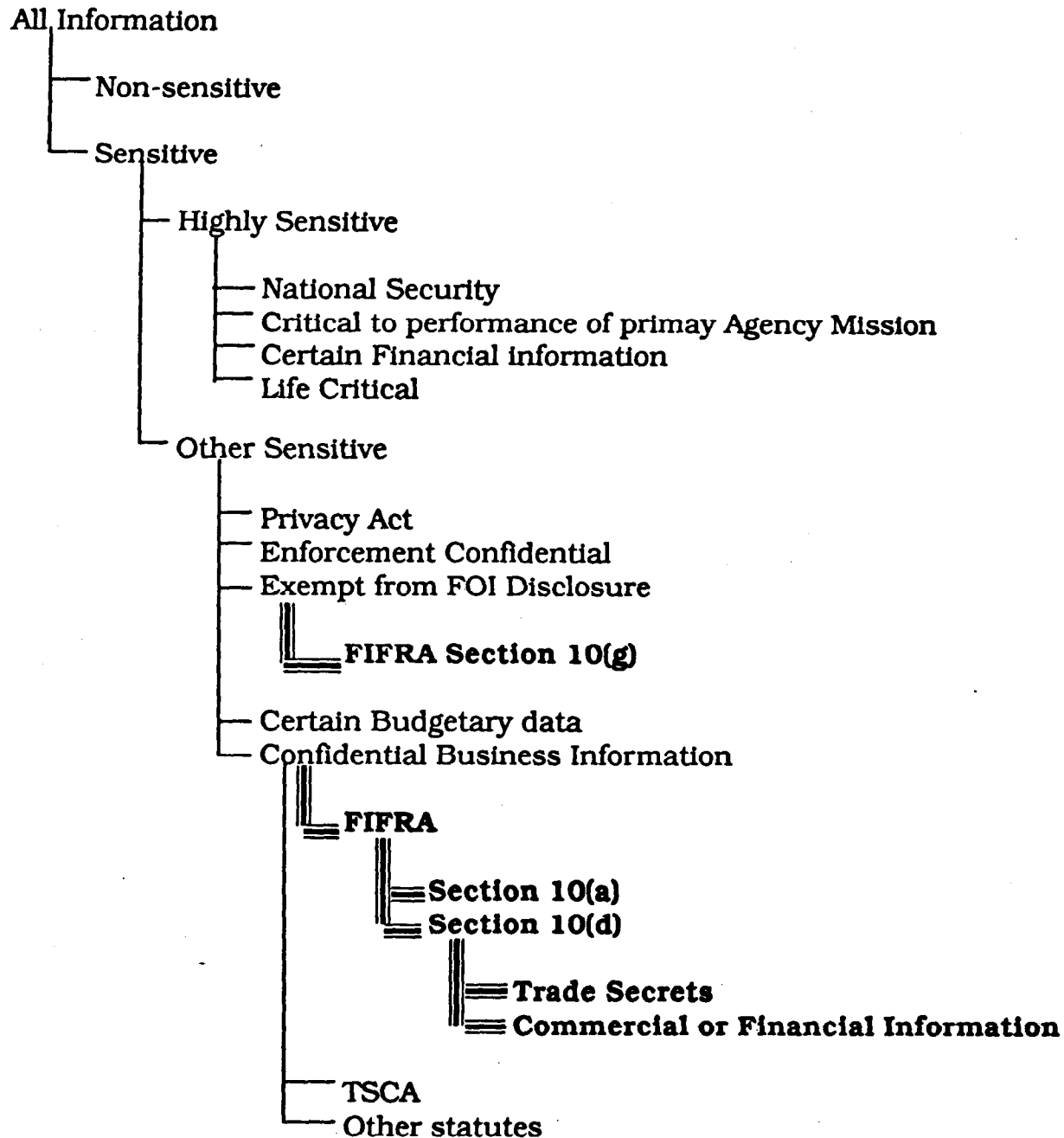


**United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460**

**FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
INFORMATION SECURITY MANUAL**

CATEGORIES OF INFORMATION - AT A GLANCE

These categories may be found in the EPA Information Resources Management Policy Manual. See Chapter 8 at page 8 - 9.



While all sensitive information generally requires protection from unauthorized disclosure or loss, FIFRA creates particular rules that pertain to information that is submitted to EPA by pesticide registrants and applicants. This Manual is devoted primarily to such information.

SCOPE OF THIS MANUAL

Among many other things the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - requires that certain information be submitted by or obtained from the pesticide industry - and provides for protection of this industry information from disclosure under certain circumstances. These provisions can be somewhat confusing: for example, all submitted health and safety data may be released to some persons under certain conditions, yet none of these data may be released (as submitted) to the public generally. One objective of this manual is to reduce (hopefully eliminate) this confusion. The other objective is to provide guidance about how this (and other) sensitive information must be protected from unauthorized disclosure or loss.

This Manual is intended to be used by all Federal employees to whom FIFRA sensitive information is made available. It is also intended to serve as a basis for guidance to contractors and subcontractors who are provided access to FIFRA information in connection with contract work they are performing for EPA or other Federal Government organizations.

This Manual is intended to convey certain information that is necessary to protect against INADVERTENT disclosure or release of information that is accorded protection by FIFRA. Deliberate disclosure or release of FIFRA sensitive information is a clear violation of the law, and is not preventable through the mere issuance of a manual and training of staff. Anyone who may be inclined toward such an act is advised to seriously contemplate the penalty provisions at section 10(f) of FIFRA.

Readers are advised to check with the Information Services Branch (ISB) in the Office of Pesticide Programs (OPP) to resolve any uncertainties about the releasability of FIFRA information.

Relationship of this Manual to other EPA guidance. The EPA INFORMATION SECURITY MANUAL contains requirements and practices that are standard throughout the Environmental Protection Agency. This FIFRA INFORMATION SECURITY MANUAL is referenced in the EPA Manual and contains guidance that is specific to information that is provided to the Agency to meet requirements contained in FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Persons who have access to information that is sensitive under FIFRA are expected to maintain such information according to standards and requirements at least as strict as those contained in these two Manuals.

HOW TO INITIATE A CHANGE IN THIS MANUAL

If you want to suggest a change to this Manual or if you have questions about the rationale behind something in it, please call (703) 557-2613. Ask for the FIFRA Security Officer, the Chief of the Document Management Section, or the Chief of the Information Services Branch.

To formally initiate a change to this Manual, send us a memorandum describing the proposed change. Include a copy of the current Manual page(s) marked with the proposed change or a draft of the proposed change along with reference to the Manual page(s) being revised. The memorandum should be sent to:

Chief, Information Services Branch, PMSD
Office of Pesticide Programs (TS-757C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

ISB will circulate the proposed change to OPP and EPA field/regional staff and other EPA offices (as appropriate to the change being proposed). After comments are evaluated and if the proposed change is accepted, the final revision will be printed and distributed for replacement into the FIFRA Information Security Manual.

Table of Contents

1. **SUBJECT INDEX (Including Definitions That are Unique to FIFRA)**
2. **WHAT FIFRA INFORMATION IS SENSITIVE?**
 - Confidential Business Information**
 - Trade Secrets (Section 10(d)(1)(A), (B), and (C))**
 - Commercial or Financial Information**
 - Other Sensitive Information**
3. **CAN FIFRA SENSITIVE INFORMATION BE DISCLOSED? (Under What Circumstances - To Whom)**
 - Disclosure to EPA Employees**
 - Disclosure to Contractors**
 - Disclosure to the Public**
 - Disclosure to Other Federal Government Agencies, and to Congress and the Courts**
 - In Special Circumstances**
4. **ACCESS TO FIFRA SENSITIVE INFORMATION**
 - PROCEDURES FOR GAINING ACCESS TO FIFRA SENSITIVE INFORMATION**
 - RESPONSIBILITIES OF ACCESS TO FIFRA SENSITIVE INFORMATION**
 - All persons to whom access is granted**
 - First and second line supervisors**
 - EPA Contract Project Officers.**
 - Division Directors**
 - Document Control Officer/Assistant (DCO/DCA).**
 - Office/Laboratory Directors, Regional Administrators**
 - FIFRA Security Officer**
 - EPA Contractors**
 - RESPONSIBILITIES OF OTHER EPA ORGANIZATIONS**
5. **OPERATIONAL PROCEDURES FOR PROTECTING FIFRA SENSITIVE INFORMATION**
6. **IF THERE ARE PROBLEMS**
 - Identifying Problems Within EPA Organizations**
 - Reporting and Investigating Problems Within EPA Organizations**
 - Remedial and Disciplinary Action**

EXHIBITS

Exhibit 1	FIFRA Access Authorization Agreement
Exhibit 2	Confidentiality Agreement for Termination/Transfer
Exhibit 3	Affirmation of Non-Multinational Status
Exhibit 4	"Disclosure of Reviews of Pesticide Test Data"
Exhibit 5	Contractor FIFRA Security Certification Form
Exhibit 6	FIFRA CBI Contract Clause
Exhibit 7	DCO/DCA Listing
Exhibit 8	Transmittal Form
Exhibit 9	CBI Stamps

Exhibit 10

FIFRA Cover Sheet

1. SUBJECT INDEX (Including Definitions That are Unique to FIFRA)

Access Authorization Agreement: Required to obtain and use FIFRA sensitive information in connection with official duties (p. 11, 15 and Exhibit 2) .

Accession Number: A number previously assigned to a physical volume of company-submitted data. One or more studies (now identified by MRID number) may have been included in a volume as submitted by the company. MRID numbers are being used in lieu of accession numbers for studies submitted after November 1986.

Active Ingredient (as used in a pesticide product): Listed on the product label. Not sensitive information.

Analytical Method (one kind of submitted data): Contains sensitive information when inert ingredient or manufacturing process quality control information is revealed. (See also Residue Analytical Method).

Applicant: A person who has submitted information (often including sensitive information) to EPA for the purpose of obtaining a pesticide registration or related regulatory approval. (See also Registrant.)

Authorized Person: A person who has received authorization for access to FIFRA sensitive information by the Division Director (or equivalent supervisor) or contractor's Project Manager.

Cancellation: Terminates registration of a product. Data submitted during the cancellation process may contain trade secrets, and are treated as sensitive information.

Chain of Custody: See Document Tracking System.

Commercial or Financial Information: Considered sensitive and, if confidential, must be protected from disclosure under FIFRA section 10(b) (p. 8).

Confidential Business Information (CBI): General term for any information submitted under FIFRA or FFDCFA that must be protected because it may be a trade secret or (confidential) commercial or financial information (p. 7).

Contractor (or Subcontractor): Any organization and its employees performing work under a contract/agreement with EPA, or with another Federal agency that has been provided access to FIFRA sensitive information (p. 15, 20).

Data: (1) "raw" (un-processed) information, or: (2) information submitted/generated in connection with requirements under FIFRA: See also "Health and Safety (or) Test Data."

Disclosure (used as a synonym for release): Results in access to information that was formerly protected (Section 3) .

