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Label Review Manual

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LABEL REVIEW MANUAL

Chapter 1 **PURPOSE OF MANUAL**

The Labeling Center for Excellence (LCE) within the Office of Pesticide Programs (OPP) developed this manual to serve as a training tool for new employees and as a source of direction for product team members who are responsible for performing label reviews. It is the goal of this manual to improve the quality of label reviews and to increase the consistency of label reviews from one branch to another within Registration Division (RD). The LCE has attempted to bring together all of the policy and guidance that affects pesticide labeling generically. This manual does not contain labeling guidance which is specific to particular products.

The first two chapters of this manual provide an overview concerning what is a pesticide and what constitutes a pesticide label and labeling. The third chapter discusses general label format and legibility requirements, identifies the major parts of the label and directs the user to the appropriate chapter which contains additional information. The remainder of the manual provides the reviewer with step-by-step instructions concerning the review of a pesticide label and any associated actions such as the Pesticide Registration Action Tracking System (PRATS) entries for label reviews and situations where the Confidential Statement of Formula (CSF) affects the label language. Information in the manual is arranged in the order of use by reviewers. The last chapter provides information about how unique labeling issues have been handled in the past, so that reviewers can apply this information to future similar situations.

This manual provides a methodical approach to the label review process. Most label reviews involve cite-all products which are not accompanied by data. Such labels are usually reviewed by comparing the new product label to a registered label. Prior to the development of this manual, the LCE conducted individual surveys of team members and from these surveys, it was recognized that many of the problems and errors on labels resulted from this way of performing label reviews. When reviewers compare new proposed labels to registered labels, which may themselves contain errors or be out-of-date, often deficiencies are not discovered and eliminated. Consequently, the label errors are perpetuated.

This manual attempts to shift the review of the label away from solely a label-to-label comparison to a review based on the guidance contained in this manual and is supported by labeling policy documents. This labeling guidance has been gathered from all of OPP's various labeling policy documents issued over time, and is believed to be current. As OPP goes forward with the reregistration process and future registrations have specifically identified data bases, it will become easier to perform thorough label reviews efficiently.

All chapters in this manual are included in the *Labeling Policy Directory*, which is located under F:\SHARED\RD\LABELING on OPP's Local Area Network (LAN). It can be accessed by activating a macro in Wordperfect (WP) by typing Alt L in any WP document or at a blank screen. The policy directories contain all policy documents related to labeling, and are organized roughly following the sections of a pesticide label. Refer to the INDEX under the directory for the chapter names.

The chapters of this manual have been numbered independently to aid future updating. Individual chapters can be updated as new policy is instituted which changes the guidance contained in a particular chapter. Each chapter will display its current issuance date. For accurate maintenance of this manual, it is imperative that everyone in OPP bring to the attention of the Labeling Unit any document which affects policy pertaining to the pesticide label in general or labeling for a specific chemical.

Chapter 2 PESTICIDES AND LABELING

Introduction

This chapter focuses on how a product is determined to be a pesticide and the exceptions to this decision process. Registration Division (RD) reviewers should use these criteria when discussing the status of products or potential products with other EPA staff, state enforcement personnel, registrants, applicants, or the general public. While it is acceptable to discuss with anyone the various points affecting the decision concerning whether or not a product is a pesticide and subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the final decision must be in writing and should be in response to a written request which includes proposed labeling and the composition of the product.

Pesticides Subject to Registration

The most important word in FIFRA is *"intended"*. Products are considered to be pesticides if they are intended for preventing, destroying, repelling, or mitigating any pest or intended for use as a plant regulator, defoliant, or desiccant. Intent is determined by claims on the label and/or composition of the product as distributed or sold.

1. CLAIMS: If the manufacturer, formulator, packager, or shipper makes claims on labels, advertising, collateral literature, or even verbally, that a product has pesticidal or plant regulator utility, then it is subject to FIFRA.

2. COMPOSITION: Even in the absence of pesticide claims, if a product is composed of ingredients that are well-known pesticides that have no other non-pesticidal utility, then the product is considered a pesticide. For example; a company markets a granular 2,4-D product that has labeling identifying the presence of 2,4-D, directions to apply it to lawns at a certain dosage rate, and warnings about over-application, but nowhere is there a claim that broad-leaved weeds will be killed. Is it a pesticide? Yes! Since 2,4-D is a well-known herbicide and has no other utility, intent is established by the act of sale or distribution.

3. MODE OF ACTION: Even if claims are not pesticidal and the active ingredient is not currently recognized as a pesticidal active ingredient, the mode of action may be pesticidal. In such a case, the producer/manufacturer must supply information on how it works.

For the finer points on EPA's guidelines for determining whether a substance is considered a pesticide, refer to 40 CFR 153.125 and Pesticide Regulation (PR) Notice 81-4.

Exceptions (Products not Subject to FIFRA)

Certain types of products or compounds have been declared as not subject to registration under FIFRA even when used as pesticides or when marketed with pesticide claims. (However, the reader should be aware that this exception does not necessarily extend to the Federal Food, Drug and Cosmetic Act.) Examples of products not subject to FIFRA:

- **Compounds that are overwhelmingly used for non-pesticidal purposes** but have occasional application against pests and are not promoted or advertised for such pest uses. Examples are diesel fuel or fuel oil used as mosquito larvicides or salt used to prevent plant growth. (See Policy and Criteria Notice 2050.1).

- **Materials that provide a physical barrier** against pests and do not contain pesticidal active ingredients. Examples are sphagnum moss used as plant growth media to retard damping-off; latex or asphalt tree wound dressing label that contain claims of preventing the entrance of insects or fungi into fresh cut surfaces of plants; cocoa bark or pine bark mulches that claim suppression of weed growth; black plastic or tar-paper used to suppress weeds or repel insects [40 CFR 152.10(c)].

- **Materials that are naturally pest-resistant** and are advertised as such, so long as claims are not made for pest mitigation beyond the material itself. Examples are cypress or redwood lumber or outdoor furniture that have claims of repellency or resistance to wood-boring insects and wood-rot fungi.

- **Materials that have been treated with a pesticide to protect the material itself** and claims are not made for pest mitigation beyond the material. Examples are shower curtains treated with a fungicide to retard mildew growth, lumber treated with a wood preservative, bathroom caulks impregnated with a mildewcide, paints with antimicrobials added for in-can preservation, fabrics and leather treated with sanitizer compounds, etc. NOTE: the above examples are limited to the treated articles themselves. The pesticides used for those purposes must be registered and bear appropriate directions for such uses. [40 CFR 152.25(a)].

- **Paints that have been treated with an antimicrobial pesticide** and bear claims that the dried paint film will be resistant to mildew. Claims, expressed or implied, may not be made for protection of the surface beneath the paint film nor for prevention of mold

spores that could infect foods or beverages. Paints that are to be used in canneries, breweries, hospitals, or other areas where a crucial consideration is prevention of bacteria or mold that would pose a health risk are NOT subject to the above exemption and, therefore, are considered to be pesticides.

- **Products that are intended solely to be used on or in the living bodies of man or other animals.** Such products are regulated by the Food & Drug Administration. Athlete's foot remedies, dandruff medications, head and body lice soaps and lotions, aquarium additives for treatment of fish diseases, dermal disinfectants, are some examples of excepted pesticide products [40 CFR 152.8(a)]. The foregoing exceptions are due to the definition of "fungi" in Section 2 of FIFRA. IMPORTANT: These exceptions apply only to antimicrobials (fungicides, disinfectants, viricides, etc.). Insecticides are not included in the "living body" exception. Thus, products such as mosquito repellents, flea and tick remedies for pets, and other insecticides and acaricides used directly on the living body of humans, pets, and livestock are considered to be pesticides and are required to be registered.

- **Mortuary supplies intended to prevent or mitigate mold and bacteria on or in human cadavers.** The rationale for this extension is that the use is limited to embalmers and morticians who are specially trained to handle such products and do not require the protection afforded by registration. No other portion of the living public would be exposed to such products [40 CFR 152.25(c)(1)].

- **Animal and animal organ preservatives** [40 CFR 152.25(c)(2)].

- **Adjuvants, extenders, spreader-stickers, protectants, and other products that have no pesticidal properties** in and of themselves, but are intended to be used in conjunction with pesticides, when sold separately from those pesticides. However, diluents or additives other than water must be specified in the Directions for Use and approved during registration.

- **Plant nutrients, fertilizers, trace elements, and other products intended solely for providing necessary nutritional needs of plants for vigorous growth.** There is a fine, and sometimes not-so-fine, line between plant nutrients, which are exempt from registration, and plant regulators, which require registration. Whether a product should be considered to be a plant growth regulator status, basically turns on whether the plant response or mode of action being claimed would go beyond what would be expected from simple nutrition. Thus, claims for increased blossom set, stimulation of root growth, prevention of sucker growth, delayed onset of sprouting of harvested root

crops, abscission stimulation for fruit crops, are considered to be plant growth regulator claims. In, this area, the composition of the product may aid in making the determination. Compounds such as auxins, cytokinins, and gibberellins have no other uses except as plant regulators. Therefore, the declaration of the presence of any of those compounds, causes a product to be considered to be a plant growth regulator [40 CFR 152.8(c)(1) & (2)]. However, products containing auxins, cytokinins, and gibberellins may be exempt from registration if the labeling meet the criteria for vitamin-hormone horticultural products [40 CFR 152.25(d)]. Such exemptions are granted on a case-by-case basis. (See FIFRA §2 for definition of plant regulators).

- **Soil amendments (ex. vermiculite, sand, lime, etc.)** intended to increase porosity, retain moisture, adjust pH, and other uses intended to benefit crop production but which do not have claims or are not of a composition that would cause them to be classified as pesticides or plant regulators. An example: although normally considered to be a fungicide or miticide, sulfur, when applied to soil to adjust the pH would not be subject to registration. Note: Sulfur may also have non-pesticidal uses as a foliar plant nutrient at low concentrations. [40 CFR 152.8(c)(4)].

- **Attractants intended for survey or census purposes only**, and not intended for control or mitigation of the pest. [40 CFR 152.10(c)].

- **Deodorizers, bleaches, soaps, and other cleaning agents** which do not bear claims for sanitizing or disinfecting properties. Bleaches are an exception to the composition rule expressed in part B of the first page of this chapter. A bleach which consists of 5.25% sodium hypochlorite must be registered if it states that bacteria will be killed at certain doses. An identical bleach is not be registered if its labeling does not contain a bactericidal claim even though it delivers the same benefits at appropriate doses. This, thankfully, is one of the few exceptions to the rule. [40 CFR 152.10(a)].

- **Pheromones labeled for use only in pheromone traps,** when the pheromone is the sole active ingredient [40 CFR 152.25(b)]. NOTE: pheromones are intra-species communicators. Using fox urine to repel rabbits is not a pheromone. It is an "allomone".

- **Plant or leaf coatings designed to protect against frost or to retard water loss through transpiration.** These types of products are usually glycerol-based. Similar products are sometimes sold as cut-flower preservatives. So long as plant disease or plant regulator claims are not made for the product and its composition is not such that pesticide benefits would be delivered, registration is not required. Products sold as vase

water additives for cut flowers bear special scrutiny. If they are composed, as many are, of simple sugars intended to supply nourishment to the cut flower, they are not under the purview of FIFRA. If, however, they are claimed to prevent bacterial or fungal growth in the vase water, have plant regulator claims such as delays flower opening, or includes claims for control of stem rot, or decay, they are subject to FIFRA and must be registered.

- **Antimicrobial products used solely in processed foods or feeds, in beverages, or in pharmaceuticals.** Cracking, milling, grinding and other processes that cause a physical change in the commodity are methods that meet the definition of "processed". Consequently, substances used in these processes for pesticidal purposes are regulated by FDA, not EPA. Drying, husking and shelling do not meet that definition so that pesticides used during these processes are regulated under FIFRA. Cosmetics are pharmaceuticals regulated by FDA.

State Restrictions on Label

On some federal labels certain restrictions or special directions may pertain only to a certain state or set of states. When these requirements are not federally mandated, but required by the state, EPA may allow such restrictions on the label. However, it is good for the label reviewer to know the provisions of FIFRA §25(b): "State(s) shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.". Therefore, review the state restrictions or directions to assure that they do not conflict with the requirements of FIFRA.

Once a Special Local Need (state) FIFRA 24(c) supplemental label has been issued and not disapproved by EPA, it may be presented (displayed) along with the complete federal FIFRA §3 text on the same product label (container or booklet).

Chapter 3 GENERAL FORMAT & LEGIBILITY REQUIREMENTS

Introduction

This chapter addresses "labels and labeling", the legibility requirements for draft labeling, the sample label format and guidance concerning specific label requirements versus preferred label requirements. The sample label format which appears at the end of this chapter is designed to illustrate the arrangement of information which may or may not have a specific location requirement on a pesticide label. [40 Code of Federal Regulation (CFR) 152.50(e) & the Blue Book, General Information on Applying for Registration of Pesticides in the United States, Second Edition, August 1992]

Definition of "Label" and "Labeling" [The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 2(p)]

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

2. Labeling - The term "labeling" means all labels and all other written, printed, or graphic matter-

   A. accompanying the pesticide or device at any time; or

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

For purposes of application for registration or amendment, copies of labeling should be submitted to the Agency on 8½" X 11" paper or mounted on 8½" x 11" paper.

Legibility Requirements

The reviewer should only accept draft labeling for review that meets the following requirements:

- The submission must include five copies of all draft labeling. (typescript or mock-up)
- All five copies must be legible and of sufficient quality for photocopying.

If the labeling submitted by the registrant does not meet the above criteria, discontinue the label review. Go to chapter four and five to open and close out the registration action. Send a letter describing to the registrant the submission deficiencies. If the labeling is acceptable, review the next two sections and then continue on to chapter four. [NOTE: Exceptions to this policy should be made only if it is advantageous to the Agency to do so.]

Guidance Concerning Specific Label Requirements Versus Preferred Label Requirements

The following chapters in this manual discuss labeling requirements in more detail and will note specific label requirements and preferred label recommendations where appropriate. In this manual, the word "must" is used to note any items and/or actions specifically required by FIFRA or the regulations. The word "should" is used to identify any items and/or actions that, while not specifically required, are preferred for the sake of increasing consistency and quality in the label review process. Reviewers using this manual must take note the uses of "must" and "should" throughout the manual. When responding to registrants concerning necessary label changes and any other recommendations resulting from the label review, the reviewer must make certain that required label changes are phrased as commands to the registrant. Commanding verbs such as *"must be revised"*, *"must be changed"*, or *"must be moved"* are to be used in the reviewer's response to the registrant. When responding to the registrant concerning preferred but not required label changes, the reviewer must use verbs that are suggestive or instructional such as, *"should be revised"*, *"should be changed"* or *"should be moved"*.

Label Format

Listed below are the various parts and statements of the sample label format which appears at the end of this chapter. Each chapter designated below corresponds to the chapter in this manual which discusses that particular part of the label in more detail.

- Ingredient Statement (Chapter 6)

  This section identifies the active ingredient(s), the percentage by weight of each active ingredient and the percentage by weight of inert ingredients in a pesticide product.

- Restricted Use Pesticide Statement (Chapter 7)

  This section identifies certain pesticide products that without additional regulatory restrictions would have been found to cause unreasonable adverse effects on the environment, including injury to the applicator. These products have been classified as *Restricted Use Pesticides* according to FIFRA §3(d).

- "Keep Out of Reach of Children" Statement (Chapter 8)

  This specific statement which is commonly referred to as the "child hazard warning" appears on almost all end use pesticide products except those pesticides which are intended for use on children or where it is demonstrated that children will not come in contact with the product, a modified statement is required.

- "Skull & Crossbones" Symbol & the word "POISON" (Chapter 8)

  These symbols identify pesticide products which are determined to be in toxicity category I based on at least one of the following acute toxicity studies: acute oral, acute dermal or acute inhalation toxicity study.

- Statement of Practical Treatment (Chapter 8)

  This section provides information to the pesticide user concerning appropriate first aid for the various routes of exposure if accidental exposure occurs.

- Environmental Hazards (Chapter 9)

  This section identifies any hazards to the environment and any necessary precautions to protect the environment.

- Physical or Chemical Hazards (Chapter 10)

  This section identifies any hazards such as flammability, explodability or dielectric breakdown.

- Directions for Use (Chapter 11)

  This section provides the instructions concerning how to use the product, the pests treated, the application sites, and any application equipment to be used.

- Re-entry Statement (Chapter 11)

  This section identifies any time period following treatment when entry into a treated area is restricted.

- Product Name (Chapter 12)

- Warranty Statement (Chapter 12)

  This is a disclaimer statement included voluntarily on most pesticide products by the registrant to reduce the company's liability concerning any damage caused by the use of a pesticide product.

- Storage and Disposal (Chapter 13)

  This section identifies the precautions necessary for storing the pesticide product and disposing of both any unused pesticide and the pesticide container.

- Registrant Name & Address (Chapter 15)

- Net Contents (Chapter 16)

  This section identifies the amount/weight of pesticide in the container.

- EPA Registration Number & Establishment Number (Chapter 17)

  This section identifies the company number and product number assigned to the pesticide product and the establishment number which identifies where the pesticide product was produced.

Final Printed Labels

The type size of final printed labels may be checked by using the following template. This is accomplished simply by overlaying the template on the final printed label and comparing the type size of the Signal Word, and the "Keep Out of Reach of Children" statement on the printed label with that of the template. Use the table at the top of the chart to determine the appropriate type size based on the size of the label.

[The following page is the template, which could be printed on a transparency for use.]

Label Type Point Chart

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

18 point POISON DANGER WARNING CAUTION

12 point KEEP OUT OF REACH OF CHILDREN

12 point Keep Out of Reach of Children

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14 point POISON DANGER WARNING CAUTION

10 point KEEP OUT OF REACH OF CHILDREN

10 point Keep Out of Reach of Children

---

12 point POISON DANGER WARNING CAUTION

8 point KEEP OUT OF REACH OF CHILDREN

8 point Keep Out of Reach of Children

---

10 point POISON DANGER WARNING CAUTION

6 point KEEP OUT OF REACH OF CHILDREN

6 point Keep Out of Reach of Children

---

6 point POISON DANGER WARNING CAUTION

6 point KEEP OUT OF REACH OF CHILDREN

6 point Keep Out of Reach of Children

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS
AND DOMESTIC ANIMALS
(Signal Word)

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RESTRICTED USE PESTICIDE

RE-ENTRY STATEMENT
(if applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

RESTRICTED USE PESTICIDE

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.

PRODUCT NAME

ACTIVE INGREDIENT(S): ..... %
INERT INGREDIENTS: ..... %
TOTAL: 100.00%

This product contains lbs of per gallon.

KEEP OUT OF REACH OF CHILDREN

Signal Word [Poison]

[Skull & Crossbones]

STATEMENT OF PRACTICAL TREATMENT (First Aid)

If Swallowed
If Inhaled
If on Skin
If in Eyes

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. _____ [Registrant Name]
EPA Establishment No. _____ [Address: City, State, zip code]

Net Contents _____

Directions for Use (continued)

CROPSITE

CROPSITE

CROPSITE

CROPSITE

CROPSITE

CROPSITE

CROPSITE

WARRANTY STATEMENT

Chapter 4 TYPES OF LABEL REVIEWS

Introduction

Label reviews are conducted for many types of submissions. How a reviewer proceeds with a label review depends on the type of action proposed by the registrant and whether the submission is a new submission (first time submitted to the Agency) or a resubmission (follow-up to a previous submission).

This chapter focuses on only those submissions that involve a label review and the specific "action codes" assigned to each of these submissions. The Registration Division (RD) has developed action codes for use in the "Pesticide Regulatory Action Tracking System" (PRATS).

The following is a list of the different types of submissions under which a label is reviewed:

A. Old Chemical, Without Data
B. Old Chemical, With Data
C. New Chemical
D. Technical Products and Manufacturing Use Products
E. Special Local Needs
F. Experimental Use Permits

Type of Action

Review Items A - F and Determine the Type of Action:

A. *Old Chemical, Without Data (Fast Track)*

This type of submission involves an old chemical (active ingredient, a.i.) previously registered for use as a pesticide, and with the current submission, "nothing new" is being proposed for the chemical or formulation. Such submissions are referred to as "Me-Too" submissions. They may either be amendments to labels of existing product registrations, or they may be applications for new product registrations. An example of such a submission is an amendment for the addition to the label of a new site or pest which has been accepted previously on labels of other products containing the chemical. Therefore, "nothing new" has been proposed for the chemical. For products composed of multiple active ingredients; the proposed addition must not be new to any of the a.i.'s.

☞ If nothing new is being proposed for the chemical, no additional data submissions are usually required, although data citations may be required (see 40 CFR § 152.80 through 152.97). If eligible for formulator's exemption data citation is not required. For example, when a crop is added to a label and it is a Me-Too submission, data must still be cited because residue data were originally required to register the use on the crop. Citation of data protects the rights of data submitter(s) by acknowledging the studies and offering to pay the submitters compensation for the cost of generating the data. If the submission is eligible for the Formulator's Exemption, data citation(s) are not required.

With a Me-Too submission, the subject product must be identical or substantially similar in uses and formulation to a currently registered pesticide, which the applicant should cite by the EPA registration number. The reviewer must ensure that the two products are substantially similar or identical in formulation. To make this determination, refer to the flow chart at the end of this chapter entitled *"PM Determination of Acute Toxicological Similarity"*. If the me-too product is a repack or an identical formulation, check the CSF with the CSF of the cited product to make certain the formulations are actually identically the same. The label reviewer must also assure that the use patterns are similar. In addition, if the label under review is a rodenticide or repellant, any changes in the inert ingredients should be cleared by the efficacy reviewers to make certain that the inert changes will not affect the efficacy of the product, (i.e., change of bait color, smell, texture, etc.).

