US Environmental Protection Agency
Office of Pesticide Programs

Pesticide Registration Notice (PR) 98-10: Notifications, Non-Notifications and Minor Formulation Amendments

October 22, 1998

Pesticide Registration Notice (PR) 2007- 4 superseeds part of this document. Consult PR 2007- 4, Section V. "Effect on Previously Issued PR Notices" for specific information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Fax-On-Demand
Telephone: (202) 401-0527
Item: 6102

October 22, 1998

PESTICIDE REGISTRATION (PR) NOTICE 98-10

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Notifications, Non-Notifications and Minor Formulation Amendments

This notice expands the changes to registration which may be made by notification and non-notification, maintains the expedited review of minor formulation changes, and modifies the procedures for notifications of antimicrobial products. This notice is effective immediately and supersedes PR Notice 95-2 (May 31, 1995), except with regard to advisory statements (see section II.D. below).

I. BACKGROUND

On August 3, 1996, the Food Quality Protection Act (FQPA) was passed with a provision that added section 3(c)(9) to FIFRA concerning notifications for labeling of antimicrobial products. This section allows a registrant to add relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to pesticide claims or activity. In addition, the FQPA describes the process which a registrant and the agency must follow with respect to notifications for antimicrobial products.

EPA is issuing this notice to meet the new requirements of the FQPA and to allow additional minor, low risk registration amendments to be accomplished through notification, non-notification or as accelerated amendments. EPA believes these changes will save registrants and the Agency time and resources, while maintaining full protection of public health and the environment. Table A lists all registration amendments which may be accomplished by notification, non-notification or accelerated minor formulation changes.

II. LABELING NOTIFICATIONS

40 CFR 152.46 was revised on August 26, 1996 to allow EPA to issue procedures describing modifications to registration that are permitted by notification. This section applies only to labeling notifications. The following registration amendments may be accomplished by notification:

A. Brand Names

A registrant may change the **primary brand name** and add or change one or more **alternate brand names** by notification. Each name must differ from the name of any other of the registrant's products so as to permit clear identification. Brand names may not be false or misleading [40 CFR 156.10(a)(5)]. The change or addition of alternate brand names for use by the registrant is not the same as supplemental distribution by a different company or individual under agreement with the registrant (see 40 CFR 152.132 for information on supplemental distribution). The registrant **must indicate** whether the name being submitted by notification is the **primary brand name** or an **alternate brand name**.

B. Adding or Deleting Pests

A claim against a pest that does not pose a threat to public health, except termites, may be added to the label provided that:

1. the registrant maintains efficacy data for each pest added;

2. the pest occurs on a specific site on the approved label;

3. the pest matches the type of product registered (e.g., a fungus may not be added to an insecticidal product);

4. the dosage, frequency, concentration or method of application do not change;

5. addition of the pest does not increase exposure of the pesticide to humans or the environment; and

6. the pests are not subject to quarantine by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

To add label claims against a public health pest, termites or pests subject to quarantine to a label, the registrant may not use notification, but must submit an Application for Amended Registration (EPA Form 8570-1). Public health pests include, but are not limited to, mosquitoes, cockroaches, fleas, ticks, biting flies, rodents, viruses and bacteria (other than odor-causing). Antimicrobial pests and claims which are related to public health are described in OPP's

Antimicrobial Division DSS/TSS Sheet #16. Questions about public health pests, termiticides and products used for plant quarantine may be referred to the appropriate Registration or Antimicrobial Division branch which manages those products.

A pest may be deleted from the label by notification at any time.

C. Adding an Indoor, Nonfood Site for an Antimicrobial Product

An indoor, nonfood site or substrate may be added to an antimicrobial product provided that:

1. no additional data (such as efficacy data for public health pests, groundwater data, ecological effects data) are required for the added nonfood site;

2. this site is within an already registered use pattern category for the product (as specified in 40 CFR Part 158);

3. exposure is not increased (examples of increased exposure include adding use in paints to a product registered for caulking, or adding broadcast treatment to a product registered for spot treatment);

4. an agency decision or directive does not explicitly prohibit addition of nonfood sites to particular products;

5. the labeling of the technical product from which the end use product is formulated does not prohibit the proposed site; and

6. the dosage, concentration, frequency or method of application are not changed.