Document Identifier: A unique number (such as an MRID number) that is assigned to a document for identification purposes, usually used in document tracking systems.

Document Control Officer/Assistant (DCO/DCA): A person designated by the Division Director as having special coordination and oversight responsibilities needed to properly protect, handle, and route FIFRA sensitive information (Section 4, p. 18) .

Document Tracking System: A mandatory system/log maintained by the DCO/DCA that records and tracks the life cycle of all documents (or other portable media) that contain FIFRA sensitive information. It must identify each document and must show the entire chain of custody, including distribution, destruction, or return to file, of all sensitive documents and all copies made of the documents (p. 24, para 6.).

Emergency Exemption: Temporary permission under FIFRA section 18 to employ an unregistered pesticide/use in an emergency. Data submitted to support requests for exemptions are developed by a State or Federal agency and do not normally contain CBI. Emergency Exemption requests may, on occasion, contain company data, which would be treated as sensitive information.

Experimental Use Permit: Temporary permission under FIFRA section 5 to employ an unregistered pesticide/use in developing required test data for subsequent registration. Data submitted to request experimental use permits are treated as sensitive information.

Federal Food, Drug, and Cosmetic Act (FFDCA): Statute under which tolerances are established for pesticide residues in raw agricultural commodities, processed foods, and animal feeds.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): Statutory basis for the pesticide program in EPA, which includes provisions under which certain information is protected and released, and penalties for unauthorized disclosure of protected information by Federal and contract contractor employees.

FIFRA Access List: A (monthly updated) compilation of the names of employees (and contractor employees) who have been authorized for access to FIFRA sensitive information (p. 12).

FIFRA Security Officer: An individual in the OPP Information Services Branch who is responsible for the FIFRA security program within OPP (p. 19).

Health and Safety (or) Test Data: A term used in OPP to describe scientific data (submitted to OPP as "studies") that are required to support product registration and related regulatory decisions under FIFRA. These data are defined in FIFRA section 10(d)(1) and may contain information described by FIFRA section 10(d)(1) (A), (B), or (C) (i.e. trade secrets). These studies are always treated as sensitive information because their disclosure is restricted under FIFRA section 10(g) (p. 12, paragraph 1).

Import Data: Information submitted by an importer when importing foreign-produced pesticides into

the United States. Required by FIFRA section 17 and sent directly to several EPA regional offices. Treated as sensitive information. (p. 9, 3rd para)

Inert Ingredient (used in a pesticide product): Deliberately added to serve a function other than the intended active pesticidal function (e.g., solvent, adjuvant, etc.) . Considered trade secret under FIFRA section 10(d) (1) (B) and (C) (p. 8, para 2, 3) .

Information (usually used as a synonym for data): The term "information" is used, but not uniformly defined, in FIFRA (Sections 2 and 3).

Media: In the context of information, media is a generic term for the form upon which (or within which) the information appears (e.g., paper, film, magnetic, electronic, etc.).

Master Record Identification (MRID) Number: A unique identification number given to each document (including submitted studies) in the Pesticide Document Management System (PDMS) that is operated by the Information Services Branch. The MRID number may be used in document tracking systems as the document identifier.

Multinational Pesticide Producer: A special category of persons to whom access to certain registrant-submitted information is denied. These are persons who engage in pesticide business outside of the United States. (Multinationals are considered by the pesticide industry to pose a threat to fair competition if they obtain test data on other registrants products and use the test data to obtain registrations that can compete for the test owner's markets in other countries. This concern contributed to the insertion of FIFRA section 10(g)) (p. 12, paragraph 1).

Normal Operations: Used in this Manual to mean (most) situations that do not involve any of the special (rarely used) FIFRA release authorities (p. 11, paragraph 2).

Pesticide: Used as a synonym for pesticide product. A generic term that, under FIFRA, includes insecticides, rodenticides, fungicides, herbicides, disinfectants, etc..

Petition: A request submitted with data for regulatory approval to establish a residue tolerance in food or feed commodities. The data are treated as sensitive information.

Product: See Pesticide.

Production Data: Information on the types and amounts of pesticides produced, submitted (usually to EPA regions) under FIFRA section 7(c) . Production data are trade secret under FIFRA section 7(d) and are treated as sensitive information (p. 8, last paragraph).

Proprietary Information: "Owned" by a registrant but may not fall within the FIFRA trade secret or confidential business information definitions. Such information, while claimed as proprietary by a registrant, may be releasable under FIFRA. Another example is: commercially produced compilations of survey data that are sold under certain restrictions, e.g. for use by the purchaser but not for subsequent sale or use by another.

Public: Used in a document release context as meaning "everyone. " It is especially significant in the context of FIFRA sensitive information because release to the public is considered to include release to multinational pesticide producers (p. 12).

Registrant: One who has obtained a registration under FIFRA. Used in this Manual as a synonym for applicant or submitter as the usual source of FIFRA sensitive information.

Registration: EPA permit (license) under FIFRA sections 3(a) and 24(c) to distribute, sell, or ship a pesticide in the United States. Health and Safety Data are required to obtain a registration.

Release: See Disclosure (p. 11).

Residue Analytical Method: Not sensitive information; published by the Food and Drug Administration in the "Pesticide Analytical Manual."

Security Inspection: An audit conducted on a periodic basis to evaluate (facility, equipment, and procedures) conformance to security requirements contained in this Manual (p. 26, para 12) .

Security Plan: A written report required from all contractors and subcontractors that describes all methods, equipment, and procedures employed at a facility to safeguard FIFRA sensitive information (p. 20) .

Sensitive Information: Information the release of which is limited or prohibited by FIFRA (in the case of FIFRA sensitive information) or in the case of other information, by another statute or regulation. Used in this Manual as shorthand for information (irrespective of media) that must be handled according to guidance in the FIFRA and EPA Information Security Manuals. Also, documents become "sensitive documents" when they contain sensitive information (Section 2) .

Supplemental Claims of Confidentiality: Claims made by the submitter under FIFRA section 10(a) that are NOT based on the trade secret definitions in section 10(d) (1)(A), (B), or (C). These claims must be substantiated by the submitter (p. 9) .

Suspension: Temporary prohibition of sale or shipment (and may prohibit the use) of a product. Sometimes precedes cancellation. Data submitted to comment on or rebut the proposed suspension action may contain trade secrets and are treated as FIFRA sensitive information.

Trade Secret Information: A special category of sensitive information that is defined explicitly by FIFRA section 10(d) (1)(A), (B), and (C) (p. 7).

Tolerance: Maximum amount of a pesticide residue that is permitted in raw agricultural and processed food commodities and animal feeds. See Petition.

Violation: has occurred when sensitive information is discovered to have been treated NOT in accordance with guidance in the EPA and FIFRA- Information Security Manuals. Unlawful disclosure may or may not have occurred as a result of a violation. All violations are reviewed for possible corrective and, under certain circumstances, disciplinary action (p. 29).

2. WHAT FIFRA INFORMATION IS SENSITIVE?

Certain information about pesticide registrants and their products, submitted or generated in connection with regulatory approvals, is granted protection from disclosure or release by FIFRA, subject to certain conditions that are described below. It is therefore sensitive information. (Other information that is collected and/or used by Agency staff and contractors in carrying out the official business of the Agency may not be protected by FIFRA but may be entitled to protection according to other laws or guidance. For example, certain records and notes developed during compliance/audit operations may not be releasable. Such materials are also sensitive.) The following categories of information are more specific categories of sensitive information.

Confidential Business Information

The following general definition of confidential business information has been provided by OGC and is to be used if the specific definitions provided below cannot be clearly applied when determining the sensitivity of FIFRA information. Contact the Public Information Branch, FOD/OPP, if you have questions about the sensitivity of FIFRA information.

Confidential Business Information (CBI) is any information in any form received from any person, firm partnership, corporation, association, or local, state, or Federal agency which contains trade secrets or commercial or financial information, and which has been claimed as confidential by the person submitting it and which has not been legally determined to be non-confidential by the EPA General Counsel under the procedures in 40 CFR Part 2, Subpart B (2.205).

Trade Secrets (Section 10(d)(1)(A), (B), and (C))

Section 10(d) (1) of FIFRA requires the Agency to disclose to the public certain types of information concerning registered or previously registered pesticides, pesticide degradation products, and pesticide ingredients. In general, the information required to be disclosed is any information on test methodology, objectives, and results, and any information on safety and health effects of the pesticide. The disclosure is subject to the limitations of FIFRA section 10(g). See Section 3 of this Manual.

The following three types of information are withheld from disclosure notwithstanding the fact that they fall within the purview of section 10(d)(1). They are characterized as "trade secrets" in this Manual to set them apart in an explicit category of information that is protected from release under all normal operations. These types of information may be released in special (very rare) circumstances.

Manufacturing or quality control process information - FIFRA section 10(d)(1)(A). We protect this information, and any other information that can lead to disclosure of it. For example, we do not disclose the identity of contaminants of manufacturing processes because this information can help someone more easily/accurately deduce the manufacturing process.

2. Details of methods for testing, detecting, or measuring the quantity of deliberately added inert

ingredients of a pesticide - FIFRA section 10(d)(1)(B).

3. The identity or percentage quantity of any deliberately added inert ingredients of a pesticide - FIFRA section 10(d)(1)(C). This information is commonly found in the "Certified Statement of Formula" (CSF) which is required to be submitted to OPP by registrants of all end-use products and other products (e.g., trade name) that are used in producing end-use products. The CSF is normally filed in the "product jacket" making this jacket a confidential (sensitive) file.

All three types of trade secret information may be found in studies that are routinely submitted to EPA by applicants or registrants, and may also be found in the confidential attachment to OPP reviews of submitted studies, having been quoted or referenced in the reviews. (OPP policy to put trade secrets in a confidential attachment to the review became effective in January 1985.) Under guidance contained in Pesticide Registration (PR) Notice 86-5 (effective November 1, 1986), the above types of information may not be imbedded in a study. Instead, submitters must segregate such trade secret information in a confidential attachment and provide references to it from within the study.

Commercial or Financial Information

This is information that is not trade secret under FIFRA section 10(d) (1) (A), (B), or (C) , but which must be protected from disclosure, if confidential, as provided by FIFRA section 10(b) . Commercial or financial information includes information listed in FIFRA section 10(d)(2): information concerning production, distribution, sale, or inventories of a pesticide. Production information as described by FIFRA section 7(c) is another example of commercial or financial information that may be confidential.

Other Sensitive Information

FIFRA section 10(a) provides that registrants may mark ANY portions of their submittals which, in their opinion, are or contain trade secrets or confidential commercial or financial information, whether or not the portions claimed fall under the above definitions. If OPP (acting for the Administrator) proposes to release such marked information, or any other information that it believes might be confidential, the releasability of the information must first be determined as provided for under FIFRA section 10(c). We call claims that are based on definitions that are not described by FIFRA section 10(d) (1) (A), (B), or (C), or IO(d) (2) "supplemental claims of confidentiality" and do not release information covered by these supplemental claims until their status has been resolved by OGC. Always check with the Public Information Branch, FOD/OPP, if there are any unresolved questions about the status of supplemental claims covering information that is to be released to anyone outside EPA.