If the submission is found toxicologically similar, the registrant must submit complete product chemistry data for technical products and Manufacturing Use Products (MPs) and End-use Products (EPs) that are produced by integrated systems. The product chemistry data should be sent to the Product Chemistry Review Section (PCRS) in the Registration Support Branch (RSB) for review. The PCRS reviewer will compare the concentrations of the same active ingredients and its associated impurities to determine substantial similarity in accordance with Standard Operating Procedure (SOP) 3068.2.

For all EPs that are formulated with a registered source product and are found to be toxicologically similar, product chemistry data are required in accordance with 40 CFR 158.150 through 158.190, and should be reviewed by PCRS for adequacy, completeness and validity of the data.

If the submission involves a Me-Too product that is found to be toxicologically dissimilar to the cited Me-Too registration when it is run through the flow chart, then the label review process is ended. The reviewer should prepare correspondence to the registrant noting that the Agency has determined that the cited registered product is not substantially similar and

that the registrant must find another product to cite, unless, of course, the registrant is willing to submit acute toxicity studies (revise PRATS code). The reviewer should then assign the action code from this chapter (listed below) and proceed to chapter 5 for instructions on how to open and close the entry into PRATS.

B. *Old Chemical With Data (Non-Fast Track)*

This type of submission involves an old chemical where "something new" is being proposed. For example, the proposal may involve an amendment or a registration with a new use, a new application rate, or a change in Precautionary statements. Basically, it is an action not previously approved by the Agency. Therefore, a more extensive review than a simple Me-Too comparison is necessary. Supporting data or data citations must accompany the submission. Review of the label will be based upon the conclusions of the data reviews from the other divisions (Health Effects Division (HED), Environmental Fate & Effects Division (EFED), Biological & Economic Analysis Division (BEAD)) or from the product chemists, toxicologists, or efficacy reviewers in RD. Generally a review from the other divisions (branches) will only affect a small portion of the label; the rest of the text should remain unchanged from the originally accepted label.

C. *New Chemical (New Label)*

This type of submission involves a new chemical (a.i.) which has never been registered by the Agency as a pesticide. It is up to the registrant to propose the labeling for the new chemical; RD does not construct the labeling to fit the profile of the chemical. The labeling should, however, follow the general label format discussed in chapter 3. The text is then referenced against the reviews from the other divisions who should have received a copy of the proposed label in the package sent to them for review.

D. *Technical Products and Manufacturing Use Products*

This type of submission involves a formulation which is used in the manufacture of other pesticides, either end-use products or other manufacturing use products. A technical product should be registered before any other manufacturing use products or end use products can be formulated from it and registered. If the technical source product is not intended to be registered, the data submissions for the MP and/or EP must include all the product chemistry data for that technical source as required in the 40 CFR 158.150 through 158.190. However, a technical/manufacturing use product (MP) must not be registered unless there is an end-use formulation also pending with the Agency in the case of a new A.I. [Pesticide Regulation (PR) Notice 87-7]

☛ A technical product is always itself a MP, however, not all MPs are technical products. The technical product contains only the a.i. with no impurities other than those that may have been introduced during the manufacturing process and contains no intentionally added inert ingredient other than those used to purify the a.i..

Again, the labeling of the technical/manufacturing use product must fit the basic label format, but will also include a statement such as "For Manufacturing Use Only" and a listing of the application sites.

E. *Special Local Need (SLN) - FIFRA Section 24(c)s)*

This is a submission which involves the states' authority under FIFRA section 24(c) to register additional uses of a federally registered pesticide. These additional uses are for distribution and use within a particular state to meet a "special local need" (SLN). Although SLNs can be approved for many different reasons and application sites, most involve use on crops. A certain crop grown within a state may be attacked by a particularly damaging pest, or state officials may expect it to be attacked sometime during the growing season, thereby creating a special pest problem. The pesticide (a.i.) must have an established tolerance associated with the crop, or be exempt from the requirement of a tolerance for that crop. SLN's also may pertain to uses for control of pests peculiar to one or several states.

Special Local Need labels are not stamped "Accepted", but they are reviewed for the required, pertinent information. The State is sent a letter acknowledging receipt of the application. If there is a problem with the SLN, (e.g. no established tolerance) a disapproval letter is sent. If something is omitted from the label, the State is informed, however, the SLN is not disapproved. Occasionally, it is necessary to send the SLN to HED for their review (e.g., if there is a question on the associated tolerance). In such cases, HED will review the label and make recommendations.

F. *Experimental Use Permits*

Experimental Use Permits (EUP), are required for authorizing extensive field trials [greater than ten (10) acres terrestrial; one acre aquatic] of unregistered pesticides or registered pesticides used at sites not claimed on the accepted registered labels. The EUP label will follow the standard label format, except that the front panel will include the statement "For Experimental Use Only."

Determine Action Code

Select the appropriate action code from the list below based on the submission type identified, and proceed to chapter 5 for details on entering the action into PRATS.

☛ Resubmissions are follow-up actions from registrants responding to objections we had to their original submissions due to data or labeling deficiencies. The entire label of the subject product should be re-reviewed with particular care to ensure that the registrant has answered all of the concerns we had expressed during the original review. The label reviewer should make sure that all the necessary revisions and corrections have been made to the label and that nothing else has been added to the label. It is not uncommon for registrants to fail to comply with all of revisions required, either inadvertently or because of disagreement. Note that resubmitted actions are assigned PRATS action codes that chronologically follow the action code assigned to the initial submission. Resubmissions may occur 2, 3, 4+ times after the original submission before the registrant "gets it right." There is, however, only one action code for every resubmission of a particular action, no matter how many times it is used. For example, 161 would be used over and over, as a follow-up to a 160.

Old Chemical Without Data:

160 - an application for a new registration of an old chemical that is a routine Me-Too.
Resubmission: 161.

170 - a Me-Too application for registration of an old chemical, with an additional use.
Resubmission: 171.

300 - an amendment submitted to revise an existing label, may not necessarily be a Me-Too action, but will not require any input (reviews) from other branches.
Resubmission: 301.

310 - an amendment to add a Me-Too use to an existing registration.
Resubmission: 311.

Old Chemical With Data:

165 - application for registration of an old chemical with minor changes requiring review from other divisions.
Resubmission: 166.

175 - application for registration of an old chemical with a new non-food or non-feed use, requiring review from other divisions.
Resubmission: 176

180 - application for registration of an old chemical, first new food or feed use.
Resubmission: 181.

305 - label revision amendment with data required, RD review only.
Resubmission: 306.

320 - label revision amendment with data requiring HED, EFED review.
Resubmission: 321.

325 - Me-Too label revision amendment with data requiring HED, EFED review.
Resubmission: 326.

370 - amendment to an existing registration adding a first food or feed use.
Resubmission: 371.

360 - action initiated by Agency
Resubmission: 361

655 - label submission resulting from a Reregistration action, ex. a data call-in.
Resubmission: 656.

674 - 8-month response to RED in support of Reregistration.
Resubmission: 675.

New Chemical:

100 - application for the registration of a new chemical, food or feed use.
Resubmission: 101

115 - application for the registration of a new chemical, nonfood or nonfeed use.
Resubmission: 116

130 - application for registration of a new biological, food or feed use.
Resubmission: 131.

145 - application for registration of a new biological, nonfood or nonfeed use.
Resubmission: 146.

Special Local Need:

580 - assigned to a 24(c) application for a food or feed use.
Resubmission: 581.

582 - an amendment to an existing food or feed SLN.
Resubmission: 583.

585 - assigned to a 24(c) application for a nonfood or nonfeed use.
Resubmission: 586.

587 - for an amendment to an existing nonfood/nonfeed SLN.
Resubmission: 588.

Experimental Use Permits:

700 - EUP for a new chemical, nonfood or nonfeed use.
Resubmission: 701. Amendment: 704, resubmission of the amendment: 705.

710 - EUP for a new chemical, food or feed use.
Resubmission: 711.
Amendment: 714, resubmission of the amendment: 715.

720 - EUP for a new biological, nonfood or nonfeed use.
Resubmission: 721. Amendment: 724, resubmission of the amendment: 725.

730 - EUP for a new biological, food or feed use.
Resubmission: 731. Amendment: 734, resubmission of the amendment: 735.

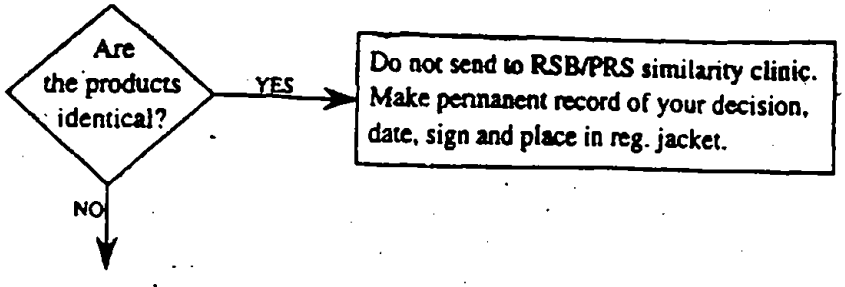
740 - EUP for an old chemical, nonfood or nonfeed use.
Resubmission: 741. Amendment: 744, resubmission of the amendment: 745.

750 - EUP for an old chemical, food or feed use. Resubmission: 751. Amendment: 754, resubmission of the amendment: 755.

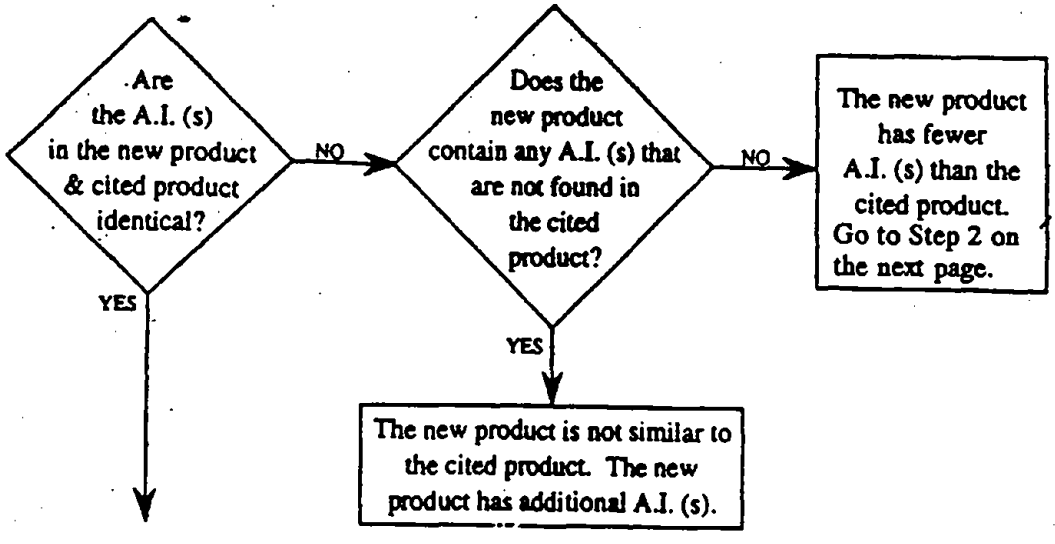
Determination of Acute Toxicological Similarity

Note: Similarity determinations are a complex process, and involve a great deal of judgement on the part of the reviewer making the comparison. Any process that involves judgement will not achieve 100% accuracy or consistency, particularly from one reviewer to the next. This flowchart is a conservative attempt to lay out the basic steps that are common to all similarity determinations and when used, will increase the likelihood that decisions are more consistent between reviewers.

This flow chart will not detect synergistic effects caused by the combination of certain ingredients (A.I.s and/or inerts). The Agency currently has no specific mechanism for detecting synergistic combinations. Section 6(a)(2) data submissions by registrants are probably the only means by which such combinations will be identified. One such combination is silica gel and chlorinated solvents. It has been reported that low concentrations of silica gel in combination with chlorinated solvents produce substantially more eye damage than products containing much higher concentrations of silica gel alone. It is believed that the chlorinated solvents displace the moisturizing properties of the eye thereby allowing the silica gel to abrade the eye surface.



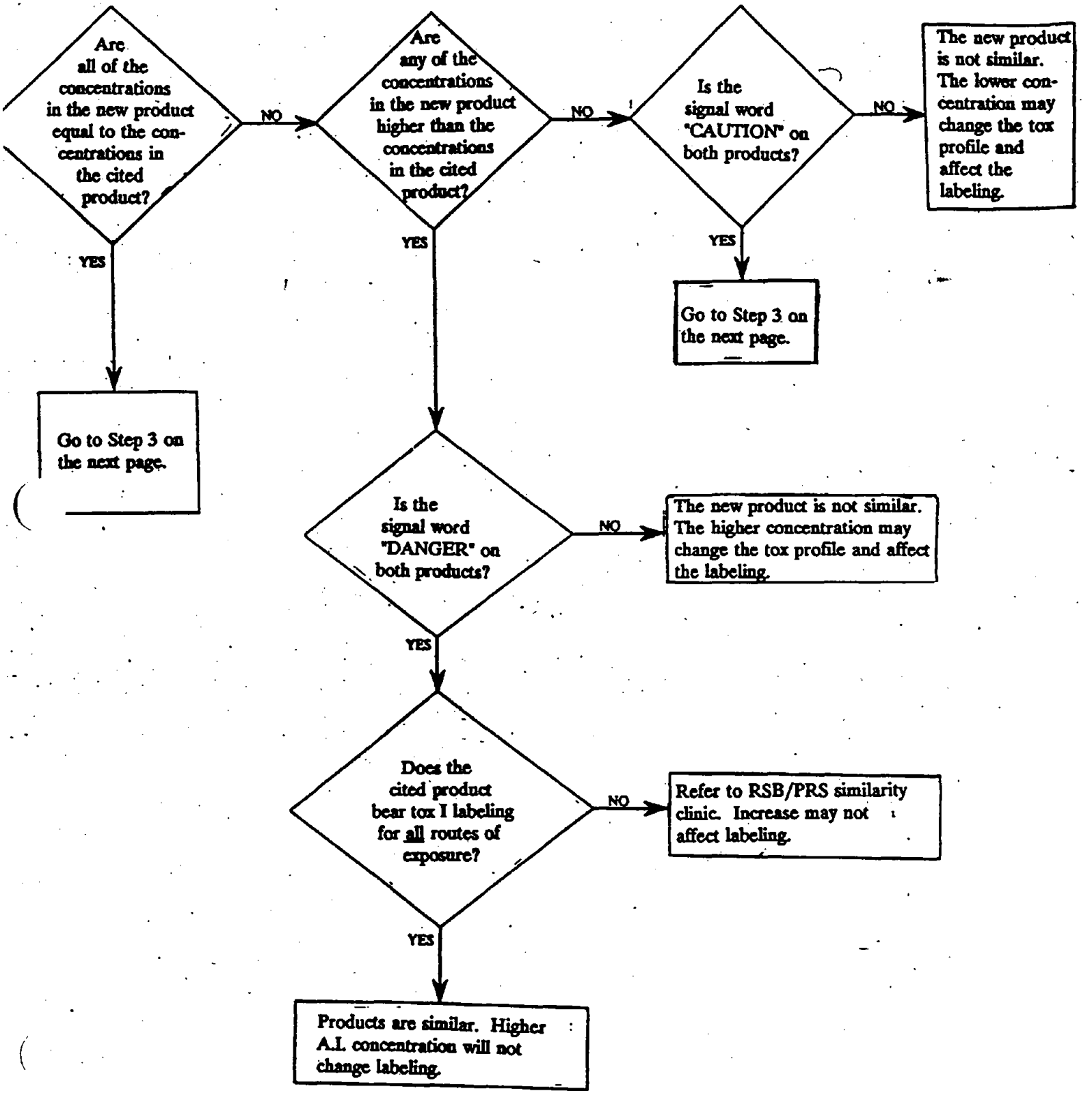
STEP 1 Type of Active Ingredient(s) (A.I.s)



Go to Step 2 on the next page.

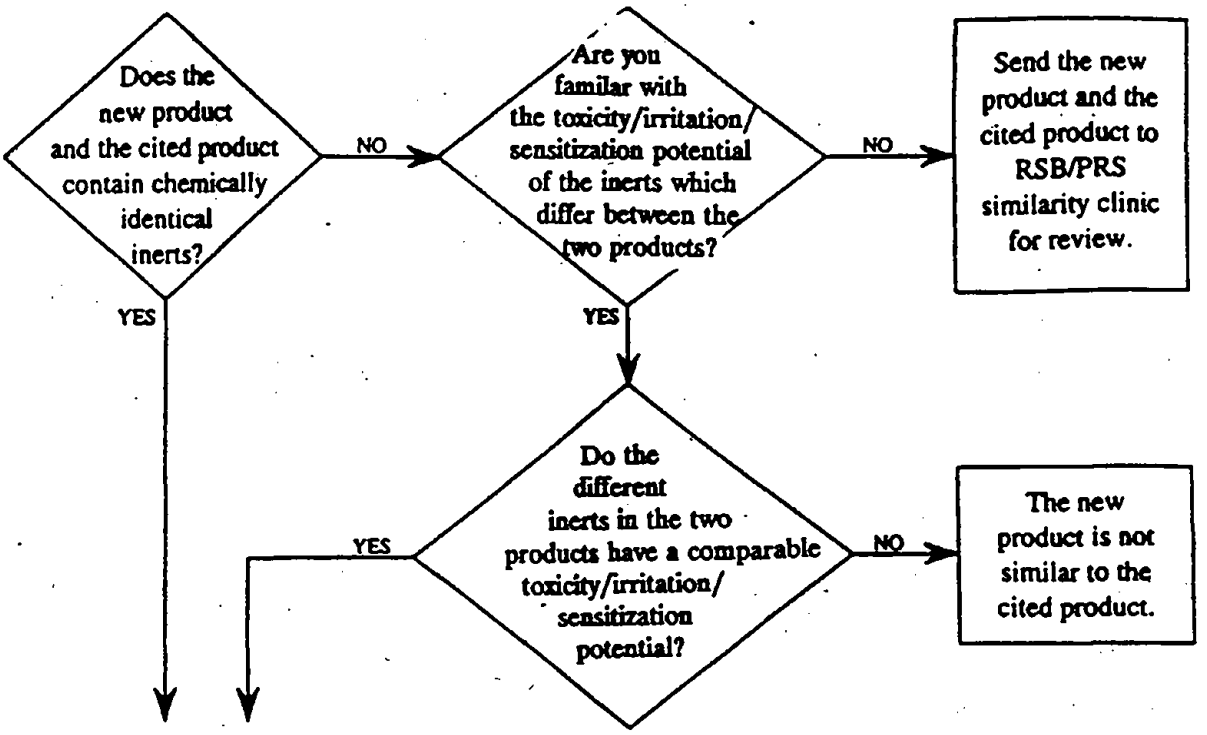
Determination of Acute Toxicological Similarity Continued

STEP 2 Concentration of Active Ingredient(s)

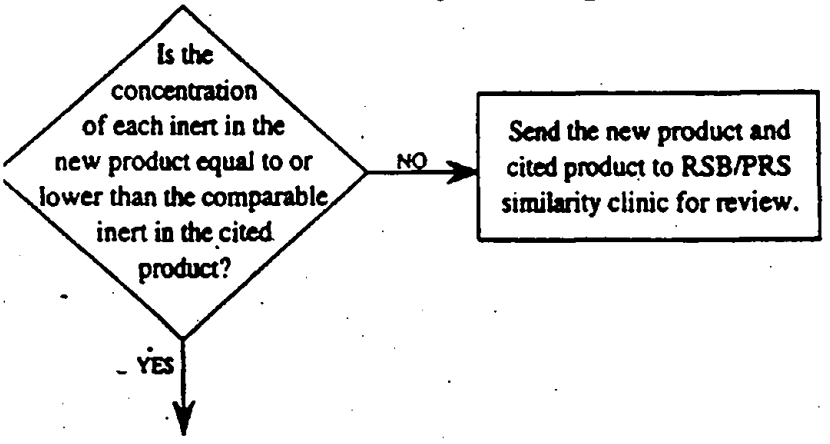


Determination of Acute Toxicological Similarity Continued

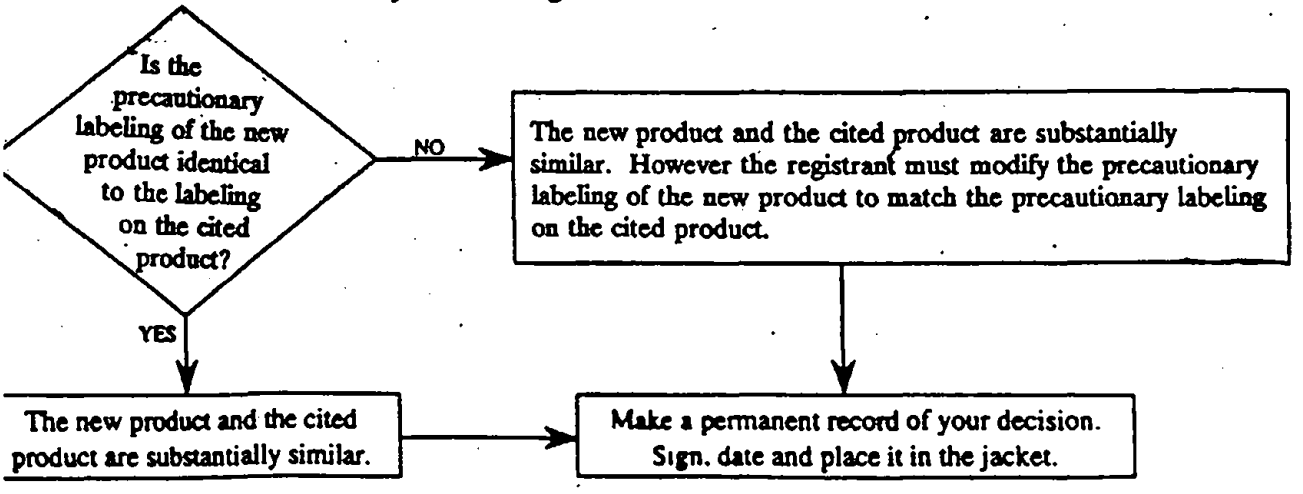
STEP 3 Type of Inert Ingredient(s)



STEP 4 Concentration of Inert Ingredients(s)



STEP 5 Precautionary Labeling



Chapter 5 **PRATS ENTRY**

Introduction

Any product regulatory action (primary submission or resubmission) should be entered into the "Pesticide Regulatory Action Tracking System" (PRATS) as soon as it is received on the team. This process enables the Registration Division (RD) to track activity on a product, since each action is dated, a history of a product's registration or a tolerance petition is composed. This information is then easily retrieved, as well as monitored for our response. The following outline provides the details for the PRATS entry of a submission (or a resubmission) requiring a label review. The "PRATS Users Guide" should be referred to for further information.

