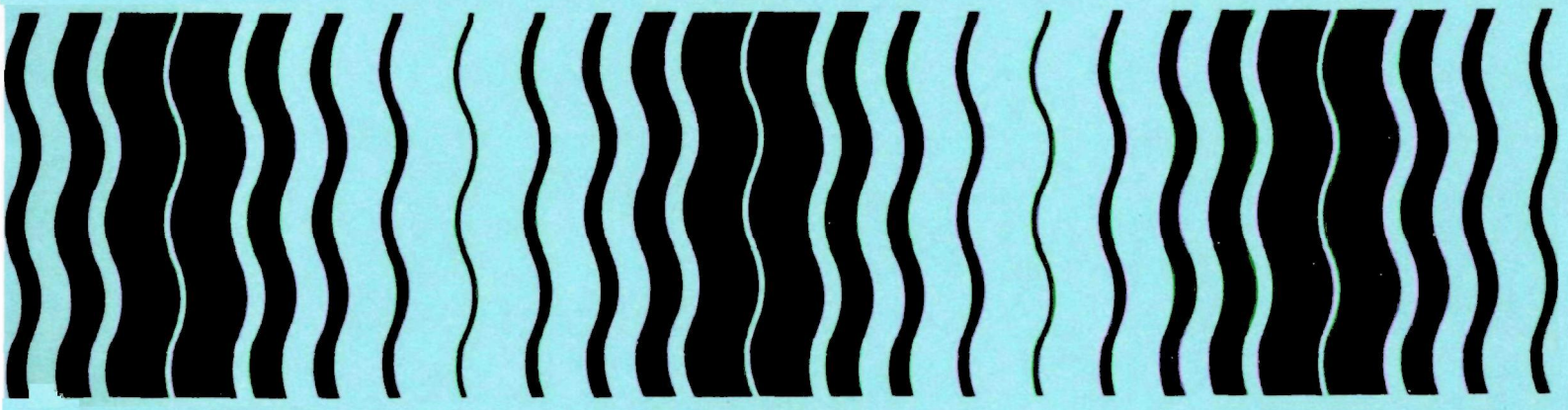
United States
Environmental Protection
Agency

Pesticides and
Toxic Sbustances
(H-7505C)

EPA

General Information On Applying For Registration Of Pesticides In The United States



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GENERAL INFORMATION
ON APPLYING FOR
REGISTRATION OF PESTICIDES
IN THE
UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

JUNE, 1989

PREFACE

This instruction manual, which is divided into 18 chapters, is only intended to provide a general overview and guidance for persons seeking to register a pesticide in the United States. Every attempt has been made to make the information contained in this Instruction Manual accurate and current, however, changes in the Federal pesticide law [Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)], regulations, policies and requirements are an ongoing process. Thus, changes may occur without your being notified directly, and will take precedence over the information contained herein.

If you wish to obtain more specific details on the laws and regulations governing the use and sale of pesticides in the United States, this information is contained in the Federal Insecticide, Fungicide and Rodenticide Act, as amended, and in the Code of Federal Regulations (40 CFR Parts 150-180). Refer to Chapter 16 for information on the source of these documents.

Applications and registration actions will be measured against actual regulatory requirements for sufficiency. Therefore this manual should be considered as a summary offering general guidance and not as a substitute for consulting applicable regulations and law.

This is the first instruction manual which has been developed in an effort to provide general guidance to applicants and registrants on registering pesticides in the U.S. Draft copies of the manual were sent to the Chemical Manufacturers Association, Chemical Producers and Distributors Association, Chemical Specialities Manufacturers Association, National Agricultural Chemicals Association, and the state pesticide lead agencies for review and comment. Numerous suggestions were received and many were incorporated in the final document. We wish to thank all of those who responded with their comments and suggestions.

We also welcome any comments on how the current manual could be made more useful, or suggestions for changes or additions. Your comments should be addressed to Mr. Herbert S. Harrison, Chief, or Mr. William H. Miller, Product Manager (16), Insecticide-Rodenticide Branch, Registration Division, Office of Pesticide Programs. Their addresses and phone numbers can be found in Chapter 18 of this manual.

CONTENTS OF THIS INSTRUCTION MANUAL

CHAPTER 8 - HOW TO APPLY FOR AN EXPERIMENTAL USE PERMIT

This chapter contains information on when you may need an experimental use permit which allows you to test an unregistered pesticide or a registered pesticide for an unregistered use, and how to submit the application.

CHAPTER 9 - WHAT FEES ARE REQUIRED FOR REGISTRATION AND TOLERANCE PETITION ACTIVITIES

This chapter contains information on the fees that are required to be paid to maintain your registration, and fees for petitions for the establishment of tolerances.

CHAPTER 10 - DEVICES - WHAT ARE THE REQUIREMENTS?

This chapter contains information concerning devices. Although devices may not require registration under Chapter 3 of FIFRA, they may be subject to other regulatory requirements.

CHAPTER 11 - HOW TO OBTAIN AN EPA ESTABLISHMENT NUMBER

This chapter contains information on the registration of your pesticide producing establishment with the EPA, when you need an establishment number, and how to obtain one.

CHAPTER 12 - CONFIDENTIAL BUSINESS INFORMATION AND HOW TO SUBMIT DATA

This chapter contains information on the protection of information (and data) that you submit to the Agency in support of your registration, tolerance petition, and experimental use permits from disclosure or release to other persons, and the proper format for the submittal of that information and/or data.

CHAPTER 13 - TRANSFER OF REGISTRATIONS AND/OR DATA

This chapter contains information on the procedures and information required to transfer a registration and/or data from one company to another.

CHAPTER 14 - STATE REGULATORY AUTHORITY UNDER FIFRA

This chapter contains information on the authority of the States to issue experimental use permits and special local need registrations.

CHAPTER 1 - WHO MUST APPLY FOR REGISTRATION OF A PESTICIDE

A. GENERAL INFORMATION

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires that before any person in any state or foreign country can sell or distribute any pesticide in the United States, they must obtain a registration (or license) from the U.S. Environmental Protection Agency (EPA). FIFRA also provides that the Administrator may specify devices that are subject to the provisions of FIFRA.

Pesticide: The term pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

Pest: The term pest, as defined in FIFRA section 2(t), means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest.

Device: A device is any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately.

B. PEST CONTROL ORGANISMS, SUBSTANCES OR DEVICES NOT SUBJECT TO REGISTRATION UNDER FIFRA

1. 40 CFR Part 152, Subpart B - Exemptions, describes those pesticides that have been exempted by the Agency from the registration requirements of FIFRA.

    a. 40 CFR section 152.20 describes those pesticides, such as (1) certain biological control agents and (2) certain human drugs, that are exempted because they are regulated by another Agency.

    b. 40 CFR section 152.25 describes those pesticides, such as (1) treated articles or substances, (2) pheromones in pheromone traps, (3) preservatives for biological

specimens, (4) vitamin-hormone horticultural products, and (5) foods, that are of a character not requiring regulation under FIFRA.

c. 40 CFR section 152.30 provides information on pesticides that may be transferred, sold, or distributed without registration.

2. Pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA under 40 CFR 158.65(b)(3).

3. Devices considered not subject to registration include articles that use physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest under 40 CFR 152.5. Other devices are subject to regulation under the provisions of FIFRA section 2(q)(1) or FIFRA section 7, even though they are not required to be registered. Refer to Chapter 10 for a more detailed discussion on the Agency's policies and regulatory requirements for devices.

C. TYPES OF PESTICIDE REGISTRATION YOU MAY OBTAIN

There are two general types of pesticide registrations available. You may (1) obtain a registration for your own product, or (2) become a supplemental registrant (often termed a "distributor" or "subregistrant") for a product that someone else has already registered. These types of registrations, together with amendments to a registration, are described in more detail below.

1. OBTAIN A REGISTRATION FOR YOUR OWN PRODUCT

If you wish to obtain the registration for your own pesticide product, you are responsible for submitting all of the information and data that are required to support the registration. The information includes forms, proposed product labeling, technical and scientific data that are required on the specific product that you intend to make (or formulate) and how you will comply with the data compensation requirements. See Chapter 2 for detailed instructions on how to submit you own application for pesticide registration.

2. OBTAIN A SUPPLEMENTAL REGISTRATION TO DISTRIBUTE A PRODUCT REGISTERED BY SOMEONE ELSE

If you do not wish to take the time and the expense

necessary to register you own product, but would rather market a product that is currently registered to another company and you are willing to enter into an agreement with that company, the basic registrant may include you as a supplemental registrant to his registration so that you may market his product under your name. See Chapter 5 for detailed instructions on how to submit an application for supplemental registration of a pesticide product.

3. AMEND THE REGISTRATION OF A PRODUCT YOU ALREADY HAVE REGISTERED WITH THE EPA

If you have a product that is already registered with the EPA, and wish to change the formulation or labeling text (i.e., add, delete or change formulation components or label precautionary statements, add or change uses) you must file an application to amend the registration of your product. There are certain changes that you may make that require that you notify the Agency of the change, and other changes that require no notification at all. See Chapter 4 for detailed instructions on how to submit an application for amended registration of a pesticide product.

D. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions, or require additional information concerning your application for registration, contact the Product Manager assigned the pesticide in your product. A listing of Product Managers and a sampling of the pesticides they are responsible for may be found in Chapter 18.

If you have questions of a general nature that do not pertain to any specific pesticide, or pertain to a new pesticide active ingredient for which you have not made an application, contact the Deputy Branch Chief or the Branch Chief's office for the type of pesticide (i.e., insecticide, fungicide, antimicrobial etc.) for which you have a question. A listing of the various Deputy Branch Chiefs, and Branch Chiefs can be found in Chapter 18.

If you have any questions concerning devices, whether they are subject to the Act, or establishment registration, please contact the Office of Compliance Monitoring, Compliance Division, (EN-342), Environmental Protection Agency, 401 M St., S.W., Washington, D.C., 20460. Telephone (202) 382-7835.

CHAPTER 1 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 152 - Pesticide registration and classification procedures

   Part 158 - Data requirements for registration

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

   Section 2 - Definitions
   Section 7 - Registration of establishments

CHAPTER 2 - HOW TO APPLY FOR REGISTRATION OF A CONVENTIONAL PESTICIDE

A. GENERAL INFORMATION

The Agency separates pesticides into two general categories, conventional chemical pesticides and 2) biochemical and microbial pesticides. Refer to Chapter 3 for information on registration requirements for biochemicals and microbial pesticides.

B. TYPES OF PESTICIDE APPLICATIONS

The Agency categorizes pesticide applications as follows:

1. **New chemical** - this is an application for registration of a product containing a new pesticide, i.e., a pesticide (active ingredient) that is not a constituent of a product currently registered with the Agency (40 CFR 152.114),

2. **New use** - this is an application for registration of a use for an active ingredient(s), or formulation type, not currently included in the directions for use of any product that contains such active ingredient(s) or formulation type. New uses are defined in 40 CFR 152.3 as follows:

   a. Any proposed use pattern (i.e., one that would result in pesticide residues in food or feed commodities) that would require the establishment of a tolerance, an increase in an established tolerance, or the exemption from the requirement of a tolerance, or food additive regulation under section 408 or 409 of the Federal Food, Drug and Cosmetic Act (refer to Chapter 7 for a discussion of tolerances),

   b. Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern, or

   c. Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure of man or other organisms to the active ingredient.

3. **"Me-too"** - a "me-too" is an application for registration of a pesticide product that is substantially similar or identical in its uses and formulation to products that are currently registered. A more detailed discussion of a "me-too" product is contained in Chapter 6, D., Question 1.

IMPORTANT NOTE: If you increase the dosage rate of your product over that which is currently registered, change a pre-harvest interval (PHI) or make other changes which might have an effect on the pesticide residues in food or feed commodities or exposure to nontarget organisms, you application is no longer considered to be a "me-too" application. Changes in the inerts in your formulation, either by varying the percent or by using inerts not registered in a similar product, may also be a determining factor as to whether your product is considered to be a "me-too". If you include an unregistered source of the active ingredient(s) in your product, the product may no longer be considered a "me-too" product.

C. CONTENTS OF APPLICATION

Your application for registration of a pesticide must include the following information, as applicable. For a more detailed discussion of this information refer to 40 CFR section 152.50, Contents of Application.

1. **Application Form** - An Application for Pesticide Registration form (EPA Form 8570-1) must be completed and submitted with each application for registration. Detailed instructions on completing the application form are provided on the back of each form. It is important that you read these instructions and that the information you provide is complete and accurate. Be certain to sign your application form.

Identity of the Applicant

Name - An applicant must identify himself. An applicant not residing in the United States must also designate a U.S. agent (see below), to act on his behalf on all registration, and if necessary, tolerance matters.

Address of record - An applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and the Agency will send all correspondence concerning the application and any subsequent registration information to that address. It is the responsibility of the applicant or registrant to ensure that the Agency has a current and accurate address.

PITFALLS TO BE AVOIDED: It is your responsibility to keep the Agency informed of your current name and address of record. If the Agency's good faith attempts to contact you are not successful, the Agency will

issue in the Federal Register a notice of intent to cancel **all of your registered products** under FIFRA section 6(b) (refer to 40 CFR 152,122). You should notify the Registration Support Branch of any changes in your company name or address. Refer to Chapter 18 for the address.

Authorized agent - You may designate a person residing in the United States to act as your agent. If you wish to designate an agent, you must send the Agency a letter stating the name and U.S. address of the agent. You must also notify the Agency if you change your designated agent. You may terminate a designated agent at any time by notifying the Agency in writing. Correspondence concerning authorized agents should be addressed to the appropriate Product Manager for your product. (See Chapter 18 for a listing of Product Managers)

2. Confidential Statement of Formula - A Confidential Statement of Formula (EPA Form 8570-4) must be completed and submitted with each application for registration. Detailed instructions for completing the form and providing acceptable information are provided on the back of the form. Additional information can be found in 40 CFR 158.150-190. You should also refer to 40 CFR 158.108 for additional discussion of the product chemistry requirements.

3. Draft Labeling - The product label is the written, printed, or graphic material on, or attached to your pesticide product. The term "labeling" includes all labels and all other written, printed or graphic material which accompanies your product, or to which reference is made on the product's label or in literature accompanying the product.

Five copies of your proposed draft labeling must be submitted with your application. The draft labeling may be typed or otherwise printed, but must be legible and complete, and submitted on 8 1/2 x 11 inch paper. Detailed information on labeling requirements, such as the ingredients statement, warnings and precautionary statements, and directions for use can be found in 40 CFR 156.10.

4. Data - Three copies of all applicable data required to support the registration of your product must be submitted with your application. The data must be formatted in accordance with the requirements which are provided in 40 CFR Part 158.32-34, and in PR Notice 86-5. You should also refer to Chapter 12 of this manual, for additional guidance on how to format your data submission. At the very minimum,

most formulated products which are substantially similar or identical to other registered products, will be required to submit the product specific chemistry data, which are discussed in detail in 40 CFR Part 158.150-190. If your product is not substantially similar or identical to another registered product, you will be required to also submit, at the minimum, the acute toxicity data on your product. The toxicology data requirements can be found in 40 CFR Part 158.340. Additional information can be found in the Pesticide Assessment Guidelines, Subdivision F. Refer to 40 CFR 158.115 for a discussion of the Pesticide Assessment Guidelines and their relationship to the data requirements. In addition, the source of the active ingredient you use to formulate your product must be registered, otherwise you must provide, at a minimum, product chemistry data on the technical grade of the active ingredient as well as on your formulated product. It should be noted that although efficacy data (product performance data) are not routinely required to be submitted for most insecticide, fungicide or herbicide products, it is the registrants responsibility to ascertain that the product performs in accordance with its labeling claims.

IMPORTANT NOTE: Efficacy data (product performance data) are routinely required for antimicrobial products and vertebrate pesticide products. You should refer to 40 CFR Part 158.640 for product performance data requirements.

PITFALLS TO BE AVOIDED: If you submit data that are not properly formatted in accordance with PR Notice 86-5, or submit fewer than the required number of copies, your application will be rejected and returned.

5. FIFRA chapter 3(c)(1)(D) data compensation requirements - Each applicant applying for registration of a pesticide must comply with the data compensation procedures under FIFRA section 3(c)(1)(D). No application for registration can be approved until you comply with these requirements. Detailed procedures are contained in 40 CFR 152.80 - 152.99. A discussion of these requirements and the applicable forms are discussed in Chapter 6 of this manual. You should refer to Chapter 6 to determine how you may wish to comply with the data compensation requirements and what forms would be applicable for the method you choose.

6. Certification relating to child-resistant packaging If your product meets the criteria which requires child-resistant packaging (refer to 40 CFR 157.20 - 157.39), you must submit a certification that the packaging that will be used for the product meets the child-resistant packaging standards in 40 CFR 157.32.

7. Restricted use classification - The Agency has classified some or all of the uses of certain pesticides as a "Restricted Use Pesticide", either by regulation, as the result of a Registration Standard, or during the registration review of individual products. A restricted use classification restricts the product "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification" [40 CFR 156.10(j)(2)]. The criteria used for determining whether your particular product requires the restricted use classification can be found in 40 CFR 152.170. A listing of those pesticides that the Agency has classified for restricted use by regulation can be found in 40 CFR 152.175. Refer to 40 CFR 152.160 - 171 for a detailed discussion on the classification of pesticides. A listing of all Restricted Use Pesticides is available from the Registration Support Branch, Registration Division. See Chapter 16 for a source of the listing.

8. Registration standards - FIFRA section 4 provides for the reregistration of registered pesticides. As a result, the Agency has developed a program for the review of the pesticide active ingredient, the data supporting the registration of products containing the active ingredient, and their uses. Upon completion of this review, a Registration Standard is issued. The Standard sets forth the Agency's position on the registrability of products containing the active ingredient(s), assesses the acceptability of existing tolerances, describes the need for additional data or information, if any, that must be submitted to complete the reregistration review, and identifies labeling changes or use restrictions needed for the product to remain in compliance with FIFRA.

If a Registration Standard has been issued for the active ingredient(s) contained in your product, your application for registration must address any data, data compensation, and labeling, or other requirements that are applicable to your product. Refer to Chapter 16 for the source of a listing of Registration Standards that have been issued.

D. COMPLETENESS OF APPLICATION

You are responsible for the accuracy and completeness of all information submitted in connection with your application. The procedures for submitting a complete application for registration are discussed below and detailed information is contained in 40 CFR Subpart C, section 152.40 - 152.55, entitled Registration Procedures.

A separate application for registration must be made for

each pesticide product. A pesticide product registration pertains to a manufacturing use product or end-use formulation with only one set of active ingredients. Variations in active ingredients or their percentage in the manufacturing use or end-use formulations are considered separate products and require separate registrations. However, EPA may approve a basic formulation and one or more alternate formulations where only the inert ingredients vary in a single product registration. In addition specific types of formulated products require separate registrations (i.e., liquids, aerosols, baits, dusts, etc.)

Your application may be screened upon receipt to determine if it is complete. If it is determined to be complete, the application will be processed and placed in review. Incomplete applications will be returned without further processing. A complete application must contain the following information which consists of two parts, one containing administrative information and the other containing data. As you read the information below, you should refer to Appendix 2-1, which is located after section H. of this Chapter, for a schematic representation of the various documents that are required to be submitted.

ADMINISTRATIVE PORTION OF APPLICATION: The Administrative portion of your application consists of the following documentation:

1. A properly completed Application for Pesticide Registration/Amendment (EPA Form 8570-1, Revised 9-88)

2. A properly completed Confidential Statement of Formula (EPA Form 8570-4, Revised 2-85)

3. Five legible, reproducible copies of the proposed draft labeling for your product.

4. FIFRA section 3(c)(1)(d) data compensation forms, as applicable. Normally the following two data compensation forms are required to be submitted with a typical "me-too" application for registration.

   a. A properly completed Certification with Respect to Citation of Data [EPA Form 8570-29 (7-86)], and

   b. A properly completed Formulator's Exemption Statement [EPA Form 8570-27 (10-86)].

You should refer to Chapter 6 of this manual for a detailed discussion of the data compensation requirements and how they may apply to your application.

IMPORTANT NOTE: Only one complete set of the documents in the administrative portion of your application is required. This information should not be bound.

PITFALLS TO BE AVOIDED: The submission of obsolete editions of the required forms is unacceptable, and will result in your application being rejected. Unsigned forms are unacceptable and will cause your application to be rejected.

DATA PORTION OF APPLICATION: The data portion of your application must address the following types of data.

1. **Product specific chemistry data** - usually required for all "me-too" applications.

2. **Acute toxicity data** - not required to be submitted under the Cite-all Method of data compensation, if your product is "substantially similar" or "identical" to another currently registered product. Required under the Selective Method of data compensation unless valid studies applicable to your product are cited. Refer to footnote in Appendix 2-1.

3. **Efficacy data** - routinely required for all antimicrobial products and for most vertebrate pesticide products, otherwise efficacy data may be required on a case by case basis.

IMPORTANT NOTE: Your application will be rejected if the required three copies of the data are not properly bound and formatted in accordance with PR Notice 86-5.

E. INCOMPLETE APPLICATIONS

If you submit an incomplete application, the processing of your application will not begin until the deficiencies are corrected. The application will be returned to you, with the deficiencies identified, for correction.

F. EXPEDITED REVIEW OF "ME-TOO" APPLICATIONS FOR REGISTRATION

On October 25, 1988, amendments to the Federal Insecticide, Fungicide, and Rodenticide Act were signed into law and for the most part became effective on December 24, 1988. One of the amendments, section 3(c)(3)(B), requires EPA to expedite the review of "me-too" applications for registration, i.e., products that are "substantially similar" or "identical" to other EPA registered pesticide products. In addition, EPA is required to (1) notify the applicant within 45 days of receipt of the application whether or not the application is complete and, if it is found to be incomplete, deny it, (2) notify the applicant within 90 days after receiving a complete application if the

application has been granted or denied and (3) if the application is denied, notify the applicant in writing of the specific reasons for the denial.

1. Applications Which Qualify for Expedited Review

"Me-too" applications for registration qualify for expedited registration under section 3(c)(3)(B) of FIFRA. A "me-too" application for registration is one that is "substantially similar" or "identical" to another EPA registered product, not only in the active and inert ingredients, but also bears the same use pattern(s) and essentially the same use directions as another currently registered product. You must provide the EPA Registration Number of the currently registered product you believe is "substantially similar" or "identical" to your product. A "me-too" application for registration requires only minimal supporting product chemistry, acute toxicity and, if applicable, efficacy data.

2. Applications Which DO NOT Qualify for Expedited Review

EPA will not expedite applications for registration of products for which the formulation or labeling vary from that of currently registered products, i.e., it is not "substantially similar" or "identical" to another EPA registered product. Examples include, but are not limited to, new inerts, changed percentages of active ingredients, new formulation types, new pests, new dosage rates, different frequency and timing of applications, geographical locations other than those previously registered, new sites, and new methods of application. These types of changes may increase the risk to humans or the environment through increased exposure and therefore require more data to assess the risks.

EPA will not expedite applications for "me-too technical-grade or "me-too manufacturing-use" products since extensive product chemistry and often toxicology data are required for these types of applications. These data are more complex and require more time to review then the data associated with the "me-too" applications for registration described above in item 1.

3. How to Submit Your "Me-too" Application for Expedited Review

If you believe your "me-too" application for registration qualifies for expedited review, you should print "EXPEDITE" at the top of the application above

the words "Application for Pesticide Registration" (EPA Form 8570-1). All applications must be on the EPA Form 8570-1 which bears a red unique identification number in the upper right hand corner. You must also identify in Section II of the application form, the EPA Registration Number and name of the product to which you believe your product is "substantially similar" or "identical". You must also enclose two self-addressed, stick-on labels for EPA to use in responding to your application. If you are resubmitting in response to an objection letter from EPA, your resubmission (on EPA Form 8570-1) must be marked "Expedite-Resubmission" at the top of the application form and must include a copy of EPA's objection letter.

You must direct your application or resubmission to the appropriate address listed below and identify the type of application in the address by using the abbreviation shown below:

(APPL) - for an application for new product registration

By Mail:

Document Processing Desk (APPL)
Office of Pesticide Programs (H7504C)
U.S. EPA
401 M Street, S.W.
Washington, D.C. 20460

By courier or hand delivery:

Office of Pesticide Programs
Document Processing Desk (APPL)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

4. Agency Screening of Your Application for Expedited Review

A Front End Processing Staff (FEPS) unit has been formed to screen and process your application for registration. The FEPS will provide an initial screen of your application to determine if (1) it qualifies for an expedited review in accordance with section 3(c)(3)(B), and (2) it is a complete application, i.e., it contains the administrative information and applicable data identified in section D of this chapter, and (3) the data are in compliance with the

data formatting requirements of PR Notice 86-5.

If your application passes the initial screening process, it will be assigned a file symbol and sent to the appropriate Product Manager Team for further processing.