D. Adding, Revising or Deleting Advisory Statements

EPA is currently examining the issue of mandatory and advisory statements and plans to propose a PR Notice regarding such statements in the near future. The proposal will be issued for public comment and then finalized upon consideration of comments received. Until that final PR Notice is issued, registrants should continue to follow the guidance in PR Notice 95-2 concerning notifications for advisory statements. Registrants should also note that advisory statements **required** by EPA may **not** be deleted by notification.

E. Changes in Packaging and Related Labeling Statements

Changes in the shape, color or composition of packaging and in labeling statements that change directly because of changes in the package size and type may be done by notification only if **all** of the following criteria are met:

1. the dosage, concentration, frequency or method of application do not change;

2. exposure is not increased (examples that increase exposure include: adding non-water soluble packaging to a product which is only registered for water-soluble packaging; protective clothing or equipment required because of the proposed package change; and new data requirements triggered for increased exposure);

3. either before or after the proposed change, the product is neither subject to child resistant packaging (CRP), nor has the registrant voluntarily used CRP;

4. the product is not a rodenticide;

5. no Worker Protection Standard labeling statements are changed;

6. the package size is not reduced to the point that the net contents of the package is smaller than the dosage required by directions for use or that a reduced package size will require CRP;

7. the package size or other characteristics is not changed in a way which violates EPA-mandated restrictions imposed on a product (e.g., size limitations may be imposed on a product to limit its use to homeowners only); and

8. no changes are made to "bait stations," "control stations," "attractant stations" or other packaging that houses the pesticide during its use.

When the size of a package is changed via non-notification per Section IV.B., associated labeling statements may be changed by notification if the above criteria are met.

F. Use Deletions Related to Data Call-In's

Section 6(f) of FIFRA requires EPA to publish in the Federal Register for public comment a notice of receipt of a voluntary cancellation of a product or deletion of one or more of its uses. If a registrant of the source(s) of an active ingredient (manufacturing use product--MP) decides to delete one or more uses in response to a data call-in, EPA will publish a Federal Register notice announcing the proposed deletion of those uses from the MP label and indicate that such uses must be deleted from the labels of all products containing the active ingredient unless someone responds within the comment period that they wish to support the continued registration of those uses. After the comment period closes and no one has requested to support the use(s) proposed for deletion, end use product registrants will be given three options: support the deleted use(s), delete use(s) by notification, or voluntarily cancel the product. **If deletion of the use(s) is chosen as a response to a data call-in, the end use product registrant should respond to the DCI and submit a notification for each changed product label rather than an amendment as described in PR Notice 91-1.** Use deletions for MP products, or for end use products not

subject to a data call-in, may only be submitted as amendments as described in PR Notice 91-1.

G. Storage and Disposal Statements (PR Notices 83-3 and 84-1). These notices permit registrants to adopt storage and disposal labeling statements as specified in those notices without submitting an amendment for approval. Registrants may continue to adopt labeling statements verbatim from those notices by notification. However, a request for variation in the wording of those statements must be submitted as an amendment.

H. Use of Symbols and Graphics

Symbols and graphics may be used in conjunction with and in close proximity to explanatory label text, provided that they do not substitute for or conflict with label text, and are not false or misleading (as described in 40 CFR 156.10(a)(5)). Examples include:

--diagrams demonstrating how to open product containers.

--graphics displaying application patterns such as aerial application.

--pictograms displaying various exposure routes.

--pictures of where the product can be used.

--pictures of persons wearing appropriate protective clothing.

I. Redundant Labeling Statements

Statements may be combined to remove redundancy anywhere on the label, provided that statements required by the Agency are not removed, changed or moved. The revised statements must be consistent with 40 CFR 156.10 and Agency policy.

J. Changes in Warranty Statement

Warranty statements may be revised provided they do not disclaim the performance or safety of the product when used in accordance with label directions, and are otherwise consistent with 40 CFR Part 156.