Examples of information that has been involved in supplemental claims:

- Portions of submittals that describe (very expensive) innovative new technology.
- Information, not described by FIFRA section 10(d)(2), that would reveal new marketing strategies.

The Agency may also determine that other information claimed confidential, aside from that submitted by a registrant, is entitled to protection. An example is information about imports to the United States that is provided by foreign producers to Agency regional offices under FIFRA Section 17.

***** BE CAREFUL

The above definitions of information that must be protected, and the descriptions, in Section 3, of information that may be released - are provided to inform and enable authorized persons to more efficiently and effectively contribute to the mission of their organization, including confidently carrying out FIFRA's provisions regarding the protection of certain information.

While we have attempted to make this material as clear and easily readable as possible, the classifications of information herein are NOT intended to result in giving these persons a sense of false confidence that could result in making, or contributing to making, an unauthorized release of sensitive information. Readers should be advised that some of these classifications may at first appear somewhat complex, therefore causing uncertainty.

If such uncertainty occurs, readers are advised to resolve it, prior to taking potentially regrettable action, by contacting the Information Services Branch at the number listed in the front of this Manual.

3. CAN FIFRA SENSITIVE INFORMATION BE DISCLOSED? (Under What Circumstances - To Whom)

Certain information that is accorded protection by FIFRA can also be disclosed under some circumstances, according to FIFRA. Several factors come into play (individually or in various combinations) in the decision to release a given document: 1) whether it contains trade secret information; 2) whether it was submitted by an applicant (or registrant) or other person; 3) whether the product supported by information in the document has been registered; 4) who wants to see the information; and 5) in what context the information is needed. In general, "sensitivity" is not just an unambiguous attribute of a document, and judgments of releasability in one instance or context may not be correct in others. Therefore, in a broader context, sensitivity refers to the complex nature of many release decisions and, conversely, the special care with which FIFRA information must be protected.

FIFRA does not make reference to the various documents in which protected information can occur in OPP. The following material refers to FIFRA-sensitive information in terms of typical OPP documents and describes its releasability under normal operations. Special disclosure authorities that are provided in FIFRA for certain (rarely needed) circumstances are referenced, but not discussed, in this Manual.

Disclosure to EPA Employees

Access to FIFRA sensitive information will be given only to persons who need the information in the conduct of official U.S. Government business, and only on the basis of a completed "FIFRA Access Authorization Agreement" (Exhibit 1).

Access will be withdrawn when an employee terminates employment or no longer requires access due to a change in duties or position. The employee must return all sensitive information and/or chain of custody records to the DCO/DCA and sign a "Confidentiality Agreement for Termination/Transfer" (Exhibit 2).

If an EPA employee already has been granted access to information that is sensitive under another statute (e.g., TSCA), the employee must be briefed on the unique FIFRA requirements in this Manual and must execute a FIFRA Access Authorization Agreement. If the employee has been briefed on other aspects of security practice that are standard throughout EPA, these aspects need not be duplicated in the FIFRA employee briefing as long as the employee shows evidence of a good understanding of the material.

FIFRA Access List

OPP maintains an alphabetic list of EPA and other Government employees who have been authorized access to FIFRA sensitive information. The FIFRA Access List is updated monthly and distributed to Division Directors, Branch Chiefs, and DCOs/DCAs. A similar list of contractor employees is maintained for the Contract Project Officer by ISB.

Disclosure to Contractors

Disclosure to contractors is provided for in FIFRA section 10(e) and 40 CFR 2.307. In addition to ensuring that normal requirements for protecting FIFRA sensitive information are met by contractors, submitters of FIFRA sensitive information to be used by the contractor must be informed of the contractor's access to it and chain of custody records that describe the information provided to the contractor must be maintained (see Section 4). The first two paragraphs under "Disclosure to EPA Employees" also apply to contractor employees.

Disclosure to the Public

NOTE : The general rule is that information that may be trade secret or confidential business information must not be disclosed to the public (and is subject to the security procedures set forth in this Manual) until it is determined by EPA not to be trade secret or confidential. Information described by FIFRA section 10(a) as well as 10(d)(1)(A), (B), and (C) must be thus protected. Disclosure of such information to certain parties outside the Agency or to the public is authorized in certain limited circumstances described in FIFRA and 40 CFR 2.307. Some of these circumstances are also discussed below.

Other applicant or registrant-submitted data, while not considered confidential business information, may only be disclosed to the public under restricted conditions as follows:

1. Health and Safety (or) Test Data about a registered or previously-registered pesticide may be released to a person who is not a multinational pesticide producer, the agent of such a producer, or is seeking access to the data for the purpose of disclosing it to such a producer or agent. (See FIFRA section 10(g)) . Prior to each such release, the Public Information Branch, FOD obtain from the person making the request a signed "Affirmation of Non-Multinational Status" (Exhibit 3).

2. Reviews of Health and Safety (or) Test Data produced by EPA staff or contractors may be released to the public as long as the following conditions are met: a) the review is of test data about a registered or previously-registered pesticide, b) the review must not contain any information that may be trade secret or business confidential, and c) the review must not contain "essentially the complete study." This guidance is contained in a Class Determination ("Disclosure of Reviews of Pesticide Test Data") made by OGC and published in the FEDERAL REGISTER dated November 27, 1985, p. 48833 (Exhibit 4). Trade secret or confidential business information that is necessary to the completeness of reviews must be put in a (nonreleasable) confidential attachment to the review when the review is written.

3. Summaries, brief abstracts, or excerpts from registrants Health and Safety (or) Test Data (studies) and summaries of OPP/EPA reviews of these data may be released to anyone, subject to the same conditions stated in para 2. above.

4. Chemical Fact Sheets, Science Chapters, Position Documents, Registration Standards, Special Review Decisions, and Toxicology "One-liners" are releasable to the public without restriction. OPP policy is to write these documents for publication. (They must not contain any trade secrets or information from unresolved supplemental claims of confidentiality.)

5. Other registrant-submitted information (e.g., the application for registration, correspondence between the registrant and OPP, and other "administrative" materials) may be released to the public under the following conditions: a) the materials released must not contain trade secrets or b) information that is part of an unresolved supplemental claim of confidentiality. (Also - as a general rule we do not release any information on pending actions - other than the Federal Register Notice of receipt of the application.)

Disclosure to Other Federal Government Agencies, and to Congress and the Courts

FIFRA information from submitters may be provided to certain other organizations outside of OPP under specified conditions. 40 CFR Part 2.209 describes disclosure to Congress and the Comptroller General, other Federal agencies, and court-ordered disclosure. In general, these types of disclosure require: 1) a determination that such release is consistent with the purposes of FIFRA; 2) the receiving organization to protect the information in the manner described in this Manual; 3) predisclosure notice to the submitter of the information being disclosed, including the purpose to be served by disclosure (except in some cases for disclosure to Congress) ; and 4) possible restrictions on subsequent disclosure of information that results from work done with the information. Contact the Public Information Branch, FOD/OPP, if you become involved with the need to disclose FIFRA sensitive information to the above organizations.

Disclosure for Protection of Public Health or the Environment (to State, to County, and Local Governments and Certain Professionals)

Under FIFRA section 12 and 40 CFR 2.307, the Administrator may release certain FIFRA confidential business information to such professionals as physicians, pharmacists, law enforcement personnel, and State and local agencies if it is determined that such disclosure is needed to prevent injury or "imminent harm" to the public or the environment. This type of release is rare and requires special authorization. Contact the Public Information Branch, FOD/OPP, if you believe a need exists to release FIFRA sensitive information for such purposes.

4 ACCESS TO FIFRA SENSITIVE INFORMATION

PROCEDURES FOR GAINING ACCESS TO FIFRA SENSITIVE INFORMATION

For EPA Employees

1. The employee is designated in Section 1 of the FIFRA Access Authorization Agreement.
2. The designated employee is briefed by the FIFRA Security Officer or DCO and then signs the Agreement at Section 2, indicating understanding and acceptance of the terms of the confidentiality agreement.
3. The FIFRA Security Officer or DCO signs the Agreement at Section 3, indicating that an appropriate briefing was conducted and the briefed employee shows understanding of the material conveyed in the briefing.
4. The Division Director signs at Section 4, indicating that the employee has been designated, briefed, and approved for access.

For EPA Division Directors

Use the Agreement as above. The Office Director, Regional Administrator, or Laboratory Director signs at Section 4 designating and approving the Division Director, and delegating the Division Director responsibilities described in this Manual. The Division Director completes Sections 1 and 2 and the FIFRA Security Officer or DCO completes Section 3.

For EPA Office Directors, Regional Administrators, and Lab Directors

As the top Agency official of the organizational component or location, these officials are accepted as having the authority to delegate security responsibilities to Division Directors. If these officials need to possess/use FIFRA sensitive information, they are expected to sign Section 2 of an agreement and send a copy of it to the Information Services Branch, OPP.

For Contractors

(The EPA or other Federal agency Contract Project Officer is the primary coordinating official for the following steps.)

1. The need for FIFRA information must be approved. OPP contract project officers certify the need to the Information Services Branch, OPP. Division Directors of other EPA programs must request approval of access for their contractor in writing to the OPP Office Director. A determination must be made between OPP and the requesting EPA program that use of FIFRA information by other EPA programs is "in connection with FIFRA."

2. The contractor must produce a security plan in which the contractor: a) describes how security requirements contained in this Manual will be implemented, b) certifies that all contractor

staff will be required to sign the agreement, and c) certifies acceptance of full responsibility for FIFRA sensitive information that will be in the contractor's possession (Exhibit 5). This security plan must be approved by the FIFRA Security Officer and implemented in all respects before the contractor is provided access to FIFRA sensitive information.

3. The submitter of the FIFRA information being requested must be notified. EPA Contract Project Officers must provide to the Information Services Branch, OPP the identity of the contractor, the contract number, the purpose(s) to be served by the contractor's use of the information, the names of specific chemicals to be worked on or other identification of the information to be used by the contractor, a certification that the information is needed (from 1. above), and a copy of the contract scope of work. From this information the Information Services Branch will prepare notification(s) to submitter(s) of the FIFRA sensitive information to be used in the contract. The notification may be by certified letter or by FEDERAL REGISTER Notice and must have been in the possession of the submitter(s) for 5 days (10 days for IAGs) before any FIFRA sensitive information may be released to the contractor.

4. The contract must contain certain provisions that describe actions to be taken by the contractor or subcontractor with regard to FIFRA sensitive information. These provisions are contained in 40 CFR 2.301 (h)(2) (ii). See Exhibit 6.

RESPONSIBILITIES OF ACCESS TO FIFRA SENSITIVE INFORMATION

The following responsibilities have been grouped by the type of function performed by the employee. Every person bears certain responsibilities. Supervisors and certain designated officials bear additional responsibilities.

