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

Second Edition

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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

SECOND EDITION -- AUGUST 1992

PREFACE

This instruction manual, which is divided into 18 chapters, is 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 you being notified directly, and will take precedence over the information contained herein. In this respect, **changes made in this second edition of the instruction manual make the previous edition obsolete. Information in the first edition should be disregarded.**

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 150-189). 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 second edition of the instruction manual has been developed in an effort to provide applicants and registrants with the most recent general guidance on registering pesticides in the U.S. Draft copies of the second edition of the manual were sent to a number of people for review and comment. Numerous suggestions were received and have been incorporated in the final document. We wish to thank all of those who responded with their comments and suggestions.

In addition to a general updating of the original instruction manual we have added the following entries:

1. A glossary of terms (following chapter 18);
2. A general index (following the glossary at the end of the manual;
3. A paragraph on clearance of adjuvants (chapter 1);
4. A paragraph on clearance of inerts for products labeled for food crops (chapter 1);
5. A clarification of "fast track" products (chapters 2, 4);
6. A section on Reregistration Eligibility Documents (REDs) (chapter 2);
7. A section on Data Waivers (chapter 2);

8. Reference to the Food, Agriculture, Conservation, and Trace Act (FACTA) of 1990 and the 1991 Amendments of FACTA making a number of amendments to FIFRA, one of which was the redesignation of FIFRA Section 3(c)(1)(D) as Section 3(c)(1)(F) (chapters 2, 4, 6,);
9. A labeling appendix, with a sample label format for restricted and non-restricted use products (chapter 2).
10. A section on final printed labeling (chapter 4);
11. A section on "certification of compliance" statements under "How to Submit Notifications." (chapter 4);
12. Reference to PR Notice 91-8 regarding third party data producers (chapter 6);
13. A note indicating that the data gap option may not be available to certain applicants (chapter 6);
14. A section on data compensation charges/payment disputes (chapter 6);
15. The addition of a question on repackaged technical grade products under the "Questions and Answers" section of Chapter 6 (question 3, chapter 6);
16. The addition of a question on how long data submitters have to respond to an offer to pay under the "Questions and Answers" section of Chapter 6 (question 11, chapter 6);
17. The addition of a question on whether an applicant is subject to the data requirements of Agency issued Data Call-Ins, Registration Standards, and Reregistration Eligibility Documents as well as the requirements of CFR 158 under the Questions and Answers" section of Chapter 6 (question 18, chapter 6);
18. A note stating that a temporary tolerance associated with an Experimental Use Permit is not required if the treated commodity is to be destroyed or consumed only by experimental animals (chapter 7);
19. The discussion of tolerance fees in Chapter 9 has been moved to Chapter 7;
20. Chapter 9 ("What Fees Are Required For Registration and Tolerance Petition Activities) has been redesignated as the "new" Chapter 8 and chapter 8 (How to Apply For An Experimental use Permit) has been redesignated as "new" Chapter 9;
21. Inclusion of an "Experimental Use Permit Summary Worksheet" to new chapter 9;
22. A note warning against the transmittal of confidential business over FAX machines (chapter 12);
23. Addition of a section on "Grounds for EPA Disapproval of State Registrations (chapter 14);

24. The addition of sections on "Shipping (Transportation) of Pesticides" and "Nonindigenous and Genetically Engineered Microbial Products" regulatory contacts to Chapter 15; and
25. The addition of a facsimile directory to Chapter 18.

We hope the changes we've made to the original manual will provide you, the reader, with more information and make the manual easier for you to use. We welcome any comments, suggestions for changes, or additions that you believe will make this manual more useful. Your comments should be addressed to Mr. Herbert S. Harrison, Chief, or Mr. Harvey L. Warnick, Deputy Chief, Insecticide-Rodenticide Branch, Registration Division, Office of Pesticide Programs. Their addresses and phone numbers can be found in Chapter 18 of this manual.

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CHAPTER 1 - WHO MUST APPLY FOR REGISTRATION OF A PESTICIDE

A. PRODUCTS THAT REQUIRE REGISTRATION

Those who develop products to control pests[1] are subject to regulation under several Federal laws. However, only certain pest control products are subject to registration. 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). The term **"pesticide"**, as defined in FIFRA section 2(u), 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.

It is important to understand that FIFRA and the implementing regulations at 40 CFR parts 150-189, are the governing federal law regarding the sale, distribution and use of pesticides. Those who are subject to the law are responsible for understanding and complying with the terms of the law.

Anyone who plans to sell or distribute a product that is intended to control a pest or manipulate a plant must become familiar with the definition of pesticide in the law and regulations. Particular attention should be paid to the terms "substance" or "mixtures of substances" in the definition of pesticide. These terms provide the key to separating pesticides from devices. If the product contains a substance that is intended to affect a pest or plant by causing a physiological reaction when the target organism is exposed to the substance then the product is considered to be a pesticide and will require registration unless exempted, as discussed below. On the other hand, if the pest is controlled by a mechanical action the product will be considered a device and registration is not required. However, devices are subject to other provisions of the law, which are more thoroughly explained in Chapter 10.

IMPORTANT NOTE: The Agency has determined that, since humans are not pests as defined by FIFRA, it will not register products whose label bears claims for control of humans.

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[1] 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.

It is also important to fully understand the term "intent". Intent under the law can simply be demonstrated by more than overt pesticidal claims. As set forth at 40 CFR section 152.15, a substance is considered to be intended for a pesticidal purpose requiring registration, if:

a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) that 1) the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or 2) the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or

b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than 1) use for pesticidal purpose (by itself or in combination with any other substance), 2) use for manufacture of a pesticide; or

c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

   EXAMPLE: Products that have no claims to control insects on the product label, but whose name includes the name of a substance commonly recognized as having pesticidal properties will be recognized as a pesticide because the targeted consumer will know that such a substance is a well established pesticide.

Additionally, it is important to note that the definition for a pesticide does not make any reference to the level or kind of toxicity that a product may exhibit in order to be considered a pesticide. Therefore, toxicity does not have any place in determining if a product is a pesticide. Toxicity is taken into consideration by EPA when it requires supporting information (i.e. data) and when it determines if a product can be registered, and if so what limitations will be placed on it before it can be registered. Products that have very minimal toxicity such as garlic, red pepper, eucalyptus, mustard, citric acid, soap, menthol and cedar wood have been required to be registered.

It is important to become familiar with the other definitions in the law and regulations. The definitions for devices, active and inert ingredients and pests are terms that will be vital in more fully understanding the definition for a pesticide.

IMPORTANT NOTE: If you need assistance in determining if your product is a pesticide or device under FIFRA, you may contact the appropriate Branch Chief in the Antimicrobial, Herbicide/ Fungicide and Insecticide/Rodenticide Branches in the Registration Division. The contact should be made in writing and should include detailed information about what is intended and what the product is made of. Submission of a proposed label for the product would also be helpful. The addresses and/or FAX numbers for the Branch Chiefs are found in Chapter 18. Please send nothing via FAX that is considered confidential.

B. PRODUCTS OR SUBSTANCES THAT DO NOT REQUIRE REGISTRATION

1. **Adjuvants:** An adjuvant is a subsidiary ingredient or additive in a mixture which contributes to the effectiveness of the primary ingredient. Adjuvants are most commonly added to pesticides use dilutions in tank mixes by growers or applicators prior to application to the crop or site to be treated.[2] Agricultural chemical adjuvants are grouped according to their intended purpose in the tank mix and include but are not limited to the following groups: acidifying agents, buffering agents, anti-foam agents, defoaming agents, anti-transpirants, color adjuvants (such as dyes and brighteners), compatibility agents, crop oil concentrates, oil surfactants, deposition agents, drift reduction agents, foam markers, feeding stimulants, herbicide safeners, spreaders, extenders, adhesive agents, suspension agents, gelling agents, synergists, wetting agents, emulsifiers, dispersing agents, penetrants, tank and equipment cleaners, neutralizers, water absorbants, and water softeners. It is important to note that although adjuvants are not subject to registration when added in tank mixes by growers, those adjuvants intended for use in conjunction with a pesticide in tank mixes for application to a food or feed crop/site are required to be cleared under the Federal Food, Drug and Cosmetic Act (FFDCA), prior to being used. Adjuvants that are to be used with pesticides are evaluated in a process similar to the one for inert ingredients. Adjuvants intended for non-pesticidal uses on a food or feed crop/site are to be cleared with the FDA prior to being used. Refer to 21 CFR 182.99 and 40 CFR 180.1001(c) and (d).

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[2] Registrants sometimes include adjuvants as part of their pesticide formulations. When an adjuvant is included as part of a pesticide formulation that ingredient is included in the Agency's review of the product for registration under 3(c)5 or 3(c)7 of FIFRA.

2. **Devices:** 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. As stated above in the previous section, registration is not applicable for devices, although devices are subject to other provisions of the law. Refer to Chapter 10 for further information.

3. **Pesticide Intermediates:** Pesticide intermediates are substances which are not themselves pesticides, but which undergo chemical reactions resulting in the formation of a pesticide. Pesticide intermediates are not subject to registration under FIFRA but are subject to regulation under the Toxic Substances Control Act (TSCA). Questions regarding intermediates should be referred to the Office of Pollution Prevention and Toxics (OPPT). Pesticide intermediates include any beginning or intermediate material which is a chemical precursor to a pesticide active ingredient, whether produced <u>in situ</u> or obtained from other sources.

4. Pesticides and pest control organisms that have been exempted from the registration requirements of FIFRA by the Agency under 40 CFR Part 152, Subpart B - Exemptions.

a. Pest control organisms such as insect predators, nematodes, and macroscopic parasites. (40 CFR section 152.20(a)).

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

c. Those pesticides, such as (1) pesticide-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. (40 CFR section 152.25)

d. Pesticides transferred between registered establishments operated by the same producer. (40 CFR section 152.30 (a)).

e. Pesticides transferred between registered establishments not operated by the same producer if the transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered and only if each active ingredient in the pesticide, at the time of transfer, is present as a result of incorporation into the pesticide of either a registered product or a pesticide that is produced by the registrant of the final product. (40 CFR section 152.30(b)).

f. Pesticides distributed or sold under an experimental use permit issued under FIFRA section 5 if the product is labeled in accordance with 40 CFR 172.6. (40 CFR section 152.30(c)(1)).

g. Pesticides distributed or sold in accordance with 40 CFR 172.3, pertaining to use of a pesticide for which an experimental use permit is not required. (40 CFR section 152.30 (c)(2)).

h. Pesticides transferred within the United States solely for export if the product is prepared and packaged according to the specifications of the foreign purchaser. (40 CFR section 152.30(d)). (Refer to Section D of this chapter for a discussion on the importation and exportation of pesticides.)

i. Pesticides distributed or sold in accordance with the terms of an emergency exemption under FIFRA section 18. (40 CFR section 152.30(e)).

j. Unregistered, suspended, or canceled pesticides transferred solely for purposes of disposal in accordance with FIFRA section 19 or an applicable Administrator's order. (40 CFR section 152.30(f)).

k. Distribution and sale of existing stocks of formerly registered pesticides to the extent and in the manner specified in an order issued by the Administrator concerning existing stocks of the pesticide. (40 CFR section 152.30(g)).

C. PESTICIDES INTENDED FOR USE ON FOOD OR FEED

No person may distribute or sell any pesticide product, whether produced domestically or imported, that is not registered under FIFRA, except as noted in CFR 40 sections 152.20, 152.25, and 152.30. (Refer to Section C. of this chapter for a discussion of pest management products that are regulated but which do not require registration and to Section D of this chapter for a discussion on the importation and exportation of

pesticides.) In addition, pesticide products intended for use on food and/or feed crops are required to have pesticide residue tolerances established under the Federal Food, Drug, and Cosmetic Act (FFDCA).

The biologically active component which is called the active ingredient.[3] In addition to the active ingredient, pesticide products may contain intentionally added biologically inactive components called inert ingredients.

As with active ingredients, inert ingredients in pesticide product formulations are regulated under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and the Federal Food, Drug, and Cosmetic Act (FFDCA). If your proposed labeling bears instructions for use of the product on food or feed crops, or if the intended use of the product results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), you must submit a statement indicating whether a tolerance, exemption from the requirement of a tolerance, or a food additive regulation has been issued by the Agency under section 408 or 409 of the Federal Food Drug and Cosmetic Act (FFDCA). If a tolerance, exemption from the requirement of a tolerance, or a food additive regulation has not been issued for such residues, your application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulation in accordance with 40 CFR 180.

D. IMPORTATION AND EXPORTATION OF PESTICIDES

Refer to FIFRA section 17 for information concerning the importation and exportation requirements for pesticides. Except for the exemptions from the requirements of FIFRA listed under 40 CFR Part 152, Subpart B (see B 1., 2., and 3 above), 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 from EPA. Pesticides produced by foreign manufacturers and imported into the U.S. must comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of

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[3] The active ingredient in any pesticide product is that component which kills, or other wise controls, the target pests and includes any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA section 2(a).

Arrival of Pesticides and Devices (EPA Form 3540-1)[4] for review and determination as to whether the shipment should be sampled and/or permitted entry into the U.S. Applicants for importation of pesticides should follow the guidance on "How to Apply For Registration of a Conventional Pesticide" in Chapter 2 of this manual.

FIFRA section 17 states that no pesticide 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), (C), (D), (E), (G) and (H), 2(q)(2)(A), (B), (C)(i) and (iii), and (D).

FIFRA section 17(a)(2) further states that prior to the export of any pesticide not registered under section 3 or sold under section 6(a)(1) of FIFRA the foreign purchaser must have signed a Prior Informed Consent statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under FIFRA. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

E. 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. TO 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 your own application for pesticide registration.

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[4] See Chapter 17 of this manual for graphic representation of EPA Form 3540-1.

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

If you do not wish to register your 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. TO 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 do not require an amendment application but simply 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.

4. UNCONDITIONAL/CONDITIONAL REGISTRATION

The Agency has discretion to review applications for registration under either the unconditional registration criteria of FIFRA section 3(c)(5) or the conditional registration criteria of FIFRA section 3(c)(7).

a. **UNCONDITIONAL REGISTRATION**: An application will be approved under the unconditional registration criteria only if the Agency has (1) determined that the application is complete and is accompanied by all materials required by FIFRA, including, but not limited to evidence that the applicant has complied with the data compensation requirements; (2) reviewed all relevant data in its possession; (3) determined that no additional data are necessary to make the determinations required under FIFRA section 3(c)(5) with respect to the subject product; (4) determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted; (5) determined that the product will perform its intended function without unreasonable adverse effects on the

environment, and that when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;and (6) that the product is not misbranded according to 40 CFR 152.2(q) and 40 CFR 156; (7) determined that, if the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient of the product in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA section 408, section 409 or both; and (8) if the product, in addition to being a pesticide, is a drug within the meaning of FFDCA section 201(q), the Agency has been notified by the FDA that the product complies with any requirements imposed by FDA.

b. **CONDITIONAL REGISTRATION**:

1. **Products that do not contain a new active ingredient**: The Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products, only if the Agency has determined that (1) it possesses all data necessary to make the determinations required under FIFRA sections 3(c)(7)(A) or (B), which includes at a minimum, data needed to characterize any incremental risk that would result from approval of the application; (2) approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; (3) the application is complete and is accompanied by all materials required by the Act, including, but not limited to, evidence of compliance with the data compensation requirements; (4) the composition of the products is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted; (5) the product is not misbranded according to 40 CFR 152.2(q) and 40 CFR 156; (6)determined that, if the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient of the product in or on food or animal feed, all

necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA section 408, section 409 or both; and (7) if the product, in addition to being a pesticide, is a drug within the meaning of FFDCA section 201(q), the Agency has been notified by the FDA that the product complies with any requirements imposed by FDA.

However, the Agency will not approve the conditional registration of (1) any pesticide unless it has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; (2) any pesticide product for a new use if (a) the pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure and (b) the proposed use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure (determined with the concurrence of the Secretary of Agriculture).

Each registration issued for substantially similar products and new uses shall be conditioned upon the submission or citation by the registrant of all data which are required for unconditional registration of his product under FIFRA section 3(c)(5), but which have not yet been submitted, no later than the time such data are required to be submitted for similar pesticide products already registered. If a notice requiring submission of such data has been issued under FIFRA section 3(c)(2)(B) prior to the date of approval of the application, the applicant must submit or cite the data described by that notice at the time specified by that notice. The applicant must agree to these conditions before the application may be approved.

If any condition of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue appropriate action toward fulfillment of any condition, the Agency will issue a notice of intent to cancel under FIFRA section 6(e) and 40 CFR 152.148.

2. **Products that contain a new active ingredient**: An application for registration of a pesticide containing an active ingredient not in any currently registered product may be conditionally approved for a period of time sufficient for the generation and submission of certain of the data necessary for a finding of registrability under FIFRA section 3(c)(5) if the Agency determines that (1) insufficient time has elapsed since the imposition of the data requirement for those data to have been developed; (2) all other required test data and materials have been submitted to the Agency; (3) the application is complete and is accompanied by all materials required by FIFRA, including, but not limited to evidence that the applicant has complied with the data compensation requirements; (4) has reviewed all relevant data in its possession; (5) that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted; (6) that the product is not misbranded according to 40 CFR 152.2(q) and 40 CFR 156; (7) determined that, if the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient of the product in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA section 408, section 409 or both; and (8) if the product, in addition to being a pesticide, is a drug within the meaning of FFDCA section 201(q), the Agency has been notified by the FDA that the product complies with any requirements imposed by FDA; (9) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment; and (10) the registration of the pesticide product and its subsequent use during the period of the conditional registration are in the public interest.

Each registration issued for a new active ingredient shall be conditioned upon the applicant's agreement to each of the following conditions: (1) the applicant will submit remaining required data (and interim reports if required) in accordance with a schedule approved by the Agency; (2) the registration will expire upon a date established by the Agency, if the registrant fails to submit data as required by the Agency. The expiration date will be established based upon the length of time necessary to generate and submit the required data. If the studies are submitted in a timely manner, the registration will be canceled if the Agency determines, based on the data (alone, or in conjunction with other data), that the product or one or more of its uses meets or exceeds any of the risk criteria established by the Agency to initiate a special review. If the Agency so determines, it will issue to the registrant a Notice of Intent to Cancel under FIFRA section 6(e), and will specify any provisions for sale and distribution of existing stocks of the pesticide product; (3) the applicant will submit an annual report of the production of the product.

If any condition of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue appropriate action toward fulfillment of any condition, the Agency will issue a notice of intent to cancel under FIFRA section 6(e) and 40 CFR 152.148.

IMPORTANT NOTE: A Data Matrix Chart, identifying the FIFRA Section 158 data requirements for the product for which registration is requested, must be submitted with your application for registration of a product containing a new active ingredient or for registration of a new use of a currently registered product. Failure to submit a Data Matrix Chart with your application could result in your application being rejected.

F. 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 to 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) 260-7835.

G. **REFERENCES CITED IN CHAPTER 1** - 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
Part 172 - Experimental Use Permits
Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities

2. Code of Federal Regulations, Title 21

Part 182 - Substances generally recognized as safe

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

Section 2 - Definitions
Section 3 - Registration of pesticides
Section 7 - Registration of establishments

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) 260-7835.

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Part 158 - Data requirements for registration
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Part 182 - Substances generally recognized as safe

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Section 2 - Definitions
Section 3 - Registration of pesticides
Section 7 - Registration of establishments

CHAPTER 2 - HOW TO APPLY FOR REGISTRATION OF A 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 (active ingredient) that is not an active ingredient in 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(p) 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, your 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 original Application for Pesticide Registration form (EPA Form 8570-1)[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 that the form has a red number in the upper right hand corner since only EPA original forms (forms with a red number in the upper right hand corner of the document) are acceptable and also be certain that you 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 certain notices (i.e., those imposing legal

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[1] See Chapter 17 of this manual for graphic representation of EPA Form 8570-1.

requirements) and 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.

IMPORTANT NOTE: You must 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 Information Services Branch (ISB), Program Management and Support Division (PMSD), 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. Authorized Agent notifications are treated by the Agency the same as company name and address changes. Correspondence concerning authorized agents should therefore be sent to the Information Services Branch (ISB), Program Management and Support Division (PMSD).

2. **Confidential Statement of Formula** - A Confidential Statement of Formula (EPA Form 8570-4)[2] 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.

IMPORTANT NOTE: The Confidential Statement of Formula (CSF) is generally considered to be a document that contains Confidential Business Information (CBI) and should not be transmitted over FAX machines unless the sender wants to clearly waive his or her CBI rights and states this on the CSF.

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[2] See Chapter 17 of this manual for graphic representation of EPA Form 8570-4.

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 when sold or distributed, 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, reproducible and on 8 1/2 x 11 inch paper. If bilingual labeling is not required by the Agency and you wish to add such text to your labeling, you may do so after notification to the Agency. Implicit in a notification of bilingual labeling is an assurance that the bilingual text is an accurate translation of the English labeling text. The Agency recognizes that translating English language terms to Spanish may be a problem because Spanish terms from different parts of the Spanish speaking world may have a whole different meaning. Registrants should use the appropriate Spanish translation for their labeling. Note that the Agency believes the Spanish language translations to be used for "Caution", "Warning", and "Danger" are "Precaucion", "Advertencia", and "Peligro", respectively.

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. Guidance for the content and format of labels and labeling is provided in Appendix 2-1 and Figures 1 and 2, which are located after section I. of this Chapter.

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 also be required to 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 158.108 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 registrant's responsibility to ascertain through testing that the product performs in accordance with its labeling claims. EPA may require the submission of the product performance data on which claims are based.

IMPORTANT NOTE: Efficacy data (product performance data) are routinely required to be submitted to support products that control pests of public health significance, i.e. products to control bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats and mice. Otherwise, efficacy data may be required to be submitted on a case by case basis. (Note: applicant are required to prove to themselves that the product is efficacious when used as directed but efficacy data need only be submitted as described above.) Refer to 40 CFR Part 158.640 for product performance data requirements.

IMPORTANT NOTE: 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 likely be rejected and returned.

5. FIFRA section 3(c)(1)(F) [formerly 3(c)(1)(D)][3] data compensation requirements -Each applicant applying for registration of a pesticide must comply with the data compensation procedures under FIFRA section 3(c)(1)(F). Refer to 40 CFR 158, especially the tables in 158.190 - 158.740, to determine what data might be required for your particular product. 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.

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[3] The Food, Agriculture, Conservation, and Trade Act of 1990 (FACTA) and the 1991 Amendments of FACTA made a number of amendments to FIFRA. One of those amendments was to redesignate Section 3(c)(1)(D) as Section 3(c)(1)(F). Therefore, when citing the data compensation section of FIFRA you should now refer to 3(c)(1)(F) and not 3(c)(1)(D).

6. **Data waivers** - A waiver of data requirements occurs when the data appear to be required by 40 CFR Part 158 but for some scientific reason in that specific instance it is not necessary for the data to be generated. There is often confusion as to what a data waiver is or is not. The regulations may say that certain data are not applicable to a category of products such as in some of the footnoted items in the Data Requirement Tables in 40 CFR 158. Inapplicability of data is not a waiver of data. Or, new data may not be necessary because there are other data that can be substituted to fulfill the data requirement, e.g., an applicant might submit studies done by the paint industry, or threshold levels determined by NIOSH/OSHA to fulfil the requirement for inhalation toxicity data for her/his product. In this situation data are needed and appropriate, but are already available from an existing source. Using data from such a source is not a waiver of data.

On the other hand, waivers from the data requirements specified in 40 CFR 158, as applicable to a category of products, may be requested for an individual product in that category, if that product has special features which make the development of such data inappropriate. For example, some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. In these cases the Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards. The Agency will also, on a case-by-case basis, consider waiving specific data requirements when an applicant demonstrates in writing that the specific data are not necessary for the Agency to address the particular concern in question. The waiver request should be accompanied by all of the pertinent information or references to which the applicant refers.

The applicant may, under 40 CFR 152.91, demonstrate compliance for a data requirement by:

a) claiming that a waiver previously granted by the Agency also applies to a data requirement for her/his product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Registration Standard/ Registration Eligibility Document and must explain why that waiver should apply to his product.

b) requesting and being granted a new waiver to satisfy the data requirement.

An applicant who plans to request a data waiver should discuss his plans with the EPA Product Manager responsible for his product before developing and submitting extensive support information for the request. To request a data waiver, the applicant must submit a written request to the appropriate Product Manager. The waiver request must specifically identify the data requirement for which a waiver is requested, and must provide specific information, relative to each requirement for the compound in question, explaining why the applicant thinks the data requirement(s) should be waived, describe any unsuccessful attempts to generate the required data, furnish any other information which the applicant believes would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement. For example, to support a waiver for inhalation toxicity data, an applicant might submit information showing that the product is of a nature that precludes the potential for exposure. **The Agency needs scientifically sound information in order to make a decisions on specific data waiver requests. Simply stating that a product is ubiquitous in nature, or is Generally Recognized as Safe (GRAS) is insufficient.** The specific waiver must allow the Agency to determine if the kind and levels of exposure resulting from the proposed pattern of use is analogous to the submitted information.

The Agency will review each data waiver request and inform the applicant in writing of its decision. In addition, for decisions that could apply to more than a specific product, the Agency may choose to send a notice to all registrants or to publish a notice in the FEDERAL REGISTER announcing its decision. An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

Agency decisions on data waiver requests are available to the public at the Office of Pesticide Programs' Docket Reading Room, Room 1132, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 from 8:00 a.m. to 4 p.m., Monday through Friday, except legal holidays.

7. <u>Certification relating to child-resistant packaging</u> - 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.

8. **Restricted use classification** - The Agency has classified some or all of the uses of certain pesticides as a "Restricted Use Pesticide". A restricted use classification generally 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 Pesticide Information Network. See Chapter 16 for further information.

9. **Compliance With Reregistration Documents**

a. **Registration Standards** - Prior to the FIFRA Amendments in 1988, the reregistration program issued documents called Registration Standards. These Registration Standards provided information similar to that described under "b" below. Until the existing Registration Standards are updated by Reregistration Eligibility Documents, the application is to be prepared by using the Registration Standard as instructed under "b".

b. **Reregistration Eligibility Documents** - FIFRA was amended in 1988 and added section 4 which 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 Reregistration Eligibility Document (RED) is issued. The RED sets forth the Agency's decision on whether products containing a pesticide are eligible for reregistration. It assesses the acceptability of existing tolerances, and describes the need for additional data or information. Following issuance of the RED, procedures will be implemented for reregistration of end-use formulations. Product specific data and revised labeling will be called in to the Agency and evaluated during this period.

If a RED and an accompanying data call-in (DCI) have 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.

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 will 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 2-2, 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,[4] Revised 9-88)

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[4] See Chapter 17 for graphic representation of EPA Form 8570-4.

2. A properly completed Confidential Statement of Formula (EPA Form 8570-4,[5] Revised 2-85)

3. Five legible, reproducible copies of the proposed draft labeling for your product on 8 1/2" x 11" paper.

4. FIFRA section 3(c)(1)(F)[6] 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] (7-86)], and

b. A properly completed Formulator's Exemption Statement [EPA Form 8570-27[8] (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.

IMPORTANT NOTE: 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.

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[5] See Chapter 17 for graphic representation of EPA Form 8570-1.

[6] The Food, Agriculture, Conservation, and Trade Act of 1990 (FACTA) and the 1991 Amendments of FACTA made a number of amendments to FIFRA. One of those amendments was to redesignate Section 3(c)(1)(D) as Section 3(c)(1)(F). Therefore, when citing the data compensation section of FIFRA you should now refer to 3(c)(1)(F) and not 3(c)(1)(D).

[7] See Chapter 17 for graphic representation of EPA Form 8570-29 .

[8] See Chapter 17 for graphic representation of EPA Form 8570-27.

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** - are routinely required to be submitted to support products that control pests of public health significance, i.e. products to control bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats and mice. Otherwise, efficacy data may be required to be submitted on a case-by-case basis. (Note: applicants and registrants are required to ensure through testing that the product is efficacious when used as directed but efficacy data need only be submitted as described above.)

4. **Generic data** -these data pertain to the active ingredient (as opposed to the total pesticide product). These data must be submitted or cited for new uses or products not formulated with a registered product and new chemicals.

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. Provide a Data Matrix Chart of the data and corresponding EPA identifier numbers if the Selective Method of data support is used. See page 6-8 and Appendix 6-2.

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.

IMPORTANT NOTE: New Chemical/First Food Use Screening Process. You should be aware of PR Notice 86-4, issued April 15, 1986, which announced the Agency policy regarding incomplete applications for registration of pesticides under section 3 of FIFRA. Under that policy EPA generally will no longer accept or process any incomplete application received after May 1, 1986, for: 1) registration of a pesticide product containing a new active ingredient or 2) registration of the first food use of a previously

registered active ingredient and 3) to petitions to establish tolerances that accompany applications for registration of the food uses of such chemicals.

PR NOTICE 86-4 REQUIREMENTS FOR APPLICANTS. Each application to which PR Notice 86-4 applies must be accompanied by a transmittal document which: 1) identifies the application as being for approval of a new chemical or the first food use of a previously registered chemical; 2) lists the studies and other materials required to support the application in accordance with 40 CFR parts 152, 156, 158, and 162; 3) states that all such required studies and other materials are submitted with or cited in the application; 4) states which requirement each study or other material satisfies; 5) lists the location in the application where each item may be found; and 6) is signed by the authorized representative of the applicant. Waivers of specific data requirements may be requested in the application, as provided by 40 CFR 158.45, but must be accompanied by all information necessary to justify a waiver.

EPA PROCEDURES UNDER PR NOTICE 86-4. 1) Screening of applications: Before commencing full evaluation of an application and supporting materials, the Agency will conduct a two-stage screen of the application. In the first stage the Agency will determine if 1) all items listed in the transmittal document are included, 2) all material is legible and written in English, and 3) all studies and other materials required by regulations (40 CFR 152, 156, 158, and 162) are included. Applications found to be incomplete will not be processed further, but will be returned to the applicant.[9]

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[9] Applications found during the screening process to be incomplete or to include unacceptable studies will not be processed further. The applicant will receive a statement of the reason(s) for the rejection and instructions to arrange the retrieval of the application within 10 days. If the applicant does not retrieve the application, the Agency will send the material to the Federal Records Center for permanent storage. The Agency may, however, decide to retain studies included in an incomplete application for review to aid in the evaluation of other existing or proposed registrations.

If the application submission passes the first-stage screen, it will be further screened by scientific reviewers to determine that any included studies appear to be acceptable with regard to experimental design and conduct (see 40 CFR 158.80). If any study is found to be unacceptable in this second-stage screen the Agency will take no further action on the application. The application will be returned to the applicant.[10]

If a rejected application is resubmitted it will again be screened as previously described.

Agency review time-tables: The Agency is committed to perform both screening processes within 15 working days of receipt of the application by OPP's mailroom. Applicants will be notified by telephone when an application has been deemed complete and acceptable for the purposes of detailed review.

The Agency is committed to completing its review of the studies contained in applications that pass the screen within the following timeframes: new chemical applications for food uses or non-food uses that require chronic toxicity data, 375 days; new chemical applications for non-food uses that do not require chronic toxicity data, 250 days; applications for a first food use product, from 205 to 375 days, depending upon the amount of data that must be submitted and reviewed. In most cases, this review will enable the Agency to decide whether each study meets the guideline requirements and whether there is sufficient information to conclude that the proposed uses will not result in unreasonable adverse effects. If the Agency finds that additional information is required to resolve issues that arise during its review, more time will be needed to reach a regulatory decision.

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[10] Applications found during the screening process to be incomplete or to include unacceptable studies will not be processed further. The applicant will receive a statement of the reason(s) for the rejection and instructions to arrange the retrieval of the application within 10 days. If the applicant does not retrieve the application, the Agency will send the material to the Federal Records Center for permanent storage. The Agency may, however, decide to retain studies included in an incomplete application for review to aid in the evaluation of other existing or proposed registrations.

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

Section 3(c)(3)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act 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 <u>will</u> <u>not</u> 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, products that contain (a) inerts ingredients that do not currently exist in any other pesticide formulation; (b) significant changes in the percentage of active ingredient; (c) new formulation types; (d) directions for controlling new pests; (e) directions for new dosage rates; (f) directions for different frequency and timing of applications; (g) directions for use in different geographical locations other than those previously registered; and (h) directions for use on new sites and for new methods of

application for that active ingredient or ingredients. 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 (fast track) review[11], 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.

GUIDELINE FOR DETERMINING AN APPLICATION'S ELIGIBILITY FOR FAST TRACK REVIEW: A new **end-use product** application qualifies for fast track review only if the proposed pesticide is identical or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, cited by EPA Reg. No., in your application.

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[11] An explanation of the 45/90-day expedited review process (fast track) and detailed procedures for processing applications under it may be found in PR Notice 89-2.

EXAMPLES OF END USE ME-TOO APPLICATIONS THAT QUALIFY FOR FAST TRACK REVIEW:

- Applicant references similar, registered pesticide product and submits Product Chemistry.

- Applicant references similar, registered pesticide product and submits Product Chemistry, bridging acutes (not more than 2 studies) and confirmatory efficacy to confirm similarity.

- Applicant is repackaging a registered product.

EXAMPLES OF END USE ME-TOO APPLICATIONS THAT DO NOT QUALIFY FOR FAST TRACK REVIEW:

- Applicant references similar, registered pesticide product and submits Product Chemistry, and **required** Efficacy for Specific Formulation purposes.

- Applicant asserts similarity but does not reference pesticide product. Submits Product Chemistry.

- Applicant references a similar pesticide product and submits Product Chemistry and **required** nitrosamine data for Specific Formulation.

- Applicant does not reference a pesticide product. Submits Product Chemistry and **required** nitrosamine data for Specific Formulation.

- Applicant does not reference a pesticide product. Submits Product Chemistry and the full battery of Acutes.

- Applicant references a similar registered pesticide product. Submits Product Chemistry, the full battery of Acutes, and **required** efficacy data.

[**Note: Applications For New Manufacturing Use Products, including Technical Grade Products**, are excluded from fast track review by FIFRA Section 3(c)(3)(B)(i)(I).]

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)[12] - for an application for new product registration

By Mail:

Document Processing Desk (Appl)[12]
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

By courier or hand delivery:

Office of Pesticide Programs
Document Processing Desk (Appl)[12]
Room 258, 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.

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[12] OPP uses Distribution Codes to facilitate the delivery of mail, data submissions, etc., within the program. "APPL" is the OPP Distribution Code for an application for new product registration. If you are submitting an application for something other than an application for new product registration refer to the Distribution Codes for OPP set forth in Chapter 18 of this manual or to PR Notice 91-5, Attachment 1. If you are unable to determine which code is appropriate for your submission, omit the code.