Logging in the PRATS Entry

1. PRATS Access

PRATS may only be accessed through the LAN system, therefore, before anything else, you must be logged into LAN. From the "OPP File Server Main Menu," make the following selections:

F3 OPP Applications II

F1 PRAT

F1 PRAT Pesticide Regulatory Action Tracking

From these selections, the "Title Screen" will appear. Press "Escape" to go to the "PRAT Main Menu." The product's file in PRAT may then be accessed by entering the Registration Number, File Symbol, or Experimental Use Permit (EUP) number. (a File Symbol is issued for an unregistered product - see chapter 17 regarding file symbols).

2. Submission Type

Chapter 4 of this manual provides information for determining the type of submission or action that you are dealing with. Once this has been determined, an action code can be assigned to the submission. Three types of actions will involve label reviews: a submission for a product already registered, a resubmission which is responding to

Agency concerns or questions from a previous submission, or an application for a new registration.

3. Submission Entry

Once the product file has been accessed, a screen will appear showing the "Case Information" in the upper half of the screen (the product name, main active ingredient, PM assignment, etc.), and the "Submission Information" in the bottom half of the screen. Press "Escape" for the following choices at the bottom of the screen (the menu):

Edit Case, New Subm., Add Resub., Case Ref., Select., Main Menu

Highlight "New Subm.," or "Add Resub.," by using the right or left arrow key and pressing Enter, or by pressing "N" or "A" (the first letter of your choice). PRATS will now ask you to fill in the blanks for the "Submission Inprocessing Information:"

A. The submission Bar Code is already assigned.

B. Select the team reviewer by using the up or down arrow key in the team window, and pressing Enter.

C. Enter the action code determined in chapter 4 by pressing the appropriate number keys. PRATS will respond with an Action Code window. Double-check the action code and its' descriptor, then press Enter. Note: if you decide the action code is not appropriate, PRATS will let you scroll up or down and look at other action codes.

D. Enter the dates for "Applied" (date on the Registrant's application or cover letter), "Received" (pin punch date) and "PM Received" (when the team received the action.

E. "Related ID's" may be entered if desired. These refer to Registration Numbers of Me-Too products or other related products. This field may be skipped by pressing Enter.

F. Add a descriptor - briefly (limited space) indicating what the submission is about. This field is also not required, but strongly recommended! The descriptor can be very helpful when scrolling through the PRATS submissions of a product, particularly if that product has been very active and has many

entries. Each submission may be highlighted and the descriptor will appear at the bottom of the screen.

G. Press Enter twice, the second time will save the information.

This entry will now appear as part of the regulatory "history" for this product in the entry listing entitled "Submission Information."

4. Resubmissions

If the action has been designated as a resubmission - representing a response by the Registrant to an Agency concern or question from a previous submission, it must be tied to or connected with the original action. More simply, if the Registrant applied for a label amendment and we turned them down or rejected the application, a resubmission may be the Registrant's attempt to "fix" whatever was wrong with the original submission.

When entering a resubmission into PRATS, you must identify the original submission. PRATS will ask for the original submission by showing a window with all primary action information. The appropriate choice is made by highlighting the item with the up or down arrow key, and pressing Enter. Once the choice is made, PRATS will automatically assign the action code. This code is designed to chronologically follow the primary action code, i.e., 160; 161 for the resubmission(s).

5. New Registrations

If the submission is an application for a new registration, PRATS will not let you add the primary submission until the Case Information section is complete. The Front End Processing Unit (FEPU) has set up the basic product information, but PRATS will force you to first complete the "Active Product Chemistry" section; FEPU does not do this. Press "Escape" to access the menu, then "Edit Case." After verifying the company number press "Page Down" to the Active Product Chemistry section. The active ingredient must be entered, either by Product Chemistry (PC) Code or name. Then the percentage concentration (label claim) must be entered. This process must be repeated for each active ingredient. Pressing Escape twice will save this information and exit you back to the Submission Information.

☞ The reviewer should note that the information in this chapter does not include submissions which must be sent for review to HED, EFED or other Branches in

Registration Division (RD). Sending a submission on for review requires the creation of a "Bean Sheet." Please refer to the *PRATS User Guide* for information on creating bean sheets. Reviews from other groups may or may not affect product labeling.

Completion of Review.

When a label review is completed, the product file is again accessed through the PRATS Main Menu via the Registration Number. Once the action to be logged out is highlighted, press Enter and options will appear at the bottom of the screen. Choose "Edit Submission," then "Outprocessing." The "Submission Outprocessing Information" section will request the following information:

Response Code: ___ Response Date: __/__/__ 75 Day _ Due Back: __/__/__
Comm: _____

The Response Code and Date are required fields. Answer "Y" (yes) to 75 Days ___ if you want the Registrant to respond within 75 days, the date this response is due back will be automatically entered. This field is not required, you may answer "N" for no, and press enter to skip the Due Back ___ space. As with the incoming submission, a descriptor under "Comments" for the response is very helpful. The comment will appear at the bottom of the screen when the product file is accessed and the submission is highlighted.

The following are the response codes that may be used when a label review is completed (these are not all the response codes that RD uses when responding to submissions.):

"11" Objection - Data Deficiency. A data deficiency will affect a label review if supporting data was necessary for the proposed action and was either absent or deficient.

"12" Objection - Label Deficiency. Any type of problem with label text which would cause the proposed action to be denied should be logged out of PRATS with this code.

"13" Objection - A combination of both data and label deficiencies.

"17" Proposed new product or amendment to a label is acceptable, no conditions associated with the acceptance.

"18" Registration of a new product or an accepted amendment that are subject to conditions.

The reviewer should note that when a 17 or 18 response code is used, PRATS will request answers to five questions; what the method of data support is (cite-all, selective or not applicable), whether the product is in child-resistant packaging, whether it is a restricted use product or not, whether it is an exclusive use, and whether it is a manufacturing use or not.

Chapter 6 **INGREDIENT STATEMENT**

Introduction

This chapter covers the ingredient statement section of the label, which must bear the name(s) and percentage(s) by weight of each active ingredient (a.i.) and the total percentage weight of all inert ingredients (including any impurities associated with the active ingredient).

General Requirements

Review the proposed label for the following items: a clear and prominent ingredient statement which contains the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The definition of *Active Ingredient* is: Any substance that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant. The definition of *Inert Ingredient* is: Any substance other than an active ingredient which is intentionally added to a pesticide product, such as solvents, stabilizers, spreaders or stickers, synergists, preservatives, surfactants, defoamers, etc.

The label's ingredients statement includes not only the percentages of active and inert ingredients, but also, if applicable, associated acid or metallic equivalents. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" must not be used as a heading for the ingredient statement.

Follow through each section below as you review the proposed label:

Appearance of the Ingredient Statement

1. The ingredient statement must contain the following items:

   A. The headings "ACTIVE INGREDIENT" and "INERT INGREDIENT" (or plural forms of these terms when appropriate), must be the same type size, aligned to the same left margin and equally prominent.

   B. The name and percentage by weight of each active ingredient must be placed under the ACTIVE INGREDIENT heading and the total percentage by weight of all inert ingredients must be placed under the heading INERT INGREDIENT.

   C. The percentages must be aligned by the decimal.

2. The ingredient statement must be presented clearly, and be neither obscured nor crowded by surrounding text.

3. Percentages cannot be expressed in a range of values, such as "20-25%".

Several examples of correct ingredient statements are shown in this chapter.

Location of Ingredient Statement

1. The ingredient statement **is required on the front panel** of the label. However, if the pesticide package is extremely small or is irregular in shape making it difficult to place the ingredient statement on the front panel of the label, permission may be granted, upon written request (this could be a part of the application), for the ingredient statement to appear on the back or side panel of the label. [40 Code of Federal Regulations (CFR) 156.10(g)(2)(i)]

2. The preferred location is immediately below the product name. (Refer to the sample label format in Chapter 3)

3. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on the outside container or wrapper.

4. The text of the ingredients statement must run parallel with, and be clearly distinguished from other text on the panel and must not be placed in the body of other text. [40 CFR 156.10(g)].

Names To Be Used In The Ingredient Statement

Review the names used on the proposed label under the ingredient statement. Check these names in the Reference Files System (REFS) on the LAN. If none of the names are shown in REFS, perhaps you have a new chemical. If so, check with your PM for the correct procedures. Look at each section below to determine the correct names to be used in the ingredient statement.

1. Common Name

   A. Common names are established by the American National Standards Institute (ANSI) or a name accepted by the Administrator, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 25(c)(6). If the common name has been accepted by ANSI, it may be used in conjunction with the proper chemical name in the ingredient statement.

   B. Check REFS to determine the accepted common name. "(ANSI)" will be shown after the accepted common name in the Chemical Name list. An additional source for this information is the EPA Manual, *Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels*, 4th edition (December 1979).

2. Chemical Name

   A. If there is no accepted common name, the chemical name alone must be used. If there is an accepted common name, the full chemical name must immediately follow the common name on the line under the ACTIVE INGREDIENT heading.

   B. Chemical names must be given according to the nomenclature used in the Chemical Abstracts (CA) Chemical Substance Index, published by the American Chemical Society. REFS reflects the correct chemical name: the entry found with the "9CI" (i.e., Ninth Collective Index) designation at the end of the name. [*REFS tip*: hit the Enter key on the chemical name to see the complete chemical name, which may not appear on the line if the name is too long to fit on the line.]

3. Biological Name

   ☞ If the active ingredient is a microbial agent, the microbial agent must be identified by genus, species and strain (if there is one). Again, this name must be identical to the name shown in REFS.

4. Descriptive Name

   ☞ Descriptive names, approved by the Agency are to be used in the ingredient statement if there is no accepted common name and no distinctive chemical name. Examples are: "Tobacco dust", "Egg solids" or "Dried blood". Approved descriptive names are listed in REFS, and the name shown on the proposed label must be identical to the name found in REFS.

5. What is NOT acceptable:

   ☞ Trademark or proprietary names may not be used in the ingredient statement unless such names have been accepted as a common name by the Administrator under the authority of FIFRA section 25(c)(6). Trademark names and other information concerning a particular ingredient may appear by reference in a footnote to the ingredient statement.

Criteria for Active or Inert Status and Related Compounds

1. The criteria for ingredients determination of active or inert status is located in 40 CFR 153.125 (and PR Notice 81-4). An ingredient will be considered an active ingredient if, by itself, it has the capacity to function as a pesticide or has the ability to elicit or enhance the pesticidal effect in another compound (i.e., the pesticidal activity is substantially increased due to the interaction of the compounds). Ingredients such as stickers and other adjuvants which function simply to enhance or prolong the activity of an active ingredient are not generally considered to be active ingredients.

   Note: Chemicals which are normally considered to be active ingredients in other pesticides may be contained in a product formulation as a preservative of the formulation, or as a plant nutrient, or some other non-pesticidal use. In this case, the chemical would be an inert ingredient and not declared on the label.

2. If one or more related compounds is pesticidal to the target pest, it must be included under the ACTIVE INGREDIENT heading.

   Example:

ACTIVE INGREDIENTS:	
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, α isomer	20.0%
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, β isomer	3.0%
INERT INGREDIENTS:	77.0%
Total	100.0%

3. Related compounds with no determined active/inert status must be included under the total percentage of the INERT INGREDIENT heading without designation as related compounds or by name (PR Notice 81-4).

4. Unless declared as an active ingredient, related compounds must not be included in expressing percent acid or metallic equivalents; nor in the declaration of "pounds active ingredient" or "acid (or metallic) equivalents per gallon" under the ingredient statement. (PR Notice 81-4).

Statement of Percentages

Every label reviewer should be aware that the Office of Pesticide Programs (OPP) is in the process of converting all labels over to the following policy: the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the **nominal concentration** of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product. **After July 1, 1997, all pesticide ingredient statements must be expressed as nominal concentration.**

Reviewers of proposed labels for products subject to deterioration, such as sodium hypochlorite, should note the section later in this chapter on Deterioration.

1. As stated above, the percent by weight of the ingredients must be stated as the nominal concentration. The upper and lower certified limits on the Confidential Statement of Formula (CSF) are to be in accordance with 40 CFR 158.175. [Pesticide Regulation (PR) Notice 91-2]

2. The definition of *Nominal Concentration* is: The amount of an ingredient which is expected to be present, expressed as percentage by weight in a typical sample of a pesticide product at the time the product is produced. The nominal concentration of the active ingredient in the product will be based on the nominal concentration **in the source product**. [Example: If the nominal concentration of the active ingredient source is 80% (as declared on the CSF, column 10) and percent by weight of the formulated product is 20% (CSF, column 13b), the nominal concentration based on the pure form of active ingredient is 16% (i.e., 20% x 0.80)]

3. Products are to convert to nominal concentration under the schedule below:

   A. Beginning July 1, 1991, all new product registrations submitted to the Agency were to comply with the requirements of PR Notice 91-2.

   B. Registrants having products subject to reregistration under FIFRA section 4(a) were to comply with the requirements of PR Notice 91-2 when specific products are called in by the Agency under Phase V of the Reregistration Program.

   C. All other products that are not subject to (A.) or (B.) above will have until July 1, 1997, to comply with PR Notice 91-2. Applications should note "Conversion to Nominal Concentration" on the application form.

4. The percentages of each active ingredient must be expressed in terms of weight-to-weight (i.e., weight of active ingredient present in the total weight of the product).

5. The percentage for inert ingredients is 100% minus the total percentage(s) of the active ingredients.

6. The sum of percentages of the active and the inert ingredients must be 100%. The term "100%" need not be expressed as part of the ingredient statement.

7. For ingredient statements which reflect the fact that the active ingredients is the only component of the product, the inert ingredients header is not necessary. Example:

   ACTIVE INGREDIENTS:
   chlorine 100.0%

8. If the proposed label is for a liquid formulation, check the Directions For Use section: if any of the use directions of the pesticide product are expressed as a certain weight of

active ingredient per unit area (such as, pounds per acre), a statement of the weight of the active ingredient per unit volume of the pesticide formulation must also appear at the end of the ingredient statement. This is very important when calculating the use rates. An example of this would be, "One gallon contains 4 pounds of the active ingredient (chemical).".

Deterioration

Pesticides which change in chemical composition significantly over time do not use the nominal concentration in the ingredient statement. They must meet the following labeling requirements:

1. In cases where it is determined that a pesticide formulation changes chemical composition significantly over time, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date].". [40 CFR 156.10(g)(6)(i)]

2. The product must meet all label claims up to the expiration time indicated on the label. To insure effectiveness, the following labeling statement is required for sodium hypochlorite (because of its rapid degradation). This requirement is for sodium hypochlorite products with a label claim of 5.25 - 12.5% active ingredient.

> "Degrades with age. Use a test kit and increase dosage as necessary to obtain the required level of available chlorine."

Specific Designations for Some Ingredient Statements

Some pesticide ingredients require specific designations on the ingredient statements for proper clarification and identification. For instance, some bromated or chlorinated compounds may require a reference in the ingredient statement to the available chlorine or bromine. Examples of some of these specific designations are shown below:

1. Microbial Pesticides

Microbial and Biochemical pesticides are generally subject to the same labeling provisions as conventional pesticides. They are viewed essentially the same as chemical pesticides with respect to label requirements, except for differences with the ingredient statement.

Products containing live microorganisms must indicate the equivalent number of viable units (spores, cells, colony forming units, etc.) per unit weight of product.

For Bacillus thuringiensis (Bt) products, the active ingredient declaration must be based upon percent by weight of insecticidal toxin(s) present. Strain variety, as well as percent active ingredient declared for each order of insects affected must appear on the label. (PR Notice 72-6 superseded PR Notice 71-6). The use of potency units expressed in terms of International Units (IU) per milligram of product is required unless the percent toxin has been shown to predict field activity. If used, it should appear on the label below the ingredient statement and should be followed by the statement "Potency units should not be used to adjust use rates beyond those specified in the Direction for Use section.".

Example of an ingredient statement for a Bt product:

ACTIVE INGREDIENTS:
Bacillus thuringiensis subspecies kurstaki
Lepidopteran active toxin 3.0%
Dipteran active toxin(s) 2.0%
INERT INGREDIENTS: 95.0%
Total 100.0%
Potency: 40,000 International Units per milligram of this product. Potency units should not be used to adjust rates beyond those specified in the Directions for Use section.

Since the reregistration data on percentage of active ingredients have not been reviewed for Bt products, labels for many Bt products still list the percentage a.i. based on potency. For potency based ingredient statements for lepidopteran active Bt products, 500,000 International Units (IU)/mg product = 100% active ingredient. Percent active ingredient is calculated on the product potency compared to the 100% active ingredient assumption of 500,000 IU/mg. Thus, a 16,000 IU/mg product would be (16,000/mg) x (100%/500,000 IU/mg) = 3.2.%

Subdivision M (Pesticide Testing Guidelines) *Microbial and Biochemical Pest Control Agents* (July 1989) addresses this topic.

Certified Limits Can Be Expressed As:

(i) Microbial Pest Control Agents (MPCA) units/unit weight or volume
(ii) International Units of Potency per unit weight
(iii) Weight percent of product

Items (i) and (ii) may be determined using biological, genetic, biochemical, serological or other appropriate data.

Examples of ingredient statements for other microbial products:

A.

ACTIVE INGREDIENT:
Pseudomonas cepacia type Wisconsin ..... 3.8% (by wt.)
INERT INGREDIENTS: ..... 96.2% (by wt.)
Total ..... 100.0% (by wt.)

Contains at least 50 million viable cells/lb (10^5 cells/gram).

B.

ACTIVE INGREDIENTS:
Trichoderma harianum (ATCC 20476) ..... 16.6% W/W
Trichoderma polysporum (ATCC 20475) ..... 16.6% W/W
INERT INGREDIENTS: ..... 66.8% W/W
Total ..... 100.0% W/W

Minimum 4.5 million colony forming units (CFU) per pound (454 grams)

2. Biochemical Pesticides

The ingredients statement for a product whose active ingredient is a naturally occurring plant regulator, (such as cytokinin, auxin, or gibberellin) for which quantitative chemical methods and units are not available, must be stated in an acceptable and generally recognized bioassay unit. Example:

ACTIVE INGREDIENT:
Cytokinin (equivalent to 200 ppm kinetin activity) 3.0%
INERT INGREDIENTS: 97.0%
Total 100.0%

3. Pheromone Products

The ingredient statement for pheromone dispenser labels show the pheromone in mg per dispenser as a footnote. This must be as reflected on the CSF.

Example:

ACTIVE INGREDIENT:
pheromone* 1.0%
INERT INGREDIENTS: 99.0%
Total 100.0%
*x mg per dispenser

4. Salts, Amine or Ester of Acids

If the active ingredient is a salt, amine or ester of an acid, the label must declare in a substatement under the ingredient statement the percentage equivalent of the acid.

Example:

ACTIVE INGREDIENTS:
Isooctyl ester of 2,4-Dichlorophenoxyacetic acid* 12.0%
Isooctyl ester of 2-(2,4-Dichlorophenoxy) propionic acid** 10.0%
INERT INGREDIENTS: 78.0%
Total 100.0%
*2,4-Dichlorophenoxyacetic acid equivalent, 9.5%
**2-(2,4-Dichlorophenoxy)propionic acid equivalent, 9%

5. Pesticide products whose active ingredients are copper salts or complexes, must declare the chemical name of the copper complex as active ingredient and the equivalent metallic copper declared in a substatement.

Example:

ACTIVE INGREDIENT:
Copper naphthenate* 93.2%
INERT INGREDIENTS: 6.8%
Total 100.0%
*Metallic copper equivalent, 22%

This type ingredient statement declaration is applicable to zinc, also. For example, Zinc naphthenate must be expressed as percent metallic zinc equivalent.

6. Metal Ion Exchange Resins

Any metal (e.g., Ag or Cu) used as pesticide, when bound to an ion exchange resin, must be declared on the label as the percent metallic equivalent with a footnote immediately below the ingredient statement specifying the identity and amount of the ion exchange resin which was used.

7. Sodium Chlorate Products

All pesticide products containing sodium chlorate must include a fire retardant in the formulation. These labels must bear in the vicinity of the ingredient statement, a statement indicating that the product contains a fire retardant. If the proposed label is a sodium chlorate product, check the CSF to verify that the product does indeed contain a fire retardant (column 15, Purpose in Formulation).

8. Additional Statements in the Ingredient Statement

Pesticide products which contain arsenic in any form, must include a substatement of the percentages of total arsenic and water-soluble arsenic calculated as elemental arsenic. The following is an example of this substatement:

"Total arsenic, all in water soluble form, expressed as elemental = xx%"

Formulations containing greater than 10% petroleum distillates, xylene or xylene range aromatic solvent must reflect the statement "Contains petroleum distillates, xylene or xylene range aromatic solvent" immediately below the ingredient statement as a footnote to the inert ingredients.

9. Fertilizer-Pesticide Combinations

Pesticides that are formulated in combination with fertilizers must declare in the label ingredient statement the same way as the other pesticides. The fertilizer composition must be separate from the pesticide ingredient statement and must not detract from or obscure the required pesticide labeling statements. Various fertilizer combinations may be registered under the same registration number provided that the percentage of active ingredient remains the same.