K. Product Composition

1. Pesticide Category. A statement identifying one of the following pesticide categories to which the product belongs may be added by notification: "fungicide," "insecticide," "rodenticide," "herbicide," "defoliant," "repellant," "desiccant," "microbiocide," "antimicrobial," "disinfectant," "sanitizer," "biochemical," "microbial,""plant regulator," "nematicide" and "plant-pesticide." Use of terms other than these is not acceptable by

notification.

2. Source of ingredient(s). If a product is derived from plant extracts and is classified for acute toxicity categories III or IV, then a statement such as the following may be added to the ingredients statement: “rotenone, a botanical insecticide.” Botanical claims may also be added by notification for inert ingredients if **all** inert ingredients are listed in the ingredients statement and is classified for acute toxicity categories III or IV. Broad, non-specific terms such as "natural" or "organic" are not acceptable.

3. Odor. If a product has been amended to add or change a fragrance, terms such as "fresh scent,""floral scent" and "lemon scent" which describe that odor may be added by notification. The terms "fragrance free" or "unscented" may be added by notification **only** if the product is odorless or nearly odorless and contains no odor-masking ingredient such as a perfume. The term “descented” may be added by notification if the product contains an odor-masking ingredient. These terms may also be added to the product name; the registrant should specify whether it is an additional brand name or a change to the primary brand name.

4. Water-based. The term “water based” may be added by notification if the product contains at least 50% water by weight, is classified in acute toxicity category III or IV, and presents no physical/chemical hazard that requires a warning statement. All ingredients must be in an aqueous solution (not a dispersion or emulsion and only be diluted with water.

5. Changed formulation. Truthful statements about alternate formulations or minor formulation changes (such as "new" or "new formula") which have been approved by EPA may be added by notification for a period of six months after EPA's approval of a revised or alternate formula and beginning when the product with this claim is first sold or distributed. The term "improved" is allowed by notification only if it is qualified as to how the product has been improved such as "improved wettability" or "improved pouring spout." Safety related claims or other false or misleading claims are not permitted (e.g., “less toxic,” “worker safe”).

L. Risk Reduction

1. Non-flammability. The claim "non-flammable" may be added by notification if a product meets the following criteria according to data entered on the confidential statement of formula:

a. If the product contains or becomes a gas, the product must not ignite when exposed to a lighted match; or

b. If the product is a liquid, the product has a flash point greater than 350^{o} F; and

c. No test of any kind demonstrates that the product is flammable. A claim of non-flammability may not be made if any test other than in (1) or (2) above demonstrates that the product is flammable.

2. Closed system. If a product has already been approved for use in a closed system for transfer during mixing and loading, or during application, a label statement such as "Closed system for (insert 'mixing,' 'loading,' 'transfer' or 'application' as applicable)" may be added by notification. A closed system is designed to eliminate worker exposure during pesticide handling.

3. Water Soluble Packaging. A phrase such as "water soluble packaging" may be added by notification for this form of packaging.

M. Directions for Use

1. Changes in mixing directions which do not affect the dilution ratio or the minimum or maximum use dilutions. Examples:

a. When a package size is changed, the use directions may be changed to accommodate the larger size, provided the dilution ratio remains constant (e.g., a one gallon package to be mixed with 2 gallons of water could be changed to a five gallon package to be mixed with ten gallons of water.

b. Instructions relating to cleaning or precleaning of surfaces prior to use of the product may be added for antimicrobial products, as long as such instructions do not change the dilution or application rate with respect to the approved pesticidal claim.

2. Addition of tables, charts or other graphics which present the same use directions already approved by EPA in narrative form. Providing graphic or tabular presentation of use directions which have already been approved is encouraged as long as the substance of the use directions remains the same. Parts of the narrative use directions may be removed if those directions are presented in the graphics or tables, and if no use limitations were omitted.

3. Addition of similar application methods. An additional method of application permitted under Sec. 2(ee)(3) of FIFRA which meets the following criteria may be added to the label by notification: (1) the application method results in exposure no greater than exposure from the currently registered method(s); (2) the new application method results in no change in dosage, concentration, timing or frequency of application of the product; and (3) the product is not registered for public health related uses or termiticides. For example, a trigger foamer sprayer may be added to a trigger sprayer product if the likely exposure is no greater, if the dosage, concentration or frequency of application falls within the range of currently approved use directions, and if the label makes no public health

related claims. The registrant must have data in its files to show that the product meets the above criteria.