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, the Product Manager Team will determine if the efficacy data requirements, which are routinely required to be submitted to support products that control pests of public health significance, i.e., products to control bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats and mice, 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 be 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. If the application is not picked up within 10 days it may be destroyed.

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 FIFRA requires EPA to review applications for expedited registration within 90 days of receipt, this turnaround time may not be met immediately due to a continuing backlog of applications. However, EPA is increasing 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.

G. WHERE TO SUBMIT YOUR APPLICATION

See section F.3. of this Chapter for the address to 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.

I. **REFERENCES CITED IN CHAPTER 2** - 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 - Registration policies and interpretations
   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 86-4 - 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.

5. 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.

6. PR Notice 89-2 - Expedited Review of Applications for Registration or Amended Registration. Issued by the Registration Division, Office of Pesticide Programs, EPA, June 6, 1989.

7. PR Notice 91-5 - Instructions for Transmitting Information to the Office of Pesticide Programs. Issued by the Program Management and Support Division, Office of Pesticide Programs, EPA, September 6, 1991.

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

8. Listing of Registration Standards and Reregistration Eligibility Documents (REDs), compiled by the Document Management Section, Information Services Branch, Program Management Support Division.

9. Food, Agriculture, Conservation, and Trade Act of 1990, November 28, 1990

   Subtitle H - Pesticides; Sections 1491 through 1499

10. Food, Agriculture, Conservation, and Trade Act Amendments of 1991, December 13, 1991

    Section 1006 - Amendments to FIFRA and Related Provisions

PESTICIDE LABELING REQUIREMENTS

EPA's requirements and policies for pesticide labels and labeling are specified in 40 CFR 156.10, Pesticide Regulatory (PR) Notices and various decision documents for specific chemicals (i.e., Special Reviews, Registration Standards, Reregistration Eligibility Documents, etc.). Following are general and specific guidelines for the contents of labels and labeling. Sample formats are shown in Figures 1 and 2.

General Guidance

Labels and labeling must accurately communicate important precautions and instructions to the user so that each product is effective without causing unreasonable adverse effects to humans or the environment. In addition, the label is a legal, enforceable document. Therefore, labels and labeling must meet the following general criteria:

- Comply with EPA's regulatory requirements.
- Be clear and understandable to the user under normal conditions.
- Provide accurate precautions and directions that protect the user, other humans and the environment.
- Contain no false or misleading statements or implied Federal Government endorsements.
- Clearly distinguish between language that is mandatory and enforceable statements and language that is only advisory and cannot be enforced.

Specific Guidance

Following is a summary of the specific items that must appear on the label and/or labeling. The location of these items is shown in Figures 1 and 2, which are sample formats for restricted use and unclassified products, respectively.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR 156.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the producer, registrant or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text. [40 CFR 156.10(c)]

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. Net contents must be expressed in conventional American units of fluid ounces, pints, quarts, and gallons. The net contents must also be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to American units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No." or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required, preferably on the front panel immediately below the product name. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients, with a total of 100%. It must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Figures 1 and 2. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 6C. NAMES TO BE USED IN INGREDIENT STATEMENT - The acceptable common name, if there is one, shall be used, followed by the chemical name. If no common name has been established, the chemical name alone shall be used.

Item 6D. INERT INGREDIENTS RECLASSIFIED AS ACTIVE INGREDIENTS - If EPA has reclassified chemicals from inert ingredient status to active ingredient status, registrants of affected products must change the ingredient statement accordingly . If such pesticides have food uses, tolerances may be required to be established if the percentage of the pesticide in the product formulation exceeds the limits set in the exemption from tolerance under 40 CFR 180.1001. (Note: If EPA has reclassified chemicals from active ingredient status to inert ingredient status, registrants of affected products must also change the ingredient statement accordingly.) [40 CFR 153.125]

Item 6E. NOMINAL CONCENTRATION - The amount of active ingredient declared in the ingredient statement must be the nominal concentration of the product as defined in 40 CFR 158.153(i) and described in PR Notice 91-2.

Item 7. WARNINGS AND PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together on the label (preferably within a block outline) so as to appear with sufficient prominence relative to other front panel text and graphic material to make then unlikely to be over-looked under customary conditions of purchase and use. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution, use or storage is unlikely, or in the instances where the pesticide has been approved for use on infants or small children. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)] The signal word is also required on the side panel under Hazards to Humans and Domestic animals (see Item 8A).

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the Word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)(A)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)][13]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel of all products unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)][13]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning sections must be headed by the appropriate subheadings (8A, 8B and 8C). [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. These statements must be preceded by the signal word. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

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[13] During the reregistration review process the Agency may require that the Statement of Practical Treatment include toxicity due to skin and eye effects in addition to oral, dermal or inhalation effects. The Agency may, in the course of that review process, also require that the Statement of Practical Treatment appear on the front panel of the label. These and other labeling requirements resulting from the reregistration review process will supersede the instructions in this manual.

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY - Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in 40 CFR 156.10(h)(2)(iii). The requirement is based on the results of required flashpoint determinations and flame extension tests submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation). If your product has been classified for restricted use, then these requirements apply:

1. **All uses restricted.** The following statements should be placed in a box (block outline) at the top of the front panel of the label and labeling:

a. The statement "Restricted Use Pesticide" <u>must</u> appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for the human hazard signal word [see table in 40 CFR 156.10(h)(1)(iv)]. (The signal word is determined by the product's toxicity category, just as it is for general use products.) **<u>No statements of any kind may appear above this RUP statement.</u>**

b. The **reason** for the restricted use classification should appear below the RUP statement. Statements may be used in combination if there is more than one reason for the RUP classification. Some examples of restricted use reason statements are listed below:

1. "Acute inhalation toxicity"
2. "Acute dermal toxicity"
3. "Acute oral toxicity"
4. "Acute eye irritation"
5. "Toxic to fish and aquatic organisms"
6. "Toxic to birds"
7. "Toxic to wildlife"

8. "Potential for groundwater contamination"

9. for teratogenicity: "Has been shown to cause birth defects in laboratory animals"

10. for oncogenicity: "The use of this product may be hazardous to your health. This product contains (Chemical Name), which has been determined to cause tumors in laboratory animals"

11. "Due to the complexity of application and use directions"

c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. If use is restricted to certified applicators, the following statement is required: "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."

2. **Some but not all uses restricted.** If some uses are classified for restricted use and some are not, several courses of action are available:

a. If you wish to include both restricted and unrestricted uses on a single product label, you may do so, but you must label the product for restricted use.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses. (Of course you lose the uses you delete, but you may sell an unrestricted product.)

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for registration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers upon registration.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a restricted entry interval (REI) has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to PR Notices 83-3 and 84-1 to determine the storage and disposal instructions appropriate for your product(s).

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. The directions for use must include the following: (a) the site(s) of application, i.e., crops, animals, areas, or objects to be treated; (b) identification of the target pest(s) associated with each site; (c) the dosage rate associated with each site and pest; (d) the method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required; (e) the frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment; and (f) any limitations or restrictions on use required to prevent unreasonable adverse effects, i.e., required intervals between application and harvest of food or feed crops, rotational crop restrictions, warnings as required against use in or adjacent to certain areas or on certain crops, animals or objects. [40 CFR 156.10(i)(2)]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers or other written, printed or graphic matter which is referred to on the label or which is to accompany the product are called collateral labeling. Such labeling may not bear claims or representations that substantially differ from those accepted in connection with registration of the product. Collateral labeling must be submitted along with the application for registration.

USE OF BILINGUAL LABELING

If bilingual labeling is not required by the Agency and you wish to add such text to your labeling, you may do so after notification to the Agency. Implicit in a notification of bilingual labeling is an assurance that the bilingual text is an accurate translation of the English labeling text. The Agency recognizes that translating English language terms to Spanish may be a problem because Spanish terms from different parts of the Spanish speaking world may have a whole different meaning.

Registrants should use the appropriate Spanish translation for their labeling. Note that the Agency believes the Spanish language translations to be used for "Caution", "Warning", and "Danger" are "Precaucion", "Advertencia", and "Peligro", respectively.

MATERIAL SAFETY DATA SHEETS (MSDS)

Material Safety Data Sheets (MSDS) are Hazard Communication Standards required by the U. S. Department of Labor's Occupational Safety and Health Administration under 29 CFR 1910.1200. They are required for chemicals, other than pesticides, and serve much like the label on a pesticide product in conveying safety information about the chemical.

FIFRA Section 2(p)(2)(A) defines labeling as "all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time." Including an MSDS in or on a carton of pesticide product would meet this definition. However, EPA does not intend to review Material Safety Data Sheets as labeling at this time but will instead permit them to accompany a pesticide product under the provisions of 40 CFR 152.46(b)(3) which permits registrants to change a product's non-mandatory labeling or packaging, including additions or changes required by other Federal statutes or regulations, without notification to or approval by the EPA, providing such labeling is consistent with the labeling requirements set forth in 40 CFR Part 156. Registrants should note that it is possible that information on an MSDS could conflict with a pesticide label (e.g., protective clothing recommendations or first aid directions) and that they should therefore assure that the MSDS and the approved pesticide labeling are not in conflict. EPA may find a conflict to be a misbranding violation under FIFRA section 12(a)(1)(E) as defined in FIFRA section 2(q).

Figure 1. Sample Format For Restricted Use Product Label -- Products With High Acute Toxicity (Toxicity Category I)

8 →

8A → PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
DANGER

8B → ENVIRONMENTAL HAZARDS

8C → PHYSICAL OR CHEMICAL
HAZARDS

9B → DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

10A → RE-ENTRY STATEMENT
(If Applicable)

10B → STORAGE AND DISPOSAL

STORAGE

DISPOSAL

10C → SITE (CROP)

R E S T R I C T E D U S E

P E S T I C I D E ← 9A

Due to (insert reason*)
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

P R O D U C T ← 1

N A M E

ACTIVE INGREDIENT: ..... % ← 6A 6C
INERT INGREDIENTS: ..... % 6D 6E

TOTAL 100.00%

THIS PRODUCT CONTAINS LBS. OF PER GALLON ← 6B

7 → KEEP OUT OF REACH OF CHILDREN ← 7A

7B → DANGER - POISON ← 7C

STATEMENT OF PRACTICAL TREATMENT ← 7D

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS ← 7E

MFG. BY ← 2
CITY, STATE
EPA REGISTRATION NO. ← 4
5 → ESTABLISHMENT NO.
NET CONTENTS ← 3

SITE (CROP)

SITE (CROP)

SITE (CROP)

SITE (CROP)

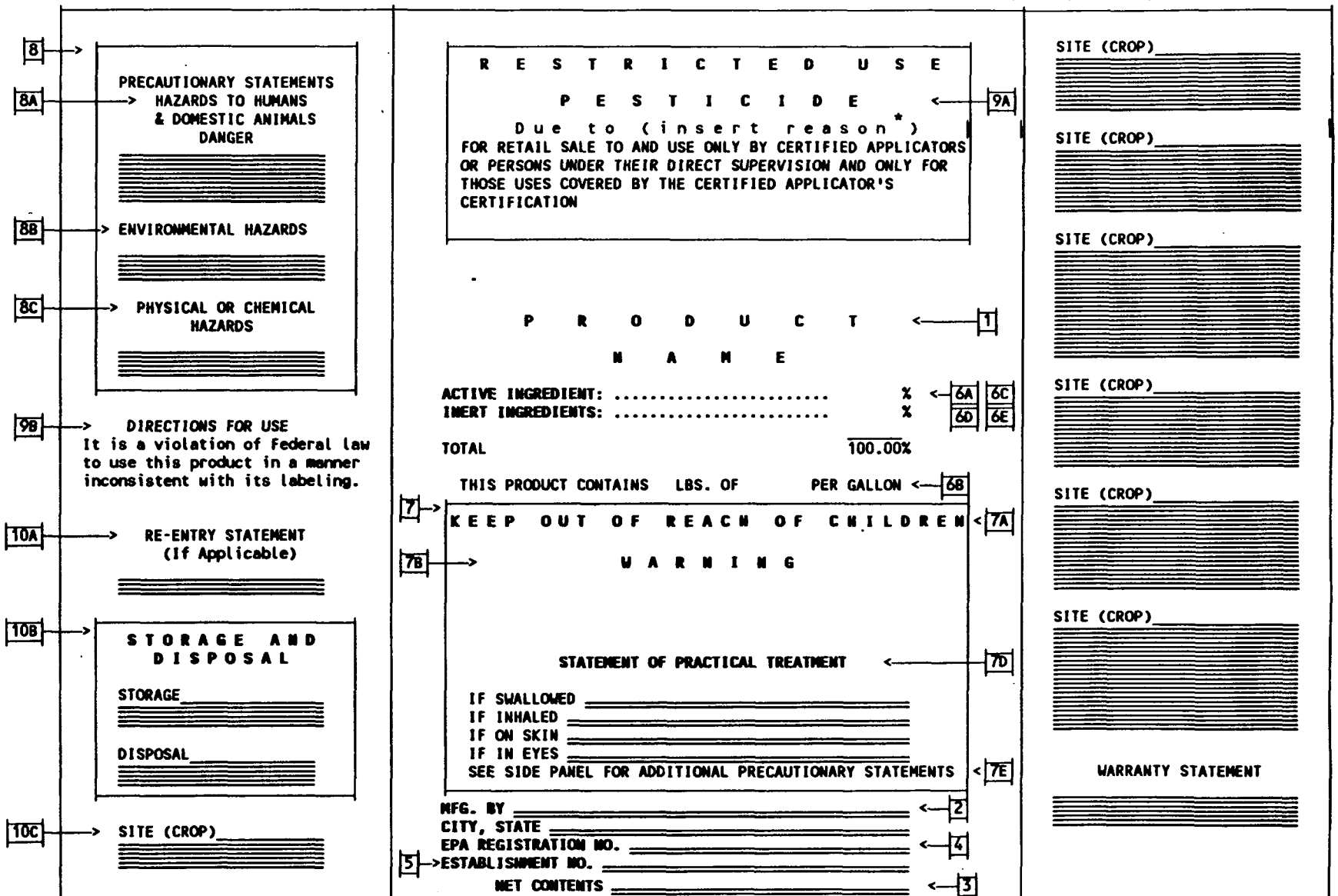
SITE (CROP)

SITE (CROP)

WARRANTY STATEMENT

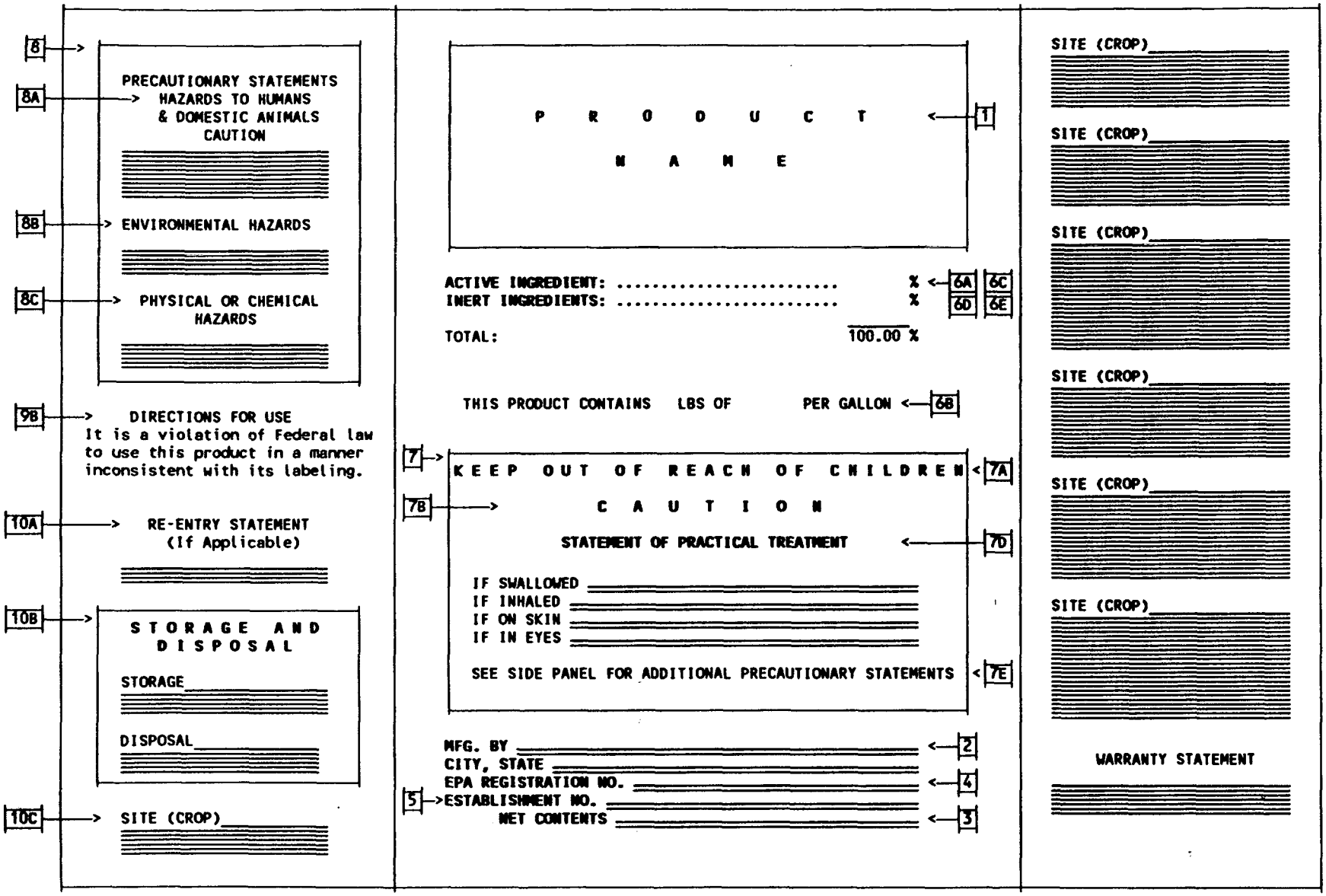
* for example, "Due to acute oral toxicity." See page 2-20, Item 9A. 1. b. of this chapter for additional examples.

Figure 2. Sample Format For Restricted Use Product Label -- Products With Other Than High Acute Toxicity (Toxicity Categories II, III, IV)



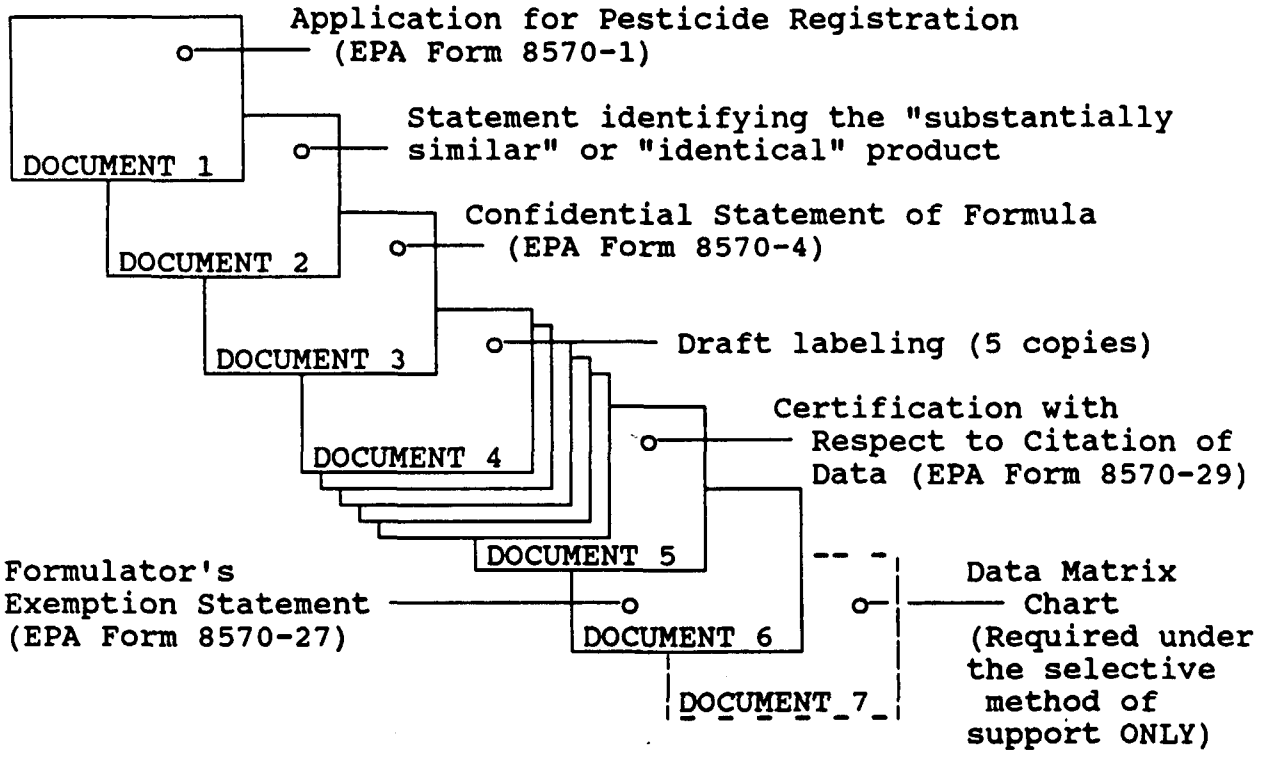
* for example, "Due to toxicity to birds." or "Due to the complexity of application and use directions." See page 2-20, Item 9A. 1. b. of this chapter for additional examples.

Figure 3. Sample Format For Unrestricted Use Product Label.

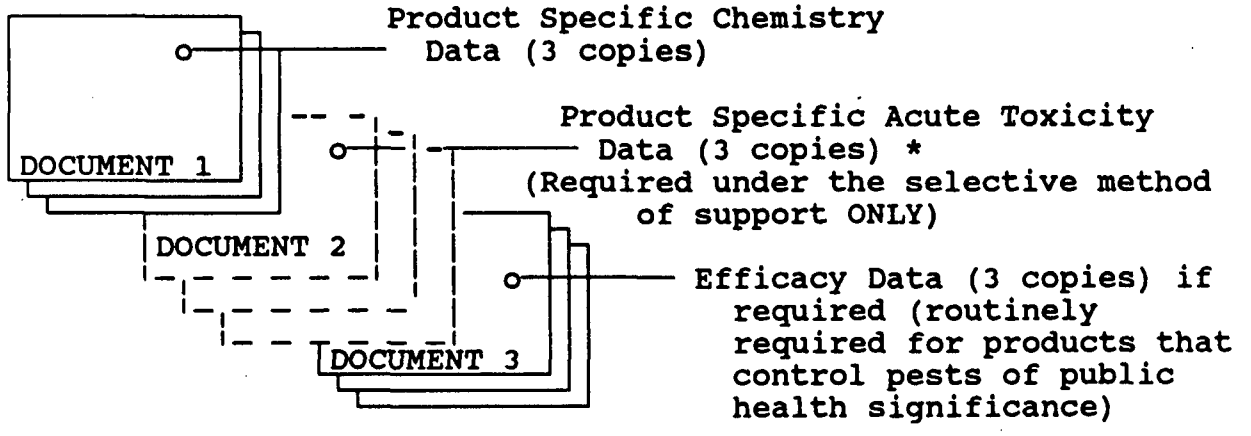


A COMPLETE APPLICATION FOR REGISTRATION OF A TYPICAL "ME-TOO" PRODUCT REQUIRES THE FOLLOWING DOCUMENTS

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



B. DATA PORTION OF APPLICATION: (FORMATTED AS DESCRIBED IN PR NOTICE 86-5)



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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 3 - CONSIDERATIONS 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 chemical pesticides by their unique modes of action, target species specificity, and natural occurrence. In addition, low use volumes microbial pesticides may be capable of growth and reproduction in the environment or in suitable hosts (40 CFR 158.65). Both naturally occurring and genetically modified microorganisms are included in the microbial pesticide group.

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 (generally reduced) set of data requirements as specified in 40 CFR 158.690 and 158.740. The Agency has 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 9 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: The Agency is developing a separate registration guidance document specifically for biochemical and microbial pesticides that may be available by the time you receive this manual. It is recommended that you contact the appropriate Product Manager (see section F.) for this document and for additional guidance prior to initiating testing, or filing an application for registration of a biochemical or microbial pesticide.

IMPORTANT NOTE: Once you have obtained the data from your EUP, follow the procedures in Chapter 2 of this manual when filing an application for registration of a biochemical or microbial pesticide.

B. PRODUCTS EXEMPT FROM REGISTRATION

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 152.20(a). 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 regulation 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 regulation under FIFRA.

C. BIOCHEMICAL PESTICIDES

Biochemical pesticides include, but are not limited to, products such as semiochemicals (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.

D. MICROBIAL PESTICIDES

Microbial pesticides are microorganisms and include but are not limited to bacteria, algae, fungi, viruses, and protozoa used as pest control agents (40 CFR 152.20). The data requirements in 40 CFR 158.740 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.

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.

E. 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 23303).

The Agency will have up to 30 days to review the above information reported 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.

IMPORTANT NOTE: Since most microbial pesticides are at least toxic to the target organism, and therefore are "pathogens", they cannot be considered under Level I but must instead be submitted under Level II.

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 23303). 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.

F. WHO TO CONTACT FOR ADDITIONAL INFORMATION

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

G. REFERENCES CITED IN CHAPTER 3 - 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 23303)

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 (EPA Form 8570-1), 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)(F) [formerly 3(c)(1)(D)][1] 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) and Confidential Statement of Formula (EPA Form 8570-4) 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 H of this Chapter.

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[1] The Food, Agriculture, Conservation, and Trade Act of 1990 (FACTA) and the 1991 Amendments of FACTA made a number of amendments to FIFRA. One of those amendments was to redesignate Section 3(c)(1)(D) as Section 3(c)(1)(F). Therefore, when citing the data compensation section of FIFRA you should now refer to 3(c)(1)(F) and not 3(c)(1)(D).

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 H 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. Labeling changes must comply with current regulations, policies and format. (See Appendices 2-1 and 2-2)

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 supersedes 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.

IMPORTANT NOTE: FIFRA section 6(F) does not apply when a registrant simply chooses to market a product with a subset of approved uses, but does not formally delete the uses from its registration. [40 CFR 152.130.]

Guidance for the content and format of labels and labeling is provided in Appendix 2-1 and Figures 1 and 2, which are located after section H. of Chapter 2.

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 pesticide products that control pests of public health significance, i.e., products to control bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats and mice, which routinely require the submission of efficacy data to support the revised formulation 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 already exists on another currently registered substantially similar or identical product. Refer to Appendix 4-2, which follows section H 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 (by EPA Registration No.) 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.

- Five (5) copies of your proposed draft labeling.It would make the Agency's review go more quickly if you 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), if needed. [This is not needed if you have already submitted it and the information is still current and if your source is registered and your application is not affected by PR Notice 91-8.]

- 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 a pesticide product that controls pests of public health significance, i.e., products to control bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats and mice. 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.

- **Use specific data** - may be required if you choose not to compensate the original submitter of the data or if the data are exclusive use.

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

Section 3(c)(3)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act 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 (provided, of course, that the "me-too" registrant cites existing data for that use) 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, unless the amendment is of a nature that review of scientific data would not be required [see FIFRA section 3(c)(3)(B)(i)(II)]. Some examples of products that may not be considered substantially similar are those which involve inerts that are (a) not currently included in registered products or (b) will change the precautions of those required for "similar" products; 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 may 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 (fast track) review[2], 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

[2] An explanation of the 45/90-day expedited review process (fast track) and detailed procedures for processing applications under it may be found in PR Notice 89-2 and the examples of fast track applications on page 4-7 of this section.

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.

GUIDELINE FOR DETERMINING AN APPLICATION'S ELIGIBILITY FOR FAST TRACK REVIEW: Amendments are entitled to fast track review under two (2) conditions:

1) Any amendment (**end-use product** or **manufacturing-use product**) that does not require scientific review of data;

2) If minimal* data submitted with the amendment for an **end-use product** are for the purpose of confirming that the changed formula or label are identical or substantially similar to a currently registered pesticide cited in your amendment application.

* Minimal data could include product chemistry, acute toxicity, or efficacy data.

Note: If your original application qualifies for expedited review, a resubmission of that application will likely also qualify for expedited review.

EXAMPLES OF AMENDMENTS THAT QUALIFY FOR FAST TRACK REVIEW

- Any amendment which asserts that the proposed change in labeling or formula is not significant.

- Either no data are required to be submitted or confirming chemistry/acute/efficacy data are submitted to support the assertion.

- Any administrative amendment (not requiring review of data).

EXAMPLE OF AMENDMENTS THAT DO NOT QUALIFY FOR FAST TRACK REVIEW

- Any amendment not identified above as qualifying for fast track review will be reviewed as a non-fast track submission.

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)[3] - to amend a currently registered product

By Mail:

Document Processing Desk (AMEND)[3]
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)[3]
Room 258, 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

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[3] OPP uses Distribution Codes to facilitate the delivery of mail, data submissions, etc., within the program. "AMEND" is the OPP Distribution Code to amend a currently registered product. If you are submitting an application for something other than an application to amend the registration of a currently registered product refer to the Distribution Codes for OPP set forth in Chapter 18 of this manual or to PR Notice 91-5, Attachment 1. If you are unable to determine which code is appropriate for your submission, omit the code.

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. If the application is not picked up within 10 days it may be destroyed.

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 FIFRA requires EPA to review applications for expedited registration within 90 days of receipt, this turnaround time may not be met immediately due to a continuing backlog of applications. However, EPA is increasing 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.

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 H 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 of Amendment Application** includes the following:

- Application for Pesticide Amendment (EPA Form 8570-1).[4]

- Five (5) copies of your proposed draft labeling. In addition submit one (1) label clearly marked to show the addition(s), deletion(s), or change(s) you plan to make on your amended labeling. This marked up label can be done on a copy of your proposed label or on the label which was previously registered. It would make the Agency's review go more quickly, if you were to highlight your proposed changes with a light colored felt tip marker.

  IMPORTANT NOTE: All other parts of the label requiring prior EPA approval and not included in your proposed amended label must remain as previously accepted by the Agency.

- Certification with Respect to Citation of Data (EPA Form 8570-29).[5]

- Formulator's Exemption Statement (EPA Form 8570-27).[6]

- Data Matrix Chart. Required if you elect to use the Selective Method of data compensation. The data required to support the application may be

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[4] See Chapter 17 of this manual for graphic representation of EPA Form 8570-1.

[5] See Chapter 17 of this manual for graphic representation of EPA Form 8570-29.

[6] See Chapter 17 of this manual for graphic representation of EPA Form 8570-27.

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 of Amendment Application** - 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 or an exemption from a tolerance. Refer to Chapter 7 of this manual for a discussion of tolerance petitions.

IMPORTANT NOTE: Efficacy (product performance) data are routinely required to be submitted to support your proposed use if you are proposing a new product that controls pests of public health significance, i.e., products to control bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats and mice. However, for most uses, i.e., insecticides, fungicides, and herbicides, the Agency does not require that these data be submitted. Each registrant must, however, ensure through testing that its products are efficacious when used in accordance with label directions and commonly accepted pest control practices. 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 or exemption from tolerance are also required. Refer to Chapter 9 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)(F)[7]. 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) marked "Notification".

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[7] The Food, Agriculture, Conservation, and Trade Act of 1990 (FACTA) and the 1991 Amendments of FACTA made a number of amendments to FIFRA. One of those amendments was to redesignate Section 3(c)(1)(D) as Section 3(c)(1)(F). Therefore, when citing the data compensation section of FIFRA you should now refer to 3(c)(1)(F) and not 3(c)(1)(D).

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. Each name must differ from the name of any other product that you have registered, so as to permit clear identification of the product in case of emergency. 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.

IMPORTANT NOTE: The additional brand name must not be false or misleading. In accordance with 40 CFR 156.10(a)(5) and (b)(2), a product is considered to be misbranded if its labeling is false or misleading in any particular way. Accordingly, product names may not contain words such as i.e., "safe" or "natural" which are considered to be implied safety claims. In addition, product names may not contain words which imply additional unapproved uses or efficacy claims that are more promising than the product can actually produce, such as the kinds of pest the product will control, i.e., "ABC Fireant Control" where the product will not control fireants and fireant is not one of the pests on the product label; "XYZ Six Month Roach Spray", where there is no data to support the "six month" efficacy claim; or "AZ Total Control Insecticide" where the product does not offer total control. Where appropriate data exists to support such claims they may be submitted for consideration to the appropriate Product Manager as a formal application for amended registration.

In addition, claims such as "professional strength", "extra strength" and similar statements may not be used on your product labeling, including in the product name. (Refer to PR Notice 91-7 for more information).

Note that the addition of a brand name should not be confused with supplemental registration by a different company under agreement with you (Refer to Chapter 5 - Supplemental Registration).

Also note that you may not change the actual product name of record (as opposed to the brand name) without making a formal application to amend your registration and receiving approval prior to sale or distribution.

2) **Use of bilingual labeling**. If bilingual labeling is not required by the Agency, you may add such text to your labeling after notification to the Agency. Implicit in a notification of bilingual labeling is an assurance that the bilingual text is an accurate translation of the English labeling text. The Agency recognizes that translating English language terms to Spanish may be a problem because Spanish terms from different parts of the Spanish speaking world may have a whole different meaning. Registrants should use the appropriate Spanish translation for their labeling. Note that the Agency believes the Spanish language translations to be used for "Caution", "Warning", and "Danger" are "Precaucion", Aviso", and "Peligro", respectively.

3) **Changes in warranty**. You may, after notification to the Agency, make changes in the warranties or warranty disclaimers on the label.

4) **Other labeling revisions**. You may, after notification to the Agency, make changes in labeling language consistent with 40 CFR Part 156, provided the changes do not involve changes in the ingredients statement, precautionary statements or directions for use.

5) **Final printed labeling**. After acceptance of a new product registration or labeling amendment, final printed labeling must be submitted before the product is sold or distributed. Such labeling may be submitted as a notification provided that three (3) copies of the final labeling are submitted which incorporate any labeling changes required by the acceptance letter.

Final printed labeling is the label or labeling which will accompany the pesticide product when distributed or sold and includes not only the container label, but also all accompanying technical information, brochures, etc., but does not include the package of the product, unless the labeling is an integral part of the package.

Final printed labeling for the Agency's files should be of a size that can be stored conveniently in 8 1/2 x 11 inch files. The label may be mounted or photoreduced to meet the size requirements provided the printing is legible and is of microfilm reproduction quality. Should

photoreduction make any of the text illegible, the text must be typed out on an accompanying sheet of paper.

Paste on labeling should be submitted as is, unless it requires photoreduction.

Screen printed labeling should be printed by taping paper on the container as it goes through the printing process. The actual container should not be submitted.

