

Department of Pesticide Regulation



Winston H. Hickox Secretary, California Environmental Protection Agency

California Notice 2002-1

February 25, 2002

TO: Registrants and Applicants of Pesticide Products

SUBJECT: California Notification Process

This notice describes the California Department of Pesticide Regulation (DPR) notification process for certain specified minor label and/or formulation changes. The criteria for allowing changes through the DPR Notification Process are outlined below. These criteria pertain to regular pesticide products and to California-only adjuvants. This notice supersedes DPR's previous California Notice to Registrants 96-4.

Please note that the criteria for allowing changes by notification are similar, but not identical, to the U.S. EPA notification process. Attached is the revised DPR Notification Form #039-031.

I Changes from DPR's previous notification process:

The addition or revision of bilingual language on the label can no longer be done through notification, but must be submitted to the company's assigned DPR registration specialist.

Changes in the name or address on the label are no longer allowed by non-notification, but must be submitted to the company's assigned DPR registration specialist.

Specific label statements allowed in U.S. EPA's PR-Notices can now be added to a label through the notification process.

Advisory label statements can no longer be added, deleted, or revised by notification, but must be submitted to the company's assigned registration specialist.

The section on changing source active ingredient, without a resulting change in inert ingredients, has been moved to the non-notification section, although notifications would still be accepted.

The <u>DPR Notification Form, PDF</u> (80 kb) has been revised.

II Label (and formulation changes) allowed by DPR Notification Process:

A. Delete pests or use sites.

Pests or use sites can be deleted, provided that all other label references pertaining to the deleted pest or use site are also deleted. Use deletions related to data call-ins are also allowed by notification.

B. Add indoor non-food sites for certain antimicrobial products.

Indoor non-food sites for antimicrobial products can be added as allowed by U.S. EPA's PR Notice 98-10. This is provided that no additional data were required by U.S. EPA, exposure is not increased, sites are within an already registered use pattern for the product, a directive does not prohibit it, the technical product label does not prohibit it, and the dosage, concentration, frequency, and method of application are unchanged.

C. Add or include U.S. EPA PR-Notice specified label statements.

Label statements specified in U.S. EPA PR-Notices may be submitted by notification, provided that the exact language in the PR-Notice is used. For example, storage and disposal statements which comply with PR-Notices 83-3 and 84-1 are allowed by notification. Also allowed are statements which comply with U.S. EPA Worker Protection Standard (WPS). It may be necessary for DPR to make exceptions as new PR-Notices are issued.

D. Change in stated nominal concentration of inert ingredient.

The stated nominal concentration of an inert ingredient may be changed by notification, provided that it falls within the certified limits for the inert ingredient as listed on the statement of formula. See also Section III. Include DPR Application Form 39-030.

E. Non-FIFRA related label elements may be revised, added, or deleted.

Non-FIFRA label elements as allowed by U.S. EPA PR Notice 98-10 may be revised, added, or deleted. Examples include symbols or graphics required by other government agencies such as the Department of Transportation (DOT). Other non-FIFRA elements are the date of manufacture, date of label approval, and use of metric units in addition to standard U.S. units.

Changes in the fertilizer analysis statement on the label are considered non-FIFRA and may be done through the notification process. However, if there is a resulting change in the active or inert ingredient percentage on the statement of formula, a new application form with the revised statement of formula must be submitted to the company's DPR assigned registration specialist. If there is a resulting brand name change, the change cannot be done through notification.

F. Removal of redundant label statements.

Statements may be removed or combined to remove redundancy, provided that required label statements are not removed or changed.

G. Adding symbols or graphics.

Symbols and graphics can be added, but cannot substitute for, or conflict with, the label text and cannot be false or misleading.

Examples of acceptable items include arrows demonstrating how to open a package, graphics displaying aerial application (if aerial application is on the approved label), pictograms of exposure routes, and pictures of persons wearing appropriate protective clothing.

H. Correcting typographical or grammatical errors.

Typographical and grammatical errors can be corrected by notification, provided that the phrasing does not change how the product will be used.

I. Redesign of label format.

A label may be redesigned or rearranged. Changes which are allowed include color, type size, style, use of space, or configuration and placement of label elements. These changes are allowed by notification, provided that they do not modify approved text and are consistent with U.S. EPA format requirements and policy.

J. Package size and net content changes for products subject to child-resistant packaging.

The package size and net contents may be changed by notification (as allowed by U.S. EPA PR-Notice 98-10) for products which <u>are</u> subject to child-resistant packaging, provided that <u>all</u> of the following criteria are met:

- Dosage, concentration, frequency, and method of application cannot change.
- Exposure is not increased.
- Product is not a rodenticide.
- Worker Protection Standard (WPS) wording is unchanged.
- Package size is not reduced to the point that net contents of the package are smaller than the dosage in the directions for use.
- Container size, net contents, and other characteristics are not changed in a way that violated U.S. EPA or other mandated restrictions (i.e. size limitations for homeowner products).
- Product is not subject to child-resistant packaging, nor has registrant voluntarily used child-resistant packaging.
- No changes can be made to bait stations, control stations, attractant stations, or other packaging that houses the pesticide during its use.

