**Pesticide Registration Manual:**

# Chapter 7 - Notifications and Minor Formulation Amendments View(active)

# Notifications, Non-Notifications, and Minor Formulation Amendments

This chapter discusses certain minor amendments that can be made to a registered product and do not require the applicant to apply to amend a registration. Such amendments are not subject to the data compensation provisions of FIFRA section 3(c)(1)(F) because they do not need to be supported by new data. To emphasize that these applications can only be submitted by the registrant of the product, the applicant is generally referred to as "the registrant" in this chapter.

Some minor changes referred to as "notifications" can be made to a registration, such as changes to a brand name, provided that the Agency is notified before the change is made and before the product is distributed or sold.

"Non-notifications" are changes that can be made to a pesticide label without notifying the Agency (such as the correction of typographical errors).

Although a formulation change may only be accomplished through applying for amended registration, the Agency has developed an accelerated review process for certain "minor formulation amendments" (such as the addition, deletion, or substitution of one or more fragrances, colorants, or other inert ingredients in a formulation).

A notification does not constitute official acceptance of the product label, nor does it guarantee the product's compliance with regulations. For more detailed information, please refer to PR Notice 98-10 Notifications, Non-Notifications and Minor Formulation Amendments.

## Parties Authorized to Submit

Only the registrant or the authorized agent for the company may submit a notification or minor formulation amendment, which must be properly signed and dated. The registrant is also responsible for ensuring that the labeling of any of its distributors or supplementally registered products is in compliance with FIFRA. (Refer to 40 CFR Part 156) Supplemental distributors, commonly known as sub-registrants, may not submit notifications, nor may registrants submit supplemental distributor labeling for notifications.

**Important Note**: An applicant or registrant should be aware that knowingly falsifying any part of any application for registration or other information submitted to the Agency is an unlawful act under FIFRA section 12 (a)(2)(M) and 18 USC 1001 and may result in civil or criminal penalties.

# Labeling Notifications

Certain permitted changes to a registration require a notice to EPA but do not require Agency approval. As provided in 40 CFR 152.46(a), minor changes that the Agency has determined have no potential to cause unreasonable adverse effects to the environment can be made to a registration, provided that the Agency is notified before the change is made. OPP refers to these changes as "notifications." As described in 40 CFR 152.46(a), the Agency has issued a notice describing which actions are appropriate as notifications and the procedures to follow. See PR Notice 98-10.

Except for the special procedures for antimicrobials discussed below, it is not necessary to obtain Agency approval of such a change or amendment, and the product may be distributed or sold, as changed, as soon as EPA receives the notification of the change, as long as EPA does not reject the notification. However, to assure the registrants and state regulatory agencies that a notification has been received and reviewed by the Agency, the Agency is attempting to respond in writing to all notifications.

FIFRA, as amended in 1996, specifies slightly different notification requirements for antimicrobial products (FIFRA section 3(c)(9)). For antimicrobial products, registrants must notify the Agency of certain labeling changes at least 60 days prior to distribution or sale of a product bearing the new label. The Agency may disapprove changes within 30 days of their receipt.

- For any requested change made through notification, the Agency reserves the right to require that a formal application for amended registration be submitted.

Normally, EPA will screen a notification within 30 days of receipt. If EPA determines that the proposed amendment (change) does not qualify as a notification, the Agency will notify the applicant, stating the reason(s) why an application is required for amended registration in lieu of a notification. If the registrant fails to submit an application for amended registration without good cause, and markets the product as if the notification was accepted, the Agency may determine that the registered product is no longer in compliance with the requirements of FIFRA and initiate regulatory action under FIFRA section 6 and/or enforcement actions under FIFRA section 13 and section 12.

# Permitted Modifications to Registrations through Notification

EPA issued general procedures for notifications in PR Notice 98-10 and a list of changes that may be made through notification. Subsequent PR Notices have modified the original list. As described in PR Notice 98-10, the following registration amendments generally may be accomplished by notification. See PR Notice 98-10 for more descriptions on these categories.

- Brand Names
- Addition or Deletion of Pests on the Label
    - Exceptions: To add claims to a label against a public health pest, termites, or pests on plants subject to quarantine, the registrant may not use notification, but must receive approval to amend the pesticide product registration. Public health pests include, but are not limited to, mosquitoes, cockroaches, fleas, ticks, biting flies, rodents, viruses, and pathogenic bacteria. Refer to PR Notice 2002-1 for list of public health pests. Special instructions to add claims for H1N1 can be found on the Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu) web page. SEARCH EPA ARCHIVE Questions about public health pests, termiticides, and products used for plant quarantine may be referred to the appropriate regulatory division that manages those products.
- Addition of Indoor, Nonfood Sites for Antimicrobial Products
- Changes in Packaging and Related Labeling Statements (except Child Resistant Packaging)
- Use Deletions Related to a Data Call-In
- Storage and Disposal Statements
    - Registrants may adopt storage and disposal labeling statements as specified in the following notices without submitting an amendment for approval:
        - PR Notice 83-3 Label Improvement Program – Storage and Disposal
        - PR Notice 84-1 Clarification of Label Improvement Program
    - Since PR Notice 98-10, the storage and disposal statements have been revised according to the following PR Notices.
        - PR Notice 2007-1 Disposal Instructions on Non-Antimicrobial Residential or Household Use Pesticide Product Labels
        - PR Notice 2007-4 Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal Standards for Pesticide Containers and Containment"
    - Registrants may continue to adopt labeling statements verbatim from these notices by notification. However, a request for variation in the wording of these statements must be submitted as an amendment.
- Use of Symbols and Graphics