The Product Manager Team will screen the application again, to determine that it is indeed a "me-too" application which qualifies for the expedited review. In addition, for those products that require efficacy data to be submitted, i.e., antimicrobial products and vertebrate pest control products, the Product Manager Team will determine if these data requirements have been addressed. If the application is determined to be complete, the application will be placed in review. If it is determined to be incomplete, the entire application will be returned to the FEPS. The FEPS will notify you that the Product Manager Team has further screened your application and determined that your application has been determined to be incomplete. Your application will be returned.

5. Timeframes for Agency Response to Expedited "Me-too" Applications

a. 45 Day Response - Within 45 days of receipt of your application, EPA will notify you whether your application is complete or incomplete. If your application is determined to be complete, you will receive a letter acknowledging receipt and the file symbol assigned to your application. If your application is determined to be incomplete, you will informed in writing of what is needed to make the application complete. For an incomplete application, the entire application will normally be returned to the address of record or to the address on the self-addressed label, if provided. (It is your responsibility for notifying EPA of any changes in name or address, or of a change in designated agent, if any, to avoid correspondence being sent to the wrong address). If an application is too large to be easily mailed, EPA will contact you by telephone and request that the application be picked up within 10 days.

IMPORTANT NOTE: If it is determined that your application does not qualify for an expedited review, you will be notified and

the application will be processed according to the regular review procedures.

Resubmissions in response to an Agency denial letter will initiate a new 45/90 day response cycle.

b. 90 Day Response - Within 90 days of receipt of your application which qualifies for expedited review, EPA will conduct a full review of the application and notify you of the results of the review. If the initial application was complete, the reviews are favorable and no additional information is required, registration will be granted. If additional information is necessary in order to complete our review, the application will be denied and you will be notified in writing of the deficiencies.

IMPORTANT NOTE: Although the 1988 FIFRA amendments require EPA to review applications for expedited registration within 90 days of receipt, this turnaround time may not be met immediately due to the backlog of applications received prior to December 24, 1988. However, EPA is increasing human and automated resources, developing instructional aids (this manual is one of these aids) for applicants and making necessary procedural changes in order to eliminate the backlog and to meet the 90 day response time for expedited reviews as soon as possible. We anticipate that we will be in a position to meet the 90 day expedited review timeframe early in 1990.

G. WHERE TO SUBMIT YOUR APPLICATION

See section F.3. of this Chapter for the address be used in submitting your application for expedited review to the Agency. Refer to Chapter 18 of this manual for the address to be used in submitting all other applications to the Agency.

H. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions, or require additional information concerning your application for registration, contact the Product Manager assigned the pesticide in your product. A listing of Product Managers and a sampling of the pesticides they are responsible for may be found in Chapter 18.

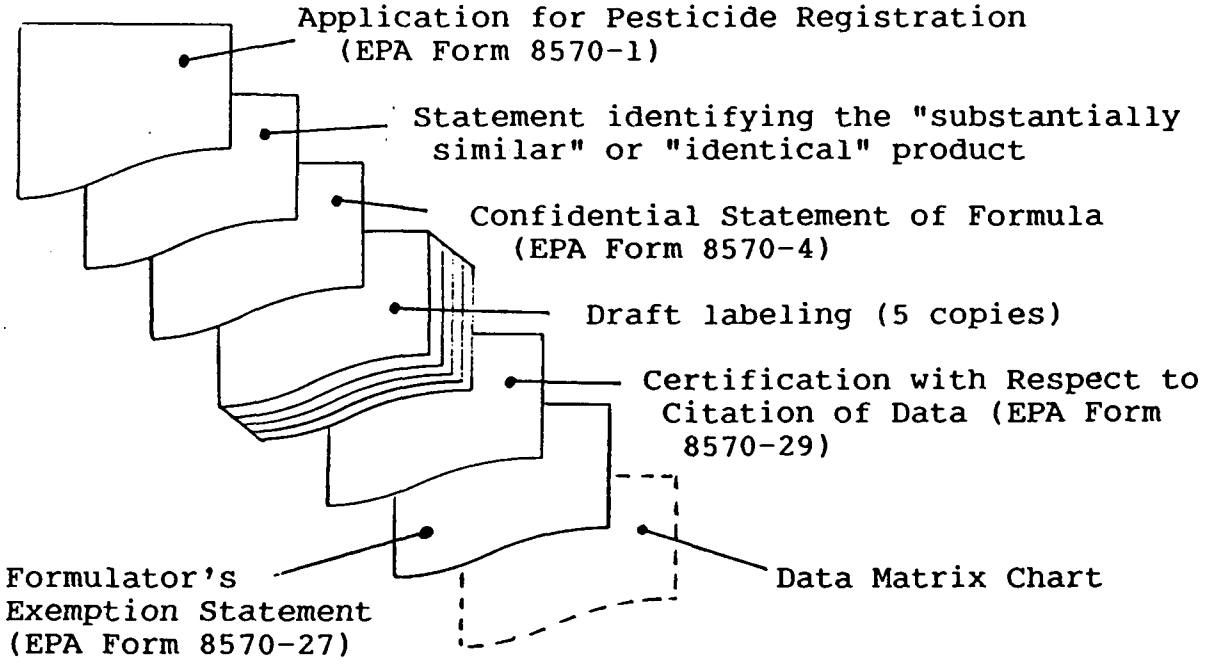
If you have any questions concerning the status of your "Me-

too" Application for Registration within the 45 day timeframe for the Agency's notifying you of whether the application is complete or has been denied, you should contact the Front End Processing Staff, Registration Support Branch. Refer to Chapter 18 for the telephone number.

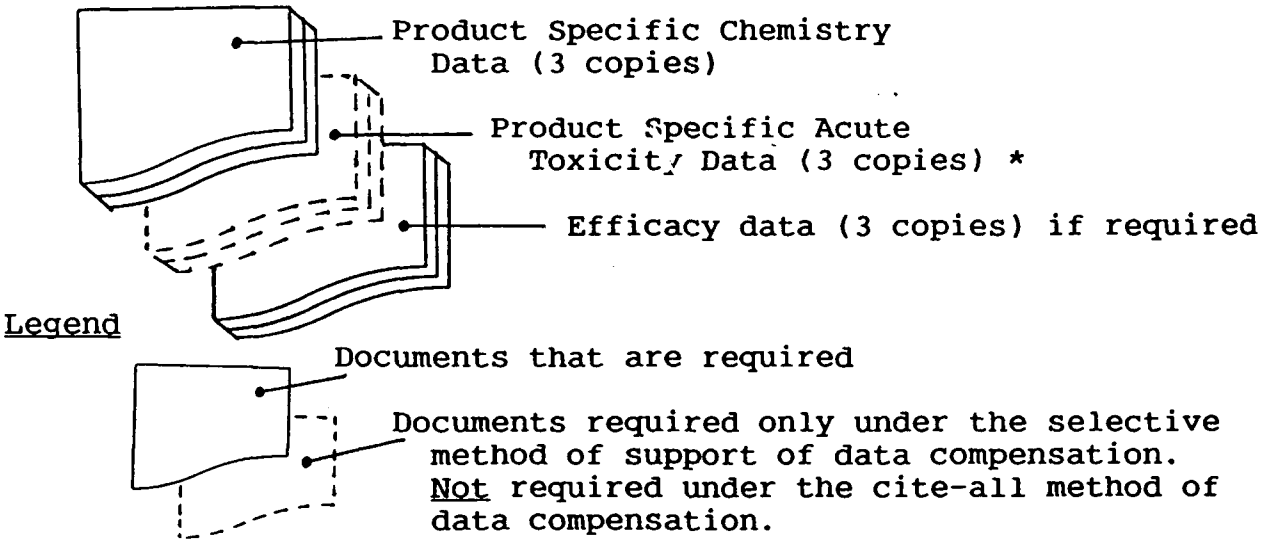
If you have questions of a general nature that do not pertain to any specific pesticide or pertain to a new pesticide active ingredient for which you have not made an application, contact the Deputy Branch Chief or the Branch Chief's office for the type of pesticide (i.e., insecticide, fungicide, herbicide, antimicrobial, etc.) for which you have a question. A listing of the various Deputy Branch Chiefs, and Branch Chiefs can be found in Chapter 18.

A COMPLETE APPLICATION FOR REGISTRATION OF A TYPICAL "ME-TOO" PRODUCT REQUIRES THE FOLLOWING DOCUMENTS

A. ADMINISTRATIVE PORTION OF APPLICATION: (DO NOT BIND TOGETHER)



B. DATA PORTION OF APPLICATION:



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* Under the selective method of support these data requirements may be addressed by either submitting the actual data, or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

CHAPTER 2 - REFERENCES CITED - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 152 - Pesticide registration and classification procedures
   Part 156 - Labeling requirements for pesticides and devices
   Part 157 - Packaging requirements for pesticides and devices
   Part 158 - Data requirements for registration
   Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities

2. Federal Food, Drug and Cosmetic Act, as amended

   Section 408 - Tolerances for pesticide chemicals in or on raw agricultural commodities
   Section 409 - Food additives

3. Federal Insecticide, Fungicide and Rodenticide Act, as amended, October 1988

   Section 3 - Registration of pesticides
   Section 4 - Reregistration of pesticides

4. PR Notice 86-5 - Standard Format for data submitted under the Federal Insecticide, Fungicide and Rodenticide Act, and certain provisions of the Federal Food, Drug and Cosmetic Act. Issued by the Registration Division, Office of Pesticide Programs, EPA, July 29, 1986.

5. Listing of Restricted Use Pesticides, compiled by the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA.

6. Listing of Registration Standards, compiled by the Document Management Section, Information Services Branch, Program Management Support Division.

CHAPTER 3 - HOW TO APPLY FOR REGISTRATION OF A BIOCHEMICAL OR A MICROBIAL PESTICIDE

A. GENERAL INFORMATION

The following discussion and information is a general overview of the Agency's policies and regulations as they relate to biochemical and microbial pesticides.

Biochemical and microbial pesticides are generally distinguished from conventional pesticides by their unique modes of action, low use volume, target species specificity or natural occurrence. In addition, microbial pesticides are living entities capable of survival, growth, reproduction and infection (40 CFR 158.65). Included in the microbial pesticide group are the "novel" microbial pesticides. Novel microbial pesticides are currently defined as "genetically modified or non-indigenous microbial pesticides."

Although the administrative contents of an application for registration of a biochemical or microbial pesticide are the same as a conventional chemical pesticide, biochemical and microbial pesticides are subject to a different set of data requirements as specified in 40 CFR 158.690 and 158.740. The Agency has also published guidance for developing these data in the Pesticide Assessment Guidelines, Subdivision M, Microbial and Biochemical Pest Control Agents (see Chapter 16 of this manual for a source.) You should also refer to Chapter 2 for general information on submitting an application for registration, and to Chapter 8 for additional information concerning experimental use permits.

The Agency's policies and requirements concerning the notification and reporting requirements for small-scale field tests and the experimental use permit and registration requirements for microbial pesticides under FIFRA were discussed in detail in the Federal Register Notice of June 26, 1986 (51 FR 23313).

The Federal Register Notice of June 26, 1986, and the 40 CFR citations provided throughout this chapter should be referred to for detailed information on these policies and regulations.

IMPORTANT NOTE - Since policies and requirements relating to biochemical and microbial pesticides are currently being revised and may be in place by the time you receive this manual, it is recommended that you contact the appropriate Product Manager (see section E.) for additional guidance prior to initiating testing, or filing an application for registration of a biochemical or microbial pesticide.

B. BIOCHEMICAL PESTICIDES

Biochemical pesticides include, but are not limited to, products such as semi-chemicals (e.g., insect pheromones), hormones (e.g., insect juvenile growth hormones), natural plant and insect growth regulators, and enzymes. When necessary, the Agency will evaluate products on an individual basis to determine whether they are biochemical or conventional pesticides.

The Agency has determined that pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA [(see 40 CFR 158.65(b)(3)]. In addition, pheromones and identical or substantially similar compounds labeled for use only in pheromone traps and pheromone traps in which those chemicals are the sole active ingredient are not subject to registration under FIFRA [(40 CFR 152.25(b)].

IMPORTANT NOTE: The use of pheromones in traps in conjunction with conventional pesticides, or in other application methods (other than traps) are subject to registration under FIFRA.

C. MICROBIAL PESTICIDES

1. Microbial pesticides - Microbial pesticides may include bacteria, algae, fungi, viruses, and protozoa used as pest control agents (40 CFR 152.20). The data requirements apply to all microbial pesticides, including those that are naturally-occurring as well as those that are genetically modified. Each "new" variety, subspecies, or strain of an already registered microbial pest control agent must be evaluated, and may be subject to additional data requirements.

2. Novel microbial pesticides - Novel microbial pesticides (i.e., genetically modified or non-indigenous microbial pesticides) may be subject to additional (or lesser) data requirements or information requirements on a case-by-case basis depending on the particular microorganism, its parent microorganism, the proposed use pattern, and the manner and extent to which the organism has been genetically modified. Additional requirements may include information on the genetic engineering techniques used, the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene), information on the control region of the gene in question, a description of the "new" traits or characteristics that are intended to be expressed, tests to evaluate genetic stability and exchange, and/or selected Tier II environmental expression and toxicology tests.

D. SMALL-SCALE FIELD TESTING LEVEL I REPORTING AND LEVEL II NOTIFICATION REQUIREMENTS

The information provided below is a general overview of the small-scale field testing requirements for microbial pesticides as described in the June 26, 1986 Federal Register Notice (51 FR 23313). It is also recommended that you contact the appropriate Product Manager listed at the end of this Chapter to determine current policies concerning testing and registration requirements for microbial pesticides, since these policies and requirements are currently being revised.

Small-scale field studies are (1) terrestrial field studies that involve 10 acres or less of land; and (2) aquatic field studies that involve 1 surface-acre or less of water.

1. Level I reporting - Level I reporting for small-scale field testing applies to all genetically engineered or non-indigenous microbial pesticides not otherwise covered by Level II notification. Detailed information on the reporting requirements is contained in the June 26, 1986, Federal Register Notice (51 FR 23313).

The Agency will have up to 30 days to review the above information to make a preliminary determination of the need for an experimental use permit (EUP). If, on preliminary assessment, the test raises sufficient concerns such that the Agency determines that additional information or monitoring is warranted (e.g., microorganisms for which there is limited scientific information or regulatory experience, or that warrant specific environmental monitoring during the test), then an EUP will be required. In this case, the applicant has two options:

1) the applicant may apply for a permit providing the necessary data and information required to support the application, or

2) the applicant may provide all additional data and information required under Level II notification.

If the latter option is chosen, the Agency will review the full notification package and make a determination as to whether an EUP is required.

2. Level II notification - Level II notification for small-scale field testing applies to microbial pesticides: Microbial pesticides formed by deliberately combining genetic material from organisms of different genera, genetically engineered microbial pesticides derived from

source organisms that are pathogens, and non-indigenous pathogenic microbial pesticides. A pathogen is defined as an organism that has the ability to cause disease in other living organisms (i.e., humans, animals, plants, or microorganisms).

Notification should include adequate background information on the microorganism, and description of the proposed test. Detailed information of the notification requirements is contained in the June 26, 1986, Federal Register Notice (51 FR 23313). The Agency encourages prospective applicants to meet with the EPA prior to submission of their notification to discuss their field test and to determine what specific data would be necessary to evaluate the product.

Once the supporting data have been submitted, the Agency has up to 90 days to review each Level II notification and determine if an EUP is required.

E. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions or require any additional information concerning biochemical, microbial or "novel" microbial pesticides, contact Product Manager 17 for insecticide products or Product Manager 21 for herbicide or fungicide products. A listing of Product Managers may be found in Chapter 18.

CHAPTER 3 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 152 - Pesticide registration and classification procedures
   Part 158 - Data requirements for registration

2. Federal Register Notice, June 26, 1986 (51 FR 23313).

3. Pesticide Assessment Guidelines, Subdivision M, Microbial and Biochemical Pest Control Agents, October 1982, (EPA No. 540/09-82-028) Environmental Protection Agency

   IMPORTANT NOTE: The Agency is currently revising the Subdivision M Guidelines. The draft document dated March, 1989 is available from the Public Docket and Freedom of Information Section, Field Operations Division. See Chapter 18 of this manual for a contact point.

CHAPTER 4 - HOW TO AMEND THE REGISTRATION OF A PRODUCT THAT IS ALREADY REGISTERED

A. GENERAL INFORMATION

Except as provided below, any proposed modifications in the composition, labeling or packaging of a registered product must be submitted, with an application for amended registration, to the Agency for prior approval. The application must contain the information required by 40 CFR 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may be legally distributed or sold.

B. AMENDMENTS THAT REQUIRE A FORMAL APPLICATION TO AMEND THE REGISTRATION OF YOUR PRODUCT

The following types of amendments that you may wish to make to your product registration, require that you 1) submit a formal application to amend the registration of your product, 2) submit or cite supporting data, as applicable, and 3) address the data compensation requirements of FIFRA section 3(c)(1)(D) to the extent that they apply to your proposed amendment.

1. "Me-Too" Amendments - "Me-too" amendments are those that you wish to make to your product registration which include for example, the addition of uses, revised dosage rates, or application methods that appear on the labeling of other currently registered products that are substantially similar or identical to your product. Changes to your basic formulation, other than those identified in section C. of this Chapter, also require a formal application (EPA Form 8570-1) to amend your registration. Some of the more general types of "me-too" amendments are discussed below. As you read this information, you should refer to the appropriate Appendices which are located after section F of this Chapter.

a. Administrative types of amendments - those amendments, for example labeling changes (such as a product name change) or revisions to your products formulation which do not require supporting data, require the following documentation. Refer to Appendix 4-1 which follows section F of this Chapter, for a schematic representation of what documentation is required with your application.

1) Labeling changes, other than those identified in section C., require an Application for Pesticide Amendment (EPA Form 8570-1), and 5 copies of the proposed labeling.

IMPORTANT NOTE: The deletion of use patterns, pests, claims, or sites of use from your registered labeling can no longer be accomplished as a Notification under PR Notice 88-6. The 1988 revisions to FIFRA [section 6 (f)], require the Agency to publish in the Federal Register, notice of receipt of requests to amend a registration by deleting one or more uses from the product labeling, in order to provide the public with knowledge of the potential loss of a product or a specific use of a product. This provision of the 1988 amended FIFRA supercedes this part of PR Notice 88-6. Your application to delete uses from your labeling must be submitted as a formal application to amend your registration.

2) Formula changes, revisions to your basic formulation or alternate formula requests, other than those identified in section C., require an Application for Pesticide Amendment (EPA Form 8570-1), and a Confidential Statement of Formula (EPA Form 8570-4). Five (5) copies of draft labeling will be required if the formula revision results in a change in the ingredient statement on the label.

IMPORTANT NOTE: Revisions to the formulation of antimicrobial products and most vertebrate pesticide products require the submission of efficacy data to support the revised formulation, and as such are not considered to be an administrative amendment. Refer to the following section on "me-too" amendments.

b. "Me-too" amendments that require supporting data - as indicated in 1. above, these are amendments you want to make to your product, that occur on another currently registered substantially similar or identical product. Refer to Appendix 4-2, which follows section F of this Chapter, for a schematic representation of what documentation is required with your application. Depending upon your proposed amendment, your application will require an administrative portion and a data portion.

IMPORTANT NOTE: The discussion provided below concerning the information to be submitted with a "me-too" amendment is general in nature and does not cover all possible types of "me-too" amendments. If you have any questions as to what information should be submitted with your application, you should contact the appropriate Product Manager for your product.

1) Administrative portion - includes the following:

- Application for Pesticide Amendment (EPA Form 8570-1)

- Statement identifying the "substantially similar" or "identical" product that is currently registered and is labeled for the change you are proposing for your product.

- Confidential Statement of Formula (EPA Form 8570-4), if required. This is not normally required unless you are proposing a change in your formulation and your product is an antimicrobial product or a vertebrate pesticide product, requiring efficacy data to support the proposed change. You should contact the Product Manager responsible for your product registration if you have any questions as to whether this is the case.

- Five (5) copies of your proposed draft labeling. It would make the Agency's review go more quickly, if you were to highlight those changes on your proposed labeling. A light colored felt tip marker could be used to highlight the proposed changes.

- Certification with Respect to Citation of Data (EPA Form 8570-29).

- Formulator's Exemption Statement (EPA Form 8570-27.

- Data Matrix Chart. Required if you elect to use the Selective Method of data compensation. The data required to support the application may be addressed by either submitting the actual data, or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

2) Data portion - includes the following data, as applicable:

- **Acute toxicity data** - required if you propose a change in the precautionary labeling or the signal word for your product.

- **Efficacy (product performance) data** - may be required if you are proposing to add a new pest to

an antimicrobial product or vertebrate pesticide product. In addition, changes to your basic formulation may require additional efficacy data. You may wish to contact the appropriate Product Manager to determine if additional efficacy data are needed to support your proposed amendment.

IMPORTANT NOTE: When submitting data, 3 copies - properly bound and formatted in accordance with PR Notice 86-5 are required. Refer also to Chapter 12 of this manual for additional information on submitting data.

c. Expedited Review of "Me-too" Applications for Amended Registration

On October 25, 1988, amendments to the Federal Insecticide, Fungicide, and Rodenticide Act were signed into law and for the most part became effective on December 24, 1988. One of the amendments, section 3(c)(3)(B), requires EPA to expedite the review of "me-too" applications for registration, i.e., products that are "substantially similar" or "identical" to other EPA registered pesticide products. In addition, EPA is required to (1) notify the applicant within 45 days of receipt of the application whether or not the application is complete and, if it is found to be incomplete, deny it, (2) notify the applicant within 90 days after receiving a complete application if the application has been granted or denied, and (3) if the application is denied, notify the applicant in writing of the specific reasons for the denial.

1. Applications Which Qualify for Expedited Review

"Me-too" applications for amended registration qualify for expedited registration under section 3(c)(3)(B) of FIFRA. A "me-too" application for amended registration is one that is "substantially similar" or "identical" to another EPA registered product, not only in the active and inert ingredients, but also bears the same use pattern(s) and essentially the same use directions as another currently registered product. You must provide the EPA Registration Number of the currently registered product you believe is "substantially similar" or "identical" to your product. A "me-too" application for amended registration would require only minimal supporting data: depending on the type of amendment, product chemistry, acute toxicity, or efficacy data, as

applicable.

2. Applications Which DO NOT Qualify for Expedited Review

- EPA will not expedite applications for amended registration of products for which the formulation or labeling vary from that of currently registered products, i.e., it is not "substantially similar" or "identical" to another EPA registered product. Examples include, but are not limited to, new inerts, changed percentages of active ingredients, new pests, new dosage rates, different frequency and timing of applications, geographical locations other than those previously registered, new sites, and new methods of application. These types of changes may increase the risk to humans or the environment through increased exposure and therefore require more data to assess the risks.

- EPA will not expedite applications for amended registration of "me-too" products proposing an unregistered source(s) of the active ingredient, since extensive product chemistry and often toxicology data are required for these types of amendments. These data are more complex and require more time to review then the data associated with the "me-too" applications for amended registration described above in item 1.

- EPA will not expedite applications to amend the labeling of your registered product to delete use patterns, pests, claims, or sites of use. The 1988 amendments to FIFRA require the Agency to publish in the Federal Register a notice of receipt of such amendments, in order to provide the public with knowledge of the potential loss of a product or a specific use of a product.

3. How to Submit Your "Me-too" Application for Expedited Review

If you believe your "me-too" application for registration qualifies for amended expedited review, you should print "EXPEDITE" at the top of the application above the words "Application for Pesticide Registration/Amendment" (EPA Form 8570-1). All applications must be on the EPA form 8570-1 which carries a red unique identification number in the upper right-hand corner. You must also identify in Section II of the application

form, the EPA Registration Number and name of the product to which you believe your product is "substantially similar" or "identical". You must also enclose two self-addressed, stick-on labels for EPA to use in responding to your application. If you are resubmitting in response to an objection letter from EPA, your resubmission (on EPA Form 8570-1) must be marked "Expedite-Resubmission" at the top of the application form and must include a copy of EPA's objection letter.

You must direct your application or resubmission to the appropriate address listed below and identify the type of application in the address by using the abbreviation shown below:

(AMEND) - to amend a currently registered product

By Mail:

Document Processing Desk (AMEND)
Office of Pesticide Programs (H7504C)
U.S. EPA
401 M Street, S.W.
Washington, D.C. 20460

By courier or hand delivery:

Office of Pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

4. Agency Screening of Your Application for Expedited Review

A Front End Processing Staff (FEPS) unit has been formed to screen and process your application for amended registration. The FEPS will provide an initial screen of your application to determine if (1) it qualifies for an expedited review in accordance with section 3(c)(3)(B), and (2) it is a complete application, i.e., it contains the administrative information and/or applicable data identified in section B.1.b. of this Chapter, and (3) the data are in compliance with the data formatting requirements of PR Notice 86-5.

If your application passes the initial screening process, it will be sent to the appropriate Product Manager Team for further processing.