Embossed labeling should be photocopied.

Unusual size labeling, such as large bags or boxes, must be photoreduced either in one reduction or in sections so that each section is 8 1/2 x 11 inches.

IMPORTANT NOTE: The following labeling changes cannot be submitted as a notification. A formal Application for Amended Registration (EPA Form 8570-1) must be submitted for Agency approval.

a) The deletion of use patterns, pests, claims, or sites of use from your registered labeling can not be accomplished as a notification. 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. In order to delete uses from your labeling, other than for the distribution or sale of a product under labeling bearing any subset of any subset of the approved directions for use as provided for under 40 CFR 152.130, you must submit a formal application to amend your registration and receive Agency approval.

b) Addition of sites or uses.

c) Deletion of precautionary language or restrictions.

d) Any actions concerning an unregistered product or an application for amended registration which has not been accepted by the Agency.

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), marked "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.

IMPORTANT NOTE: The following changes are not acceptable as notifications; a formal Application for Amended Registration (EPA Form 8570-1), and EPA approval must be obtained prior to sale and distribution:

a. You may not make any change in the source of an active ingredient, or any other change in the formulation, This change will require a formal application for amended registration and Agency approval.[8]

b. You may not make any change in the source of an active ingredient which necessitates changing either the nominal concentration of a solvent or that of any other inert ingredient so that it would exceed its certified limits. This would be considered

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[8] Registrants of products containing or manufactured with Chlorofluorocarbons (CFCs), Hydrochlorofluorocarbons (HCFCs), Carbon tetrachloride, or Methyl chloroform should refer to PR Notice 92-3 "Pesticides and the Clean Air Act: Stratospheric Ozone Protection", issued March 19, 1992, for instructions regarding amendment of such labels.

an alternate formulation and require a formal application for amended registration and Agency approval. Such a change may result in significant changes in the toxicological or chemical properties of the product.

c. 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.

d. 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.

e. You may not make a change in the stated nominal concentration of any active ingredient, or add certified limits not shown on the previously submitted Confidential Statement of Formula (EPA Form 8570-4). Such changes require a formal application for amended registration and Agency approval.

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.

b) You may change, by notification, the stated nominal concentration[9] of any other

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[9] Note that the Agency believes that if you go above one-tenth (1/10) of the concentration of that presently approved the toxicity of the product may be affected. Appropriate acute toxicity data may have to be generated to make this determination. If a change does result labeling revision and data will be required to be submitted to the Agency as a regula amendment. In some cases you may be required to submit an application for a new product.

inert ingredient provided the certified limits for that ingredient are not exceeded and the composition of the ingredient is known to you.

IMPORTANT NOTE: Note particularly that all of the above changes in a), b), and c) are limited to inert ingredients whose complete identity or specific 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 made by a formal application for amended registration and Agency approval. Since you do not know the composition of such inert ingredients, the Agency must determine its acceptability based upon information on its composition supplied by the producer.

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, by notification, modify a formulating operation [defined in 40 CFR 158.153(c)], i.e., a unit operation such as blending, diluting or drying, as distinguished from a unit process involving a chemical reaction, provided that the certified limits of the active and inert ingredients will not change as a result.

c. **HOW TO SUBMIT NOTIFICATIONS**

1) To submit a notification, you must use the Application for Registration/Amendment Form (EPA Form 8570-1), and write the word **"NOTIFICATION PER PR NOTICE 88-6"** 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.

If a product chemistry notification is being made, a new Confidential Statement of Formula (EPA Form 8570-4) must accompany the notification application, together with a copy of the latest accepted Confidential Statement of Formula.

If a labeling change notification 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 and the latest accepted labeling are required for this purpose.

2) Certification of Compliance - each notification must bear in Section II of the Application for Pesticide Registration/Amendment (EPA Form 8570-1) the statement **"This is to certify that this notification meets every requirement of PR Notice 88-6".**

IMPORTANT NOTE: Only you, the registrant or your authorized agent may submit a notification. Each notification must be properly signed and dated.

In accordance with 40 CFR 152.46(a) if the Agency determines that formal application for amended registration must be submitted rather than a notification 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 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 must be sent to the Information Services Branch (ISB), Program Management and Support Division (PMSD), notifying the Agency of the changed company name and/or address. See Chapter 18 for the address.

IMPORTANT NOTE: 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) A date that indicates date of manufacture or label approval.

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

IMPORTANT NOTE: Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government constitutes misbranding under FIFRA section (2)(q)(1)(A) and 40 CFR 156.10(a)(5)(v), and is a violation of section 12(a)(1)(F) of FIFRA.

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 label color, type size or style, use of space, configuration or placement of label elements.

IMPORTANT NOTE: Changes in color or type size should not reduce the readability of the labeling text or minimize the precautionary statements.

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.

F. LEGAL COMPLIANCE - ENFORCEABLE

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.

G. 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.

H. REFERENCES CITED IN CHAPTER 4 - 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.

5. PR Notice 89-2 - Expedited Review of Applications for Registration or Amended Registration. Issued by the Registration Division, Office of Pesticide Programs, EPA, June 6, 1989.

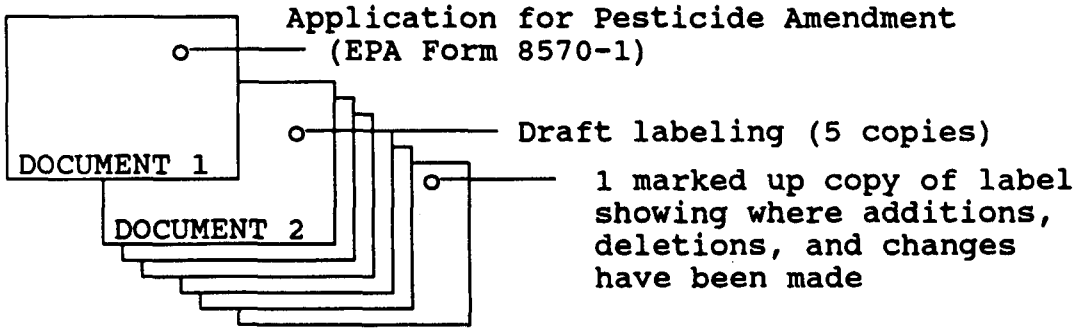
7. PR Notice 91-5 - Instructions for Transmitting Information to the Office of Pesticide Programs. Issued by the Program Management and Support Division, Office of Pesticide Programs, EPA, September 6, 1991.

6. PR Notice 91-7 - False and Misleading Statements. Issued by the Registration Division, Office of Pesticide Programs, EPA, December 30, 1991.

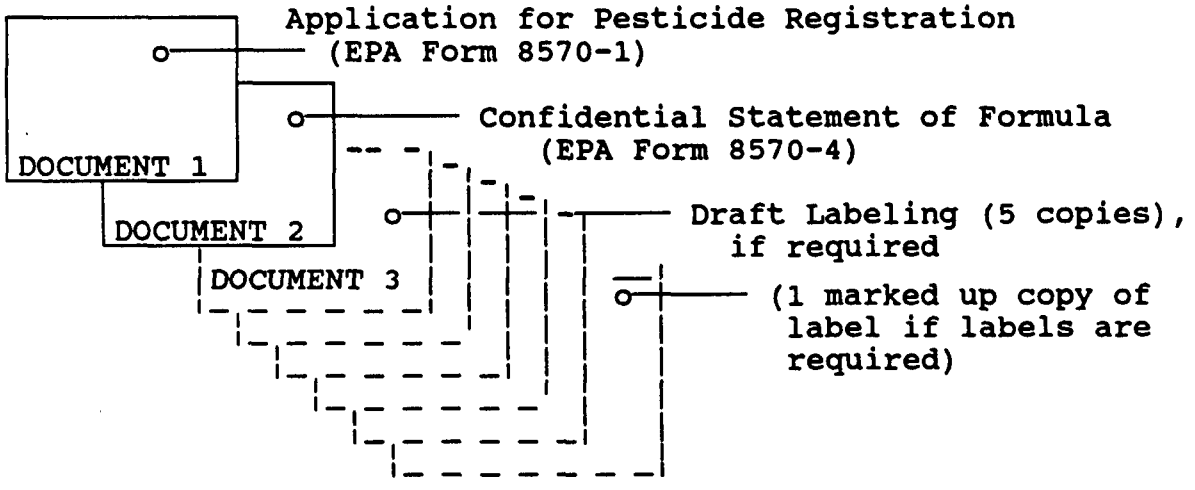
7. PR Notice 92-3 - Pesticides and the Clean Air Act: Stratospheric Ozone Protection. Issued by the Office of Pesticide Programs, EPA, March 19, 1992.

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 DOCUMENTS OR PAGES TOGETHER)



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



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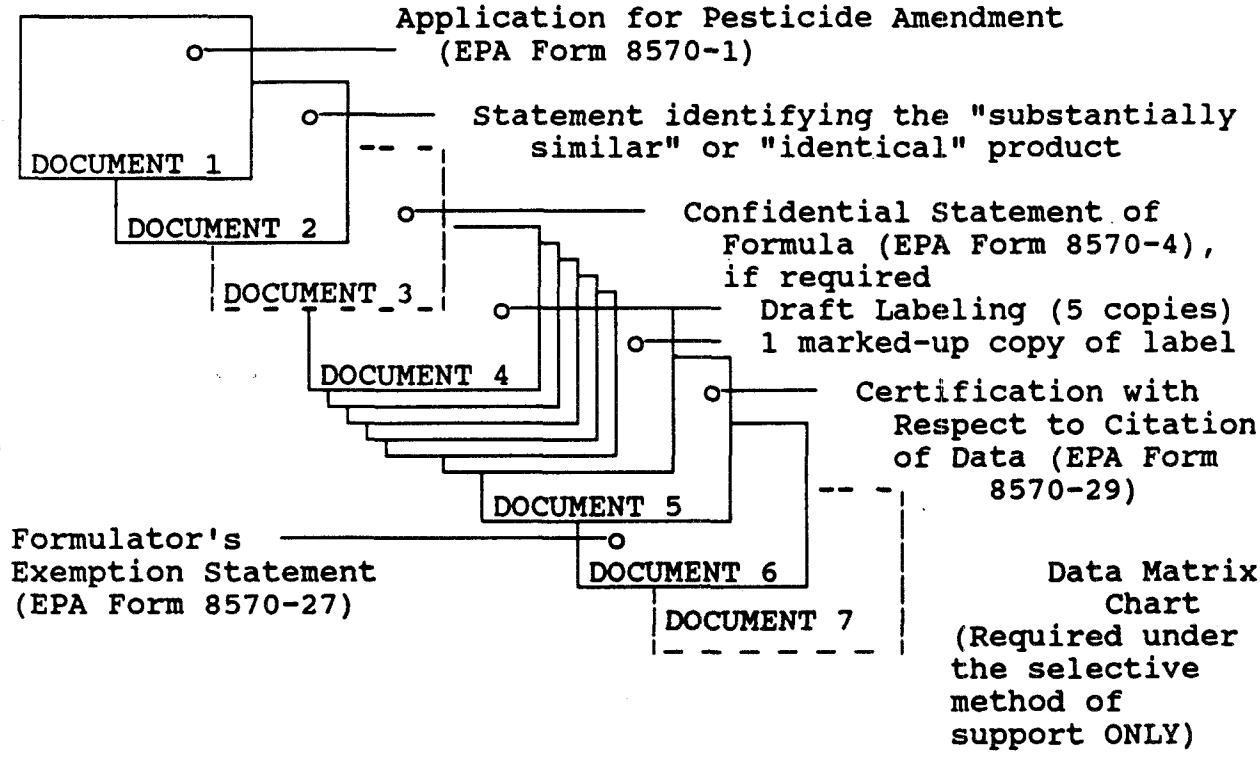
* Revisions to the basic formulation for antimicrobial and vertebrate pesticide products generally require supporting efficacy (product performance) data, and are not considered to be administrative amendments. (Refer to Appendix 4-2)

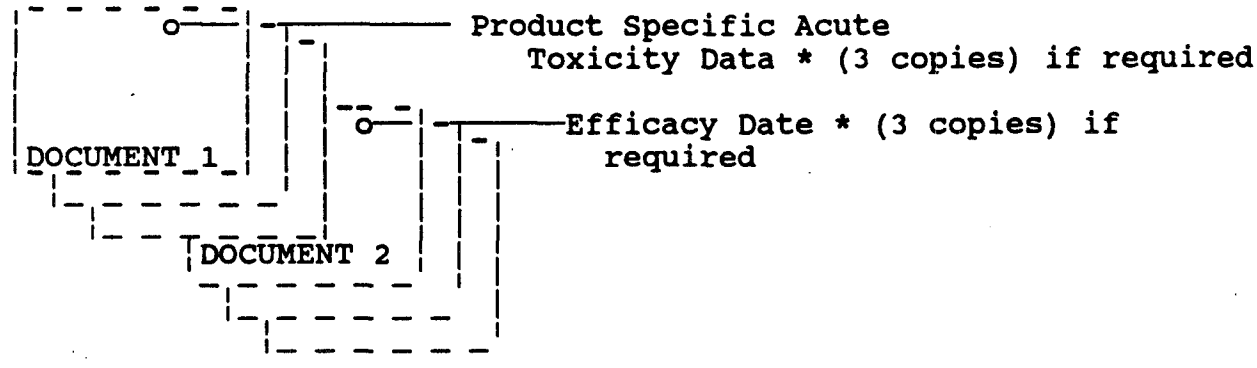
Materials Belong To:
OPPT Library
401 M Street, SW (TS-793)
Washington, DC 20460

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 DOCUMENTS OR PAGES TOGETHER)



B. DATA PORTION OF APPLICATION: (FORMAT AS DESCRIBED IN PR NOTICE 86-5)



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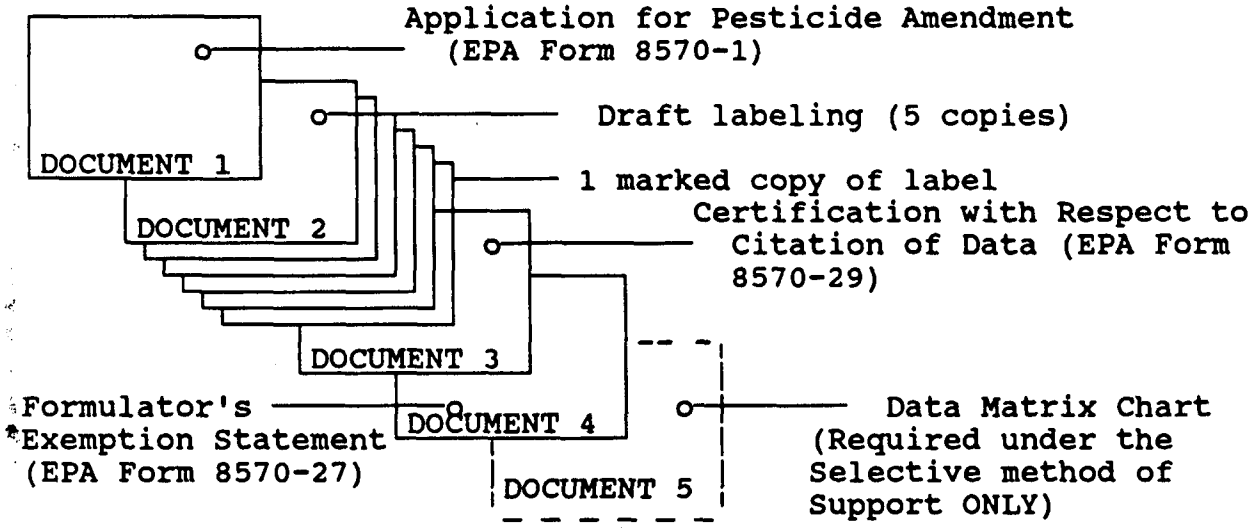
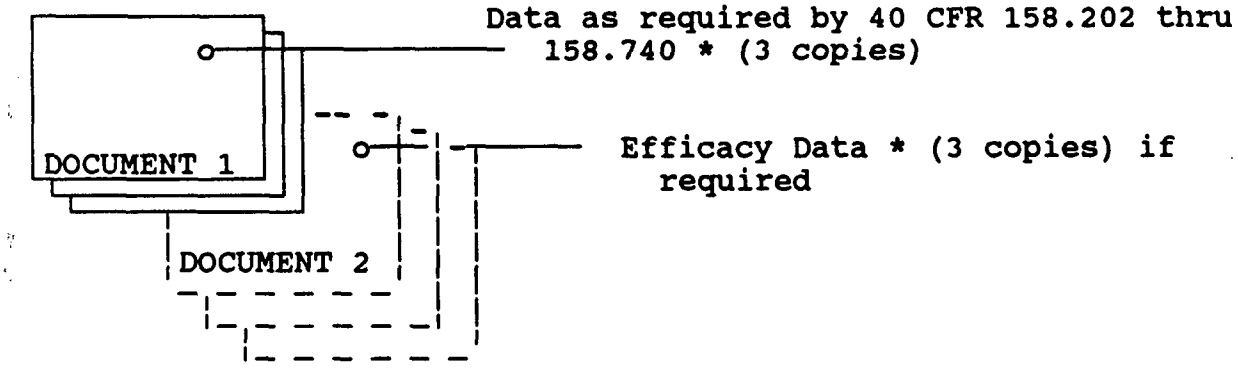
* Under the selective method of support these data requirements may be addressed by either submitting the actual data, or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

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 DOCUMENTS OR PAGES TOGETHER)



B. DATA PORTION OF APPLICATION: (FORMAT AS DESCRIBED IN PR NOTICE 86-5)



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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 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/her registered product under another person's name and address instead of (or in addition to) his/her 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 within the same timeframe imposed on the basic registration. 2) If the basic registration is canceled, the supplemental registration is automatically canceled effective the same date as the basic registration.

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 the second party wishes 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 the second party ("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 Division's Registration Support Branch. Refer to Chapter 18 for the address.

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

2. The product the "Distributor" intends 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 "Distributor's" product may not be repackaged: it must remain in the basic registrant's or producer's original unopened container. However, a "Distributor" may repackage the registered product for the distributor's use if he/she has a contract with the basic registrant to do so, and if the "Distributor" has his/her establishment registered. Refer to Chapter 11 which explains how to obtain an establishment registration.

4. The labeling associated with the product the "Distributor's" wishes to distribute must be the same as that of the basic registered product, except that:

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

b. The name and address of the "Distributor's" 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 the "Distributor's" company number; (For example, if the registration number of the basic registrant's product is EPA Reg. No. 999999-88888, and the "Distributor's" company number is 777777, then the "Distributor's" number that would appear on the 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; 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 the "Distributor's" label provided that no changes are necessary in any of the precautionary or other labeling of the basic product.

IMPORTANT NOTE: The "Distributor" may not make additions to the basic registrants label (for example, add claims, additional sites or pests), nor 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 AND ESTABLISHMENT REGISTRATION

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. If you plan to enter into a contract to produce a pesticide an establishment registration for each separate location must first be obtained from the Agency. Refer to Chapter 11.

E. REFERENCES CITED IN CHAPTER 5 - 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. EPA Form 8570-5

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 (which was changed to 3(c)(1)(F))[1] 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.

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[1] The Food, Agriculture, Conservation, and Trade Act of 1990 (FACTA) and the 1991 Amendments of FACTA made a number of amendments to FIFRA. One of those amendments was to redesignate Section 3(c)(1)(D) as Section 3(c)(1)(F). Therefore, when citing the data compensation section of FIFRA you should now refer to 3(c)(1)(F) and not 3(c)(1)(D).

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)(F) [formerly 3(c)(1)(D)] of FIFRA.

Section 3(c)(1)(D) [now 3(c)(1)(F)] 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 to support your application. After the 10 year "exclusive use" period has expired, you may still be required to offer to compensate the data submitter for use of the data, but written authorization from the data submitter 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 to EPA only if the applicant has certified to the Agency that he/she 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)(F).

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 <u>do not</u> 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. WHAT INFORMATION MUST YOU SUBMIT WITH YOUR APPLICATION FOR REGISTRATION OR AMENDED REGISTRATION ?

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 (EPA Form 8570-27) 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.

IMPORTANT NOTE: Since data costs associated with EPA's reregistration program has caused many basic producers to request the deletion of uses which are important to many users, special provisions are made available to third party data producers which may affect the availability of the formulators' exemption to certain registrants. Refer to PR Notice 91-8 for important details.

2. <u>Certification With Respect to Citation of Data</u> (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)(F). In order to comply with the FIFRA section 3(c)(1)(F) data compensation requirements, you must:

a. <u>Submit an acknowledgement of reliance on data</u> in accordance with 40 CFR 152.86(d) you must include an acknowledgement that for purposes of FIFRA section 3(c)(1)(F) 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> - Effective beginning September 30, 1978, 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, for a period of 10 years after the initial registration has been issued. 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 which are listed under the active ingredient chemical code numbers. Refer to Chapter 16 of this manual for information on how to obtain the Data Submitters List. A source of published Registration Standards and Registration Eligibility Documents (REDs) 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)] or RED, 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)(F), 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. <u>Methods for complying with the data compensation requirements of FIFRA section 3(c)(1)(F)</u> - 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) <u>THE CITE-ALL METHOD OF SUPPORT</u> - 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)(F), 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)(F).

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 studies, 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.

IMPORTANT NOTE: The Data Gap option may not be available to certain applicants, i.e., those seeking the registration of a product containing a new active ingredient or those seeking to add a new use pattern to a registered product.

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, a Registration Standard or a Reregistration Eligibility Document (RED) 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). Note: The Data Gap option may not be available to certain applicants, i.e., those seeking the registration of a product containing a new active ingredient or those seeking to add a new use pattern to a registered product.

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

D. DATA COMPENSATION CHARGES/PAYMENT DISPUTES

40 CFR 152, Subpart E - Procedures To Ensure Protection of Data Submitters' Rights [specifically 40 CFR 152.80; 152.86 (b)(2)(iii); 152.93 (b)(2)(iv); 152.95(b)(2)(iv); 152.99 (a)(i) and 152.99(a)(iii)] describes the procedures by which data submitters may challenge registration actions which allegedly failed to comply with FIFRA section 3(c)(1)(F). Applicants

relying on another person's data to support their registration are required to certify to the Agency, with respect to each person on the Data Submitters List, for the chemical in question, an offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of any study.

FIFRA sections 3(c)(1)(F)(ii) [formerly 3(c)(1)(D)(ii) and 3(c)(2)(B)(iii) states that the terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, by binding arbitration under the procedure and rules of the Mediation and Conciliation Service. The arbitrator to be appointed from the roster of arbitrators maintained by such Service. The findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. Refer to 29 CFR 1440 for details on the arbitration procedures.

E. 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 non-end-use product, e.g., a manufacturing-use or a formulating-use only product (including technical grade products), 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**: After reading the regulations, it is my belief that if I simply repackage a registered technical grade, manufacturing-use or end-use product and use the same labeling, I need only claim the formulator's exemption under FIFRA section 3(c)(2)(D) and not submit any other information under the Cite-all or Selective Method of Support or include any product specific data, e.g., product chemistry, acute toxicity or efficacy data.

Answer: You are correct provided you simply repackage another registered product and do not change the purchased formulation in any manner.

In this case your application for registration would consist of an Application for Registration (EPA Form 8570-1), a Confidential Statement of Formula (EPA Form 8570-4), the Formulator's Exemption Statement (EPA Form 8570-27) and 5 copies of your draft labeling.

4. **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 (either generic data or product specific 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)(F) of FIFRA, within the limits prescribed by your eligibility under the formulator's exemption under section 3(c)(2)(D) of FIFRA.

There are several possible situations, as discussed below, which are dependent on whether you choose the cite-all or selective method of support. It is assumed that you are eligible for the formulator's exemption for the active ingredient(s) in your product, and that your labeling claims, or use patterns, do not exceed those supported by the labeling of the product from which you are formulating.

Cite-all Method of Support: If you wish to use the cite-all method of support (and you are eligible for the formulator's exemption), you must make written offers to pay to all of the data submitters listed on the Data Submitter's List who have claimed product specific types of data for each active ingredient in your product. Since product-specific chemistry data is generally required to be submitted by you to support your initial application for registration, and is unique to a particular formulated product, these data which were furnished by you would not normally be subject to the data compensation requirements. Acute toxicity data would be compensable since these data could support the registration of any number of similar or identical products, and are not necessarily product specific. If EPA has not issued a Registration Standard or RED 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: If you wish to use the selective method of support (and you are eligible for the formulator's exemption) 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 or Reregistration Eligibility Document(if any) or the data tables in 40 CFR Part 158. Since product-specific chemistry data is generally required to be submitted by you to support your initial application for registration, these data would not normally be required for an amendment to your registration. Acute toxicity data would need to be addressed, if additional acute toxicity data were required to support the amendment or a previously submitted study was invalidated. If a data matrix previously submitted in support of the product's initial registration or amendment is still valid, and no additional data are required, you may reference that data matrix in support of your current application for amended registration. If additional data are required to support your current amendment request, an updated data matrix should be submitted.

5. **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. However, only in the case of exclusive use is explicit permission required. Otherwise, if you go through the proper data compensation procedures, permission from the data submitter is not required.

6. **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.

The Agency will honor the terms and conditions of an original letter of authorization to cite data and will not accept a letter withdrawing that authorization unless both the original data submitter and the registrant(s) or applicant(s) relying on the data submitter's data agree that such authorization has been withdrawn. See PR Notice 91-6.

7. **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, unless use patterns on your label are not supported by your source. See PR Notice 91-8. Submit a properly completed Formulator's Exemption Statement (EPA Form 8570-27).

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

Answer: Yes, you may. It is not a violation of FIFRA to purchase and use an unregistered product in the formulation of your product. However, you should be aware that administrative complications and data requirements are reduced if your source of the active ingredient(s) is registered. Normally it is illegal under FIFRA to sell or distribute an unregistered pesticide, and this also pertains to unregistered sources of the active ingredient. However, in accordance with 40 CFR 152.30, you may use an unregistered source 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)).

Therefore, should you decide to use an unregistered source of an active ingredient, you need to be aware that you are responsible for providing any information or data the Agency would need to accept that new source for registration. 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 also be aware 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.

9. **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.

10. **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.

11. **Question**: I have sent offers to pay compensation to use data to support my application for registration or amendment to all data submitters listed on the most recent Data Submitter's List and if applicable the most recent Registration Standard or Reregistration Eligibility Document. I have not received any replies. How long do the data submitters have to respond to my offer to pay, and if they do not respond am I still liable to pay for data compensation?

Answer: FIFRA and the regulations in 40 CFR do not require a registrant to respond to offers within a specific time frame to preserve data compensation rights. Accordingly, provided such data are compensable, a data submitter may request compensation at any time.

12. **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: It is EPA's position 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.

13. **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 satisfy residue chemistry data requirements. Such applicants must obtain permission or make an offer to pay to use these data (if data exist), if they choose the Cite-All Method of Support. There may be exceptions, i.e., where the source of the active ingredient has not supported the use(s) you claim in your labeling. In such cases, applicants will be required to generate the necessary residue data. See PR Notice 91-8.

There are other cases when residue chemistry data may be required, for example an applicant 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.

14. **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.

15. **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.

16. **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.

17. **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.

18. **Question**: If I submit an application to register a new product that contains an active ingredient for which the Agency has issued a Data Call-In (DCI), Registration Standard (RS), or Reregistration Eligibility Document (RED), am I subject to the data requirements in those documents as well as those in 40 CFR 158 or just those in 40 CFR 158 and am I subject to the Data Compensation regulations?

Answer: You are subject to the all of the data requirements and submittal times set forth in 40 CFR 158 as well as the data requirements and submittal times set forth in any DCI issued by the Agency in connection with a RS, or RED, regardless of whether your new product is a technical grade product, manufacturing use product, or an end use product. If the timeframe for generating and submitting a given data set has past, then you must submit those data with your application or you may cite data submitted by someone else. If a timeframe has not yet past, then you must submit the required data by the date specified. If data gaps were declared in the RS or RED, you may rely on the RS or RED for the identification of those gaps. But, under the Selective Method of Support you must still provide a list of the requirements in accordance with 40 CFR 152.90(a), and may

not simply cite the RS or RED. You may, however, indicate on your list of data requirements that the existence of a data gap is documented in the RS or RED.

You are also subject to the Data Compensation requirements under 3(c)(1)(F) [formerly 3(c)(1)(D)] of FIFRA.

Refer to PR Notice 85-3, 40 CFR 152.90 through 152.96 and 40 CFR 158 for full details on data requirements and to FIFRA Section 3(c)(1)(F) for data compensation information.

19. **Question:** If I am submitting a complete set of supporting data with the application, do I need to fill out the Certification form?

Answer: No. So long as you are not submitting required data that has been previously submitted by another submitter. If you have previously submitted data you should cite those data rather than submit them again.

20. **Question:** Do I have to fill out all items under 2 and 3 on the Certification form?

Answer: Mark only those items that are appropriate for your application.

21. **Question:** When does the 10 years "exclusive use" period expire for data generated 12 years after the first registrants?

Answer: Data submitted 12 years after the original registration are not covered by exclusive use at all. Exclusive data rights exist only for the registrant who obtained the first registration that contains a new active ingredient or new mixture of active ingredients and only for that first registration and subsequent amendments to that original registration for a 10 year period. Data submitted 11 years after the date of the original registration are not covered by exclusivity. These data are covered by data compensation rights for another fifty years.

E. GOOD LABORATORY PRACTICE STANDARDS - PHYSICAL AND CHEMICAL HAZARDS FOR PRODUCT SPECIFIC DATA.

40 CFR 160 sets forth good laboratory practices for conducting studies that support or are intended to support applications for registration, amended registration, or reregistration of a pesticide product, applications for an experimental use permit, petitions for establishment or modification of a tolerance or food additive regulation, exemptions from the requirement of a tolerance or food additive regulation. Although all studies have to be conducted in

accordance with some of the good laboratory standards, only physical and chemical characterization studies to determine solubility, octanol water partition coefficient, stability (product chemistry data requirement 63-8, 63-10, 63-13 respectively), volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation (environmental fate 163-2, 163-3, 161-1; 161-2; 161-3; and 161-4 respectively) studies are subject to the full good laboratory practice standards. All other studies are subject only to the good laboratory provisions set forth in 40 CFR 160.33, 41, 51, 61, 63, 83, 105(e), 107, 120(13) and (14), 130,185(a)(1) through (4), (9), (11), (13), 190, 195(a),(b),(e),(f),(g),(h),(i).

F. 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.

G. REFERENCES CITED IN CHAPTER 6 - 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 152, Subpart E - Procedures to ensure protection of data Submitters' rights

   Part 158 - Data requirements for registration

2. Code of Federal Regulations, Title 29

   Part 1440 - Arbitration of Pesticide Data Disputes

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

   Section 3 - Registration of pesticides

4. Food, Agriculture, Conservation, and Trade Act of 1990, November 28, 1990

   Subtitle H - Pesticides; Sections 1491 through 1499

5. Food, Agriculture, Conservation, and Trade Act Amendments of 1991, December 13, 1991

   Section 1006 - Amendments to FIFRA and Related Provisions

6. PR Notice 85-3 - Effective Date of Data Compensation Procedures under FIFRA, Issued by the Registration Division, Office of Pesticide Programs, EPA, May 14, 1985.

7. PR Notice 91-6 - EPA Policy Regarding Requests to Withdraw Authorization to Cite Data, Issued by the Registration Division, Office of Pesticide Programs, EPA, December 13, 1991.

8. PR Notice 91-8 - Revised Policy to Provide Applicants Other Than Basic Manufacturers An Opportunity To Submit Generic Data and Receive Data Compensation For It, Issued by the Registration Division, Office of Pesticide Programs, EPA, December 31, 1991.

9. Data Submitters' List

10. Listing of Registration Standards

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

COMPARISON OF THE CITE-ALL AND SELECTIVE METHODS OF SUPPORT

If an applicant chooses this method ------> can he/she satisfy a data requirement by the means listed below?		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/her 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 for the formulator's exemption and one for all of the rest of the active ingredients that qualify for the formulator's exemption. 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 or a Reregistration Eligibility Document 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 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. Guide-line Refer-ence Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permis-sion (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Litera-ture	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							
63-3	Physical State							
63-5	Melting Point							
63-6	Boiling Point							

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. Guide-line Refer-ence Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permis-sion (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Litera-ture	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	PRODUCT CHEMISTRY (continued)							
63-7	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							
63-15	Flammability							
63-16	Explodability							

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. Guide-line Refer-ence Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permis-sion (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Litera-ture	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	PRODUCT CHEMISTRY (continued)							
63-18	Viscosity							
63-19	Miscibility							
63-20	Corrosion characteristics							
63-21	Dielectric break-down 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. Guide-line Refer-ence Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permis-sion (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Litera-ture	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.340	TOXICOLOGY (continued)							
81-3	Acute inhalation toxicity, rat							
81-4	Primary eye irritation, rabbit							
81-5	Primary dermal irritation							
81-6	Dermal sensiti-zation							

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. Guide-line Refer-ence Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Permis-sion (P) or Offer to Pay (OTP) enclosed: indicate "P" or "OTP"	9e. Public Litera-ture	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.								

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. 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 pesticide residues in processed food or feed commodities which exceed the raw food tolerance.

40 CFR Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities, provides 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 177 - Issuance of Food Additive Regulations provides information on definitions, procedures for filing petitions for establishment, modification, or revocation of a food additive regulation, withdrawal of petitions, submission of scientific and technical information required to support petitions, and waiver of requirements. In addition, procedures for filing objections and requests for hearings on food additive regulations or petition denials under section 409(f) of the FFDCA are found in 40 CFR Part 178; rules governing formal evidentiary hearings under FFDCA section 409(f) are found in 40 CFR Part 179.

40 CFR Part 185 - Tolerances for Pesticides in Processed Food, provides a listing of tolerances established for residues of pesticides in processed 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 Processed Animal Feeds, provides a listing of tolerances established for residues of pesticides in processed animal feeds, which may be present as a result of application of the pesticide to growing crops. (Prior to June 29, 1988, 40 CFR Part 186 was designated 21 CFR Part 561.)

B. WHEN ARE PETITIONS FOR TOLERANCES REQUIRED?

Tolerances and food/feed additive regulations are required to be established to cover residues resulting from treatment of raw agricultural commodities or processed food; inadvertent residues in rotational or replacement crops; primary or secondary residues in meat, milk, poultry, and eggs; residues in processed food resulting from treatment of the raw commodity and exceeding the raw food tolerance; and expected residues in imported food commodities. Registration of a pesticide is not, however, a prerequisite for establishing a tolerance. For example, EPA may establish a temporary tolerance under section 408(j) to permit the experimental use of a non-registered pesticide, or EPA may establish a tolerance for a pesticide residue resulting from the use of the pesticide in food or feed production in a foreign country.

