UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

5/31/95

PR NOTICE 95-2

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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 describes new policies and procedures effective immediately which will help streamline and accelerate many registration amendments. Highlights of this notice include:

- expanding the types of labeling and product chemistry amendments which may be accomplished by notification,
- accelerating the review of minor formulation amendments, and
- a new certification statement which affirms compliance with this PR Notice and applicable regulations, and which describes the consequences of non-compliance.

This PR Notice supersedes PR Notice 88-6 (August 12, 1988) and the second edition of General Information On Applying For Registration of Pesticides In The United States (The Blue Book, Chapter 4. C. and D). This PR Notice also modifies parts of PR Notices 83-3 and 84-1 (Storage and Disposal Statements), and PR Notice 91-1 (Use Deletions). Table A lists the registration amendments which may be accomplished by notification, non-notification or accelerated minor formulation changes as described in this notice.

I. BACKGROUND

On August 12, 1988, the Agency issued PR Notice 88-6 to implement 40 CFR 152.46, Modifications To Registration Not Requiring Amended Applications. §152.46(a) allows certain registration amendments to be accomplished by notifying the Agency of those changes before the product is distributed or sold. §152.46(b) allows other minor changes in labeling or packaging to be made without notification to the Agency. PR Notice 88-6 described the Agency's policies and procedures at that time for notifications and non-notifications under §152.46.

§152.44(b), Application for Amended Registration, requires any modification in the composition, labeling or packaging of a registered product to be submitted with an application for amended registration, with the exception of notifications and non-notifications under §152.46. §152.44(b) provides that the Agency may waive the requirement for an amendment or permit a registrant to certify compliance with an Agency requirement instead of submitting an amendment.

EPA is issuing this notice to allow minor, low risk registration amendments to be accomplished through notification, non-notification or as accelerated amendments. EPA believes these streamlining changes will speed up the process, reduce the waiting time for registrants and maintain protection to the public health and the environment.

II. NOTIFICATIONS

The following registration amendments may be accomplished by notification.

A. Labeling

1. Adding Alternate Brand Names

A registrant may sell a product under one or more **alternate brand names** provided he/she notifies the Agency of those names. 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. The 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). Changing the **primary brand name** of a product must be done by submitting an application for amendment.

2. Adding or Deleting Pests

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

(a) the registrant maintains efficacy data for each pest added;

(b) the pest occurs on one or more sites on the approved label;

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

(d) the dosage, frequency, concentration or method of application do not change.

To add public health pests or termites to a label, the registrant must submit an Application for Amended Registration (EPA Form 8570-1). Public health pests include, but are not limited to, mosquitoes, rodents, viruses and bacteria (other than odor-causing). Microbial pests and claims which are related to public health are described in OPP's Antimicrobial Program Branch DSS/TSS Sheet #16. Questions on whether other pests are

considered public health related may be referred to the appropriate branch or PM team. Questions on termiticide products may be referred to the Insecticide-Rodenticide Branch.

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

3. Adding Indoor, Nonfood Sites for Antimicrobial Products

Indoor, nonfood sites, subsites or substrates may be added to antimicrobial products provided that:

(a) no additional data (such as efficacy data for public health pests or termites, groundwater data, ecological effects data, etc.) are required for the added nonfood sites;

(b) these sites are within an already registered use pattern category for the product (as specified in 40 CFR Part 158);

(c) 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);

(d) an agency decision or directive does not explicitly prohibit addition of nonfood sites to particular products;

(e) the labeling of the technical product from which the end use product is formulated does not prohibit the proposed site; and

(f) the dosage, concentration, frequency or method of application do not change.

4. Adding, Revising or Deleting Advisory Statements

Advisory statements (such as those related to use precautions, efficacy, crop damage and product incompatibility) may be added or revised provided that the statements:

(a) are not mandatory phrases such as: "do not," "must not" and "shall not;"

(b) do not negate or detract from the required precautionary statements or other label statements;

(c) do not trigger efficacy, human health or environmental concerns;

(d) do not change the dosage, frequency, concentration or method of application;

(e) are not false or misleading; and

(f) do not negate or conflict with statements made on any other product label which refers to use of the subject product or chemical.