The Product Manager Team will screen the application again, to determine that it is indeed a "me-too" application which qualifies for the expedited review. In addition, for those amendments that require efficacy data to be submitted, i.e., antimicrobial products and vertebrate pest control products, the Product Manager Team will determine if these data requirements have been addressed. If the application is determined to be complete, the application will be placed in review. If it is determined to be incomplete, the deficiencies will be identified and the entire application will be returned.

5. Timeframes for Agency Response to Expedited "Me-too" Applications for Amended Registration

a. 45 Day Response - Within 45 days of receipt of your application, EPA will notify you whether your application is complete or incomplete. If your application is determined to be complete, you will receive a letter acknowledging receipt. If your application is determined to be incomplete, you will informed in writing of what is needed to make the application complete. For an incomplete application, the entire application will normally be returned to the address of record or to the address on the self-addressed label, if provided. (It is your responsibility for notifying EPA of any changes in name or address, or of a change in designated agent, if any, to avoid correspondence being sent to the wrong address). If an application is too large to be easily mailed, EPA will contact you by telephone and request that the application be picked up within 10 days.

IMPORTANT NOTE: If it is determined that your application does not qualify for an expedited review, you will be notified and the application will be processed according to the regular review procedures.

Resubmissions in response to an Agency denial letter will initiate a new 45/90 day response cycle.

a. 90 Day Response - Within 90 days of

receipt of your application which qualifies for expedited review, EPA will conduct a full review of the application and notify you of the results of the review. If the initial application was complete, the reviews are favorable and no additional information is required, the amendment will be accepted. If additional information is necessary in order to complete our review, the application will be denied and you will be notified in writing of the deficiencies.

IMPORTANT NOTE: Although the 1988 FIFRA amendments require EPA to review applications for expedited registration within 90 days of receipt, this turnaround time may not be met immediately due to the backlog of applications received prior to December 24, 1988. However, EPA is increasing human and automated resources, developing instructional aids (this manual is one of those aids) for applicants and making necessary procedural changes in order to eliminate the backlog and to meet the 90 day response time for expedited reviews as soon as possible. We anticipate that we will be in a position to meet the 90 day expedited review timeframe early in 1990.

2. New Use Amendments - These are amendments to add "new uses" to your product labeling that are not currently registered for the active ingredient or combination of active ingredients contained in your product, for example, a new food or feed use or a change in use pattern from indoor to outdoor use. New uses are defined in 40 CFR 152.3(p). Your application to amend your registration should contain an administrative portion and a data portion. Refer to Appendix 4-3 which follows section F of this Chapter, for a schematic representation of the types of documentation required with your application. Your proposed amendment will require an administrative portion and a data portion.

IMPORTANT NOTE: The discussion provided below concerning the information to be submitted with a new use amendment is general in nature and does not cover all possible types of new use amendments. If you have any questions as to what information should be submitted with your application, you should contact the appropriate Product Manager for your product. You should also be aware that applications proposing the registration of the first food use for a previously registered active ingredient are subject to the screening procedures in PR Notice 86-4. Under these

procedures if your application is determined to be incomplete your application will not be processed and will be returned.

1) Administrative portion includes the following:

- Application for Pesticide Amendment (EPA Form 8570-1)

- Five (5) copies of your proposed draft labeling. It would make the Agency's review go more quickly, if you were to highlight those changes on your proposed labeling. A light colored felt tip marker could be used to highlight the proposed changes.

- Certification with Respect to Citation of Data (EPA Form 8570-29).

- Formulator's Exemption Statement (EPA Form 8570-27.

- Data Matrix Chart. Required if you elect to use the Selective Method of data compensation. The data required to support the application may be addressed by either submitting the actual data, or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

2) Data portion - You should refer to 40 CFR sections 158.202 thru 158.740 to determine what data are required to support your proposed use. You may be required to submit data on both the technical grade of the active ingredient and on your formulated product. In addition, new food or feed uses will require a petition for a tolerance. Refer to Chapter 7 of this manual for a discussion of tolerance petitions.

IMPORTANT NOTE: Efficacy (product performance) data are usually required to be submitted to support your proposed use if you are proposing a new antimicrobial use or vertebrate pest control use. However, for most uses, i.e., insecticides, fungicides, and herbicides, the Agency does not require that these data be submitted. The Agency expects the applicant to develop efficacy data to satisfy himself that the use for which registration is sought will be effective. In order to generate efficacy data for your proposed new use, it is usually necessary to conduct large scale testing. It is necessary to obtain an experimental use permit (EUP) in order to carry out this testing, and if a food or feed use is involved, temporary tolerances are required. Refer to Chapter 8 of this manual for a discussion of EUP's. You may wish to contact the appropriate Product Manager to determine if additional

efficacy data and EUP's are needed to support your proposed amendment.

IMPORTANT NOTE: When submitting data, 3 copies, properly bound and formatted in accordance with PR Notice 86-5 are required. Refer also to Chapter 12 of this manual for additional information on submitting data.

C. AMENDMENTS THAT DO NOT REQUIRE A FORMAL APPLICATION TO AMEND THE REGISTRATION OF YOUR PRODUCT

As provided in 40 CFR 152.46, there are certain changes or amendments that can be made to your registered product that do not require you to make a formal application to amend your registration, and are not subject to the data compensation provisions of FIFRA section 3(c)(1)(D). Refer also to PR Notice 88-6.

1. NOTIFICATIONS - Changes that you can make to your registered product that require Agency notification, but not approval.

As provided in 40 CFR section 152.46(a), there are certain changes, or amendments, you may make to your registration, provided that you notify the Agency that you have made the change before the product with the changes is distributed or sold. You need not obtain Agency approval of such changes, or amendments, and you may distribute or sell the product, as changed, as soon as you submit your notification of the change to the Agency.

You should note, however, that with each notification the Agency reserves the right to require that you submit a formal application for amended registration. If a formal application is required, the Agency will notify you and state the reasons for requiring a formal application for amended registration in lieu of your notification. If, as a result of our request you fail to submit a formal application for amended registration without good cause, the Agency may determine that the product is no longer in compliance with the requirements of FIFRA, and initiate cancellation proceeding under FIFRA section 6. In addition, you should be aware that your notification to the Agency is considered to be a report filed under FIFRA for the purposes of FIFRA section 12(a)(2)(M). In part, FIFRA section 12 (a)(2)(M) states that it is unlawful for you to distribute or sell your pesticide product, if you have knowingly falsified any part of any application for registration submitted to the Agency.

a. LABELING CHANGES

The following label revisions may be accomplished by notification. Notification of these changes must be accomplished by submission of an Application for Pesticide Registration/Amendment (EPA Form 8570-1) identifying the changes as a notification.

1) Addition or substitution of brand names. You may market your product under separate brand names provided you notify the Agency of the additional brand name(s) you intend to use. However, you should continue to refer to the product by its official name of record (i.e., the name of your product as it appears on the Notice of Registration, unless a product name change was approved by the Agency) in all correspondence with the Agency.

PITFALLS TO BE AVOIDED: The additional brand name must not be false or misleading. Examples of false or misleading names would be those that imply a safety claim, or imply use of the product in areas or on pests that are not approved on the product's label, or make excessive claims for control of pests. Also, the addition of brand names is not the same as supplemental registration by a different company under agreement with you (Refer to Chapter 5 - Supplemental Registration). You may not change the official product name of record without making a formal application to amend your registration and receiving approval prior to sale or distribution.

2) Bilingual text on labeling may be added under the notification provision unless such labeling is required by the Agency.

PITFALLS TO BE AVOIDED: It is your responsibility to make certain that the second language text will be an accurate translation of the English text on the accepted label.

3) The use of symbols in conjunction with label text. Symbols may not be substituted for label text, but may be used in conjunction with and in close proximity to existing explanatory label text.

4) You may combine labeling statements to remove redundancy, provided all required information is maintained.

5) Changes in warranty or warranty disclaimer statements.

6) Any other revision of label language consistent with 40 CFR Part 156, which involves no change in the ingredients statement, precautionary statements or directions for use.

IMPORTANT NOTE: The deletion of use patterns, pests, claims, or sites of use from your registered labeling can no longer be accomplished as a Notification under PR Notice 88-6. The 1988 revisions to FIFRA [section 6 (f)], require the Agency to publish in the Federal Register, notice of receipt of requests to amend a registration by deleting one or more uses from the product labeling, in order to provide the public with knowledge of the potential loss of a product or a specific use of a product. This provision of the 1988 amended FIFRA supercedes this part of PR Notice 88-6. Your application to delete uses from your labeling must be submitted as a formal application to amend your registration.

b. PRODUCT CHEMISTRY CHANGES

The following product chemistry changes may be accomplished by notification. Notification of these changes must be accomplished by submission of a revised Confidential Statement of Formula (EPA Form 8570-4), together with an Application for Pesticide Registration/Amendment Form (EPA Form 8570-1) identifying the change as a notification.

1) Active ingredient - You may change the source of an active ingredient in your product by notification to the Agency, provided that the alternate source(s) is an EPA-registered product. This applies whether the alternate source is purchased by you from another company, or is part of an integrated system [as defined in 40 CFR 158.153(g)] used by you.

If changing the source of the active ingredient would necessitate changing the nominal concentration [as defined in 40 CFR 158.153(i)] of an inert ingredient, an alternate formulation may result, and the action would be considered an amendment to add an alternate formulation. (See also Part b.2)b) of this Chapter for changes in non-proprietary inert ingredients that are notifications.)

PITFALLS TO BE AVOIDED: You may not change to an unregistered source of an active ingredient without submitting a formal application for amended registration, with the required product chemistry data, and obtaining EPA approval prior to sale and distribution.

You may not change the stated nominal concentration of any active ingredient without submitting a formal application for amended registration and obtaining EPA approval prior to sale or distribution.

You may not add, delete or substitute active ingredients by notification. The addition, deletion, or substitution of active ingredients constitutes a new formulation which requires a separate registration.

2) Inert ingredients

a) If for any reason, you have been required by the Agency to identify the source of an individual inert ingredient whose identity and composition are known to you, you may change the source of that inert ingredient by notification to the Agency.

If you have not been required by the Agency to identify the source of an individual inert ingredient, you may change sources freely, without notification to the Agency, provided the composition of the inert is not changed.

b) You may change the stated nominal concentration of any particular inert ingredient by notification to the Agency, provided that:

(1) the certified limits for that ingredient are not exceeded, and

(2) the composition of the ingredient is known to you.

PITFALLS TO BE AVOIDED: Note particularly that both of the above changes are limited to inert ingredients whose complete composition is known to you, such as specific solvents or common commodity diluents. Changes in

proprietary ingredients, which generally are composed of a mixture of ingredients and whose composition is not disclosed to you, may not be made by notification but must be accomplished by a formal application for an amendment. Since you do not know the composition of such inert ingredients, the Agency must review the composition of the new proprietary inert based on information supplied by its producer to determine its acceptability.

3) Starting materials for integrated system products

If you produce a product by an integrated system, [defined in 40 CFR 158.153(g)], you are required to supply the Agency with the sources of the starting materials for each such ingredient. If you propose to change the source of your starting materials, you may do so by notification to the Agency if the change will not result in:

a) a significant increase in the level of any existing impurity of toxicological concern (to exceed the upper certified limit of that impurity), or

b) the formation of any new impurity at a level greater than 0.1 percent by weight of the technical grade active ingredient.

4) Change in formulation process

You may modify a formulation process, [defined in 40 CFR 158.153(c)], i.e., a blending or dilution process involving no chemical reactions -- distinguished from a production process (described in 40 CFR 158.162) by notification, provided that the certified limits of the active and inert ingredients would not change as a result.

c. HOW TO SUBMIT NOTIFICATIONS

To submit a notification, you must use the Application for Registration/Amendment Form (EPA Form 8570-1), and write the word **"NOTIFICATION"** prominently in the explanation part of Section II. A separate application (EPA Form 8570-1) must be submitted for each product registration for which you are submitting a notification. A Confidential Statement of Formula

(EPA Form 8570-4) should accompany the notification application if changes in product composition are being made. If a labeling change is being made, the revised label text should be included as an attachment, including "before" and "after" text for comparison. On the "after" labeling, text which has been revised should be highlighted, preferably with a light colored felt tip marker, for easy comparison. A final printed label may be used for this purpose.

PITFALLS TO BE AVOIDED: If the notification that you submit is determined not to be a notification in accordance with 40 CFR section 152.46(a), your application will be returned and the Agency will require that it be resubmitted as a formal application for amended registration.

You are also responsible for ensuring that the labeling of any distributor or supplementally registered product you may have is in compliance with FIFRA. (Refer also to 40 CFR section 156.10.)

2. NON-NOTIFICATIONS - Changes to your registration that can be made without notifying the agency.

In accordance with 40 CFR section 152.46(b), the following changes can be made in the product's composition, labeling or packaging without notification to or approval by the Agency:

a. Correction of typographical or printing errors in the labeling.

b. Changes in the net contents necessary to accommodate changing package sizes or contents variability, provided such changes would not require changes in the use directions, or the requirement for child-resistant packaging under 40 CFR Part 157, or other Agency requirements pertaining to size.

c. The use of metric units in addition to standard U.S. units for net contents, dosages and other numeric expressions.

d. Routine changes in the name and address of the registrant on the label. A registrant is required to keep the Agency current as to his address of record; therefore an address change necessitates informing the Agency. However, such changes may be made on labeling as soon as they occur. A separate letter should be sent to the Registration Support Branch, notifying the Agency of the changed company name and/or address. See

Chapter 18 for the address.

PITFALLS TO BE AVOIDED: If you change your name and/or address, and fail to notify the Agency, and the Agency's good faith attempts to contact you are not successful, the Agency will issue in the Federal Register a notice of intent to cancel all of your products under FIFRA section 6(b).

e. Revision, addition, or deletion of non-mandatory label elements, such as the following:

1) Inclusion of the DOT hazard diamond when a shipping container is also the immediate container offered for sale,

2) Addition of State-required analysis of the fertilizer component of a pesticide/fertilizer product,

3) Inclusion of lot or batch codes, or other production identifiers, or

4) Date of manufacture or label approval.

5) Addition of State-required analysis of a wood-preservative product.

f. Redesign of label format that does not modify approved label text, consistent with the format requirements of 40 CFR section 156.10. These may include, among other things, changes in color, type size or style, use of space, configuration or placement of label elements.

PITFALLS TO BE AVOIDED: Changes in color or type size should not reduce the readability of the labeling text.

D. SUBMISSION OF FINAL PRINTED LABELING

When submitting final printed labeling for Notifications or Non-Notifications, you must use the Application for Registration/Amendment (EPA Form 8570-1). A separate application must be submitted for each product registration. Indicate the reason for the submission in the explanation part of Section II.

1. Notifications and non-notifications

The final printed labeling for all notifications must be submitted before the product, as revised, is sold or distributed. The final printed labeling may be submitted as the notification, thereby requiring only one submission.

The Agency expects that final printed labeling for a notification, or a formal amendment under FIFRA section 3, will include non-notification changes also. However, no submission of final printed labeling is required for changes that are only "non-notifications".

2. Labeling for amendments requiring a formal application to amend the registration

After approval of an amendment based upon draft labeling, final printed labeling must be submitted before the product, as revised, is sold or distributed. The Agency expects that this final printed labeling will include non-notification changes that may have been made after submission of the approved draft labeling, but prior to printing the final printed labeling for submission to the Agency.

E. INCOMPLETE APPLICATIONS

If you submit an incomplete application, the processing of your application will not begin until the deficiencies are corrected. Incomplete applications will be returned, with the deficiencies identified, for correction.

E. ENFORCEMENT

You are reminded that you are entirely responsible for the content and accuracy of labeling, and for compliance with labeling requirements, whether or not the Agency chooses to review and approve labeling changes. Any product that is misbranded under FIFRA section 2(q), or that is in violation of FIFRA section 12 may be the subject of an enforcement action.

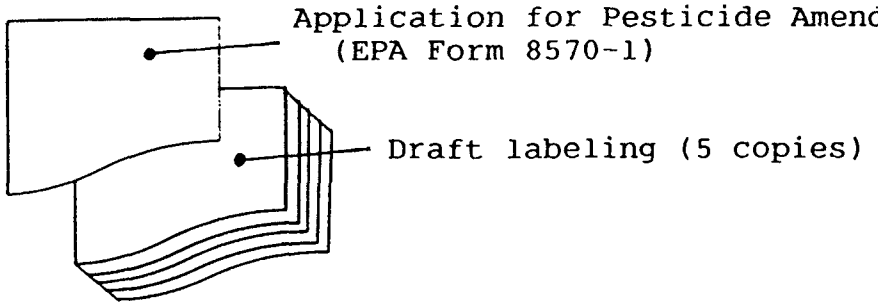
F. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions or require any additional information as to whether the changes you propose to make under this chapter are appropriate, contact the Product Manager assigned to the product in question. A listing of Product Managers may be found in Chapter 18.

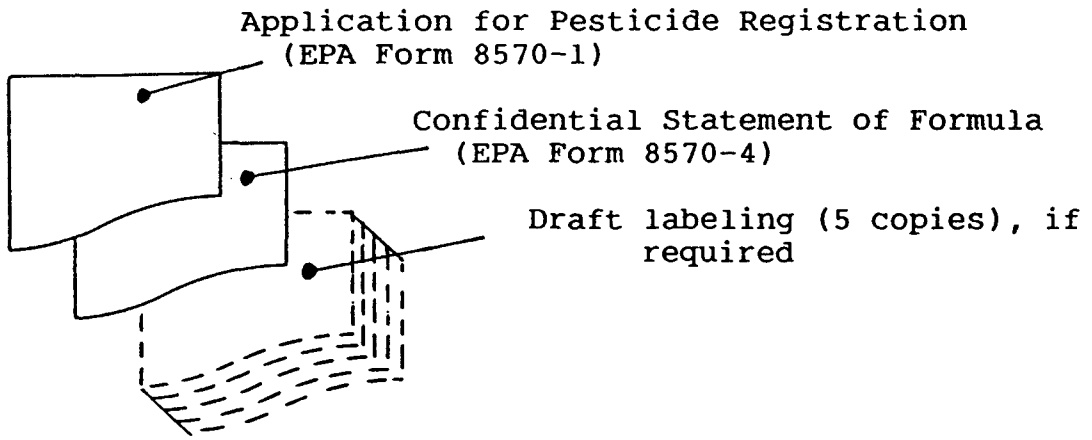
If you have any questions concerning the status of your "Me-too" Application for Amended Registration within the 45 day timeframe for the Agency's notifying you of whether the application is complete or has been rejected, you should contact the Front End Processing Staff. Refer to Chapter 18 for the telephone number.

TYPICAL ADMINISTRATIVE AMENDMENTS FOR A LABELING CHANGE OR A REVISION TO THE BASIC FORMULATION REQUIRE THE FOLLOWING DOCUMENTS

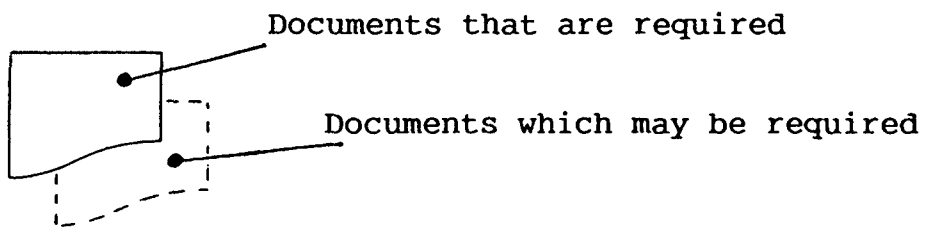
A. AMENDMENT FOR AN ADMINISTRATIVE LABELING CHANGE:
(DO NOT BIND TOGETHER)



B. AMENDMENT FOR A REVISION TO YOUR BASIC FORMULATION *:
(DO NOT BIND TOGETHER)



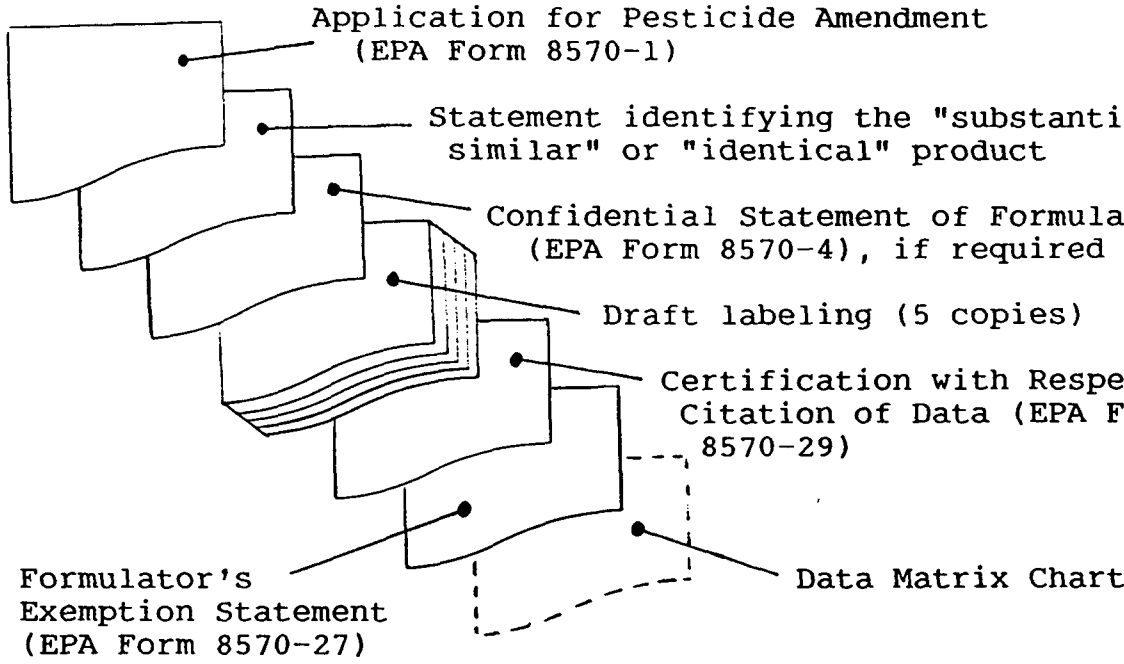
Legend



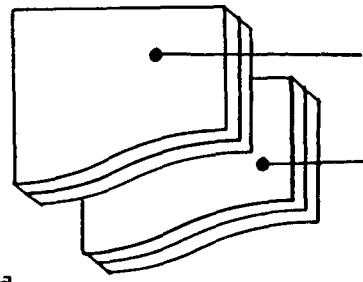
* Revisions to the basic formulation for antimicrobial and vertebrate pesticide products generally require supporting efficacy (product performance) data, and are not considered to be administrative amendments. (Refer to Appendix 4-2)

A TYPICAL "ME-TOO" APPLICATION TO AMEND THE REGISTRATION OF A REGISTERED PRODUCT, REQUIRES THE FOLLOWING DOCUMENTS

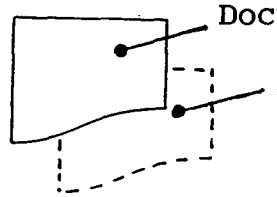
A. ADMINISTRATIVE PORTION OF APPLICATION: (DO NOT BIND TOGETHER)



B. DATA PORTION OF APPLICATION:



Legend



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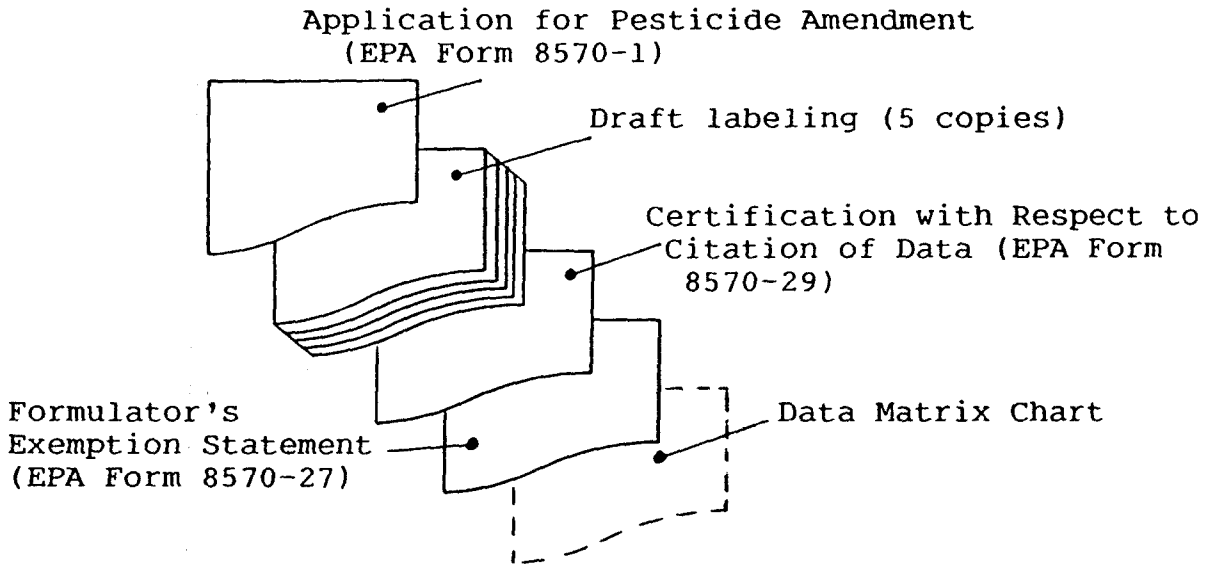
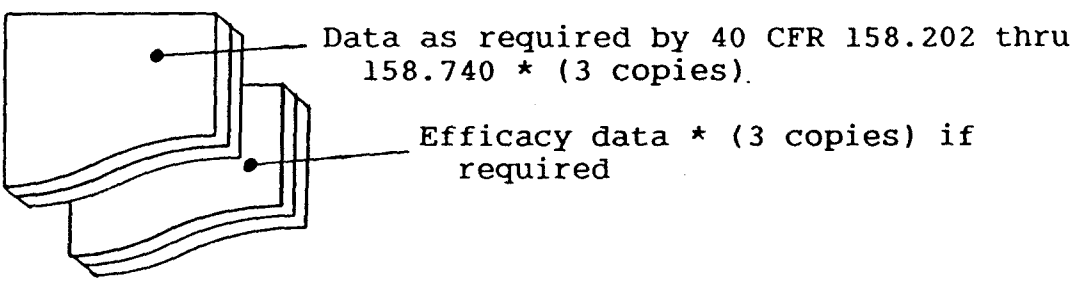
* Under the selective method of support these data requirements may be addressed by either submitting the actual data, or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

A TYPICAL APPLICATION TO AMEND THE REGISTRATION OF A REGISTERED PRODUCT TO ADD A NEW USE, REQUIRES THE FOLLOWING DOCUMENTS

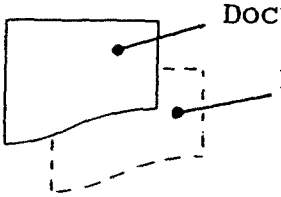
A. ADMINISTRATIVE PORTION OF APPLICATION: (DO NOT BIND TOGETHER)



B. DATA PORTION OF APPLICATION:



Legend



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* Under the selective method of support these data requirements may be addressed by either submitting the actual data, or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

CHAPTER 4 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 152 - Pesticide registration and classification procedures
   Part 156 - Labeling requirements for pesticides and devices
   Part 157 - Packaging requirements for pesticides and devices
   Part 158 - Data requirements for registration

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988.