- Redundant Labeling Statements
- Changes in Warranty Statement
- Labeling Statements about Product Composition (such as pesticide category, source of ingredient(s), odor or fragrance statements, and water-based statements)
- Risk Reduction Statements (such as non flammability or closed system statements)
- Minor Changes to Directions for Use (such as changes in mixing directions that do not affect the dilution ratio or the minimum or maximum use dilutions; addition of tables, charts, or other graphics; addition of similar application methods; and mixing with a fertilizer).

**Other Allowable Minor Label Revisions**

There are additional minor label changes not described above that may be made by notification, provided they:

- are consistent with or specified by a PR Notice; or
- are consistent with 40 CFR Part 156; and
- 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.

# Product Chemistry Notifications

See PR Notice 98-10 for more descriptions on these categories.

## Source of Active Ingredients

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

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

## Changes to Active Ingredients That Are Not Allowed by Notification

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 that would result in a change 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 ingredients. This 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.
- A new source that is not registered for the complete set of uses as the existing source. An amendment for registration and a FIFRA 6(f) request must be submitted to delete unsupported uses from the formulated product, or an amendment for registration citing or providing appropriate data to support the additional uses must be submitted.

## Change in Source of Inert Ingredients

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.

- If EPA has not required identification of the source of an inert ingredient, the registrant may change a source without notification to the Agency.

## Change in Nominal Concentration of Inert Ingredients

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

- the nominal concentration falls within the certified limits for that ingredient as listed on the accepted CSF; and
- the composition of the ingredient is known to the registrant.

## Change in the Certified Limits of Inert Ingredients

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 158.350 for 40 CFR 161.175 for antimicrobials.

## Changes to Inert Ingredients Not Permitted by Notification

EPA does **not** permit changing proprietary ingredients such as specific solvents or common commodity diluents by notification because they are generally composed of a mixture of ingredients and the registrant does not disclose their composition. Such changes would require the Agency to determine their acceptability based upon information on their composition supplied by the producer.

The Agency also does not permit changing inert ingredients by notification for:

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

Certified limits of inert ingredients may not be changed via notification for products for which:

- the Agency has previously determined that alternative certified limits will apply; or
- the registrant has already changed the nominal concentration consistent with the requirements for changes in nominal concentrations of inert ingredients as listed in 40 CFR 158.350 and for antimicrobials, in 40 CFR 161.175.

## Sources for Starting Materials for Integrated Systems Products

An integrated system is a process for producing a pesticide product that: (1) contains any active ingredient derived from a source that is not an EPA-registered product; or (2) contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA section 9(a) before its use in the process. Refer to 40 CFR 158.300 and for antimicrobials, 40 CFR 161.153.

A registrant who produces a product by an integrated system and 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 158.325 and for antimicrobials, 40 CFR 161.160).

Registrants may change the source of the starting materials to other sources by notification if the integrated system product is:

- not a microbial pesticide, a botanical pesticide, or any other pesticide produced via any methods other than man-made chemical synthesis; and
- the change will not result in:
    - an increase in the upper certified limit of any existing impurity,
    - the formation of any new impurity at a level greater than 0.1 percent by weight of the technical grade active ingredient, or
    - the formation of other impurities of toxicological significance (e.g., dioxins, furans, nitrosamines, arsenicals) that have not previously been reported to, or that occur above levels previously permitted by, the Agency.

**Changes to the Formulation Process for Non-Integrated Systems**

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:

- the certified limits of the active and inert ingredients do not change as a result; and
- the physical/chemical/biological characteristics or the effectiveness (efficacy) of the product will not change.

# Submitting Notifications

**Application Form**: 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."

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

**Confidential Statement of Formula (CSF)**: Two 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.

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

Address: Notifications should be sent to the address listed in Chapter 21.

# Non-Notifications

In accordance with 40 CFR 152.46(b) and PR Notice 98-10, a registrant may make certain changes to its pesticide label without notifying the Agency. See PR Notice 98-10 for more descriptions on these categories.

- Typographical and Printing Errors
- Changes in Package Size and Net Contents
- Revision, Addition, or Deletion of Non-FIFRA Related Label Elements
- Transfer of Ownership
- Changes in the Name or Address of the Registrant on the Label
- Redesign of Label Format
- Nonpesticidal Characteristics
    - The following are examples of nonpesticidal characteristics statement changes allowed by non-notifications:
    - Nonpesticidal Effectiveness;
    - Cleanup or Ease of Removal;
    - Effects on Treated Objects or Sites;
    - Price or Price-Related Marketing;
    - Where a Product Is Made;
    - Approval by Other Federal Agencies;
    - Consumer Access Numbers; and
    - Use of the Words “Other Ingredients” in the Ingredients Statement.