Examples of advisory statements include: "This product is not recommended for use on natural marble surfaces" and "This product should not be used with products containing X due to risk of explosive reaction."

Advisory statements may be deleted by notification at any time.

5. Changes in Packaging and Related Labeling Statements

Changes in the shape, color or composition of packaging and in related labeling statements may be done by notification only if all of the following criteria are met:

(a) the dosage, concentration, frequency or method of application do not change;

(b) exposure is not likely increased (examples that might 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);

(c) the product is not subject to child resistant packaging (CRP), either before or after the proposed change;

(d) the product is not a rodenticide;

(e) no Worker Protection Standard labeling statements are changed;

(f) 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;

(g) 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

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

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

Section 6(f) of FIFRA requires EPA to publish a notice of receipt of a voluntary cancellation of a product or one or more of its uses in the Federal Register for public comment. If a registrant of the source(s) of an active ingredient (manufacturing use product--MP) decides to voluntarily cancel one or more uses in response to a data call-in, EPA will

publish a Federal Register notice announcing the proposed voluntary cancellation of those uses on the MP and indicate that such uses will be deleted from 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 registrants will be given three options: support the deleted use(s), request deletion of the 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 registrant should submit a notification for each product rather than an amendment as described in PR Notice 91-1.** Use deletions for MP products, or for end use not responding to a data call-in, may only be submitted as amendments as described in PR Notice 91-1.

7. Storage and Disposal Statements

PR Notices 83-3 and 84-1 permitted registrants to adopt storage and disposal labeling statements as specified in those notices without amendment. Registrants may continue to adopt labeling statements verbatim from those notices by notification. However, a request for variation in the wording of those statements should be submitted as an amendment.

8. Bilingual Labeling

The Agency may require bilingual labeling to protect public health and the environment [40 CFR 156.10(a)(3)]. When bilingual labeling is not required by the Agency, registrants may submit by notification a copy of the foreign language labeling. The foreign text must be a true and accurate translation of the English text. Note: Both language versions of the labeling should appear on a container in their entirety.

9. 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:

- arrow 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.

10. Redundant Labeling Statements

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

11. 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.

12. Other Revisions

Minor label changes not described in Section II.A.1.-11. and Section III. which are related to FIFRA may be made by notification, provided they:

(a) are consistent with 40 CFR Part 156; and

(b) 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; and/or

(c) are permitted or required by a PR Notice.

B. Product Chemistry

1. Active Ingredients

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

(a) is registered for at least the same uses for which the formulated product is registered; and

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

A registrant should 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 change in the amount of any inert ingredient such that it would fall outside its certified limits. This would be considered an alternate formulation. Such a change may result in significant changes in the toxicological or chemical properties of the product.

- 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 requires a separate registration.

- A change in the stated nominal concentration of any active ingredient or change of certified limits that are not shown on the previously submitted Confidential Statement of Formula (CSF), EPA Form 8570-4.

- If the new source is not registered for 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.

2. Inert Ingredients

a. 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.

b. Change in Nominal Concentration

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

(1) the nominal concentration falls within the certified limits for that ingredient as listed on the accepted CSF; and

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

c. 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:

(1) the Agency has previously determined that alternative certified limits will apply; or

(2) the registrant has already changed the nominal concentration per Section II.B.2.b. above.

d. 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) or (2) products used for the control of vertebrate animals (because odor, taste and dye are usually crucial to product effectiveness).

- Minor formulation changes covered in Section IV. below.

3. 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 his starting materials to other sources if the change will not result in:

(a) an increase in the upper certified limit of any existing impurity;

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

(c) the formation of other impurities of toxicological concern (e.g., dioxins, furans, nitrosamines, arsenicals) above levels previously permitted by the Agency.

4. 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:

(a) the certified limits of the active and inert ingredients do not change as a result;

and

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

III. 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. 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) provided that the use directions, signal words or requirement for child-resistant packaging does 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 the net contents, except for:

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

(2) product subject to other special Agency-mandated size-related requirements; and

(3) rodenticidal products.