   Section 2 - Definitions
   Section 3 - Registration of pesticides
   Section 6 - Administrative review; suspension
   Section 12 - Unlawful acts

3. PR Notice 86-4 - Submission of Incomplete Applications for Registration of Pesticides Under Section 3 of FIFRA, Issued by the Registration Division, Office of Pesticide Programs, EPA, April 15, 1986.

4. PR Notice 88-6 - Change in Registration Procedures - Agency Approval Not Required for Certain Amendments. Issued by the Registration Division, Office of Pesticide Programs, EPA, August 12, 1988.

CHAPTER 5 - HOW TO APPLY FOR SUPPLEMENTAL REGISTRATION OF A REGISTERED PESTICIDE

A. GENERAL INFORMATION

40 CFR 152.132 provides specific information on the supplemental distribution or supplemental registration of another registered pesticide. A supplemental registration is also referred to as a "distributor product."

40 CFR 152.132 states that a registrant may distribute or sell his registered product under another person's name and address instead of (or in addition to) his own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product." The distributor is considered an agent of the registrant and both the registrant and the distributor may be held liable for violations pertaining to the distributor product.

IMPORTANT NOTE: 1) Supplemental registrations are only an extension of a currently registered pesticide product. They are a duplication of the basic registration and must reflect any changes made to the basic registration. 2) If the basic registration is cancelled, the supplemental registration is automatically cancelled.

B. REQUIREMENTS FOR SUPPLEMENTAL DISTRIBUTION APPROVAL

Supplemental distribution is permitted upon notification to the Agency if all the following conditions are met:

1. The registrant of the product for which you wish to obtain supplemental registration has submitted to the Agency a statement (EPA Form 8570-5, Notice of Supplemental Registration of Distributor) signed by both the registrant of the basic registered product and you "the distributor." The following information is required on the application form:

    a. The name and address of the basic registrant and the registration number of the registered product;

    b. The name and address of the distributor, the distributor's company number, and the name of the product to be used on the product you plan to distribute. If you do not already have a company number assigned to your company, a company number will be assigned by the Agency upon written request, to the Registration Support Branch. Refer to Chapter 18 for the address.

IMPORTANT NOTE: You must have a company number prior to your notification to the Agency of supplemental distribution. (See section D of this Chapter.)

2. The product you intend to distribute must be produced, packaged, and labeled in a registered establishment operated by the same producer who produces, packages, and labels the basic registered product.

3. The product you wish to distribute may not be repackaged: it must remain in the basic registrant's or producer's original unopened container. However, you may repackage the product if you have a contract with the basic registrant to do so, and if your establishment is registered.

4. The labeling associated with the product you wish to distribute must be the same as that of the basic registered product, except that:

a. The product name of your product may be different from that of the basic registrant's, but it may not be misleading;

b. The name and address of your company may appear instead of that of the basic registrant's name and address;

c. The EPA registration number of the registered product must be followed by a hyphen, followed by your company's number; (For example, if the registration number of the basic registrant's product is EPA Reg. No. 999999-88888, and your company number is 777777, then your distributor number that would appear on your label would be EPA Reg. No. 999999-88888-777777);

d. The establishment number must be that of the final establishment at which the registered product was produced and/or packaged, (see Chapter 11 - How to Obtain an EPA Establishment Number); and,

e. Any specific claims on the basic registrant's label, such as the sites of application or pests to be controlled, may be deleted from your label provided that no changes are necessary in any of the

precautionary or other labeling of the basic product.

PITFALLS TO BE AVOIDED: You may not make additions to the basic registrants label (for example, add additional sites or pests), nor can you alter the precautionary labeling statements or directions for use.

C. WHERE TO SUBMIT AN APPLICATION FOR SUPPLEMENTAL REGISTRATION OF A DISTRIBUTOR PRODUCT

The registrant of the basic product should submit the completed application to:

Document Processing Desk (DIST)
Office of Pesticide Programs - H7504C
U.S. EPA
401 M St., S.W.
Washington, D.C. 20460

D. WHERE TO REQUEST A COMPANY NUMBER

If you do not already have an EPA assigned company number, submit your request in writing to the Registration Support Branch. Refer to Chapter 18 for the address.

CHAPTER 5 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

Part 152 - Pesticide registration and classification procedures

CHAPTER 6 - WHAT ARE THE DATA COMPENSATION REQUIREMENTS

A. GENERAL INFORMATION

By the late 1960's the amount of scientific data that was required to support the registration of a pesticide began to increase rapidly. Applicants and registrants who were required to generate these data, which were quite costly, asked Congress to provide protection for their investment, since by the time they obtained their registration or amended registration, most of or all of the pesticide's patent life had expired. Other registrants were then able to obtain a registration for the same type of product by relying on the data generated by the original data submitter, without having to share the burden of the cost of generating the data. In response to this concern, Congress amended the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) in 1972. Section 3(c)(1)(D) of the amended FIFRA placed data compensation obligations on those applicants for registration of a pesticide who would use the data submitted by another applicant or registrant in support of their own application for registration. In 1978, a second amendment to FIFRA granted "exclusive use" rights, for a 10 year period, to the original data submitter for certain data that were submitted to support the first registration of a product containing a new pesticide (active ingredient) or combination of active ingredients. An applicant must satisfy these data compensation requirements to obtain a registration, reregistration, or amend the registration of a registered product.

In order for the Agency to evaluate your application for registration or to amend the registration of a registered product, data must be submitted to support the application or amendment. The applicant is responsible for supplying the data necessary for the Agency to make this evaluation. You may address the data requirements in several ways. One method is to develop and submit all of the data necessary to support your application, a second method would be to rely on data that has been submitted to the Agency by other applicants in support of their applications for registration, and a third method would be to develop some of the data to support your application and to rely on other's data to complete your data requirements.

If you rely on data that were developed and submitted to the Agency in support of another persons application for registration, you must comply with the data compensation provisions of section 3(c)(1)(D) of FIFRA.

Section 3(c)(1)(D) established two categories of data.

1. One category of data pertains to that data submitted in support of the registration of a pesticide containing active

ingredients that were first registered after September 30, 1978, and to the data submitted with an application to add a new use to the original registration. These data are termed "exclusive use" data and the Agency may not consider these data to support your application for registration for a period of 10 years after the date of initial registration, unless you have written authorization from the original data submitter authorizing the Agency to use these data. After the 10 year "exclusive use" period has expired, you must still offer to compensate the data submitter for use of the data, but written authorization is no longer needed.

2. The second category of data pertains to data submitted after December 31, 1969, in support of an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain an existing registration, or for reregistration. The Agency may, without the permission of the original data submitter, consider such data to support an application by another applicant within the 15 year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter.

40 CFR Parts 152.80-99 and 152.116-119 provide detailed information on how you may comply with the data compensation provisions of FIFRA section 3(c)(1)(D).

B. <u>WHEN MUST YOU COMPLY WITH THE DATA COMPENSATION PROCEDURES?</u>

1. The data compensation procedures apply to the following:

a. Each application for registration of a new product, and

b. Each application for an amendment of a registration, except as noted below.

2. The data compensation procedures do not apply to the following types of registration applications:

a. Applications for experimental use permits, or

b. Applications to make the following amendments to existing registrations unless it is determined that scientific data would be necessary:

1) An increase or decrease in the percentage of one or more of the active ingredients or deliberately added inert ingredients in a product,

2) A revision of the identity or amount of impurities in the product,

3) The addition or deletion of one or more deliberately added inert ingredients,

4) The deletion of one or more active ingredients,

5) A change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under section 3 of FIFRA,

6) Deletion of approved uses from the label,

7) Redesign of the label format, which involve no substantive changes in the directions for use, claims, representations, or precautionary statements,

8) Change in the product name, or addition of an additional brand name,

9) Clarification of directions for use,

10) Corrections of typographical errors,

11) Changes in the registrant's name and address,

12) Adding or deleting supplemental registrants (distributors),

13) Changes in the package or container size,

14) Changes in warranty, warranty disclaimer, or liability limitation statements, or addition or deletion of such statements,

15) "Splitting" the label for the purpose of marketing the product in different geographic regions with appropriate labels, where each amended label will contain previously approved use instructions (and related label statements) appropriate to a particular geographic region, and

16) Any other type of amendment, if the Agency determines that scientific data would not be needed in order to approve the amendment.

C. <u>WHAT INFORMATION MUST YOU SUBMIT WITH YOUR APPLICATION FOR REGISTRATION OR AMENDED REGISTRATION</u> ?

1. **FORMULATOR'S EXEMPTION STATEMENT (EPA Form 8570-27)**

Under FIFRA section 3(c)(2)(D) you are excused (i.e., eligible for the formulator's exemption) from the requirement to submit or cite data pertaining to the safety of any ingredient, or mixture of ingredients, contained in your product if the source(s) of each of these ingredients is an EPA registered product, and you purchase each active ingredient from another producer.

a. Application for registration - If your product contains one or more active ingredients eligible for the formulator's exemption, you need not comply with the requirements of 40 CFR 152.90 through 152.96, with respect to any data requirements pertaining to the safety of these ingredients provided you submit a completed Formulator's Exemption Statement with your application for registration.

b. Application for amended registration - You are not required to submit a new Formulator's Exemption Statement if your current statement on file with the Agency is complete and accurate. However, if you change from a registered source of any active ingredient to an unregistered source, you are required to submit an application for amended registration, together with a revised Confidential Statement of Formula. If your new source of the ingredient is not registered, you are no longer eligible for the formulators's exemption for that ingredient.

2. Certification With Respect to Citation of Data **(EPA Form 8570-29)**

The Agency has developed this form to enable you to certify how you will comply with data compensation requirements under FIFRA section 3(c)(1)(D). In order to comply with the FIFRA section 3(c)(1)(D) data compensation requirements, you must:

a. Submit an acknowledgement of reliance on data in accordance with 40 CFR 152.86(d) you must include an acknowledgement that for purposes of FIFRA section 3(c)(1)(D) your application relies on the following data:

1) All data submitted with or specifically cited in your application, and

2) Each item of data in the Agency's files which:

(a) concerns the properties or effects of

your product, of any product which is identical or substantially similar to your product, or of one or more of the active ingredients in your product, and

(b) Is one of the types of data the Agency would require to be submitted if you sought initial registration under FIFRA section 3(c)(5) of a substantially similar or identical product, at the time the Agency approves your application for registration.

Item 1 on the Certification with Respect to Citation of Data form (EPA Form 8570-29) satisfies this acknowledgement requirement.

b. <u>Exclusive use data certification</u> - Exclusive use data pertains to those data that were submitted to the Agency in support of the registration of a new active ingredient, a new combination of active ingredients, or an application to amend the original registration to add a new use, after September 30, 1978 for a period of 10 years after the registration. In order for the Agency to consider these data in support of your application for registration or amendment, you must in accordance with 40 CFR 152.86(a) certify to the Agency that you have obtained from each data submitter listed on the Data Submitters List, and/or the bibliography of an applicable Registration Standard, as an exclusive use data submitter written authorization which contains at least the following information:

1) Identification that you are the applicant to whom the authorization is granted,

2) Written authorization has been granted to you by the data submitter to allow the Agency to use all applicable data to satisfy the data requirements for the application in question, and

3) The signature and title of the original data submitter or his authorized representative and the date of authorization.

If the Agency identifies any exclusive use data submitter not on the Data Submitters List or in the bibliography of a published Registration Standard, you will also be required to obtain written authorization from that person.

(The Data Submitters List is a listing of data submitters listed by chemical code numbers. Refer to

Chapter 16 of this manual for information of how to obtain the Data Submitters List. A source of published Registration Standards is also listed in Chapter 16.)

Item 2 on the Certification with Respect to Citation of Data form (EPA Form 8570-29) satisfies this exclusive use certification requirement.

IMPORTANT NOTE: You must submit with your application a copy of the letter of authorization from the exclusive use data submitter authorizing use of these data by the Agency, to support your application for registration.

c) Data other than exclusive use data - You must, in accordance with 40 CFR 152.86(b), certify to the Agency that with respect to each other data submitter on the Data Submitters List, and/or the bibliography of an applicable Registration Standard [40 CFR 152.90(a)(1)], for the active ingredient in question:

1) You have obtained from that person written authorization containing the information identified above under "Exclusive use data" or,

2) You have furnished to that person:

(a) A notification of your intent to apply for registration, including the name and a list of the active ingredients in the proposed product,

(b) An offer to pay the person compensation, to the extent required by FIFRA section 3(c)(1)(D), for any data required to support your application,

(c) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the data, and

(d) Your name, address, and telephone number.

Item 3 on the Certification with Respect to Certification of Data form (EPA Form 8570-29) provides methods for satisfying these requirements.

d. Methods for complying with the data compensation requirements of FIFRA section 3(c)(1)(D) - There are two methods of complying with the data compensation requirements, these are 1) the "cite-all" method and 2)

the "selective" method of support. These two methods are described below. In addition, a table (Appendix 6-1 which follows section E of this Chapter) comparing these methods is also provided.

1) THE CITE-ALL METHOD OF SUPPORT - You may comply with the data compensation requirements under the cite-all method (40 CFR 152.86) for your application to register a new product or to amend a product you already have registered by:

(a) citing all pertinent data in the Agency's files involving "exclusive use" data only with the written permission of the exclusive use data submitter, or

(b) citing all pertinent data in the Agency's files, no exclusive use data involved, with permission of the original data submitter or by offering to pay compensation for use of the data in accordance with FIFRA section 3(c)(1)(D) and 3(c)(2)(D), and

(c) submitting to the Agency a General offer to pay statement, in accordance with 40 CFR 152.90(c), in which you state your offer and agree to pay compensation to other data submitters to the extent required by FIFRA section 3(c)(1)(D).

If you check the first box in item 3 of the Certification with Respect to Citation of Data form (EPA Form 8570-29), and sign the General Offer to Pay statement at the bottom of the form, you are certifying to the Agency that you have complied with these requirements.

IMPORTANT NOTE: In accordance with 40 CFR 158.99, an original data submitter may petition the Agency to deny or cancel your registration if he has submitted a study that he claims satisfies a data requirement and for which you have either failed to receive authorization to use, or have not made a proper offer to pay compensation.

2) THE SELECTIVE METHOD OF SUPPORT - You may comply with the data compensation requirements under the selective method by listing the specific data requirements that apply to your product, its active ingredients, and use patterns, and demonstrating compliance with the data requirements by either submitting the actual data,

or citing individual studies, or by demonstrating that no study has been previously submitted to the Agency (a data gap). Refer to 40 CFR 152.90 for a detailed discussion of the selective method, and sections 152.91 through 152.96 for specific procedures for citing or submitting a study or for demonstrating a data gap.

If you chose the Selective Method of complying with the data compensation requirements you must:

(a) submit the Certification with Respect to Citation of Data form (EPA Form 8570-29) on which you have checked the second box in item 3, indicating you have chosen the Selective Method, and

(1) sign the signature block immediately below, or

(2) if you are using the cite all option under the Selective Method to address specific data requirements [see b)(2)(iii) and (iv) below], sign the last signature block on the form.

b) submit a data matrix chart which addresses the items listed below. Refer to Appendix 6-2, which follows section E. of this Chapter, for a sample data matrix format and instructions on how to complete it.

(1) List of data requirements applicable to your product [see 40 CFR 152.90(a)]. The list must be based on the data guidelines in 40 CFR Part 158 - Data Requirements for Registration, or a Registration Standard for the active ingredient(s) in your product, if applicable. Refer to Chapter 16 of this manual for a source of the Registration Standards that have been issued.

(2) How you intend to satisfy each of the data requirements identified on the data matrix chart. There are several ways to satisfy these data requirements.

(i) Reference data originally submitted to the Agency by you, the applicant [See 40 CFR 152.93(a)].

(ii) Reference data previously submitted to the Agency by someone other than you and obtain their permission to cite the data. You must certify that you have obtained written authorization from the original data submitter. For an exclusive use procedures outlined in section C.2.a.1), must be followed. Refer also to 40 CFR 152.93(b)(1).

(iii) Reference data previously submitted to the Agency by someone other then you (that is not an exclusive use study) and make a proper offer to pay to such person (40 CFR 152.93(b)(2).

(iv) Reference all data in the Agency's files pertinent to the specific data requirement and make a proper offer to pay to all data submitters on the Data Submitter's List for those specific data (40 CFR 152.90).

(v) Submit data not previously submitted or submit data from the public literature (40 CFR 152.94).

(vi) Document waivers of data previously allowed by the Agency (40 CFR 152.91). Refer to Chapter 15 of this manual for information on how to obtain information on chemicals for which data waivers have been granted.

(vii) Demonstrate that a data gap(s) exist. Submit a completed EPA Form 8570-28, Certification of Compliance with Data Gap Procedures (see 40 CFR 152.96).

IMPORTANT NOTE: The Data Tables and bibliography in an applicable Registration Standard can be very helpful in developing a data matrix.

D. QUESTIONS AND ANSWERS

The following questions are those most frequently asked by interested persons regarding data compensation procedures:

1. Question: What is a "me-too product"?

Answer: The term "me-too product" refers to a pesticide product that is identical or substantially similar to another pesticide product that is currently registered by EPA.

The term "identical product" means a product, when compared to a currently registered product:

a) Contains the same active and intentionally added inert ingredients, and in the case of a technical grade product, the same impurities, each ingredient being the same percentage, and

b) Includes identical or substantially similar uses.

The term "substantially similar product" for a non-technical grade product, e.g., an end-use product, means a product when compared to a currently registered product:

a) Contains the same active ingredients,

b) The percentages of the active ingredients and the intentionally added inerts and their percentages may vary only to the extent that it is reasonable to conclude that the hazards are not different from those associated with the registered product, and

c) Includes identical or substantially similar uses.

The term "substantially similar product" for a technical grade product, e.g., a manufacturing-use or a formulating-use only product, means a product when compared to a currently registered product:

a) Contains the same active ingredient,

b) The percentage of the active ingredient and the impurities and their percentages may vary only to the extent that it can be reasonably established that the hazards are

not different from those associated with the registered product, and

c) Includes identical or substantially similar uses.

2. **Question**: When applying for a registration of a "me-too product" under the Cite-all Method of Support, must I submit additional information other than 1) a completed and signed Application for Registration form (EPA Form 8570-1), 2) a completed and signed Confidential Statement of Formula (EPA Form 8570- 4),3) proposed labeling, and 4) a completed and signed Certification With Respect to Citation of Data (EPA Form 8570-29)?

Answer: Yes, routinely more information is required. First, you must tell us the name and EPA registration number of the currently registered product that you believe your proposed product is identical with or substantially similar to. Second, since product chemistry data are specific to each formulation, you must submit the product chemistry required in 40 CFR section 158.20 unless you are certain that your proposed formulation is identical to the registered product you have cited to support your "me-too" claim. Please note however, that short of extensive chemical analysis, there are only a few ways to be certain that your proposed formulation is identical to the registered product you cite. These ways include situations where the cited product's label actually identifies each active and inert ingredient and associated percentages, or you produce or repackage the cited product.

An Application for Amended Registration for an amendment involving data requirements would be a situation analogous to an application for registration of an identical product.

If, during our review of your application, we find that the product you have cited as the "me-too" is not at least substantially similar to your proposed product, we will inform you that you are not eligible for the Cite-All Method of Support and will have to either identify another product as the "me- too" or proceed under the Selective Method of Support. If you chose to proceed under the Selective Method of Support you may have to actually generate data to support your application for registration.

If you are eligible for the formulator's exemption, usually this will involve a requirement to submit

product chemistry and acute toxicology data. Occasionally, efficacy data may also be required. In those cases where new chemicals or changed use patterns are involved, extensive data requirements may be imposed.

3. Question: When I submit an application for a "me-too" amendment to the registration of my product, and data is required to support the proposed amendment, under the data compensation requirements do I have to again offer to pay compensation for all of the data necessary to support the registration of the entire product, or only offer to pay compensation for the data necessary to support the amendment?

Answer: Your entire product is subject to the data compensation provisions including your amendment. There are several reasons for this requirement. Data may have been submitted to the Agency to fill data gaps since you first offered to pay compensation with your initial application for registration for your product, or when it was last amended. Also, some of the data initially used to support your registration may have been determined to be unacceptable and may have been replaced. As a result, if additional data are required to support the proposed amendment to your registration, your entire product including the proposed amendment is subject to the data compensation requirements of section 3(c)(1)(D) of FIFRA, within the limits prescribed by your eligibility under the formulator's exemption. You may address the data compensation requirements as indicated below.

Cite-all Method of Support: If you wish to use the cite-all method of support, you must make offers to pay to all of the data submitters listed in the bibliography of the most recent Registration Standard issued by EPA (if any) and in addition write those data submitters listed on the Data Submitter's List who have claimed product specific types of data on the Data Submitter's List. If EPA has not issued a Registration Standard for one or more of the active ingredients contained in your product, you must write all of the data submitters on the Data Submitters List for each of the active ingredients contained in your product. The offer to pay must identify your total product as well as your amendment.

Selective Method of Support: You must submit a data matrix chart with appropriate information as to how each data requirement is to be satisfied for your total product as well as for the amendment, taking into consideration the most up to date information, i.e.,

the data tables and bibliography in the most recent registration standard.

4. Question: I have obtained letters from companies on the Data Submitters List who say that they do not want any compensation for their data. May I use these letters as if they were giving me permission to use their data?

Answer: You may not. The data submitter must explicitly grant permission and cannot be presumed to do so.

5. Question: I have in my files a number of letters from data submitters that give me permission to use their data to support my application for registration. May I use these letters to support my application without getting new authorization?

Answer: Yes, provided those letters are written to clearly state that they cover your present application either specifically or generically and they also give permission to use the relevant data to support your application for registration. If this is the case, you may certify to the Agency that you have received written permission to cite the data.

6. Question: If I have a product that contains multiple active ingredients, some of which are purchased from registered sources and others that are not, may I claim a formulator's exemption for those active ingredients that are purchased from registered sources?

Answer: Yes, you may. Submit a properly completed Formulator's Exemption Statement (EPA Form 8570-27).

7. Question: May I use an unregistered source of an active ingredient to formulate my product.

Answer: Administrative complications and data requirements are reduced if your source of the active ingredient(s) is registered. As you may know, normally it is illegal under FIFRA to sell or distribute an unregistered pesticide, which also pertains to unregistered sources of the active ingredient. However, in accordance with 40 CFR 152.30, you may use an unregistered source under certain circumstances. An unregistered source may be used provided the source is:

a. Reformulated into a registered product within the same registered establishment.

b. Transferred from one EPA registered establishment to another EPA registered establishment, both of which are owned or leased by the same company.

c. Transferred between two EPA registered establishments not operated by the same producer if:

1) the transfer is only for the purpose of further formulation, packaging or labeling into a product that is registered, and

2) each active ingredient in the pesticide, at the time of transfer, is present as a result of incorporation into the pesticide of either:

i) a registered product; or

ii) a pesticide that is produced by the registrant of the final product; and

3) the product as transferred is labeled in accordance with 40 CFR 156.

d. Transferred by a producer who does not have actual or constructive knowledge that his product is intended to be used or is used for pesticidal purposes (40 CFR 152.15(c).