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 or if the commodity is to be marketed. The petition for the temporary tolerance must be submitted with the application for the experimental use permit.

IMPORTANT NOTE: A temporary tolerance is not required if the commodity is to be destroyed or consumed only by experimental animals.

3. Importation of Pesticide Treated Food - The requirements of sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) apply equally to domestically produced and imported food and feed found to contain pesticide residues. Therefore, even though the use of a pesticide in a foreign country is not subject to EPA registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a pesticide residue in imported food or feed must be in conformity with a tolerance, tolerance exemption, or food additive regulation established by EPA or, where appropriate an action level established by the Food and Drug Administration. Shipments of imported food/feed items found to have pesticide residues for which a tolerance, exemption from the requirement of a tolerance, or a food additive regulation has not been issued will be held up and the importer required to either file for a tolerance or exemption from a tolerance, or a food additive regulation; return the shipment to the country of origin; or destroy the shipment.

4. Inerts - Inert ingredients in pesticide product formulations are regulated under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and the Federal Food, Drug, and Cosmetic Act (FFDCA). Inert ingredients in products labeled for food use must be cleared by EPA before the product can be registered. 40 CFR 152.55 requires that inert ingredients, metabolites, and degradation products, as well as active ingredients, be cleared by the Agency if your product is to be used on food or feed crops. If your proposed labeling bears instructions for use of the product on food or feed crops, or if the intended use of the product results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed, you must submit a statement indicating whether a tolerance, exemption from the requirement of a tolerance, or a food additive regulation has been issued by the Agency under section 408 or 409 of the Federal Food Drug and Cosmetic Act (FFDCA). If a tolerance, exemption from the requirement of a tolerance, or a food additive regulation has not been issued for such residues, your application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations in accordance with 40 CFR 177 (food additive petitions) or 40 CFR 180 (tolerance or exemption petitions). Traditionally, the Agency has recommended against the establishment of a tolerance for a pesticide product unless all of the inert ingredients in the product have been cleared for use on food/feed items. Refer to 40 CFR 180.1001 for a listing of the inert ingredients that have been cleared for use on food/feed items.

5. Adjuvants - Although adjuvants are not subject to registration, those adjuvants intended for use in conjunction with a pesticide in tank mixes for application to a food or feed crop/site are required to be cleared with the EPA, under the Federal Food, Drug and Cosmetic Act (FFDCA) prior to being used. Such adjuvants are evaluated by EPA as inert ingredients and undergo the appropriate product chemistry review. Adjuvants cleared for use on food/feed items are listed in 40 CFR 180.1001.

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.

Procedures for filing a petition for establishment, modification, or revocation of a food additive regulation for pesticide residues in or on a particular processed food or group of such foods are described in detail in 40 CFR section 177.81. Additional information concerning requests for amendments or supplements to petitions can be found in 40 CFR 177.92. There is no application form for petitions for food additive regulations. You must submit your request in the format provided in 40 CFR 177.81(e).

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.

IMPORTANT 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 of toxicological concern. 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, restrictions, pre-harvest intervals, 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 validation 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 may need to 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.

The petition for food additive regulations must include the following information as set forth at 40 CFR 177.102.

a. The name and composition of the food additive that is a subject of the petition, and the chemical composition of each component of the food additive.

The name, chemical identity, and composition of each pesticide residue that is a subject of the petition.

The identity of the processed food(s) in question.

b. A statement of any conditions of use proposed for the food additive, including all directions, recommendations, and suggestions proposed regarding the use of the food additive, i.e., the amount, frequency, method, and time of application or other use, and copy of its proposed labeling.

c. Full reports of investigations made with respect to the toxicity of the food additive and of its safety for the proposed use, including full information as to the methods and controls used in conducting such investigations.

d. The results of tests to determine the identity and amount of pesticide residues in or on the processed food resulting from the proposed use of the food additive, including a description of the analytical methods used, and a description of practicable methods for measuring such pesticide residues.

e. Full reports of investigations made with respect to the toxicity of such pesticide residues, including full information as to the methods and controls used in conducting such investigations.

f. All relevant data bearing on the physical or other technical effects such food additive is intended to produce, and the quantity of such food additive required to produce such effect.

g. The terms of each food additive regulation proposed.

h. Any other information relevant to the approval of the petition known to the petitioner that is unfavorable to the petition.

i. A statement of why, in the petitioner's opinion, it would be reasonable for the Administrator to approve the petition, taking into account the terms of the FFDCA and FIFRA, 40 CFR Part 177, the petition, the data and information submitted or cited in support of the petition, and other information available to the Agency.

j. An informative summary of the petition and of the data information, and arguments submitted or cited in support of the petition, and a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice to the public under 40 CFR 177.88 or as part of a proposal under 40 CFR 177.130. The summary need not refer to any method or process that is entitled to protection as a trade secret under FFDCA section 301(j).

3. **Data** - Three copies of any data required to be submitted in support of the petition must be submited 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 photo-copy of the fee check were submitted with the petition request in case any questions arise concerning whether the fee was submitted as required.

The fees will be adjusted annually in accordance with section 180.33(o). You should refer to the February 7, 1991 Federal Register Notice (56 FR 4946) for a more detailed discussion of tolerance processing fees.[1]

The fees vary considerably according to type of petition requested and its complexity. 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 $52,000, plus $1,300 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 $11,900 plus $825 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 $9,575.

d. For temporary tolerances or a temporary tolerance exemption from the requirement of a tolerance the fee is generally $20,775, except as provided below. A request for an extension or renewal of a temporary tolerance or temporary exemption requires a fee of $2,950.

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[1] The fee schedule changes annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale. In addition, processing costs and fees will periodically be reviewed and changes will be made to the schedule as necessary. When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the FEDERAL REGISTER as a Final Rule to become effective 30 days or more after publication, as specified in the rule. Normally the fee schedule for the current fiscal year will be published in the FEDERAL REGISTER shortly after the first of the calendar year. However, the publication of the fee schedule may be impeded by such things as executive regulatory relief initiatives.

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 $10,375 plus $825 for each raw agricultural commodity on which the temporary tolerance is sought.

f. Waiver or refund request must be accompanied by a fee of $1,300, which will be refunded if the waiver is granted. 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).

IMPORTANT NOTE: Fee waiver requests affect the processing times for the petition since the fee waiver request must be processed before the petition is put into review. The fee waiver review can typically take 2-3 months. To avoid this delay, petitioners can submit the full fee with the petition and request that the fee be returned if the Agency agrees with the applicant that the petition is in the public interest. The petition can then be put under review while the refund request is being evaluated.

IMPORTANT NOTE: These fees may change without notice being published in this manual.

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 Petition 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.

Refer to Chapter 8 of this manual for additional information on tolerance petition fees and other 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 of $1,300 for handling and initial review, will also be returned.

If a petition is withdrawn by the petitioner after initial processing but before significant scientific review has begun, the original fee, less $1,300 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.

D. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions concerning 1) whether a petition for a tolerance is required, 2) the appropriate fee, 3) how to submit your request for a petition for tolerance and/or application for product registration, or 4) what data are required to support your petition for tolerance and/or application for product registration, 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.

E. REFERENCES CITED IN CHAPTER 7 - 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 177 - Issuance of Food Additive Regulations.

Part 178 - Objections and Requests for Hearings.

Part 179 - Formal Evidentiary Public Hearing.

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

8. Federal Register Notice, Tolerance Processing Fees, February 7, 1991 (56 FR 4946).

CHAPTER 8 - WHAT FEES ARE REQUIRED FOR REGISTRATION MAINTENANCE, REREGISTRATION AND TOLERANCE PETITION ACTIVITIES

A. GENERAL INFORMATION

The 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) require that annual maintenance fees be paid by registrants for a period of 9 years beginning March 1, 1989, of pesticide products registered under Section 3 or 24(c) of FIFRA, and provide for the collection of a fee for the reregistration of pesticides. In addition, the Federal Food, Drug and Cosmetic Act (FFDCA) provides for fees for the processing and review of tolerance petitions. These fees are discussed in more detail below.

IMPORTANT NOTE: Fees are not required for:

- Registering a product with a new active ingredient.
- Registering a new use of a previously registered active ingredient.
- Registering a product substantially similar or identical to a previously registered active ingredient.
- Amending a registered product label.
- Obtaining an Experimental Use Permit.

B. ANNUAL REGISTRATION MAINTENANCE FEES

Section 4(i)(5) of FIFRA requires each registrant of pesticide products to pay an annual registration maintenance fee based on the number of registrations held. The current fee (January 15, 1992) is $650 for the first registration held by any registrant and $1300 for each subsequent registration. The maximum fee for registrants holding 50 or fewer registrations is $55,000, except for small businesses[1] for which it is $38,500. The maximum fee for registrants holding more than 50 registrations is $95,000, except for small businesses[1] for which it is $66,500. Registrations for which the fee is not paid by

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[1] A "small business" registrant eligible for these lower fee payment caps is defined as one which employs 150 or fewer people and, during the three year period prior to the most recent maintenance fee billing cycle (i.e., December 31, 1990) had average annual gross revenue from chemical sales not exceeding $40 million, taking into account any parents' and subsidiaries' employees and gross revenues.

January 15, 1992, will be canceled, by order and without a hearing. If you do not pay the fee to keep a registration in effect, you will be permitted until January 15, 1993, to dispose of existing stocks of the pesticide, except in special circumstances when less time may be granted. You will be billed by the Agency at the beginning of each calendar year. If you need assistance in interpreting the instructions for filing your maintenance fee, you can get help from our toll-free maintenance fee information line at 1-800-444-7255.

IMPORTANT NOTE: 1) FIFRA was amended by a 1991 amendment to the Food, Agriculture, Conservation, and Trade Act which changed the due date for paying the maintenance fee from March 1 to January 15 each year. 2) You should also be aware that the annual maintenance fee may be increased each year as appropriate. 3) In general, there are no provisions for any waiver or refund of registration maintenance fees. However, the Food, Agriculture, Conservation, and Trade Act of 1990 did amend FIFRA to allow the Administrator to reduce or waive maintenance fees for minor agricultural use registrations, when he determines that the fee would be likely to cause significant impact on the availability of the pesticide for the use. This determination will be made only after all the 1992 maintenance fee responses have been received. If at that time the Agency determines that product cancellation resulting from nonpayment of the fee would significantly impact the availability of a particular pesticide for a specific minor agricultural use, the Agency will defer cancellation of the registrations in question, and will provide affected registrants the opportunity to maintain these registrations by paying a reduced maintenance fee. 4) Registrations under section 24(c) of FIFRA are deemed registration under section 3 of FIFRA and thus are subject to this fee requirement. 5) The maintenance fee requirement does not apply to supplemental registrations of distributors. Such supplemental registrations are identified by a three-element registration number in which your EPA Company Number is the third element.

C. REREGISTRATION FEES

Section 4(i)(1-4) of FIFRA states that registrants of pesticides shall collectively pay a fee for the reregistration of an active ingredient. These fees vary considerably and are based on among other things, whether the pesticide is an active ingredient of any pesticide registered for a major food or feed use, or is registered only for non-food or non-feed uses. Provisions are made for the reduction or a waiver of fees for minor use and other pesticides and for small business registrants of pesticides. In accordance with section 4(c) of FIFRA, the Agency has published lists of active ingredients subject to reregistration. List A was published in the Federal Register of February 22, 1989 (54 FR 7740), List B in the Federal Register of

May 25, 1989 (54 FR 22706), List C in the Federal Register of July 24, 1989 (54 FR 30846) and the last list, List D in the Federal Register of October 24, 1989 (54 FR 43388). 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 of registered pesticides and the 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.

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 vary considerably according to type of petition requested and its complexity and they will be adjusted annually in accordance with section 180.33(o). You should refer to the February 7, 1991 Federal Register Notice (56 FR 4946) for a more detailed discussion of the tolerance processing fee requirements and to Chapter 7 of this manual for a very brief, general discussion of some of the fees required for the more frequently requested petitions for tolerance.

E. WHO TO CONTACT FOR ADDITIONAL INFORMATION

If you have any questions concerning 1) whether a petition for a tolerance is required, 2) the appropriate fee, 3) how to submit your application for product registration and/or a petition for tolerance, or 4) what data are required to support your application for product registration and/or petition for tolerance, please contact the appropriate Product Manager for that pesticide. If the petition for tolerance and/or application for product registration 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.

F. REFERENCES CITED IN CHAPTER 8 - 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, February 7, 1991 (56 FR 4946)

- 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)
  - (List C), July 24, 1989 (54 FR 30846)
  - (List D), October 24, 1989 (54 FR 43388)

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

Section 4 - Reregistration of registered products

5. Food, Agriculture, Conservation, and Trade Act of 1990, November 28, 1990

Subtitle H - Pesticides - Sections 1493

6. Food, Agriculture, Conservation, and Trade Act Amendments of 1991, December 13, 1991

Section 1006 - Amendments to FIFRA and Related Provisions

CHAPTER 9 - 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 testing of pesticides in a comparable indoor situation, for example a pesticide to control roaches in domestic dwellings, institutions, etc. and for field testing of swimming pool sanitizers and disinfectants under actual use conditions.

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

IMPORTANT NOTE: It is very helpful in the Agency's review process if you include a table which indicates the states to which the product is to be shipped, and the pounds of product to be shipped to each state for each pest or pest complex, along with the total pounds of product to be shipped to each state. For example:

EXPERIMENT USE PERMIT SUMMARY WORKSHEET

COMPOUND: Cryptop
TOTAL ACRES: 700
POUNDS A.I. REQUESTED: 2300
NUMBER OF APPLICATIONS (By Site): 1-Soybeans 2-Corn 5-Cotton

STATE	SITE 1 / Cotton ACRES	SITE 2 / Corn ACRES	SITE 3 / Soybeans ACRES	SITE 4 / ACRES	TOTAL ACRES	TOTAL LB. AI SHIPPED
AL	200		50		250	1050
AR	100		50		150	550
GA	100	100	100		300	700
TOTALS:	400	100	200		700	2300

A tabular summary of this kind speeds review and processing of the experimental use permit. (See Appendix 9-1 for blank format).

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

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 to be used only for testing purposes (not for food or feed).

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.

IMPORTANT NOTE: Each study must be separately bound. Confidential attachments and supplemental statements of data confidentiality must be included within the binding of the body of the study. All bindings must be secure, but easily removable to permit microfilming. (See PR Notice 86-5 and PR Notice 89-3 for specific instructions on binding of studies.)

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

IMPORTANT NOTE: Refer to Chapter 2, page 2-16 for label/labeling format information.

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 Chapters 7 and 8 of this manual. An extension or renewal request for a temporary tolerance is also subject to a fee requirement.

IMPORTANT NOTE: 40 CFR 152.55 requires that inert ingredients, metabolites, and degradation products, as well as active ingredients, be cleared by the Agency if your product is to be used on food or feed crops. If your proposed labeling bears instructions for use of the product on food or feed crops, or if the intended use of the product results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed, you must submit a statement indicating whether a tolerance, exemption from the requirement of a tolerance, or a food additive regulation has been issued by the Agency under section 408 or 409 of the Federal Food Drug and Cosmetic Act (FFDCA). If a tolerance, exemption from the requirement of a tolerance, or a food additive regulation has not been issued for such residues, your application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulation in accordance with 40 CFR 180. Alternatively you may certify that the food or feed derived from the experimental program will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment.

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 and/or transgenic plants you should contact Product Manager 18 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.

E. **REFERENCES CITED IN CHAPTER 9** - 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
   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.

5. PR Notice 89-3 - Format standards for Reregistration Phase 3 summaries and reformatted versions of studies previously submitted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). Issued December 20, 1989.

EXPERIMENTAL USE PERMIT SUMMARY WORKSHEET

COMPOUND:
TOTAL ACRES:
POUNDS A.I. REQUESTED:
NUMBER OF APPLICATIONS (By Site):

STATE	SITE 1 / ACRES	SITE 2 / ACRES	SITE 3 / ACRES	SITE 4 / ACRES	TOTAL ACRES	TOTAL LB. AI SHIPPED
AL						
AR						
AZ						
CA						
CO						
DE						
FL						
GA						
HI						
IL						
ID						
IA						
KS						
KY						
LA						
MA						
ME						
MD						
MI						
MN						
MO						
MS						
MT						
NE						
NV						
NM						
NY						
NC						
ND						
NH						
NJ						
OH						
OK						
OR						
PA						
RI						
SC						
SD						
TN						
TX						
UT						
VA						
WA						
WI						
WV						
WY						
TOTALS:						

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 that 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) 260-7835.

G. REFERENCES CITED IN CHAPTER 10 - 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.

E. REFERENCES CITED IN CHAPTER 11 - 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 - HOW TO SUBMIT DATA AND CONFIDENTIAL BUSINESS INFORMATION

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 this type that qualify for confidential treatment.

Data submitted in support of your application for registration, amendments to a registration, petitions for tolerance, 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 provides that health and safety data on registered or previously registered pesticides shall be made available to the public, <u>except</u> that it does not authorize the release of 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 to the same extent as EPA staff. We provide notification to submitters of CBI that their data will be provided to 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)(A).

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).

IMPORTANT NOTE: Documents containing CBI, i.e., a Confidential Statement of Formula (CSF), should not be transmitted over FAX machines unless the sender wants to clearly waive his or her CBI rights and states this on the documents being "FAXed."

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

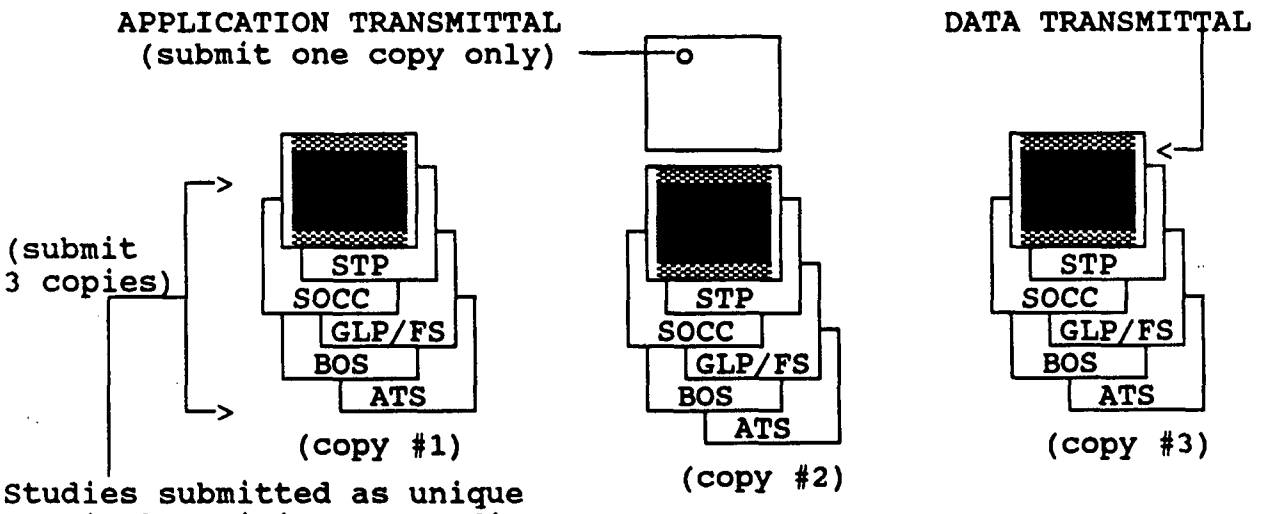
The following individuals in the Information Services Branch of OPP's Program Management and Support Division may be contacted for assistance in answering questions or to provide guidance concerning the data formatting procedures as required by PR Notice 86-5:

Theresa Downs	(703) 305-5363,
Maureen Sherrill	(703) 305-5361,
Kris Pappajohn	(703) 305-5316.

Master Record Identifier (MRID) number and entered into the Agency's Pesticide 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.

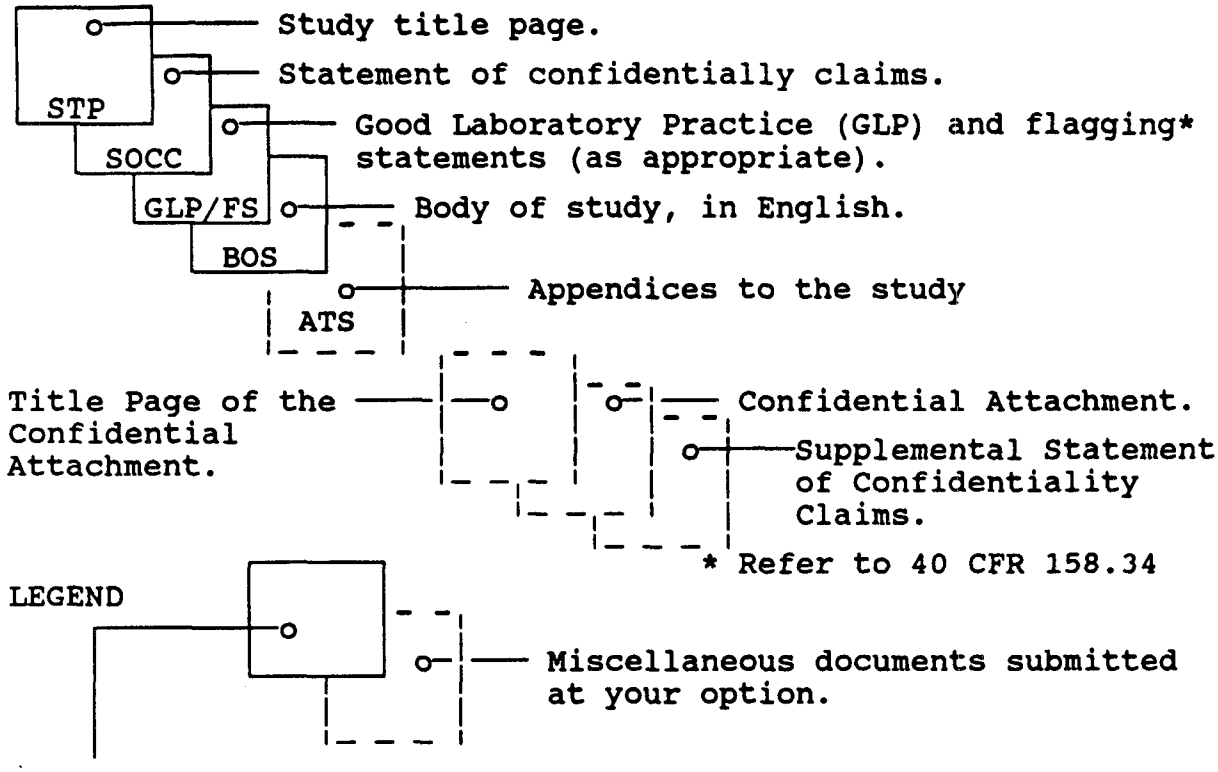
NOTE: As indicated in the above illustration, three identical copies of the data transmittal must be submitted.

LEGEND:

STP	=	Study title page.
SOCC	=	Statement of confidentially claims.
GLP/FS	=	Good Laboratory Practice (GLP) and flagging*.
BOS	=	Body of study, in English.
ATS	=	Appendices to the study.

* Refer to 40 CFR 158.34.

FORMAT OF THE SUBMITTED STUDIES



Documents which must be submitted as appropriate to meet established requirements.

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 in this sub-section address non-data requirements for registration, and are filed in the Agency's registration jacket (file) 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.

Each study must be separately bound. Confidential attachments and supplemental statements of data confidentially must be included within the binding of the body of the study. All bindings must be secure, but easily removable to permit microfilming.

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.

IMPORTANT NOTE: Documents for which a statement of data confidentiality claim has been made should not be transmitted over FAX machines unless the sender wants to clearly waive his or her CBI rights and states this on the documents being "FAXed."

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.

E. REFERENCES CITED IN CHAPTER 12 - 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.

4. PR Notice 89-3 - Format standards for Reregistration Phase 3 summaries and reformatted versions of studies previously submitted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). Issued December 20, 1989.

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 transferor,

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: Notary rules do not generally allow a person to notarize their own signature. Therefore, it is recommended that the same person not sign both the transfer document and the notarized statement.

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)(F) 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 from a company official or from the company legal counsel 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.

IMPORTANT NOTE: Notary rules do not generally allow a person to notarize their own signature. Therefore, it is recommended that the same person not sign both the transfer document and the notarized statement.

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)(F), 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.

E. **REFERENCES CITED IN CHAPTER 13** - 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 the following conditions exist:

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 canceled by EPA, or voluntarily canceled by the registrant because of health or environmental concerns about an ingredient contained in the product, unless EPA has reversed the original action,

4. the registration is in accord with the purposes of FIFRA.

24(c)s which amendments federal registrations (new uses). States may register:

1. subject to the limitations set forth in 40 CFR Part 162, any new use of a federally registered pesticide product.

2. any use of a federally registered product for which registration of other uses of the product was denied, disapproved, suspended, or canceled by the EPA, provided that the proposed use was not considered by the EPA in reaching such a determination and only after the State consults with appropriate EPA personnel on its acceptability.

3. any use of a federally registered product for which registration of some or all uses has been voluntarily canceled by the registrant unless such voluntary cancellation follows the issuance of an EPA Notice of Intent to cancel <u>for human health or environmental reasons</u>. States may only grant 24(c) registrations for voluntarily canceled uses of products after consulting with appropriate EPA personnel.

<u>IMPORTANT NOTE</u>: A State may not register an amendment to a federally registered manufacturing-use product.

24(c)s which are new products (not previously federally registered). States may register:

1. a product which is <u>identical in composition</u> to a federally registered product, but which has differences in packaging, or in the identity of the formulator,

2. a product which contains the same active and inert ingredients as a federally registered product, but in different percentages,

3. a product containing a new combination of active, or active and inert, ingredients only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product,

4. a product containing an ingredient that (1) has had one or more of its formulations or uses denied, disapproved, suspended, or canceled by EPA because of human health or environmental concerns or (2) the

registrant has voluntarily canceled a formulation or use following the issuance of an EPA Notice of Intent to Cancel because of health or environmental concerns, provided the 24(c) formulation and/or use was not considered in EPA's action and was not included in a Notice of Intent to Cancel and only after the State consults with appropriate EPA personnel regarding the acceptability of the 24(c) application.

IMPORTANT NOTE: A State may not register a new manufacturing-use product.

Requests for Special Local Need (SLN) registrations are generally made by pesticide companies to the specific state. Once a state approves the application, the state then forwards notification of the SLN registration to EPA for review. Provided the state has complied with the requirements of FIFRA section 24(c) and 40 CFR Part 162, the registration becomes effective immediately.

The EPA has 90 days from receipt of the SLN notification from the state to disapprove the registration. Otherwise it becomes a Federal registration under FIFRA section 3 for the use only within the state.

General Disapproval of State Registration

EPA may disapprove any state registration on any reasonable grounds (excluding solely lack of essentiality), any state registration which, when compared to a federally registered product, does not have both a similar composition and use pattern. Grounds for disapproval may include, but are not limited to:

1. the 24(c) will probably create an unreasonable adverse effect upon man and/or the environment;

2. the refusal of the registering State to submit information supporting the registration, i.e., application form (within 10 working days), Labeling for the 24(c), Confidential Statement of Formula (new product only), final printed label (within 60 days), State revocation notice with date of revocation and reason(s) for revocation, and scientific studies supporting a "no unreasonable adverse effects" findings by the State (within 15 working days);

3. Failure of the information submitted by the State to support the State decision to issue the 24(c);

Special Disapproval of State Registrations

EPA may disapprove any SLN registration at any time (even beyond the 90 day period) if it is determined that the 24(c):

(a) would constitute an imminent hazard;

(b) may result in a residue on food or feed exceeding, or not covered by, a tolerance, exemption, or other clearance under the FFDCA.

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 8 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.

There are four types of emergency exemptions which may be authorized:

1. Specific exemption. A specific exemption may be authorized in an emergency condition to avert a significant economic loss, or a significant risk to endangered species, threatened species, beneficial organisms, or the environment. EPA shall allow the use of a pesticide under a specific exemption for as long a period as is reasonably expected to be necessary but in no case for longer than 1 year.

2. Quarantine exemption. A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories. EPA shall allow use of a pesticide under a quarantine exemption for as long a period as is deemed

necessary but in no case for longer than 3 years. Quarantine exemptions may be renewed. Interim reports containing the information specified in 40 CFR 166.32(b) to the extent available shall be filed annually.

3. Public health exemption. A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health. EPA shall allow the use of a pesticide under a public health exemption for as long a period as is reasonably expected to be necessary but in no case for longer than 1 year.

4. Crisis exemption. A crisis exemption may be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption. The crisis provisions may not be utilized to authorize a pesticide use if any of the following has occurred:

- EPA has informed the head of the Federal or State agency, the Governor, or their official designee, not to issue such an exemption;
- The pesticide use has been suspended under section 6(c) of FIFRA;
- The pesticide use has been canceled following a notice issued under section 6(b) of FIFRA;
- The pesticide contains a new chemical; or
- The application proposes the first food use of a pesticide.

A crisis exemption may be authorized for: (a) only as long as is necessary to control the pest or conditions causing the emergency; (b) no longer than 15 days, unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the Agency.

The documents **EMERGENCY EXEMPTIONS UNDER SECTION 18 OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT: I. Guidance for State and Federal Agencies**, and **II. Instructions for submission of emergency exemption applications** can be obtained from the National Technical Information Service (NTIS) by calling (703) 487-4650. If you have any questions, or require any further information, please call the Communications Branch in OPP's Field Operations Division at (703) 305-5017.

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.

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

1. Code of Federal Regulations, Title 40

   Part 162 - State registration of pesticide products

   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 FEDERAL OR STATE AGENCIES OTHER THAN EPA's PESTICIDE PROGRAMS

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 Federal, State, or local requirements that you must satisfy. 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 may 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:

Product Assessment Division
Compounds and Packaging Branch
RP, FSIS, U.S. Department of Agriculture
Building 306, BARC-East
Beltsville, MD 20705

(301) 504-8566

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 food contact 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 a food additive regulation has been issued for the active and inert ingredients or the ingredients are "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)**

Other than EPA responsibilities under FFDCA and FIFRA, FDA evaluates the safety and efficacy of pesticides used in paper or other materials which are not themselves regulated as pesticides 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 used on medical devices 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

F. SHIPPING (TRANSPORTATION) OF PESTICIDES

The U.S. Department of Transportation (DOT) and the Environmental Protection Agency (EPA) have several areas of mutual regulatory responsibility which may require review by one or both agencies.

The Hazardous Material Transportation Uniform Safety Act, as amended in 1990, requires that pesticides being shipped are properly packaged, marked and labeled. If the pesticide to be shipped is considered a hazardous material, it will need to bear the proper DOT Hazard Warning Labels prominently on the product labeling. Also, depending upon the size of the shipment, trucks may need to be placarded.

If you wish to transport pesticides which may present physical or chemical hazards, you must obtain shipping papers from DOT prior to such shipment.

WHO TO CONTACT:

For additional information on the transportation of pesticides, and how to obtain shipping papers, contact:

Office of Hazardous Material Standards
Department of Transportation
ATTN: Ed Mazzullo
Rm. 8100
400 7th St., SW
Washington, DC 20590-0001

Phone: (202) 366-4488

G. NON-INDIGENOUS AND GENETICALLY ENGINEERED MICROBIAL PRODUCTS INCLUDING KILLED MICROBIALS

1. Toxic Substances Control Act (TSCA). Products of recombinant DNA technology are also regulated by EPA under TSCA by the Office of Pollution Prevention and Toxics (OPPT) during stages of production before the products become pesticides (such as during fermentation). A Pre-Manufacturing Notice (PMN) may be required for these products. PMNs are not required while the product is under research and development (such as under an EUP), and are also not required for nonindigenous or trans-conjugant organisms. For information on TSCA requirements related to microbial pesticide production contact:

EPA Office of Pollution Prevention and Toxics
Chemical Control Division
Program Development Branch

Kathleen Bailey (202) 260-5591 or
David Giamporcaro (202) 260-6362

2. U.S. Department of Agriculture (USDA). Any organism (including plants) may be considered a potential plant pest. Such organisms may be regulated under either the Plant Pest Act and/or the Plant Quarantine Act. Such organisms may require a permit for import and/or introduction testing, and use. For information on USDA permit requirements contact:

USDA
Animal and Plant Health Inspection Service

Sally McCammon (301) 436-8761
John Payne (301) 436-8378

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 (includes Reregistration Eligibility Documents (REDs)

3. Pesticide Fact Sheets (includes Pesticide R.E.D. 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) 305-5240

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).

EPA Headquarters Telephone Directory

A copy of an order form for ording the EPA Headquarters Telephone Directory can be found at the end of this chapter.

C. DOCUMENTS AVAILABLE FROM THE ENVIRONMENTAL PROTECTION AGENCY

The following documents are available from the Environmental Protection Agency:

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

Copies of the FIFRA 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) 305-7700

2. **List of all federally registered pesticide products classified as "Restricted Use Pesticides" (RUP).**

This listing is available through the Pesticide Information Network (PIN), an on-line, no cost computer bulletin board operated by OPP. This system can be reached with a PC by data-phone (modem), similar to many popular PC-to-PC bulletin boards. Completely menu driven, it is very "user friendly" and contains several informative data bases, such as the "Restricted Use Products" file, which is a monthly updated listing of all RUPs.

Questions about the PIN may be referred to the User Support Group at 703-305-7499 between the hours of 7:00 AM to 4:00 PM EST. The phone number for accessing the PIN is: 703-305-5919, 24 hours a day, except for some periods of time between 1:00 PM to 3:00 PM any weekday for updating and maintenance.

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 1132
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) 305-5805

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 AND REREGISTRATION ELIGIBILITY DOCUMENTS ISSUED**

This listing, entitled the "Registration Standard Report" provides information of all registration standards and reregistration eligibility documents 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) 305-5240

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).

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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.

Copies of the following forms may be obtained, FREE OF CHARGE, from the Registration Support Branch, Registration Division (H7505C), Office of Pesticide Programs, Washington, D.C. 20460. Telephone: (AC 703) 305-7700.

EPA FORM	TITLE
8570-1	Application for Pesticide Registration/Amendment (Revised 12-90, previous editions are obsolete)
8570-4	Confidential Statement of Formula (Revised 12-90, previous editions are obsolete)
8570-5	Notice of Supplemental Registration of Distributor (Revised 8-91, previous editions are obsolete)
8570-17	Application for an Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only (Revised 2-91, Previous editions may be used until supply is exhausted)
8570-20	Data Reference Sheet (1-91)
8570-25	Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need (12-87)
8570-27	Formulator's Exemption Statement (7-91)
8570-28	Certification of Compliance with Data Gap Procedures (1-91)
8570-29	Certification with Respect to Citation of Data (7-91)
8570-31	Certification With Respect to Data Compensation Requirements (4-90)
8570-32	Certification of Offer to Cost Share in the Development of Data with Other Registrants (05-91)

EPA FORM	TITLE
8580-1	FIFRA Section 3(c)(2)(B) Summary Sheet
8580-4	Product Specific Data Report

The following forms may be obtained, FREE OF CHARGE, 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

Graphic representation copies of the above forms are presented below in Figures 17-1 through 17-15. You should note that the forms represented below are for ILLUSTRATION PURPOSES ONLY and should not be used when submitting an application to the Agency.