C. Revision, addition or deletion of non-FIFRA related label elements, such as the following:

- Symbols and graphics required by other government agencies such as the Department of Transportation.
- State-required analysis of a fertilizer 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, except for a change resulting from transfer of ownership, which requires Agency approval in accordance with 40

CFR 152.135. 40 CFR Section 152.122 requires, however, that a registrant notify EPA of a change in its company name, address or designated agent.

E. Redesign of label format 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.

IV. 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.

A. Minor Formulation Amendments

Amendments involving the following types of formulation changes will be considered eligible for accelerated review subject to these 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; and

(d) the product is not intended for use on seed.

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.

(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;

(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 intended for use in public health antimicrobial products, baits or repellents.

Applications for accelerated review of the above kinds of amendments should **not** be submitted if the proposed reformulation will:

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

(2) affect the product's efficacy so that supporting data are required (such as for vertebrate control products, tin-based antifoulant paints, food-contact sanitizing solutions subject to regulation under 21 CFR 178.1010, 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 95-2 ."** The submission should be

addressed to the Product Manager 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).

The PM 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.

V. 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. The application should bear the following statements:

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

- **"This notification is consistent with the provisions of PR Notice 95-2 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 95-2 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. 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.**

3. 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) should be submitted for any change in the identity or source of active ingredients.

4. Signature

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

5. EPA Mailing Address

All correspondence concerning notification actions should be addressed and mailed 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

6. 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

7. EPA Processing of Notifications

EPA will screen all notifications to determine whether they meet the criteria in this PR Notice or other notices. If a notification is determined not to qualify for notification, EPA will inform the registrant via letter that the submission does not qualify and is being sent to the RD PM team for processing as an application for amended registration. EPA will attempt to screen each notification within 30 days of receipt.

B. Pending Applications

If a registrant has an application for amended registration pending with the Agency which qualifies for notification pursuant to this Notice, the registrant should: (1) send a letter to the PM requesting that the application for amended registration be withdrawn and (2)

submit a notification to one of the addresses above. The Agency will then process the notification in lieu of the application for amended registration.

C. Distribution and Sale

When amendment of a registration is permissible by notification, the notification must be received by the Agency before the registrant may distribute or sell the product. 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)]. For notifications, one (1) copy of the final printed labeling is required per product, either with or separate from the notification. For all other amendments, two (2) copies of the final printed labeling are required. A product distributed or sold before a notification and final printed labeling are received is in violation of FIFRA.

VII. COMPLIANCE

Notifications and non-notifications should comply with Agency regulations and policy. Notifications and non-notifications which are not in compliance may be subject to enforcement action under FIFRA sections 12 and 14. 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 Ms. Sherada Hobgood (703-308-8352).

Stephen L. Johnson, Director
Registration Division

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	Alternate brand name (II.A.1.)			Primary brand name
Add/Delete Pests	(II.A.2.) Non-Public Health Pests Except Termites			Public Health Pests and Termites
Add Indoor, Non-Food Use Sites	(II.A.3.) Antimicrobials only			
Advisory Statements	(II.A.4.)			
Packaging & Related Labeling	(II.A.5.)			
Use Deletions	(II.A.6.)			
Storage and Disposal Statements	(II.A.7)			
Non-Mandatory Bilingual Labeling	Non-English (II.A.8.)			English
Symbols or Graphics	(II.A.9)			
Redundant Statements	(II.A.10.)			
Warranty Statements	(II.A.11.)			

TABLE A. (Continued)

TYPE OF CHANGE	NOTIFICATION	NON-NOTIFICATION	ACCELERATED REVIEW	AMENDMENT
Typos		(III.A.)		
Package Size and Net Contents		(III.B.)		
Non-FIFRA Related Elements		(III.C)		
Name and Address		(III.D.)		
Format		(III.E).		
PRODUCT CHEMISTRY				
Source of Active	Criteria are met. (II.B.1)			Criteria not met. (II.B.1)
Source of Inert	EPA has asked for source (II.B.2.a)	EPA has not asked for source (II.B.2.a)		
Nominal Concentration of Inert	(II.B.2.b)			
Certified Limits of Inert	(II.B.2.c)			
Proprietary Inerts				(II.B.2.d.)
Minor Reformulation			(IV.)	