Every person who has custody of FIFRA sensitive information is responsible for protecting such information from disclosure to anyone who is not authorized to have access to it. In order to carry out this responsibility, every such person is expected to:

- Know what FIFRA information is sensitive.
- Follow the operational procedures in this Manual that are appropriate to carrying out your duties.
- Cooperate with your DCO/DCA and follow security procedures established for your office.
- Check with your supervisor or DCO/DCA to resolve questions/problems.
- Promptly report any apparent violation of FIFRA security procedures to your supervisor.

First and second line supervisors (Branch Chiefs, Section Chiefs, Team Leaders) have additional responsibilities for the manner in which their staff handle FIFRA sensitive information.

- Carry out the "Every Person" responsibilities listed above.
- Ensure that authorized persons in your organization attend refresher security training at least annually.
- If your organization uses contracts, ensure that your contract project officer(s)

- follows the contract procedures in this Manual.
- Review documents produced within your organization when there is a question as to whether the documents contain FIFRA sensitive information. Contact the Public Information Branch, FOD/OPP, if you have any questions.
 - Counsel employees who do not follow the procedures in this Manual and as necessary reflect improper handling of sensitive information in the yearly performance appraisals.
 - Pass violation reports to your supervisor via the chain of command.

EPA Contract Project Officers. In addition to the "Every Person" responsibilities listed above, project officers have additional responsibilities with respect to how FIFRA sensitive information is used and protected by the contractor:

- Ensure that the Statement of Work contains the CBI contract clauses (Exhibit 6).
- Ensure that contractor access is provided using procedures listed in Section 4.
- Ensure that the contractor implements the approved security plan in all respects.
- Ensure that FIFRA sensitive documents are transferred to the contractor via procedures in this Manual, that the contractor maintains tight accountability over all such documents, and that the contractor releases no FIFRA sensitive information to anyone without specific project officer approval.
- Ensure that all FIFRA sensitive information is returned to EPA when the contract is completed or terminated. If the contractor is authorized to dispose of FIFRA sensitive information, certificates of destruction must be provided to the EPA project officer.

Division Directors

- Designate (via memorandum) DCOs/DCAs for your Division.
- Designate/approve Division staff members for access to FIFRA sensitive information and ensure that they receive adequate security training.
- Ensure that your employees follow security procedures.
- Approve transport of FIFRA sensitive information to facilitate official work at home or on official travel.
- Carry out the investigation procedures listed in Section 6.
- Counsel with and/or discipline violators as appropriate.

Document Control Officer/Assistant (DCO/DCA). These employees (listed in Exhibit 7) are the focal point within Divisions for FIFRA security operations. Their responsibilities include: .

- Conduct and/or arrange for FIFRA security briefings.
- Develop/operate a document tracking system for proper document accountability within the organization.
- Maintain a record of the names of employees to whom access has been granted. Provide the original of all signed agreements to ISB (Exhibits 1 and 2).
- When directed, assist in investigating violations.
- Carry out other information security duties as assigned by the supervisor and/or Division Director.

- Conduct periodic security inspections of the division for conformance with this Manual.

Office/Laboratory Directors, Regional Administrators

- Designate Division Directors for access to FIFRA sensitive information, including assignment of responsibility for carrying out the security guidance in this Manual.
- As the top official of your organization, provide to the Office of the Inspector General (OIG) (or the OIG field division representative for your location):
 - . your investigation reports of violations that may have resulted (or that did result) in the unlawful disclosure of FIFRA sensitive information.
 - . access to all files and personnel involved in the violations you report.

FIFRA Security Officer

- Develop FIFRA information security guidance for use by any person who is provided access to FIFRA sensitive information.
- Coordinate with OIRM and FMSD on security guidance and matters related to information security operations.
- Provide information security liaison with other organizations that are provided access to FIFRA sensitive information.
- Provide information security training (and/or training materials) that cover the FIFRA information security program.
- Provide FIFRA information security support for EPA Contract Project Officers, including submitter notification.
- Approve contractor security plans.
- Conduct/support security inspection activities.

EPA Contractors (All communication referenced below is via the EPA Contract Project Officer.)

- Prepare a security plan that describes how the contractor will implement security guidance in this Manual.
- After the security plan is approved by the FIFRA Security Officer (Exhibit 5, Step 1), implement the approved plan and certify in writing to the FIFRA Security Officer that the contractor is prepared to assume full responsibility for the security of all FIFRA sensitive information that is transferred to the contractor. (See Exhibit 5, Step 3)
- Secure a FIFRA briefing from the FIFRA Security Officer and brief own contract staff.
- Appoint a DCO with overall responsibility for accounting for and tracking all FIFRA sensitive information.
- Handle FIFRA sensitive information using operational procedures that are described in the approved security plan.
- Conduct periodic security inspections to evaluate conformance to security practices.
- Report any/all violations to the FIFRA Security Officer.

- Ensure that all FIFRA sensitive information is returned to EPA when the contract is completed or terminated. If the contract includes disposal of FIFRA sensitive information, disposal certificates will be returned to EPA.

OTHER EPA ORGANIZATIONS

Office of the Inspector General (OIG)

- Establish and implement personnel security standards, guidelines, and procedures in accordance with EPA information security policy and all applicable Federal laws and regulations.
- Conduct or arrange investigations of known or suspected personnel security violations as deemed appropriate.

Office of Information Resources Management (OIRM)

- Develop and issue EPA information security policy.
- Monitor compliance with the information security program.
- Establish training criteria and coordinate development of information security training and awareness programs.
- Provide guidance on selecting and implementing safeguards.

- Participate, as appropriate, in management and internal control reviews conducted by the Office of the Comptroller to ensure compliance with the information security program.

Facilities Management and Services Division (FMSSD)

- Establish and implement physical security standards, guidelines, and procedures in accordance with EPA information security policy.

Office of the General Counsel (OGC)

- Provide legal advice concerning the treatment and protection of FIFRA sensitive information.
- Issue final confidentiality determinations and class determinations concerning FIFRA sensitive information.

5 OPERATIONAL PROCEDURES FOR PROTECTING FIFRA SENSITIVE INFORMATION

The material in this section is intended to provide quick and clear reference to principal requirements that must be met, and security practices that must be used, to protect FIFRA sensitive information from unauthorized disclosure. The EPA Information Security Manual contains detailed guidance that covers all aspects of handling sensitive information. Readers are referred to the EPA Information Security Manual for additional information on the following requirements and practices.

1. **GENERAL SECURITY AWARENESS.** All employees must be aware that certain information used in their organization may need to be protected from unauthorized disclosure. They may not have been provided official access to FIFRA sensitive information, but they must be sufficiently advised of the need for information security, so that they can support the security activities of the organization and avoid acts that make the security program more difficult to carry out.

2. **ACCESS TO FIFRA SENSITIVE INFORMATION.** Access must be limited to authorized persons only. Unauthorized access is to be prevented by keeping the information locked up when not in use, and using the information in a manner that prevents it from being seen by unauthorized persons. (For example, information must not be left unsecured at unattended workstations.)

3. **SECURITY TRAINING.** All persons in the organization, before they are first provided access to FIFRA sensitive information, must undergo a security briefing and sign the FIFRA Access Authorization Agreement indicating that they have received the initial briefing and understand their security responsibilities. Refresher training should be provided on a periodic basis (at least annually) to reinforce awareness of their responsibilities and provide an opportunity for critique as a means to improve security program operations.

4. **DESIGNATED FIFRA DCOS.** Division Directors of organizations that use FIFRA sensitive information must designate a Document Control Officer to provide an operating focus for handling that information within the organization. If the organization wishes to designate one DCO to provide this focus for other information (e.g., TSCA) as well, the designated DCO must be able to fully represent the special nature and requirements that are associated with FIFRA sensitive information. See Section 2.

5. **SECURE FACILITIES.** Facilities and equipment that are adequate to meet the special needs of the security program must be provided. At least two levels of physical protection must be provided. These must normally include one at the perimeter level and one at the file level, unless a different mix is authorized in writing by the Division Director. (Such authorization is meant to provide flexibility that may be needed to meet special operating or file requirements. The requirement to have two levels of security must not be reduced or waived.) Secure means of making copies of FIFRA sensitive documents and (when appropriate) destroying them after they are no longer needed, must also be provided. Perimeter Security is required during nonbusiness hours, and includes for example the posting of a security guard, locking the building, or locking office doors. Some form of access control should also be provided during business hours (via guard,

receptionist, or electronic pass-card actuated locks). File Security includes metal file cabinets with bars and combination locks, which are the minimum required for securing file cabinets that contain sensitive documents. Combinations must be registered with the DCO and EPA facilities security official or contractor security official at the site.

6. CUSTODY OF FIFRA SENSITIVE INFORMATION. A complete inventory of documents* that contain FIFRA sensitive information and a documented chain of custody must be maintained by the DCO at all times using some form of a document tracking system. Organizations are free to use any method that works (such as manual logs, computer logs, receipts, invoices, etc. (e.g., Exhibit 8), which list specific documents.* Mandatory requirements to be met are: 1) The custody of a particular document* must be traceable at all times to a person; 2) The authorized recipient of the document* must acknowledge receipt in an undisputable fashion; and 3) The last person of recorded custody is held responsible for the document* and may be subject to disciplinary action if a violation occurs while the document* is in his/her custody. The document tracking system must provide to all employees a list of the sensitive documents* in their custody and must be used periodically to verify the accuracy of the document tracking system.

* Some organizations handle large sets of related documents (e.g., reports from importers that are periodically provided to regional offices). Since it would be impractical to control each such document individually as directed in 6. above, they may be controlled as a set, as long as individual documents are not permitted to become separated from the set. The number of individual documents within such a set must be established and used to ensure the integrity of the set.

7. MARKING DOCUMENTS THAT CONTAIN FIFRA SENSITIVE INFORMATION . All documents (or bound sets of documents) that contain FIFRA sensitive information shall be marked or covered to show that they must be protected. When used, the marking shall consist of the FIFRA CBI stamp (Exhibit 9) placed on the outside of the first and last pages of the bound document or set of documents. If marking is not used, the document shall at all times be covered with a red FIFRA CBI cover page (Exhibit 10).

8. MAKING COPIES OF FIFRA SENSITIVE INFORMATION. If copies are made, they must immediately be marked as in 7. above and entered into the chain of custody. Copies must be made only in a manner that prevents them from being seen by unauthorized persons, and the copy machine and area must be cleared after the copies are made.

9. CREATING SENSITIVE DOCUMENTS. When new documents that contain FIFRA sensitive information are created, they must immediately be marked as in 7. above and they must be entered into the chain of custody.