FIGURE 17-1. REPRESENTATIVE COPY OF EPA FORM 8570-1
FOR ILLUSTRATION PURPOSES ONLY

Please read instructions on reverse before completing form Form Approved OMB No. 2070-0060, Approval expires 11-30-93

(A) E P A

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460
Application for Pesticide:

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
169993

Section I

1. Company/Product Number

2. EPA Product Manager

3. Proposed Classification
☐ None ☐ Restricted

4. Company/Product (Name)

PM#

5. Name and Address of Applicant (include Zip Code)

☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No._____
Product Name_____

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated_____.
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated_____.
☐ "Me Too" Application
☐ Other - Explain below

I I L L U S T R A T I O N

S A M P L E

F O R

P U R P O S E S

O N L Y

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging
☐ Yes
☐ No
* Certification must be submitted.

Unit Packaging
☐ Yes
☐ No
If "Yes," Unit Package wgt. | No. Per container

Water Soluble Packaging
☐ Yes
☐ No
If "Yes," Package wgt. | No. Per container

2. Type of Container
☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify)_____

3. Location of Net Contents Information
☐ Label ☐ Container

4. Size(s) of Retail Container

5. Location of Label Directions
☐ On Label
☐ On Labeling accompanying product

6. Manner In Which Label Is Affixed To Product
☐ Lithograph
☐ Paper glued
☐ Stenciled
☐ Other (_____)

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name | Title | Telephone No. (Include Area Code)

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature

3. Title

4. Typed Name

5. Date

EPA Form 8570-1 (Rev. 12-90) Previous editions are obsolete.

FIGURE 17-2. REPRESENTATIVE COPY OF EPA FORM 8570-4 **FOR ILLUSTRATION PURPOSES ONLY**

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved OMB No. 2070-0060. Approval Expires 11-30-93

E P A United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Confidential Statement of Formula	A. ☐ Basic Formulation ☐ Alternate Formulation	B. Page of	See Instruction on Back
1. Name and Address of Applicant/Registrant (Include ZIP Code)	2. Name and Address of Producer (Include ZIP Code)		
3. Product Name	4. Registration No./File Symbol	5. EPA Product Mgr/Team No.	6. Country Where Formulated
	7. Pounds/Gal or Bulk Density	8. pH	9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number)	11. Supplier Name and Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	b. % by weight	14. Certified Limits % by Weight a. Upper Limit	b. Lower Limit	15. Purpose in Formulation
	S A M P L E	F O R I L L U S T R A T I O N	P U R P O S E		O N L Y			
				E S				
16. Typed Name of Approving Official				17. Total Weight	100%			
18. Signature of Approving Official		19. Title		20. Phone No. (Include Area Code)		21. Date		

EPA Form 8570-4 (Rev. 12-90) Previous editions are obsolete. White - EPA File Copy (Original) Yellow - Applicant Copy

FIGURE 17-3. REPRESENTATIVE COPY OF EPA FORM 8570-5
FOR ILLUSTRATION PURPOSES ONLY

Form Approved. OMB No. 2070-0044
Approval expires 1-31-95

Please Read All Instructions Before Completing This Form (Form must be typed)

E P A

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
401 M Street SW
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)	Distributor Product Name

Name and Address of Distributor (Type; include ZIP code)

S L U
A F U R O
M O S P N
P R T O L
L R S Y
E A E
T A
I
O
N

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacture's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for..., "distributed by..."; or sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor _____ Date _____

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant _____ Date _____

EPA Form 8570-5 (Rev. 2-92) Previous editions are obsolete.

FIGURE 17-4. REPRESENTATIVE COPY OF EPA FORM 8570-17
FOR ILLUSTRATION PURPOSES ONLY

Please read instructions on reverse before completing form Form Approved OMB No. 2070-0040, Approval expires 11-30-93

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460
Application for an Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only

OPP Identifier Number
0 0 2 8 0 8

1. Type of Application
|__| New |__| Amendments (See No. 11)
|__| Extension (Give Permit Number below)

Permit Number

2. EPA Company Number

3. Name and Address of Firm/Person to Whom the Experimental Use Permit is To Be Issued (include ZIP Code) (Type or Print)
S I P O
A F L U N
M O L R L
P R U P Y
L S O
E T S

4. Name and Address of Shipper (if shipment is intended and if different from applicant's name and address) (include ZIP Code) (Type or Print)

5. Name of Product
R E
A S
T
I
O
N

6. Is Product Registered with EPA?
|__| Yes (Give registration number or file symbol below). |__| No
Reg. No._____
File Symbol_____

7. Total Quantity of Product Proposed for Shipment/Use
A._____ Pounds of formulated product
B._____ Pounds of active ingredient

8. Acreage or Area to be Treated

9. Proposed Period of Shipment/Use

10. Places from which Shipped

11. Briefly explain (attach separate sheet if necessary)

12. Specify the name & telephone no. of the individual most familiar with this application who can be contacted directly, if necessary to process this application.

13. Signature of applicant or authorized firm representative

14. Title

15. Date Signed

Certification

This is to certify that food or feed derived from the experimental program will not be used or offered for consumption or sale for consumption except by laboratory or experimental animals if illegal residues are present in or on such food or feed.
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Below for EPA Use Only

In any correspondence on this application, refer to this number

Received by EPA-OPP Registration Division Washington, DC 20460

Normal review time indicates that processing of this application should be completed by (date)

Name of EPA Contact

Telephone No.

EPA Form 8570-17 (Rev. 2-91) Previous editions are obsolete.

FIGURE 17-5. REPRESENTATIVE COPY OF EPA FORM 8570-20 **FOR ILLUSTRATION PURPOSES ONLY**

Form Approved OMB No. 2070-0060. Approval Expires 11-30-93

E P A

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (H7505C)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET
(See instructions on the back of the last page before completing)

1 PAGE OF

2. EPA REGISTRATION NO./FILE SYMBOL

3. APPLICANT'S NAME AND ADDRESS

4. PRODUCT NAME

5. PRODUCT MANAGER

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED:

7. NAME OF STUDY	SOURCE OF STUDY a. APPLICANT	SOURCE OF STUDY b. OFFBRAND	SOURCE OF STUDY c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	SOURCE OF STUDY d. OBTAINED FROM PUBLIC LITERATURE (give reference)	SOURCE OF STUDY e. OTHER (explain)	f. ACCESSION NUMBER (if known)
			SAMPLE	FILL	PUROSE	
				FORUS	TRPOLY	
					RASES	
					TION	
	X					

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? |__| YES |__| NO

EPA Form 8570-20 (Rev. 1-91) APPLICANT - RETAIN THE LAST COPY EPA COPY

FIGURE 17-6 REPRESENTATIVE COPY OF EPA FORM 8570-25
FOR ILLUSTRATION PURPOSES ONLY

Form Approved. OMB No. 2070-0055. Approval expires 6-30-90

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

E P A

Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need
(Pursuant to Section 24(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as Amended)

For State Use Only
Registration No. Assigned
Date Registration Issued

1. Name and Address of Applicant for Registration

2. Product Is (Check one)
EPA-Registered |__|
EPA Registration Number
New (not EPA-registered)
|__| Attach EPA Form 8570-4, Certified Statement of Formula, for new products
EPA Company Number

3. Active Ingredient(s) in Product

4. Product Name

5. If this is a food/feed use, a tolerance or other residue clearance is required. Cite appropriate regulations in 40 CFR Part 180, 21 CFR Part 193, and/or 21 CFR Part 561.

6. Type of Registration (Give details in Item 12 or a separate page, properly identified and attached to this form):
a. To permit use of a new product.
b. To amend EPA registrations for one or more of the following purposes:
(1)To permit use on additional crops or animals.
(2)To permit use at additional sites.
(3)To permit use against additional pests.
(4)To permit use of additional application techniques or equipment.
(5)To permit use at different application rates
(6)Other (specify below)

7. Nature of Special Local Need (Check one)
a. |__| There is no pesticide product registered by EPA for such use.
|__| There is no EPA-registered pesticide product which, under the conditions of use within the State, would be as safe and/or as efficacious for such use within the terms and conditions of EPA registration.
|__| An appropriate EPA-registered pesticide product is not available.

8. If this registration is an amendment to an EPA-registered product, is it for a "changed use pattern" as defined in 40 CFR 162.3(k)?
|__|Yes (discuss in item 12 below) |__|No

9. Has an EPA Registration or Experimental Use Permit for Use of this chemical ever been: (Check applicable box(es))
|__|Sought |__|Issued |__|Denied |__|Canceled |__|Suspended
Previous Permit Action:
|__|Registration |__|Experimental Use Permit |__|No Previous Permit Action

10. Has a FIFRA Section 24(C) registration for this use of the product ever, by another State been (Check applicable box(es))
|__|Sought |__|Issued |__|Denied |__|Revoked
If any of the above are checked, list States in(s)
|__|No FIFRA Section 24(C) Action

11. Endangered Species Act: (Give details in Item 12 or on a separate page, properly identified and attached to this form)
Identify the counties where this pesticide will be used. If State-wide, indicate "all."
Provide a list of Federally protected endangered/threatened species which occur in the areas of proposed use.

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.
Signature of Applicant or Authorized Representative
Title
Telephone Number Date

12. Comments
I
S L P
A F L U O
M O U R N
P R S P L
L T O Y
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Determination by State Agency
This registration is for a Special Local Need and is being issued in accordance with section 24(c) of FIFRA, as amended. To the best of our knowledge, the information above is correct, except as noted in "Comments" below or in attachments.

Name, Title, and Address of State Agency Official
Title
Telephone Number Date

Comments by State Agency Only

Received by EPA

EPA Form 8570-25 (12-87) EPA COPY

FIGURE 17-7 REPRESENTATIVE COPY OF EPA FORM 8570-27
FOR ILLUSTRATION PURPOSES ONLY

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

E P A

United States Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption statement
(40 CFR 152.85)

Applicant's Names and Address	EPA File Symbol/Registration Number
	Product Name
	Date of Confidential Statement of Formula (EPA Form 8570-4)

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

	Source	
Active Ingredient	Product Name	Registration Number
SAMPLE	IPLUS TRATION	
Signature	Name and Title	Date

EPA Form 8570-27 (Rev. 7-91) White - EPA copy Yellow - Applicant copy

FIGURE 17-8 REPRESENTATIVE COPY OF EPA FORM 8570-28
FOR ILLUSTRATION PURPOSES ONLY

E P A	United States Environmental Protection Agency Washington, DC 20460 **Certification of Compliance with Data Gap Procedures** (40 CFR 152.96)	Form Approved. OMB No. 2070-0060 Approval expires 11/30/93

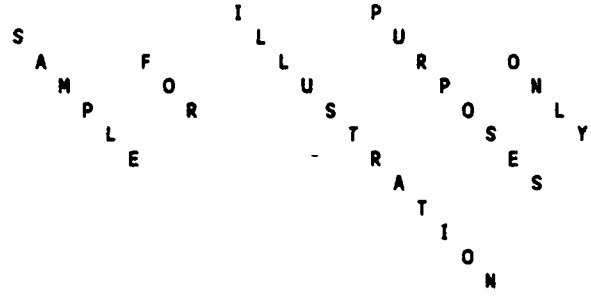
Applicant's Names and Address	EPA File Symbol/Registration Number
	Product Name
	Date of Application

I certify that:

1. I have notified in writing each person on the Pesticide Data Submitters' List for each active ingredient in this product, in accordance with the requirements of 40 CFR 152.96; and

2. I have waited 60 days following such written notice; and

3. I have received no response indicating that any person has submitted a valid study that would satisfy any of the requirements for which a data gap is claimed, and therefore, I have no basis for believing that such data have been submitted to EPA by any other person.



Signature	Name and Title	Date

EPA Form 8570-28 (Rev. 1-91)

FIGURE 17-9 REPRESENTATIVE COPY OF EPA FORM 8570-29
FOR ILLUSTRATION PURPOSES ONLY

E P A	United States Environmental Protection Agency Washington, DC 20460 Certification with Respect to Citation of Data	Form Approved OMB No. 2070-0060 Approval Expires 11-30-93

Applicant's Name and Address SAMPLE FORMULATION SAMPLE FORMULATION	EPA File Symbol/Registration Number
	Product Name
	Date of Application

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

   | | I am the original submitter*; or

   | | I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

   a. | | I am the original data submitter*; or

   | | I have obtained the written permission of the original data submitter to cite that study*; or

   b. | | I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

   | | All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also sign the General Offer Statement below.)

   | | Those companies that have submitted the studies which I have cited (Selective Method*).

   * A Data Matrix identifying these studies is attached. (Note: A Data Matrix is not required under the cite-all method.)

Signature	Name and Title	Date

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date

EPA Form 8570-29 (Rev. 7-91)

FIGURE 17-10 REPRESENTATIVE COPY OF EPA FORM 8570-31
FOR ILLUSTRATION PURPOSES ONLY

United States Environmental Protection Agency Washington, DC 20460 E P A CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS	Form Approved OMB No. 2070-0106 Approval Expires 12-31

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below. S A M F O R I L L U P P O N L Y

Company Name P L S T O S	Company Number
Chemical Name E R A E S	EPA Chemical Number

I Certify that: T I O N

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-90)

FIGURE 17-11 REPRESENTATIVE COPY OF EPA FORM 8570-32
FOR ILLUSTRATION PURPOSES ONLY

E P A	United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA	Form Approved OMB No. 2070-0106 Approval Expires 12-31

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all items could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s) I L P S F L U O A O U R N M R S P L P T O Y L R S E A E T S I O N	Date of Offer

Certification:

I certify that I am duly authorized to represent the company name above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5-91) Replaces EPA Form 8580-6, which is obsolete

FIGURE 17-12 REPRESENTATIVE COPY OF EPA FORM 8580-1
FOR ILLUSTRATION PURPOSES ONLY

Form Approved. OMB Nol 2070-0057. Approval expires 11-30-89.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

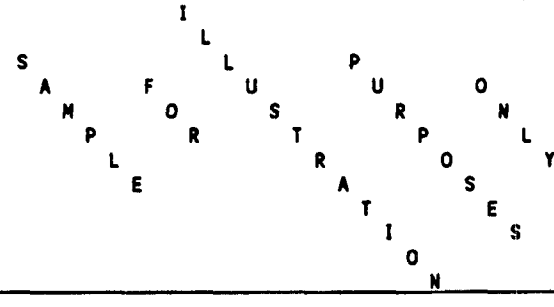
|__| 1. I will submit data in a timely manner to satisfy the following requirements. if the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Report of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use.

|__| 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

|__| 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

|__| 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):



|__| 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

FIGURE 17-13 REPRESENTATIVE COPY OF EPA FORM 8580-4
FOR ILLUSTRATION PURPOSES ONLY

EPA	US Environmental Protection Agency Washington, DC 20460 **Product Specific Data Report**	Registration Standard for:	EPA Registration Number	Form Approved OMB # 2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above (check below)	I am complying with Data Requirement by - Citing MRID No.	Submitting Data (Attached) (Check below)	(For EPA Use Only) Accession numbers assigned
Sec. 158,120 Product Chemistry		S	I L L	P	
61-1	Identity of ingredients	A	F	U U	O
61-2	Statement of composition	M	O	S R	N
61-3	Discussion of formation of ingredients	P	R	T	P L
62-1	Preliminary analysis	L		R	O Y
62-2	Certification of limits		E	A	S
62-3	Analytical methods for enforcement limits			T	E
63-2	Color			I	S
63-3	Physical state				O
63-4	Odor				N
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				
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				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

FIGURE 17-14 REPRESENTATIVE COPY OF EPA FORM 3540-1
FOR ILLUSTRATION PURPOSES ONLY

Form Approved. OMB No. 2070-0020. Expires 3-31-88

U. S. Environmental Protection Agency

NOTICE OF ARRIVAL OF PESTICIDES AND DEVICES

NOTE: Read instructions on reverse before completing form.

SEND COMPLETED FORM TO:

PART I — TO BE COMPLETED BY IMPORTER OR HIS AGENT

1. NAME AND ADDRESS OF IMPORTER OR AGENT (Include Zip Code)

2. NAME AND ADDRESS OF CONSIGNEE (Include Zip Code

3. NAME AND ADDRESS OF SHIPPER

4. EPA REGISTRATION NO.

5. EPA PRODUCER ESTABLISHMENT NO.

6. BRAND NAME OF PRODUCT

7. MAJOR ACTIVE INGREDIENTS AND PERCENTAGE OF EACH

8. UNIT SIZE

9. QUANTITY

10. TOTAL NET WGT.

11. COUNTRY OF ORIGIN

12. PORT OF ENTRY

13 CARRIER

14. ENTRY NUMBER

15. ENTRY DATE

16 MARKS AND NUMBERS

17. LOCATION OF GOODS FOR EXAMINATION

INVOICE DATA

18. NUMBER

19. DATE

20. PLACE

21. REMARKS

22. I ASSERT THAT INFORMATION CONSTITUTING CONFIDENTIAL BUSINESS INFORMATION IS SHOWN IN THE ABOVE BLOCKS NUMBERED:

23. SIGNATURE OF IMPORTER OR AGENT

24. DATE

PART II — TO BE COMPLETED BY U.S. ENVIRONMENTAL PROTECTION AGENCY

Action to be taken on shipment by U.S. Customs:

- [ ] Release shipment.
- [ ] Detain shipment for inspection by EPA
- [ ] Release shipment to consignee under bond. Shipment must be held intact pending EPA inspection.
- [ ] Sample desired under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended and Customs Regulations 19 CFR 12.116. Please forward a sample of the merchandise identified above, together with all accompanying labels, circulars, and advertising matter pertaining to such merchandise, to the address shown above. If it is necessary to take subsamples from bulk containers, contact the EPA office for sampling instructions.
- [ ] Other (Specify):

REMARKS

SIGNATURE AND TITLE OF EPA OFFICIAL

DATE

PART II — TO BE COMPLETED BY U.S. CUSTOMS SERVICE

The information shown in Part I was compared with the entry papers for this shipment and no discrepancies were noted. The shipment was handled as instructed by EPA in Part II. Any deviations should be brought to the attention of EPA before releasing shipment and also be noted in remarks.

REMARKS

SIGNATURE OF DISTRICT DIRECTOR OF CUSTOMS

DATE

EPA Form 3540-1 (Rev. 5-77) Previous editions are obsolete.

FIGURE 17-15 REPRESENTATIVE COPY OF EPA FORM 3540-8
FOR ILLUSTRATION PURPOSES ONLY

U. S. ENVIRONMENTAL PROTECTION AGENCY

APPLICATION FOR REGISTRATION OF PESTICIDE - PRODUCING ESTABLISHMENT
(SECTION 7, FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AS AMENDED, 86 Stat. 973.999)

Form Approved
OMB No. 2070-0045
Approval expires 11-30-89
DOCUMENT NUMBER
D. TRANS. TYPE (EPA USE ONLY)

NOTE: READ ALL INSTRUCTIONS BEFORE COMPLETING.

1. COMPANY NAME
6. EPA REGISTRANT NUMBER
2. STREET ADDRESS
7. COMPANY DUNS NUMBER
3. CITY
4. STATE
5. ZIP CODE
8. ENTER APPROPRIATE OWNERSHIP CODE
1 - INDIVIDUAL
2 - PARTNERSHIP
3 - COOPERATIVE ASSOCIATION
4 - CORPORATION
5 - OTHER
11. COMPANY HEADQUARTERS (if different from Number 1)
12. STREET ADDRESS
9. DATE OF INCORPORATION (Mo.Day.Year)
13. CITY
14. STATE
15. ZIP CODE
10. STATE OF INCORPORATION

NAME, SITE LOCATION, AND MAILING ADDRESS OF EACH PRODUCING ESTABLISHMENT

A	16. NAME OF ESTABLISHMENT	17. ESTAB. NO. (EPA Use Only)		18. DUNS NUMBER
	19. LOCATION (Street, City)	20. STATE	21. ZIP CODE	22. CUSTOM BLENDER
	23. MAILING ADDRESS OF ESTABLISHMENT (Street, City)	24. STATE	25. ZIP CODE	26. SIC CODES
B	16. NAME OF ESTABLISHMENT	17. ESTAB. NO. (EPA Use Only)		18. DUNS NUMBER
	19. LOCATION (Street, City)	20. STATE	21. ZIP CODE	22. CUSTOM BLENDER
	23. MAILING ADDRESS OF ESTABLISHMENT (Street, City)	24. STATE	25. ZIP CODE	26. SIC CODES
C	16. NAME OF ESTABLISHMENT	17. ESTAB. NO. (EPA Use Only)		18. DUNS NUMBER
	19. LOCATION (Street, City)	20. STATE	21. ZIP CODE	22. CUSTOM BLENDER
	23. MAILING ADDRESS OF ESTABLISHMENT (Street, City)	24. STATE	25. ZIP CODE	26. SIC CODES
D	16. NAME OF ESTABLISHMENT	17. ESTAB. NO. (EPA Use Only)		18. DUNS NUMBER
	19. LOCATION (Street, City)	20. STATE	21. ZIP CODE	22. CUSTOM BLENDER
	23. MAILING ADDRESS OF ESTABLISHMENT (Street, City)	24. STATE	25. ZIP CODE	26. SIC CODES
E	16. NAME OF ESTABLISHMENT	17. ESTAB. NO. (EPA Use Only)		18. DUNS NUMBER
	19. LOCATION (Street, City)	20. STATE	21. ZIP CODE	22. CUSTOM BLENDER
	23. MAILING ADDRESS OF ESTABLISHMENT (Street, City)	24. STATE	25. ZIP CODE	26. SIC CODES

☐ CONTINUED ON ATTACHED SHEET

27. SIGNATURE OF COMPANY OFFICER	28. NAME AND TITLE	29. DATE (Mo.Day.Yr)
30. TELEPHONE NUMBER	31. DATE APPLICATION RECEIVED	
THE ESTABLISHMENTS ASSIGNED NUMBERS ABOVE HAVE BEEN REGISTERED IN ACCORDANCE WITH SECTION 7, FIFRA AS AMENDED	EPA USE ONLY: 32. SIGNATURE	
	33. EPA REGIONAL OFFICE	34. DATE REVIEWED

EPA FORM 3540-8 (REV. 10-81) PREVIOUS EDITIONS ARE OBSOLETE

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 (Distribution Code) **
Office of Pesticide Programs (H7504C)
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. 258
Document Processing Desk (Distribution Code) **
1921 Jefferson Davis Highway
Arlington, VA 22202

** Insert appropriate Distribution Code identified below.

3. Distribution Codes

When you send mail to either of the above addresses, we will be able to process your application more expeditiously if you indicate the type of application you 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.

SECTION 3 PRODUCT REGISTRATIONS

DISTRIBUTION CODE	TYPE OF APPLICATION
APPL	Application for Product Registration
AMEND	Amendment to Registration
CAN/WD	Request to Cancel a Registered Product or to Withdraw a Pending Registration
CERT	Certifications of Product Registration
LIP	Label Improvement Program Response
XFER	Transfer Products to a Different Company
	OTHER ACTIONS
BIOTECH	Biotech Applications and Pre-EUP Notifications
EMEX	Emergency Exemption
EUP	Experimental Use Permit
IR4	Minor Use Petition
PETN	Petition for Tolerance
SLN	Special Local Need Registration
	INFORMATION PERTAINING TO ADVERSE EFFECTS
6(a)(2)	Unreasonable Adverse Effects Data
	COMPANY NAME AND ADDRESS
COADR	Company Name and Address Change
DIST	Supplemental (Distributor) Registration
NEWCO	Request for a Company Number (Register an Establishment)
	DATA CALL-IN RESPONSES (PRODUCT SPECIFIC)
DCI-RD-PMxx	Response to a Data Call-In
RED-RD-PMxx	Response to a Reregistration Eligibility Document

(xx identifies the PM Team)

	DATA CALL-IN RESPONSES (GENERIC)
DCI-SRRD-xxx	Response to a Data Call-In
RED-SRRD-xxx	Response to a Registration Eligibility Document

(xxx identifies the regulatory case number or chemical name as as specified in individual OPP instructions)

OTHER REGULATORY RESPONSES

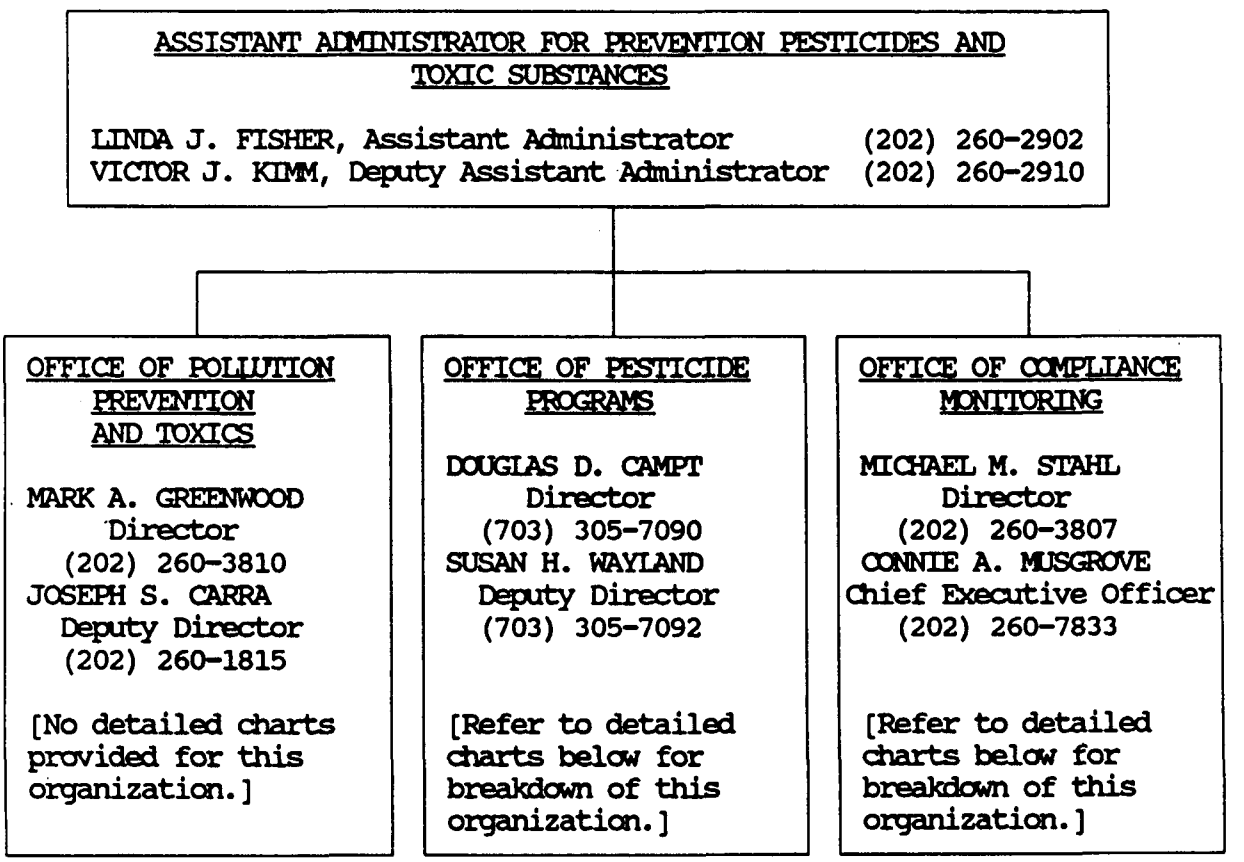
RS-xxx Response to a Registration Standard (including Second Round Reviews)

(xxx identifies the regulatory case number or chemical name as as specified in individual OPP instructions)

C. ORGANIZATIONAL CHARTS: OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

This section contains organizational charts for the Office of Prevention, Pesticides and Toxic Substances, including names and telephone numbers for the heads of each organization. Detailed charts are provided for the Office of Pesticide Programs and the Office of Compliance Monitoring but not for the Office of Pollution Prevention and Toxics.

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES



OFFICE OF PREVENTION, PESTICIDES & TOXIC SUBSTANCES

OFFICE OF PESTICIDE PROGRAMS (OPP)

DOUGLAS D. CAMPT, Director (703) 305-7090 SUSAN H. WAYLAND, Deputy Director (703)305-7090

Responsible for the overall management of the Pesticide Program. Activities of the OPP include control and regulation of pesticides and reduction in their use to assure human safety and protection of environmental quality; establishment of tolerance levels for pesticides which occur in or on food; monitoring of pesticide residue levels in food, humans, and nontarget fish and wildlife and their environments; and investigation of pesticide accidents.

POLICY AND SPECIAL PROJECTS STAFF (PSPS)
WILLIAM JORDAN, Chief (703) 305-7102

Analyzes and responds to external critiques of program activities and policies; analyzes the impact of legislative amendments; analyzes and responds to activities of other Federal Agencies as they may affect the pesticide program.

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION (BEAD)
ALLEN L. JENNINGS, Director
(703) 308-8200

Responsible for pesticide use and benefit analysis and data gathering support for the OPP.

FIELD OPERATIONS DIVISION (FOD)
STEPHEN L. JOHNSON, DIRECTOR
(703) 305-7410

Oversees the implementation of EPA's pesticide regulatory actions, policies and programs.

PROGRAM MANAGEMENT AND SUPPORT DIVISION (PMSD)
ALLAN S. ABRAMSON, Director
(703) 305-5440

Responsible for administrative management, information resources management and services, automated system development and management, and OPP budget formulation and management.

SPECIAL REVIEW AND REREGISTRATION DIVISION (SRRD)
DANIEL M. BAROLO, Director
(703) 308-8000

Manages the special review and reregistration of pesticide products under the authority of sections 3 and 6 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

ENVIRONMENTAL FATE AND EFFECTS DIVISION (EFED)
ANNE L. BARTON, Director
(703) 305-7695

Reviews, evaluates, and validates all data submitted on the toxicological and adverse effects on fish and wildlife, and other biological species resulting from the use of pesticides.

HEALTH EFFECTS DIVISION HED)
PENELOPE FENNER-CRISP, Director
(703) 305-7351

Reviews, evaluates, and validates all data submitted on the toxicological and adverse effects on humans and domestic animals resulting from the use of pesticides and performs risk assessments on proposed and existing pesticide uses.

REGISTRATION DIVISION (RD)
ANNE E. LINDSAY, Director
(703) 305-5447

Manages the registration of pesticide products, under the authority of section 3 of FIFRA and establishes tolerances for pesticide residues on food and animal feed under the Federal Food, Drug and Cosmetic Act. Issues experimental use permits under FIFRA section 18.

OFFICE OF PESTICIDES PROGRAMS

POLICY AND SPECIAL PROJECTS STAFF (PSPS)

WILLIAM JORDAN, Chief (703) 305-7102

GROUNDWATER PROTECTION AND SPECIAL REVIEW CHEMICALS SECTION (GPSRCS)

JAMES ROELOFS, Section Head (703) 305-7102

Responsible for issues involving pesticides in special review process (except chemicals raising issues primarily involving the Federal Food, Drug and Cosmetic Act), as well as issues involving the protection of groundwater from unacceptable pesticide contamination.

FOOD SAFETY AND REGULATIONS SECTION (FSRS)

DEBORAH SISCO, Section Head (703) 305-7102

Responsible for functions relating to issues of food safety, arising principally under the Federal Food, Drug, and Cosmetic Act, as well as issues involving EPA regulations affecting pesticides (except regulations primarily involving groundwater).

REREGISTRATION AND INTERNATIONAL ACTIVITIES SECTION (RIAS)

CATHLEEN BARNES, Section Head (703) 305-7102
JANE HOPKINS, Section Head (703) 305-7102

Responsible for functions relating to international pesticide issues and issues involving the pesticide reregistration process.

OFFICE OF PESTICIDE PROGRAMS

BIOLOGICAL AND ECONOMIC ANALYSIS DIVISION (BEAD)

ALLEN L. JENNINGS, Director (703) 308-8200
KATHLEEN F. KNOX, Deputy Director (703) 308-8200

PLANNING AND EVALUATION STAFF (PES)
V A C A N T , Chief (703)308-8141

Responsible for formulation of BEAD budgets and program plans, administrative management science integration and program evaluation, and coordination of preparation for hearings. Also evaluates biological and economic assessments, produced in support of Section 18 and Special Review decisions and for coordinating BEAD support to FIFRA hearings.

BIOLOGICAL ANALYSIS BRANCH (BAB)
JANET ANDERSON, Chief (703)308-8181

Provides biological and technical data relevant to the use and performance of pesticide products in terms of crop yield or quality. Provides comprehensive use data assessments which predict the duration and frequency of worker exposure for use in support of Pesticide Risk Assessments. Participates in the assessment of new and innovative developments in the field of Integrated Pest Management and Biotechnology.

ECONOMIC ANALYSIS BRANCH (EAB)
ARNOLD L. ASPELIN, Chief (703) 308-8111

Provides economic analysis as part of EPA's pesticide regulatory program. EAB focuses on the benefits of pesticide use versus focusing on the health and environmental risk hazards. EAB gathers economic data and does economic impact analyses of pesticide regulatory actions affecting industrial, home and garden, governmental, urban, institutional, forestry, aquatic and other natural resources, and agricultural sectors.

ANALYTICAL CHEMISTRY BRANCH (ACB)
DONALD A. MARLOW, Chief (703) 308-8198

Provides analytical and environmental chemistry services to the OPP by supporting the pesticide registration, special review and tolerance petitions programs. ACB also provides support to the Office of General Counsel for hearings, the Regional Enforcement Program, and the National Groundwater Monitoring Program.

OFFICE OF PESTICIDES PROGRAMS

ENVIRONMENTAL FATE AND EFFECTS DIVISION (EFED)

ANNE L. BARTON, Director (703) 305-7695
PAUL F. SCHUDA, Deputy Director (703) 305-7695

ECOLOGICAL EFFECTS BRANCH (EEB)
DOUGLAS J. URBAN, Chief(Acting)(703) 305-7347

Responsible for determining the impact of pesticides to non-target organisms through the examination and analysis of data from a wide variety of documents. These data are assimilated and analyzed to determine the adverse effects to individual species of fish, shellfish, invertebrate, wildlife, microbes, plants, and beneficial insects; on populations of species and their community assemblages; and to overall aquatic and terrestrial toxicology, environmental chemistry, environmental fate and transport of pesticides, agronomy and agricultural practices, wildlife ecology, aquatic ecology, statistics, botany and plant ecology, and microbiology.