4. Mixing with a fertilizer. The use directions may be modified by notification to include mixing with a fertilizer, provided that the dosage, concentration and frequency of the pesticide application do not change.

N. Other Revisions

Minor label changes not described in Section II.A.-M. and Section III. which are related to FIFRA may be made by notification, provided they:

1. are consistent with or specified by a PR Notice; or

2. are consistent with 40 CFR Part 156; and

3. involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.

III. PRODUCT CHEMISTRY NOTIFICATIONS

A. Source of Active Ingredients

A registrant may change the source of an active ingredient by notification, provided that the alternate source:

1. is registered for at least the same uses for which the formulated product is registered; and

2. is similar to the current source, i.e., meets the criteria given in 40 CFR 152.43(b)(1) and (2).

A registrant must submit a Formulator's Exemption (EPA Form 8570-27) along with the notification of source change if the new source is registered for the same uses as the existing source [40 CFR 152.85(c)].

A registrant may NOT make the following active ingredient related changes by notification, but must submit an application for amendment:

--A change in the source of an active ingredient which would result in a nominal inert ingredient total, or result in a changed toxicological category or chemical property of a product.

This changed formula would be considered an alternate formulation.

--A change to an unregistered source of an active ingredient.

--Addition, deletion, or substitution of an active ingredient or increase or decrease in the amounts of existing active ingredient would constitute a new formulation, which may require a separate registration.

--A change in the stated nominal concentration of any active ingredient or change of certified limits from that shown on the previously submitted Confidential Statement of Formula (CSF), EPA Form 8570-4.

--If the new source is not registered for at least the same uses as the existing source, an amendment for registration must be submitted to delete unsupported uses from the formulated product, or to support the additional uses with data.

B. Inert Ingredients

1. Change in Source

If the Agency has required that a registrant identify the source of an individual inert ingredient, the identity of which is known to the registrant, the registrant may change the source of that inert ingredient by notification. However, if the Agency has not required identification of the source of an inert ingredient, the registrant may change a source without notification to the Agency.

2. Change in Nominal Concentration

A registrant may change the stated nominal concentration of any inert ingredient by notification, provided that:

a. the nominal concentration falls within the certified limits for that ingredient as listed on the accepted CSF; and

b. the composition of the ingredient is known to the registrant.

3. Change in Certified Limits

A registrant may change the certified limits of any inert ingredient(s) in a formulation by notification, provided that they fall within the standard certified limits in 40 CFR 158.175(b)(2). Certified limits may not be changed via notification for products for which:

a. the Agency has previously determined that alternative certified limits will apply; or

b. the registrant has already changed the nominal concentration per Section III.B.2. above.

4. Inert Changes **Not** Permitted by Notification

--Changes in proprietary ingredients such as specific solvents or common commodity diluents, which generally are composed of a mixture of ingredients and whose composition is not disclosed to the registrant, require the Agency to determine their acceptability based upon information on their composition supplied by the producer.

--Changes of inerts for: (1) antifoulant paints (because such changes may affect the release rate of these products); (2) products used for the control of vertebrate animals (because odor, taste and dye are usually crucial to product effectiveness); and (3) baits used to control insects and other vertebrates.

--Minor formulation changes covered in Section V. below.

C. Sources for Starting Materials for Integrated Systems Products

A registrant who produces a product by an integrated system [40 CFR 158.153(g)] which uses an unregistered source of active ingredient is required to supply the Agency with the sources of the starting materials for each ingredient (40 CFR 158.153). A registrant may change the source of the starting materials to other sources by notification if the integrated systems product is (1) not a microbial pesticide, a botanical pesticide, or any other pesticide produced via any methods other than man-made chemical synthesis and (2) the change will not result in:

1. an increase in the upper certified limit of any existing impurity;

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

3. the formation of other impurities of toxicological significance (e.g., dioxins, furans, nitrosamines, arsenicals) that have not previously been reported to the agency or that occur above levels previously permitted by or reported to the Agency.