10. SENDING FIFRA SENSITIVE INFORMATION THROUGH THE NAIL. Make sure the recipient is cleared for access to FIFRA sensitive information! Use two envelopes. The inside envelope (which must be sealed) must be marked " CBI - TO BE OPENED BY ADDRESSEE ONLY." The outside envelope should be addressed normally; do not mark the outside envelope with any indication of the sensitivity or classification of its contents. Recipients (intra government transfers) must return some form of written acknowledgement of receipt (e.g., Exhibit 8) to the

sender to maintain the chain of custody. Senders should provide some form of returnable invoice for this purpose, and if several documents are being sent, they must be itemized in the invoice. Recipients must immediately enter the received information into a chain of custody record in their organization. The above procedure must be used for interoffice, pouch, and public mail. Courier services may also be used.

11. **DISPOSING OF FIFRA SENSITIVE INFORMATION.** When no longer needed* documents or other portable media that contain FIFRA sensitive information must be destroyed. (Shredding, pulverizing, or burning are the usual means.) Custodial records must reflect the "death" of all documents that have been destroyed. The OPP Document Center can assist persons in the nearby area. Regions and field organizations that need to dispose of sensitive information are expected to provide and follow secure disposal procedures.

* Be sure to check the appropriate Record Retention Schedule.

12. **ROUTINE SECURITY FOLLOW-UP.** Organizations that maintain FIFRA sensitive information are expected to conduct security checkups/inspections to ensure that security practices are being followed. Such inspections should be conducted by DCOS, first or second line supervisors, or Division Directors. Such inspections should be unannounced and promptly documented and critiqued.

13. **SENSITIVE INFORMATION IN MEDIA OTHER THAN PAPER DOCUMENTS .** The above statements are written using paper documents as the context, but sensitive information is stored and used in other media, and must also receive careful protection to avoid unauthorized disclosure. Examples of other (portable) media are microforms, floppy disks, magnetic tapes, photographs, typewriter ribbons and ribbon cartridges, and other forms of carbonless reproduction media (e.g., NCR paper). Similar practices must be applied (as appropriate) to achieve the objective of full protection from unauthorized disclosure: control access, maintain records of current custodianship, control needed copies, provide for secure transfer, and ensure positive destruction and disposal with appropriate recordkeeping.

14. **SENSITIVE INFORMATION IN RESIDENT COMPUTER FILES.** This form of sensitive information introduces new requirements to prevent unauthorized disclosure (and irrecoverable loss) and depends on methods that are beyond the practical scope of this Manual. For more detailed guidance refer to the EPA Information Security Manual, which applies to FIFRA sensitive information in resident computer files.

15. **SENSITIVE INFORMATION IN MEETINGS.** Discussion of FIFRA sensitive information in meetings should be preceded by a check to determine that all participants are cleared for access to it. Meeting notes/minutes etc. should be treated as sensitive until they are determined to be free of FIFRA sensitive information.

16. **EMERGENCY EVACUATIONS AND SHUTDOWNS.** In the event of an emergency evacuation (fire drill, etc.) , priority is obviously directed to protecting life over locking up sensitive documents. However, vulnerability can be reduced during emergency evacuations by following normal procedure, which calls for keeping all sensitive documents locked up when not in use.

16. CORRESPONDENCE FROM REGISTRATION DIVISION PRODUCT MANAGERS TO THEIR COUNTERPARTS IN THE REGULATED INDUSTRY. Such correspondence may address matters that require including information that is sensitive within the definitions contained in this manual. It is not the purpose of this Manual to impose upon the Registration Division new restrictions on the conduct of normal business that would result in destroying a practice that

has been acknowledged as satisfactory over many years by the regulated industry. Accordingly, this correspondence shall be sent in whatever manner is determined by the Registration Division Director to be acceptable to the regulated industry, as long as the chosen method provides adequate protection against unauthorized disclosure.

6 IF THERE ARE PROBLEMS

Identifying Problems Within EPA Organizations

Problems will usually become visible in three ways: a needed (sensitive) document will be unlocatable; some obvious violation of a security practice will be observed during the business day; and/or an unannounced security inspection will pick up one or more violations of security practice.

Note that a violation is any treatment of sensitive information not in accordance with established Security Manual guidance; unlawful disclosure may not have occurred as a result of the violation. The following are examples of possible violations.

- Sensitive documents are unsecured and unattended at any time.
- Sensitive documents are left out of the document tracking system.
- Sensitive documents are transferred incorrectly.
- Sensitive documents are destroyed in other than an authorized manner.
- Unauthorized staff are given access to sensitive documents.
- A file cabinet that contains sensitive documents is discovered unlocked after business hours.

Reporting and Investigating Problems Within EPA Organizations

All employees shall promptly report observed violations to their supervisor. In those cases where disclosure of sensitive information to unauthorized persons cannot be ruled out by the supervisor, the report must be passed via the chain of command to the Division Director. The Division Director assigns the DCO and/or Branch Chief the responsibility of investigating the violation and preparing a report of the investigation. If the organization has a designated information security officer (like the FIFRA Security Officer at OPP Headquarters), that individual must be informed of the violation and may be asked by the Division Director to assist in the investigation.

In cases where security procedures have been violated but no release of the sensitive information to unauthorized persons occurred, the Division Director must see that the errant employee (and last custodian of record in the document tracking system) is advised of the violation and warned about repeat violations. The Division Director should keep a record of violations for use during performance evaluations.

In cases where the violation of security procedures results in the release of sensitive information to an unauthorized staff person, the Division Director must advise his Office Director, Laboratory Director, or Regional Administrator of the violation and the results of the investigation report. If the unauthorized person to whom the release was made is outside of EPA, the Office Director, Laboratory Director, or Regional Administrator must also notify the EPA Inspector General, who may decide to conduct an investigation.

Remedial and Disciplinary Action

In the case of a violation of security procedures that has not resulted in the release of sensitive information to unauthorized persons, the supervisor will take appropriate action with the advice and consent of the Division Director. Action can be an oral or written reprimand and may include removal from the FIFRA Access List. The action taken must be documented.

An employee who repeatedly violates security practices shall be disciplined, at the discretion of the Division Director, with penalties of increasing severity, ultimately including loss of pay or loss of job. The Regional Administrator, Laboratory Director, or Office Director may be required to consent to the more severe penalties, depending on adverse action guidance that is appropriate for use at the time.

If the violation has been referred for OIG investigation, and this investigation indicates that a criminal violation has been committed, the investigation may be referred to the Justice Department and may result in prosecution.

EXPLANATION OF THE AFFIRMATION OF NON-MULTINATIONAL STATUS

Pesticide information that is responsive to your recent FOI request includes information that was submitted to EPA by pesticide applicants or registrants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In the 1978 amendments to FIFRA, Congress expressly limited who may receive this information and how it may be used by recipients. These limits, expressed in FIFRA section 10(g), were imposed by Congress to protect registrants of pesticides in the U.S. against unauthorized use of their health and safety data by competitors to obtain pesticide registrations in foreign countries. (Those who obtain pesticide registrations in foreign countries are called "Foreign or Multinational Pesticide Producers" in section 10(g), abbreviated "Multinational" herein.)

FIFRA section 10(g) therefore requires EPA to avoid knowingly disclosing this information to a Multinational, or to agents or employees of a Multinational. Numbered paragraphs (1) and (2) of the "Affirmation of Non-Multinational Status" are designed to allow EPA to implement this requirement. Section 10(g) also requires each person who seeks to obtain this information from EPA to affirm that he or she does not intend to, and will not purposefully or negligently deliver (or cause delivery of) the information to a Multinational. Numbered paragraph (3) of the Affirmation is designed to allow EPA to implement this requirement. The remainder of this explanation is provided to further assist you in understanding section 10(g) and the implications of signing the Affirmation.

Section 10(g) makes it unlawful for a person requesting registrant-submitted pesticide information to furnish a false or misleading Affirmation of Non-Multinational Status to EPA; such violations are punishable under 18 USC 1001. Thus, for example, it is EPA's position that it would be unlawful for a person to execute the Affirmation while having the intent to publish (or otherwise to deliver in any way to a Multinational in its entirety) a previously unpublished toxicity study submitted by a registrant. This is because the information delivered likely could be used to satisfy a data requirement imposed by a foreign country as a condition of producing, distributing, selling, shipping, or using the product in that country. However, section 10(g) would not restrict an intent to publish or deliver brief excerpts from such information or summaries or critiques of it, identified as such, since these likely would not be useful in satisfying data requirements imposed by other countries. Of course, the prohibition does not apply to publication or delivery of information that is already freely available to the public (such as data that has been published) or to publication of data with the consent of the registrant that submitted it to EPA.

It is less clear whether the statute imposes any other duties or prohibitions on persons once they have received the information from EPA, and EPA has taken no position on this issue. Some firms who have submitted data to EPA, however, argue vigorously that section 10(g) governs the use or disclosure of data by persons who have obtained it from EPA. Accordingly, you should be aware that if your disclosure of data obtained by you from EPA results in its becoming available to a Multinational (in a form that enables it to be used to satisfy foreign data requirements), it is possible that the firm that submitted it to EPA may seek relief against you in court, and may argue in court that you were required by section 10(g) to guard against disclosing data to a Multinational or allowing such disclosure. You may therefore wish to take steps to avoid inadvertent disclosure of the data by keeping it in a secure place. Before publishing it or deliberately disclosing it to others, you may wish to seek legal advice.

October 1984

Instruction for Completing the FIFRA Agreement

- 1. Person applying for access to FIFRA sensitive information should complete Section 1. (Contractor staff should use employee's ID Number if not assigned an EPA Badge/ID Number.) - PRINT.**
- 2. The employee will READ the Agreement carefully. Sign and date Section 2 acknowledging full understanding of the stated procedures.**
- 3. FIFRA Security Officer or DCO shall BRIEF the employee and after he/she has briefed the employee sign and date Section 3 of the Agreement.**
- 4. Division Director or Contractor Project Manager, who is requesting that the employee be granted access to FIFRA sensitive information, should complete Section 4 and return to the FIFRA Security Officer or DCO. (All agreements for contractor staff should be sent to the appropriate EPA Project Officer.)**

This FIFRA Agreement should be forwarded to the Information Services Branch, OPP (TS-757C) by the 25th of the month to be incorporated in the next published FIFRA Access List.

Date of Refresher Briefings

For ISB/OPP Use Only

CONFIDENTIALITY AGREEMENT FOR TERMINATION/TRANSFER

In accordance with my official duties, I have had access to Confidential Business Information under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA, 7 U.S.C. 135 et seq). I understand that FIFRA CBI may not be disclosed except as authorized by FIFRA or Agency regulations.

I certify that I have returned all copies of any FIFRA CBI or provided a chain of custody of such information to the appropriate Document Control Officer as specified in the procedures of the FIFRA Information Security Manual.

I agree that I will not remove any copies of FIFRA CBI from the premises of my work site upon my termination or transfer. I further agree that I will not disclose any FIFRA CBI to any person after my termination or transfer.