Inert Ingredients

1. Special Labeling Requirements for Inerts of Toxicological Concern (List 1)

According to PR Notice 87-6, issued May 12, 1987, registrants of products containing one or more inert ingredients on List 1 (inert ingredients of toxicological concern) were required to amend their label to include the statement: "This product contains the toxic inert ingredient (name of inert).". This statement was to be placed in close proximity to the ingredient statement in a type size comparable to other front panel text. The Release for Shipment date was October 20, 1988. Most registrants substituted a List 3 or 4 inert for an inert on List 1. In general, after the PR Notice was issued EPA did not register any new products containing a List 1 inert. The PR Notice 87-6 contains all the lists of inert ingredients for your reference. [Refer to Chapter 8 also]

The List 1 inert ingredients are as follows:

LIST 1. -- INERTS OF TOXICOLOGICAL CONCERN

CAS No.	Chemical Name
62-53-3	Aniline
1332-21-4	Asbestos fiber
1332-21-9	1,4-Benzenediol
7440-43-9	Cadmium compounds
56-23-5	Carbon tetrachloride
67-66-3	Chloroform
106-46-7	p-Dichlorobenzene
103-23-2	Di-(2-ethylhexyl)adipate
78-87-5	1,2-Dichloropropane
117-87-8	Di-ethylhexylphthalate
66-12-2	Dimethylformamide
123-91-1	Dioxane
106-89-8	Epichlorohydrin
110-80-5	2-ethoxyethanol
111-15-9	Ethanol ethoxyacetate
107-06-2	Ethylene dichloride
109-86-4	Ethylene glycol monomethyl ether
140-88-5	Ethyl acrylate
110-54-3	n-Hexane
302-01-2	Hydrazine

CAS No.	Chemical Name
78-59-1	Isophorone
7439-92-1	Lead compounds
568-64-2	Malachite green
591-78-6	Methyl n-butyl ketone
74-87-3	Methyl chloride
75-09-2	Methylene chloride
25154-52-3	Nonylphenol
127-18-4	Perchloroethylene
108-95-2	Phenol
90-43-7	o-Phenylphenol
75-56-9	Propylene oxide
8003-34-5	Pyrethrins
81-88-9	Rhodamine B
10588-01-9	Sodium dichromate
26471-62-5	Toluene diisocyanate
79-00-5	1,1,2-Trichloroethane
56-35-9	Tributyl tin oxide
79-01-6	Trichloroethylene
1330-78-5	Tri-orthocresylphosphate (TOCP)
78-30-8	Tri-orthocresylphosphate (TOCP)

2. Inert ingredients are not required to be identified individually in the ingredient statement label except when determined that such inert ingredient may pose a hazard to man or the environment. In such a situation, it may be required that the name of the inert be listed in the ingredient statement. However, a registrant may voluntarily list an inert ingredient or all inert ingredients as long as there are no advertising or marketing claims made.

Chapter 7 **USE CLASSIFICATION**

Introduction

Pesticide products may be classified as restricted use pesticides (RUP), general use, or unclassified. A product may be classified as a restricted use pesticide when the product meets certain criteria indicating that it poses a threat to man, non-target organisms or the environment and labeling cannot sufficiently mitigate the hazard (40 §CFR 152.170). The sale and use of restricted use pesticides are limited to certified applicators (or those under the direct supervision of a certified applicator). The use of unclassified products are not limited in any manner except in cases where a product bears labeling limiting the use to a specific group such as veterinarians, etc.

Unclassified Products

1. Determination of Classification

Review the criteria below which identify unclassified products.

A. The product under review is a me-too registration, and the product cited as substantially similar is unclassified.

B. The product under review is a new product for which data are submitted and none of the following data reviews indicate that the product should be considered for restricted use classification.

- Ecological Effects Branch (EEB) Review: Assesses the toxicity to fish, wildlife, and endangered species.
- Environmental Fate & Groundwater Branch (EFGB) Review: Assesses the possibility of groundwater contamination and persistence in soil.
- Occupational & Residential Exposure Branch (OREB) Review: Assesses the hazard of handler exposure.
- Precautionary Review Section (PRS) Review: Assesses the acute toxicity of the product.

C. The product under review is a manufacturing use product (MP). MP's must bear labeling indicating that the product is used solely for formulating end-use products. Please note that a MP may not have end-use directions (40 CFR § 152.166). However, the label for a MP should list the uses identifying the types of end-use products into which it may be formulated. Do not confuse this list of uses with end-use directions. A separate registration is required for end-use products.

D. The product under review does not contain active ingredient(s) and use(s) which have been classified as restricted use.

To check: Refer to 40 CFR §152.175, or if the product is currently registered, the RUP classification can be checked on "Page 2" of the product information. Another reference source for this information is the Pesticide Information Network (PIN). This database includes registration numbers of Restricted Use Products and lists the reason for restricted use classification. (Instructions for accessing data base are located at the end of this chapter).

If the label under review meets any of the above criteria, then the product is unclassified. Review Item 2. below and then Skip to the next chapter. If the label under review does not meet any of the above criteria, then the product may be classified as a RUP. Go to the next section entitled "Products Which May Be Classified as a RUP".

2. Discontinuance of Term "General Use"

Unclassified products with one exception do not bear the term "General Use" as discussed in 40 CFR § 152.160. The one exception involves products containing the active ingredient, chlorine gas. These products are the only products which may bear the classification "General Use". If the label under review involves a product containing an active ingredient other than chlorine gas and the label contains the pesticide classification "General Use", instruct the registrant to remove the designation in accordance with Policy and Criteria Notice 2460.2 dated 1/30/85.

Products Which May Be Classified as RUP

1. Determination of Classification

Review the criteria below to determine whether the product should be classified as a RUP.

A. If the product under review is a me-too registration and the cited product is classified as a RUP, then the product label under review must bear the Restricted Use classification. Go to Section 2 below on "Labeling Requirements for Restricted Use Pesticides".

B. If the product under review was accompanied by data and any of the data reviews from EEB, EFGB, or OREB indicate that the product should be classified as a RUP, then the product label under review must bear the Restricted Use classification. Go to Section 2 below on "Labeling Requirements for Restricted Use Pesticides".

C. If the product under review was accompanied by data and the data review from PRS indicates that the product meets the criteria for consideration as a RUP, then the PM team member should check with the Product Manager to determine if the product should actually be classified as a RUP.

If the PM determines that the product should not be classified as a RUP, then the PM team member must include a memo to the file noting this decision. The memo must specify the basis for the decision under 40 CFR § 152.170 (e) and detail the reason why the product was not classified as a RUP including the alternative labeling language required. The PM team member must sign and date the memo and place it in the registration jacket. The PM team member should make sure the product label under review does not bear any use classification (Refer to Section 2 above on Discontinuance of Term "General Use"). The remainder of this chapter can be skipped as it is not relevant to the label under review.

If the PM determines that the product should be classified as a RUP, go to the Section 2 below on "Labeling Requirements for Restricted Use Pesticides".

2. Labeling Requirements for Products Classified as Restricted Use Pesticides

The product under review is a Restricted Use Pesticide. Restricted use pesticides are subject to the labeling requirements specified in 40 CFR § 156.10 (j) (2) and PR Notice 93-1. Check the label under review to make certain that the label meets the RUP labeling requirements listed below:

A. The statement "Restricted Use Pesticide" appears at the very top of label's front panel.

B. No other wording or symbols may appear above the RUP statement.

C. RUP statement is followed by the reason for RUP classification.

D. RUP statement is enclosed in a box so that it is more visible on label.

E. RUP statement appears with sufficient prominence in relation to other label text and graphics so as not to be overlooked [(40 CFR 156.10 (j) (2)].

F. The label must bear the phrase "Restricted Use Pesticide" under the heading "Directions for Use" (40 CFR 156.10 (i) (2) (ii).

G. The phrase "Restricted Use Pesticide" meets the minimum type size requirements. If type size appears small, the label reviewer should remind the registrant of the type size requirements specified in the code of federal regulations at 40 CFR 156.10 (h) (1) (iv).

H. The label may not bear any type of designation indicating that certain uses are restricted and other uses are not restricted. If the product has uses which are not restricted and the registrant desires to market or make available these uses to the general public, then the registrant must seek a separate registration for these uses.

I. Label must bear the correct RUP statement [40 CFR 156.10(j)(2)(i)(B] or other specific statements required for certain chemicals as listed below.

(1) General RUP Statement listed at 40 CFR 156.10(j)(2)(i)(B).

☞ "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) Pesticides Requiring A Specific RUP Statement

(NOTE: Additional specific RUP statements will be added to the manual as they are identified. Check with your product manager to determine if a specific RUP statement is required.)

Ethyl Parathion

- "For retail sale only to certified commercial aerial applicators or persons under their direct supervision. For use only by certified commercial aerial applicators. Direct supervision for this product is defined as the certified commercial aerial applicator being physically present during mixing, loading, repair and cleaning of application equipment. Certified commercial aerial applicators must also ensure that all persons involved in these activities are informed of the precautionary statements."

Sodium Fluoroacetate (when used on sheep or goats to kill depredating coyotes)

- "Collars shall be sold or transferred only by registrants or their agents and only to certified Livestock Protection Collar applicators. Collars may be used only by specifically certified Livestock Protection Collar applicators or by persons under their direct supervision."

Accessing the PIN

The Pesticide Information Network (PIN) is an interactive database containing current and historic pesticide information. The system is operational 24 hours a day, and is all menu driven, easy to use and can be accessed by anyone with a computer through the LAN (modem pool). The phone number for accessing the PIN is **305-5919**. The system is run from a computer on the tenth floor on Crystal Mall 2 (EFED/EFGB). Once into the PIN, simply follow the instructions in the menu driven system. Various reports can be down loaded from the Restricted Use Products file. Call Leslie Davies-Hilliard for user support at 305-7499.

Chapter 8 PRECAUTIONARY LABELING

Introduction

The precautionary labeling provides the pesticide user with a general idea of the potential toxicity, irritation and sensitization hazard associated with the use of a pesticide. The precautionary labeling also identifies the precautions necessary to avoid exposure, any personal protective equipment (PPE) which should be used when handling a pesticide and the statements of practical treatment in case of accidental exposure.

This chapter is organized into the following four major parts:

Background Information
Determination of Products Subject to the Worker Protection Standard
Precautionary Labeling
Statements of Practical Treatment (First Aid)

Background Information

1. Acute Toxicity Data

The precautionary labeling which includes the signal word, personal protective equipment and statements of practical treatment is normally determined by six acute toxicity studies and product composition. The acute oral, acute dermal and acute inhalation studies measure the lethality of a product via the designated route of exposure. The primary eye irritation and primary skin irritation studies measure the severity of irritation or corrosivity caused by a product. The dermal sensitization study determines whether a product is capable of causing an allergic reaction. With the exception of the dermal sensitization study each acute toxicity study is assigned a toxicity category (See Table 1 below).

Table 1 - Toxicity Categories

Study	Category I	Category II	Category III	Category IV
Acute Oral	Up to and including 50 mg/kg	> 50 thru 500 mg/kg	> 500 thru 5000 mg/kg	> 5000 mg/kg
Acute Dermal	Up to and including 200 mg/kg	> 200 thru 2000 mg/kg	> 2000 thru 5000 mg/kg	> 5000 mg/kg
Acute Inhalation	Up to and including 0.05 mg/liter	> 0.05 thru 0.5 mg/liter	> 0.5 thru 2 mg/liter	> 2 mg/liter

Study	Category I	Category II	Category III	Category IV
Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or irritation clearing in 8-21 days	Corneal involvement or irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation (no irritation or slight erythema)

2. Guidance Documents Used to Determine Labeling

The Code of Federal Regulations specifies both acute toxicity categories [40 CFR 156.10(h)(1)(i)] and precautionary labeling statements associated with each toxicity category [40 CFR 156.10(h)(2)]. These acute toxicity categories and precautionary labeling statements are not currently being used by the Agency as they are less detailed and provide less protection for pesticide users than other guidance. The 40 CFR § 156.10(h)(2)(i) states that precautionary labeling statements listed therein can be modified or expanded to reflect specific hazards. The precautionary labeling provided in the Federal Register notice issued on 9/26/84 entitled Proposed Rule on Labeling Requirements (Vol. 49, No. 188, § 156.52) is being used because it is more detailed and provides better protection. The acute toxicity categories listed in the proposed rule are also being used with one exception. The acute inhalation toxicity categories currently used are from a 2/1/94 Health Effects Division paper entitled "Interim Policy for Particle Size and Limit Concentration Issues in Inhalation Toxicity Studies. The Worker Protection Standard issued in 1992 is the major guidance document for labeling of agricultural products. That document is also being used to determine type of respiratory protective equipment for products which are not subject to the WPS.

Determination of Products Subject to the Worker Protection Standard (WPS)

Review this section to determine whether the label under review involves a product which is subject to the WPS. This determination is important when reviewing the following sections of this manual because the personal protective equipment for WPS products is more specific and there are some additional labeling requirements.

☞ Does the product bear directions for use involving the production of an agricultural plant on a farm, forest, nursery, or greenhouse or does the product bear labeling which could reasonably permit such a use?

- ☞ **NO:** The product is not subject to the WPS. Go to the next section on Precautionary Labeling.

- ☞ **YES:** Does the product meet any of the exceptions listed below?

EXCEPTIONS: Does the product bear directions solely for any of the following uses?

- For mosquito abatement, Mediterranean fruit fly eradication, or similar wide-area public pest control programs sponsored by governmental entities.
- On livestock or other animals, or in or about animal premises.
- On plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses.
- On plants that are in ornamental gardens, parks, and public or private lawns and grounds and that are intended only for aesthetic purposes or climatic modification.
- In a manner not directly related to the production of agricultural plants, including, but not limited to, structural pest control, control of vegetation along rights-of-way and in other noncrop areas, and pasture and rangeland use.
- For control of vertebrate pests.
- As attractants or repellents in traps.
- For research uses of unregistered pesticides.

- ☞ **NO:** The product is subject to the WPS.

- ☞ **YES:** The product is not subject to the WPS.

Precautionary Labeling

If toxicity categories are known: Use the toxicity categories to determine the appropriate labeling identified in the following sections of this chapter.

If toxicity categories are not known as in the case of many me-too submissions: The label review will essentially involve a comparison of the draft label against the cited label. Review the following sections of this chapter as some errors can be identified and eliminated.

1. Signal Word Determination

The signal word is determined by the most severe toxicity category assigned to the five acute toxicity studies or by the presence of special inerts (carbon tetrachloride in any amount or methanol in concentrations of 4% or more). Refer to the acute toxicity data review to determine the most severe toxicity category. Also check the confidential statement of formula to determine if carbon tetrachloride or methanol are present. If acute toxicity categories are not known, the signal word on the label under review must be identical to the signal word on the cited product. Signal words are as follows:

Toxicity Category I - DANGER
Toxicity Category II - WARNING
Toxicity Categories III & IV - CAUTION

A. Required Location: The signal word may only appear in three places on the label. It must appear on the front panel of the label immediately below the child hazard warning statement, in the precautionary labeling section immediately below the subheading "Hazards to Humans and Domestic Animals" and in the posting statement if one is on the label.

B. Other Requirements: Make sure that the label under review does not contain more than one signal word (ex., "CAUTION: Wash hands before eating, or smoking" on a "WARNING" label). Make sure that the signal word does not appear on the same line with the child hazard warning and that the signal word runs parallel with other label text. It is preferred that the signal word appears in all capital letters.

C. Products subject to the WPS which are classified as toxicity category I or II must also bear the corresponding Spanish signal word and the Spanish statement provided below. The Spanish signal word and the statement below must appear in close proximity to the English signal word. The Spanish signal word for toxicity category I is "PELIGRO" and the Spanish signal word for toxicity category II is "AVISO". The statement which must appear on toxicity category I and II WPS products is as follows:

"Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle." The Spanish signal word and the statement must appear in close proximity to the English signal word."

2. Poison - Skull & Crossbones Determination

The word "POISON" and the skull and crossbones symbol are required whenever a product is classified as toxicity category I due to the results of either the acute oral, acute dermal, or acute inhalation toxicity studies [40 CFR 156.10(h)(1)(i)] or if the inerts (Carbon Tetrachloride in any amount or Methanol 4% or more) are present in the product [1984 proposed labeling rule, 156.50].

A. Required Location: The word "Poison" and the skull and crossbones symbol must appear in immediate proximity to the signal word which must be "DANGER".

B. Display Requirements: "Poison" must appear in red on a contrasting background. If the proposed label does not indicate these display requirements, include this requirement in your response to the registrant.

Table 2 - Acute Toxicity Category Determination For Sample Products

Type of Study	Product A	Product B	Product C	Product D	Product E
Acute Oral	III	IV	I	III	II
Acute Dermal	IV	III	III	IV	II
Acute Inhalation	III	IV	III	III	II
Primary Eye	III	II	I	I	II
Primary Skin	IV	IV	II	IV	II
Special Inert	No	No	No	No	Yes
CORRECT SIGNAL WORD	**CAUTION**	**WARNING**	**DANGER***	**DANGER**	**DANGER***

*Product C and Product E must also bear additional labeling (Skull & Crossbones symbol in close proximity to the word "POISON" which must appear in red on a contrasting background). Product C must bear the additional labeling as a result of the toxicity category I classification for the acute oral toxicity study. Product E must bear the additional labeling because it contains a special inert (Carbon Tetrachloride or Methanol) which is described above in the first paragraph.

3. Child Hazard Warning Statement

The phrase "Keep Out Of Reach Of Children" is required on all product labels except the following: manufacturing use products; products intended for use on children (ex. a tick spray) or; products which are expected to come in contact with children as a result of an accepted use pattern (ex., a child handling a pet wearing a flea collar).

The child hazard warning statement may be completely omitted for manufacturing use products. A modified child hazard warning statement is required for products where child contact is expected. For products requiring a modified statement, make sure that the statement is appropriate for the use pattern. Examples of appropriate statements are as follows: "Do not allow children to apply product" or "Do not allow children to play with pet collar" (1984 proposed labeling rule, 156.46).

A. Required Location: The child hazard warning statement must appear on the front panel [40 CFR 156.10(h)(1)(ii)].

B. Other Requirements: It is also preferred that the child hazard warning appears on a separate line above the signal word. The CFR does not include this specific requirement. However, it is included in the 1984 proposed labeling rule. When the signal word and child hazard warning appear on the same line, a pesticide user may assume that the signal word is intended more so for children rather than as a general precaution for all persons. If the label under review has the signal

word and child hazard warning on the same line, instruct the registrant to revise the label. Also make sure that the child hazard warning statement runs parallel with other label text.

Make sure that the "Precautionary Statements" and the "Directions for Use" do not contain any statements which imply that the product may be used by children. For example, draft labels of products intended to repel insects may contain instructions such as "Do not allow use by small children without close adult supervision." Such labeling is unacceptable as it implies that a child can apply the product as long as an adult watches. Such a statement conflicts with the child hazard warning statement. Pesticide products should not be applied by children because they may be incapable of reading and correctly following the directions for use.

4. Precautionary Statements

Precautionary statements are required for each acute toxicity study classified as toxicity category I, II, or III and for products found to be dermal sensitizers.

A. Required Header: The precautionary statements must appear under the heading "Precautionary Statements" and the appropriate subheading "Hazard to Humans and Domestic Animals". The phrase "... and Domestic Animals" may be left off if it is inappropriate. The signal word must appear after the subheading.

B. Required Location: The precautionary statement section may appear on any panel. Please note that the precautionary statements must not be included within the "Directions For Use" section. With the exception of PPE for early reentry, all PPE must be located in the precautionary labeling section.

C. Fumigants: Refer to PR Notice 84-5 and Registration Standards for precautionary statements.

D. Determining Statements For All Other Products: Select precautionary statements from the tables below based on the toxicity category assigned to each study. In cases where the toxicity categories are not known, the precautionary labeling for at least one route of exposure must be consistent with the signal word. Sentences from the various tables may be combined to form a concise paragraph containing the precautionary labeling statements. Repetitious sentences should be omitted.

(1.) Products Not In Scope of WPS: Use the precautionary statements and PPE contained in this section, Tables 3 through 8 and then go to the section entitled Statements of Practical Treatment.

(2.) Products In Scope of WPS: Use the precautionary statements in this section, Tables 3 through 8. Disregard the PPE contained in the Tables 3 through 8. Refer to Sections 5 through 8 to determine the PPE for WPS products.

Table 3 - Acute Oral Toxicity Study*

Tox Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER Skull & Crossbones required	Fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.
II	WARNING	May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.
III	CAUTION	Harmful if swallowed. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

*Products Containing 4% or more of Methanol: Add the following to the precautionary statements: "Methanol may cause blindness."

Table 4 - Acute Dermal Toxicity Study

Tox Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER Skull & Crossbones required	Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.
II	WARNING	May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

Table 5 - Acute Inhalation Toxicity Study

Tox Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER Skull & Crossbones required	Fatal if inhaled. Do not breathe (dust, vapor, or spray mist).* [Identify specific respiratory protective device approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.]** Remove contaminated clothing and wash clothing before reuse.
II	WARNING	May be fatal if inhaled. Do not breathe (dust, vapor or spray mist).* Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Harmful if inhaled. Avoid breathing (dust, vapor or spray mist).* Remove contaminated clothing and wash clothing before reuse.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

* Choose the word which appropriately describes the product during application.
** Refer to Section 7 to determine the specific respiratory protective device. This section can be used for both WPS and Non-WPS products.

Table 6 - Primary Eye Irritation Study

Tox Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER	Corrosive.* Causes irreversible eye damage. Do not get in eyes or on clothing. Wear (goggles, face shield, or safety glasses).** Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
II	WARNING	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear (goggles, face shield, or safety glasses).** Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Causes (moderate) eye injury (irritation). Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

*The term "corrosive" is not required if only eye irritation (redness) was observed during the study and was still present at day 21.