D. Change in Formulation Process

A registrant may modify a formulation process of a product made by a non-integrated system (a blending or dilution of product components involving no chemical reaction--distinguished from a reaction process), provided:

1. the certified limits of the active and inert ingredients do not change as a result; and

2. the physical/chemical/biological characteristics and/or the effectiveness (efficacy) of the product will not change.

IV. NON-NOTIFICATIONS

In accordance with 40 CFR 152.46(b), a registrant may accomplish the following types of actions without notification to the Agency:

A. Typographical and Printing Errors. Correcting typographical and printing errors in labeling as well as changes in grammar and/or phrasing that do not change how the product will be used (e.g., adding and/or changing prepositions) are permitted by non-notification, provided that the use directions, signal words or requirement for child-resistant packaging do not change and that the format is consistent with Agency labeling requirements. Any corrections which result in changes in use directions, use precautions or the ingredient statement must be submitted as a notification or an amendment as described in this PR Notice.

B. Changes in Package Size and Net Contents. These changes are permitted by non-notification, except for:

1. products subject to or which voluntarily adopt child-resistant packaging requirements under 40 CFR Part 157 (either before or after the package size change);

2. products subject to other special Agency-mandated size-related requirements; and

3. rodenticide products; or

4. changes which would change the toxicity category or chemical properties of the product.

C. Revision, Addition or Deletion of Non-FIFRA Related Label Elements. Changes such as the following are permitted by non-notification:

--Symbols and graphics required by other Federal agencies such as the Department of Transportation.

--State-required analysis of the fertilizer component of a pesticide product.

--Lot or batch codes, barcodes or other production identifiers.

--Date of manufacture or label approval.

--Use of metric units in addition to standard U.S. units for net contents, dosages and other

numeric expressions.

D. Changes in the Name or Address of the Registrant on the Label.

1. In accordance with 40 CFR 152.135, the transfer of ownership must be approved by the Agency. Once a product's ownership has been approved by EPA, the registrant need not submit labeling reflecting the new registrant's company name and address.

2. In accordance with 40 CFR 152.122, registrants are required to notify EPA of a change in the company name, address or designated agent. Subsequent product labels must bear the new name and/or address of the registrant. However, the registrant need not submit copies of the amended labeling reflecting the registrant's new company name and/or address to the Agency.

E. Redesign of Label Format. A label format change that does not modify approved label text and is consistent with the format requirements of 40 CFR 156.10 and Agency policy. These may include, among other things, changes in color, type size or style, use of space, configuration or placement of label elements.

F. Non-Pesticidal Characteristics

1. Non-pesticidal effectiveness. A non-pesticidal claim, provided it is not false or misleading, does not conflict with the pesticide labeling and is consistent with other applicable statutes or regulations that may apply to such claims. Examples of such claims include "Cleans," "Whitens and brightens laundry," "Removes soap scum," and "eliminates odors." In addition, brief directions which pertain only to these non-pesticidal uses may be added by non-notification. For example, "Use at full strength (2 cups per gallon) to remove tough stains."

2. Cleanup. A statement with respect to the ease of cleanup or removal after use, such as "leaves no film or deposit" and "cleans easily with water" as long as such statement does not conflict with the use directions or adversely affect the efficacy or safety of the product.

3. Effects on treated objects or sites. Beneficial product attributes not related to pesticidal effect, such as "non-staining" and "non-corrosive to metals."

4. Price. Claims regarding price or price-related marketing information such as "low price," "25 cents off" and "rebate available."

5. Where product is made. Factual statements about where the product was made ("Made in U.S.A."), provided these comply with other regulatory requirements.

6. Approval by other federal agencies. Factual statements about uses approved by government agencies other than EPA provided such statements do not imply endorsement

by those agencies. An example of an acceptable statement would be "Approved for use in USDA-inspected meat and poultry plants." An unacceptable statement would be "Contains materials that meet all FDA standards and regulations."

7. Consumer Access Numbers. Per PR Notice 97-4, telephone numbers and internet addresses may be added to the label without notification.

8. Use of "Other Ingredients" in the Ingredients Statement. Per PR Notice 97-6, the term "Other Ingredients" may be substituted for "Inert Ingredients" in the label ingredients statement without notification.