I understand that as a employee who has had access to CBI, under FIFRA Section 10(f) I am liable for a possible fine of up to \$10,000 and/or imprisonment for up to one (1) year or both, if I willfully disclose FIFRA CBI to any person not authorized. Additionally, I understand that according to Section 14(b)(3), FIFRA provides for a penalty of up to \$10,000 and up to three(3) years imprisonment for disclosure of formula (manufacturing process, quality control processes and production data) with intent to defraud.

If I am still employed (transferred) I also understand that I may be subject to disciplinary action for violation of this agreement.

I am aware that I may be subject to criminal penalties under 18 U.S.C. 1001 if I have willingly made any false statements or if I willfully concealed any material fact.

_____ Signature	_____ Date
_____ Full Name (Print)	_____ Badge/ID Number
_____ Office Affiliation/Contractor Name	_____ Contract Number, if applicable
_____ Signature of FIFRA Security Officer or DCO	_____ Date

Instructions on back

EXHIBIT 2

Instructions for Completing the Form

DCO

- 1. Please provide a copy of this form to those individuals who are terminating or transferring from your organization and no longer need access to FIFRA sensitive information.***
- 2. Ensure that the employee has returned all FIFRA CBI assigned to him/her or provided a chain of custody. Check with the Information Service Branch, OPP to see what sensitive information the employee has signed for from the Document Center, OPP.***

Employee

- 3. Please complete the front of this form and return it to your DCO along with all CBI or a documented chain of custody of any CBI not returned.***

FIFRA Security Officer or DCO

- 4. Brief the employee on the statements on front of this form.***
- 5. Forward original signed copy to the FIFRA Security Officer (TS-757C).***

AFFIRMATION OF NON-MULTINATIONAL STATUS

This affirmation is required by the EPA interim procedures to implement Section 10(g) of the Federal Insecticide, Fungicide, and Rodenticide Act. Section 10(g) is reproduced on the reverse side for your reference.

I have requested access to information submitted by an applicant or registrant under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) to the Environmental Protection Agency. I hereby affirm that:

(1) I am not a business, or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States; and I am not an employee or agent of any such business or entity;

(2) I do not seek access to the information for purposes of delivering it or offering it for sale to any such business or entity or to any of its employee or agents;

(3) I will not purposefully deliver the information (or negligently cause it to be delivered) to any such entity or to any of its employees or agents.

I am aware that I may be subject to criminal penalties under 18 U.S.C. 1001 if I have made any statement of material facts knowing that such statement is false or if I willfully conceal any material fact.

Date _____ Signature _____

Name _____

Address _____

Organization _____

If you are requesting access on behalf of someone else, you must give the name of your client and your client's organization:

RETURN THIS FORM TO

Freedom of Information (A-101), Office of Pesticide Programs, U.S. Environmental Protection Agency,
Washington, D.C. 20460

For office use only:

RIN _____ Date mailed _____ Caseworker _____

(10/84)
EXHIBIT 3

**The Federal Insecticide, Fungicide, and Rodenticide Act
as Amended**

**Public Law 92-516 October 21, 1972 as amended by
Public Law 94-140 November 28, 1975
and Public Law 95-396 September 30, 1978**

▼ USC 1302

****SEC. 16. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.**

**P.L. 95-396,
92 Stat. 531.**

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

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

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

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

By mail: William Grosse, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20490.
Office location and telephone number: Room 222, CM # 2, 1921 Jefferson Davis Highway, Arlington, VA (703-557-2613).

SUPPLEMENTARY INFORMATION: On September 24, 1985, EPA's Office of General Counsel issued the following class determination:

Disclosure of Reviews of Pesticide Test Data Submitted by Applicants and Registrants

[Class Determination 3-85].

Background

A. Data

EPA's Office of Pesticide Programs (OPP), other EPA offices, and EPA contractors prepare reviews of data received under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. This class determination, made under 40 CFR 2.207, concerns the extent to which certain of these reviews may be disclosed publicly by EPA and the procedures that EPA may use to make disclosures.

Businesses which are applying for registration of pesticide products or for experimental use permits or emergency exemptions, or which hold registrations, submit test data to OPP for the purpose of satisfying requirements of FIFRA. (Some such data are submitted for the additional purpose of satisfying requirements imposed under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq.; EPA's regulations, 40 CFR 2.307(b), require such data to be treated as data submitted under FIFRA.)

EPA may not withhold information from disclosure for reasons of business confidentiality if a statute specifically requires disclosure of the information. To the extent information submitted under FIFRA concerns any test or experiment on a registered (or previously registered) pesticide or any of its ingredients FIFRA sections 10(d) and 10(g) largely govern the extent to which the information may be disclosed to members of the public. FIFRA section 10(d)(1) [7 U.S.C. 136h(d)(1)] states:

All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans

and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. Provided, That the use of such data for any registration purpose shall be governed by section 3 of this act [7 U.S.C. 136a]; Provided further, That this paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

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

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

Section 10(d)(2) provides that information concerning the production, distribution, sale, or inventories of a pesticide may be entitled to confidential treatment.

Therefore, if the data in question concern tests or experiments on a registered or previously registered pesticide product or any ingredient, impurity, or degradation product of a registered or previously registered pesticide product, FIFRA section 10(d) and 40 CFR 2.208 provide that those data are disclosable to most members of the public subject to section 10(g). However, those portions of the data described by paragraph (A), (B), or (C) of section 10(d)(1), or described by section 10(d)(2), may be entitled to protection from disclosure as confidential business information.

Despite the provisions of section 10(d), FIFRA section 10(g) limits EPA's right to disclose to some persons data which are otherwise disclosable under section 10(d). Section 10(g) [7 U.S.C. 136h(g)] states in pertinent part:

"The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure."

B. Reviews of Data

EPA employees and EPA contractors prepare reviews of the data described in paragraph A for use by EPA in making or explaining various decisions under FIFRA. In some cases, the review

[OPP-100C34 PH-FRL 2930-8]

Disclosure of Reviews of Pesticide Test Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is notifying interested persons of the issuance of a class determination concerning the disclosure of certain EPA-prepared review of data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The class determination concludes that certain of those reviews are not entitled to confidential treatment. EPA also is notifying interested persons that EPA will disclose such reviews to the extent permitted by the class determination. The class determination is reproduced in this notice. In brief, it states that if a review (or portion thereof) (1) was prepared by EPA or its contractor, (2) concerns data or information pertaining to a test or experiment on a registered or previously registered pesticide or any of its ingredients, impurities, or degradation products, (3) contains no other business information, (4) contains no information which is described by FIFRA section 10(d)(1) (A), (B), or (C) or section 10(d)(2), and (5) does not contain a complete or essentially complete unpublished report, it may be disclosed to any member of the public, without regard to FIFRA section 10(g). 85P-2192.
DATE: EPA will commence making the reviews available to the public on January 13, 1986 unless the EPA Office of General Counsel has first been notified on the commencement by an affected business of an action in Federal court to obtain judicial review of the determination or to obtain a declaratory judgment under section 10(c) of FIFRA and to obtain preliminary injunctive relief against disclosure.

ADDRESS: A notice of commencement of litigation should be submitted in writing to: Jane Roemer, Office of General Counsel (LE-132C), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460 (202-382-5460).
FOR FURTHER INFORMATION CONTACT:

concerns a particular study. In other cases, data from a number of studies (which may have been submitted by different businesses) are reviewed, and conclusions are drawn from the combined data.

EPA receives many requests for disclosure of these reviews of data. EPA also desires to clarify the extent to which it may disclose such reviews for its own purposes. In a memorandum to the Office of General Counsel dated May 28, 1985, OPP stated:

"We have an imperative need to freely disclose our evaluations of registrant-submitted data and present our conclusions and the reasons for our decisions. We wish to explain our decisions by sharing data reviews freely with all interested parties."

OPP recommended that these reviews of pesticide data be treated as disclosable to any person, without regard to section 10(g), if the reviews (1) concern data that would be disclosable under FIFRA section 19(d) (1), and (2) have been carefully scrutinized by OPP to ensure that they contain no data entitled to confidential treatment under FIFRA section 10(d)(1) (A), (B), or (C). OPP further suggested that it would be proper to disclose such reviews without case-by-case prior notification to the submitter(s) of the item(s) of data which are the subject of the reviews, if a one-time notice were provided. Finally, OPP requested that the Office of General Counsel consider issuing a class determination concerning these matters.

Findings

Under 40 CFR 2.207 I have authority to issue class determinations concerning entitlement of business information to confidential treatment. In the case of pesticide data reviews, I find that:

(1) EPA possesses (and will continue to generate) a large number of reviews, prepared by EPA employees or by EPA contractors, of data submitted under FIFRA by registrants applicants for registration, applicants for experimental use permits, and applicants for emergency exemptions.

(2) To the extent that the reviews concern submissions (or portions thereof) which are themselves disclosable under FIFRA section 10(d), then disclosure of the reviews is mandatory. Reviews are disclosable without regard to FIFRA section 10(g), provided that the reviews do not set forth essentially complete reports of the data or information submitted to the Agency. Reviews of data concerning submissions which are themselves disclosable under FIFRA section 10(d)

therefore may properly be treated as a class.

(3) A class determination will serve the useful purpose of establishing the procedures and restrictions that will apply to the disclosure of pesticide data reviews, thereby allowing OPP to better conduct its future activities.

The Office of General Counsel has not been asked to decide, and these findings do not address, whether the underlying data on which the reviews are based may be the subject of a class determination. The conclusions reached in this determination with respect to disclosure of pesticide data reviews therefore do not control the disclosability of the underlying data.

Determinations

I have determined that pesticide data reviews will be treated as follows:

I. The information covered by this class determination consists of each review, whether now existing or prepared at a future date:

(A) which was prepared by EPA personnel or prepared under an EPA-funded contract; and

(B) which, to the extent it contains or refers to any unpublished "business information" (as defined in 40 CFR 2.201(c)), contains or refers only to data or information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide product or any of its separate ingredients, impurities, or degradation products, or concerning the effects of any such substance on any organism or the behavior of any substance in the environment; and

(C) which does not contain (or from which has been deleted) any information the disclosure of which would disclose:

(1) manufacturing or quality control processes; or

(2) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide product; or

(3) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide product; or

(4) unpublished information concerning the production, distribution, sale, or inventories of a pesticide (such information might appear in reviews which discuss the amount of a pesticide sold or used in a given time, and thus might concern the "significance" of data from a test or experiment); and

(D) which does not contain or consist of any complete unpublished report submitted to EPA by an "affected

business" (see definition at 40 CFR 2.201(d)); and

(E) which does not contain or consist of excerpts or restatements of any such report which reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results.

II. The information covered by this determination is not entitled to confidential treatment, because it consists entirely of information required by statute (FIFRA section 10(d)) to be disclosed.