**Statement of Practical Treatment**

The heading “First Aid” may be substituted for “Statement of Practical Treatment” without notification to the Agency.

**Product Packaging**

The Agency allows the addition of "Recycled Content" claims to the pesticide label without prior notification. A statement about the recycled content of pesticide packaging itself may be made in accordance with guidance from the Federal Trade Commission.

**Bilingual Labeling**

A registrant may provide bilingual labeling on any product without notification to the Agency. EPA may require bilingual language as well. Refer to 40 CFR 156.10(a)(3). The foreign text must be a true and accurate translation of the English text.

**Important Note**: Foreign text may be used on all or part of the labeling.

**Recycling of Containers**

The Agency allows certain types of statements regarding the recycling of containers to be added to the label without prior notification. Refer to 40 CFR Part 156, Subpart H Container Labeling 156.140, 156.144, 156.146, and 156.156 for appropriate statements.

# Minor Formulation Amendments

Although a formulation change may only be accomplished through submission of an application for amended registration, the Agency has developed an accelerated review process for certain minor formulation amendments.

The criteria for accelerated review 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**.

## Criteria for Accelerated Review

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

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

- the total percentage of changed colorant does not exceed 1 percent by weight of the formulation;
- the component(s) of the colorant are listed on EPA's Pesticide Inert Ingredient List;

- the colorant has the appropriate exemption from the requirement of a tolerance under 40 CFR 180.910 – 180.960 if the product is registered for food use; and
- the product is not intended for use as a seed treatment or rodenticide.

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

- the total percentage of changed, added or deleted fragrance does not exceed 1 percent by weight of the formulation;
- information on the composition of the fragrance has been provided to the Agency by the fragrance manufacturer or registrant;
- 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 List;
- the fragrance components are exempt from the requirement of a tolerance under 40 CFR 180.910 – 180.960 if the product is registered for food use; and
- the product is not intended for use in baits or repellents.

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

- the nominal concentration of active ingredient does not change;
- the change does not invalidate any product-specific data submitted in support of the initial registration that causes additional data to be required;
- the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient List;
- the inert ingredient is exempt from the requirement of a tolerance under 40 CFR 180.910 – 180.960 if the product is registered for food use;
- any change involves inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant); and
- the product is not a bait or repellent and is not intended to be used to control pests of significance to public health.

## Grounds for Denying Accelerated Review

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

- a change would alter the product's acute toxicity category or physical/chemical characteristics such that label modifications become necessary; or
- a change would affect the product's efficacy such that supporting data become necessary (such as for vertebrate control products, tin-based antifoulant paints, food-contact surface sanitizers and liquid or aerosol insecticides intended for household use).

## Submitting Minor Formulation Amendments

If a registrant believes that an amendment meets the criteria above, he/she should highlight this 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 appropriate regulatory division's Product Manager/Team Leader and to the address listed in Chapter 21 and include:

- EPA Form 8570-1, Application For Pesticide Registration/Amendment;
- one copy of the existing formulation, EPA Form 8570-4, Confidential Statement of Formula (CSF);
- two copies of the CSF of the proposed formulation;
- any supporting information such as the Material Safety Data Sheet (MSDS) on the added inert ingredient(s); and
- 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 the application except when confirmatory data are submitted. Additional time is required for review of such data.

# Final Printed Labeling

After acceptance of a new product registration, labeling amendment or labeling notification, final printed labeling must be submitted before the product is sold or distributed. Two copies of the final printed labeling that incorporate any labeling changes required by the acceptance letter and/or notification must be submitted.

# Contacts for Additional Information

Any questions or need for additional information regarding notifications should be directed to the appropriate Product Manager assigned the product in question. Refer to Chapter 21 for a listing of Product Branches.

# References Cited in Chapter 7

Refer to Chapter 19 for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 157 - Packaging Requirements for Pesticide and Devices
- Part 158 - Data Requirements for Registration
- Part 161 - Data Requirements for Registration of Antimicrobial Pesticides
- Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Foods

Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 - Definitions
- Section 3 - Registration of pesticides
- Section 6 - Administrative review; suspensions
- Section 12 - Unlawful Acts

## Pesticide Registration Notices

- PR Notice 83-3 Label Improvement Program – Storage and Disposal Statements
- PR Notice 84-1 Clarification of Label Improvement Program
- PR Notice 91-1 Procedures for Voluntarily Requesting Deletion of Approved Uses from Registered Labels
- PR Notice 94-2 Recycling Empty Aerosol Pesticide Container
- PR Notice 97-4 Consumer Access Numbers on Pesticide Labels
- PR Notice 97-6 Use of Term “Inert” in the Label Ingredients Statement
- PR Notice 98-10 Notifications, Non-Notifications and Minor Formulation Amendments
- PR Notice 2007-1 Disposal Instructions on Non-Antimicrobial Residential/Household Use Pesticide Product Labels
- PR Notice 2007-4 Labeling Revisions Required by the Final Rule “Pesticide Management and Disposal Standards for Pesticide Containers and Containment

## Label Review Manual