**Choose appropriate type of eyewear. Use the term "goggles and face shield" in the precautionary labeling for agricultural or industrial use products. Use the term "safety glasses" in the precautionary labeling for residential use products.

Table 7 - Primary Skin Irritation Study

Tox Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER	Corrosive. Causes skin burns. Do not get in eyes or on clothing. Wear protective clothing and rubber gloves.* Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
II	WARNING	Causes skin irritation. Do not get on skin or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

*The need for rubber gloves must be determined on an individual basis. Some products cause blistering if confined under clothing.

Table 8 - Dermal Sensitization Study

Study Results	Precautionary Statement
Product is a sensitizer or is positive for sensitization.	Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
Product is not a sensitive or is negative for sensitization.	No labeling is required for this hazard.

5. WPS Personal Protective Equipment (PPE) Requirements

Personal protective equipment is required for both pesticide handlers as well as workers who reenter treated areas prior to the expiration of the restricted entry interval (REI).

A. Determining toxicity Categories for Each Route of Exposure: If all acute toxicity categories are known, skip to Section B. If any acute toxicity categories are unknown, review this section to determine the preferred order for selecting alternate data to establish a toxicity category for the missing data:

(1.) If available, use the toxicity categories assigned to the acute dermal toxicity, acute inhalation toxicity, primary eye irritation, and primary skin irritation data on the end-use product.

(2.) If either the acute dermal toxicity or acute inhalation toxicity data are missing, use the toxicity category assigned to the acute oral toxicity data.

(3.) If the acute oral, acute dermal and acute inhalation toxicity data are missing, use the product signal word to determine the equivalent toxicity category.

B. WPS Products: Use the toxicity categories to determine from Table 9 whether the label under review contains the appropriate PPE.

Table 9 - Personal Protective Equipment for WPS Products

Route of Exposure	Toxicity Category of End-Use Product			
	I (DANGER)	II (WARNING)	III (CAUTION)	IV (CAUTION)
Dermal Toxicity or Skin Irritation Potential[1]	Coveralls worn over long-sleeved shirt and long pants Socks Chemical-resistant footwear Chemical-resistant gloves[2]	Coveralls worn over short-sleeved shirt and short pants Socks Chemical-resistant footwear Chemical-resistant gloves[2]	Long-sleeved shirt and long pants Socks Shoes Chemical-resistant gloves[2]	Long-sleeved shirt and long pants Socks Shoes No minimum[4]
Inhalation Toxicity	Respiratory protection device[3]	Respiratory protection device[3]	No minimum[4]	No minimum[4]
Eye Irritation Potential	Protective eyewear	Protective eyewear	No minimum[4]	No minimum[4]

[1]If dermal toxicity and skin irritation toxicity categories are different, PPE shall be determined by the more severe toxicity category of the two. If dermal toxicity or skin irritation is category I or II, refer to Section C below to determine if additional PPE is required beyond that specified in Table 9.

[2]Refer to Section 6 to determine the specific type of chemical-resistant glove.

[3]Refer to Section 7 to determine the specific type of respiratory protection.

[4]Although no minimum PPE is required for these toxicity categories and routes of exposure, the Agency may require PPE on a product-specific basis.

C. PPE for Dermal Protection: Additional PPE is required for products which are classified as toxicity category I or II for acute dermal toxicity or skin irritation. If the label under review does not involve a category I or II classification for either of these studies, skip this section and go to Section 6. If the label under review does involve a category I or II classification for

either the acute dermal toxicity or skin irritation, review the following table to determine the additional PPE which must appear on the label under review.

Table 10 - Additional Dermal toxicity and/or Skin Irritation PPE

Conditions Requiring Additional PPE and Labeling	Required PPE and Labeling
All products which are not ready to use and do not require a chemical resistant suit must bear the corresponding statement:	"Mixers/Loaders: Wear a chemical resistant apron."
All products having applications which might involve overhead exposure must bear the corresponding statement:	"Overhead Exposure: Wear chemical-resistant headgear."
All products involving use of equipment other than the product container to mix, load or apply the product must bear the corresponding statement:	"For Cleaning Equipment: Add a chemical-resistant apron."

7. Chemical Resistant Glove Selection For Handlers

Chemical resistant gloves are required for all WPS products classified as toxicity category I, II, or III for acute dermal toxicity or primary skin irritation. Review the types of chemical resistant gloves below, and determine if the label lists the appropriate glove type based on the product formulation. Please note that the registrant can specify another chemical resistant glove type other than those specified below if information is available that indicates that another glove type provides greater protection. If the label bears another chemical resistant glove type and the registrant has indicated that it is more protective based on available information, allow that glove type to remain on the label. If the label bears another chemical resistant glove type than those listed below and the registrant has not indicated that it is more protective based on available information, request that the registrant verify that the appropriate chemical resistant glove type is on the label. The label must indicate the specific type of chemical resistant glove (such as nitrile, butyl, neoprene, and/or barrier laminate). Listed below are the standard glove types required by the WPS.

A. **Solid Formulations** applied as solids or diluted solely with water for application, the glove statement shall specify "waterproof gloves".

B. **Aqueous-Based Formulations** applied as formulated or diluted solely with water for application, the glove statement shall specify "waterproof gloves" ".

C. **Other Liquid Formulations** which are formulated or diluted with liquids other than water, the glove statement shall specify "chemical-resistant (such as nitrile or butyl) gloves".

D. **Gaseous Formulations or Formulations applied as Gases** will retain any existing glove statement established before 10/20/92 including any glove prohibition statement. If no glove statement or glove prohibition currently exist on the label, then the glove statement shall be "chemical-resistant (nitrile or butyl) gloves".

8. Specific Respiratory Protection Device (RPD) Selection For Handlers

RPD(s) are required for all products classified as toxicity category I or II for acute inhalation. Review the RPD types below and determine if the label lists the appropriate type based on the product description and toxicity category. Please note that if the registrant has submitted information to support the selection of another type of RPD which is more protective, allow the registrant to retain that RPD requirement on the label under review. Information that could support an alternate RPD could be the submission of the product vapor pressure indicating that the RPD specified in the list below would not provide adequate protection or may pose an increased risk to the user unnecessarily.

A. **Gases Applied Outdoors**: Products that are formulated or applied as a gas (space and soil fumigants) and that may be applied outdoors must bear labeling specifying the following RPD requirements and statement:

> **"For handling activities outdoors, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."**

B. **Gaseous Products Used in Enclosed Areas**: Products that are formulated or applied as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas must bear labeling specifying the following RPD requirements and statement:

"For handling activities in enclosed areas, use either a supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C, or a self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F."

C. **Solid Products:** Products that are formulated and applied as solids must bear labeling specifying the following RPD requirements and statement:

"For handling activities, use a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

D. **Liquid Products in Toxicity Category I:** Products that are formulated and applied as liquids must bear labeling specifying the following RPD requirements and statement:

"For handling activities, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G)."

E. **Liquid Products in Toxicity Category II:** Products that are formulated or applied as liquids must bear labeling specifying the following RPD requirements and statement:

"For handling activities during [insert applicable terms based on directions for use: airblast, mistblower, pressure greater than 40 p.s.i. with fine droplets, smoke, mist, fog, aerosol or direct overhead] exposures, wear either a respirator with an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

9. Labeling and PPE for Early Reentry Workers - WPS Products

A. All products subject to the WPS must bear the following statements for workers who reenter the treated area prior to the expiration of the reentry interval:

"For early entry to treated areas that is permitted under the Worker Protection standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: **(Insert all PPE required for applicators and other handlers. Omit any respiratory protective devices).**

B. Additional Early Reentry Worker PPE Requirements: The following modifications must be made to the early reentry worker labeling and PPE required in Section A. above:

☛If the handler body clothing requirement is a long-sleeved shirt and long pants, then the early-entry worker requirement shall be "coveralls over long-sleeved shirt and long pants" over the long-sleeved shirt and long pants.

☛If there is no handler requirement for or against gloves, then the early-entry requirement shall be "waterproof gloves".

C. Required Location for Early-Reentry Worker Labeling and PPE Labeling: PPE statements for early-reentry workers must appear in the "DIRECTIONS FOR USE" section of the labeling under the heading "AGRICULTURAL USE REQUIREMENTS" immediately after the restricted-entry statement.

STATEMENTS OF PRACTICAL TREATMENT (First Aid)

A statement of practical treatment is required for each route of exposure (oral, dermal, inhalation, eye & skin) where the toxicity study has been classified as category I, II, or III. It is acceptable for the registrant to include statements of practical treatment (category III statements) for studies that are classified as category IV.

1. Required Header: Any of the following headings are acceptable: Statement of Practical Treatment, Practical Treatment, or First Aid. The heading "Antidote" cannot be used unless a specific antidote is recommended. The label should bear the heading which is most readily recognize by the intended users of the product. This determination will be made by the registrant.

2. Content and Clarity: Statements of practical treatment must be brief, clear, simple and in straightforward language so that the average person can easily and quickly understand the instructions. The statements of practical treatment should be appropriate for all ages or when necessary, should include distinctions between the treatments for different ages, i.e., children vs. adults. The statements should be such that any reasonably competent individual could perform them. Statements of practical treatment should not include procedures which must be performed by medical personnel or require specialized equipment (See Note to Physician) section.

3. Order of Statements: The statement of practical treatment should be organized so that the most severe routes of exposure as demonstrated by the toxicity category classification are listed first.

4. Required Location: The statement of practical treatments must appear on the front panel of the label for all products that are classified as toxicity category I for acute oral, acute dermal, or acute inhalation exposure [40 CFR 156.10(h)(1)(i)] unless the label contains a referral statement such as "See statement of practical treatment on back panel". This referral statement must appear in close proximity to the word "Poison" and skull and crossbones symbol. If statements of practical treatment are located on a back or side panel, they should be grouped in close proximity to the other precautionary statements; however, they should be set apart or distinguishable from other label text.

5. Determining Statements of Practical Treatment for Fumigants: Refer to PR Notice 84-5 and Registration Standards.

6. Determining Statements of Practical Treatment for All Other Products: Review the next following sections to determine the appropriate statement of practical treatment for each route of exposure.

   A. Acute Oral: Use the following flow chart to determine the appropriate oral statement of practical treatment. Please note that oral statements of practical treatment are controversial and there are differing opinions within the medical community concerning whether emesis (vomiting) should be recommended. Until the Agency resolves this issue, in situations where the registrant has recommended an oral statement of practical treatment that differs from those on the flowchart, instruct the registrant to modify the statement according to the flowchart or provide a justification for the use of the alternate statement.

If the registrant's justification indicates that the proposed statement of practical treatment was based on medical staff evaluation of the product, let the registrant retain the proposed statement of practical treatment as long as it meets the requirements set forth in "Content and Clarity of Statements" and does not involve the use of salt water for emesis (PR notice 80-2). If the registrant indicates that the statement was selected by simply referring to another product, request that the registrant revise the statement based on the flow chart.

Determining the Oral Statement of Practical Treatment

Is the active ingredient zinc phosphide? → YES → Use the following Statement:

IF SWALLOWED: Immediately call a Poison Control Center or doctor, or transport the patient to the nearest hospital. Do not drink water. Do not administer anything by mouth or make the patient vomit unless advised to do so by a doctor."

NO ↓

Is the product tox category I or II for oral toxicity? → YES → Use the below for "All other Products". → → → → → → → ↓

↓ ↓

NO

↓ ↓

Is product corrosive (pH < 2 or > 11.5) or is product tox category I or II for eye or dermal irritation? → YES → Use the following statement:

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol." ↓

↓

NO ↓

↓

Does the product contain > 10% petroleum distillates? → YES → Use the following statement: ↓

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol. ↓

↓

NO

↓ ↓

All other Products. → YES → Use either of the following statements: ← ← ← ← ←

NOTE: Products in tox category IV for oral toxicity, do not require a statement of practical treatment. If the registrant chooses, he may use either of these statements on his label.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

OR

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

B. Acute Dermal and Primary Skin Irritation: Since both these studies focus on the dermal route of exposure, the statements of practical treatment for these two studies can be combined when required for both studies. If a statement is required for both studies, use the statement of practical treatment required for the acute dermal toxicity study if both studies are in the same acute toxicity or for the more severe acute toxicity category if the studies are in different acute toxicity categories.

Table 11 - Skin Irritation Statements

Toxicity Category	Required Statement of Practical Treatment
I	IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
II	Same as above
III	IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.
IV	Statement not required. Registrant may use category III statements if he chooses.

Table 12 - Dermal Toxicity Statements

Statement of Practical Treatment Based on Acute Dermal Toxicity Study	
Toxicity Category	Required Statement of Practical Treatment
I	IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
II	Same as above
III	Same as above
IV	Statement not required. Registrant may use category III statements if he chooses.

C. Acute Inhalation: Selection of statement of practical treatment is straightforward and is based on the toxicity category assigned to the particular study.

Table 13 - Acute Inhalation Statements

Toxicity Category	Required Statement of Practical Treatment
I	IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention
II	Same as above
III	Same as above.
IV	Statement not required. Registrant may use category III statements if he chooses.

D. Primary Eye irritation: Selection of statement of practical treatment is straightforward and is based on the toxicity category assigned to the particular study.

Table 14 - Eye Irritation Statements

Toxicity Category	Required Statement of Practical Treatment
I	IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
II	Same as above
III	IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IV	Statement not required. Registrant may use category III statements if he chooses.

6. Note to Physician

A. When Required: The "Note to Physician" is not required nor mentioned in the 40 CFR. If the label under review is for a product which is a fumigant, refer to PR Notice 84-5 or relevant Registration Standards for the "Note to Physician". For all other products, we are currently requiring a "Note to Physician" as specified in the proposed rule for the following types of products:

☛All products that are classified as toxicity category I.

☛Any product which is corrosive or classified as toxicity category I or II for eye or skin irritation.

☛Products that are in acute oral toxicity categories III or IV, and contain $\geq$ 10% petroleum distillates.

☛Any product that produces physiological effects requiring specific antidotal or medical treatment such as: Cholinesterase Inhibitors (ex., carbamates and phosphorothioates); Metabolic Stimulants (ex., dichlorphenols); Anticoagulants (ex., warfarin).

B. Contents of Note: The proposed rule does not provide specific notes to physicians except for corrosive and toxicity category I and II eye and skin irritants. The proposed rule does provide the following guidance concerning the content of notes to physicians. Check the label under review to make certain that it conforms with the following guidance:

-technical information on symptomatology;
-use of supportive treatments to maintain life functions;
-medicine that will counteract the specific physiological effects of the pesticide;
-company telephone number to specific medical personnel who can provide specialized medical advice.

C. Specific Note for Corrosive or Toxicity Category I or II Eye and Skin Irritants:

Use the following Note to Physician:

"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

D. Required Location: The "Note to Physician" should be located in close proximity to the "Statements of Practical Treatment" but should be clearly distinguished from it. In other words, it should not be mixed in with the "Statement of Practical Treatment" but should appear below the last statement of practical treatment.

Chapter 9 ENVIRONMENTAL HAZARDS

Introduction

The Environmental Hazards statement provides the precautionary language advising of the potential hazards from transport, use, storage, or spill of the product. The hazards may be to water, soil, air, beneficial insects, plants, and/or wildlife. Generally, the information contained in this section is based upon the results of six basic acute toxicity studies performed on the technical grade of the active ingredient(s) in the formulation. These six studies are: (1) avian oral LD_{50} (with mallard or bobwhite), (2) avian dietary LC_{50} (mallard), (3) avian dietary LC_{50} (bobwhite quail), (4) freshwater fish LC_{50} (rainbow trout), (5) freshwater fish LC_{50} (bluegill sunfish), and (6) acute LC_{50} freshwater invertebrates (Daphnia magna). The data generated from these studies support the wording for the Environmental Hazards statement. Review of the data is performed by the Ecological Effects Branch (EEB) of the Environmental Fate and Effects Division who also review any label text proposed by the registrant, or determine what statements are required.

Reviewing the Statement

1. The reviewer must first determine whether the use patterns on the label require an Environmental Hazards Statement:

> Products which are intended for use exclusively indoors may omit the Environmental Hazards statement. Products applied to domestic animals, such as flea collars or ear tags may also omit the statement. However, a domestic use product such as a dog dip may still require the statement since a potential for contamination of water exists from the use of a dip.
>
> Manufacturing use products (MUPs), although used indoors to formulate other products, require some Environmental Hazards text because MUPs are highly concentrated and could pose a serious hazard if a spill occurred during transport.
>
> All products labeled for use outdoors must have an Environmental Hazards statement.

If the reviewer determines that the use pattern triggers the need for Environmental Hazards labeling, the proposed draft labeling must be reviewed according to the requirements outlined in the remainder of this chapter.

2. The reviewer must check if the statement is in the appropriate location on the label, with the correct heading:

   The Environmental Hazards section of the label should be located under the general heading "Precautionary Statements." It must have the heading "Environmental Hazards" (not "Environmental Precautions," "Environmental Protections," or anything similar).

3. The text of the statement is then reviewed according to the type of action:

   A. If the action represents a submission accompanied by data, the Ecological Effects Branch will review the environmental hazards statements and recommend any necessary label changes as part of their data review. The reviewer must specify all requested changes in their response to the registrant.

   EEB is responsible for reviewing data on all technical products and may also review data associated with end-use formulations also. This occurs when an end-use formulation is suspected of being potentially harmful to the environment (for example, microencapsulated insecticides which are used on crops are potentially harmful to pollinators). Once EEB has reviewed any data, the Environmental Hazards statement is drafted and will be included in a Reregistration Eligibility Document (RED), or in the past, the Registration Standard. If the reviewer is working on a Me-Too application for registration (where another similar formulation is already registered), the Environmental Hazards statement should be the same as currently registered products. If there are no similar products to compare the statement to, the application should be routed to EEB for their comments. Additionally, if a registrant wishes to amend the Environmental Hazards statement, EEB may need to see the application.

   B. If the submitted action has been determined to be a **Me-Too** submission (chapter 4), the reviewer must make certain that the draft label bears all the statements that the cited label bears. Additionally, since the cited label may have some statements that are outdated and/or missing and were required since the label was accepted, check the required statements outlined in the rest of this chapter to make sure that both the cited label and the draft label reflect current Agency policy.

   IMPORTANT: If an error is discovered in the ENVIRONMENTAL HAZARDS section of the cited Me-Too label, the reviewer should take the time to write a letter informing the registrant of the error(s) and require correction/revision in a suitable time

frame such as 30 days. (If the error is minor in nature, it would be acceptable to allow the registrant to correct the error at the next printing of the label.)

4. General Statements

A. All commercially applied products with directions for outdoor terrestrial uses must have the following statements in the Environmental Hazards section:

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters."

This statement should be preceded by **"For terrestrial uses,"** if the product has terrestrial, forestry (except aerial application) and domestic outdoor uses in addition to aquatic sites. This revised statement would then **not** apply to other general use patterns -- aquatic (e.g., mosquito larvicides or adulticides, aquatic herbicides, piscicides, slimicides, etc.), greenhouse and indoor uses.

B. For residential consumer products, the required statement is:

"Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."

☞ The reviewer must keep in mind the use pattern of the product undergoing a label review. If the product is actually intended for application to water - to control algal growth, for example, the above two statements would be inappropriate. Or, if the product is an aerosol spray for application to wasp or hornet nests, there would be no equipment used, and the statement regarding cleaning of equipment may be omitted.

C. The following statement is required when a pesticide intended for outdoor use contains an active ingredient which has a mammalian acute oral $LD_{50} \leq 100$ mg/kg, an avian acute oral $LD_{50} \leq 100$ mg/kg, or a subacute dietary $LC_{50} \leq 500$ ppm[1]:

"This pesticide is toxic to wildlife."

---

[1] This information will be found in submitted data, the RED, or the Registration Standard. It may not necessarily be available to the RD reviewer, but helps you to understand the origin of the statements.

D. The following statement is required when a pesticide intended for outdoor use contains an active ingredient with a fish acute $LC_{50} \leq 1$ ppm:

"This pesticide is toxic to fish."

E. If field studies or accident history, such as FIFRA § 6(a)(2) reports, indicate that use of the pesticide may result in fatality to birds, fish or mammals, the following statement is required:

"This pesticide is extremely toxic to wildlife (fish)."

F. If a pesticide is used outdoors as a foliar application, especially to crops, and it is toxic to pollinating insects, a "Bee Hazard" warning must be included in the Environmental Hazards. The following table sets out the toxicity groupings and required label statements for honey bees:

Honey Bee Toxicity Groups and Cautions

Toxicity Group	Precautionary Statement if Extended Residual Toxicity is Displayed	Precautionary Statement if Extended Residual Toxicity is not Displayed
I Product contains any active ingredient with acute LD_{50} of 2 micrograms/bee or less	This product is highly to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.	This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.
II Product contains any active ingredient(s) with acute LD_{50} of greater than 2 micrograms/bee but less than 11 micrograms/bee.	This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area.	This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area.
III All others.	No bee caution required.	No bee caution required.

G. For registered technical products and other manufacturing use products, i.e. those used to formulate other products, a "point source discharge" is a possibility - where effluent from the manufacturing plant may contain pesticides. This does not include those products used to control roaches or other pests in the facilities, but applies to those chemicals used in the formulation processes. The following NPDES* statement (as outlined in Pesticide Regulation (PR) Notice 93-10) is required on such products:

> **"Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."**

* NPDES = National Pollutant Discharge Elimination System

H. If a pesticide product contains directions for use in treating seed, the Environmental Hazards section must include the following statements:

> **Exposed treated seed may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water."**

5. Chemical Specific Statements

Some Environmental Hazards statements are prepared specifically for certain chemicals (a.i.'s). Some of those are shown below:

A. Chlorpyrifos

> **"This pesticide is extremely toxic to fish, birds, and other wildlife. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Cover or incorporate spills. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters."**

B. Dimethoate

"This pesticide is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

"This pesticide is toxic to wildlife and aquatic invertebrates. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning equipment or disposal of wastes."