III. The information covered by this determination is not subject to FIFRA section 10(g), and thus may be disclosed to any person. Section 10(g) is intended to prevent a person from obtaining, under FIFRA, data generated at another person's expense and then using the data to obtain the approval of another country's government to manufacture, sell, or use pesticides in that country. See, e.g., Congressional Record, October 31, 1977, page H 11864 (daily ed.) (remarks of Congressman Fithian): "[Under new section 10(g)], foreign competitors or multinational corporations could not legally obtain research data, paid for by others, and utilize it for registration abroad—where compensation would not have to be paid." Disclosure of EPA reviews of data (provided that they are truly reviews, and not essentially complete reports) will not be useful in obtaining approvals by governments of other countries. To the extent that such a country requires data to evaluate the request, it is unlikely to be satisfied with a review of data conducted by EPA; to the extent that such a country is willing to accept an EPA review in lieu of data, it is just as likely to accept other readily available information indicating EPA's position, such as evidence that EPA has registered the product. It should also be noted that EPA has for years published many quite comprehensive reviews of information submitted under FIFRA in various formats (e.g., registration standard science chapters, proposed and final regulations setting tolerances for pesticide residues on food, special review notices) without objection from data submitters that such publication violates FIFRA section 10(g).

IV. If OPP concludes that a review clearly is covered by this determination, OPP need not follow the procedures set forth in 40 CFR 2.204(c), (d)(1), and (e) which provide affected businesses an opportunity to assert and attempt to substantiate a business confidentiality claim prior to EPA's final confidentiality determination). In most cases, OPP will

be able to determine readily whether a review is described by paragraphs I (A) and (B) above. With regard to paragraphs I (C), (D), and (E) above, in most cases it also should be apparent from the face of the review whether its disclosure would reveal information described by FIFRA section 10(d)(1) (A), (B), or (C) or 10(d)(2), and if so, what pre-disclosure deletions would be necessary. However, in any case where OPP has doubt on either score, the procedure set forth in 40 CFR 2.204(d)(1) and (e) must be followed.

V. The pre-disclosure notice requirements in FIFRA section 10(c) and 40 CFR 2.204(d)(2), 2.205 (f), and 2.307 (d) and (e) may be satisfied, insofar as information covered by this determination is concerned, by:

(A) Furnishing to each current registrant of a pesticide product, each current applicant for registration, and each other data submitter whose identity is now known to EPA a copy of this determination and a notice of the Agency's intent to disclose and all information covered by this determination, in the form required by §§ 2.205(f) and 2.307, by certified mail, return receipt requested, or by personal delivery;

(B) Publishing a copy of this determination and a copy of a notice of intent to disclose the information covered by this determination in the Federal Register; and

(C) Continuing the current practice of requiring each person (other than a government agency) who applies for an experimental use permit or a registration to first obtain a company number, and furnishing to each person who applies for assignment of a company number:

(1) A copy of this determination; and
 (2) A notice stating that disclosure of any review which EPA may prepare of any data submitted by the person under FIFRA will be governed by this determination, and that EPA will furnish no further notice prior to disclosure of such information.

The Class Determination was signed by Lee A. DeHihns, III, Associate General Counsel, Grants, Contracts, and General Law Division.

Final Determination and Notice That Information Will Be Disclosed

In view of Class Determination 85-3, the information covered by that class determination clearly is not entitled to confidential treatment, within the meaning of 40 CFR 2.204(d)(2). Accordingly, I am hereby notifying all affected businesses that:

(1) For the reasons stated in Class Determination 85-3, EPA will disclose to any member of the public any and all

reviews covered by the class determination without further notice to affected businesses.

(2) Disclosure of reviews covered by Class Determination 85-3 and concerning data or information submitted by an affected business may commence on January 13, 1986, unless before that date the EPA Office of General Counsel has been notified by that affected business of the business's commencement of any action in a Federal court to obtain judicial review of the determination or to obtain a declaratory judgment under section 10(c) of FIFRA and to obtain preliminary injunctive relief against disclosure (see 40 CFR 2.205(f) and 2.307(e)).

(3) If such litigation is timely commenced by the affected business, EPA may nonetheless make the information available to the public (in the absence of an order by the court to the contrary), once the court has denied a motion for a preliminary injunction in the action or has otherwise upheld the EPA determination, or whenever it appears to the EPA Office of General Counsel, after reasonable notice to the business, that the business is not taking appropriate measures to obtain a speedy resolution of the action (see 40 CFR 2.205(f) and 2.307(e)).

This notice constitutes final agency action concerning any and all business confidentiality claims that may have been or could have been made, or that may be made in the future, with regard to any information covered by Class Determination 85-3. This final agency action may be subject to judicial review under Chapter 7 of Title 5, United States Code, under FIFRA section 10(c), or other law.

Dated November 18, 1985.

Steven Schatzow,
 Director, Office of Pesticide Programs
 [FR Doc. 85-38157 Filed 11-26-85; 8:45 am]
 BILLING CODE 6560-50-01

CONTRACTOR FIFRA SECURITY CERTIFICATION

STEP 1 - by FIFRA Security Officer

I have reviewed the Security Plan submitted by	
(Contractor Name) _____	
under EPA contract number _____	
_____	The security plan has been approved.
_____	The security plan has not been approved. (Deficiencies are noted in attachment)
_____	_____
FIFRA Security Officer /s/	Date

STEP 2 - by Contractor

(Contractor Name) _____	
hereby certifies to the FIFRA Security Officer that we have implemented our security plan as submitted and approved above, and that we are prepared in all respects to assume full responsibility for the security of all FIFRA sensitive information that is transferred to us under this contract.	
_____	_____
Contractor Project Manager /s/	Date

Return this certification to : US Environmental Protection Agency
FIFRA Security Officer (TS-757C)
Office of Pesticide Programs
401 M Street, S.W.
Washington, DC 20460

STEP 3 - by Project Officer

This certification is approved: _____
EPA Project Officer /s/

FIFRA CBI Contract Access Clauses

Screening Business Information For Claims Of Confidentiality
(EPAAR 1552.235-70 (APR 1984))

(a) Whenever collecting information under this contract, the Contractor agrees to comply with the following requirements:

(1) If the Contractor collects information from public sources, such as books, reports, journals, periodicals, public records, or other sources that are available to the public without restriction, the Contractor shall submit a list of these sources to the appropriate program office at the time the information is initially submitted to EPA. The Contractor shall identify the information according to source.

(2) If the Contractor collects information from a State or local Government or from a Federal agency, the Contractor shall submit a list of these sources to the appropriate program office at the time the information is initially submitted to EPA. The Contractor shall identify the information according to source.

(3) If the Contractor collects information directly from a business or from a source that represents a business or businesses such as a trade association

(i) Before asking for the information, the Contractor shall identify itself, explain that it is performing contractual work for the Environmental Protection Agency, identify the information that it is seeking to collect, explain what will be done with the information, and give the following notice

(A) You may, if you desire, assert a business confidentiality claim covering part or all of the information. If you do assert a claim, the information will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2, Subpart B.

(B) If no such claim is made at the time this information is received by the Contractor, it may be made available to the public by the Environmental Protection Agency without further notice to you

(C) The Contractor shall, in accordance with FAR Part 9, execute a written agreement regarding the limitations of the use of this information and forward a copy of the Agreement to the Contracting Officer.

(ii) Upon receiving the information, the Contractor shall make a written notation that the notice set out above was given to the source, by whom, in what form, and on what date.

(iii) At the time the Contractor initially submits the information to the appropriate program office, the Contractor shall submit a list of these sources, identify the information according to source, and indicate whether the source made any confidentiality claim and the nature and extent of the claim.

(b) The Contractor shall keep all information collected from nonpublic sources confidential in accordance with the clause in this contract entitled "Treatment of Confidential Business Information" as if it had been furnished to the Contractor by EPA

(c) The Contractor agrees to obtain the written consent of the Contracting Officer, after a written determination by the appropriate program office, prior to entering into any subcontract that will require the subcontractor to collect information. The Contractor agrees to include this clause, including this paragraph (c), and the clause entitled "Treatment of Confidential Business Information" in all subcontracts awarded pursuant to this contract that require the subcontractor collect information.

Treatment Of Confidential Business Information
(EPAAR 1552.235-71) (APR 1984)

(a) The Contracting Officer, after a written determination by the appropriate program office, may disclose confidential business information to the Contractor necessary to carry out the work required under this contract. The Contractor agrees to use the confidential information only under the following conditions

(1) The Contractor and Contractor's Employees shall: (i) use the confidential information only for the purposes of carrying out the work required by the contract; (ii) not disclose the information to anyone other than EPA employees without the prior written approval of the Assistant General Counsel for Contracts and Information Law; and (iii) return to the Contracting Officer all copies of the information, and any abstracts or excerpts therefrom, upon request by the Contracting Officer, whenever the information is no longer required by the Contractor for the performance of the work required by the contract, or upon completion of the contract.

(2) The Contractor shall obtain a written agreement to honor the above limitations from each of the Contractor's employees who will have access to the information before the employee is allowed access.

(3) The Contractor agrees that these contract conditions included for the benefit of, and shall be enforceable by, both EPA and any affected business having a proprietary interest in the information.

(4) The Contractor shall not use any confidential information supplied by EPA or obtained during performance hereunder to compete with any business to which the confidential information relates.

(b) The Contractor agrees to obtain the written consent of the Contracting Officer, after a written determination by the appropriate program office, prior to entering into any subcontract that will involve the disclosure of confidential business information by the Contractor to the subcontractor.

The Contractor agrees to include this clause, including this paragraph (b), in all subcontracts awarded, pursuant to this contract, that require the furnishing of confidential business information to the subcontractor.

Data Security-FIFRA And/Or TSCA Confidential Business Information
(EPAAR 1552.235-72) (APR 1984)

The Contractor shall handle Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and/or Toxic Substances Control Act (TSCA) confidential business information in accordance with the contract clause entitled "Treatment of Confidential Business Information" and "Screening Business Information for Claims of Confidentiality;" the provisions set forth below, and the Contractor's approved detailed security plan.

(a) The Contracting Officer, after a written determination by the appropriate program office, may disclose confidential business information to the Contractor necessary to carry out the work required under this contract. The Contractor shall protect the confidential business information and confidential business information used in its computer operations in accordance with the following requirements.

(1) The Contractor and Contractor's employees shall follow the security procedures set forth in the Contractor's security plan(s) approved by EPA

(2) The Contractor shall, upon request by the Contracting Officer, permit access to and inspection of the Contractor's facilities in use under this contract by representatives of EPA's Assistant Administrator for Administration and Resources Management, EPA's Program Management Support Division of the Office of Pesticide Programs, EPA's Management Support Division of the Office of Toxic Substances, EPA's Management Information System Division or by the Project Officer.

(3) The Contractor Document Control Officer (DCO) shall obtain a signed copy of the FIFRA/TSCA "Contractor Employee Confidentiality Access Agreement" from each of the Contractor's employees who will have access to the information before the employee is allowed access.

(b) The Contractor agrees that these requirements concerning protection of confidential business information are included for the benefit of, and shall be enforceable by, both EPA and any affected business having a proprietary interest in the information.