G. Statement of Practical Treatment. The heading "First Aid" may be substituted for "Statement of Practical Treatment."

H. Product Packaging

1. Recycled content. A statement about the recycled content of pesticide packaging itself may be made in accordance with guidance from the Federal Trade Commission.

2. Refillable. After obtaining approval from EPA for a refillable container (including instructions), a registrant may add a claim that a pesticide package is refillable if:

a. if a system exists for the collection and return of the package to a dealer for refill with the same pesticide, and instructions on how to do so are provided, or

b. if the pesticide container may be refilled from a larger container of the same product, and instructions for refilling are provided.

I. Bilingual Labeling. A registrant may provide bilingual labeling on any product without notification. The foreign text must be a true and accurate translation of the English text. Note: Both language versions of the labeling must appear on a container. Foreign text may be used on all or part of the labeling.

J. Recycling of Containers. The following statements may be added:

a. Aerosol Containers. As described in PR Notice 94-2, the following statement may be added to pesticide aerosol containers:

"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 recycling is not available, wrap the container and discard in the trash."

b. Residential Use Containers Other Than Aerosols. For either refillable or non-refillable containers (other than aerosol containers), the following statement may be added:

"Use product until container is empty. Offer for recycling if possible. If recycling is not available or if the container is not empty, wrap the container in several layers of paper and discard in the trash."

As permitted by Section II.D. of this notice, the registrant may add relevant advisory language pertaining to recycling by notification, such as "It is recommended that you contact your local waste management facility about recycling."

V. ACCELERATED REVIEW OF MINOR FORMULATION CHANGES

Although a formulation change may only be accomplished through submission of an application for amended registration, the Agency has developed an accelerated review for certain minor formulation amendments. The criteria are listed below, followed by a description of the review process. Note that confirmatory efficacy data are not required for minor formulation amendments, except for aerosols.

A. Minor Formulation Amendments

Amendments involving the following types of formulation changes will be considered eligible for accelerated review subject to the following limitations:

1. Addition, deletion or substitution of one or more colorants in a formulation:

a. the total percentage of changed colorant does not exceed 1% by weight of the formulation;

b. the component(s) of the colorant are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;

c. if the product is registered for food use, the colorant has the appropriate exemption from the requirement of a tolerance under 40 CFR 180.1001(c), (d) or (e); and

d. the product is not intended for use as a seed treatment or rodenticide.

2. Addition, deletion or substitution of one or more fragrances in a formulation:

a. the total percentage of changed, added or deleted fragrance does not exceed 1% by weight of the formulation;

b. information on the composition of the fragrance has been provided to the Agency by the fragrance manufacturer or registrant;

c. the fragrance has been determined to be acceptable for such use by the Agency at the proposed concentration or the component(s) of the fragrance are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4; and

d. if the product is registered for food use, the fragrance components are exempt from the requirement of a tolerance under 40 CFR 180.1001(c), (d) or (e).

e. the product is not intended for use in baits or repellents.

3. Addition, deletion or substitution of one or more inert ingredients (other than fragrances or dyes) in a formulation:

a. the nominal concentration of active ingredient does not change;

b. the change does not invalidate any product-specific data submitted in support of the initial registration which causes additional data to be required;

c. the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;

d. if the product is registered for food use, the inert ingredient is considered to be exempt from the requirement of a tolerance under 40 CFR 180.1001(c), (d) or (e);

e. any change is for inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant); and

f. the product is not a bait or repellent and is not intended to be used to control pests of significance to public health.

Applications for the above kinds of amendments will not be considered for accelerated review if they will:

--change the product's acute toxicity category or physical/chemical characteristics necessitating label modifications; or

--affect the product's efficacy so that supporting data are required (such as for vertebrate control products, tin-based antifoulant paints, food-contact surface sanitizers, and liquid or aerosol insecticides intended for household use).

B. Review Process

If a registrant believes that an amendment meets the criteria above, he/she should identify it as such on the application for amended registration with a statement such as **"Minor Formulation Amendment per PR Notice 98-10.**" The submission should be addressed to the Minor Formulation Review Coordinator (MFRC), Registration Support Branch and contain:

1. an application (EPA Form 8570-1),

2. one (1) copy of the CSF for the existing formulation,

3. two (2) copies of the CSF of the proposed formulation, and

4. any supporting information such as MSDS sheets on the added inert ingredient(s).