C. Resmethrin labeled for mosquito abatement and pest control treatments at nonagricultural sites

"This pesticide is highly toxic to fish. Drift and runoff from treated sites may be hazardous to fish in adjacent waters. Consult your State's Fish and Wildlife agency before treating such waters."

☞ The use pattern of a pesticide also helps determine the need for and the specific text of the Environmental Hazards section. Generally, the label reviewer may conclude that all pesticides used outdoors must have the statement. The reviewer should also look at the statement with a critical eye towards its applicability. Does it makes sense for the product? For example, a granular herbicide should not have a statement warning of potential spray drift problems since granular formulations are not "sprayed" and are seldom associated with any "drift".

☞ NOTE: Chemical specific statements, such as groundwater/surface water, spray drift/runoff, or endangered species statements will be added to manual as they are identified. The label reviewer should consult with product manager and EFED.

Chapter 10 PHYSICAL OR CHEMICAL HAZARDS

Introduction

This chapter covers the Physical or Chemical Hazards statements that are required for certain pesticide products. Such hazard statements include flammability, explodability and precautions necessary when handling liquid products used around electrical equipment. In addition, there are special hazard statements for certain fumigants.

The reviewer should look through the following sections to determine which are pertinent to the proposed label under review.

Placement of the "Physical or Chemical Hazards" Statement

Placement of the Physical or Chemical Hazards statement shall be immediately below the Environmental Hazards statement, which is located below the Precautionary Statements, Hazards to Humans & Domestic Animals. [Federal Register (FR) Notice Proposed Rule on Labeling Requirements, Vol. 49, No. 188, §156.56, September 26, 1984]

Labeling for Flammable Products

Precautionary statements relating to flammability of a product are required on the label if the product meets the criteria shown below. Review the following chart to determine the flammability statement that should be included on the proposed label.

Subdivision D (Product Chemistry) of the Pesticide Assessment Guidelines, (§63-15) covers the **flash point** and **flame extension** of a product. The flash point is the lowest temperature at which a combustible liquid will give off a flammable vapor which will burn momentarily. The flame extension test is required for aerosol products. This test measures the flammability of aerosol products by placing a flame 18 inches from the aerosol product, then discharging the propellant to evaluate the flammability. Flashback can occur, which is when the flame is drawn back toward the aerosol can by the stream of propellant. This would indicate a highly flammable product.

The product's flash point is shown in block 9 on the Confidential Statement of Formula (CSF) and should be expressed in degrees fahrenheit (° F); in addition for aerosol products, the registrant is required to report the results of the flame extension test and any positive flashbacks. This requirement does not apply to products that are typically incombustible, such

as most dust or granular formulations, pellets/tablets (baits), impregnated materials, etc. If block 9 on the CFS indicates "not applicable", you may skip this section on flammability.

Flash Point	Required Text
(A) Pressurized Containers	
Flash point at or below 20° F; if there is a flashback at any valve opening	**Extremely flammable.** Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 inches long at a distance of 6 inches from the flame.	**Flammable.** Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 20° F	**Extremely flammable.** Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	**Flammable.** Keep away from heat and open flame.
Above 80° F and not over 150° F	Combustible. Do not use or store near heat or open flame.
Over 150° F	No text required.

[40 CFR 156.10(h)(2)(iii)]

☞ **CAUTION, WARNING, DANGER (human signal words) are NOT to be used in conjunction with the flammability statements.**

Criteria for Declaration of Non-flammability

Certain products may reflect a claim of non-flammability, with terms like "non-flammable" or "non-flammable (gas, liquid, etc.)". If the draft label does not have any claim of non-flammability, skip this section. However, if the proposed draft label has such a claim, the reviewer must check to see that the terms "Extremely Flammable" or "Flammable" are not being used in the *Physical or Chemical Hazards* section of the proposed label. Obviously, if either terms are being used in the *Physical or Chemical Hazards* section, the claim of non-flammability CAN NOT be used as well. If the proposed label reflects a non-flammable claim, it must meet the following criteria for non-flammability:

1. Criteria for Declaring Non-flammability

   A. If a gas or mixture of gases: the product must not ignite when a lighted match is placed against the open cylinder valve.

   B. If a liquid: the product must have a flash point greater than 350° F (177° C). Refer to the CSF for the flash point.

   If you are unsure of whether the product meets the criteria for declaring non-flammability, route the label package to the Product Chemistry Review Section in Registration Support Branch (RSB) for a determination.

2. Non-flammability Labeling Statement and Placement

   The phrase "non-flammable" or "non-flammable gas" or "non-flammable liquid", etc., can appear as a sub-statement to the ingredient statement, or on a back or side panel. The phrase must not be highlighted or emphasized (such as inordinately large type size, or sharply contrasting color, etc.) so as to constitute a misleading safety claim.

Labeling for Liquid Products Used Near Electrical Equipment (Dielectric Breakdown Voltage)

Some products may pose a shock hazard when used near electrical equipment or outlets. The dielectric breakdown voltage is a measure of a liquid's capacity to conduct electricity and is required if the End Use product is a liquid and could be used near electrical equipment. [40 CFR §158.190(a)] If the proposed draft label is not a liquid, skip this section. If the proposed label is for a liquid product, review the criteria below:

1. Criteria for determining the requirement of the shock hazard statement:

   A. The use directions may permit use of the product near electrical equipment or electrical outlets, (transformers, cable TV pedestals, conduits, etc.);

   and

   B. the data matrix does not provide a dielectric breakdown voltage;

   or

   C. the dielectric breakdown voltage is less than 5,000 volts.

2. Shock Hazard Labeling Statement and Placement

If the product meets the criteria above, the following statement must be shown under the heading "Physical or Chemical Hazards".

> **Do not apply this product in or on electrical equipment due to the possibility of shock hazard.**

[Section 63-21 of Subdivision D, Product Chemistry, Pesticide Assessment Guidelines]

Labeling for Explosiveness Potential

When data submitted in accordance with 40 CFR 158.120 demonstrate hazards of a physical or chemical nature other than flammability (such as potentially explosive), appropriate statements of hazard must be included on the label. Such statements should address hazards of explosiveness.

Chemicals which require specific statements for explodability include: sulfur dust, carbon dust, potassium nitrate, sodium nitrate and potassium chlorate. If based on your review of the CSF you believe the product might require labeling for explodability, route the label package to the Product Chemistry Review Section in RSB for a determination.

Additional Label Statements for Certain Fumigants

For some fumigant chemicals, statements of flammability or other physical or chemical hazards are required. A couple of fumigants are highly flammable in the liquid or vapor form. The statements of flammability listed below for the following chemicals should be located on the side panel under the heading "Physical or Chemical Hazards". [reference: PR Notices 84-5 and 85-6.]

Sodium and Calcium Cyanides

In the presence of moisture, highly poisonous gas (hydrogen cyanide) is formed.

Warning Statements about Mixing Certain Products

Certain products react with certain surfaces such as galvanized steel to form highly combustible gas. Therefore, under the Directions for Use section, some product labels will prohibit mixing, storing, or applying the product in galvanized steel or unlined steel containers.

This is acceptable, however, no toxicity signal word (Caution, Warning, or Danger) may be used with this information. The registrant may use "Attention", "Note" or a similar word or phrase to alert the user. (Refer to Chapter 11, Direction for Use for more information on this.)

Requirement for Use of Fire Retardant

Because of its combustion capability, all formulations of **sodium chlorate** must include an appropriate fire retardant chemical. Refer to Chapter 6, The Ingredient Statement for placement instructions of the required statement.

Chapter 11 **DIRECTIONS FOR USE**

Introduction

The "Directions for Use" section of a pesticide label must provide the necessary information to answer four major categories of questions regarding the use of the pesticide. These four questions are:

1. Why is the pesticide being used?
2. Where is the pesticide applied? (where should it not be applied?)
3. How is the pesticide applied? (what special precautions must the user take? how much should they use?)
4. When should the pesticide be applied?

If these questions are adequately addressed the person likely to use (or supervise the use of) the pesticide should be able to do so correctly. The directions for use should be adequate to protect the public from fraud and personal injury, and the environment from unreasonable adverse effects.

Most misuse of pesticides results from failure of the applicator to read and understand or follow the directions for use. Therefore, this section of the label must be reviewed very carefully.

General Requirements

1. The title of this section must be **"Directions for Use."** It must not be "General Directions," "Use Directions," "How to Use," or any other similar wording.

2. All registered pesticides must bear labeling which has the following general misuse statement:

> **"It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."**

This statement must appear immediately after the "Directions for Use" heading.

☞ The general misuse statement should be modified for Experimental Use Permits (EUPs), to read as follows:

"Use of this product in a manner inconsistent with the terms of the Experimental Use Permit is a violation of Federal Law."

3. The directions for use section may actually be omitted from the label for certain very specific types of products. If the pesticide is a manufacturing use product (MP) intended only for use by formulators preparing end-use products, or if the pesticide is intended for use only by physicians, veterinarians or druggists, the directions for use may be very limited. This is acceptable, however, MPs must have a statement under Direction for Use such as, "Only For Formulation Into A [type of pesticide]." followed by a continued statement of the uses (crops/sites) for which the EP could be registered. If the label under review is claimed to be for one of these types of products, the label reviewer must verify the presence of the statement as mentioned above or a statement about use by physicians, veterinarians or druggists.

4. Worker Protection Standard (WPS) Requirements - refer to chapter 8 for the criteria necessary to determine if the label under review is subject to the WPS requirements. If the product is subject to the WPS, refer to the requirements listed at the end of this chapter.

Type of Review

1. Is the label review for a Me-Too application?

2. Is the label review for an application other than a Me-Too?

A. Review of a Me-Too Application

If the application is a Me-Too submission (chapter 4), reviewing the directions for use is fairly straight forward. A side-by-side comparison of the two sets of directions is made. The sites and pests must be the same, although not all must be present on the pending application. In other words, the Me-Too label can drop uses (pests) or sites on the main label. For example, an application is made for an insecticide formulation to add structural perimeter treatments for crickets, ants, and sowbugs. The main (cited) Me-Too product must have this site, and it's label must claim crickets, ants, and sowbugs; but other species (earwigs, millipedes) also may be claimed. The pending submission need not have all the pests listed on the Me-Too label, however, no new sites or pests may appear on the labeling for the pending product.

A major pitfall in side-by-side label comparisons is the possible presence of an unacceptable use or error on the label of the registered product. If reviewers are not careful, such errors may be repeated, sometimes over and over.

- If an error is discovered in the directions for use of the cited Me-Too label, the reviewer should take the time to write a letter informing the registrant of the error(s) and require correction/revision in a suitable time frame such as 30 days. (If the error is minor in nature, it would be acceptable to allow the registrant to correct the error at the next printing of the label.) This action may be entered into "Pesticide Regulatory Action Tracking System" (PRATS) under action code 360, "Action Initiated by Agency" (see chapter 5). This is a judgement call, if an error is too minor to warrant this extra effort, it may be flagged and corrected during the review and response to a subsequent submission on the product, or during the reregistration process. However, if the error raises a safety, environmental, or legal issue (i.e. conflict with current regulations or policies), the reviewer must require the registrant to correct the problem.

If a Reregistration Eligibility Decision (RED) has been issued for the active ingredient in the product undergoing review, the reviewer must ensure that all of the sites on the label are in Appendix A of the RED and that any other limitations are not exceeded. If any one of the use sites is not in Appendix A, it is considered to be "new" and the submission may not be considered to be a Me-Too.

B. Review of Applications That Are **Not** Me-Too's

When a Registrant proposes a new use, new application rate, preharvest interval (PHI) change, or a similar action not previously approved by the Agency, a more extensive review than the simple Me-Too comparison is necessary. Such applications usually should be accompanied by data, or should include data citations, and should be sent for review. The directions for use will be affected by the reviews from Health Effects Division (HED) (use rates on crops, PHI's, reentry intervals), Environmental Fate and Effects Division (EFED) (for restrictions such as bee hazards), and Registration Division (RD)/Efficacy (for application rates and methods). The use rate, or application rate, may be the most difficult to interpret and review for this section. Application rates, and number of applications per season, for agricultural products, will be based on the residue data submitted or cited by the registrant. Approval of most agricultural uses require an established tolerance (tobacco being an exception).

Once the type of review has been determined for the submitted action, the label reviewer may proceed with an actual analysis of the directions for use. The reviewer must not assume that because a registrant is adding to or changing only one part of this section that the rest of the directions for use is "ok," even though the label has been accepted in the past. A number of years may pass between submissions on a product, some labels may be quite old (even as much as 20 years) and uses and language previously accepted may be objectionable now.

Reviewers must also examine use directions carefully for unannounced changes; changes made by the registrant that they did not tell us about.

Site, Pest, Application Analysis of the Label

The Directions for Use section usually will be revised more frequently than any other section of the label and should be carefully scrutinized by the label reviewer. The following basic procedure should be applied to the review process for the directions for use.

1. Why is the pesticide being used -

   - ☞ what is (are) the target pest(s)?
   - ☞ what is the crop, animal or site the product is intended to protect?
   - ☞ Is this an appropriate and Agency-accepted use of this pesticide?

Target Pests may be invertebrates, vertebrates, nematodes, plants, algae, fungi, viruses or bacteria. The directions for use section of the label must identify the target pest(s) and must be consistent with the pests mentioned elsewhere on the label. Pest claims often appear on the front panel. **The reviewer must make sure that the directions for use actually include and are applicable to all pests listed anywhere on the labeling.** For example, if the front panel lists fire ants as a target pest, then the directions for use must include the appropriate treatment directions for fire ants.

A product may be intended for a number of different pests, or directed at only one specific pest. Frequently, there will be specific sets of application directions on the same label, each applying to one or several of the pests claimed on the label. Pests for which special or unique application techniques are needed (e.g. fire ants), will require their own detailed set of directions. It is acceptable to group directions according to the sites to be treated (e.g. broccoli, cabbage, cauliflower: cutworms, fall armyworms, cabbage loopers). For fungicides, grouping may be used ONLY if all pests occur and are controlled on all of the crops in the group. Diseases which occur on a single type of plant such as Black Spot on roses, must be associated with that particular plant.

Target pests may be named very generally in the directions for use section of some labels (e.g. ants), other labels will identify them specifically, (e.g. carpenter ants). The directions for use should be determined by and reflect the biology and behavior of the pest as closely as possible. Some knowledge of the pest is helpful, and may in some cases be critical. However,

comparison to similar product labels, as well as information from the Product Manager, and eventual experience, will help the reviewer become more familiar with a pest's biology and behavior and therefore, with typical treatment techniques. Two important relationships to keep in mind while analyzing the target pests are:

A. Pest-Product Formulation: For example, if the product is a granular formulation, it will have no effect on a flying insect. A liquid formulation restricted to foliar aerial application (like parathion) would be unlikely to control soil inhabiting insects such as corn rootworm larvae. If the reviewer is unsure of the practicality of a formulation as targeted against a certain pest on a label, the reviewer may need to consult with the efficacy reviewers in the branch. The registrant must be informed that the use is not acceptable. They may appeal by providing information (data) to persuade us that the formulation is in fact appropriate for the proposed use.

B. Pest-Site: the label may contain claims for control of a pest in an inappropriate site, misleading the consumer and possibly causing a misapplication of the pesticide. Examples of inappropriate pest/site claims are algae control in toilet bowls, or brown dog ticks in a commercial kitchens. The registrant must be informed that such a claim is denied.

Sites and pests also should be appropriate for the intended end-user or customer of the product. For example, pests and sites listed on the labels of residential consumer (general public) products should be typical household/garden pests or plants, and not something crop specific like cotton bollworm or plants unlikely to be found in home gardens, for example "cranberries".

☞ "No Pest" Products: Several pesticides are not intended to control pests, i.e. they have no "target" pest. Examples are: plant regulators, desiccants and defoliants.

2. Where is the pesticide used -

☞ what are the intended sites of application?

☞ are the sites clearly listed and identified?

The application or treatment sites must be clearly identified and specified as much as possible on the label. For example, if residential dwellings are listed as an application site, where in a dwelling would the pesticide be applied? The reviewer may need to inform the

registrant that the application sites need to be identified more specifically (as for example, cracks and crevices in kitchen areas of residential dwellings).

Are the sites listed on an end-use product label compatible with the labeling of the manufacturing use product (MP) which is used as the source of the active ingredient in the formulation? If the MP label does not specifically list acceptable sites (such as individually named crops), or general uses such as whether products formulated from it may be used indoors or outdoors, it should at least not prohibit uses appearing on the end-use labeling undergoing review. If this is the case, the registrant must be informed that they must change their source of the active ingredient to one with compatible labeling, or delete the questionable use.

For residential consumer-use products, the application sites listed on the label should be limited to the home, yard, garden, and pets. Products intended for use by commercial applicators may include residential sites, but also industrial and institutional sites such as areas in food processing plants and hospitals.

3. How is the pesticide applied -

- ☞ in what form is it applied?
- ☞ is it mixed, and if so, how?
- ☞ how much product is used?
- ☞ is equipment necessary and if so, what type?
- ☞ is it compatible with other products?

First, the reviewer must identify what form the product is in (dry, liquid, a gas or a fumigant). This information is more readily apparent to the applicator than to a label reviewer. If the product name does not identify the formulation (such as "Sevin Dust"), the reviewer may have to search the label briefly to determine the formulation type, for example, by checking the net contents statement (gallon or pounds?), by checking the Physical & Chemical Hazards section to see if the product is pressurized, or by looking at the container disposal instructions. Reference should also be made to the Confidential Statement of Formula (CSF) for the product. Column 15 of the CSF indicates the purpose of an ingredient in a formulation. If something is identified as a propellant in column 15, then the product is pressurized (an aerosol). Dust and granular products will contain ingredients which are referred to as

"carriers." Liquid formulations will contain ingredients which may be identified as solvents, emulsifiers, and defoamers. The product chemistry (if available, some very old registrations often do not have product chemistry data) will include the manufacturing process which also provides information on the formulation type.

Secondly, the reviewer should determine if the formulation is "ready-to-use" or a concentrate which requires mixing. Aerosols, dusts, baits, granules and some liquids are examples of ready-to-use formulations. Formulations requiring mixing such as liquids which are referred to as concentrates, as well as wettable powders, must have direction for dilution. These directions should be reasonable, easily understood, and presented as obvious usable units of measure, i.e., not "add 2.678 ounces to a gallon." The units of measurement must be by weight for dry formulations (lbs, oz.), or volume for liquids (pints, fl.oz.). One of the most frequent labeling errors observed by the Office of Pesticide Program (OPP) is the use of "oz" for liquids instead of "fl.oz.". Metric units may be used in parentheses after the accepted units.

The label reviewer must examine the proposed label for ambiguous language. This kind of vague or unclear text can often be found in the Directions for Use section of the label. For example, here is some language from an actual label's Direction for Use: "Mix 1½ to 2 pints of [pesticide] in 100 gals. of water. Apply 100 to 200 gals. per acre depending on spray equipment and tree size.". The ambiguity: What does the language "Apply 100 to 200 gals per acre..." refer to, spray solution, or does the applicator simply add more water to the 100 gallon mix to cover larger trees? If an applicator interpreted the directions in this way, only half of the dose would be applied. Obviously, there is a more precise means of expressing the directions for dilution and application rate.

The clearest method of presenting directions for dilution may involve the use of a chart or table. Basically, the dilution directions should state mix "X" amount of pesticide with "X" amount of water (or oil) to achieve a particular dilution, such as a 1% emulsion. When percentages are included in application rates, it should be indicated whether percentages are by weight or volume and whether the percentage refers to the product or a.i., unless this is obvious from the labeling.

Labels for agricultural uses, nursery uses, uses on golf courses, sodfarms or in greenhouses must comply with Pesticide Registration (PR) Notice 87-1, unless the product is solely for residential use, direct injection into plants, post-harvest application, or is applied as a gas, or solid (pellets, tablets, granules, or dusts). This PR Notice states that labels must include the statement, "Do not apply this product through any type of irrigation system." or

include labeling statements regarding chemigation contained in the PR Notice. Refer to PR Notice 87-1 for appropriate chemigation statements.

How the product is applied and whether special equipment is needed to mix and/or apply the product must be detailed in this section. The application rate, (how much to apply per unit area) must also be stated. Agricultural products usually express the application rate as pints/acre for liquid formulations, or pounds/acre for granulars. For residential consumer use products, the application rate should be expressed in much smaller units, such as pounds/square feet since this is much more appropriate for the home garden or yard. Additionally, if equipment is required to apply a product purchased by a residential consumer, it should be the common hardware store type, such as a spreader. The public generally does not have access to (and does not use) fancy or specialized equipment. They also do not put out the quantities of pesticides that growers or pest control operators do and will not need or have equipment for handling large volumes of pesticide.

As mentioned above, labels which have directions for use instructing user to mix a spray solution should indicate the spray volume per acre or per unit area. For some applications it is acceptable for the label to indicate something like, "apply sufficient volume for through coverage". For dust applications of consumer products, a statement such as "apply uniformly for through coverage of plant surfaces" may adequately substitute for a specific application rate. For aerial applications, spray volumes **must** be stated. *Note:* Spreader settings may vary from product to product. Such changes in spreader settings are not usually considered significant.

4. When should the pesticide be applied -

   ☛ are there seasonal, time-of-day, or weather restrictions or limitations?

   ☛ does it stain? (so it should not be used around certain fabrics, papers. or other materials)

   ☛ is it phytotoxic (to some plants in the application area)?

   ☛ is it best to treat some pests at different times of the day, or in certain kinds of weather?