ENVIRONMENTAL FATE AND GROUNDWATER BRANCH (EFGWB)
HENRY JACOBY, Chief (703) 305-5734

Evaluates data on the fate and transport of pesticide chemicals and on the exposure of humans and non-target organisms to pesticides. EFGWB has responsibility for management and coordination of human and environmental monitoring activities in support of the pesticide regulatory program. Reviews data on aspects of pesticide leachability and groundwater effects and related environmental chemistry and exposure. EFGWB also prepares portions of the pesticide guidelines related to these areas of expertise.

SCIENCE ANALYSIS AND COORDINATION STAFF (SACS)
AMY S. RISPIN, Chief (703) 305-5327)

Supports the assessment of pesticide hazard through the integration of individual discipline-specific review components into an overall statement of risk. Provides OPP lead for biotechnology and pesticide disposal.

OFFICE OF PESTICIDE PROGRAMS

FIELD OPERATIONS DIVISION (FOD)

STEPHEN L. JOHNSON, Director (703) 305-7410
JUDY K. HECKMAN, Deputy Director (703) 305-7410

LIAISON AND ADMINISTRATIVE STAFF (LAS)
THERESE MURTAGH, Chief (703)305-7410

Provides special liaison with the agricultural community. Responsible for development of issues involving Integrated Pest Management (IPM).

PUBLIC RESPONSE AND PROGRAM RESOURCE BRANCH (PRPRB)
SUSAN H. LAWRENCE, Chief (703) 305-5805

Works to increase public awareness and understanding of pesticide issues and regulatory decisions and policies and thus functions as an OPP information center. Manages the National Pesticide Telecommunications Network (NPTN) which provides a variety of information about pesticides through a toll-free 24 hour telephone service. Handles Freedom Of Information (FOI) requests and public docketing.

CERTIFICATION AND TRAINING BRANCH (CTB)
ARTHUR-JEAN WILLIAMS, Chief (703) 305-7371

Responsible for the direction and implementation of EPA's regulatory and non-regulatory pesticide applicator training and certification activities under FIFRA sections 4 and 23 and assists in the upgrading of states, federal and Indian tribe pesticide applicator certification training programs and the supporting applicator training activities conducted cooperatively between EPA and USDA with State Cooperative Extension Services.

REGIONAL OPERATIONS BRANCH (ROB)
KATHERINE TAYLOR, Chief (703) 305-5239

Provides the EPA regions and state lead agencies, on a regular basis, information on pesticide strategic initiatives and pesticide regulatory decisions. Coordinates groundwater and endangered species activities with EPA regions and state lead agencies. Coordinates Integrated Pest Management (IPM) activities within OPP. Directs OPP activities concerning pesticide disposal, storage and transportation (including the preparation of nationwide assessments of pesticide disposal problems).

COMMUNICATIONS BRANCH (CB)
MAJORIE FEHRENBACH, Chief (703) 305-5017

Responsible for formulating communication strategies and plans for communicating OPP regulatory decisions to affected and interested parties.

OCCUPATIONAL SAFETY BRANCH (OSB)
JAMES J. BOLAND, Acting Chief (703) 305-7666

Coordinates and directs the pesticide user safety programs (including farm safety) for OPP. Develops and recommends Agency policy for pesticide occupational safety. Develops general information on farm workers, pesticide applicators and others who, in the course of their employment, may be routinely exposed to pesticides.

OFFICE OF PESTICIDE PROGRAMS

HEALTH EFFECTS DIVISION (HED)

PENELOPE FENNER-CRISP, Director (703) 305-7351
RICHARD SCHMITT, Deputy Director (703) 305-7351

PROGRAM PLANNING AND SUPPORT STAFF (PPSS)
GLENN WILLIAMS, Staff Chief (703) 305-7560

Performs services in the area of personnel and administrative management. Performs the financial management functions relating to the Document Control Register.

SCIENTIFIC ADVISORY PANEL (SAP)
ROBERT B. JAEGER, Senior Science Advisor
(703) 305-5369

SCIENCE ANALYSIS AND COORDINATION BRANCH (SACB)
WILLIAM BURNAM, Acting Chief (703) 305-6193

Provides scientific analysis and evaluation in the areas of statistical analysis of biological data, evaluation of laboratory animal pathology and genetic engineering. Coordination and integration of human and animal toxicological data along with dietary and non dietary exposure data to determine risk of pesticides in the registration and reregistration processes. Conducts assessments of potential dietary exposures to pesticides. Coordinates the Tolerance Assessment System.

CHEMISTRY BRANCH I (CB I)
DEBRA EDWARDS, Acting Chief (703) 305-7484

Responsible for the evaluation of analytical methods, residue data, and metabolism data leading to recommendations for or against proposed permanent and temporary pesticide residue tolerances in food or feed, and applications for pesticide product registration under sections 3,5,18, and 24(c) of FIFRA. Branch responsibilities are carried out under FIFRA and sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA).

CHEMISTRY BRANCH II (CB II)
EDWARD ZAGER, Chief (703) 305-7324

Evaluates the residue chemistry data supporting tolerances for pesticide residues in foods under the provisions of sections 408 and 409 of the Federal Food, Drug and Cosmetic Act, submitted to support reregistration under the provisions of FIFRA and develops Reregistration Eligibility Documents (REDs) and special review technical support documents. The Branch also conducts dietary exposure analyses as part of the Agency's pesticide risk assessments.

TOXICOLOGY BRANCH I (TB I)
KARL P. BAETCKE, Chief (703) 305-7712

Evaluates and analyzes the full range of toxicological data on pesticides and related exposure information to determine risks and hazards associated with pesticide uses. Examples include mutagenic, reproductive, neurotoxic, and teratogenic reviews.

TOXICOLOGY BRANCH II (TB II)
MARCIA VAN GEMERT, Chief (703) 305-6300

Evaluates and analyzes the full range of toxicological data on pesticides and related exposure information to determine risks and hazards associated with pesticide uses. Examples include mutagenic, reproductive, neurotoxic, and teratogenic reviews.

OCCUPATION AND RESIDENTIAL EXPOSURE BRANCH (OREB)
CHARLES L. TRICHILO, Chief (703) 305-6094

Evaluates and analyzes data on the occupational and residential exposure of humans to pesticides. Provides scientific recommendations and technical advice for pesticide registration under sections 3, 5, 18, and 24(c) of FIFRA. Responsible for reviewing human applicators and post-application/reentry exposure data in order to determine conditions under which pesticides should be registered for use.

OFFICE OF PESTICIDE PROGRAMS

PROGRAM MANAGEMENT AND SUPPORT DIVISION (PMSD)

ALLAN S. ABRAMSON, Director (703) 305-5440
NORMAN W. CHLOSTA, Deputy Director (703) 305-5440

SPECIAL PROJECTS AND COORDINATION STAFF (SPCS)
KATHRYN S. BOUVE, Chief (703) 305-5440

Responsible for the Agency's Four Year Strategic Planning process. Also serves as the Agency's coordinator for 6(a)(2) (unreasonable adverse) data.

ADMINISTRATION BRANCH (AB)

SHERRI Y. SHEPPARD, Chief
(703) 305-5725

Provides personnel and administrative management functions for both the Office Director (and staff) and for the Divisions within OPP. In addition the financial management functions relating to the Document Control Register are provided for the Office Director (and staff) and for the PMSD staff. The Branch also provides overall OPP training courses, maintenance of the personnel roster, telephone listing, staffing plans, and reviews all personnel actions.

INFORMATION SERVICES BRANCH (ISB)

JOHN M. CARLEY, Chief
(703)305-5613

Provides information management support to the OPP regulatory program in carrying out certain information-related provisions of FIFRA and the FFDCA. Information services are provided to OPP staff, registrants, and other governmental agencies. The Branch maintains central collections of technical and administrative documents and provides information and open literature retrieval services to OPP staff. The Document Management Section (Headed up by Clare Grubbs, (703) 305-7460)) has responsibility for document management and maintenance of the Company Name and Address file. The Information Resources Section (Headed up by John Jamula (703) 305-6426)) provides consulting assistance for compliance with data formatting requirements.

RESOURCE MANAGEMENT AND EVALUATION BRANCH (RMEB)

DENNIS J. O'CONNOR, Chief
(703) 305-5047

Assists the Office Director and the OPP Division Directors in the preparation of program plans and related budget proposals and evaluates the costs and the effectiveness of program activities, program alternatives and policy positions.

SYSTEMS BRANCH (SB)

GERALD O. MILLER, Chief
(703) 305-5484

The central point within OPP for all automated system requirements. The Branch provides systems analysis design, systems data banks, ADP facilities and hardware. Support services are available in the Branch to all organizational elements within OPP and as directed, to other organizations within the Office of Prevention, Pesticides and Toxic Substances.

OFFICE OF PESTICIDE PROGRAMS

REGISTRATION DIVISION (RD)

ANNE E. LINDSAY, Director (703) 305-5447
STEPHANIE R. IRENE, Deputy Director (703) 305-5447

ANTI-MICROBIAL PROGRAM BRANCH (APB)

JAUNITA WILLS, Chief
WALTER C. FRANCIS, Deputy Chief
(703) 305-6661

Responsible for the registration activities of pesticides uses as hospital sterilants, disinfectants, water treatment products, anti-fouling paints, swimming pool chemicals, and fumigants.

Product Manager 31:
JOHN H. LEE (703) 305-5676

Product Manager 32:
RUTH G. DOUGLASS (703) 305-7964

See Section D. 3. ANTIMICROBIAL PROGRAM BRANCH below for a listing of the types of products within the area of responsibility of each Product Manager.

FUNGICIDE-HERBICIDE BRANCH (FHB)

FRANK T. SANDERS, Chief
THOMAS E. ADAMCZYK, Deputy Chief
(703) 305-6250

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.

Product Manager 21:
SUSAN LEWIS (703) 305-6900

Product Manager 22:
CYNTHIA GILES-PARKER (703) 305-5540

Product Manager 23:
JOANNE MILLER (703) 305-7830

Product Manager 25:
ROBERT TAYLOR (703) 305-6800

See Section D. 2. FUNGICIDE-HERBICIDE BRANCH below for a listing of the types of products within the area of responsibility of each Product Manager.

INSECTICIDE-RODENTICIDE BRANCH (IRB)

HERBERT S. HARRISON, Chief
HARVEY L. WARNICK, Deputy Chief
(703) 305-5200

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.

Product Manager 10:
DICK MOUNTFORT (703) 305-6502

Product Manager 13:
GEORGE LaROCCA (703) 305-6100

Product Manager 14:
ROB FORREST (703) 305-6600

Product Manager 18:
PHIL HUTTON (703) 305-7690

Product Manager 19:
DENNIS EDWARDS (703) 305-6386

See Section D. 1. INSECTICIDE-RODENTICIDE BRANCH below for a listing of the types of products within the area of responsibility of each Product Manager.

REGISTRATION SUPPORT BRANCH (RSB)

[NOTE: Telephone Numbers Will Change]*

DONALD R. STUBBS, Chief
JAMES TOMPKINS, Deputy Chief
(703) 305-7700

Responsible for the processing and review of Section 18 Emergency Exemption requests, minor use (IR-4) petitions, inert ingredient clearance, and the review of product chemistry and precautionary labeling (acute toxicology) data. Also responsible for tolerance reassessment, policy and regulation development and Office of Management and Budget (OMB) clearance, the processing of product registration transfer requests, and registration cancellation requests, and front-end application processing.

Front End Processing Staff:
EDITH MINOR (703) 305-6978

Precautionary Review Section:
TOM ELLWANGER (703) 305-7783

Product Chemistry Review Section:
DONALD R. STUBBS (Acting) (703) 305-7700

Emergency Response and Minor Use Section:
REBECCA S. COOL (703) 305-5806

See Section D. 4. REGISTRATION SUPPORT BRANCH below for a listing of the types of functions within the area of responsibility of each Section.

* In late summer or early fall of 1992 all members of the Registration Support Branch (RSB) will move to Crystal Station Building 1 (CS-1) and their telephone numbers and room numbers will change from those listed in this manual. However, you can continue to call their old telephone number for a period of time after the move occurs and you will be given the new telephone number. Otherwise, you may call the EPA's Directory Assistance/Personnel Locator number (202) 260-2090.

SPECIAL REVIEW AND REREGISTRATION DIVISION (SRRD)

DANIEL BAROLO, Director (703) 308-8000
PETER P. CAULKINS, Deputy Director (703) 308-8000

POLICY, PLANNING AND OPERATIONS STAFF (PPOS)

JAMES H. KEARNS, Chief (703) 308-8009

Formulates policies, plans, and procedures for the reregistration of pesticides and the review of chemicals which have the potential to cause unreasonable adverse effects on human health and the environment; ensures consistent development and application of pesticide policy in carrying out SRRD's regulatory responsibilities; manages the development of pesticide regulations related to the reregistration and special review processes; evaluates and recommends solutions to pesticide policy problems or issues of a conceptual nature; serves as the focal point for division liaison activities.

SPECIAL REVIEW BRANCH (SRB)

JACK E. HOUSENGER, Chief (703) 308-8010

Responsible for managing the special review for chemicals which have met or exceeded the risk criteria of unreasonable adverse effects as set forth in 40 CFR 154. The special review process provides a procedure for risk/benefit reviews of pesticide products and preparation of documents stating the Agency's position. Regulatory action includes risk reduction measures, cancellation of some or all uses, and suspension. SRB issues Grassley Allen notifications to registrants that initiation of a special review is under consideration. Coordinates the SAP on proposed Agency decisions. Responsible for providing support to the OGC for hearings resulting from special review actions. Responsible for preparing other Federal Register Notices relating to special reviews such as amendments to proposed or final decisions or notices that a special review was considered but not initiated.

REREGISTRATION BRANCH (RB)

LOIS A. ROSSI, Chief (703) 308-8080

Manages the reregistration process for selected existing chemicals. This process, authorized under section 3(g) of FIFRA, provides for the review of all pesticides registered prior to 1984. Management of the process includes planning, scheduling, and coordinating HED, EFED, PMSD, RD, and BEAD inputs; conducting the review; and preparing and issuing documents.

ACCELERATED REREGISTRATION BRANCH (ARB)

JAY S. ELLENBERGER, Chief (703) 308-8064

Manages the reregistration and data call-in processes authorized under sections 3 and 4 of FIFRA. The reregistration process provides for the reregistration of all pesticides first registered before November 1984. Of these pesticides, ARB is responsible for those for which a registration standard was not completed (these are commonly referred to as List B, C, and D chemicals). The data call-in process includes the identification of necessary data for pesticide regulation, notifying the registrants of these requirements, reviewing data upon receipt, and corresponding with registrants about the adequacy of the data. Management of these processes includes planning, scheduling, and coordinating input from the PMSD, HED, EFED, BEAD, and OCM; conducting reviews; and preparing and issuing regulatory documents.

OFFICE OF COMPLIANCE MONITORING (OCM)

MICHAEL M. STAHL, Director (202) 260-3807 KATRINA CHERRY, Special Assistant to Director (Regional Liaison) (202) 260-7457
CONNIE A. MUSGROVE, Chief Executive Officer (202) 260-7833
JOHN MACKENZIE, Western Compliance Director (415) 744-1091) [OCM coordinator with Regions VI through X; OCM liaison with SFIREG and AAPCO activities; OCM manager of UC-Davis Pilot Program and Executive Secretary of Steering Committee.]

OCM directs and coordinates national compliance monitoring activities under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), the Emergency Planning and Community Right-to-Know Act (EPCRA),the Asbestos Hazard Emergency Response Act (AHERA), and the Organotin Antifouling Paint Control Act (OAPCA). Provides compliance overview and program policy direction to the Regions and States, establishes national compliance priorities, develops enforcement response policies and national inspection/guidance documents, offers technical support for litigation activity, concurs on enforcement actions, maintains liaison with the National Enforcement Investigations Center (NEIC), collects/analyzes national enforcement data for the aforementioned statutes, develops annual fiscal budgets for the national programs, and manages fiscal and personnel resources for the Headquarters programs. Coordinates with the Office of General Counsel (OGC) and the Office of Enforcement (OE) in an attorney-client relationship. Also coordinates with the Office of Pesticide Programs (OPP) in the implementation of pesticide regulatory and compliance programs under FIFRA, and with the Office of Pollution, Prevention and Toxics (OPPT) in the implementation of regulatory and compliance programs under TSCA, AHERA, and EPCRA.

OCM PROGRAM SUPPORT STAFF (PSS)

ROBERTA MILLER, Chief (202) 260-7691

POLICY AND GRANTS DIVISION (P&GD)

JOHN J. NEYLAND III, Director (703) 308-8383 and (202) 260-7825

Responsible for developing compliance monitoring policies and strategies, and federal enforcement response policies for the Region/States under FIFRA, TSCA, AHERA, EPCRA and OAPCA. Also responsible for representing OCM views at regulatory workgroup meetings, and for reviewing regulatory documents to assure their enforceability. Develops and revises procedures and programs under FIFRA and TSCA state cooperative enforcement agreement programs, and assists the Regions in the implementation and management of these programs. Revises policy, guidance, priorities, and strategies following program evaluations made by Divisions within the OCM.

LABORATORY DATA INTEGRITY ASSURANCE DIVISION (LDIAD)

DAVID L. DULL, Director (703) 308-8300
FRANCIS LIEM, Special Assistant to Division Director (703) 308-8265
ROBIN NOGLE, International Activities liaison (703) 308-8269

Develops and executes Good Laboratory Practice (GLP) compliance programs under both FIFRA and TSCA. Validates studies submitted to the Agency as required by either FIFRA or TSCA and monitors compliance to requirements published under both regulations. Provides compliance, data audit guidance, policies and procedures for the operations of FIFRA Section 3(c) and TSCA Section 4, 5(e) compliance monitoring programs and for the conduct and reporting of the results of GLP compliance inspections and data audits. Assesses the quality and effectiveness of these programs and provides normal administrative support for the Program Support and Compliance Referral Branch and the Scientific Support Branch. Provides national and international liaison with other Federal Agencies, and foreign governments to conserve resources and standardize procedures.

COMPLIANCE DIVISION (CD)

MICHAEL F. WOOD, Director (202) 260-7835

Responsible for developing procedures for controlling imminent hazards involving pesticides and toxic substances. Develops national compliance monitoring procedures and regional coordination functions in support of TSCA, AHERA, FIFRA, EPCRA, and OAPCA. Performs Regional coordination functions for the purpose of compliance monitoring, provides guidelines for training programs for the regions and the states, promulgates guidelines concerning administrative rules in case preparation procedures for enforcement cases, and provides case development support for Headquarters and Regional enforcement cases. Coordinates intra- and inter- agency case development efforts, and provides scientific and technical support to Headquarters, the Regions and the States for investigations and case development efforts. Manages contracts for inspection support and sample analysis, develops or revises reference manuals, publishes FIFRA Notices of Judgement.

OFFICE OF COMPLIANCE MONITORING

POLICY AND GRANTS DIVISION (P&GD)

JOHN J. NEYLAND III, Director (703) 308-8383 and (202) 260-7825

PESTICIDES ENFORCEMENT POLICY BRANCH (PEPB)
PHYLLIS FLAHERTY, Chief (703) 308-8383

Develops Headquarters and Regional compliance monitoring policies, strategies and priorities relating to FIFRA and OAPCA. Develops regulations, federal enforcement response policies, and strategies in support of FIFRA and OAPCA. Members of the branch serve as OCM representatives on FIFRA regulatory workgroups, and serve as expert witnesses during hearings.

See Section E. 1. PESTICIDES ENFORCEMENT POLICY BRANCH below for a listing of the types of functions within the area of responsibility of each staff person.

GRANTS AND EVALUATION BRANCH (G&EB)
LINDA FLICK, Acting Chief (202) 260-7841

Responsible for developing, reviewing and revising policy and procedures for FIFRA and TSCA state cooperative enforcement agreement programs. Assists the regions in implementing and managing state cooperative enforcement agreement programs and develops procedures for information flow.

See Section E. 2. GRANTS AND EVALUATION BRANCH below for a listing of the types of functions within the area of responsibility of each staff person.

TOXICS ENFORCEMENT POLICY BRANCH (TEPB)
JANET BEARDEN, Chief (202) 260-7832

Develops compliance monitoring and strategies, proposed legislation and regulations, and guidance to the states and the regions concerning the national toxic substances, AHERA and EPCRA compliance programs. Provides OCM policy input for agency-wide enforcement special projects and the four-year strategic plan.

See Section E. 3. TOXICS ENFORCEMENT POLICY BRANCH below for a listing of the types of functions within the area of responsibility of each staff person.

OFFICE OF COMPLIANCE MONITORING

LABORATORY DATA INTEGRITY ASSURANCE DIVISION (LDIAD)

DAVID L. DULL, Director (703) 308-8300
FRANCIS LIEM, Special Assistant to Division Director (703) 308-8265
ROBIN NOGLE, International Activities liaison (703) 308-8269

SCIENTIFIC SUPPORT BRANCH (SSB)

FRANCES LIEM, Acting Chief (703) 308-8333

Responsible for the detailed planning of all national and international inspections and data audits, both regularly scheduled and priority. Provides liaison with the Food and Drug Administration (FDA) field investigators to coordinate joint inspections and audits, and prepares training programs and manuals for inspection and audit activities.

DAWN BANKS (703) 308-8251
Biology

ASHUTOSH DIWAN (703) 308-8257
Biology

CLINTON FLETCHER (703) 308-8261
Chemistry

ELMER GRIFFIN (703) 308-8263
Chemistry

JOHN McCANN (703) 308-8266
Ecotoxicology

BRENDA F. MOSLEY (703) 308-8268
Chemistry

FREDERICK SIEGELMAN (703) 308-8272
Chemistry

EVA ZUREK (703) 308-8279
Mammalian Toxicology/Histopathology

The Scientific Support Branch employees listed above conduct Good Laboratory Practice (GLP) compliance inspections of laboratories and other test facilities and performs data audits in the disciplines indicated above.

PROGRAM SUPPORT AND COMPLIANCE REFERRAL BRANCH (PS&CRB)

ROBERT ZISA, Chief (703) 308-8400

Provides operational and information management support for LDIAD'a GLP inspection and FIFRA/TSCA testing requirement compliance programs. Supports the GLP inspection program by targeting laboratories for inspection through Neutral Administrative Inspection Scheme (NAIS) selection procedures, identifying relevant FIFRA and TSCA studies to audit, and participating in the review of inspection/data audit reports for compliance. Operates the Laboratory Inspection and Study Audit (LISA) computer system in support of these activities. Supports the FIFRA/TSCA testing requirement program by monitoring documentation submitted by registrants, chemical manufacturers, and laboratories for compliance with FIFRA and TSCA testing requirements. This includes monitoring compliance with FIFRA '88 product reregistration requirements, issuing Notices of Intent to Suspend (NOITS) for pesticide product registrations, and working with OPP and OGC to settle NOITS actions. PSCRB operates the Pesticide Registration Enforcement System (PRES) data base in support of of these activities.

See Section F. 1. PROGRAM SUPPORT AND COMPLIANCE REFERRAL BRANCH below for a listing of the types of functions within the area of responsibility of each staff person.

OFFICE OF COMPLIANCE MONITORING

COMPLIANCE DIVISION (CD)

MICHAEL F. WOOD, Director (703) 260-7835

COMPLIANCE BRANCH (CB)

MAUREEN T. LYDON, Chief (202) 260-5567

Develops national compliance monitoring procedures, inspection guidance, and targeting lists to help ensure compliance with FIFRA, TSCA, EPCRA, AHERA, OAPCA, and associated specific regulatory actions. Issues investigation Requests, and coordinates with the Regions on compliance monitoring activities initiated from the HQ level, as well as follow-up to GAO/IG audits. Working with the Regions, the Branch collects/analyzes national enforcement data for the aforementioned statutes by developing/using national automated data processing (ADP) systems. Develops STARS measures and coordinates STARS input at the national level for OPTS enforcement activities. Serves as the liaison with the Office of Criminal Investigations and the national program coordinator for TSCA enforcement AARP grants, and coordinates national toxics enforcement conferences. The Compliance Branch includes the OCM document control officer, the OCM Coordinator for Regional reviews, and the office coordinator for enforcement/certified statement requests.

See Section G. 1. COMPLIANCE BRANCH below for a listing of the types of functions within the area of responsibility of each staff person.

CASE SUPPORT BRANCH (CSB)

GERALD STUBBS, Chief (202) 260-7861

Provides case development support in relation to the enforcement of TSCA, FIFRA, and EPCRA. Responsible for promulgating guidelines, administrative rules or case preparation procedures for enforcement cases, providing Regional coordination for case development purposes, coordinating intra- and inter-agency case development efforts, providing scientific and technical support to Headquarters, the Regions and the states for case development purposes, and providing Headquarters concurrence on enforcement cases. Makes revisions to the Case Proceedings Manual, Publishes Notices of Judgement, and updates publication of the Suspended, Canceled and Restricted Pesticide List (SAC List) under FIFRA.

See Section G. 2. CASE SUPPORT BRANCH below for a listing of the types of functions within the area of responsibility of each staff person.

D. REGISTRATION DIVISION, WASHINGTON D.C.

1. INSECTICIDE - RODENTICIDE BRANCH

BRANCH CHIEF - Herbert S. Harrison (703) 305-5200
DEPUTY BRANCH CHIEF - Harvey Warnick (703) 305-5200

The various Product Manager Teams that are responsible for certain types of products are indicated below.

PRODUCT MANAGER 10 - Dick Mountfort (703) 305-6502

TYPE OF PRODUCTS: Pyrethrins, Insect Repellents, Certain Synthetic Pyrethroids (including Resmethrin, Allethrin, Tetramethrin, d-Phenothrin

PRODUCT MANAGER 13 - George LaRocca (703) 305-6100

TYPE OF PRODUCTS: Chlorinated Organic Insecticides, Drug/Pesticide Combinations, Dichlorvos, Endosulfan, Fenthion, Fensulfothion, Disulfoton, Second Generation Pyrethroids (i.e., Permethrin and Cypermethrin)

PRODUCT MANAGER 14 - Rob Forrest (703) 305-6600

TYPE OF PRODUCTS: Most Organo-Phosphorus products i.e., malathion, dimethoate, except those listed with PMs 13 and 19, Boric Acid, Vertebrate Pesticides, Animal and Bird Repellents

PRODUCT MANAGER 18 - Phil Hutton (703) 305-7690

TYPE OF PRODUCTS: Microbials, Biologicals, Insect Growth Regulators, Most Botanicals

PRODUCT MANAGER 19 - Dennis Edwards (703) 305-6386

TYPE OF PRODUCTS: Carbamates, Miticides, Toxaphene, Carbaryl, Chlorpyrifos, Parathion, Azinphos-methyl

2. FUNGICIDE - HERBICIDE BRANCH

BRANCH CHIEF - Frank Sanders (703) 305-6250
DEPUTY BRANCH CHIEF - Thomas Adamczyk (703) 305-6250

The various Product Manager Teams and their area of responsibility are listed below.

PRODUCT MANAGER 21 - Susan Lewis (703) 305-6900

TYPE OF PRODUCTS: Fungicides, Nematicides, Wood Preservatives, Microbials

PRODUCT MANAGER 22 - Cynthia Giles-Parker (703) 305-5540

TYPE OF PRODUCTS: Fungicides, Herbicides which include Arsenicals, Copper, and some Plant Growth Regulators

PRODUCT MANAGER 23 - Joanne Miller (703) 305-7830

TYPE OF PRODUCTS: Herbicides: Phenoxys, Aquatics

PRODUCT MANAGER 25 - Robert Taylor (703) 305-6800

TYPE OF PRODUCTS: Herbicides, Plant Growth Regulators (shared with PM Team 22), Desiccants, Defoliants

3. ANTIMICROBIAL PROGRAM BRANCH

The Antimicrobial Program Branch is responsible for the registration activities of pesticides used as hospital sterilants, disinfectants, water treatment products, anti-fouling paints, swimming pool chemicals, and fumigants.

BRANCH CHIEF - Juanita Wills (703) 305-6661

DEPUTY BRANCH CHIEF - Walter C. Francis (703) 305-6661

PRODUCT MANAGER 31 - John H. Lee (703) 305-5676

TYPE OF PRODUCTS - Anti-fouling Paints, Quaternary Ammonium and Water Treatment Compounds, Hospital Sterilants

PRODUCT MANAGER 32 - Ruth G. Douglas (703) 305-7964

TYPE OF PRODUCTS - Hypochorites, Halides, Chlorophenolics, Swimming Pool Chemicals, Fumigants

4. **REGISTRATION SUPPORT BRANCH** **(These telephone numbers will change)**[1]

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, and registration cancellation requests, and front-end application processing.

BRANCH CHIEF - Donald R. Stubbs (703) 305-7700
DEPUTY BRANCH CHIEF - James Tompkins (703) 305-7700

FRONT END PROCESSING STAFF

STAFF LEADER - Edith Minor (703-305-6978)

AREA OF RESPONSIBILITY: Front-end applications processing. 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) 305-7783

AREA OF RESPONSIBILITY: Precautionary labeling (acute toxicity) reviews.

PRODUCT CHEMISTRY REVIEW SECTION

SECTION HEAD - Donald R. Stubbs (Acting) (703) 305-7700

AREA OF RESPONSIBILITY: Review of product chemistry data.

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[1] In late summer or early fall of 1992 all members of the Registration Support Branch (RSB) will move to Crystal Station Building 1 (CS-1) and their telephone numbers and room numbers will change from those listed in this manual. However, you can continue to call their old telephone number for a period of time after the move occurs and you will be given the new telephone number. Otherwise, you may call the EPA's Directory Assistance/Personnel Locator number (202) 260-2090.

EMERGENCY RESPONSE AND MINOR USE SECTION (These telephone numbers will change)[2]

SECTION HEAD - Rebecca S. Cool (703) 305-5806

AREA OF RESPONSIBILITY: Emergency Exemptions (Section 18's) and Minor Use (IR-4) petitions.

PROJECT COORDINATION SECTION

SECTION HEAD - Tina Levine (703) 305-5179

AREA OF RESPONSIBILITY: Inert clearance requests, 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 - Donald R. Stubbs, Acting (703) 305-7700

AREA OF RESPONSIBILITY: Product registration transfers, cancellation requests, program status and reporting, and ADP processing.

E. OFFICE OF COMPLIANCE MONITORING: POLICY AND GRANT DIVISION

1. PESTICIDE ENFORCEMENT POLICY BRANCH

BRANCH CHIEF - Phyllis Flaherty (703) 308-8383

The types of functions within the area of responsibility of each staff person are indicated below:

DAN HELFGOTT (703) 308-8288

FUNCTIONS: FIFRA Section 6(g) Policy; FIFRA ERP; Labeling, including State-Labeling Issues Committee; Existing Stocks.

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[2] In late summer or early fall of 1992 all members of the Registration Support Branch (RSB) will move to Crystal Station Building 1 (CS-1) and their telephone numbers and room numbers will change from those listed in this manual. However, you can continue to call their old telephone number for a period of time after the move occurs and you will be given the new telephone number. Otherwise, you may call the EPA's Directory Assistance/Personnel Locator number (202) 260-2090.

STEPHEN HOWIE (703) 308-8290

FUNCTIONS: Export and Biotechnology; Policy Support for Record Keeping Regulations and GLP Standards.

VIRGINIA LATHROP (703) 308-8292

FUNCTIONS: Pesticides and Groundwater Coordination; Revised Policy Compendia (5 Volumes); Contract Coordinator; Generic Compliance Monitoring Strategy for Cancellations/Suspensions; FIFRA section 6(g) Outreach Plan; FIFRA Policy Search System.

GINAH MORTENSEN (703) 308-8293

FUNCTIONS: Worker Protection Standards; Endangered Species.

DAVID STANGEL (703) 308-8295

FUNCTIONS: FIFRa section 19/Disposal; Section 19(d)(4)/Primacy; Worker Protection Regulation; Communication Strategies; State Labeling Improvement Committee; FIFRA: Contract Manufacturing and Custom Blending; FIFRA section 6(g) Policy; Special Review Chemical.

BEVERLY UPDIKE (703) 308-8296

FUNCTIONS: Develop Compliance Strategies for FIFRA Enforcement of Maintenance Fee Cancellations; Special Review Chemical; Advertising.

2. GRANTS AND EVALUATION BRANCH

BRANCH CHIEF - Linda Flick (Acting) (202) 260-7841

The types of functions within the area of responsibility of each staff person are indicated below:

LORILYN McKAY (202) 260-6733

FUNCTIONS: Regional Liaison: VII, & IX; Asbestos and Multi-Media Branch Lead; Groundwater Branch Lead; TSCA Enforcement Decentralization Branch Lead; Co-lead on State Pesticide Lab Issues.

CURTIS FOX (202) 475-8318

FUNCTIONS: Regional Liaison: IV, VIII, & X; FOSTTA Work Coordinator; QUIPE (Pesticides Inspector Newsletter) Editor; Worker Protection Branch Lead.

SUSAN KAVANAUGH (202) 475-7008

FUNCTIONS: FIFRA '88; Regional Liaison: I & III; PCB Branch Lead; Lawn Care Initiative Lead; OCM Tribal Contact.

MARY ELLEN PODNIESNISKI (202) 382-7422

FUNCTIONS: Regional Liaison: II, V, & VI; EPCRA Branch Lead; Endangered Species Protection Program; Hexavalent Chromium; Enforcement Special Projects; Pesticide Grant Allotments; Branch Lead on State Pesticide Lab Issue; Branch Lead for Pesticide Project Officer Oversight Manual.

3. TOXICS ENFORCEMENT POLICY BRANCH

BRANCH CHIEF - Janet Bearden (202) 260-7832

The types of functions within the area of responsibility of each staff person are indicated below:

KENNETH O'REILLY (202) 260-6747

FUNCTIONS: Asbestos Ban and Phase Out Rule; EPA Asbestos Worker Protection Rule; TSCA Good Laboratory Practices; TSCA Section 4 and Section 21; Asbestos in Public and Commercial Buildings.

SALLY SASNETT (202) 260-1376

FUNCTIONS: Biotechnology (TSCA); AHERA; Pollution Prevention (ITP); Geographic TSCA; New Chemical Exposure Limits.

CARY SECREST (202) 260-8660

FUNCTIONS: PCBs; Manager, Ability to Pay Study; OCM Representative, PCB Steering Committee; Dioxin in Sludge.

BRIDGET SULLIVAN (202) 260-8418

FUNCTIONS: EPCRA Section 313; TSCA Section 5 and Section 8; Hazardous Communications Rule; Lead Acid Batteries; Pollution Prevention Act.