Should you decide to use an unregistered source of an active ingredient, you are responsible for providing any information or data the Agency would need to accept that new source. If the unregistered source is to replace the original registered source of an active ingredient in your currently registered product, it may not be added to your product until the Agency has approved the new unregistered source. Finally, you should understand that the use of an unregistered source of an active ingredient will cause you to be ineligible for the formulator's exemption provision under FIFRA section 3(c)(2)(D), at least for the active ingredient(s) from the unregistered source.

8. Question: May I use both the Selective and Cite-All Methods of Support for one product application, if I have more than one active ingredient in my product?

Answer: Yes, you may.

9. Question: If I use the Cite-All Method of Support, do I also have to submit a list of data requirements and references?

Answer: No, the cite-all method requires no accompanying list (or data matrix) such as that required for the selective method.

10. Question: If I write to a company on the Data Submitters' List via certified mail and my letter is returned with an indication that the data submitter's company cannot be located,

how much more must I do to find the company?

Answer: We generally believe that if you have obtained a certified or registered mail statement that there is no known address for that company, you have made a reasonable effort to notify that company. Of course, you may pursue the matter further if you wish. Indicate in your application what you have done to locate the data submitter. Should a data submitter wish to challenge a registration in the future because of not being notified, 40 CFR 152.99 provides for that situation.

11. Question: Who has to cite or submit residue chemistry data under the Selective Method of Support?

Answer: Only applicants who do not qualify for the formulator's exemption under FIFRA section 3(c)(2)(D) must reference and satisfy residue chemistry data requirements. These same applicants must obtain permission or make an offer to pay to use these data, if they choose the Cite-All Method of Support.

There are other cases when residue chemistry data may be required, for example an application for registration of an end-use product in a substantially different form (e.g., an emulsifiable concentrate vs. a wettable powder) from that which is currently registered, may be required to submit additional residue chemistry data even if they are eligible for the formulator's exemption.

12. Question: If I am eligible for the formulator's exemption do I have to submit anything more than the Formulator's Exemption Statement (EPA Form 8570- 27) and the Confidential Statement of Formula (EPA Form 8570-4)?

Answer: Yes, in addition to those forms, you must submit information required for either the Selective or the Cite-All Method of Support. Usually the data required for those eligible for the formulator's exemption are the product specific product chemistry and product specific acute toxicology data.

13. Question: Do I have to get permission from, or make an offer to pay, to the person who generated the data from the public literature that I have cited or submitted?

Answer: No.

14. Question: If I am the first applicant/registrant to cite or submit a public literature data source, do I acquire data submitter's rights?

Answer: No, applicants do not need permission to cite public literature. No one acquires "data submitters' rights" from public literature submissions.

15. **Question**: If I submit an application in which I declare one or more data gaps under the Selective Method of Support, without having waited for the 60 day period to elapse to receive a reply from all on the Data Submitters' List, will the Product Manager process my application?

Answer: Yes. However, the Product Manager will not approve your application until you have certified that you have waited the required 60 days and no one has disputed your assertion that one or more data gaps exist as you have declared in your application. You may wish to await the 60 day period and certification before submitting your application to the Agency.

E. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions concerning the data compensation procedures and whether they apply to your application, please contact the appropriate Product Manager for your pesticide. Refer to Chapter 18 of this manual for a listing of the various Product Managers and the type of products for which they are responsible.

COMPARISON OF THE CITE-ALL AND SELECTIVE METHODS OF SUPPORT

If an applicant chooses this method ----------> / Can he satisfy a data requirement by this means? ↓		Cite-all	Selective
1. Requesting and obtaining a waiver		No 1/	Yes
2. Submission of a new study		No 1/	Yes
3. Citation of his own study		No 1/	Yes
4. Citation of another person's exclusive use study	a. With permission	No	Yes
	b. With offer to pay	No	No
5. Citation of another person's study that is not exclusive use	a. With permission	No	Yes
	b. With offer to pay	No	Yes
6. Citation of all pertinent studies in Agency files - exclusive use studies involved	a. With permission	Yes	Yes
	b. With offer to pay	No	No
7. Citation of all pertinent studies in Agency files - no exclusive use studies involved	a. With permission	Yes	Yes
	b. With offer to pay	Yes	Yes
8. Citation of public literature study		No	Yes
9. Documentation of a data gap		No	Yes

1/ It should be noted that applicants under the cite-all method will not be precluded from obtaining waivers, or submitting or

citing their own studies, but that taking these actions would affect neither their obligation to cite all data, nor the procedures that require offers to pay or in certain cases, permission of each previous data submitter. Therefore, as the table indicates, none of the actions would suffice in and of itself, to demonstrate compliance under the cite-all method. Requesting a waiver would be of concern primarily to those who choose the selective method of demonstrating compliance. An applicant under the cite-all method might, nonetheless, wish to establish that a data requirement has been waived in order to reduce the amount of data needed for an incremental risk assessment, or to limit his obligation to pay compensation (as contrasted to his obligation to tender offers to pay compensation.

Similarly, the submission of a new study or the citation of a previously submitted study will be of most interest to applicants under the selective method, which involves meeting individual data requirements rather than referencing all previously submitted data. While no applicant is precluded from submitting his own data, under the cite-all method submission of a new study or citation of an old study would be in addition to the citation of all other relevant data in EPA's files. Under the selective method, however, the applicant may submit his own study to satisfy a data requirement and thereby can avoid the need to offer to pay compensation for other studies in EPA's files that satisfy the same data requirement.

SAMPLE MATRIX FORMAT FOR DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

The following matrix is a sample of an acceptable matrix format that can be used to satisfy the data requirement in 40 CFR 152.90(a). Applicants for registration using the selective method must prepare a list of the data requirements (refer to 40 CFR 158 - Data Requirements for Registration) for their product and indicate how those requirements are being satisfied. You may use this sample matrix or you may develop a similar matrix to satisfy this requirement.

The sample matrix has been developed for a typical product where the applicant qualifies for the formulator's exemption. If you are eligible for the formulator's exemption you may use the data requirements shown on this sample matrix as a guide for determining the requirements for your products.

If you are not eligible for the formulator's exemption you may use the single page blank matrix as a guide to develop a list of the data requirements for your products.

HOW TO COMPLETE THE SAMPLE MATRIX

Block 1. Insert the name of your product.

Block 2. Insert the EPA registration number or file symbol (if known) as appropriate, for your product.

Block 3. Indicate whether you are eligible for the Formulator's Exemption by checking either yes or no.

Block 4. Fill in the page number for that page as well as the total number of pages in your listing.

Block 5. Fill in your company's name and address.

Block 6. Insert the date of your application for registration or amended registration.

Block 7. List the active ingredient(s) in your product. If you have more than one active ingredient in your product and one or more do not qualify for the formulator's exemption, you must fill out a separate list for each active ingredient that does not qualify and one for all of the rest of the qualifying active ingredients. If all of the active ingredients in your product qualify for the formulator's exemption, you need complete only one set of forms and list all of the active ingredients in this box.

Block 8a. Indicate the Part 158 and guideline reference number for each data requirement applicable to your product. If a Registration Standard has been issued, the data requirements and their guideline reference numbers are listed in the Standard.

Block 8b. Show the name of the test, e.g., Acute oral LD-50 - rat. Applicants who do not qualify for the formulator's exemption must cite or submit the acute toxicology battery of tests for both the active ingredient and the product as formulated (if they are different). Those who qualify for the formulator's exemption need cite or submit tests only for the product as formulated.

Block 9a. Use this block if you, the applicant, are relying on your own data to satisfy the requirement. Indicate whether you are citing or submitting the data. See "CITING DATA" entry below.

Block 9b. Indicate the date you originally submitted the data to EPA.

Block 9c. Use this block if you are relying on data submitted by another company or individual. Insert the name of the company or individual who has rights to the data.

Block 9d. If you cite data submitted by another company or individual you must have his permission to use the data to support your application or you must have made a proper offer to pay to that person. If you are certifying to having received permission, you should write in "P" in this block. If you are certifying to having made an offer to pay, write in "OTP" in this block.

IMPORTANT NOTE: If the data you are citing are exclusive use data, you must have permission to cite the data. You may not comply by making an offer to pay.

Block 9e. If you are relying on public literature to support your application check this block. If you check this block you must submit a copy of the data on which you rely.

Block 9f. Check this block, if you believe that either (1) according to Part 158 and the guidelines, the data requirement is not applicable (NA) or, (2) the data requirement has been previously waived by EPA for similar products, or (3) you can satisfy the data requirements by some other means not provided on the sample matrix. You must attach an explanation sheet to

this list which provides the rationale for using this block.

Block 10. Insert the MRID (EPA's Master Record Identification) number, EPA accession number, or other EPA identification number.

CITING DATA

Applicants must indicate whether data submitted with the application have or have not previously been provided to the Agency by the applicant. Previously submitted data may not be resubmitted. Rather, such data should be cited and the following information given:

a. The title of the study, author(s), data completed, test substance, identity of the laboratory performing the study (if any).

b. EPA's Master Record Identification (MRID) Number or EPA's data catalogue accession number (if known).

c. The identity of the original submitter.

d. The date on which the cited data were originally submitted to the Agency.

e. One of the following if the data were not originally submitted by you:

1) Evidence of transfer of ownership of rights to the data to you.

2) Certification of written permission from the original submitter to cite the data.

3) Certification that a proper offer to pay has been made to the original data submitter. (One certification suffices for all offers to pay.)

SAMPLE MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME:	2. EPA REG.NO./FILE SYMBOL:	3. FORMULATOR'S EXEMPTION SELECTED: YES_____ NO_____	4. PAGE 1 OF ___
5. APPLICANT'S (COMPANY) NAME AND ADDRESS:	6. APPLICATION FOR REGISTRATION DATED: _____ MONTH DAY YEAR	7. NAME OF ACTIVE INGREDIENT(S):	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	PRODUCT CHEMISTRY							
61-1	Identity of ingredients							
61-2	Statement of composition							
61-3	Discussion of formation of ingredients							
62-1	Preliminary analysis							
62-2	Certification of limits							
62-3	Analytical method for enforcement limits							
63-2	Color							
63-3	Physical State							
63-4	Odor							

SAMPLE MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME:	2. EPA REG.NO./FILE SYMBOL:	3. FORMULATOR'S EXEMPTION SELECTED: YES_____ NO_____	4. PAGE 2 OF ___
5. APPLICANT'S (COMPANY) NAME AND ADDRESS:	6. APPLICATION FOR REGISTRATION DATED: MONTH DAY YEAR	7. NAME OF ACTIVE INGREDIENT(S):	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	PRODUCT CHEMISTRY (continued)							
63-5	Melting point							
63-6	Boiling point							
63-7	Density, bulk-density, or specific gravity							
63-8	Solubility							
63-9	Vapor Pressure							
63-10	Dissociation constant							
63-11	Octanol/water partition coefficient							
63-12	pH							
63-13	Stability							
63-14	Oxidizing/reducing reaction							

SAMPLE MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME:	2. EPA REG.NO./FILE SYMBOL:	3. FORMULATOR'S EXEMPTION SELECTED: YES_____ NO_____	4. PAGE 3 OF ___
5. APPLICANT'S (COMPANY) NAME AND ADDRESS:	6. APPLICATION FOR REGISTRATION DATED: _____ MONTH DAY YEAR	7. NAME OF ACTIVE INGREDIENT(S):	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	PRODUCT CHEMISTRY (continued)							
63-15	Flammability							
63-16	Explodability							
63-17	Storage stability							
63-18	Viscosity							
63-19	Miscibility							
63-20	Corrosion characteristics							
63-21	Dielectric breakdown voltage							
Section 158.340	TOXICOLOGY							
81-1	Acute oral toxicity, rat							
81-2	Acute dermal toxicity, rabbit							

SAMPLE MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME:	2. EPA REG.NO./FILE SYMBOL:	3. FORMULATOR'S EXEMPTION SELECTED: YES_____ NO_____	4. PAGE 4 OF ___
5. APPLICANT'S (COMPANY) NAME AND ADDRESS:	6. APPLICATION FOR REGISTRATION DATED: MONTH DAY YEAR	7. NAME OF ACTIVE INGREDIENT(S):	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	TOXICOLOGY (continued)							
81-3	Acute inhalation, toxicity, rat							
81-4	Primary eye irritation, rabbit							
81-5	Primary dermal irritation							
81-6	Dermal sensitization							

SAMPLE MATRIX FORMAT - DATA REQUIREMENT LISTING FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME:	2. EPA REG.NO./FILE SYMBOL:	3. FORMULATOR'S EXEMPTION SELECTED: YES_____ NO_____	4. PAGE 5 OF ___
5. APPLICANT'S (COMPANY) NAME AND ADDRESS:	6. APPLICATION FOR REGISTRATION DATED: MONTH DAY YEAR	7. NAME OF ACTIVE INGREDIENT(S):	

8. 40 CFR Part 158 - DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						
8a. Guideline Reference Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permission (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.								

CHAPTER 6 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 152 - Pesticide registration and classification procedures
   Part 158 - Data requirements for registration

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

   Section 3 - Registration of pesticides

3. Data Submitters' List

4. Listing of Registration Standards

5. Listing of Chemicals for Which Data Waivers Have Been Granted

CHAPTER 7 - HOW TO SUBMIT AN APPLICATION TO REQUEST A PETITION FOR A TOLERANCE (PERMANENT OR TEMPORARY), OR AN EXEMPTION FROM THE REQUIREMENT OF A TOLERANCE

A. GENERAL INFORMATION

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Environmental Protection Agency (EPA) is responsible for regulating the amount of pesticide residues that can remain in or on food or feed commodities as the result of pesticide application. A tolerance is the legal maximum residue concentration of a pesticide chemical allowed in food or feed. By establishing tolerances at safe levels EPA minimizes concerns about residues in our foods. It should be noted that a tolerance is not necessarily the maximum safe level, since tolerances are set no higher than necessary. If residues of a pesticide exceed the established tolerance, or no tolerance has been established, the crop may be considered adulterated and may be seized by the Food and Drug Administration, the United States Department of Agriculture, or a state enforcement agency.

Tolerances are set under the authority of the FFDCA. FFDCA Section 408 applies to residues on/in raw agricultural commodities (RACs) and Section 409 applies to processed food or feed commodities. FFDCA Section 409 includes the so-called Delaney Clause. EPA's position concerning the Delaney Clause is that the FFDCA section 409's so-called Delaney Clause - which, read literally, purports to bar absolutely the issuance of a food additive regulation for a food additive that has been found to induce cancer in test animals - is subject to a de minimis exception where the human dietary risk from residues of the pesticide is at most negligible. The Agency's policy regarding rulemaking under FFDCA section 409 is set forth in the Federal Register Notice of October 19, 1988 (53 FR 41104).

40 CFR Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities, provides comprehensive information on definitions and interpretative regulations, procedures for filing petitions, temporary tolerances, exemptions from the requirement of a tolerance, residue data, fee requirements, specific tolerances and exemptions which have been established for raw agricultural commodities.

40 CFR Part 185 - Tolerances for Pesticides in Food Administered by the EPA, provides a listing of tolerances established for residues of pesticides in foods (food additive tolerances) resulting from pesticide application during the growing process, direct application to the end food product, or indirect application to the end food product by treating the processing or storage area. (Prior to June 29, 1988, 40 CFR Part 185 was designated 21 CFR Part 193.)

40 CFR Part 186 - Tolerances for Pesticides in Animal Feeds Administered by the EPA, provides a listing of tolerances established for residues of pesticides in animal feeds, which may be present as a result of application of the pesticide to growing crops which may also be used for animal feed. (Prior to June 29, 1988, 40 CFR Part 186 was designated 21 CFR Part 561.)

B. WHEN ARE PETITIONS FOR TOLERANCES REQUIRED?

1. Applications for registration or amended registration - Before a pesticide can be registered for use on a food or feed crop or for use in a food processing or storage area under FIFRA section 3, a tolerance or the exemption from the requirement of a tolerance must be established. In addition, if you propose to amend a currently registered use, for example, by increasing the dosage rates or frequency of application, which might result in residues higher than the established tolerance, a petition to amend the established tolerance may be required.

2. Experimental Use Permits - An application for an experimental use permit proposing use on a food or feed crop or for the proposed experimental use in food processing or storage areas, requires a temporary tolerance for the proposed use if no tolerances are currently established, or if the proposed experimental use might result in residues higher than the established tolerance. The petition for the temporary tolerance must be submitted with the application for the experimental use permit.

C. PROCEDURES FOR FILING A PETITION

1. General - Procedures for filing a petition requesting the establishment of a tolerance, a temporary tolerance, or an exemption from the requirement of a tolerance or a temporary exemption from a tolerance, are described in detail in 40 CFR section 180.7. Additional information concerning requests for temporary tolerances, or a temporary exemption from a tolerance, in conjunction with an experimental use permit can be found in 40 CFR 180.31. There is no application form for petitions. You must submit your request in the format provided in 40 CFR section 180.7.

2. Completeness of Application - The petition must include the following information in clearly designated sections as follows:

a. Section A - The name, chemical identity and composition of the pesticide chemical. To assess the composition of the pesticide, information is required on the manufacturing process, chemical analysis of the active ingredient, certified limits for ingredients of a product, and analytical methods to determine the composition of the pesticide. You should also refer to 40 CFR Parts 158.150 - 190, Product Chemistry Data Requirements and the Pesticide Assessment Guidelines, Subdivision D - Product Chemistry for more detailed information.

NOTE: The Agency evaluates the composition data to determine whether impurities could constitute a significant component of the residues in food and feed commodities. Impurities that arise in the manufacture of pesticides can become a residue problem, if they are not identified before tolerances are established. Dioxins and nitrosamines are the best known examples of significant impurities. If impurities are at levels that may lead to toxicologically significant residues in crops, then tolerances would be established for them, as well as for the active ingredient. Once problem impurities are identified, adjustments to the manufacturing process or additional purification steps may be necessary to reduce the impurities to a safe level.

b. Section B - The amount, frequency, and time of application of the pesticide chemical. This refers to the directions for use, dosage rates, number of applications and times of application that you intend to provide on the label of the product you intend to market.

c. Section C - Full reports on investigations made with respect to the safety of the pesticide chemical. 40 CFR Part 158.340, Toxicology Data Requirements, identifies the types of toxicity data that are needed to support a petition request. The required data are identified under the "Food Crop" headings.

d. Section D - The results of tests on the amount of residue remaining, including a description of the analytical method used. Information on testing for the amount of residue remaining in the raw agricultural commodity or processed food or feed, when the pesticide is applied according to the proposed label directions, is provided in 40 CFR Part 180.34 - Tests on the amount of residue remaining, Part 158.240 - Residue Chemistry Data Requirements, and the Pesticide Assessment Guidelines, Subdivision O - Residue

Chemistry. (Refer to Chapter 16 of this manual for a source.)

Submission of analytical methods to EPA for use in tolerance enforcement - You will need to develop and submit accurate and precise analytical methods for identifying and measuring the amount of pesticide residues in the agricultural commodity and processed foods. Those methods need to be practical in order to be used in tolerance enforcement and should meet all of the requirements for pesticide residue methods identified in the Pesticide Assessment Guidelines, Subdivision O - Residue Chemistry. The analytical method for enforcement cannot be marked as Confidential or Trade Secret. In addition, registrants need to submit to EPA pesticide residue data showing the results from their own laboratory as well as the results from an independent laboratory tryout that confirms those results. The exact procedure for conducting an independent laboratory tryout can be found in PR Notice 88-5.

IMPORTANT NOTE: If EPA does not receive all of the items identified above, the petition will be considered incomplete and returned without further notice.

e. Section E - Practical methods for removing residue that exceeds any proposed tolerance. Tolerances are usually set at levels which are adequate to cover residues that are likely to result from a proposed use without any special processing of the commodities to reduce residues to the tolerance level. Information in this section would provide for a necessary and useful pesticide treatment which results in residues larger than a safe tolerance level, but which can be reduced to the tolerance level by washing or some other means proposed in the petition.

f. Section F - Proposed tolerances for the pesticide chemical if tolerances are proposed. Tolerances should be proposed in terms which best represent the total toxic residues on the raw agricultural commodity, whether it be the parent pesticide or altered forms of it, or both.

An exemption from the requirement of a tolerance may be proposed when appropriate. According to 40 CFR 180.1001(a) " An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no

hazard to human health". When an exemption is proposed, data must be presented to show the level of residues to be expected.

When residues on a processed food derived from the raw agricultural commodity exceed the proposed tolerance on the raw agricultural commodity, appropriate tolerances should also be proposed in this section for the processed food under FFDCA Section 409.

g. Section G - Reasonable grounds in support of the petition. This section should include a rationale of how the residue data support the proposed tolerance, brief discussions on the adequacy of the analytical method with respect to sensitivity and determination of total toxic residues, an explanation of any aberrant residue values reported, an explanation for the omission or substitution of required data or information, discussion of fate of the pesticide in the environment (i.e., soil persistence, contamination of ground water or run-off water) and any residue considerations applicable to the proposed use. In addition a summary of the grounds for safety of the proposed tolerance based on the toxicology data submitted under Section C, may also be included.

3. Data - Three copies of any data required to be submitted in support of the petition must be submitted in accordance with the data formatting requirements set forth in PR Notice 86-5.

4. Application for registration or amendment under FIFRA section 3 - Except in certain instances, a petition request must be accompanied with an application for registration, an application to amend the registration of a currently registered product, or an experimental use permit for the uses proposed in the petition. A request for an import tolerance generally would not require an accompanying application for registration.

5. Fee Requirements - Each petition request must be accompanied by the appropriate fee as specified in 40 CFR 180.33. It would be helpful if a copy of the fee check were submitted with the petition request in case any questions arise concerning whether the fee was submitted as required. Refer to Chapter 9 of this manual for detailed information on tolerance petition fees.

6. Incomplete Petitions - Petitions will not be accepted for processing if the proper fee has not been

submitted, if any of the required data are lacking or the petition is otherwise determined to be incomplete. If a petition is not accepted for processing because it is incomplete, it will be returned. The original fee amount submitted, less a charge for handling and initial review, will also be returned. Refer to Chapter 9, Section C.4. - Incomplete Petition Applications.

D. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions concerning whether a petition for a tolerance is required, the appropriate fee, how to submit the request for a petition, or data required to support the petition, please contact the appropriate Product Manager for the pesticide. If the petition request involves a new chemical not yet assigned to a Product Manager, you should contact the appropriate Deputy Branch Chief, or Branch Chief for a Product Manager assignment. Refer to Chapter 18 of this manual for a listing of the various Product Managers, Deputy Branch Chiefs and Branch Chiefs.

CHAPTER 7 - REFERENCES CITED - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 158 - Data requirements for registration
   Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities.
   Part 185 - Tolerances for pesticides in food administered by the Environmental Protection Agency (Prior to June 29, 1988, 40 CFR Part 185 was designated 21 CFR Part 193)
   Part 186 - Tolerances for pesticides in animal feeds administered by the Environmental Protection Agency (Prior to June 29, 1988, 40 CFR Part 186 was designated 21 CFR Part 561)

2. Federal Food Drug and Cosmetic Act

   Section 408 - Tolerance for pesticide chemicals in or on raw agricultural commodities
   Section 409 - Food additives

3. Pesticide Assessment Guidelines, Subdivision D, Product Chemistry, EPA-540/09-82-018.

4. Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, EPA-540/09-82-023.

5. PR Notice 86-5 - Standard Format for data submitted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug and Cosmetic Act FFDCA). Issued July 29, 1986.

6. PR Notice 88-5 - Tolerance Enforcement Methods - Independent Laboratory Confirmation by Petitioner, Issued July 15, 1988.

7. Federal Register Notice, October 19, 1988, Regulation of Pesticides in Food: Addressing the Delaney Paradox - Policy Statement (53 FR 41104).

CHAPTER 8 - HOW TO APPLY FOR AN EXPERIMENTAL USE PERMIT

A. GENERAL INFORMATION

Experimental Use Permits (EUPs) are issued under FIFRA section 5 to allow prospective registrants to generate information or data necessary to register a pesticide under section 3 of FIFRA. You should refer to 40 CFR Part 172 for detailed information on EUPs. In general EUPs are issued for:

1. A pesticide not registered with the Agency, or

2. A registered pesticide for a use not registered with the Agency.

Pesticides under experimental use permits may not be sold or distributed other than through participants in the approved experimental use program. They may only be used at the application site of a cooperator in the program, and only in accordance with the terms and conditions of the experimental use permit.