Label reviewers should be aware of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 2(ee) which allows the applicator of a pesticide to apply the pesticide under certain conditions not specified on the label. These conditions are as follows:

- a product may be applied at any dosage, concentration, or frequency less than that specified on the label, unless the label specifically prohibits such an application,

- it may be applied against any target pest not listed on the label as long as the crop/animal/site is on the label, unless the Administrator has forbidden it,

- any method of application not specified on the label, and not forbidden by the label text, may be used, and

- a pesticide may be mixed with a fertilizer if the label text does not prohibit it.

These provisions of the law do not relieve the registrant from the requirement of providing complete directions for use, they only clarify what is not considered misuse.

Not only should the directions for use provide the basic application information, it must also be reasonable and make sense. Any applicator, and especially the general consumer or homeowner - who is a nontechnical and occasional applicator - should be able to easily understand the directions for use.

Review Instructions

As the directions for use can be very complex, it is best to review this section step by step, starting with the first site/pest combination on the label, and going through the series of review points, listed below.

(1) Is the formulation acceptable for this site/pest combination?

(2) Is the site appropriate for the pest? Is it included in Appendix A of the RED, if there is one for the active ingredient (ai)?

(3) Can you calculate the application rate? Is it acceptable (i.e. does it agree with the rates in the Registration Standard or RED (if one is available)?

(4) Is there a tolerance?

(5) Is the PHI (preharvest interval, i.e., the minimum amount of time allowed between the last application and the harvest of the crop) or PSI (preslaughter interval - for animals) correct?

(6) Is the application frequency acceptable? (i.e. within requirements for the tolerance, appropriate for controlling pests, etc.).

(7) Is the restricted entry interval (REI) appropriate? (refer to the WPS appendix at the end of the chapter)

(8) Is the timing of the applications acceptable? (i.e., prebloom?).

(9) Is the method of application appropriate?

(10) Is all required equipment identified/specified?

(11) Is the rate of application consistent with the packaging of the product? The directions for use should not call for more than the net contents of the product (i.e., if a granular product is packaged as a 1 pound unit, its application rate should not require 200 pounds of product).

(12) If the product contains more than one active ingredient, are all the uses acceptable for all the actives? For example, an ethyl parathion/methyl parathion product may only be used on the nine crops registered for ethyl parathion applications, even though methyl parathion is registered on additional crops. If there is more than one ai and a RED is available for each, all sites on a label must be listed in all associated REDs.

Once the first site/pest combination is "analyzed," the procedure should be repeated for each successive site/pest combination until all uses are reviewed. However, some of the review points noted above do not apply for all pesticides. For example, most of these questions are inappropriate for a dog collar that controls fleas (which has one "site" and very simple directions). However, the basic question regarding use applies to all pesticides: **Does the use of the product make sense and will the applicator understand what to do with the product?**

When answering the questions noted above, the reviewer should refer, as needed and as appropriate, to labels of substantially similar products for Me-Too applications, to the RED (if there is one), to the Registration Standard (if there is one and if it is not superseded by a RED), and, for new or revised uses, to any reviews from HED, EFED, or RD/Efficacy. The Code of Federal Regulations, Title 40, should be consulted for published tolerances.

The directions for use section can become very involved depending on the site and biology of the pest. Also, individual Branches may have their own label requirements. Your Product Manager and fellow reviewers are your best sources of such specific information.

Worker Protection Standard (WPS) Requirements

Chapter 8 provides the information necessary to determine whether the label under review is subject to the requirements of the Worker Protection Standard (WPS). Products are referred to as being "in scope" or "out of scope/not in scope." The following are the WPS requirements for the Directions for Use section. [40 CFR 156, Subpart K (156.200 - 212)]

Products Subject to the WPS Must Bear Labeling in the Four Sections Listed Below:

1. General Statements
2. Restricted Entry Interval (REI)
3. Notification-to-workers Statements
4. Non-Agricultural Use Requirements

1. General Statements

The following statements must appear on all labels.

A. "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Statement Location Requirement: Must appear near the beginning of the Directions for Use section of the labeling and must appear in a box with the heading "AGRICULTURAL USE REQUIREMENTS".

B. "Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170."

Statement Location Requirement: Must appear on the product label under the heading "AGRICULTURAL USE REQUIREMENTS".

C. "This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label [in this labeling][1] about [use any of the following that are applicable][2] personal protective equipment, restricted-entry interval, and notification to workers."

Statement Location Requirement: Must appear immediately following Statement No. 2 or these statements can be placed in supplemental product labeling under the heading "AGRICULTURAL USE REQUIREMENTS".

C_1. "Refer to supplemental labeling entitled AGRICULTURAL USE REQUIREMENTS in the DIRECTIONS FOR USE section of the labeling for information about this standard."

> **Special Note:** Statement No. C or C_1 can be used on the label. If statement No. C_1 is used on the label, then statement No. C must appear on supplemental labeling.

Statement Location Requirement: If Statement Number C appears on supplemental labeling, then the referral statement (Number C_1) must appear on the label immediately following Statement Number B.

4. "For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation."

Statement Location Requirement: Must appear under the heading "AGRICULTURAL USE REQUIREMENTS".

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[1]The appropriate phrase must be used. When reviewing a label, the phrase "on the label" should be used. When reviewing supplemental labeling, the phrase "in this labeling" should be used.

[2]Only relevant items should be included in statement (Example: if label does not require PPE, the phrase "personal protective equipment" should not be included as part of Statement No. 3.)

2. Restricted-entry Statements

All product labeling must display a Restricted Entry Interval (REI). An REI is the time period immediately following a pesticide application during which entry into the treated area is restricted. Some labels may have several different REIs for different crops.

- **REI(s) for Fumigants**: Current REI(s) will be retained or at the time of registration, an REI will be determined on a case-by-case basis.

- **REIs determined by Subdivision K Data (158.390)**: REI(s) will be retained.

- **All Other REI(s)**: Follow the steps below.

Step 1: Identify Acute Toxicity Data and/or Signal Word to Be Used in Determining REI(s)

REI(s) are based on the most severe acute toxicity category assigned to the acute dermal, eye irritation and skin irritation data for all of the active ingredients (A.I.) in a product. In many instances, these data are not always available. The following list indicates the preferred order for selecting data on which to determine the toxicity category for each A.I:

1. Use the acute dermal, eye irritation and skin irritation data for each active ingredient;

2. Use the acute oral and eye irritation and/or skin irritation data for any active ingredient missing acute dermal data;

3. Use the eye irritation and/or skin irritation data for any active ingredient missing the acute oral and acute dermal data;

4. Use the signal word of the registered manufacturing use product that is the source of the active ingredient which does not have any acute oral, acute dermal, eye irritation, or skin irritation data;*

5. Use the signal word of the product under review if none of the above data is available on the active ingredient or if the active ingredient without data is not a registered manufacturing use product.*

*When signal words are used to determine the toxicity category, the signal words correspond to the following toxicity categories: DANGER = Category I; WARNING = Category II; and CAUTION = Category III and IV

The chart below provides examples of how the acute toxicity category is determined for purposes of determining the REI.

Product A	Available Acute Tox Data for Each Active Ingredient	Tox Cat.	Tox Cat. Used to Determine REI
Sole A.I.	Acute dermal tox data Eye irritation data	III II	II
Product B	**Available Acute Tox Data for Each Active Ingredient**	**Tox Cat.**	**Tox Cat. Used to Determine REI**
A.I. #1	Acute dermal tox data Eye irritation data Skin irritation data	III II III	
A.I. #2	Acute oral tox data	III	
A.I. #3	Signal word of registered MP (source of A.I.)	I	I

Step 2: Determine appropriate REI(s) using the chart below and note exceptions:

Most Severe Tox Category Used to Determine the REI	Length of Required REI
When the most severe tox category is III or IV	The REI is 12 hours
When the most severe tox category is II	The REI is 24 hours
When the most severe tox category is I	The REI is 48 hours
In addition: if the product is an organophosphorus ester that inhibits cholinesterase and may be applied outdoors in an area where the average rainfall for the application site is less than 25 inches per year,	Add an additional 12 hours, for an total REI of 60 hours

Exceptions:

- If any existing interim REI(s) which were established prior to 10/20/92 are longer than the REI(s) based on the table above, the existing interim REI(s) should be retained.

- If a product bears REI(s) for uses not subject to the WPS, those REI(s) should be retained; however they can not be placed under the "AGRICULTURAL USE REQUIREMENTS".

REI(s) Location Requirement: Must appear in the box with the heading "AGRICULTURAL USE REQUIREMENTS".

REI(s) Format Requirement: The REI must appear in the following format:

> "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) [include single REI here, see A. & B. below]."
>
> A. Single REI: If a product has only one REI, then the REI shall appear as a continuation of the above required sentence in one of the following formats: "of X hours"; "of X days" or "until the acceptable exposure level of X ppm or mg/m^3 is reached".
>
> B. Multiple REI(s): If different REI's exist for certain crops or uses, then the REI must appear in the directions for use for that crop or use. The REI must be immediately preceded or followed by the word "Restricted Entry Interval" or the letters "REI".

3. Notification-to-workers Statements

A notification to workers statement is required if the product meets the criteria below.

Fumigants: Fumigants that are registered for use in greenhouses or whose labeling allows use in greenhouses must bear the following statement:

> "For greenhouse applications, notify workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse."

All Other Products: Products which contain any active ingredient classified as toxicity category I based either on acute dermal toxicity data, skin irritation data, or the criteria below shall bear the notification statement.

Step 1: Determine available data for toxicity category determination. Since acute dermal and skin irritation data may not always be available, use the following list to guide you in selecting which data/signal word should be used for determining the acute toxicity category:

1. Consider acute dermal and skin irritation data on all A.I.(s) in the product;

2. If acute dermal data are missing for any A.I., consider acute oral data on that A.I. in addition to the primary skin irritation data on the A.I.

3. If acute oral and acute dermal data are missing for any A.I., consider the skin irritation data on the A.I.;

4. If the acute oral, acute dermal, and skin irritation data are missing for any A.I., consider the signal word of the registered manufacturing use product for the A.I.;

5. If none of the above data is available on any A.I. in the product, consider the signal word of the end-use product.

Step 2: If any data used in Step 1, No. 1-5 are toxicity category I or the equivalent signal word of "DANGER", then a notification statement is required.

Required Statement:

> "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

Location of Statement:

All notification statements must be located in the DIRECTIONS FOR USE section in the box with the heading AGRICULTURAL USE REQUIREMENTS.

4. Non-Agricultural Use Requirements

If the label your are reviewing contains only uses within the scope of the WPS, you may skip this section. If the label contains entry restrictions, notification requirements, or other instructions similar to WPS requirements that apply to uses NOT within the scope of the WPS (non-agricultural uses), there should be a second box on the label called: "Non-Agricultural Use Requirements". This box may be placed anywhere in the Directions for Use section of the label **after** the Agricultural Use Requirements box.

The following statements must be contained in the non-agricultural use requirements box:

"Non-Agricultural Use Requirements"

"The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses."

In addition, place into the Non-Agricultural Use Requirements box all the entry restrictions, notification requirements, or other statements and instructions (except personal protective equipment requirements) that apply to the non-WPS uses on the label. Examples: "Keep children and pets out of the treated area until sprays have dried." or " Keep unprotected persons out of treated areas until sprays have dried.".

Chapter 12 EFFICACY CLAIMS & MARKETING STATEMENTS

Introduction

Efficacy data generally are only required to be submitted for products claiming to control pests which pose a threat to human health, either by direct action or through transmission of diseases [40 Code of Federal Regulations (CFR) 158.640]. This chapter provides guidance for reviewing claims made on proposed labels.

Products Requiring Efficacy Data

1. *Disinfectants* - All products (excluding those which are recommended for use in or on living man or animals) intended to control microorganisms infectious to man.

2. *Invertebrate Control* - Products intended for use in or on humans (or in or on pets for control of pests which attack humans) such as fleas, ticks, mosquitoes, biting flies, and in premises or in the environment to control pests of sanitary or public health significance such as the above as well as wasps, scorpions, poisonous spiders, fire ants, cockroaches, centipedes and bedbugs.

3. *Rodenticides and Repellents* - Rat and mouse control products; products used to disperse or control birds that pose health threats; products used to control rabies vectors such as bats, skunks, raccoons, foxes, coyotes; products used to control rodents considered to be disease vectors, products used to control vertebrate animals such as poisonous snakes, dogs, and bears that can injure humans by direct attacks.

4. *Potential Hazards* - Those products that are potentially very hazardous, and for which the Agency determines that it is necessary to conduct a "risk-benefits" analysis.

5. *New Actives or New Uses* - Formulated products which either contain new active ingredients or have proposed use patterns which differ greatly from any previously accepted for a similar formulation, and which may have public health uses.

6. *Products to Control Aflatoxin-Producers* - Products intended to control organisms that produce aflatoxins (organic compounds produced by the fungus *Aspergillus flavus* which are highly toxic and carcinogenic to mammals). No such products are currently registered.

☞ **Important:** Although the Agency does not require submission of efficacy data (except for the above listed types of products), the applicant or registrant is required to have such data on hand. EPA reserves the right to call in such data at any time, either during initial review or subsequent to registration. The PM team reviewer should be alert to label claims that seem to promise control or performance beyond that of similar products. For example; a 2,4-D product that claims control of weeds in lawns for one full year or a cotton insecticide that claims total season-long elimination of pink bollworm with just one application. When the reviewer spots such suspicious claims, the Product Manager should be consulted and, if warranted, the applicant should be told to delete the claims or to submit efficacy data which support the claims. In cases where such data have been required, the applicant often withdraws the application or submits revised labeling deleting the claims.

Product Performance Data

Efficacy data (also referred to as product performance data) are generated by studies designed to document how candidate pesticide formulations perform as pest control agents. These studies include tests run to determine the lethality of a formulation against a certain pest species, to document control under actual use situations, and to determine whether claims beyond mere control are supported (i.e., length of a residual effect).

The Agency has standard protocols for certain efficacy tests. In general, standard methods have been developed for tests needed to substantiate claims that have been made frequently for pesticide products. As the scope of potential pesticidal claims is extremely broad, the Agency does not have standard methods for tests needed to substantiate many of these claims, especially those that are uncommon. The Product Performance Guidelines, Subdivision G, offer general guidance for developing protocols for efficacy testing. Proposed protocols should be submitted to the Agency for review before tests are initiated.

Label Reviewer's Role

Within the Registration Division, product performance data is specific to and evaluated by the three product Branches: Antimicrobial Programs Branch (APB), Fungicide-Herbicide Branch (FHB), and the Insecticide-Rodenticide Branch (IRB).

APB has developed guidance documents called DIS/TSS enclosures for the review of antimicrobial pesticides, including determination of health-related and non-health-related issues (DIS/TSS-16) and label requirements. Efficacy issues including label review are handled by the Efficacy Evaluation and Technical Management Section (EETMS). The microbiologists

within EETMS are responsible for determining whether the product claims are supported by the data and that the directions for use are appropriate for the claims.

Within FHB, requiring efficacy data is not generally an issue as the target pests seldom affect human health. Specific claims are evaluated by the individual teams.

IRB routes insecticide efficacy reviews to technical reviewers on the Branch's staff for evaluation. Rodenticide efficacy data are reviewed specifically by a reviewer on PM Team 14.

The following points should be kept in mind when reviewing labels bearing public health efficacy claims:

- Ambiguous and generic claims of efficacy such as "kills germs" are not acceptable.
- Use directions should be clear and easily understood by the applicator.
- Check with the efficacy reviewers if the label makes unusual claims, deviates from a standard use pattern, or if the formulation changes (minor formulation changes in an antimicrobial product can alter the efficacy of the product, alternate formulations are not acceptable for rodenticides). Request a formal efficacy review for all claims which differ significantly from existing claims.
- Do not allow any claim that would render the product misbranded under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 40 CFR part 156.10(a)(5).

Product Name

The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label. No name, brand, or trademark may appear on the label which is false or misleading, or has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to 40 CFR 152.132.

Sometimes the product's name on the label can be construed as a claim. The label reviewer should scrutinize the product name to determine there is nothing false or misleading about the product's name.

The exact same name cannot be used for different products by any one registrant. The product name must be sufficiently different to clearly distinguish one product from another.

Warranty Statement

Warranty statements contain language intended to limit liability, or act as disclaimers or warranties for the product. Generally, we don't concern ourselves too much about these statements, however there are three generally recognizable types of unacceptable label language associated with disclaimers, warranties and limitations of liability are as follows:

a. Broad statements detracting from use instructions or other label language. (i.e., precautionary statements);

b. Label language asserting that the buyer has accepted the manufacturer's statement of his respective rights. (i.e., manufacturer states buyer's rights are extremely limited);

c. Over-broad language implying buyer has no legal right to recover damages from manufacturer.

Review proposed label's warranty/disclaimer/liability limitation language for statements which appear to negate or detract from use instructions or other legal language.

Chapter 13 **STORAGE AND DISPOSAL**

Introduction

All pesticide products are required to bear instructions for the storage and disposal of pesticides and pesticide containers. One exception are homeowner products which are only required to contain instructions for pesticide container disposal. Storage and disposal instructions cover the appropriate storage of the pesticide product; disposal of any unused pesticide product or any rinse liquids resulting from cleaning of pesticide application equipment; and the disposal of the pesticide container.

Statement Location

The storage and disposal instructions must appear grouped together, preferably blocked, near the beginning or end of the "Directions for Use" section [40 Code of Federal Regulations (CFR) 156.10 (2)(ix)]. It is preferred that the storage and disposal instructions appear at the end of the use direction section. This placement eliminates the break between the heading "Directions for Use" and the body of the use directions.

Format

All products, except products labeled for home and garden use by homeowners, must bear the heading "STORAGE AND DISPOSAL". These instructions must be set apart and clearly distinguishable from other directions for use. Blocking these statements with a solid line is suggested as a means of increasing their prominence. See example below:

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage . . .
Pesticide Disposal . . .
Container Disposal . . .

Type Size Requirement

The heading "STORAGE AND DISPOSAL" must appear in the specific type size requirement as stated in Pesticide Regulations (PR) Notice 83-3.

Determining Storage and Disposal Labeling

1. *Pesticide Storage Statements:* Review the information below to determine the appropriate document to use as the source of pesticide storage statements.

   A. RECENT Registration Standard or Reregistration Eligibility Document (RED): If a Registration Standard or RED exists, and is more recent than PR notices 84-1 (issued 2/17/84) or 84-5 (issued 11/15/84), refer to the Registration Standard or RED to determine whether there are specifically required storage statements. If the Registration Standard or RED does not contain storage statements, use the general guidance contained in this section under B. 3. Storage Guidance from PR Notice 83-3.

   B. Old/No Registration Standard or NO RED: If there is no Registration Standard or RED, or if the Registration Standard is older than PR notices 84-1 or 84-5 (see dates above), review one through three below to determine the appropriate document to use as the source of the pesticide storage statements.

      (1.) Statements for Specific Chemicals: PR Notice 84-1 and an errata sheet dated 4/12/84 contain specific storage statements for the active ingredients listed in the Table 1 below:

Table 1

Active Ingredient	Pesticide Storage Statements
Aspon	Label must be modified to include a warning against transporting or storage in unlined steel containers.
Aluminum phosphide	The following statement must be used in addition to the guidance in PR Notice 83-3: "Not for use or storage in or around inhabited areas".
Ethoxyquin	The following statement must be used in addition to the guidance in PR Notice 83-3: "Open dumping is prohibited."
Liquid Sodium hypochlorite Liquid Calcium hypochlorite	"Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not reuse empty container but place in trash collection. Do not contaminate food or feed by storage, disposal or cleaning of equipment."
Magnesium phosphide	The following statement must be used in addition to the guidance in PR Notice 83-3: "Store only in cool, dry locked, and ventilated room. Protect from moisture, open flames or heat".
Solid Calcium hypochlorite	"Keep this product dry in a tightly closed container, when not in use. Store in a cool, dry, well ventilated area away from heat or open flame. In case of decomposition, isolate container (if possible) and flood area with large amounts of water to dissolve all materials before discarding this container. Do not reuse empty container but place in trash collection. Do not contaminate food or feed by storage or disposal, or cleaning of equipment."
Terrazole	All manufacturing use products must contain the statement, "This product is corrosive to steel and many other metals. Do not transport or store in unlined metal containers".
Zinc phosphide	The following statement must be used in addition to the guidance in PR Notice 83-3: "Store in a dry place. Do not store around the home."

(2.) Fumigants: Refer to PR notice 84-5 for specific storage guidance for the following chemicals: methyl bromide; methyl bromide & 2% or less chloropicrin; aluminum & magnesium phosphide; chloropicrin; calcium & sodium cyanide; ethylene oxide; sulfuryl fluoride; ethylene dichloride; carbon tetrachloride; carbon disulfide; mixtures of carbon tetrachloride & carbon disulfide; and mixtures of carbon tetrachloride & ethylene dichloride. For all other fumigants, refer to number 3 below (Storage Guidance from PR Notice 83-3).

(3.) Storage Guidance from PR Notice 83-3: Review the general guidance on appropriate pesticide storage instructions from PR Notice 83-3 listed below to determine if the label under review meets the requirements of PR Notice 83-3 Section I (A).

- Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

- Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage temperature, potential for breakage of glass, crushing or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

- Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

- Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

- General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

- General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

2. *Pesticide Disposal Statements:* The label of all pesticide products excluding those products labeled specifically for homeowner use are required to bear pesticide disposal statements.

   A. General Statement: All products, except those labeled for household or domestic use only, must bear the following statement according to the 2/12/86 memo by D. Campt entitled Updated Hazardous Waste Listings under the Resource and Conservation Recovery Act (RCRA):

      "Do not contaminate water, food, or feed by storage and disposal."

   This statement should appear immediately under the heading "Storage and Disposal".

   B. Other Pesticide Disposal Statements: Review number one and two below to determine the appropriate document to use as the source of the pesticide disposal statements.

      (1.) Registration Standard or RED Issued After 2/12/86. If the label under review involves a chemical for which a Registration Standard or RED was issued after 2/12/86, refer to the Registration Standard or RED to determine if any specific pesticide disposal statements exists. If no specific guidance exists, refer to the 2/12/86 memorandum by D. Campt to determine the appropriate pesticide disposal statement.