PETER PAGANO (202) 260-4889

FUNCTIONS: Hexavalent Chromium; Lead in Solder, Lead in Brass Fittings; Clean Air Act Amendments; Acrylamide; TSCA Export/Import.

F. OFFICE OF COMPLIANCE MONITORING: LABORATORY DATA INTEGRITY ASSURANCE DIVISION

1. PROGRAM SUPPORT AND COMPLIANCE REFERRAL BRANCH

BRANCH CHIEF - Robert Zisa (703) 308-8400

The types of functions within the area of responsibility of each staff person are indicated below:

RAY BROWN (703) 308-8252

FUNCTIONS: Post-GLP Inspection/Data Audit Monitoring; Review of GLP Inspection Reports; Requests to OPP/OPPT for Regulatory Review of Audited Studies; Response to FOIA Requests.

STEPHEN BROZENA (703) 308-8267

FUNCTIONS: FIFRA '88 Pesticide Reregistration Compliance Program; Issuance of Notice of Intent to Suspend (NOITS) Actions for Non-Compliance with Pesticide Testing Requirements; Liaison with OGC and OPP for Settlement of NOITS Actions; Assistance with GLP Inspection/Data Audit Targeting.

CAROL BUCKINGHAM (703) 308-8254

FUNCTIONS: Assistance with FIFRA '88 Registration Compliance Program; Operation of LDIAD Computer Tracking Systems; Response to FOIA Requests.]

DORIS DYSON (703) 308-8260

FUNCTIONS: Computer Contract Administration; Systems Support.

YVETTE HELLYER (703) 308-8256

FUNCTIONS: Pre-GLP Inspection/data Audit Activities; GLP Inspection/data Audit Targeting; OPPT Chemical Testing Monitoring; Memoranda of Understanding (MOU) with Foreign Governments for GLP Programs. FDA Liaison for GLP Inspection/ data audit Program.

FRANKLIN SMITH (703) 308-8273

FUNCTIONS: ADP Systems Support; ADP Extramural Budget Management; Computer Contract Administration; Local Area Network (LAN) Administration.

G. OFFICE OF COMPLIANCE MONITORING: COMPLIANCE DIVISION

1. COMPLIANCE BRANCH

BRANCH CHIEF - Maureen T. Lydon (202) 260-5567

The types of functions within the area of responsibility of each staff person are indicated below:

MIKE CALHOUN (202) 260-3375

FUNCTIONS: Team Leader for PCBs and Pesticides; PCB General Information and PCB Natural Gas Pipelines; Pesticides General Information and Pesticide Exports; OCM Criminal Liaison.

ANN CLAVIN (202) 260-9438

FUNCTIONS: Mercury in Paints; PCB Co-lead; Hexavalent Chromium Rule; Enforcement Requests.

KENNETH GUTTERMAN (202) 260-6902

FUNCTIONS: FOIA Coordinator, Credentials Officer, Regional Review and National Meeting Coordinator, Inspection Forms Coordinator, Inspection Manual Custodian.

RICHARD KRATOFIL (202) 382-3487

FUNCTIONS: FIFRA Section 7 Foreign Establishment Registration and Product Distribution; FIFRA DCO.

TERESA LITTLE (202) 260-4985

FUNCTIONS: Asbestos (AHERA) Regional Coordinator, AHERA Compliance Monitoring; OCM TSCA Document Control Officer.

JOHN MASON (202) 260-2301

FUNCTIONS: FIFRA Related Activities such as Canceled and Suspended Products and Initiatives (e.g., Dinoseb, Lawn Care, Malathion); Section 6(g) Compliance; Foreign Purchaser Acknowledgement Statements tracking; Deliver, Order, Project Officer.

DAVID MEREDITH (202) 260-7864

FUNCTIONS: Project Manager for the National Compliance Database, FIFRA/TSCA Tracking System, and the EPCRA Targeting System; OCM Coordinator for Strategically Targeted Activities for Results System (STARS); Project Officer for CSC Contract Support to FTTS and SSTS in Regional Offices, ADP Issues.

PHILIP MILTON (202) 260-8598

FUNCTIONS: TSCA Sections 4,5,8,12 and 13 Regional Coordinator; Hexavalent Chromium Rule; Asbestos Ban and Phase out Rule; OCM Enforcement Coordinator.

PAMELA SAUNDERS (202) 260-1809

FUNCTIONS: Inspector Training; Contract Management/extramural Funding Support; FIFRA Section 7 Tracking System Manager; Pesticide Export (USDA/FDA issues); AHERA AARP Inspectors Grants; Canadian Liaison Issues; Project Officer for General Programming Support Contract (PRC).

AMAR SINGH (202) 260-3868

FUNCTIONS: FIFRA General, including: Worker Protection Standards, Endangered Species, Groundwater, Disinfectants.

JULIE VANDENBOSCH (202) 260-9335

FUNCTIONS: EPCRA Compliance Monitoring; EPCRA Regional Coordinator - all regions; Investigation Requests under EPCRA; EPCRA AARP Grants for Inspectors.

2. CASE SUPPORT BRANCH

BRANCH CHIEF - Gerald Stubbs (202) 260-7861

The types of functions within the area of responsibility of each staff person are indicated below:

ROSE BURGESS (202) 260-4328

FUNCTIONS: TSCA Section 5/8 Case Development; Region IV Coordinator; FIFRA Section 8 - Books and Records.

CINDY COLDIRON (202) 382-3801

FUNCTIONS: Program Attorney - Advisor; General TSCA Issues (Section 5 PMN, Section 8 NOC, Self Confessors); FIFRA Section 3 Registration (3(c)(2)(B)); Region V Coordinator; FIFRA - Water Purifiers; TSCA Section 5/8 Case Development; TSCA and FIFRA GLP Case Review/Enforcement; Multi-media Issues.

BETH CROWLEY (202) 260-8464

FUNCTIONS: TSCA Section 5/8 Development; Region II Coordinator; PCB Issues; Contract Issues.

BRIAN DYER (202) 260-3477

FUNCTIONS: FIFRA Devices; FIFRA NOJ; TSCA Section 8(c) and 8(d); FTTS Case Tracking; TSCA Section 5/8 Case Development; Region VII Coordinator.

H. ABBREVIATED HEADQUARTERS FACSIMILE DIRECTORY

Many of the program offices at EPA Headquarters have purchased facsimile machines and fax users can now send urgent information directly to the program office. Priority letters, drawings, charts, forms, labels, and photographs are particularly appropriate for facsimile communications. However, you are requested to limit your transmission of information to 12 pages or less in order to prevent the facsimile machine from being tied up for long periods of time by a single user. Documents containing more than 12 pages should be sent to the Agency by express mail. For best results use only black ink on white paper.

IMPORTANT NOTE: Confidential Business Information (CBI), i.e., Confidential Statement Formula (CSF) should not be transmitted over the facsimile machine unless the sender wants to clearly waive his or her CBI rights and states this on the CSF.

If the FAX Number for the office to which you wish to send information is not listed below, please call the intended recipient of your document to obtain the appropriate transmission number.

PROGRAM OFFICE	FAX NUMBER
Office of Pesticide Programs	(703) 305-6244
Registration Division	(703) 305-6920
Antimicrobial Program Branch	(703) 305-5786

Fungicide- Herbicide Product Branch	(703) 308-1825
Insecticide-Rodenticide Branch	(703) 305-6596
Registration Support Branch	(703) 308-1848
Special Review and Reregistration Division	(703) 308-8773
Program Management and Support Division	
Information Services Branch	(703) 305-7670
Office of Pollution, Prevention and Toxics	(202) 260-0575
Office of Compliance Monitoring (Immediate Office)	(202) 260-1474
Compliance Division	(202) 260-0646
Policy and Grants Division	(202) 260-0641
Pesticide Enforcement Policy Branch	(703) 308-8218
Laboratory Data Integrity Assurance Division	(703) 308-8285
Program Support and Compliance Referral Branch	(703) 308-8286
Office of General Counsel	
Pesticides and Toxic Substances Division	(202) 260-2432
Science Advisory Board	(202) 260-9232
Office of Administrative Law Judges	(202) 260-3720
Office of Ground Water and Drinking Water	(202) 260-4383
Emergency and Remedial Responses (SUPERFUND)	(202) 260-4386
Associate Administrator for Communication, Education and Public Affairs	
Press Relations Division	(202) 260-4309

I. 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) 565-3420

REGION 2

Jurisdiction: New Jersey, New York, Puerto Rico, Virgin Islands

Environmental Protection Agency
26 Federal Plaza
New York, NY 10278
(212) 264-2657

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) 353-2000

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) 551-7000

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) 744-1305

REGION 10

Jurisdiction: Alaska, Idaho, Oregon, Washington

Environmental Protection Agency
1200 Sixth Avenue
Seattle, WA 98101
(206) 442-1200

H. 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) 242-2631
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 Governor Pago, American Samoa 96799
Arizona	State Chemist Office of State Chemist P.O. Box 1586 Mesa, AZ 85211-1586 (602) 542-3579
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) 322-6315
Colorado	Chief, Pesticide Applicator Section Division of Plant Industry Colorado Dept. of Agriculture 4th Floor, 1525 Sherman Street Denver, CO 80203 (303) 239-4140
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) 739-4811
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) 404-1167
Florida	Administrator Pesticide Registration Section Bureau of Pesticides Division of Inspection Florida Dept. of Agric. & Consumer Services 3125 Doyle Conner Blvd. Tallahassee, FL 32399-1650 (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) 548-7119
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) 782-3817
Indiana	Pesticide Compliance Officer Indiana State Chemist Office Dept. of Biochemistry Purdue University West Lafayette, IN 47907 (317) 494-1492
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) 841-5710

Massachusetts	Manager, Technical Assessment Sect. Pesticides Bureau Maine Dept. of Food and Agriculture 100 Cambridge Street, 21st Floor Boston, MA 02202 (617) 727-3020
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) 296-1161
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) 471-2394
Nevada	Director, Division of Plant Industry Nevada Dept. of Agriculture P.O. Box 11100 Reno, NV 89510-1100 (702) 688-1180

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) 530-4123
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

GLOSSARY OF SELECTED TERMS, ABBREVIATIONS AND ACRONYMS USED IN THE OFFICE OF PESTICIDE PROGRAMS

AA - Assistant Administrator

AAPCO - Association of American Pesticide Control Officials. An association of state pesticide regulatory officials dedicated to the effective enforcement of laws and implementation of programs that relate to proper and safe use of pesticide chemicals.

ACB - The Analytical Chemistry Branch (ACB) within the Biological and Economic Analytical Division (BEAD) of the Office of Pesticide Programs (OPP). ACB provides analytical and environmental chemistry services in support of pesticide registration, special review, and tolerance petition programs. ACB also provides support to the Office of General Counsel, the EPA Regional Enforcement Program, and the National Ground Water Monitoring Program. There are two laboratories in this branch, one in Beltsville, Maryland and one in Bay St. Louis, Mississippi.

ACCELERATED REREGISTRATION BRANCH - The Accelerated Reregistration Branch (ARB) within the Special Review and Reregistration Division (SRRD) of the Office of Pesticide Programs (OPP) is responsible for the reregistration activities of List B, C, And D Chemicals. ARB staff manage data requirements, issue Data Call-In Notices, process industry's data and requests, and coordinate internal reregistration eligibility decisions.

ACCEPTABLE DAILY INTAKE - ADI. A now defunct term for reference dose.

ACCESSION NUMBER - An identification number that used to be assigned (for cataloging purposes) to physical volumes of studies submitted to the Office of Pesticide Programs; this numbering system has been replaced by the Master Record Identification (MRID) system, which identifies each individual study.

ACTIVE INGREDIENT - In any pesticide product, the active ingredient is the component which kills, or other wise controls, the target pests and includes any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA section 2(a). Pesticides are regulated primarily on the basis of active ingredients. Abbreviated AI.

ACUTE TOXICITY - The ability of a substance to cause poisonous effects resulting in harm or death soon after exposure. Acute toxicity is established through scientifically verifiable data from animal or human exposure tests. Values are usually expressed as LD_{50} or LC_{50} and mg/kg. Acute toxicity studies include oral, dermal, and inhalation studies.

ADI - See Acceptable Daily Intake.

ADDRESS OF RECORD - The applicant's or registrant's United States address for correspondence purposes. It is the address to which the Agency will send certain notices (i.e., those imposing legal requirements) concerning the application and any subsequent registration information. It is the responsibility of the applicant or registrant to ensure that the Agency has a current and accurate address.

ADJUVANT - A subsidiary ingredient or additive in a mixture which contributes to the effectiveness of the primary ingredient. Adjuvants are added to pesticides use dilutions in tank mixes by growers or applicators prior to application to the crop to be treated. Agricultural chemical adjuvants are grouped according to their intended purpose in the tank mix and include but are not limited to the following groups: acidifying agents, buffering agents, anti-foam agents, defoaming agents, anti-transpirants, color adjuvants, dyes, brighteners, compatibility agents, crop oil concentrates, oil surfactants, deposition agents, drift reduction agents, foam markers, gustatory stimulants, feeding stimulants, herbicide safeners, spreaders, extenders, adhesive agents, suspension agents, gelling agents, synergists, tank and equipment cleaners, neutralizers, water absorbants, and water softeners. Adjuvants intended for pesticidal use in tank mixes are required to be cleared under the Federal Food, Drug and Cosmetic Act prior to being used. Adjuvants intended for non-pesticidal uses are to be cleared with the FDA prior to being used.

ADMINISTRATIVE PORTION OF APPLICATION FOR REGISTRATION - That portion of the Application Package comprised of the administrative paperwork, i.e., the Application for Registration/Amendment (EPA Form 8570-1); the Confidential Statement of Formula (EPA Form 8570-4); the Certification with Respect to Citation of Data (EPA Form 8570-29); the Formulator's Exemption Statement (EPA Form 8570-27); the Draft Labeling; the Statement identifying the "substantially similar" or "identical" product (if a "me-too" amendment); and the Data Matrix Chart (if the selective method of support is used). The administrative documents are <u>not</u> to be bound together.

ADMINISTRATOR - The Administrator of the United States Environmental Protection Agency or his/her delegate.

AGENCY - The United States Environmental Protection Agency (EPA), unless otherwise specified.

AI - See Active ingredient.

ANALYTICAL CHEMISTRY BRANCH - See ACB.

AOAC - Association of Official Analytical Chemists.

APPLICANT - A pesticide chemical company or person who intends to or has applied to the Agency (Office of Pesticide Programs, Registration Division) for a registration, amended registration, or reregistration for registration of a pesticide product, under FIFRA section 3.

ARB - See Accelerated Reregistration Branch.

ASTHO - Association of State and Territorial Health Officials.

ASSOCIATION OF AMERICAN PESTICIDE CONTROL OFFICIALS - See AAPCO.

ASSOCIATION OF OFFICIAL ANALYTICAL CHEMISTS - See AOAC.

AUTHORIZED AGENT - A person residing in the United States who is designated by an applicant or registrant to act as their agent in matters pertaining to pesticide registration.

BAB - The Biological Analysis Branch (BAB) within the Biological and Economic Analysis Division (BEAD) of the Office of Pesticide Programs (OPP). BAB is responsible for the preparation of use-data software programs for exposure assessments, qualitative use assessments, and biological analyses of pesticides.
Bilingual labeling.

BEAD - The Biological and Economic Analysis Division (BEAD) is one of the seven Divisions that constitutes the Office of Pesticide Programs (OPP). BEAD conducts analyses on pesticide use and benefits; acquires, validates, and interprets technical data relative to pesticide use; conducts economic analyses on the impacts of regulatory options; and validates analytical chemistry methods. BEAD is comprised of the Planning and Evaluation Staff, and three branches: Biological Analysis Branch (BAB), Economic Analysis Branch (EAB), and Analytical Chemistry Branch (ACB).

BIOCHEMICAL PESTICIDES - Biochemical pesticides include, but are not limited to, products such as semiochemicals (e.g., insect pheromones), hormones (e.g., insect juvenile growth hormones), natural plant and insect growth regulators, and enzymes.

BIOLOGICAL ANALYSIS BRANCH - See BAB.

BIOLOGICAL AND ECONOMIC ANALYSIS DIVISION - See BEAD.

CB - The Communications Branch (CB) within the Field Operations Division (FOD) of the Office of Pesticide Programs (OPP) develops and operates programs that disseminate pesticide and OPP information to the public. CB also manages the OPP public docket (see docket file).

CB I - See Chemistry Branch I and II.

CB II - See Chemistry Branch I and II.

CBI - Confidential Business Information - material that contains trade secrets or commercial or fiancial information that been claimed as confidential by the submitter (usually the registrant). Procedures for handling CBI material can be found in the OPP and the OPTS CBI manuals. CBI material <u>should</u> <u>not</u> be sent over FAX machines unless the sender wants to clearly waive his or her CBI rights and so states on the CBI material being FAXed.

CERCLA - The Comprehensive, Environmental, Response, Compensation, and Liability Act (CERCLA). Commonly known as "Superfund," this statute includes provisions for the cleanup of existing hazardous waste sites and requires that releases of hazardous substances in quantities greater than established reportable quantities be reported to the National Response Center. Under CERCLA section 103, the application of a pesticide product registered under FIFRA is exempt from regulation. CERCLA in implemented by the Office of Solid Waste and Emergency Response, Office of Emergency and Remedial Response. Also see the Superfund Amendments and Reauthorization Act of 1986 (SARA).

CERTIFICATION AND TRAINING BRANCH - The Certification and Training Branch (CTB) within the Field Operation Division (FOD) of the Office of Pesticide Programs (OPP) is responsible for directing and implementing the Agency's regulatory and non-regulatory pesticide applicator training and certification activities under section 4 and section 23 of FIFRA. CTB also acts as OPP's liaison to state governments and tribal governments.

CFR - The Code of Federal Regulations. A codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. Regulations that pertain to EPA are at 40 CFR. Thus, 40 CFR 152.40 refers to title 40, part 152, section 40; the section on who may

apply for new registration of a pesticide product. Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
Title 28 through Title 41.....as of July 1
Title 42 through Title 50.....as of October 1

The appropriate revision date is printed on the cover of each volume.

CHEMICAL CASE - For purposes of review and regulation, individual active ingredients that are chemically similar (e.g., salts and esters of the same chemical) are grouped into chemical cases by the Agency.

CHEMICAL MANUFACTURERS ASSOCIATION - The Chemical Manufacturers Association (CMA).

CHEMICAL PESTICIDES - Synthetic or natural occurring chemicals that exhibit pesticidal properties and are formulated into products intended for preventing, destroying, repelling, or mitigating a pest, or intended for use as a plant regulator, defoliant, or desiccant.

CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION - The Chemical Producers and Distributors Association (CPDA).

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION - The Chemical Specialties Manufacturers Association (CSMA); was originally named the National Association of Insecticide and Disinfectant Manufacturers.

CHEMISTRY BRANCH I AND II - Chemistry Branch I (CB I) -- Tolerance Support and Chemistry Branch II (CB II) -- Reregistration Support are two branches within the Health Effects Division (HED) of the Office of Pesticide Programs (OPP) that were formerly known as the Dietary Exposure Branch (DEB). CB I and CB II evaluate analytical methods and residue, metabolism, and dietary exposure data. These analyses are used to estimate dietary exposure to pesticides and may lead to recommendations for or against proposed pesticide residue tolerances in food or feed, and reassessment of tolerances.

CHILD-RESISTANT PACKAGING - (CRP) - Packaging that is designed and constructed to be significantly difficult for young children to open. Registrants of pesticide products required to be in child-resistant packaging are required to certify to the Agency that the package meets the standards of 40 CFR 157.32.

CHRONIC TOXICITY - The capacity of a substance to cause long-term poisonous human health effects.

CITE-ALL METHODS OF SUPPORT - One of two methods by which an applicant for registration may comply with the data compensation requirements of FIFRA section 3(c)(1)(F). Under this method the applicant, where "exclusive use" data is involved, cites all pertinent data in the Agency's files only with the written permission of the exclusive use data submitter; where there is no exclusive use data involved, the applicant cites all pertinent data in the Agency's files with permission of the original data submitter or by offering to pay compensation for use of the data in accordance with FIFRA sections 3(c)(1)(F) and submits a general offer to pay statement to the Agency stating his or her offer and agreeing to pay compensation to other data submitters t the extent required by FIFRA section 3(c)(1)(F).

CMA - See Chemical Manufacturers Association.

CODE OF FEDERAL REGULATIONS - See CFR.

COLLATERAL LABELING - Collateral labeling must be submitted along with the application for registration and includes bulletins, leaflets, circulars, brochures, data sheets, flyers or other written, printed or graphic matter which is referred to on the label or which is to accompany the product.

COMMUNICATIONS BRANCH - See CB.

COMPREHENSIVE ENVIRONMENTAL, RESPONSE, COMPENSATION, AND LIABILITY ACT - See CERCLA.

CONFIDENTIAL BUSINESS INFORMATION - See CBI.

CONFIDENTIAL STATEMENT OF FORMULA - (CSF). A list showing the identity of the ingredients contained in a pesticide formulation. The list is submitted by a registrant or applicant, on the Confidential Statement of Formula form (EPA Form 8570-4), at the time of application for registration or change in formulation.

CORT STUDIES - The set of toxicology studies of chronic feeding, oncogenicity (which is now referred to as carcinogenicity), reproduction, and teratology. These studies are required for all food/feed use pesticides and one or more may also be required for nonfood/feed use pesticides.

CPDA - See Chemical Producers and Distributors Association.

CRP - See Child-Resistant Packaging.

CSF - See Confidential Statement of Formula.

CSMA - See Chemical Specialties Manufacturers Association.

CTB - See Certification and Training Branch.

DAA - Deputy Assistant Administrator.

DATA CALL-IN NOTICE - (DCI). As provided by FIFRA section 3(c)(2)(B), data call in is a notice/letter that is issued by the Reregistration Division and/or Registration Division to pesticide registrants requiring them to submit specific data or scientific studies to support the registration of a pesticide. Failure to submit this data can result in suspension of the registered products.

DATA GAP - The absence of any valid study or studies in the Agency's files which would satisfy a specific data requirement for a particular pesticide product.

DATA MATRIX CHART - A matrix chart showing all of the data required to support the application for registration. The applicant indicates on the matrix how he/she is satisfying the data requirements, i.e., by submitting the actual data or by referencing EPA's Master Record Identification (MRID) number. The Data Matrix Chart is required to be submitted only if the applicant elects to use the Selective Method of Support for his/her application.

DATA PORTION OF APPLICATION FOR REGISTRATION - The portion of the Application Package comprised of the actual data required to support your application for registration, i.e., product specific chemistry data, acute toxicity data, efficacy data, generic data (if the application is for a new use or a new active ingredient). Applicants are required to submit three copies of the data, properly bound and formatted in accordance with PR Notice 86-5.

DATA REVIEW RECORD - A form attached to material (e.g., data submitted by a registrant) transferred from one Office of Pesticide Programs (OPP) Division to another for review. The material is assigned a record number and a bar code which are used to track the material in the Pesticide Registration Action Tracking System (PRATS) (formerly the On-Line Tracking System (OLTS)).

DATA SUBMITTER'S LIST - The current Agency list, entitled Pesticide Data Submitters by Chemical," of persons who have submitted data to the Agency.

DCI - See Data Call-In Notice.

DEB - See Chemistry Branch I and II.

DESIGNATED U.S. AGENT - See Authorized Agent.

DEVICE - 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.

DIETARY EXPOSURE BRANCH - (DEB) - See Chemistry Branch I and II.

DIETARY RISK EVALUATION SYSTEM - The Dietary Risk Evaluation System (DRES) is a computerized tool for analyzing human dietary exposures to individual pesticides and comparing the exposures to known toxicity levels. The DRES is the responsibility of the Science Analysis and Coordination Branch (SACB) within the Health Effects Division (HED) of the Office of Pesticide Programs (OPP). DRES was formerly known as the Tolerance Assessment System (TAS).

DOCKET FILE - A file maintained in the public docket (Room 1128, Crystal Mall Building 2 (CM2), for the Office of Pesticide Programs (OPP)) for materials that pertain to Special Review and Reregistration of pesticides. Instructions for docketing can be found in 40 CFR 155. Materials in the docket are available for public inspection unless they are marked as confidential business information. It is the responsibility of the OPP product managers and review managers to submit materials to the docket.

DOMESTIC APPLICATION - Pesticide application in and around houses, office buildings, motels and other living or working areas; now termed residential use. See residential use.

DRES - See Dietary Risk Evaluation System.

EAB - The Economic Analysis Branch (EAB) within the Biological and Economic Analysis Division (BEAD) provides economic analyses for EPA's pesticide regulatory program, including analyses of economic impacts of pesticide regulatory policies and of individual program actions under the various sections of FIFRA.

EC - An Emulsifiable Concentrate (EC) is a type of pesticide formulation that contains the active ingredient, one or more petroleum solvents, and an emulsifier that allows the formulation to be mixed with water. The strength of this concentrate usually is stated in pounds of active ingredient per gallon of concentrate.

ECOLOGICAL EFFECTS BRANCH - The Ecological Effects Branch (EEB) within the Environmental Fate and Effects Division (EFED) of the Office of Pesticide Programs (OPP) is responsible for assessing pesticide effects on non-target species including fish, birds, small mammals, beneficial insects, and plants.

ECONOMIC ANALYSIS BRANCH - See EAB.

EDF - The Environmental Defense Fund (EDF).

EEB - See Ecological Effects Branch.

EEC - Estimated Environmental Concentration. An estimate of the concentration of a pesticide occurring in or on various media (i.e., soil, water, air) aftr pesticide application, as determined from the results of environmental fate or environmental expression testing.

EFED - The Environmental Fate and Effects Division (EFED) is one of seven Divisions that constitutes the Office of Pesticide Programs (OPP) and is responsible for assessment of pesticide effects on non-target animal and plant species in the natural environment and groundwater. EFED is made up of the Science Analysis and Coordination Staff (SACS), the Ecological Effects Branch (EEB), and the Environmental Fate and Groundwater Branch (EFGWB). This Division was created by the OPP reorganization of July 1988 when the Hazard Evaluation Division was split into the Environmental Fate and Effects Division (EFED) and the Health Effects Division (HED).

EFFICACY DATA - Data showing that the pesticide is effective in controlling the pests for which control claims are made on the product label.

EFGWB - The Environmental Fate and Groundwater Branch (EFGWB) within the Environmental Fate and Effects Division (EFED) of the Office of Pesticide Programs reviews and evaluates data on : pesticide fate and transport; aspects of pesticide leachability; and ground water effects. EFGWB also manages and coordinates human and environmental monitoring activities in support of the pesticide regulatory program.

ELI - The Environmental Law Institute (ELI) conducts research on current developments in environmental law; publishes the "Environmental Reporter."

EMERGENCY EXEMPTION - A provision in FIFRA (Section 18) which permits the Administrator to exempt any Federal or State agency form any of the requirements of FIFRA if emergency conditions exist. The term "emergency conditions" is defined at 40 CFR 166.3(d). Pursuant to the provisions of FIFRA section 18, EPA has promulgated regulations at 40 CFR Part 166 under which EPA can grant an emergency exemption to a state or another federal agency that allows, subject to certain restrictions, the use for a limited period (usually one year) of a pesticide product that is not registered for that particular use.

EMERGENCY SUSPENSION - Suspension of registration under FIFRA section 6(c) due to an imminent hazard. See Suspension of Registration also.

EMULSIFIABLE CONCENTRATE - See EC.

EMULSIFIER - A chemical that aids in suspending one liquid in another, usually an organic chemical in an aqueous solution.

END-USE PRODUCT - EP - A pesticide product whose labeling bearing instructions for using or applying the product (as packaged and sold, or after dilution by the applicator) for controlling pests or regulating plant growth. The term excludes products with labeling wich allows663Xusef the product to formulate other pesticide products.

ENVIRONMENTAL DEFENSE FUND - See EDF.

ENVIRONMENTAL EXPRESSION - The extent and manner in which a microorganism establishes and maintains its presence in an ecological habitat.

ENVIRONMENTAL FATE DATA - Scientific data that characterize a pesticide's fate in the ecosystem, considering its degradation inducers (light, water, microbes), pathways, and resultant degradation products.

ENVIRONMENTAL FATE AND EFFECTS DIVISION - See EFED.

ENVIRONMENTAL FATE AND GROUNDWATER BRANCH - See EFGWB.

ENVIRONMENTAL LAW INSTITUTE - See ELI.

EP - See End-Use Product.

EPA - The Environmental Protection Agency.

EPA COMPENDIUM OF ACCEPTABLE USES - A list of federally registered pesticides with their uses and approved maximum acceptable application rates and other use restrictions; this outdated system was replaced by the use index. The use index has subsequently been replaced by LUIS. See LUIS.

EPA ENDANGERED SPECIES BULLETIN - A bulletin that contains lists of endangered species (including birds, fish, mammals, and plants) which may be exposed to a pesticide or pesticides in a given county. The bulletin also contains pesticide use information necessary to protect the species from exposure to pesticides.

ESTABLISHMENT REGISTRATION - The assignment of a registration number to a site where a pesticide or device is produced. The number is a two part hyphenated number referred to as an EPA Establishment Number. The first part of the number is series of numerals that identifies the company and the second part is a two letter code identifying the state or country in which the establishment is located. The establishment number is required to be on the product label.

ESTIMATED ENVIRONMENTAL CONCENTRATION - See EEC.

EUP - See Experimental Use Permits.

EXCLUSIVE USE DATA - Beginning September 30, 1978, 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, for a period of 10 years after the initial registration has been issued. In order for the Agency to consider such data in support of an applicant's application for registration or amendment, the applicant must obtain for each data submitter listed on the Data Submitters List, as an exclusive use data submitter, written authorization identifying the applicant as the applicant to whom authorization has been granted to allow the Agency to use all applicable data to satisfy the data requirements for the application in question.

EXPERIMENTAL USE PERMITS - EUP - A permit authorized under FIFRA, section 5, which is granted to applicants allowing them to conduct testing of a new proposed pesticide product and/or use outside of the laboratory and generally on 10 acres or more of land or water surface. EUPs are most commonly used for larger scale testing of efficacy and gathering of crop residue chemistry data. EUPs are processed by Product Manager (PM) Teams in the Office of Pesticide Programs' Registration Division Product Branches.

FACTA - Food, Agriculture, Conservation, and Trade Act of 1990.

FDA - The Food and Drug Administration. This agency is responsible for carrying out the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which includes pesticide tolerance enforcement. See FFDCA.

FEDERAL FOOD, DRUG, AND COSMETIC ACT - FFDCA - The Federal Food, Drug and Cosmetic Act. The law which regulates, among other things, the use of drugs (human and veterinary), chemicals in cosmetics, and human and animal foods; this includes the legal requirement of tolerances for pesticide residues (Sections 408 and 409) in or on food and feed items. These tolerances are established by EPA.

FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT - The Federal Insecticide, Fungicide And Rodenticide Act. The law which sets forth the regulation of the sale, distribution and use of pesticides in the United States.

FEDERAL RECORD CENTER - The Federal Records Center provides economical storage of and access to noncurrent records. The agency stores noncurrent, inactive, and permanent records at the Center.

FEDERAL REGISTER - (FR) A daily government publication where all federal regulatory actions, including proposed rules, final rules, and notices are published.

FEEDING STIMULANT - When Included in a pesticide formulation, feeding stimulants are treated as inert ingredients and are required to go through the same Agency clearance under FIFR2100Xand the FFDCA that inert ingredients are subject to. When feeding stimulants are added to a pesticide in a tank mix at a use site they do not require registration but are subject to the FFDCA.

FFDCA - See Federal Food, Drug, and Cosmetic Act.

FHB - The Fungicide-Herbicide Branch (FHB) within the Registration Division (RD) of the Office of Pesticide Programs (OPP) carries out regulatory responsibilities on herbicide and fungicide products. FHB is responsible for processing applications for registration, experimental-use permits, and petitions for tolerances for these classes of pesticides.

FIELD OPERATIONS DIVISION - The Field Operations Division (FOD) is one of seven Divisions that constitutes the Office of Pesticide Programs (OPP). It oversees implementation of OPP regulatory actions, directs pesticide applicator training and certification, and manages the public docket. Within FOD there are five branches: the Regional Operations Branch (ROB); the Public Response and Program Resources Branch (PRPRB); the Communications Branch (CB); the Occupational Safety Branch (OSB); and the Certification and Training Branch (CTB).

FIFRA - See Federal Insecticide, Fungicide and Rodenticide Act.

FIFRA SCIENTIFIC ADVISORY PANEL - The FIFRA Scientific Advisory Panel (SAP) is an independent group of scientists, authorized under FIFRA, to comment on notices of intent issued under FIFRA section 6 and final form regulations issued under FIFRA section 25(a). The SAP also comments, evaluates, and makes recommendations regarding the scientific analyses made by the Agency.

FIFRA SECTION 18 - See Emergency Exemption.

FIFRA SECTION 24(C) - (Special Local Need (SLN)) - Authorizes a state lead agency to register additional uses of federally registered pesticides. Special Local Needs (SLNs) may only be used in the registering state, but otherwise have full federal registration status. All SLNs must be submitted to EPA for review subsequent to registration by a state.

FINAL PRINTED LABELING - The label or labeling which will accompany the pesticide product when distributed or sold.

FLOWABLE - A formulation in which the active ingredients are finely ground insoluble solids mixed with a liquid as a suspension. Flowables are mixed with water for application.

FOD - See Field Operations Division.

FOIA - The Freedom of Information Act (FOIA); legislation that generally makes available to the public, documents possessed by the federal government.

FR - See Federal Register.

FREEDOM OF INFORMATION ACT - See FOIA.

FUNGICIDE-HERBICIDE BRANCH - See FHB.

GENETIC ENGINEERING - Directed transfer of permanent genetic information between species. This may include organisms that the Agency considers to be microbial pest control agents. Some higher plants have been "genetically engineered" to produce a pesticide or other compound not produced by the native plant.

GENERIC DATA - Generic Data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. Generic Data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. Any registrant who does not qualify for the formulator's exemption (FIFRA section 3(c)(2)(D) and 40 CFR 152.85) is required to submit generic data to support the his/her product registration.

GLP - Good Laboratory Practices (GLP) are standards established in 40 CFR 160 to assure the quality and integrity of data submitted by registrants. Provisions of the GLP standards include record keeping, personnel, and laboratory equipment requirements.

GOOD LABORATORY PRACTICE - See GLP.

GPO - U.S. Government Printing Office, 16-2

HEALTH EFFECTS DIVISION - The Health Effects Division (HED) is one of the seven Divisions that constitutes the Office of Pesticide Programs (OPP). It is responsible for assessment of pesticide effects on human health. This Division was created by the OPP reorganization of July 1988 when the Hazard Evaluation Division was split into the Environmental Fate and Effects Division (EFED) and the Health Effects Division (HED). HED is made up of six branches: the Science Analysis And Coordination Branch (SACB); the Toxicology -- Insecticide and Rodenticide Support Branch; Toxicology -- Herbicide, Fungicide, and Antimicrobial Support Branch; Chemistry Branch I -- Tolerance Support; Chemistry Branch II -- Reregistration Support; and the Occupational and Residential Exposure Branch (OREB).