B. WHEN IS AN EXPERIMENTAL USE PERMIT REQUIRED?

1. Generally, an EUP is required before you can conduct large scale field testing. Large scale field testing would be any instance other than those described in item 2 below. However, in certain cases (e.g., "novel" microbial pesticides -- certain genetically altered and non-indigenous microbial pest control agents as discussed in item 3 below) small scale field tests may require an EUP.

IMPORTANT NOTE: EUPs are required for field testing of pesticides in an indoor situation, for example a pesticide to control roaches in domestic dwellings, institutions, etc.

2. EUPs are generally presumed not to be required for a substance or mixture of substances being put through laboratory or greenhouse tests, or limited replicated field trials, in which the purpose is only to determine its value for pesticidal purposes or to determine its toxicity or other properties, under the following circumstances:

a. Land use - For tests conducted on a cumulative total of not more than 10 acres involving use of the test material against a particular pest, provided that any food or feed crops involved in or affected by the tests are destroyed or consumed only by experimental animals, unless a tolerance or exemption from a tolerance has been established.

b. Aquatic use - For tests conducted on a total of not more than one surface-acre of water involving use of a test material against a particular pest, provided that such waters involved in or affected by the tests will not be used for irrigation, drinking water supplies, or body contact recreational activities. In addition, no tests may be conducted in waters that contain, or which affect any fish, shellfish or other plants or animals which may be taken and used for food or feed unless a tolerance or exemption from a tolerance has been established.

c. Animal treatments - For tests conducted only on experimental animals. No animal may be tested if it may be used for food or feed purposes, unless a tolerance or exemption from a tolerance has been established.

3. Small scale field testing for "novel" microbial pesticides requiring an EUP - Due to concerns about the capability of microorganisms to reproduce and multiply in the environment and the potential for these microbials to cause unforseen adverse impacts, the Agency may require an EUP for small scale field testing of certain "novel" microbial pesticides (i.e., genetically-altered and non-indigenous microbial pest control agents). Refer also to the section on Application Requirements for an Experimental Use Permit, C.1.b. below.

C. APPLICATION REQUIREMENTS FOR AN EXPERIMENTAL USE PERMIT

Your application for an experimental use permit must contain or address the following:

1. General Requirements

a. Conventional, Biochemical, and Most Microbial Pesticides

1) Application for Experimental Use Permit, EPA Form 8570-17.

2) EPA Registration Number of the product to be used, if registered.

3) Purpose or objectives of proposed testing.

4) A description in detail of the proposed testing program including:

a) Test parameters

b) A designation of the pest organism(s) involved

c) The amount of pesticide product proposed for use

d) The crops, fauna, flora, sites, modes, dosage rates and situations of application on or in which the pesticide is to be used

e) The states, and counties within the state, in which the proposed program will be conducted

f) The number of acres, number of structural sites, or number of animals by state and county to be treated or included in the area of experimental use

g) The proposed dates or period(s) during which the testing program is to be conducted

h) The manner in which supervision of the program will be accomplished

5) The name, street address, telephone number, and qualifications of all participants in the program (whether or not in the employ of the applicant). A participant is any person acting as a representative of the permittee and responsible for making available for use, or supervising the use or evaluation of an experimental pesticide to be applied at a specific application site.

6) The name and street address of all cooperators, if available at the time the application is submitted or as soon as possible thereafter. Cooperators are persons who grant permission for an experimental use pesticide to be used on application sites which they own or control.

7) Information on prior testing - a description and the specific results of any appropriate prior testing of the product conducted by the applicant to determine, (a) toxicity and effects in or on any target organisms at the site of application, and (b) phytotoxicity and other forms of toxicity or effects on nontarget plants, animals and insects, at or near the site of application, or (c) any adverse effects on the environment.

8) The proposed method of storage and disposition of any unused experimental pesticide and its containers.

9) Any other additional pertinent information as the Agency may require.

b. Small scale field testing - "novel" microbial pesticides (i.e., genetically altered and non-indigenous microbial pest control agents)

Prior to the initiation of any small scale field testing which involves genetically altered or non-indigenous microbial pest control agents, the research organization, company, or individual must submit a notification to the Agency so that a determination can be made as to whether an EUP is required.

You should also refer to Chapter 3 - Biochemical and Microbial Pesticides, Section D., Small-scale field testing Level I reporting and Level II notification requirements, for a more detailed discussion of the Agency's policy and requirements for small-scale field testing for microbial pesticides.

2. Tolerance requirements

If the proposed experimental use pesticide is to be used in such a manner that any residue can reasonably be expected to result in or on food or feed, the applicant must either 1) submit evidence that a tolerance or an exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food Drug and Cosmetic Act (FFDCA), or a regulation promulgated under section 409 of that Act, or 2) submit a request proposing establishment of a tolerance or a temporary tolerance under FFDCA section 408, or a regulation under section 409. Refer to Chapter 7, for a further discussion of tolerances.

In lieu of submitting a request for a tolerance or temporary tolerance, the applicant may certify that the food or feed item resulting from the experimental use program will be destroyed or fed only to experimental animals for testing purposes.

3. Data requirements

If the proposed EUP is for an unregistered pesticide, the following information and/or data are required:

a. Completed Confidential Statement of Formula, EPA Form 8570-4.

b. Appropriate data in accordance with the data requirements identified in 40 CFR Part 158 for an experimental use permit.

c. Reentry data, if available.

d. Submitted data (3 copies) must be bound and formatted in accordance with the requirements of PR Notice 86-5.

4. Labeling requirements

All pesticides shipped or used under an experimental use permit must be labeled with directions and conditions for use including the following:

a. The prominent statement "For Experimental Use Only"

b. The Experimental Use Permit Number

c. The statement "Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program"

d. The name, brand or trademark

e. The name and address of the permittee, producer, or registrant

f. The net contents

g. An ingredient statement

h. Warning or caution statements

i. Any appropriate limitations on entry of persons into treated areas

j. The establishment registration number, except in those cases where application of the pesticide is made solely by the producer

k. The directions for trial use

5. Extensions or renewal of Experimental Use Permits

Experimental Use Permits and associated temporary tolerances are usually issued for a period of one or two years. The permit and any associated temporary

tolerances, may be extended, renewed, or amended upon written request to the Agency, if circumstances warrant.

6. Fee Requirements

If your application for an Experimental Use Permit is accompanied by a petition for a tolerance, temporary tolerance, an exemption from the requirement of a tolerance or a temporary tolerance exemption, the petition is subject to fee requirements as discussed in Chapter 9. An extension or renewal request for a temporary tolerance is also subject to a fee requirement.

D. WHO TO CONTACT FOR ADDITIONAL INFORMATION

Please contact the appropriate Product Manager for your pesticide if you have any questions such as whether an experimental use permit is required, whether a temporary tolerance is required for the proposed use, the appropriate fee, how to submit the application for an experimental use permit, or data required to support the application. If you have questions concerning the testing of "novel" microbial pesticides you should contact Product Manager 17 for insecticide products and Product Manager 21 for fungicide or herbicide products. If the EUP is for a new chemical which has not been assigned to a Product Manager, you should contact the appropriate Deputy Branch Chief, or Branch Chief for a Product Manager assignment. Refer to Chapter 18 of this manual for a listing of the various Product Managers, Deputy Branch Chiefs and Branch Chiefs.

CHAPTER 8 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 158 - Data requirements for registration
   Part 172 - Experimental use permits

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988.

   Section 3 - Registration of pesticides

3. Federal Food Drug and Cosmetic Act

   Section 408 - Tolerances for pesticide chemicals in or on raw agricultural commodities
   Section 409 - Food additives

4. PR Notice 86-5 - Standard Format for data submitted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug and Cosmetic Act (FFDCA). Issued July 29, 1986.

7740), and list B in the Federal Register of May 25, 1989 (54 CFR 22706). The remaining lists, List C and List D are scheduled to be listed by July 24 and October 24, 1989. In addition, registrants will be notified of the time by which they are to notify the Agency whether or not they intend to seek reregistration. For a detailed discussion of the reregistration fee schedules, you should refer to section 4 of FIFRA as amended October, 1988.

D. TOLERANCE PETITION FEES

Under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), fees may be charged to cover the cost of the processing and review of tolerance petitions. Tolerances are required to be established for residues of a pesticide whose use may result in residues on a food or feed commodity.

1. GENERAL FEE SCHEDULE - EFFECTIVE March 15, 1989 (revised annually)

Refer to 40 CFR section 180.33 for a detailed discussion of the various fees required for the type of petition for which you intend to make application. The fees will be adjusted annually in accordance with section 180.33 (o). You should refer to the March 15, 1989 Federal Register Notice (54 FR 10962) for a more detailed discussion of tolerance processing fees.

The fees vary considerably according to type of petition requested and its complexity. Again, you should refer to 40 CFR 180.33 for a detailed discussion of fee requirements. A very brief, general discussion of some of the fees required for the more frequently requested petitions follows:

a. For the establishment of a new tolerance or a tolerance higher than that already established (with certain exceptions) the fee is $48,225, plus $1,200 for each raw agricultural commodity more than nine on which the establishment of a tolerance is requested.

b. For the establishment of a tolerance at a lower numerical level(s) than already established for the pesticide, or for additional raw agricultural commodities at the same numerical level as already established the fee is $11,025 plus $775 for each raw agricultural commodity on which a tolerance is requested.

c. For requests for an exemption from the requirement of a tolerance or repeal of an exemption the fee is $8,875.

d. For temporary tolerances or a temporary tolerance exemption from the requirement of a tolerance the fee is generally $19,250, except as provided below. A request for an extension or renewal of a temporary tolerance or temporary exemption requires a fee of $2,725.

e. For requests for a temporary tolerance for a pesticide which has a tolerance for other uses at the same numerical level or a higher numerical level the fee is $9,625 plus $775 for each raw agricultural commodity on which the temporary tolerance is sought.

2. WAIVERS AND REFUNDS

The Agency may waive or refund part or all of any tolerance petition fee, if it is in the public interest to do so, or if the fee would result in unreasonable hardship on the applicant. A request for a waiver or a fee refund must be submitted in writing to the Agency in accordance with 40 CFR section 180.33(m). The waiver or refund request must be accompanied by a fee of $1,200.

3. WHERE TO SUBMIT YOUR FEE AND YOUR PETITION REQUEST

All fees must be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency. All payment of fees must be forwarded to the following address:

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs
(Tolerance Fees)
P.O. Box 360277M
Pittsburgh, PA 15251

The payments should be specifically labeled "Tolerance Fees" and should be accompanied only by a copy of the letter or petition requesting the tolerance. The actual letter or petition, along with supporting data should be forwarded within 30 days of payment of the fee to the following address:

Document Processing Desk (PETN)
Office of Pesticide Programs - H7504C
U.S. EPA
401 M Street, S.W.
Washington, D.C. 20460

A petition will not be accepted for processing until the required fees have been submitted. A petition for which a waiver of fees has been requested will not be accepted for processing until the fee has been waived, or if the waiver is denied, the proper fee is submitted. A request for waiver or refund will not be accepted after scientific review of a petition has begun.

4. INCOMPLETE PETITION APPLICATIONS

If a petition is not accepted for processing because it is determined to be incomplete, the fee, less $1,200 for handling and initial review will be returned. If a petition is withdrawn by the petitioner after initial processing but before significant scientific review has begun, the fee, less $1,200 for handling and initial review, will be returned. If an unacceptable petition is resubmitted, it will require the appropriate fee that would be required if it were submitted for the first time.

E. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions concerning whether a petition for a tolerance is required, the appropriate fee, how to submit the application for a petition, or data required to support the application, please contact the appropriate Product Manager for that pesticide. Refer to Chapter 18 of this manual for a listing of the various Product Managers.

CHAPTER 9 - REFERENCES CITED - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities

2. Federal Food, Drug and Cosmetic Act

   Section 408 - Tolerances for pesticide chemicals in or on raw agricultural commodities

3. Federal Register Notices

   - Tolerance Processing Fees, March 15, 1989 (54 FR 10962)

   - Pesticides For Which Registration Standards Have Been Issued (List A), February 22, 1989 (54 FR 7740)

   - Pesticides Required To Be Reregistered (List B), May 25, 1989 (54 FR 22706)

4. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

   Section 4 - Reregistration of registered products

CHAPTER 10 - DEVICES - WHAT ARE THE REQUIREMENTS?

A. GENERAL INFORMATION

Section 25(c)(4) of FIFRA provides that the Administrator may specify devices which are subject to any provision of FIFRA section 2(q)(1) or section 7. Devices are defined in FIFRA Section 2(h).

The Agency's policy concerning its authority and activities with respect to devices was published in the Federal Register of November 19, 1976 (41 FR 51065).

B. DEFINITION OF DEVICES

40 CFR Section 153.240 defines a device as "any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacterium, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom".

In general, if an article uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest at 40 CFR 152.5, it is considered to be a device, and not subject to registration under FIFRA section 3. However, if the article incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, it is considered to be a pesticide and as such is subject to registration under FIFRA section 3.

C. DEVICES SUBJECT TO THE ACT

The Agency, in the November 19, 1976 Federal Register Notice, stated that devices subject to FIFRA section 2(q)(1) and section 7 include but are not limited to:

1. Certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances which are pesticides), and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites,

2. Certain high frequency sound generators, carbide cannons, foils, and rotating devices, for which claims are made to repel birds,

3. Black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper for which claims are

made to kill or entrap certain insects, and

4. Mole thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain mammals.

IMPORTANT NOTE: Although not specifically mentioned in the November 19, 1976 Federal Register Notice, the Agency has determined the electromagnetic devices are also subject to FIFRA section 2(q)(1) and section 7.

D. DEVICES NOT SUBJECT TO THE ACT

The November 19, 1976 Federal Register Notice provided the following examples of those types of devices that are not subject to FIFRA:

1. Devices which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself, and

2. Devices which operate to entrap vertebrate animals.

Products generally falling within these two categories include rat and mouse traps, fly swatters, tillage equipment for weed control and fish traps.

E. REQUIREMENTS FOR DEVICES

1. Registration Not Required

A device is not required to be registered under FIFRA section 3. However, devices are subject to certain other requirements of FIFRA as indicated below.

2. Labeling Requirements

Devices are subject to the labeling requirements of FIFRA section 2(q)(1) and 40 CFR Part 156. These requirements are summarized below.

a. Under FIFRA section 2(q)(1) a device is considered to be misbranded and subject to enforcement action if:

1) Its labeling bears any statements, designs, or graphic representations, which are false or misleading (see 2.b. below for examples of false or misleading statements),

2) Its packaging or wrapping must conform to standards established pursuant to FIFRA section 25(c)(3) (as of this date, such standards have yet to be established for devices),

3) It is an imitation of, or is offered for sale under the name of another device,

4) It's label fails to bear the establishment number,

5) Required information is not prominently displayed on the label,

6) It lacks adequate directions for use, or

7) It lacks an adequate warning or caution statement.

b. 40 CFR section 156.10 (a)(5) provides the following examples of labeling statements or representations which constitute misbranding:

1) A false or misleading statement concerning the composition of the product,

2) A false or misleading statement concerning the effectiveness of the product as a pesticide or device,

3) A false or misleading statement about the value of the product for purposes other than as a pesticide or device,

4) A false or misleading comparison with other pesticides or devices,

5) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government,

6) A true statement used in such a way as to give a false or misleading impression to the purchaser,

7) Label disclaimers which negate or detract from labeling statements required under the Act and regulations, and

8) Non-numerical and/or comparative statements on the safety of the product.

3. Establishment Registration and Reporting, Books and Records

Devices are subject to the establishment registration and reporting requirements FIFRA section 7 and Part 40 CFR Part 167. All establishments in which devices subject to the Act

are produced must be registered with the Agency as producing establishments. This includes foreign establishments in which devices shipped to the U.S. are produced, as well as establishments located in the U.S. which produce devices for export. Refer to Chapter 11 for information on how to obtain an EPA establishment number.

FIFRA section 8 and 40 CFR 169 provide information on such records that are required to be maintained by producers of devices.

4. Inspection of Establishments

Refer to FIFRA section 9 for information concerning inspection of establishments.

5. Violations, Enforcement Activities, and Penalties

Refer to FIFRA sections 12, 13, and 14 for information concerning violations, enforcement activities and penalties.

6. Importation and Exportation of Devices

Refer to FIFRA section 17 for information concerning the importation and exportation requirement for devices. Regulations (19 CFR Part 12.1) for the implementation of section 17 were published in the Federal Register (40 FR 32321) August 1, 1975. These regulations require, in part, that devices produced by foreign manufacturers and imported into the U.S. comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1) for review and determination as to whether the shipment should be sampled and/or permitted entry into the U.S.

FIFRA section 17 states that no device produced solely for export to any foreign country, shall be deemed in violation of FIFRA, when prepared or packaged to the specifications or directions of the foreign producer, except that producers of such devices are subject to sections 2(p), 2(q)(1)(A),(C),(D),(E),(G) and (H), 2(q)(2)(A),(B),(C)(i)and (iii), and (D).

In addition, devices are subject to the record keeping and inspection requirements in accordance with section 8 of FIFRA.

7. Child-resistant Packaging

Refer to FIFRA section 25(c)(3) and 40 CFR section 157.20 for information concerning child-resistant packaging

requirements.

F. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions concerning devices, whether they are subject to the Act, or establishment registration, please contact the Office of Compliance Monitoring, Compliance Division (EN-342), Environmental Protection Agency, 401 M St., S.W., Washington, DC, 20460. Telephone (202) 382-7835.

CHAPTER 10 - REFERENCES CITED - Refer to Chapter 16 for information on the source of these documents.

1.Code of Federal Regulations, Title 40

Part 152 - Pesticide registration and classification procedures
Part 153 - Statement of policies and interpretations
Part 156 - Labeling requirements for pesticides and devices
Part 157 - Packaging requirements for pesticides and devices
Part 167 - Registration of pesticide-producing establishments, submission of pesticide reports, and labeling
Part 169 - Books and records of pesticide production and distribution

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

Section 2 - Definitions
Section 3 - Registration of pesticides
Section 7 - Registration of establishments
Section 8 - Books and records
Section 12 - Unlawful acts
Section 13 - Stop sale, use, removal, and seizure
Section 14 - Penalties
Section 17 - Imports and exports
Section 25 - Child resistant packaging

3. Federal Register Notice (40 FR 32321), August 1, 1975.

4. Federal Register Notice, Pest Control Devices and Device Producers, (41 FR 51065), Nov. 19, 1976.

CHAPTER 11 - HOW TO OBTAIN AN EPA ESTABLISHMENT NUMBER

A. GENERAL INFORMATION

If you produce or formulate your own pesticide, then the place(s) [or establishment(s)] in which you produce a pesticide, or device, is subject to registration. (Refer to FIFRA section 7). However, if you produce the pesticide only for application by yourself and not for sale or distribution, you are not required to register your establishment.

40 CFR Part 167 entitled "Registration of Pesticide-Producing Establishments, Submission of Pesticide Reports, and Labeling", provides detailed information concerning definitions, registration procedures, labeling, and reporting requirements.

An "establishment" is defined as any site where a pesticide or device is produced, regardless of whether:

1) the site is independently owned or operated, or

2) the site is domestic (located in the U.S.) and is producing the pesticide or device only for export, or

3) the site is located in a foreign country and is producing the pesticide or device for importation into the United States.

The term "produce" is defined as the manufacture, preparation, propagation, compounding, or processing of any pesticide or device, (including pesticides produced for use under an Experimental Use Permit), or the repackaging or the changing of the container of any pesticide or device.

You should refer to 40 CFR Part 167 for more detailed information regarding the registration of your establishment, labeling and reporting requirements.

B. APPLICATION FOR REGISTRATION OF PESTICIDE-PRODUCING ESTABLISHMENTS

1. Complete the application form EPA Form 3540-8, Application for Registration of Pesticide-Producing Establishments.

2. Where to submit your application:

   a. **Domestic Establishments** - Submit your application to the EPA Regional Office having jurisdiction over the State in which the headquarters of your company is located. Refer to Chapter 18 for a listing of the various EPA Regional Offices.

b. Foreign Establishments - Foreign companies should submit their application to EPA's headquarters office at the address listed below:

Environmental Protection Agency
Office of Compliance Monitoring (EN-342)
401 M St., S.W.
Washington, D.C. 20460 U.S.A.

C. INFORMATION REQUIRED

Your application for the registration of your establishment requires the following information:

1) The name and address of your company,

2) The type of ownership (individual, partnership, cooperative association, corporation, or any organized group of persons whether incorporated or not), and

3) The names and addresses of all producing establishments.

D. WHERE TO OBTAIN APPLICATION FORMS

EPA Form 3540-8, Application for the Registration of Pesticide-Producing Establishments may be obtained from your EPA Regional Office (see Chapter 18), or from the Office of Compliance Monitoring (EN-342), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

CHAPTER 11 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 167 - Registration of pesticide-producing establishments, submission of pesticide reports, and labeling

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

   Section 7 - Registration of Establishments

CHAPTER 12 - CONFIDENTIAL BUSINESS INFORMATION AND HOW TO SUBMIT DATA

A. GENERAL INFORMATION

Some of the information (and data) you must submit to EPA is protected by FIFRA from disclosure or release to certain persons under certain circumstances. These protections are found in FIFRA Section 10. A brief synopsis is given below.

You may also make confidentiality claims covering information other than that described in FIFRA Section 10(d)(1)(A), (B), or (C). If such claims are made, you will have to substantiate each claim, and the EPA General Counsel will rule on each claim before any disclosure or release of the information is made. The substantiation process is provided to afford protection to certain information that is not explicitly described in FIFRA or EPA Regulations. Consider making claims of confidentiality only after carefully reading the citations listed in section B. of this chapter. Normally, we see very few claims of confidentiality of this type.

Data submitted in support of your application for registration, amendments to a registration, petitions, experimental use permit, etc., must be submitted in a standard format in accordance with 40 CFR 158.32-33 and PR Notice 86-5. Refer to section C. of this chapter for a general discussion of these requirements.

B. SYNOPSIS OF FIFRA SECTION 10 - CONFIDENTIAL BUSINESS INFORMATION

In brief, Section 10 says that health and safety data on registered or previously registered pesticides shall be made available to the public, except that the following information cannot be released:

1. Information that discloses manufacturing or quality control processes.

2. Information that discloses testing for and measuring the quantity of deliberately added inert ingredients, and

3. Information that discloses the identity or percentage quantity of deliberately added inert ingredients.

When data are submitted, information of the types 1, 2, and 3, above must be physically separated from the rest of the data (study) and placed in a confidential attachment to the study. (See PR Notice 86-5 for specific instructions about study formatting.)

FIFRA Section 10(b) protects certain confidential business information, such as trade secrets and commercial or financial information.

FIFRA Section 10(e) permits EPA to give confidential business information (CBI) you submit to its contractors who are helping to do the work of the Agency. Such contractors are bound to protect this information just like the EPA staff is required to protect it. We provide notification to submitters of CBI that their data will be used by a contractor. This is usually done by publishing a Notice in the Federal Register and always precedes giving the CBI to the contractor.

FIFRA Section 10(g) prohibits the disclosure of information submitted by an applicant or registrant to any representative of a multinational pesticide producer or to anybody who intends to deliver such information to a multinational pesticide producer.

FIFRA provides that in certain circumstances the EPA Administrator may disclose information that is otherwise protected. Such action is rare, and is described in FIFRA Section 10(b), 10(d)(3), and 10(g).

Information about registered pesticide products that can be released is normally not released until 30 days after the product is registered. See FIFRA Section 3(c)(2).

This has been a very brief review of certain points about CBI that may be of special interest to you. Please also see: FIFRA Section 10, 40 CFR 2.307, and the citations listed in 40 CFR 2.307(c).

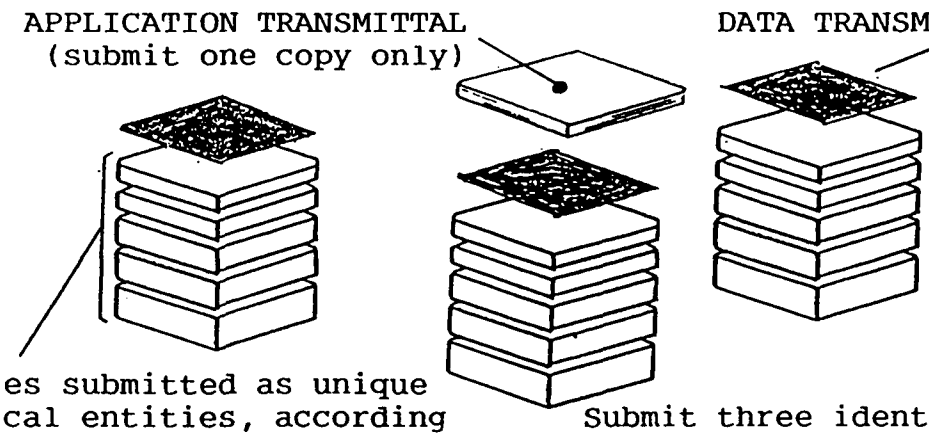
C. HOW TO SUBMIT DATA

The following discussion highlights some of the more important points that you should follow when submitting data. You should also refer to 40 CFR 158.32-33 and PR Notice 86-5 for a more detailed discussion of how to format your data submission.