5. confirmatory efficacy data only if the product is an aerosol or bears a public health claim.

EPA will make every effort to prepare an appropriate response to the registrant either accepting or rejecting the amendment within **45 days** of receipt of application except when confirmatory data are submitted; additional time is required for review of such data. The MFRC will refer applications to the appropriate offices for review.

VI. PROCEDURES FOR NOTIFICATIONS

A. Notifications

1. Notification Submission. For **each product** a notification should be submitted with a completed Application for Registration (EPA Form 8570-1). A **photocopy** of the EPA application form is acceptable; an original form is not needed. In order for the application to be processed, include the following statements on the application:

- **"Notification of (insert type of change, such as 'Alternate Brand Name') per PR Notice 98-10."**

- **"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."**

2. Procedures for notification for **antimicrobial products**. All notifications for antimicrobial products must be submitted in accordance with the procedures of this paragraph and any supplemental notice to registrants.

a. **Submission.** A registrant must submit the notification to the Agency at least 60 days before distribution or sale of a product as modified.

b. **Substantiation.** A registrant must retain in his files, and make available for inspection or copying, substantiating information or data supporting the proposed modification. These data need not be submitted with the notification, but may be required by the Agency if the notification is disapproved.

c. **Agency decision.** Within 30 days after receipt of a notification, the Agency will notify the registrant in writing if the notification is disapproved and state the reasons why it is unacceptable.

d. **Objection.** A registrant may file an objection in writing to a disapproval not later than 30 days after receipt of the Agency's disapproval. If the basis for the disapproval is that substantiating information is needed, the registrant must submit such information as part of the objection. A decision by EPA after receipt and consideration of an objection is a final agency action.

e. **Distribution or sale.** A registrant may not distribute or sell an antimicrobial product for which a modification by notification is proposed until he receives EPA notice of approval, or until 60 days after submission, whichever comes first. A registrant may not sell or distribute a product bearing a disapproved modification.

3. Procedures for notification for **products other than antimicrobials**. Notifications for non-antimicrobial products must be submitted in accordance with the procedures of this paragraph and any supplemental notice to registrants.

a. **Submission.** A registrant must submit a notification to the Agency before distributing or selling a product amended in accordance with this notice or any other notice authorizing specific amendments by notification. A registrant wishing to be informed of an acceptable notification may submit a stamped, self-addressed postcard identifying the notification and EPA Registration number of the product.

b. **Agency objection.** Normally within 30 days of receipt of a notification, the Agency will notify the registrant if the application does not qualify as a notification and state the reasons why. The application will then be processed as an amendment.

c. **Distribution or sale.** A registrant may distribute or sell a non-antimicrobial product

modified by notification once EPA receives that notification. However, a registrant may not sell or distribute a product bearing a disapproved modification.

4. Labeling

For each notification involving labeling changes, one (1) copy of the labeling must be submitted **with the changes clearly marked so that they can be photocopied.**

5. Confidential Statement of Formula (CSF)

Two (2) original and signed CSFs must be submitted for either a notification or an amendment involving a CSF change. In addition, a Formulator's Exemption form (EPA Form 8570-27) must be submitted for any change in the identity or source of active ingredients.

6. Signature

Each notification must be signed by the registrant or authorized agent and include that person's current address and telephone number.

7. EPA Mailing Address

All mail concerning notification actions should be addressed to:

Document Processing Desk (NOTIF) or (AMEND) (as applicable)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460-0001

8. EPA Delivery Address

The official delivery address used for notification actions hand-carried or courier delivered Monday through Friday, 8:00 AM to 4:30 PM, excluding Federal holidays is:

Document Processing Desk (NOTIF) or (AMEND) (as applicable)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

B. Pending Applications

If a registrant has an application for amended registration pending with the Agency which qualifies for notification, and wishes to have it processed as a notification, then he/she should: (1) send a letter to the relevant PM or Branch requesting that the application for amended registration be withdrawn and (2) submit a notification to one of the addresses above.