HED - See Health Effects Division.

ICR - An Information Collection Request (ICR) is prepared pursuant to the requirements of the Paperwork Reduction Act (PRA) for rules, proposed rules, surveys, or other documents that contain information gathering requirements. The ICR is a description of what information is needed, why the information is needed, how it will be collected, and how much the information collection will cost. An ICR is submitted to OMB for approval.

IDS - Incident Data System. A computerized system, currently under development in the Information Services Branch of the Office of Pesticide Programs' Program Management Support Division, for receiving incident reports.

INCIDENT DATA SYSTEM - See IDS.

IMMINENT HAZARD - A situation that exists when the continued use of a pesticide during the time required for a cancellation proceeding would be likely to result in unreasonable adverse effects on humans or the environment or will involve unreasonable hazard to the survival of an endangered species.

INDEMNIFICATION - A provision of FIFRA section 15 that requires EPA to pay certain persons for the cost of stock on hand at the time a pesticide registration is suspended.

INERT INGREDIENT - Pesticide components such as solvents, carriers, and surfactants that are not active against target pests and includes any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

Inert ingredients in pesticide product formulations are regulated under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and the Federal Food, Drug, and Cosmetic Act (FFDCA).

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) 463-7549
Utah	Director, Division of Plant Industry Utah Dept. of Agriculture 350 North Redwood Road Salt Lake City, UT 84116 (801) 538-7180
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) 371-6558
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) 735-5062
West Virginia	Administrator Regulatory & Inspection Division W. Va. Dept. of Agriculture Charleston, WV 25305 (304) 348-2209
Wisconsin	Certification & Licensing Wisconsin Dept. of Agriculture, Trade & Consumer Protection P.O. Box 8911 Madison, WI 53708 (608) 266-7131

Wyoming

Manager, Technical Services
Wyoming Dept. of Agriculture
2219 Carey Avenue
Cheyenne, WY 82002-0100
(307) 777-6590

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THE END

INFORMATION COLLECTION REQUEST - See ICR.

INFORMATION SERVICES BRANCH - The Information Services Branch (ISB) within the Program Management and Support Division (PMSD) of the Office of Pesticide Programs (OPP) provides inomation management support to the OPP regulatory program. These services include assessing information needs, directing the OPP security program, and maintaining liaison with information contacts and organizations outside OPP.

INSECTICIDE-RODENTICIDE BRANCH - The Insecticide-Rodenticide Branch (IRB) within the Registration Division (RD) of the Office of Pesticide Programs is responsible for processing applications for registration, experimental-use permits, and petitions for tolerances for pesticides in these use classes.

INSTITUTIONAL USE - Any application of a pesticide in or around any property or facility that functions to provide a service to the general public or to public or private organizations, including but not limited to hospitals and nursing homes; schools other than preschools and day care facilities; museums and libraries; sports facilities; and office buildings.

INTEGRATED PEST MANAGEMENT - Integrated Pest Management (IPM) is the concept and practice of using a variety of methods (cultural, pesticidal, biological, etc.) to control pests.

INTERMEDIATES: Pesticide intermediates are substances which are not themselves pesticides, but which undergo chemical reactions resulting in the formation of a pesticide. Pesticide intermediates are subject to regulation under TSCA. Pesticide intermediates include any beginning or intermediate material which is a chemical precursor to a pesticide active ingredient, whether produced in situ or obtained from other sources.

INTERREGIONAL RESEARCH PROJECT NO. 4 - The Interregional Research Project Number 4 (IR-4) is a program sponsored by the U.S. Department of Agriculture (USDA). IR-4 provides national leadership and coordination for information on the clearance of minor use pesticides and generates data to support minor-use registrations.

INTRASTATE PRODUCT - A pesticide product that was registered by a state for sale and use only in that state. new intrastate registrations are no longer permitted, and existing products must be converted to full federal registration or canceled. Because these products are not federally (EPA) registered, they may only distributed or sold in the state of registration. Intrastate products were identified by a product number greater than 3000 (e.g., 1573-4880).

IPM - See Integrated Pest Management.

IR-4 - See Interregional Research Prct No. 4.

IRB - See Insecticide-Rodenticide Branch.

ISB - See Information Services Branch.

LABEL USE INFORMATION SYSTEM - See LUIS.

LUIS - The Label Use Information System (LUIS) is a computer data base of label directions for pesticide usage. Information contained in LUIS includes: use sites, application type, timing, equipment, dosage, application frequency, reentry and preharvest restrictions, geographic limitations, and selected limitations to use. Data are extracted by product but may be aggregated by active ingredient. The system currently focuses on information needed to support reregistration. Additional information (e.g., pests, more use limitations) will be added to the system to support special reviews and other reregistration activities.

MAINTENANCE FEE - An annual fee required of registrants for each pesticide product retained for registration.

MANUFACTURING-USE PRODUCT - A Manufacturing-Use Product (MP or MUP) is any product intended (labelled) for formulation or repackaging into other pesticide products.

MARGIN OF SAFETY/MARGIN OF EXPOSURE - The Margin of Safety/Margin of Exposure (MOS/MOE) is a numerical value that characterizes the amount of safety to a toxic chemical -- a ratio of exposure to a toxicological endpoint, usually the NOEL.

MASTER RECORD IDENTIFICATION NUMBER - See MRID Number.

"ME-TOO" PRODUCT - 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. See Chapter 6, D., Question 1 of this manual for a more detailed discussion of a "me-too" product.

MICROBIAL PESTICIDES - Microbial pesticides are microorganisms and include but are not limited to bacteria, algae, fungi, viruses, and protozoa used as pest control agents (40 CFR 152.20).

MISCIBLE - Capable of being mixed. Often used to describe certain pesticide formulations.

MOS/MOE - See Margin of Safety/Margin of Exposure.

MP- See Manufacturing-Use Product.

MRID NUMBER - The Master Record Identification (MRID) Number is a unique cataloging number assigned to an individual study at the time of submission to the Agency. It is EPA's system of tracking studies used in support of pesticide product registration.

MUP - See Manufacturing-Use Product.

NACA - The National Agricultural Chemicals Association (NACA).

NARA - The National Agrichemical Retailers Association.

NAS - The National Academy of Sciences (NAS).

NASDA - The National Association of State Departments of Agriculture.

NATIONAL ACADEMY OF SCIENCES - See NAS.

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION - See NACA.

NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES - The National Coalition Against the Misuse of Pesticides (NCAMP).

NATIONAL INSTITUTE FOR ENVIRONMENTAL HEALTH SCIENCES - As part of the National Institute of Health, the National Institute for Environmental Health Sciences (NIEHS) performs basic research, including genetic and cancer studies, that relates to environmental health sciences.

NATIONAL PEST CONTROL ASSOCIATION - The National Pest Control Association (NPCA).

NATIONAL PESTICIDE INFORMATION RETRIEVAL SYSTEM - The National Pesticide Information Retrieval System (NPIRS), located at Purdue University, is the commercially-available version of the Pesticide Product Information System (PPIS). In addition to PPIS information, NPIRS also includes Pesticide Document management System data (e.g., MRID number, study title, title page from submitted study). Also see Pesticide Product Information System.

NATIONAL PESTICIDE TELECOMMUNICATIONS NETWORK - The National Pesticide Telecommunications Network (NPTN), located at Texas Tech University, is a network from which the public can get answers to their pesticide-related questions by calling a toll-free phone number (1-800-858-7378) that is funded by EPA.

NATIONAL TECHNICAL INFORMATION SERVICE - (NTIS). An organization that sells certain government publications including EPA documents such as testing guidelines. Orders can be placed at NTIS, Attention: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Telephone: (703) 487-4650.

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NATURAL RESOURCES DEFENSE COUNCIL - The Natural Resources Defense Council (NRDC).

NCAMP - See National Coalition Against the Misuse of Pesticides.

NEW CHEMICAL - An application for registration of a product containing a new pesticide (active ingredient) that is not an active ingredient in a product currently registered with the Agency (40 CFR 152.114).

NEW USE - 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. When used with respect to a product containing a particular active ingredient "New Use" means (1) any proposed use pattern that would require the establishment of, increase in, or exemption from the requirement of a tolerance or food additive regulation under section 408 or 409 of the FFDCA; (2) any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or (3) any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms. (See 40 CFR 152.3(p)).

NIEHS - See National Institute for Environmental Health Sciences.

NOAEL - No Observable Adverse Effect Level.

NOEC - No Observed Effects Concentration.

NOEL - No Observed Effects Level.

NOIC - The Notice of Intent to Cancel (NOIC).

NOIS - The Notice of Intent to Suspend (NOIS).

NOMINAL CONCENTRATION - The amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

NO OBSERVED ADVERSE EFFECT LEVEL - See NOAEL.

NO OBSERVED EFFECT CONCENTRATION - See NOEC.

NO OBSERVED EFFECT LEVEL - See NOEL.

NOTICE OF INTENT TO CANCEL - See NOIC.

NOTICE OF INTENT TO SUSPEND - See NOIS.

NPCA - See National Pest Control Association.

NPIRS - See National Pesticide Information Retrieval System.

NPTN - See National Pesticide Telecommunications Network.

NRDC - See Natural Resources Defense Council.

NTIS - See National Technical Information Service.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE BRANCH - The Occupational and Residential Exposure Branch (OREB), within the Health Effects Division (HED) of the Office of Pesticide Programs (OPP) is responsible for review and evaluation of data in the exposure of people to pesticides.

OCCUPATIONAL SAFETY BRANCH - The Occupational Safety Branch (OSB) within the Field Operations Division (FOD) of the Office of Pesticide Programs (OPP) develops and recommends Agency policy and implements a strategy for pesticide occupational safety programs. Through cooperative agreements, grants, or contracts, OSB manages external efforts that contribute to a better understanding of the phenomena of worker exposure to pesticides, the health problems created, and identification and demonstration of practicable and effective means to reduce exposure.

OCM - The Office of Compliance Monitoring.

OD - Office Director.

ODW - Office of Drinking Water (ODW) is the former name of the Office of Drinking Water and Ground Water. The Office of Drinking Water and Ground Water promulgates drinking water standards (MCLs) and/or issues Health Advisories for pesticides known or suspected to contaminate groundwater.

OECD GUIDELINES - Guidelines prepared by the Organization of Economic and Cooperative Development of the United Nations; these guidelines assist in the preparation of protocols for toxicological, environmental fate, etc. studies.

OES - The Office of Endangered Species (OES) is part of the Fish and Wildlife Service of the Department of Interior.

OFFICE OF DRINKING WATER - See ODW.

OFFICE OF DRINKING WATER AND GROUND WATER - See ODW.

OFFICE OF ENDANGERED SPECIES - See OES.

NPCA - See National Pest Control Association.

NPIRS - See National Pesticide Information Retrieval System.

NPTN - See National Pesticide Telecommunications Network.

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OFFICE OF DRINKING WATER - See ODW.

OFFICE OF DRINKING WATER AND GROUND WATER - See ODW.

OFFICE OF ENDANGERED SPECIES - See OES.

OFFICE OF PESTICIDE PROGRAMS - The Office of Pesticide Programs (OPP) and the Office of Pollution Prevention and Toxics comprise the two offices within the Office of Prevention, Pesticides, and Toxic Substances. OPP is comprised of seven Divisions: the Biological and Economic Analysis Division (BEAD); the Environmental Fate and Effects Division (EFED); the Field Operations Division (FOD); the Health Effects Division (HED); the Program Management and Support Division (PMSD); the Registration Division (RD);and the Special Review and Reregistration Division (SRRD).

OLTS - The On-Line Tracking System (OLTS) is a computerized tracking system used to track data review records. OLTS was replaced by the Pesticide Registration Activity Tracking System (PRATS). See PRATS also.

OMB - The Office of Management and Budget.

ON-LINE TRACKING SYSTEM - See OLTS and PRATS.

OPM - The Office of Personnel Management.

OPP - See Office of Pesticide Programs.

OREB - See Occupational and Residential Exposure Branch.

ORGANIZATION OF ECONOMIC AND COOPERATIVE DEVELOPMENT - An organization of the United Nations that prepares guidelines that assist in the preparation of protocols for toxicological, environmental fate, etc. studies. Also see OECD Guidelines.

OSB - See Occupational Safety Branch.

PAG - Pesticide Assessment Guidelines (PAG) are protocols referenced in 40 CFR 158 that provide registrants with guidance on how to conduct required studies. Copies of the Guidelines can be obtained from the National Technical Information Service.

PAI - A Pure Active Ingredient (PAI) is a test substance required for certain pesticide studies. PAIs do not have inert ingredients added.

PBA - A Preliminary Benefit Analysis (PBA) is a summary of a pesticide's uses and benefits; developed by the Biological and Economic Analysis Division (BEAD) of the Office of Pesticide Programs (OPP) for the preliminary determination (PD 2/3) stage of a Special Review.

PCO - Pest Control Operator. A term not employed by FIFRA which is often used to describe a person or company that applies pesticides as a business (e.g., exterminator); often used to describe such a service for household applications as compared to agricultural applications.

PDMS - The Pesticide Document Management System (PDMS) is a collection of documents of regulatory significance to pesticides, including submitted studies, maintained by the Agency. The documents are microfiched and indexed by an on-line retrieval system that anyone in the Office of Pesticide Programs (OPP) can use.

PES - The Planing and Evaluation Staff (PES) within the Biological and Economic Analysis Division (BEAD) of the Office of Pesticide Programs (OPP) is primarily responsible for formulating BEAD budgets and program plans, administrative management, science integration and program evaluation, and coordination of preparation for hearings.

PEST - any insect, rodent, nematode, fungus, weed, or 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) that is injurious to health or the environment. (See FIFRA section 2(t) and 25(c)(1).

PEST CONTROL OPERATOR - see PCO.

PESTICIDE - 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.

PESTICIDE ASSESSMENT GUIDELINES - see PAG.

PESTICIDE DOCUMENT MANAGEMENT SYSTEM - See PDMS.

PESTICIDE INCIDENT MONITORING SYSTEM - The Pesticide Incident Monitoring System (PIMS) is a collection of human and environmental poisoning events related to specific pesticides that were reported to the Office of Pesticide Programs (OPP). PIMS was discontinued in 1981 due to budgetary constraints and the unverifiable nature of its data; it was based on volunteered information.

PESTICIDE INTERMEDIATES: See Intermediates.

PESTICIDE PRODUCT INFORMATION SYSTEM - The Pesticide Product Information System (PPIS) is a data base that provides information on more than 60,000 currently and formerly federally registered pesticide products and other non-pesticide chemicals. For each federally registered product, PPIS can provide the product name, registrant name and address, EPA registration number, type of formulation, signal word, types of pesticide activity, active ingredient names and percentages, application sites, and pests controlled. PPIS also contains information on whether the product has been classified for restricted or general use.

PESTICIDE REGISTRATION ACTIVITY TRACKING SYSTEM - See PRATS.

PESTICIDE REGULATION NOTICE - See PR Notice.

PHI - The Pre-harvest Interval (PHI) is the time between the last pesticide application and harvest of the treated crop.

PIMS - See Pesticide Incident Monitoring System.

PLANNING AND EVALUATION STAFF - See PES.

PM - Product Manager. See Product Manager Team.

PMSD - The Program Management and Support Division (PMSD) is one of the seven Divisions that constitutes the Office of Pesticide Programs (OPP). PMSD provides administrative support to all OPP Divisions; prepares program plans and budget proposals; manages the indemnification process; and provides overall leadership for OPP management program. PMSD is comprised of four branches: the Administrative Branch (AB); the Resources Management and Evaluation Branch (RMEB); the Information Services Branch (ISB); and Systems Branch (SB).

POLICY AND SPECIAL PROJECTS STAFF - The Policy and Special Projects Staff (PSPS) within the Office of Pesticide Programs (OPP) serves as the Office Director's primary means for analyzing and responding to external critiques of program activities and policies.

PPIS - See Pesticide Product Information System.

PRATS - The Pesticide Registration Activity Tracking System (PRATS) is an on-line tracking system to monitor the science reviews of data submissions. PRATS is also used to request actions (e.g., risk assessments, DRES runs, etc.) from the science divisions. PRATS replaced the On-Line Tracking System (OLTS).

PRE-HARVEST INTERVAL - See PHI.

PRELIMINARY BENEFIT ANALYSIS - See PBA.

PR NOTICE - A Pesticide Regulation (PR) Notice is a written notice generally issued by the Registration Division to pesticide registrants that communicates important changes in regulatory policy or procedures. Each PR Notice is assigned a two part number beginning with the year issued and the cardinal number issued within that year (e.g., 87-1, 87-2, 92-1, etc.). The name of the notice derives from the Pesticide Regulation Division, a precursor organization to the Registration Division of the Office of Pesticide Programs.

PRODUCT MANAGER TEAM - PM Team - An organizational unit in each of the three Registration Division Product Branches which is primarily responsible for processing applications for new and amended product registration, petitions for tolerances, experimental use permits, special local need applications, and reregistration of currently registered pesticides. There are currently 11 PM Teams, each headed by a product manager and staffed by 4 - 7 reviewers. Each PM Team has a number (e.g., PM 10; PM 21; PM 31). There are currently five teams in the Insecticide-Rodenticide Branch, four teams in the Fungicide-Herbicide Branch, and two teams in the Antimicrobial Branch.

PROGRAM MANAGEMENT AND SUPPORT DIVISION - see PMSD.

PROTOCOL - A study plan or method.

PSPS - See Policy and Special Projects Staff.

PURE ACTIVE INGREDIENT - See PAI.

RAC - See Raw Agricultural Commodity.

RAF - See Risk Assessment Forum.

RAW AGRICULTURAL COMMODITY - Raw Agricultural Commodities (RAC) include, among other things, fresh fruits, whether or not they have been washed and colored or otherwise treated in their unpeeled natural form; vegetables in their raw or natural state, whether or not hey have ben stripped of their outer leaves, waxed, prepared into fresh green salads, etc.; grains, nuts, eggs, raw milk, meats, and similar agricultural produce. It does not include foods that have ben processed, fabricated, or manufactured by cooking, freezing, dehydrating, or milling.

RB - The Reregistration Branch (RB) within the Special Review and Reregistration Division (SRRD) of the Office of Pesticide Programs (OPP) manages the reregistration process that provides for the review of all List A pesticides. Management of the process includes planning, scheduling, and coordinating Health Effects Division (HED), Environmental Fate and Effects Division (EFED), Program Management and Support Division (PMSD), and Biological and Economic Analysis Division (BEAD) inputs, conducting the administrative review, and preparing and issuing documents. These documents include Reregistration Eligibility Documents (REDs) and Tolerance Reassessments.

RCRA - The Resource Conservation and Recovery Act (RCRA) is a law under which EPA regulates the transportation, storage, and disposal of hazardous waste. it is implemented by the Office of Solid Waste and Emergency Response's Office of Solid Waste.

RD - Registration Division of the Office of Pesticide Programs. The Registration Division is primarily responsible for implementing the provisions of FIFRA relating to the registration of pesticide products.

REBUTTABLE PRESUMPTION AGAINST REGISTRATION - Rebuttable Presumption Against Registration (RPAR) is the former name for Special Review.

RED - Reregistration Eligibility Document (RED) - A document issued at the completion of the Agency's reregistration review of a registered pesticide active ingredient. The RED sets forth the Agency's decision on whether products containing a pesticide are eligible for reregistration. The RED also assesses the acceptability of existing tolerances, and describes the need for additional data or other information. It is accompanied by a data call-in if additional data are required.

REENTRY INTERVAL - The Reentry Interval (REI) is t1950Xrequire

has been treated with a pesticide; required in order to reduce or avoid real or perceived toxicity risks to field workers.

REFERENCE DOSE - The Reference Dose (RfD) is an estimate of the acceptable daily exposure of humans to a pesticide. RfDs are derived for the noncarcinogenic effects of substances which may also be carcinogenic. Formerly called the acceptable daily intake (ADI).

REGISTRANT - The term given to a person or entity that has registered a pesticide product under FIFRA.

REGISTRATION DIVISION - See RD.

REGISTRATION NUMBER - The EPA registration number is a hyphenated, two part number assigned by the Registration Division to identify each product registration (e.g., 1253-79); the first number is the assigned company number and the second number is the specific product number. The registration number is required by FIFRA to appear on the product's label.

REGISTRATION PROCESS - The process and final Agency action authorizing the legal sale, distribution, and use of a pesticide product. The process includes OPP's consideration of scientific, legal, and regulatory requirements of the product and results in the Agency issuing either a Notice of Registration or a denial to the applicant.

REGISTRATION STANDARD - Registration Standard (RS) is a document issued in connection with the Agency's reregistration program prior to the enactment of FIFRA '88 that characterizes a pesticide's available scientific data base and the Agency's position on the registered uses of that pesticide. Registration Standards were accompanied by data call-ins requiring submission of additional data. All chemical cases that had Registration Standards issued prior to the enactment of FIFRA '88 are on reregistration List A.

REGISTRATION SUPPORT BRANCH - The Registration Support Branch (RSB) within the Registration Division (RD) of the Office of Pesticide Programs (OPP) is responsible for: the emergency exemption program under section 18 of FIFRA; review of state issued section 24(c) special local needs registrations; the clearance requests for exemption from a tolerance for inert ingredients; the tolerance revocation program; the management and coordination of minor or specialty use tolerance petitions submitted under the Federal Food, Drug, and Cosmetic Act; and child-resistant packaging.

REI - See Reentry Interval.

REREGISTRATION - Section 4 of FIFRA requires EPA to reregister all pesticides originally registered before 1984 on specified timetables. Reregistration priority is given to chemicals with the highest potential for exposure -- high-volume and food-use chemicals (i.e., List A chemicals). Through this priority process, four lists of pesticides (Lists A, B, C, and D), were established under FIFRA '88.

The reregistration process consists of: the Agency identifying the studies necessary to conduct human health and environmental risks assessments; obtaining and reviewing these studies; and determining whether the pesticide's uses do not pose unreasonable adverse risks.

Also see Reregistration Branch; Accelerated Reregistration Branch; Data Call-In; and List A, B, C, and D Pesticides.

REREGISTRATION BRANCH - See RB.

REREGISTRATION ELIGIBILITY DOCUMENT - See RED.

RESIDENTIAL USE - Pesticide application in and around houses, apartment buildings, motels, and other living areas.

RESOURCE MANAGEMENT AND EVALUATION BRANCH - The Resource Management and Evaluation Branch within the Program Management and Support Division (PMSD) of the Office of Pesticide Programs (OPP) provides overall management, direction, guidance, and support to divisions and offices on the development and implementation of program and budget plans.

RESTRICTED USE PESTICIDE - (RUP) - If the Agency determines that a pesticide, when applied in accordance with its labeling or in accordance with widespread and generally recognized practices may generally cause, without additional restrictions, unreasonable adverse effects on the environment. EPA will classify the pesticide or the particular use or uses to which the determination applies for restricted use. Restricted-use pesticides may generally be applied only by trained, certified applicators or those under their direct supervision, and may be subject to other regulatory restrictions.

RESOURCES CONSERVATION AND RECOVERY ACT - See RCRA.

REVIEW MANAGER - A Review Manager (RM) is an employee in the Special Review Branch (SRB) or Reregistration Branch (RB) of the Special Review and Reregistration Division (SRRD) whose responsibility is to coordinate the review process for one or more pesticide chemicals. This includes leading review teams for pesticides or issues under review.

RfD - See Reference Dose.

RISK ASSESSMENT - In general, a risk assessment (RA) is a determination of the likelihood of a hazard to occur from population exposed to pesticide chemicals. This likelihood may be expressed as a numerical probability or as a margin of safety/margin of exposure. Simply stated: RISK = Hazard x Exposure.

RISK ASSESSMENT COUNCIL - The Risk Assessment Council reviews the policy and procedural aspects of the Risk Assessment Forum's (RAF) technical findings. After approval by the RAC and the Administrator, the Forum's findings become policy.

RISK ASSESSMENT FORUM - The Risk Assessment Forum (RAF) consists of Agency risk assessment (RA) expert scientists who study technical Agency-wide RA issues and refer their findings to the Risk Assessment Council. The RAF was established to promote consensus on RA issues within the Agency.

RM - See Review Manager.

RMEB - See Resource Management and Evaluation Branch.

RPAR - See Rebuttable Presumption Against Registration.

RS - See Registration Standard.

RSB - See Registration Support Branch.

RUP - See Restricted use Pesticide.

SAB - The Science Advisory Board (SAB) is an Agency-wide series of committees that advises the Administrator on scientific issues.

SACB - The Science Analysis and Coordination Branch (SACB) within the Health Effects Division (HED) of the Office of Pesticide Programs (OPP) coordinates and integrates human and domestic animal toxicological data along with dietary and non-dietary exposure to determine the risk for pesticides.

SACS - The Science Analysis and Coordination Staff (SACS) within the Environmental Fate and Effects Division (EFED) of the Office of Pesticide Programs supports the assessment of environmental pesticide hazards by integrating individual discipline-specific review components into an overall statement of risk. The SACS also generally reviews EFED's scientific output, analyzes science policy issues, and recommends resolution of issues.

SAFE DRINKING WATER ACT - The Safe Drinking Water Act (SDWA) requires the Agency to set health standards for water sources used for public drinking water systems. It directs the EPA administrator to develop: (1) National primary drinking water regulations that incorporate maximum contaminant levels; (2) Underground Injection Control regulations to protect underground sources of drinking water; and (3) Groundwater protection grant programs for the administration of sole source aquifer demonstration projects and for wellhead protection area programs.

SAP - See FIFRA Scientific Advisory Panel.

SARA - The Superfund Amendments and Reauthorization Act of 1986 (SARA) is the legislation that reauthorized the Superfund program in 1986. In addition, this law made several amendments to CERCLA and established the provisions for SARA Title III -- Emergency Planning and Community Right-to-Know.

SB - The Systems Branch (SB) within the Program Management and Support Division (PMSD) of the Office of Pesticide Programs (OPP) is the central point within OPP for automatic data processing systems analysis and design. Services provided include: Automated Data Processing (ADP) facilities and hardware, data input, and retrieval support from the computerized data bases.

SCIENCE ADVISORY BOARD - See SAB.

SCIENCE ANALYSIS AND COORDINATION BRANCH - See SACB.

SCIENCE ANALYSIS AND COORDINATION STAFF - See SACS.

SDWA - See Safe Drinking Water Act.

SECTION 18 - See FIFRA Section 18 (Emergency Exemption).

SECTION 24(c) - See FIFRA section 24(c) (special local need).

SELECTIVE METHOD OF SUPPORT - One of two methods by which an applicant for registration or amended registration may comply with the data compensation requirements of FIFRA section 3(c)(1)(F). Under this method the applicant lists the specific data requirements that apply to his or her product, its active ingredients, and use patterns, and demonstrates compliance with the data requirements by either submitting the actual studies, or citing individual studies, or by demonstrating that no study has bously submit20Xto the Aency (a datp1680Xgap).

SETAC - The Society for Environmental Toxicology and Chemistry (SETAC) is a professional society for environmental toxicologists and chemists; publishes a journal entitled Environmental Toxicology and Chemistry and sponsors symposia on various environmental issues that relate to toxicology and chemistry.

SFIREG - The State FIFRA Issues, Research Evaluation Group (SFIREG) is a group of state regulatory officials who work with Office of Pesticide Programs (OPP) staff to identify and resolve overlapping state and federal regulatory and research issues.

SLN - See FIFRA Section 24(c).

SMALL BUSINESSES - The term "small business" in regard to eligibility for reduced registration maintenance fees means a business that employees 150 or fewer people and, during the three year period prior to the most recent maintenance fee billing cycle (i.e., December 31, 1990) had average annual gross revenue from chemical sales not exceeding $40 million, taking into account nay parents' and subsidiaries' employees and gross revenues.

SOCIETY FOR ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY - see SETAC.

SOLUTION - A formulation or use dilution of a pesticide that dissolves in the carrier liquid or diluent and will not settle out or separate in an aqueous medium.

SOP - A Standard Operating Procedure (SOP) is a written procedure that conveys procedures for various functions performed by Office of Pesticide Programs (OPP) staff. SOPs address both technical and administrative matters.

SPECIAL LOCAL NEED - See FIFRA Section 24(c).

SPECIAL REVIEW - The purpose of the Special Review (SR), formerly known as Rebuttable Presumption Against Registration (RPAR), process is to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The process is intended to ensure that the Agency assesses risks that may be posed by pesticides, and the benefits of use of those pesticides, in an open and responsive manner. The issuance of a Notice of Special Review means that the Agency has determined that one or more uses of a pesticide may pose significant risks and that, following completion of the Special Review process, the Agency expects to initiate formal proceedings seeking to cancel, deny, reclassify, or require modifications to the registration of the product(s) in question unless it has been shown during the Special Review that the Agency's initial determination was erroneous, that the risks can be reduced to acceptable levels without the need for formal proceedings, or that the benefits of the pesticide's use outweigh the risks. Following completion of the Special Review process, a pesticide in question may be returned to the registration process. Regulations pertaining to Special Review procedures are at 40 CFR 154.

SPECIAL REVIEW BRANCH - The Special Review Branch (SRB) within the Special Review and Reregistration Division (SRRD) of the Office of Pesticide Programs (OPP) is responsible for managing the Special Review process for chemicals that have been placed in Special Review. The Special Review process provides a framework for risk/benefit reviews of pesticide products and preparation of documents stating the Agency's position (i.e., Position Documents). Subsequent action may include risk reduction measures, cancellation of some or all uses, emergency suspension/cancellation.

SPECIAL REVIEW AND REREGISTRATION DIVISION - The Special Review and Reregistration Division (SRRD) is one of the seven Divisions that constitutes the Office of Pesticide Programs (OPP). It manages special reviews and reregistration of pesticide products; issues data call-ins related to the special review and reregistration processes; and issues position documents and follow-up reports. This Division is comprised of the immediate office staff and three branches: the Special Review Branch (SRB); the Reregistration Branch (RB); and the Accelerated Reregistration Branch (ARB).

SR - See Special Review.

SRB - See Special Review Branch.

SRRD - See Special Review and Reregistration Division.

STANDARD OPERATING PROCEDURES - See SOP.

STATE FIFRA ISSUES, RESEARCH EVALUATION GROUP - See SFIREG.

SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT OF 1986 - See SARA.

SUPPLEMENTAL REGISTRATION - Common term for a process through which a registrant may permit the distribution or sale of his or her registered product under another's name and address. Such distribution or sale is termed a supplemental distribution under EPA regulations at 40 CFR 152.132. Also called distributor registrations/products. A supplemental registration is identified by a three part number (e.g.,1342-6-2) in which the first and second numbers make up the primary registrant's registration number, followed by the third part which is the supplemental registrant's company number.

SURROGATE DATA - Data from studies which involve test organisms on a test substance that are used to estimate the characteristics or effects on another organism or of another substance.

SUSPENSION - Finely divided solid particles mixed in a liquid.

SUSPENSION OF REGISTRATION - An action authorized under FIFRA section 3(c)(2)(B) or section 4 that temporarily halts further distribution and sales of a pesticide product. Suspension under 3(c)(2)(B) or section 4 is imposed because the registrant has failed to meet data submission requirements. The registrant can request a hearing to challenge the notice. Suspension can be lifted when the requirements are met.

A suspension of registration also can be issued under FIFRA section 6(c) due to an imminent hazard. The registrant has the right to an expedited hearing on the question of whether an imminent hazard exists. Also see NOIS and Emergency Suspension.

SYSTEMS BRANCH - See SB.

TECHNICAL GRADE ACTIVE INGREDIENT - A Technical Grade Active Ingredient (TGAI) is the pesticide chemical in pure form (usually 95 - 100% active ingredient) as it is manufactured by a chemical company prior to being formulated (i.e., wettable powders, granules, emulsifiable concentrates).

TECHNICAL GRADE PRODUCT - A registered manufactured-use product that is composed of technical grade active ingredient.

TEP - A Typical End-use Product (TEP) is a term used in data requirements to convey direction to a data producer to use a commonly used end-use product as the test substance.

TGAI - See Technical Grade Active Ingredient.

THE ACT - In this manual this term refers to FIFRA (the Federal Insecticide, Fungicide, and Rodenticide Act).

THEORETICAL MAXIMUM RESIDUE CONTRIBUTION - The Theoretical Maximum Residue Contribution (TMRC) is the theoretical maximum amount of a pesticide in the daily diet of an average human. This theoretical amount assumes that the diet is composed of all food items for which there are tolerance-level residues of the pesticide. The TMRC unit is expressed as mg (of pesticide)/kg (of body weight)/day.

TMRC - See Theoretical Maximum Residue Contribution.

TOLERANCE - The maximum permissible residue levels for pesticides in raw agricultural produce and processed foods. Whenever a pesticide is registered for use on a food or a feed crop, a tolerance (or exemption from the tolerance requirement) must be established. EPA establishes the tolerance levels, which are enforced by the Food and Drug Administration and the Department of Agriculture. Whenever a pesticide is registered for use on a food or feed crop, a tolerance or an exemption from the tolerance must be established. Established tolerances and exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities are listed in 40 CFR Section 180; tolerances for food additives in food for human consumption are listed in 40 CFR Section 185; and tolerances for feed additives in animal feed are listed in 40 CFR Section 186.

TOLERANCE PETITION - A formal request to establish a new tolerance or modify (raise, lower or revoke) existing tolerances.

TOXIC SUBSTANCES CONTROL ACT - The Toxic Substances Control Act (TSCA) is a law administered by the Office of Pollution Prevention and Toxics that governs the manufacture processing distribution, use and disposal of chemical substances. Pesticides, tobacco and tobacco products, nuclear materials, foods, food additives, drugs and cosmetics are excluded from TSCA's coverage.
TSCA - See Toxic Substances Control Act.

TYPICAL END-USE PRODUCT - See TEP.

USE INDEX - A compilation of everything on a label for each pesticide product including the sites the pesticide is used on and the application rate. The Use Index is prepared by the Biological and Economic Analysis Division (BEAD).

VOLTILITY - The property of a substance to become a vapor or gas without chemical change.

WATER SOLUBLE PACKAGING - Packaging that dissolves in water; this type of packaging is used to reduce exposure risks to mixers and loaders.

"WEIGHT OF EVIDENCE" APPROACH - Evaluation based on a qualitative assessment of the available scientific evidence.

WETTABLE POWDER - Wettable Powder (WP) is a dry formulation materials that must be mixed with water or other liquid before it is applied.

WP - See Wettable Powder.

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