When you submit data, the data will be reviewed to determine whether it meets the data formatting requirements set forth in PR Notice 86-5. If major problems are found during this screening process, the studies will be returned to you for correction. Studies that meet the formatting requirements will be assigned a Master Record Identifier number (MRID) and entered into the Agency's Document Management System. These studies are then able to be retrieved by the MRID number at any time. You may refer to these MRID numbers in lieu of sending in additional copies of these data to support additional applications for registration.

The following diagrams are meant to provide guidance on how to format your data submission. Again you should refer to PR Notice 86-5 for more detailed information.

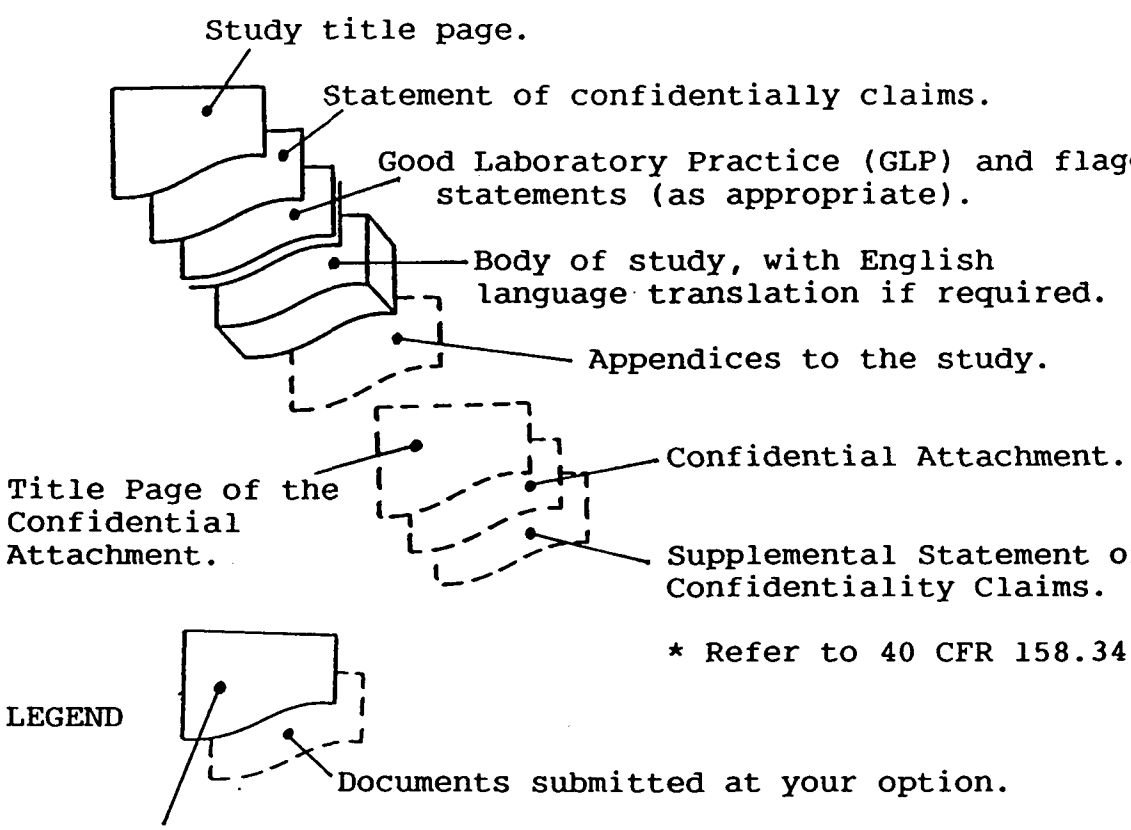
FORMAT OF THE SUBMITTAL PACKAGE



Studies submitted as unique physical entities, according to the format below.

Submit three identical copies of the data submittal.

FORMAT OF THE SUBMITTED STUDIES



1. APPLICATION TRANSMITTAL

The application transmittal may include any or all of the following:

a. Application forms
b. Formulator's exemption statements
c. Confidential Statement of Formula
d. Certification with Respect to Citation of Data
e. Data requirement matrices
f. Data waiver request and supporting rationales
g. Labeling

IMPORTANT NOTE: PR Notice 86-5 does not change the registration requirements for applications for registration or amendments as set forth in 40 CFR 152 and elsewhere. PR Notice 86-5 only applies when you submit data to support the application, and then only to the data. All of the items listed above address non-data requirements for registration, and are filed in the registration jacket for your product. Thus they need not be submitted in three copies like the data.

2. DATA TRANSMITTAL DOCUMENT

You should provide a copy of the Data Transmittal for each set of studies. Bind it separately, and be certain that it itemizes all studies that are physically included in the submittal. You will be sent a copy of your data transmittal document with the MRID numbers assigned to each piece of data or study. Refer to PR Notice 86-5 for a sample transmittal document.

3. BIND STUDIES SEPARATELY

If a study addressed several data requirements, do not include it in your submittal more than once. Identify its full subject scope on its title page, and then cite the same study in your application in all appropriate contexts.

4. WHAT TO INCLUDE IN A STUDY

All study-specific supplements, addenda, supporting analyses, protocols, or correspondence submitted at the same time as the report of the study itself should be included within the binding and pagination of the primary study.

5. IDENTIFYING SUPPLEMENTS TO PREVIOUSLY SUBMITTED STUDIES

Whenever you submit information to supplement a

previously submitted study, whether at your own initiative or in response to a request by EPA, it must be prepared in the format required by PR Notice 86-5. Submit three complete sets under an appropriate transmittal document, including supplemental information for only one study in each binding, and identifying the previously submitted study in supplements as clearly as possible, i.e., by EPA Accession Number or (preferably if you know it) the Master Record Identifier (MRID) number on its title page.

6. STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Each submitted study must have this Statement. The exact text of one of the two alternative forms of the statement (Refer to PR Notice 86-5) must appear on page 2 of the study. You may add to the required text a reference to the proprietary nature of the document, and you may assert that it may not be copied, quoted, etc. by any recipients other than EPA. You may not, however, assert a right of prior approval for use, copying, or distribution of the data by EPA, as required and constrained by Sections 3 and 10 of FIFRA. If there are markings (such as "Company Confidential") in your study documents, you must add to the required text an explicit statement that over-rides the implicit supplemental claims of confidentiality that result from these markings. This over-ride statement may specify that it applies only to use of the data by EPA in connection with the provisions of FIFRA.

D. WHO TO CONTACT FOR ADDITIONAL INFORMATION:

If you have any questions concerning confidential business information as it may concern your application or how to format and submit supporting data, please contact the Information Resources Development Section, Information Services Branch, Program Management and Support Division. Refer to Chapter 18 of this manual.

CHAPTER 12 - REFERENCES CITED - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 2 - Public information

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

   Section 3 - Registration of pesticides
   Section 10 - Protection of trade secrets and other information

3. PR Notice 86-5 - Standard format for data submitted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug and Cosmetic Act (FFDCA), Issued July 29, 1986.

CHAPTER 13 - TRANSFER OF PRODUCT REGISTRATIONS AND/OR DATA RIGHTS FROM ONE PERSON OR COMPANY TO ANOTHER

A. GENERAL INFORMATION

40 CFR 152.135 provides information necessary for the transfer of the registration of a product from one person or company to another. Applications for the registration of products which are still pending registration (not registered) may also be transferred. 40 CFR 152.98 provides information for the transfer of data rights from one person or company to another. You should refer to these references for specific details on the transfer of registrations and/or data rights. A discussion of transfer requirements is provided below.

B. TRANSFER OF PRODUCT REGISTRATIONS

A registrant may transfer the registration of a product to another person, and the registered product may be distributed and sold without the requirement of a new application for registration by that other person, if the parties submit to the Agency the documents as described in 40 CFR 152.135 and receive approval by the Agency.

1. Persons seeking approval of a transfer of a product registration must provide a document (a Transfer Document) signed by the authorized representative of the registrant of the product to be transferred (the transferor) and of the person to whom the product registration is to be transferred (the transferee) that contains the following information:

a. The name, address, phone number, EPA-assigned company number, and State of incorporation (if any) of the transferor,

b. The name, address, phone number, EPA-assigned company number, and State of incorporation of the transferee (If the transferee does not have an EPA-assigned company number, he or she should request that one be assigned),

c. The product name(s) and EPA registration number(s), or the EPA File Symbol for pending products, of the products to be transferred,

d. A statement that the transferor transfers irrevocably to the transferee all right, title, and interest in the EPA registration(s) listed by product name and EPA Registration Number in the document,

e. A statement that the transferred registration(s) shall not serve as collateral or otherwise secure any

loan or other payment arrangement or executory promise, and that the registration(s) shall not revert to the transferor unless a new transfer agreement is submitted to and approved by the Agency,

f. A description of the general nature of the underlying transaction, e.g., merger, spinoff, bankruptcy transfer (no financial information need be disclosed),

g. A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001, and

h. An acknowledgement by the transferee that his rights and duties concerning the registration under FIFRA and this chapter will be deemed by EPA to be the same as those of the transferor at the time the transfer is approved.

2. In addition, the transferor must submit to the Agency as required by 40 CFR 152.135(c) a notarized statement affirming that:

a. The person signing the transfer agreement is authorized by the registrant to bind the transferer,

b. No court order prohibits the transfer, and that any required court approvals have been obtained, and

c. The transfer is authorized under all relevant Federal, State and local laws and all relevant corporate charters, bylaws, partnerships, or other agreements.

IMPORTANT NOTE: In the event that the original documents cannot be submitted for the attachments to the transfer document, each of the copied documents must be notarized and certified as a true copy of the originals.

3. If the required documents are submitted, and no information available to the Agency indicates that the information is incorrect, the Agency will approve the transfer without requiring that the transferee obtain a new registration(s). The Agency will notify the transferor and the transferee of its approval.

4. The transfer will be effective on the date of Agency approval. Thereafter, the transferee will be regarded as the registrant for all purposes under FIFRA.

5. The rights to exclusive use of data or data compensation

under FIFRA section 3(c)(1)(D) are separate from the product registration itself and may be retained by the transferor, or may be transferred independently in accordance with 40 CFR 152.98. If the registrant as the original data submitter wishes to transfer data rights at the same time as he transfers the registration, he may submit a single transfer document containing the information required by this section for both the registration and the data.

IMPORTANT NOTE: When product registrations are transferred from one registrant to another, all restrictions, data requirements, conditions of registration, including timeframes for the submittal of data or other information, suspensions or any other requirements existing on the registration are transferred with the registration. The new registrant (transferee) is responsible for adhering to or complying with all such restrictions, data requirements, conditions of registration, timeframes, suspensions or any other requirements that have been imposed on the acquired product registration.

With respect to timeframes for the submittal of data or other information, the new registrant is responsible for the submittal of all required data according to the schedules already established by the Agency as a result of a data call-in under FIFRA section 3(c)(2)(B), or a condition of the registration under FIFRA section 6(e), for the acquired product registrations. Failure to comply with these timeframes, may result in the issuance of a Notice of Intent to Suspend the registration of the affected product under FIFRA section 3(c)(2)(B), or a Notice of Intent to Cancel the registration of the affected product under FIFRA section 6(e).

Requests for the extension of time to submit required data or other information from the new registrant, merely because they acquired the registration after the 3(c)(2)(B) data call-in was issued, or after the conditions of registration under section 6(e) were imposed will not be granted. If the new registrant has other valid reasons for delays in the testing which were clearly outside their control, then such a request for time extensions will be considered in accordance with established procedures. If such delays are expected to be encountered, and a time extension is believed to be necessary, the Agency should be informed as soon as possible, and in any event prior to the due date.

Transfers that occur while a 3(c)(2)(B) data call-in is being issued or during the 90 day response time to the data call-in are subject to the same conditions expressed above.

C. TRANSFER OF DATA RIGHTS

A person who possesses rights to exclusive use data or data compensation under FIFRA section 3(c)(1)(D) may transfer such

rights to another person in accordance with 40 CFR 152.98. In order for the Agency to process a request for the transfer of data rights, certain documentation is required.

1. The original data submitter must submit to the Agency a transfer document that contains the following information:

a. The name, address, phone number and State of incorporation (if any) of the original data submitter (the transferor),

b. The name, address, phone number and State of incorporation of the person to whom the data rights are being transferred (the transferee),

c. Identification of each item of data transferred including:

1) The name of the study or item of data,

2) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires,

3) The name of the person or laboratory that conducted the study,

4) The date the study was submitted to the Agency,

5) The EPA document number assigned to the item of data [the Master Record Identification Number (MRID) or Accession Number], if known. If not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data.

6) A statement that the transferor transfers irrevocably to the transferee all rights, and interest in the items of data named,

7) A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001, and

8) The names, signatures and titles of the transferor and transferee, and the date signed.

2. In addition, the transferor must submit to the Agency as required by 40 CFR 152.98, a notarized statement affirming that:

a. The person signing the transfer agreement is authorized by the original data submitter to bind the data submitter,

b. No court order prohibits the transfer, and any required court approvals have been obtained, and

c. The transfer is authorized under Federal, State and local laws and relevant corporate charters, bylaws or partnership agreements.

3. The Agency will acknowledge the transfer of the data by notifying both transferor and transferee, and will state the effective date of the transfer. Thereafter the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(D), unless a new transfer agreement is submitted to the Agency.

D. **WHO TO CONTACT FOR FURTHER INFORMATION:** If you have any questions or require additional information concerning the transfer of product registrations or data rights please contact the Administrative Processing Section, Registration Support Branch. Refer to Chapter 18 of this manual.

CHAPTER 13 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 152 - Pesticide registration and classification procedures

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

   Section 3 - Registration of pesticides
   Section 6 - Administrative review; suspension

CHAPTER 14 - STATE REGULATORY AUTHORITY UNDER FIFRA

A. STATE ISSUANCE OF EXPERIMENTAL USE PERMITS

Section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) authorizes any State to issue an experimental use permit for a pesticide in accordance with a State plan approved by the Agency. 40 CFR Part 172, Subpart B - State Issuance of Experimental Use Permits, provides detailed information on state experimental use permits. In general, authorized states can issue experimental use permits for the purpose of gathering data necessary to support the State registration of a pesticide to meet special local needs under FIFRA Section 24(c) and for the purpose of experimentation.

To date, Idaho, Florida and Vermont have received authorization from the Agency to issue state experimental use permits.

WHO TO CONTACT: For additional information concerning state EUPs, you should contact the pesticide regulatory authority in the state in which you wish to obtain a state EUP. A listing of the state regulatory agencies can be found in Chapter 18.

B. STATE REGISTRATION OF SPECIAL LOCAL NEEDS

FIFRA Section 24(c) authorizes a State to provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accordance with the provisions of the Act. 40 CFR Part 162, Subpart D - Regulations Pertaining to State Registration of Pesticides to Meet Special Local Needs, provides detailed information on the scope and authority of the states to issue registration of pesticide products.

Under FIFRA Section 24(c), states are authorized to register new end-use products or additional uses of federally registered pesticides if there is:

1. a special local need for that product use,

2. the use, if a food or feed use, is covered by an appropriate tolerance or has been exempted from the requirement of a tolerance,

3. registration for the same use has not previously been denied, disapproved, suspended, or cancelled by EPA, and

4. the EPA has registered products that contain the active ingredient(s), and each of the inert ingredients is contained in a federally registered product.

Requests for Special Local Need (SLN) registrations are generally made by pesticide companies to the specific state. If the state approves the application, the (SLN) registration issued by the state is then forwarded to the EPA for acknowledgement.

The EPA has 90 days from receipt of the SLN application from the state to either disapprove or deny the application. Otherwise it becomes a Federal registration under FIFRA section 3.

Once the SLN is registered under FIFRA, it is subject to any additional data requirements that may be required by the EPA either as the result of a Registration Standard or any other FIFRA Section 3(c)(2)(B) data call-in.

FEE REQUIREMENTS FOR SLN'S

The 1988 amendments to FIFRA requiring that annual maintenance fees be paid by registrants of pesticide products apply to registrations under Section 24(c) of FIFRA. You should refer to Chapter 9 for a discussion of registration maintenance fees.

C. EMERGENCY EXEMPTIONS

FIFRA section 18 authorizes the Administrator to exempt State and Federal agencies from any provision of FIFRA, if he determines that emergency conditions exist which require an exemption. The regulations in 40 CFR Part 166 establish procedures by which the Administrator may exempt a Federal or State agency from the provisions of FIFRA which regulate the manner in which a pesticide is made available for use or is used.

WHO TO CONTACT: Additional information concerning applications for a state special local need registration should be addressed to the state in which you wish to make an application for a SLN registration. A listing of the various state pesticide agencies can be found in Chapter 18 of this manual.

CHAPTER 14 - **REFERENCES CITED** - Refer to Chapter 16 for information on the source of these documents.

1. Code of Federal Regulations, Title 40

   Part 162 - Regulations for the enforcement of the Federal Insecticide, Fungicide and Rodenticide Act
   Part 166 - Exemption of Federal and State agencies for use of pesticides under emergency conditions
   Part 172 - Experimental use permits

2. Federal Insecticide, Fungicide and Rodenticide Act, as amended October, 1988

   Section 3 - Registration of pesticides
   Section 5 - Experimental use permits
   Section 18 - Exemption of Federal and State agencies
   Section 24 - Authority of states

CHAPTER 15 - OTHER TYPES OF REGISTRATIONS AND/OR APPROVALS THAT MAY BE NEEDED FROM OTHER FEDERAL OR STATE AGENCIES

A. GENERAL INFORMATION

Although you may have obtained a Federal registration for your pesticide product, which allows you to distribute and sell your product in the U.S., there are state regulations that you may have to comply with before you can distribute and/or sell the product within that state.

In addition, there may be other approvals that you must obtain in order to use the product in a specific area. The following listing is intended only to provide general information on some of these requirements, or to provide a point of contact. It should be noted that the listing is not all inclusive, nor is it complete. It is your responsibility to comply with all federal, state or local regulations.

B. STATE REGULATION OF FEDERALLY REGISTERED PESTICIDES

FIFRA Section 24(a) states that "A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act".

Even though you have obtained a Federal registration for your pesticide product which allows you to distribute and sell the product within the U.S., the various states in which you may wish to distribute and sell your product and have additional requirements for the regulation of pesticides within the state. The requirements vary from state to state, and may include additional data requirements, additional restrictions on pesticide use within their jurisdiction, and licensing requirements. You should contact each state in which you intend to market your product to determine what additional requirements may affect the sale, distribution or use of your product.

WHO TO CONTACT: For additional information concerning state registration requirements for your Federally registered pesticide product, you should contact the pesticide regulatory authority in the state in which you intend to market your product. A listing of state regulatory authorities can be found in Chapter 18 of this manual.

C. USE OF PESTICIDES IN MEAT AND POULTRY PLANTS

Federally registered pesticides intended for use in federally inspected meat and poultry plants must be appropriately labeled and authorized by the U. S. Department of Agriculture (USDA).

The Federal Meat Inspection Act, as amended by the Wholesome Meat Act of 1967, and the Poultry Products Inspection Act, as amended by the Wholesome Products Act of 1968, require the maintenance of safe and sanitary conditions in federally inspected meat and poultry plants. These Acts are enforced by the Animal and Plant Health Inspection Service through the Meat and Poultry Inspection Program (MPIP).

The Inspection Program calls for the authorization of the use of substances and compounds in the plants, because use of such materials may result in adulteration or unwholesomeness of meat and poultry being processed. All chemicals produced in the U.S. for marketing to federally inspected meat and poultry plants must be evaluated by the USDA in order to provide assurance that the chemicals used in federally inspected plants are authorized for use and that their proper use will not result in adulteration or contamination of food products.

1. Labeling Requirements - Before directions for use in federally inspected meat and poultry plants can be accepted under the Federal Insecticide, Fungicide and Rodenticide Act, (FIFRA), you must obtain authorization from the USDA. Upon receipt of confirmation of USDA authorization, your product labeling can be amended to include the following statement:

> **"Authorized by USDA for use in federally inspected meat and poultry plants."**

2. Application for USDA Authorization - If you wish to have your product approved for use in a federally inspected meat or poultry plant, you must make an application to obtain authorization from the USDA.

WHO TO CONTACT: For additional information on the use of pesticides in federally inspected meat and poultry plants, and where to obtain application forms for authorization from the USDA, contact:

Compound Evaluation Laboratory
Scientific Services, FSQS
Food Ingredient Assessment Division
U.S. Department of Agriculture
Building 306, BARC-East
Beltsville, MD 20705

D. USE OF PESTICIDES ON FOOD CONTACT SURFACES, FOR PAPER AND PAPERBOARD (FOOD USES), ON MEDICAL DEVICES, AS HUMAN AND ANIMAL DRUGS, AND IN CANE-SUGAR AND BEET SUGAR MILLS

The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have several areas of mutual regulatory responsibility which may require review by one or both agencies.

The following is a brief summary of these areas:

1. Sanitizers (pesticides used on food contact surfaces)

Any pesticide product intended for sanitizing inanimate surfaces must be approved by the FDA pursuant to 21 CFR 178.1010. Ingredients in these products are considered to be Indirect Food Additives. EPA will not register sanitizer products unless the active and inert ingredients have been specifically approved or "generally recognized as safe" by FDA. Persons who wish to obtain FDA approval must submit a Food Additive Petition or similar request to:

Division of Food and Color Additives (HFF-330)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

2. Microbiocides in paper and paperboard (food use)

FDA evaluates the safety and efficacy of pesticides used in paper or other materials which come into contact with food. FDA must approve the ingredients of a pesticide as indirect food additives under 21 CFR Part 176 before EPA will approve a registration. Petitions or requests may be sent to the same address as in 1. above.

3. Antimicrobial pesticides used on medical devices

An antimicrobial agent is considered by FDA to be an accessory to a medical device. Accordingly, FDA requires premarket notification under section 510(k) of the FFDCA for marketing of such agents. FDA reviews the safety and efficacy of these antimicrobial products. Approval by both FDA and EPA must be obtained before these products may be sold or distributed. Section 510(k) petitions may be submitted to:

Division of Gastroenterology-Urology
and General Use Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration (HFZ-332)
8757 Georgia Avenue
Silver Spring, MD 20910

4. Human and Animal Drugs

FDA and EPA have areas of mutual responsibility with respect to applications for drugs under FFDCA and for registration of pesticides under FIFRA. In 1971, FDA and EPA issued a Memorandum of Agreement stating which agency has primary or

secondary responsibility on specific matters (See Federal Register Notice, 36 FR 24234). This agreement was updated in 1973 (38 FR 24233) and in 1979 (44 FR 63749). Briefly, EPA has primary jurisdiction for disinfectants and sanitizers, treatments of certain pests on animals, aquatic treatments solely for algae or bacterial slime, sanitizers for aquarium equipment, and sanitizers for inanimate surfaces or drinking water of animals which do not claim disease control. FDA has primary jurisdiction for new human or animal drugs, and products which are intended to: control parasites on humans, relieve the effect of insect bites, prevent diaper rash through treatment of diapers, treat athletes foot, treat certain animal diseases and pests, treat water for fish parasites or diseases, and treat drinking water to control animal parasites or diseases. Questions on these areas of jurisdiction may be referred to the EPA's Antimicrobial Program Branch. Refer to Chapter 18 of this manual.

5. Cane-sugar and beet-sugar mills

Pesticides used for controlling microorganisms in cane-sugar and beet-sugar mills must be approved by the FDA under 21 CFR 173.320. Petitions may be directed to the following address:

Division of Food and Color Additives (HFF-330)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

E. ANTIMICROBIAL FUEL ADDITIVES

Any pesticide product intended for use in aviation fuel must have the approval of the Federal Aviation Administration (FAA) for use in aircraft engines. Persons who wish to obtain FAA approval must submit their request to:

FAA Flight Standards Service
Engineering and Manufacturing Division
Federal Aviation Administration
Washington, D.C. 20591

CHAPTER 16 - HOW TO OBTAIN PUBLICATIONS

A. DOCUMENTS AVAILABLE FROM THE NATIONAL TECHNICAL INFORMATION SERVICE

The listing entitled "Availability of OPP Publication Listings" includes information on various OPP documents that are available at the National Technical Information Service (NTIS). The listing includes information on the following:

1. Information for Ordering OPP Publications from the National Technical Information Service
2. Registration Standards Report
3. Pesticide Fact Sheets
4. Special Review Position Documents
5. Hazard Evaluation Division (HED) - Pesticide Assessment Guidelines
6. Hazard Evaluation Division (HED) - Standard Evaluation Procedures
7. Pesticide Product Information - Compact Label File
8. Miscellaneous Publications/Documents
9. Pesticide Data Submitters List by Chemical (listed under Miscellaneous Publications/Documents)

Copies of the listing, which includes the NTIS Document order number, the EPA Document Number and the cost of the document on either microfiche or hard copy, are available from the following address:

U.S. EPA
Document Management Section (H7502C)
Information Services Branch, PMSD
Office of Pesticide Programs
401 M Street, S.W.
Washington, D.C. 20460

Telephone: (703) 557-4474

B. DOCUMENTS AVAILABLE FROM THE U.S. GOVERNMENT PRINTING OFFICE

The following documents are for sale, and are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Code of Federal Regulations, Title 40 (40 CFR)

- 40 CFR, Part 2 - Public information
- 40 CFR, Parts 150 to 189 - Protection of Environment

The Code of Federal Regulations is also available for examination at Government depository libraries and many other libraries. A complete listing of only Government Depository Libraries is available without charge from The Library, U.S. Government Printing Office, 5236 Eisenhower Avenue, Alexandria, VA 22304. A listing of libraries where the Code of Federal Regulations is available, which includes both Government depository libraries and other libraries that maintain copies of the Code of Federal Regulations can be found in the Federal Register of April 18, 1989 (54 FR 15608).