C. Final Printed Labeling

Two (2) copies of final printed labeling must be also be submitted to the Agency before a product, as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a)(6)].

VII. COMPLIANCE

Notifications and non-notifications must comply with Agency regulations. As provided in 40 CFR 152.46(c), if the Agency determines that a product has been modified through notification or without notification in a manner inconsistent with this notice or applicable law or regulations, EPA may initiate regulatory or enforcement action without first providing the registrant with an opportunity to submit an application for amended registration. The Agency will audit notifications to assure that the process is working properly and that such submissions are in compliance.

VIII. ADDITIONAL INFORMATION

If you have questions about this notice, call Linda Arrington, Registration Division (703-305-5446), Robert Torla, Biopesticides and Pollution Prevention Division (703-308-8098) or Walter Francis, Antimicrobial Division (703-308-6419).

/signed by Marcia E. Mulkey/

Marcia E. Mulkey, Director
Office of Pesticide Programs

TABLE A. Registration Changes Described in this PR Notice (Applicable section of this notice is in parenthesis).

TYPE OF CHANGE	NOTIFICATION	NON-NOTIFICATION	ACCELERATED REVIEW	AMENDMENT
LABEL OR PACKAGE				
Brand Name	All brand names (II.A.)			
Add/Delete Pests	Non-Public Health Pests (II.B.)			Public Health Pests,Termites and Quarantined Pests
Add Indoor, Non-Food Use Sites	Antimicrobials only (II.C.)			Indoor, Food and all Outdoor Uses
Advisory Statements	(II.D.)			
Packaging & Related Labeling	(II.E.)			
Use Deletions	(II.F.)			
Storage and Disposal Statements	(II.G)			
Symbols or Graphics	(II.H.)			Explanatory text requires amendment
Redundant Statements	(II.I.)			
Warranty Statements	(II.J.)			
Product Category	(II.K.1.)			
Source of Ingredients	(II.K.2.)			

TABLE A. (Continued)

TYPE OF CHANGE	NOTIFICATION	NON-NOTIFICATION	ACCELERATED REVIEW	AMENDMENT
Odor	(II.K.3.)			
"Water-based"	(II.K.4.)			
"New" or "Improved" formula	(II.K.5.)			
Non-flammable	(II.L.1.)			
Closed system	(II.L.2.)			
Water Soluble Packaging	(II.L.3.)			
Mixing directions	(II.M.1.)			
Tables/Charts of Use Directions	(II.M.2.)			
Additional application methods	(II.M.3.)			
Mixing with a fertilizer	(II.M.4.)			
Use with another pesticide	(II.M.5.)			
Other minor revisions	(II.N.)			
Typos		(IV.A.)		
Package Size and Net Contents		(IV.B.)		
Non-FIFRA Related Elements		(IV.C)		
Name and Address		(IV.D.)		
Format		(IV.E).		
Non-pesticidal effectiveness		(IV.F.1.)		
Cleanup		(IV.F.2.)		
Effects on objects		(IV.F.3.)		

TYPE OF CHANGE	NOTIFICATION	NON-NOTIFICATION	ACCELERATED REVIEW	AMENDMENT
Price		(IV.F.4.)		
Where product is made		(IV.F.5.)		
Approval by other Federal agencies		(IV.F.6.)		
Telephone or Internet address		(IV.F.7.)		
“Other ingredients”		(I		
First Aid heading		(IV.G.)		
Recycled content of packaging		(IV.H.1.)		
Refillable package		(IV.H.2.)		
Bilingual Labeling		Non-English (IV.I)		English
Recycling of Containers		(IV.J.)		
PRODUCT CHEMISTRY				
Source of Active	Criteria are met. (III.A.)			Criteria not met. (II.A.)
Source of Inert	EPA has asked for source (III.B.1.)	EPA has not asked for source (III.B.1.)		
Nominal Concentration of Inert	Criteria are met. (III.B.2.)			
Certified Limits of Inert	Criteria are met. (III.B.3.)			
Proprietary Inerts				(III.B.4.)
Starting Materials for Integrated Systems	Criteria are met. (III.C.)			
Change in Formu-lation Process	Criteria are met. (III.D.)			
Minor Formulation Amendment			(V.)	