Note: Products which are not subject to child-resistant packaging and are not a rodenticide may change package size and net contents through non-notification. See section IV for details.

K. Warranty Statements.

Warranty statements may be added, revised, or deleted by notification as allowed in U.S. EPA's PR Notice 98-10 and California Food and Agriculture Code Sections 12853 and 12854, provided that the statements do not disclaim the efficacy or safety of the product when used in accordance with label directions.

III Changes not allowed by DPR Notification Process. These must be submitted to the company's assigned DPR registration specialist for review.

Pests cannot be added to the label by notification.

Sites cannot be added to the label by notification. (Antimicrobial non-food sites are the exception as described in Section II-B.)

Brand names cannot be added or altered by notification.

Name and address cannot be changed by notification.

Increase or decrease in the percentage of active ingredient (including nominal concentration) cannot be made by notification. This is considered an alternate formula.

Change in identity or percentage of an inert ingredient cannot be done by notification. This is considered an alternate formula. Changes to Water Soluble Packaging (WSP) are included in this and cannot be made by notification.

Addition or revision of bilingual labeling cannot be made by notification.

Rodenticide label, formulation, or packaging cannot be changed by notification.

Any other changes not listed in Section II or IV cannot be changed by notification.

IV Changes allowed without notification or submission to DPR (Non-notification).

Changes in source of inert ingredient are allowed.

Changes in the source of starting materials for "integrated systems products" are allowed. See the Code of Federal Regulations for a definition.

Changes in the formulation process of a product made by a "non-integrated system" are allowed. See the Code of Federal Regulations for a definition.

The source of active ingredient can be changed without notification, provided that there is no resulting change in inert ingredient and the new source product is U.S. EPA registered.

Changes in the package size or net contents are allowed for products that are not subject to child-resistant packaging and that are not rodenticides, provided that all of the following criteria are met:

- Dosage, concentration, frequency, and method of application are not changed.
- Exposure is not increased.
- Product is not a rodenticide.
- Product is not subject to child-resistant packaging nor has the registrant voluntarily used child-resistant packaging.
- Worker Protection Standard (WPS) wording is not affected.
- Package size is not reduced to the point that net contents of the package are smaller than the dosage in the directions for use.
- Container size, net contents, and other characteristics are not changed in a way that violated U.S. EPA or other mandated restrictions.
- No changes are made to bait stations, control stations, attractant stations, or other packaging that houses the pesticide during its use.

V Process for submitting Notifications to DPR. The following items are required.

- 1. Submit a completed <u>DPR Notification form, PDF</u> (80 kb) for each product. If a cover letter is submitted, indicate that the submission is a Notification per California Notice to Registrants 2002-1.
- 2. For label changes allowed by this notice, submit three (3) copies of the final printed or printer's proof label.
- 3. For formulation changes allowed by this notice, submit one (1) copy of the Application for Pesticide Product Registration form #39-030 filled out. In lieu of filling out items 20 through 29 only, you may attach a copy of your federal Confidential Statement of Formula (CSF). Remember to sign and date the form.
- 4. Attach a copy of your U.S. EPA notification including any other documents submitted to U.S. EPA in support of the notification. This is not needed for California-only adjuvants.
- 5. Mail the above items to:

Pesticide Registration Branch, Notification Process Department of Pesticide Regulation P.O. Box 4015 Sacramento, California 95812- 4015

Submission by registered or certified mail or courier service is recommended to provide date-specific verification of delivery to DPR. If submitted by registered or certified mail or courier service mail to:

Pesticide Registration Branch, Notification Process Department of Pesticide Regulation 1001 I Street Sacramento, California 95814-2828

VI Compliance

Notifications must be received by DPR before the registrant can distribute or sell product with the changed label or formulation and must comply with this notice.

The applicant will receive a DPR response only if the submission does not meet the criteria for notification.

A product distributed or sold with a changed label or formula before DPR receives the notification submission is considered unregistered and subject to enforcement action.

A product distributed or sold with a changed label or formula that was submitted through the DPR Notification process, but does not comply with the criteria, is considered unregistered and subject to enforcement action. This is also the case for non-notification criteria.

VII Questions about this notice

For questions about this notice, please contact Ms. Martha Sanchez at (916) 324-3911. If you have product-specific questions, contact your assigned DPR registration specialist.

Sincerely,

original signed by Barry Cortez	02/25/2002
Barry Cortez, Chief	Date
Pesticide Registration Branch	
(916) 445-4377	

Attachment DPR Notification form, PDF (80 kb)

FLEX YOUR POWER! The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption. For a list of simple ways you can reduce demand and cut your energy costs, see our Web site at <www.cdpr.ca.gov>.

1001 I Street - P.O. Box 4015 - Sacramento, California 95814-4015 - www.cdpr.ca.gov A Department of the California Environmental Protection Agency