      (2.) Registration Standard or RED Issued before 2/12/86. If the label under review involves a chemical for which a Registration Standard or RED was issued before 2/12/86, refer to the 2/12/86 memorandum by D. Campt to determine the appropriate pesticide disposal statement.

4. *Container Disposal Statements:* All pesticide products must bear container disposal statements which are specific for each type of container. PR notice 94-2 allows registrants, at their discretion, to use alternate container disposal statements permitting the recycling of empty aerosol pesticide containers. The alternate statements must specify that containers be emptied through normal use and that recycling centers for aerosol containers are not available in many areas. The alternate statements are in addition to the disposal instructions.

Review sections A and B below to determine the appropriate document to use as the source of the container disposal statements.

A. Homeowner Products: If the label under review involves a chemical for which a recent Registration Standard or RED was issued (after the 2/12/86 memo by D. Campt), refer to the Registration Standard or RED to determine if specific container disposal statements are provided. If no specific labeling is provided or if no Registration Standard or RED exists, use the following container disposal statement from the 2/12/86 D. Campt memo for homeowner products or a revised statement allowing recycling:

Statement from D. Campt Memo: "Securely wrap original container in several layers of newspaper and discard in trash."

PR notice 94-2 sample statement: "This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label (DO NOT PUNCTURE!). If the recycling is not available, wrap the container and discard in the trash."

B. All Other Products: If the label under review involves a chemical for which a Registration Standard or RED was issued after PR notice 83-3 (issued 3/29/83), refer to the Registration Standard or RED to determine if specific container disposal statements are provided. If no specific labeling is provided or if no Registration Standard or RED exists, refer to Table 2 below which provides the container disposal statements from PR notice 83-3.

Table 2

Container Type	Disposal Statements
Metal Containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Paper and Plastic Bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Glass Containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.
Fiber Drums with Liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Plastic Containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Compressed Gas Cylinders	Return empty cylinder for reuse (or similar wording).

Chapter 14 GRAPHICS & SYMBOLS ON LABELS

Introduction

Graphics and symbols are often found on pesticide labels, but may or may not appear on the draft labeling under review. They may appear for various reasons especially in association with the Directions for Use section, or as a marketing tool. Graphics and symbols are acceptable on product labels in addition to written text as long as they afford greater comprehension of the label language, do not obscure or crowd required label language, or misbrand the product. Symbols may not be used instead of text. Refer to the information below for guidance in determining whether graphics and symbols the reviewer may see during the label review process are acceptable or unacceptable. Consultation with the Product Manager and/or Branch Chief may be necessary if a close judgement call is involved. (Reference: **FEDERAL REGISTER** (FR) Proposed Rule on Labeling Requirements, Vol. 49, No. 188, § 156.10(e) [9/26/84])

Acceptable Graphics & Symbols

Graphics and symbols are acceptable on product labels if they serve to enhance the understanding of the accompanying text. Examples of acceptable graphics and symbols include:

- Arrow diagrams of how to open product containers.
- Graphics which display spray patterns of nozzles and/or application patterns and are supported by the label text.
- Skull and Crossbones next to the word DANGER on products classified as Toxicity Category 1 based on acute oral, acute dermal and/or acute inhalation toxicity data.
- Pictograms near the precautionary labeling statements depicting the different exposure routes (oral, inhalation, and/or dermal) to pesticides.
- Pictures showing examples of places where the pesticide may be used, such as in a household or a specific commercial site which are supported by the label text.
- Child hazard drowning pictogram and labeling (a picture inside a circle with a line through it showing a bucket with a child turned upside down in the bucket).

Such pictograms may be seen on the labels for large buckets. This pictogram may not obscure or detract from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) required text. Since the pictogram may be accompanied by the word "WARNING", this pictogram should not appear on the front panel or near the precautionary statements as it may be confused with the pesticide product signal word. (Reference: Stephen L. Johnson letter of 9/30/93)

- Mr. Yuk symbol on the label and or outer container of product. Mr. Yuk is pictured as a green frowning face with his tongue hanging out.

- Pictures depicting appropriate protective gear.

- Pictures illustrating proper use.

Unacceptable Graphics & Symbols

If the draft label under review contains any of the following graphics/symbols, inform the registrant that they must be removed from the label.

1. Graphics and Symbols which are unrelated to the use pattern on the draft label. Some examples are listed below:

   - A food pictured on a label which bears no directions for use on that food. A picture of cherries may not appear on a label if the product is not registered for use on cherries.

   - Pictures of people using a product without the required personal protective equipment. Pictures of users must be consistent with personal protective equipment (PPE) requirements on the label. For example, if the label requires that the applicator wear full chemical resistent coveralls with goggles, the label illustration cannot show a person wearing shorts and no protective eyewear.

   - National Fire Protection Association (NFPA) system for hazard codes may not be placed on the label. (Reference: L. Culleen letter dated 6/14/93)

   - Pictures of a pest not claimed to be controlled by the product.

   - Pictures depicting any nonfood site not claimed on the label.

2. Graphics and symbols which are misleading to the user. Some examples are:

   - Pictures of children playing, unless the product is registered for use on children.
   - Pictures of candy.
   - Symbols implying safety or nontoxicity, such as a red cross or a medical seal of approval.
   - Pictures of flowers or fruit on a label which imply that the product has a floral or fruity fragrance and the formula does not contain such ingredients.
   - Pictures of use sites in a residence when the product label is limited to use in commercial or industrial sites.
   - The EPA logo or any other Agency logo which implies endorsement by a Government Agency.

Graphics & Symbols Not Subject to FIFRA Which are Acceptable

The following graphics and symbols are not required under FIFRA and are not part of the label review.

- Department of Transportation symbols indicating the hazard and flammability of a particular chemical or pesticide.
- Barcodes which allow for easier scanning of prices in retail stores. (Reference: Larry Culleen letter of 11/13/92)

Chapter 15 COMPANY NAME AND ADDRESS

Introduction

The company name and address of the registrant are required features of the pesticide product label. These features must be displayed prominently and within the range of type size that is required for all label text [see chapter 3 of the manual]. These may be found any where on the label, but are most commonly found on the front panel of the pesticide label [see 156.10 (c)].

Foreign Registrants

If the registrant is not residing in the United States, he must designate an agent who resides in the United States and to whom all correspondence concerning the product or any subsequent registration actions will go [see 40 Code of Federal Regulations (CFR) 152.50 which outlines the requirements of a foreign registrant].

Chapter 16 CONTENTS/NET WEIGHT STATEMENT

Introduction

The Net Contents statement identifies how much pesticide is in the container. Usually draft labels will only include the phrase "Net weight: ___" or "Net Contents: ___" as a means of identifying where the statement will actually appear on the final printer label. The actual amount of pesticide is usually left blank because the registrant often intends to market the product in various sizes. The reviewer can refer to the Application for Pesticide Registration form (EPA Form 8570-1) for information on the various container net weights. Actually, the regulations, [40 Code of Federal Regulations (CFR) 156.10(d)] does not require the term/heading "Net Weight" or "Net Contents" to be stated on the label, although it does require that the weight/volume be expressed as the net weight/contents. Even so, the Agency strongly recommends that the term "Net Weight" or "Net Contents" be reflected on the label, since it describes the amount of material in the container as opposed to the weight of the entire product. This could reduce the possibility of confusion and/or questions by users.

Location of Contents/Net Weight Statement

There is no required location for the Contents/Net Weight Statement. The preferred location is the bottom of the front panel below the company name and address. If the draft label under review contains the contents/net weight statement in some other location, the reviewer should suggest that the statement be placed on the lower third of the front panel.

Type of Measurement

Check the draft label to determine if the contents/net weight statement is expressed correctly. [40 CFR 156.10(d)]

1. *Dry formulations* (includes solids or semisolids such as dusts, granulars, pelleted or tableted baits, wettable powders, microencapsulated product, impregnated materials): The net weight must be expressed as pounds or ounces.

2. *Liquid formulations* (includes pressurized products): The net contents must be expressed as gallons, quarts, pints or fluid ounces.

3. *Gases:* The net contents must be expressed as pounds.

Expression of the Statement

Review the draft label to make sure that it meets the following requirements:

1. Conventional "American" (U.S.) units of measurement are used. It is permissible, but not required, for labeling to declare net contents in metric units (liters, kilograms, etc.), so long as U.S. units of measurement are also declared. For example, "Net Contents: 1 gallon (3.785 liters)". **It is not acceptable to list ONLY metric units.** The same policy holds for the Directions for Use. For example, the applicant may elect to use the equivalent kilograms per hectare in addition to expressing application rates as pounds per acre.

2. The Net Contents must be stated in terms of the largest suitable units. For example, "1 pound (lb.) 10 ounces" would be shown on the draft label instead of "26 ounces".

3. The Directions for Use on the label must not call for more than the net contents of the package. An extreme example is a granular product may not have labeling stating: "Net Contents: 1 pound" and then have an application rate in the directions for use of 200 lbs/acre. This problem often occurs with baits used to control rodents.

Chapter 17

EPA REGISTRATION NUMBER, ESTABLISHMENT NUMBER AND OTHER NUMBERS ASSOCIATED WITH FIFRA

Introduction

The EPA Registration Number and the Establishment Number are required on all pesticide labels and labeling. This section also covers Distributor Registration Numbers, Special Local Need Registration Numbers, and Experimental Use Permit Registration Numbers.

EPA Registration Number

1. Before a pesticide product is registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3, the reviewer may see an **EPA File Symbol** composed of a company number followed by a series of letters representing the future product number. The letters come from the word "**REGULATION.**" Each letter represents a number starting with "**1 (one),**" and ending in "**0 (zero).**" Accordingly, R=1, E=2, G=3, U=4, L=5, A=6, T=7, I=8, O=9, and N= 0. Therefore, if 6767-EGN is registered, it would become EPA Registration Number 6767-230. "6767" is the number identifying the company holding the registration and "230" is the number identifying that specific product. Product numbers are assigned sequentially.

2. The **EPA Registration Number** indicates which company holds the registration for the pesticide, and in which sequence the product was registered by the company. For example, the first product for a particular company will be product number one, and the second will be two, and so on. The reviewer will see the registration number preceded by the phrase, "**EPA Registration No., or EPA Reg. No.**" This will be followed by a company number then a dash (-) then the product number.

   This phrase and number has no location requirement but is often found on the front panel of the product label. [40 Code of Federal Regulations (CFR) 156.10 (e)].

3. FIFRA and the regulations permit a registrant to distribute or sell a registered product under a distributor's name and address [40 CFR 152.132]. This is called "supplemental distribution". Although distributor labels are not submitted to EPA for review and stamped approval, questions that concern them may arise from internal or external customers. The distributor label must be the same as the

registered product (basic registration) except for: product name, name and address of distributor, and any claims (uses, for example) that are deleted from the label. The Distributor label must show the EPA Est. No. of the final establishment at which the product was produced.

Distributor products must bear the EPA Registration Number of the basic product, followed by a dash [-], and then followed by the distributor's company number. For example, Rhone-Poulenc has a registered product, FOLEX 6EC Herbicide, EPA Registration No. 264-498. By notification to the Registration Support Branch of the Registration Division, Rhone-Poulenc adds Cornbelt Chemical Company as a distributor. Cornbelt's assigned company number is 10107. The FOLEX EC marketed by Cornbelt (under their product name) must bear EPA Registration No. 264-498-10107. An EPA Registration Number consisting of three sets of numbers partitioned by dashes can be identified as a distributor product. Distributors may not amend their product labels. Only the basic registrant (in this example, Rhone-Poulenc) can amend registered labels.

EPA Establishment Number

1. The **Establishment Number** indicates where the final phase of production of the pesticide product took place. This number is preceded by the phrase, "EPA Est. No.," and may appear anywhere on the pesticide product label, or on the outer container or packaging of the product. It often is grouped together with the **EPA Registration Number**, but is not required to be. [40 CFR 167.3].

   The establishment number must appear on the product label, or on the immediate container of the product. If the EPA Establishment number cannot be seen or clearly read through the wrapping or packaging of the pesticide container, it must also appear on the outside container or wrapper of the product [40 CFR 156.10 (f)]. Since the reviewer may never see the actual outside container of the product, the establishment number may not be shown on the draft product label submitted for review by the company.

2. **Letters** such as MO, AZ, or PA, appear after the establishment number, and these letters represent the state that the product was produced in. For example, you may see an establishment number written as EPA Est. No. Company No.-MO-1, which would indicate that the establishment number is a 1 (one), and that the producing establishment exists in Missouri.

- For example: If the company is Cornbelt Chemical Company, and their company number is 10107, and the last phase of pesticide production took place at producing establishment number 89 in Hawaii, then the Establishment number for this product would read 10107-HI-89.

[Note: The establishment number is not reviewed or assigned by PM teams. It is assigned by EPA Regional Offices and the Office of Enforcement and Compliance Assurance (OECA).]

Special Local Need (SLN) Registration Number

The Special Local Need registration number (SLN number) is also known as a FIFRA Section 24(c) Registration Number. These federal registrations are issued by the states to meet special local needs. [40 CFR 162] The number is written as **"EPA SLN No."** followed by the last two digits of the year of issuance, then a four digit number which is the consecutive number of registrations that the registering state has issued in that particular year.

- *For example:* If the company, FMC applies for a section 24(c) registration in the State of North Carolina, and is the 34th consecutive state registration in North Carolina in the year 1995, then the 24(c) registration number would be **EPA SLN No. NC950034**.

Although most 24(c) registrations amend federally registered products with supplemental labels, the state may also register a new end-use product (not federally registered) as a 24(c) registration. The ingredients (including inerts) of the new end-use product must be contained in one or more federally registered (section 3) product. [CFR 162.152(b)(2)].

The EPA 24(c) registration number is assigned by the state and entered on the state registration application form (different from section 3, Application for Pesticide Registration form, EPA Form 8570-1). In addition, if the 24(c) registration is an amendment to a federal section 3 registration, the EPA registration number of the federal product is also entered on the application form.

Experimental Use Permit Number

Experimental Use Permits (EUPs) are issued by the Agency under Section 5 of FIFRA to anyone who wants to develop data on either a new product or a new use site for a future FIFRA Section 3 registration. EUP applications are assigned file symbols, by the Registration Support Branch of the Registration Division, which are written as **Company Number-EUP-File Symbol**. The file symbol is translated to an EUP registration number once the EUP has been approved by the Agency and/or an associated temporary tolerance has been established. Refer back to part 1.A. for information on the translation of file symbols to registration numbers. [See 40 CFR 172.6]

☞ For example: FMC, whose company number is 279, applies for an EUP to collect data on the crop kale and no tolerance is yet established for kale. It is given the file symbol RLE until the EUP has been approved and the temporary tolerance has been established, if applicable. Once this EUP application is approved, the file symbol 279-EUP-RLE will become EUP Number, 279-EUP-152, since this is the 152nd permit for which this company has applied.

Chapter 18 UNIQUE PRODUCT LABELING

Introduction

Certain specialty products pose a challenge for meeting the regulatory labeling requirements. Package size, shape, and composition often dictate unorthodox approaches to attaching the necessary information. The following examples have been accepted by Registration Division (RD), often after intense discussion with the registrants, and may be used as models for new and novel products that will undoubtedly be developed in the future. REMEMBER - one rule always applies: the required front panel statements [ingredient statement, signal word, skull and crossbones (if required), child hazard warning, EPA Registration No., RESTRICTED USE PESTICIDE, (if so classified) and a reference to the location of other precautions] must always be visible on the outer container label sold as a retail unit.

Our regulations, 40 Code of Federal Regulations (CFR) 152.3(t) make it clear that the "pesticide product" includes the entire package as the product is intended to be distributed or sold. Therefore, we have full jurisdiction regarding the labeling of any "non-pesticide" which is part of the package.

Multi-Packs: This category has two situations: 1) a pesticide product in one container and a non-pesticide component such as an adjuvant in a separate container (which is to be added to the pesticide during mixing) sold together in two separate containers in a single retail unit; and 2) two or more pesticide products in separate containers sold as a single retail unit and intended to be used as tank mixes just before application.

In the first instance, according to the definitions set forth in 40 CFR part 152.3, the products are distributed and sold as a single retail unit and together comprise the pesticide product. Accordingly, the Agency has jurisdiction to review the labeling of the pesticide product as well as the non-pesticide component. If the components are attached together, such with a shrink-wrap sleeve or in a box, the front panel of the pesticide must be visible. If it isn't, the front panel must be duplicated and attached to or printed on the outermost container.

In the case of two or more pesticide products being sold as a single retail unit, each container must bear or be accompanied by full labeling and the front panel must be visible under conditions of purchase. As above, if the outermost packaging obscures the front panels of the pesticides, the front panels must be duplicated and attached to the outermost container.

Small Containers

Certain containers are too small to bear all required labeling. In those cases, it is permissible to have all text except the required front panel information located on accompanying pamphlets which are considered labeling. The following information shall be the minimum requirement for the label of small containers: statement of active ingredient(s), signal word, skull and crossbones (if required), child hazard warning, EPA Registration Number, the phrase "RESTRICTED USE PESTICIDE" if classified, and a reference statement to any accompanying pamphlets. Outer boxes, bubble-packs, accordion-pleated attached labels, and plastic ziploc envelopes containing additional labeling have been accepted. Whatever the approach, it is important to stress that ALL labeling must accompany the product at point of sale, and that the immediate container must contain a statement directing the user to the location of any additional labeling which is securely affixed to the container. All of this labeling must be reviewed and found to be acceptable.

Soluble Packets

An increasingly popular means of packaging is the water-soluble packet. It is also an Agency-mandated approach to reducing exposure of mixer-loaders to dust, vapor, or liquid pesticides. This method of packaging, however, presents problems in labeling. Since the immediate container is the film, a strict application of the regulations would require front panel text to be printed on the film itself. Although recent technological advances have made such printing possible, most standard printing technique and inks are not compatible with the polyvinyl alcohol films. In order to accommodate this desirable method of packaging, the Agency has accepted other labeling approaches. The most widely used is another tear-open foil envelope containing each soluble packet; the foil bears the required labeling. This foil envelope method has the added benefit of protecting the soluble packet from moisture which could cause shelf-life problems. Another acceptable method is a muffin-pan type of package where each packet is enclosed in a depression with a tear-off top that seals each such depression. The tear-off top bears the required labeling. The vital consideration in dealing with soluble packets is reducing the likelihood of the consumer removing unlabeled packets from labeled containers long before use and then forgetting what they are. Since laundry detergents and dry bleaches are also manufactured in soluble packets, the risk of a serious case of mistaken identity must be avoided. It is NOT permissible to simply package a quantity of unlabeled soluble packets in an outer container where they could be easily separated from the accompanying labeling. EACH packet must either bear identifying labeling on the film itself (where feasible) or on packaging immediately enclosing that packet.

Bulk Containers

Agricultural pesticides are often sold by dealers out of bulk tanks directly into spray rigs or truck-mounted tanks brought to the dealer by the farmer or applicator. This method of sale has the advantage of reducing the number of empty pesticide containers and the attendant disposal problems. In such cases, the dealer is obligated to deliver the full label to the purchaser at the time of sale. Such labels are supplied to the dealer by the registrant. When reviewers receive such submissions, it should include the label which appears on the tank container which contains all the front panel information and a separate full label for review.

Non-FIFRA Labeling Text

Some labels submitted to the Agency have a panel devoted to Department of Transportation (DOT) shipping rules, or have New York City fire code symbols, bar codes, PA Dept. of Ag. numbers, etc. Such text is permissible and not objectable to OPP review unless it obscures or crowds the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) required text.

Since the National Fire Protection Association (NFPA) rating system (hazard codes) is not consistent with our precautionary labeling requirements, the NFPA system CAN NOT be used on pesticide labels. [Larry Culleen letter of 6/14/93] See Chapter 14.

Foreign Language Labeling

Foreign language text, in addition to English, is permitted so long as the applicant certifies that it is an accurate translation of English. It is NOT the responsibility of the Office of Pesticide Programs (OPP) to attempt the review of such text. If the foreign text is inaccurate or goes beyond the reviewed and accepted English labeling, the certification on record is the evidence that will be used by the Office of Enforcement and Compliance Assurance in taking the appropriate enforcement action.

Pesticides Used to Treat Seeds

The Federal Seed Act, administered by USDA, requires pesticide-treated food crop seeds to be discolored before they may be sold in interstate commerce. It is OPP policy to require pesticides bearing directions for commercial seed treatment (as opposed to drill-box, planter-box, and slurry treatments done by the farmer immediately before planting) to have either a dye in the formulation OR bear labeling warnings in the directions informing the user that treated seeds must be discolored before being sold. The labeling option is the

overwhelming choice of registrants since a product intended to treat a broad spectrum of crop seeds cannot have any one dye that will discolor every seed. Seeds come in many colors. For example, red dye would not discolor kidney beans, black dye would not discolor cotton seed, and yellow dye may not show up on corn.

Child-Attracting Packaging

From time to time, registrants attempt to package pesticides in containers attractive to the consumer and the consumer's children. Bait-type pesticides for rodents and roaches are a favorite type of product that have been marketed in little doll houses, fire trucks, and other toy-like dispensers. These types of packages are not acceptable. They add nothing to the efficacy of the pesticide and increase the hazard to small children. It is recognized that it may be difficult for the reviewer to determine the package style when the final printed label is only a printer's proof and not usually given a final review. However, certain types of products amenable to such unacceptable packaging should be checked and if any doubt or suspicion arises, the applicant may be contacted.

Rodenticide place packs often appear in brightly colored labels which can resemble certain candy wrappers. Labels for these products require that they not be used and stored in locations accessible to children under six years of age. Due to the dose convenience that this type of borderline child-attractive packaging offers to product users, EPA accepts it as long as the appropriate precautions and use restrictions appear on the label.