(c) The Contractor understands that confidential business information obtained by EPA under FIFRA and/or TSCA may not be disclosed except as authorized by the Act(s), and that any unauthorized disclosure by the Contractor or the Contractor's employees may subject the Contractor and the Contractor's employees to the criminal penalties specified in FIFRA [7 U.S.C. 136h(f)] and/or TSCA [15 U.S.C. 2613(d)].

For purposes of this contract, the only disclosures that EPA authorizes the Contractor to make are those disclosures set forth in the clause entitled "Treatment of Confidential Business Information."

(d) The Contractor agrees to include the provisions of this clause, including this paragraph (d), in all subcontracts awarded pursuant to this contract that require the furnishing of confidential business information to the subcontractor.

(e) The Contractor shall return all logs and employee confidentiality agreements to EPA at the end of the contract.

(f) If, subsequent to the date of this contract, the Government changes the security requirements, the Contracting Officer shall equitably adjust affected provisions of this contract in accordance with the "Changes" clause when:

(1) The Contractor submits a timely written request for an equitable adjustment; and

(2) The facts warrant an equitable adjustment.

DOCUMENT CONTROL OFFICERS & ASSISTANTS

Immediate Office of the Administrator (A)			
AA for Enforcement and Compliance Monitoring (OECM) . Carolyn Young . . 475-8690			
Associate Enforcement Counsel (AEC)			
Special Litigation Division (SLD)			
Office of General Counsel (GC)			
Office of the Inspector General (IG)	Brenda K. Bray . . 382-4115		A-109
. (DCA)	Shirley K. Loftin 382-4115		A-109
AA for International Activities (IA)	Djuna E. King . . 382-4870		A-106
AA for Policy, Planning and Evaluation (OPPE).			
AA for External Affairs (EA)	Joe Montgomery . . 475-8793		A-104
.	Judith Troast . . 382-5905		A-104
Office of Federal Activities (OFA)			
Special Programs & Analysis Division (SPAD)			
AA for Water (W)			
Office of Water Regulations & Standards (WRS). . . James Lund. . . . 382-7811			WH-586
Monitoring & Data Support Division (MDS)			
Analysis & Evaluation Division (AED).	Lynne G. Tudor. . 382-5894		WH-586
Industrial Technology Division (ITD)			
Criteria & Standards Division (CSD)			
Office of Drinking Water (DW).	Bruce Mintz. . . .475-9569		WH-550
. (DCA)	Amal Mahfouz . . .475-9568		WH-550
Criteria & Standards Division (CSD)			
Office of Water Enforcement & Permits (WEP)			
Enforcement Division (ED)			
AA for Solid Waste & Emergency Response (SWER)		382-4676	WH-562
Office of Solid Waste (SW)			
Office of Policy Planning & Information (PMS). . . Dina Villari. . . 382-4670			WH-563
Office of Emergency & Remedial Response (ERR)			
Office of Waste Programs Enforcement (WPE) Estelle Bulka . . 475-6720			WH-527
AA for Pesticides & Toxic Substances (OPTS).	Creavery Lloyd. . 382-2902		TS-788
Office of Compliance Monitoring (OCM).	Richard Kratofil. 382-7835		EN-342
Office of Pesticide Programs (OPP)	Anne Lindsay. . . 557-7102		TS-766C
Benefits & Use Division (BUD)	Tom Burkhalter . . 557-2329		TS-768C
.	Robert Maxey. . . . FTS-494-1225		
. (DCA)	Don Eckerman. . . 557-7356		TS-768C
. (DCA)	Roger Holtorf . . 557-7335		TS-768C
Hazard Evaluation /Division (HED)	Rachelle Kudrik . 557-0465		TS-769C
Toxicology Branch (DCA)	Millie Lassman. . 557-1004		TS-769C
. (DCA)	Carletta Mitchell 557-7351		TS-769C
Ecological Effects Branch (DCA)	Allen Vaughn. . . 557-1737		TS-769C
Exposure Assessment Branch. (DCA)	Emil Regelman . . 557-1984		TS-769C
Residue Chemistry Branch. (DCA)	Marvin Hawkins. . 557-7324		TS-769C

DOCUMENT CONTROL OFFICERS, Cont'd

Program Management & Support Division (PMSD)	Emory Eldredge	.557-3240	TS-75
(DCA)	BeWanda Alexander	.557-4459	TS-75
(DCA)	Evelyn Alston	.557-3240	TS-75
(DCA)	Cliff Fields	.382-7691	TS-75
(DCA)	Laverne Jones	.557-3240	TS-75
(DCA)	Frances Mann	.557-3262	TS-75
Registration Division (RD)	Owen Beeder	.557-7893	TS-76
	Yvonne Brown	.557-1900	TS-76
	Marianne Clark	.557-3965	TS-76
	Martha Delaney	.557-3663	TS-76
	Joe Diggs	.557-3106	TS-76
	Arvella Farmer	.557-7402	TS-76
	Bipin Gandhi	.557-1758	TS-76
	Josie Hollingsworth	.557-1800	TS-76
	Doris Jackson	.557-1700	TS-76
	Grace Kaiser	.557-2600	TS-76
	Joann King	.557-1806	TS-76
	Patricia Quarles	.557-2690	TS-76
	Richard Mountfort	.557-1830	TS-76
	Dana Pilitt	.557-2400	TS-76
	Ruby Whitters	.557-2557	TS-76
Office of Toxic Substances (OTS)			
Information Management Division (IMD)	Anthony Cheatham	.382-3532	TS-79
Economics & Technology Division (ETD)			
Chemical Control Division (CCD)			
Existing Chemical Assessment Division (ECAD)	Linda A. Goodman	.382-3679	TS-77
Exposure Evaluation Division (EED)			
Health & Environmental Review Division (HERD)			
AA for Research & Development (RD)			
Office of Exploratory Research (ER)			
Office of Health & Environmental Assessment (HEA)	Marie Pfaff	.382-7345	RD-689
Environmental Criteria & Assessment Office (ECA)			
(Lab - Cincinnati, OH)	Robert Carr	.(8) 684-7967	
	(DCA) Flora Scarpino		
Office of Health Research (OHR)			
Office of Environmental Processes & Effects Research (EPE)			
Office of Environmental Engineering & Technology (EET)			
Hazardous Waste Engineering Research Lab (HWER)	Sandra L. Paolucci	.(8) 684-7418	
Water Engineering Research Laboratory (WERL)			
National Enforcement Investigations Center (NEIC)	Kaye Mathews	.(8) 776-6241	
Region III (R3)	Gordan E. Moore	8-597-9868	N/A
Region V (R5)	Anthony R. Carlson		
	(DCA) Judith L. Rudman		
U.S. Government Accounting Office (GAO)	J. Kevin Donohue	.382-4326	N/A

Please read instructions on the reverse before completing this form.

<b style="margin-left: 20px;">FIFRA Sensitive Information Transmittal		
Sender		
Name	Badge/ID Number	Date
Office/Division	Telephone Number	Mail Code
Description of Data		
Document Identifier		<input type="checkbox"/> List Attached
Description/Title		
Type of Media	<input type="checkbox"/> Paper Copy <input type="checkbox"/> Fiche <input type="checkbox"/> Floppy Diskette <input type="checkbox"/> Other (Specify)	
Recipient		
Name	Badge/ID Number	Date
Office/Division	Telephone Number	Mail Code
I acknowledge receipt of the FIFRA Sensitive Information identified above. I understand that I am responsible for its safeguard and will return it to the OPP Document Center for disposal or provide a documented chain of custody, in accordance with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act Security Manual. I also understand that under FIFRA section 10(f) I am liable for a possible fine of up to \$10,000 and/or imprisonment for up to one year, or both, if I willfully disclose FIFRA Sensitive Information to unauthorized persons. I further understand that any false or misleading statement made on this form may be punishable under applicable law.		
Signature		

FRONT

EPA Form 8500-24 (2-88)

BACK

Instructions

Sender

- Provide your name, badge/ID number, office and division names, telephone number, and mail code.
- Fill in the document identification number that has been assigned to the document, accession, MRID, etc. (If several documents are being transmitted, list on a separate sheet and staple appropriate number of copies to form.)
- Provide the title or a brief description of the document.
- Indicate the type of media.
- Keep two copies: one for sender and one for sender's Document Control Officer (DCO) (Documented Chain of custody). (See Security Manual, Section 5)
- Sender is responsible for obtaining the Recipient's signed copy.

Recipient

- Complete bottom of form, sign, and date.
- Retain two copies: one for recipient and one for recipient's DCO.
- Return original to sender for his/her DCO.

Copies:

Original - Sender's DCO (signed copy)
 Yellow - Recipient
 Green - Recipient's DCO
 Blue - Sender's DCO (duplicate copy)
 Pink - Sender

EPA Form 8500-24 (2-88) Reverse

EXHIBIT 8

**FIFRA
CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12356)**

**FIFRA
CONFIDENTIAL BUSINESS INFORMATION**

**FIFRA
CONFIDENTIAL BUSINESS INFORMATION
TO BE OPENED BY ADDRESSEE ONLY!**

[Printed on Red Cover Stock]

FIFRA

CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN
NATIONAL SECURITY INFORMATION (EO 12356)

SOME INFORMATION IN THE ATTACHED MATERIAL MAY BE ENTITLED TO TREATMENT AS TRADE SECRET OR PROPRIETARY DATA UNDER SECTION 7(d) AND SECTION 10 THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA) AS AMENDED.

ANY PERSON HANDLING OR USING THE ATTACHED DATA IN ANY WAY IS RESPONSIBLE FOR PREVENTING UNAUTHORIZED DISCLOSURE WHILE IN HIS POSSESSION. SECTION 12(a)(2)(D) MAKES IT UNLAWFUL FOR ANY CONFIDENTIAL INFORMATION (EXCEPT TO PERSONA NEED- ING THE INFORMATION FOR THE PERFORMANCE OF OFFICIAL DUTIES). A PENALTY OF UP TO \$10,000 FINE AND UP TO 3 YEARS IMPRISONMENT MAY RESULT FROM CONVICTION OF A VIOLATION ON SECTION 12(A)(2)(D).

SECTION 10(f) MAKES IT A CRIME FOR EMPLOYEE TO DISCLOSE CONFIDENTIAL INFORMATION EXCEPT AS AUTHORIZED BY SECTION 7 AND 10 OF FIFRA. A PENALTY OF UP TO \$10,000 FINE AND UP TO ONE YEAR IN JAIL MAY RESULT FROM CONVICTION OF A VIOLATION OF SECTION 10(f).

THE ATTACHED INFORMATION IS NOT TO BE PUBLISHED, REPRODUCED, PUBLICLY DISCUSSED, INCLUDED IN RESPONSE TO AN FOI REQUEST OR OTHERWISE RELEASED WITHOUT THE EXPLICIT WRITTEN AUTHORIZATION OF THE APPROPRIATE DIVISION DIRECTOR OR HIS DESIGNEE.

EXHIBIT 10