C. DOCUMENTS AVAILABLE FROM THE ENVIRONMENTAL PROTECTION AGENCY

The following documents are available from the Environmental Protection Agency:

1. Federal Insecticide, Rodenticide and Fungicide Act, as amended, October 1988, EPA 540/09-89-012.

2. LISTING OF FEDERALLY REGISTERED "RESTRICTED USE PESTICIDES"

The listing provides, by active ingredient, information on those active ingredients and products that have been classified as "Restricted Use" pesticides.

Copies of the two documents listed above are available from the following address:

Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Registration Support Branch (H7505C)
401 M Street, S.W.
Washington, D.C. 20460

Telephone: (703) 557-7700

3. Chemicals for Which Data Waivers Have Been Granted

As outlined in 40 CFR Part 158.45(d), Agency decisions on data waivers are available to the public at the following location:

Environmental Protection Agency
Office of Pesticide Programs
Docket Reading Room, Room 236
Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Office hours are from 8:00 AM to 4:00 PM, Monday through

Friday, except legal holidays. Telephone: (703)557-2805

Written Requests: Any person may obtain a copy of any waiver decision by written request to the following address:

Environmental Protection Agency
Freedom of Information (A-101)
401 M Street, SW
Washington, DC 20460

4. LISTING OF REGISTRATION STANDARDS ISSUED

This listing, entitled the "Registration Standard Report" provides information of all registration standards which have been issued, is contained in a general listing entitled "OPP Publication Listings" (see above).

5. PR NOTICES

Pesticides Regulation Notices (PR Notices) are mailed to registrants of record when issued. Additional copies, or back copies are available from:

U.S. EPA
Document Management Section (H7502C)
Information Services Branch, PMSD
Office of Pesticide Programs
401 M Street, S.W.
Washington, D.C. 20460

Telephone: (703) 557-4474

D. FEDERAL REGISTER NOTICES

The Federal Register is available for examination at Government depository libraries and many other libraries. A complete listing of only Government Depository Libraries is available without charge from The Library, U.S. Government Printing Office, 5236 Eisenhower Avenue, Alexandria, VA 22304. A listing of libraries where the Federal Register is available, which includes both Government depository libraries and other libraries that maintain copies of the Federal Register, can be found in the Federal Register of April 18, 1989 (54 FR 15608).

CHAPTER 17 - FORMS, AND HOW TO OBTAIN THEM

The various forms required to be submitted with various types of applications for registration, experimental use permits and distributors are listed below.

EPA FORM	TITLE
8570-1	Application for Pesticide Registration/Amendment (Revised 9-88, previous editions are obsolete)
8570-4	Confidential Statement of Formula (Revised 2-85, previous editions are obsolete)
8570-5	Notice of-Supplemental Registration of Distributor (Revised 4-83, previous editions are obsolete)
8570-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data (10-82)
8570-17	Application for an Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only (Revised 2-85, Previous editions may be used until supply is exhausted)
8570-20	Data Reference Sheet (1-81)
8570-27	Formulator's Exemption Statement (10-86)
8570-28	Certification of Compliance with Data Gap Procedures (10-86)
8570-29	Certification with Respect to Citation of Data (7-86)

Copies of these forms may be obtained from the Registration Support Branch, Registration Division (H5704C) Office of Pesticide Programs, Washington, D.C. 20460. Telephone; (AC 703) 557-7700.

The following forms may be obtained from the Office of Compliance Monitoring (EN-342), 401 M Street, SW, Washington DC, 20460, or your EPA regional office. See Chapter 18 for a listing of the Regional Offices.

EPA FORM	TITLE
3540-1	Notice of Arrival of Pesticides or Devices
3540-8	Application for Registration of Pesticide-Producing Establishments

CHAPTER 18 - WHO TO CONTACT FOR ASSISTANCE AND WHERE TO SEND YOUR APPLICATIONS AND SUBMISSIONS

A. GENERAL INFORMATION

The Registration Division, Office of Pesticide Programs, consists of three pesticide product branches, the Insecticide-Rodenticide Branch, the Fungicide-Herbicide Branch, the Antimicrobial Program Branch, and one support branch, the Registration Support Branch. The pesticide product branches are further subdivided into Product Manager Teams which are responsible for the review and processing of applications for registration, amended registration, petitions for tolerances, and experimental use permits.

B. WHERE TO SUBMIT YOUR APPLICATION

1. Applications for registration, petitions, experimental use permits, etc., must be mailed to the following address:

Document Processing Desk ( ) **
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

** Insert Appropriate Distribution Code identified below.

2. Hand-delivered applications must be delivered to the following address:

U.S. Environmental Protection Agency
Crystal Mall, Bldg. #2, Rm. 266A
Document Processing Desk ( ) **
1921 Jefferson Davis Highway
Arlington, VA 22202

** Insert appropriate Distribution Code identified below.

3. Distribution Codes

When you send mail that to either of the above addresses, we will be able to process your application more expeditiously if you indicate the type of application your are submitting. The following Distribution Codes are designed to enable the Agency to identify, route and process your incoming mail more quickly and accurately. The Distribution Code should be used as indicated in the addresses cited above.

DISTRIBUTION CODE	TYPE OF APPLICATION
APPL	Application for Product Registration
AMEND	Application to Amend a Product Registration
BIOTECH	Biotech Applications and pre-EUP Noticifactions
DIST	Supplemental (Distributor) Registration
EUP	Application for an Experimental Use Permit
PETN	Petition Request for Tolerance/Exemption
SLN	Special Local Need Registration
CAN/WD	Request to Cancel a Registered Product or to Withdraw a Pending Application for Registration, Experimental Use Permit, Petition, etc.
NEWCO	Request for a Company Number (Register an Establishment)
COADR	Company Name and Address Change
XFER	Transfer Products to a Different Company

C. REGISTRATION DIVISION, WASHINGTON D.C.

1. INSECTICIDE - RODENTICIDE BRANCH

The Insecticide-Rodenticide Branch is responsible for the registration and tolerance activities of pesticides used to control insects, mites, snails and slugs, and vertebrate pests (such as rats and mice), and used for animal repellents (such as deer, rabbit, dog and cat), and insect repellents, and used for biochemical, microbial and genetically engineered insecticide control agents. The various Product Manager Teams that are responsible for certain types of products are indicated below.

BRANCH CHIEF - Herbert S. Harrison (703) 557-2200
DEPUTY BRANCH CHIEF - Harvey Warnick (703) 557-2200

PRODUCT MANAGER 12 - Dennis Edwards (703) 557-2386

TYPE OF PRODUCTS: Carbamates, Miticides, Toxaphene, Carbaryl, Chlorpyrifos, Parathion

PRODUCT MANAGER 15 - George LaRocca (703) 557-2400

TYPE OF PRODUCTS: Chlorinated Organic Insecticides, Drug/Pesticide Combinations, Dichlorvos, Endosulfan, Fenthion, Fensulfothion, Disulfoton, Second Generation Pyrethroids (i.e., Permethrin and Cypermethrin)

PRODUCT MANAGER 16 - William H. Miller (703) 557-2600

TYPE OF PRODUCTS: Most Organo-Phosphorus products i.e., malathion, dimethoate, except those listed with PMs 12 and 15, Boric Acid, Vertebrate Pesticides, Animal and Bird Repellents

PRODUCT MANAGER 17 - Phil Hutton (703) 557-2690

TYPE OF PRODUCTS: Biologicals, Insect Repellents, Pyrethrins, First Generation Pyrethroids (i.e., Resmethrin), Herbs, Botanicals and Natural Oils

2. FUNGICIDE - HERBICIDE BRANCH

The Fungicide-Herbicide Branch is responsible for the registration activities of pesticides used for fungus and plant disease control, weed control (herbicides), fungicides, nematicides, wood preservatives, defoliants, desiccants, plant growth regulators, and some genetically engineered products. The various Product Manager Teams and their area of responsibility are listed below.

BRANCH CHIEF - Frank Sanders (703) 557-1650
DEPUTY BRANCH CHIEF - Thomas Adamczyk (703) 557-1650

PRODUCT MANAGER 21 - Lois Rossi (703) 557-1900

TYPE OF PRODUCTS: Fungicides, Nematicides, Wood Preservatives, Microbials

PRODUCT MANAGER 23 - Richard Mountfort (703) 557-1830

TYPE OF PRODUCTS: Herbicides: Arsenicals, Phenoxys, Aquatics

PRODUCT MANAGER 25 - Robert Taylor (703) 557-1800

TYPE OF PRODUCTS: Herbicides, Plant Growth Regulators

3. ANTIMICROBIAL PROGRAM BRANCH

The Antimicrobial Program Branch is responsible for the registration activities of pesticides used for disinfectants, water treatment, anti-fouling paints, swimming pool chemicals, sterilants and fumigants.

BRANCH CHIEF - Juanita Wills (703) 557-3661

PRODUCT MANAGER 31 - John Lee (703) 557-3676

TYPE OF PRODUCTS - Anti-fouling Paints, Quaternary Ammonium and Water Treatment Compounds, Sterilants

PRODUCT MANAGER 32 - Jeff Kempter (703) 557-3964

TYPE OF PRODUCTS - Hypochorites, Halides, Chlorophenolics, Swimming Pool Chemicals, Fumigants

4. REGISTRATION SUPPORT BRANCH

The Registration Support Branch is responsible for the processing and review of Section 18 Emergency Exemption requests, minor use (IR-4) petitions, inert ingredient clearances, and the review of product chemistry and precautionary labeling (acute toxicology) data. Additional responsibilities include tolerance reassessment, policy and regulation development and Office of Management and Budget (OMB) clearance, the processing of product registration transfer requests, company name and address changes, and registration cancellation requests, and front-end application processing.

BRANCH CHIEF - Ferial S. Bishop (703) 557-7700
DEPUTY BRANCH CHIEF - Donald R. Stubbs (703) 557-1806

AREA OF RESPONSIBILITY: Front-end applications processing.

FRONT END PROCESSING STAFF

STAFF LEADER - (vacant) (703-557-8977)

Processing and status of expedited review applications. When inquiring about the status of your application, you must be able to provide the red number in the upper right-hand corner of the Application for Registration/Amendment form (EPA Form 8570-1).

PRECAUTIONARY REVIEW SECTION

SECTION HEAD - Tom Ellwanger (703) 557-1700

AREA OF RESPONSIBILITY: Precautionary labeling (acute toxicity) reviews.

PRODUCT CHEMISTRY REVIEW SECTION

SECTION HEAD - Lynn Bradley (703) 557-7700

AREA OF RESPONSIBILITY: Review of product chemistry data, inert clearance requests.

EMERGENCY RESPONSE AND MINOR USE SECTION

SECTION HEAD - Donald R. Stubbs (703) 557-1806

AREA OF RESPONSIBILITY: Emergency Exemptions (Section 18's) and Minor Use (IR-4) petitions.

PROJECT COORDINATION SECTION

ACTING SECTION HEAD - Mark Dow (703) 557-7700

AREA OF RESPONSIBILITY: Tolerance revocation, regulation and standard operating procedures development, Office of Management and Budget (OMB) clearance of programs, and intra and intercoordination of lab audits and other media programs within the Agency

ADMINISTRATIVE PROCESSING SECTION

SECTION HEAD - Art Donner (703) 557-2126

AREA OF RESPONSIBILITY: Product registration transfers, cancellation requests, program status and reporting, and ADP processing.

D. FIELD OPERATIONS DIVISION

PUBLIC INFORMATION BRANCH

PUBLIC DOCKET AND FREEDOM OF INFORMATION SECTION

SECTION HEAD: Marcia Humbaugh (Acting)
(703) 557-4457

AREA OF RESPONSIBILITY: Freedom of information requests, public docketing.

E. PROGRAM MANAGEMENT AND SUPPORT DIVISION

INFORMATION SERVICES BRANCH

DOCUMENT MANAGEMENT SECTION

SECTION HEAD: Catherine Grimes (703) 557-4460

AREA OF RESPONSIBILITY: Document management and distribution.

INFORMATION RESOURCES DEVELOPMENT SECTION

SECTION HEAD: John Carley (703) 557-2315

AREA OF RESPONSIBILITY: Consulting assistance for compliance with data formatting requirements.

The following individuals may be contacted for assistance in answering questions or to provide guidance concerning the data formatting procedures as required by PR Notice 86-5:

Kris Pappajohn (703) 557-2316, or
Maureen Sherrill (703) 557-2361

F. EPA REGIONAL OFFICES

REGION 1

Jurisdiction: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Environmental Protection Agency
John F. Kennedy Federal Building, RM 2203
Boston, MA 02203

(617) 565-3715

REGION 2

Jurisdiction: New Jersey, New York, Puerto Rico, Virgin Islands

Environmental Protection Agency
26 Federal Plaza
New York, NY 10278

(212) 264-2525

REGION 3

Jurisdiction: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia

Environmental Protection Agency
841 Chestnut Street
Philadelphia, PA 19107

(215) 597-9800

REGION 4

Jurisdiction: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

Environmental Protection Agency
345 Courtland Street, N.E.
Atlanta, GA 30365

(404) 347-4727

REGION 5

Jurisdiction: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Environmental Protection Agency
230 South Dearborn Street 5 SPT 7
Chicago, IL 60604

(312) 353-2192

REGION 6

Jurisdiction: Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Environmental Protection Agency
1445 Ross Avenue
12th Floor, Suite 1200
Dallas, TX 75202

(214) 655-6444

REGION 7

Jurisdiction: Iowa, Kansas, Missouri, Nebraska

Environmental Protection Agency
726 Minnesota Avenue
Kansas City, KS 66101

(913) 236-2800

REGION 8

Jurisdiction: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

Environmental Protection Agency
999 18th Street
Suite 500
Denver, CO 80202-1603

(303) 293-1603

REGION 9

Jurisdiction: Arizona, California, Hawaii, Nevada, American Samoa, Guam

Environmental Protection Agency
215 Fremont Street
San Francisco, CA 94105

(415) 974-7054

REGION 10

Jurisdiction: Alaska, Idaho, Oregon, Washington

Environmental Protection Agency
1200 Sixth Avenue
Seattle, WA 98101

(206) 442-5810

F. STATE AGENCIES WITH LEAD PESTICIDE RESPONSIBILITY

Alabama

Director
Ag Chemistry/Plant Industry Division
Alabama Dept. of Agriculture & Industry
P.O. Box 3336
Montgomery, AL 36193
(205) 261-2631

Alaska	Pesticide Specialist Alaska Dept. of Environmental Conservation 500 S. Alaska St., Suite A Palmer, AK 99645 (907) 745-3236
American Samoa	Director, American Samoa EPA Office of the Govenor Pago Pago, American Samoa 96799
Arizona	State Chemist Office of State Chemist P.O. Box 1586 Mesa, AZ 85211-1586 (602) 833-5442
Arkansas	Director Division of Feed, Fertilizer & Pesticides Arkansas State Plant Board P.O. Box 1069 Little Rock, AR 72203 (501) 225-1598
California	Chief, Pesticide Registration Branch Division of Pest Management California Dept. of Food & Agriculture 1220 N Street, Room A-447 Sacramento, CA 95814 (916) 322-5130
Colorado	Chief, Pesticide Applicator Section Division of Plant Industry Colorado Dept. of Agriculture 4th Floor, 1525 Sherman Street Denver, CO 80203 (303) 866-2838
Commonwealth of the Northern Mariana Islands	Chief, Division of Environmental Quality Commonwealth of the Northern Mariana Islands (CNMI) P.O. Box 1304 Saipan, MP 96950
Connecticut	Senior Environmental Analyst Pesticide Control Section Department of Environmental Protection State Office Building Hartford, CT 06106 (203) 566-5148

Delaware	Pesticide Compliance Supervisor Delaware Dept. of Agriculture 2320 South DuPont Highway Dover, DE 19901 (302) 736-4811
District of Columbia	Section Chief, Pesticide Section Environmental Control Division Dept. of Consumer & Regulatory Affairs 5010 Overlook Avenue, S.W., Room 114 Washington, D.C. 20023 (202) 727-7432
Florida	Administrator Pesticide Registration Section Bureau of Product Data Evaluation Division of Inspection Florida Dept. of Agric. & Consumer Services Mayo Building, Rm. 208A Tallahassee, FL 32399-0800 (904) 487-2130
Georgia	Ag. Manager II Entomology & Pesticide Division Georgia Dept. of Agriculture Capitol Square Atlanta, GA 30334 (404) 656-4958
Guam	Director, Air & Land Programs Division Guam Environmental Protection Agency Harmon Plaza Complex, Unit D-107 130 Rojas St. Harmon, Guam 96911
Hawaii	Registration Specialist, Pesticides Branch Plant Industry Division Hawaii Dept. of Agriculture 1428 South King Street Honolulu, HI 96814 (808) 548-7125
Idaho	Supervisor, Pesticide Programs Division of Plant Industries Idaho Dept. of Agriculture P.O. Box 790 Boise, ID 83701-0790 (208) 334-3243

Illinois	Chief, Bureau of Plant & Apiary Protection Illinois Dept. of Agriculture State Fairgrounds Springfield, IL 62791-9281 (217) 785-2427
Indiana	Pesticide Compliance Officer Indiana State Chemist Office Dept. of Biochemistry Purdue University West Lafayette, IN 47907 (317) 494-1585
Iowa	Supervisor, Pesticide Section Iowa Dept. of Agriculture Wallace Bldg. East 7th Street and Court Avenue Des Moines, IA 50319 (515) 281-8591
Kansas	Administrator, Pesticide Registration Plant Health Division Kansas Dept. of Agriculture 109 S.W. Ninth Street Topeka, KS 66612-1281 (913) 296-2263
Kentucky	Director Kentucky Dept. of Agriculture Capitol Plaza Tower Frankfort, KY 40601 (502) 564-7274
Louisiana	Director, Pesticides & Environmental Programs Louisiana Dept. of Agriculture P.O.Box 44153 Baton Rouge, LA 70804-4153 (504) 925-3763
Maine	Pesticides Registrar Board of Pesticides Control Maine Dept. of Agriculture State House Station #28 Augusta, ME 04333 (207) 289-2731

Maryland	Registrar, State Chemist Section Plant Industries & Resource Conservation Maryland Dept. of Agriculture 0233 Chemistry Bldg. College Park, MD 20742 (301) 454-2722
Massachusetts	Manager, Technical Assessment Sect. Pesticides Bureau Maine Dept. of Food and Agriculture 100 Cambridge Street, 21st Floor Boston, MA 02202 (617) 727-7712 or 2863
Michigan	Supervisor, Product Registration Pesticide & Plant Management Div. Michigan Dept. of Agriculture P.O. Box 30017 Lansing MI 48909 (517) 373-1087
Minnesota	Pesticide Control Specialist Agronomy Services Division Minnesota Dept. of Agriculture 90 West Plato Blvd. St. Paul, MN 55107 (612) 297-2530
Mississippi	Pesticide Registration Division of Plant Industry Dept. of Agriculture and Commerce P.O. Box 5207 Mississippi State, MS 39762 (601) 325-3390
Missouri	Supervisor, Bureau of Pesticide Control Plant Industries Division Missouri Dept. of Agriculture P.O. Box 630 Jefferson City, MO 65102-0630 (314) 751-2462
Montana	Chief, Technical Services Bureau Environmental Management Division Montana Dept. of Agriculture Agriculture-Livestock Bldg. Capitol Station Helena, MT 59620-0205 (406) 444-2944

Nebraska	Director, Bureau of Plant Industry Nebraska Dept. of Agriculture 301 Centennial Mall Lincoln, NE 68509 (402) 471-2341
Nevada	Director, Division of Plant Industry Nevada Dept. of Agriculture P.O. Box 11100 Reno, NV 89510-1100 (702) 789-0180
New Hampshire	Director, Division of Pesticide Control New Hampshire Dept. of Agriculture Caller Box 2042 Concord, NH 03301 (603) 271-3550
New Jersey	Chief, Bureau of Pesticide Control NJ Dept. of Environmental Protection 401 East State Street CN 411 Trenton, NJ 08265 (609) 530-4134
New Mexico	Chief, Bureau of Pesticide Management Division of Agric. & Environmental Sciences New Mexico Dept of Agriculture P.O.Box 30005, Dept 3AQ Las Cruces, NM 88003 (505) 646-2133
New York	Director, Bureau of Pesticide Management Dept. of Environmental Conservation Rm. 404, 50 Wolf Road Albany, NY 12233-7254 (518) 457-7482
North Carolina	Assist. Pesticide Administrator Food & Drug Protection Division North Carolina Dept. of Agriculture P.O. Box 27647 Raleigh, NC 27611-0647 (919) 733-3556
North Dakota	Director, Registration Division North Dakota Dept. of Health and Consolidated Labs P.O. Box 937 Bismarck, ND 58502 (701) 221-6149

Ohio	Specialist in Charge Pesticides Regulation Ohio Dept. of Agriculture Division of Plant Industry 8995 East Main Street Reynoldsburg, OH 43068-3399 (614) 866-6361
Oklahoma	Program Manager Pesticide Registration Program Oklahoma Dept. of Agriculture 2800 North Lincoln Blvd. Oklahoma City, OK 73105-4298 (405) 521-3864
Oregon	Program Coordinator, Plant Division Oregon Dept. of Agriculture 635 Capitol Street, N.E. Salem, OR 97301 (503) 378-3776
Pennsylvania	Use & Investigation Specialist Bureau of Plant Industry Division of Agronomic Services Penna. Dept. of Agriculture 2301 N. Cameron Street Harrisburg, PA 17110 (717) 787-4843
Puerto Rico	Director, Analysis & Registration of Agricultural Materials Puerto Rico Dept. of Agriculture P.O. Box 10163 Santurce, PR 00908 (809) 796-1710, 1735
Republic of Palau	Executive Officer Palau Environmental Quality Protection Board Republic of Palau P.O. Box 100 Koror, Palau 96940
Rhode Island	Senior Plant Pathologist Division of Agriculture & Marketing Dept. of Environmental Management 22 Hayes Street Providence, RI 02908 (401) 277-2782

South Carolina	Department Head Dept. of Fertilizer & Pesticide Control 256 Poole Agricultural Center Clemson, SC 29634-0394 (803) 656-3171
South Dakota	Supervisor, Pesticide Activity Division of Regulatory Services South Dakota Dept. of Agriculture Anderson Bldg., 445 East Capitol Pierre, SD 57501 (605) 773-3724
Tennessee	Pesticide Registration Division of Plant Industries Tennessee Dept. of Agriculture P.O.Box 40627, Melrose Station Nashville, TN 37204 (615) 360-0130
Texas	Director Texas Dept. of Agriculture P.O. Box 12847 Austin, TX 78711 (512) 463-7526
Utah	Director, Division of Plant Industry Utah Dept. of Agriculture 350 North Redwood Road Salt Lake City, UT 84116 (801) 533-4107
Vermont	Director, Plant Industry Laboratory & Standards Division Vermont Dept. of Agriculture 116 State St., State Office Bldg. Montpelier, VT 05602 (802) 828-2435
Virginia	Supervisor Office of Pesticide Regulation VA Dept. of Agriculture & Consumer Service P.O. Box 1163 Richmond, VA 23209 (804) 786-3798
Virgin Islands	Director, Pesticide Programs Division of Natural Resources Management Dept. of Conservation and Cultural Affairs P.O. Box 4340 St. Thomas, VI 00801 (809) 774-6420

Washington	Chief, Registrations & Services Washington Dept. of Agriculture 406 General Administration Bldg. AX-41 Olympia, WA 98504 (206) 735-5064
West Virginia	Administrator Regulatory & Inspection Division W. Va. Dept. of Agriculture Charleston, WV 25305 (304) 348-2208
Wisconsin	Certification & Licensing Wisconsin Dept. of Agriculture, Trade & Consumer Protection P.O. Box 8911 Madison, WI 53708 (608) 267-9148
Wyoming	Manager, Technical Services Wyoming Dept. of Agriculture 2219 Carey Avenue Cheyenne, WY 82002-0100 (307) 777-6590

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THE END