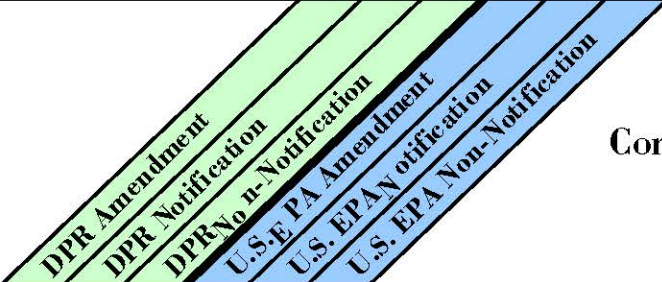


The Department of Pesticide Regulation (DPR) vs. U.S. Environmental Protection Agency (U.S. EPA) Amendment, Notification, and Non-Notification Comparison Table

The criteria for allowing minor label and formulation changes by notification or non-notification at DPR and the U.S. EPA are not identical. This table lists common types of changes and indicates if the changes can be submitted to DPR and U.S. EPA as a notification or non-notification, or if they must be submitted as an amendment. Many of the comments in this table are simplified. Please consult [California Notice 2002-1](#) and U.S. EPA's Pesticide Registration (PR) Notice 98-10 for more detailed information about the notification process. In general, specific label statements allowed in U.S. EPA's [PR Notices](#) can be added to the label through DPR's notification process.

Type of Change	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">DPR Amendment</div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">DPR Notification</div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">DPR Non-Notification</div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">U.S. EPA Amendment</div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">U.S. EPA Notification</div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">U.S. EPA Non-Notification</div> </div>						Comment
	LIST OF ACRONYMS: CFR: Code of Federal Regulations CRP: Child-Resistant Packaging CSF: Confidential Statement of Formula DCI: Data Call-In FDA: U.S. Food & Drug Administration FIFRA: Federal Insecticide, Fungicide, & Rodenticide Act MUP: Manufacturing Use Product PR Notice: Pesticide Registration Notice (U.S. EPA) USDA: United States Department of Agriculture WPS: Worker Protection Standard						
ADD/DELETE PESTS							
Add a pest that poses a threat to human health, a pest subject to quarantine, or termites	•			•			Pests that pose a threat to human health include: a. Microorganisms that are infectious to man in any area of the inanimate environment; b. Vertebrates (e.g., rodents, birds, bats, and skunks) that may transmit diseases to or injure humans; c. Cockroaches that may spread asthma, allergies, and food contamination; and d. Insects that carry human diseases (e.g., mosquitoes, ticks). U.S. EPA's list of public health pests is found in Appendix A of PR Notice 2002-1 .
Add a pest that does not pose a threat to human health (except termites)	•			•			U.S. EPA: Registrants may add a pest through U.S. EPA's notification process if: a. The registrant maintains efficacy data for each pest added; b. The pest occurs on a specific site 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); d. The dosage, frequency, concentration, or method of application do not change; e. Addition of the pest does not increase exposure of the pesticide to humans or the environment; and f. The pests are not subject to quarantine by USDA Animal & Plant Health Inspection Service.
Delete a pest		•		•			A pest may be deleted through both notification processes if all references to the deleted pest are also deleted.

Type of Change						Comment
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ADD/DELETE USE SITES

Add a use site other than a non-food antimicrobial site	•			•		
Delete a use site		•		•	•	<p>DPR: A use site may be deleted through DPR’s notification process if all references to the deleted use site are also deleted. Use deletions related to DCIs are also allowed through DPR’s notification process.</p> <p>U.S. EPA: Approved uses from a particular version of the label may be omitted (vs. deleted) via notification. Also, if the use deletion is chosen as a response to a DCI, the end use product registrant should respond to the DCI and submit a notification for each changed product label instead of an amendment, as described in U.S. EPA PR Notice 91-1. Use deletions for products NOT subject to DCIs must be submitted as an amendment. When a use is deleted by amendment, the registrant is not obligated to address any outstanding data requirements triggered solely by the deleted use. See U.S. EPA PR Notice 98-10 for more information about use deletions related to DCIs.</p>
Add an indoor, non-food site for an antimicrobial product		•			•	<p>May be added through both notification processes if:</p> <ol style="list-style-type: none"> No additional data (e.g., efficacy, groundwater, ecological effects) are required for the added nonfood site; The site is within an already registered use pattern category for the product (as specified in 40 CFR Part 158); Exposure is not increased (e.g., adding broadcast treatment to a product registered for spot treatment); An agency decision or directive does not explicitly prohibit addition of the nonfood sites to particular products; The technical product label from which the product is formulated does not prohibit the proposed site; and Dosage, concentration, frequency or method of application are not changed.

PRODUCT NAME CHANGES

Change primary brand name or change one or more alternate brand names	Other, see comment		•	<p>DPR: Registrants that wish to sell their product under additional/alternate brand names in California must register each brand name separately. This includes changes made to the product name as it is currently registered and sold/distributed in California.</p>
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Type of Change							Comment
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LABEL STATEMENT CHANGES

Add, revise, or delete advisory statements	•			•			In accordance with PR Notice 2000-5 , registrants may no longer add or change advisory labeling statements to existing products by notification as previously permitted by PR Notice 95-2 and PR Notice 98-10 .
Add, revise, or delete first aid statements	•			•			
Revise directions for use	•			•	•	•	<p>DPR: Changes in directions for use must be submitted through DPR’s amendment process.</p> <p>U.S. EPA: The following changes may be made through U.S. EPA’s notification process:</p> <ul style="list-style-type: none"> a. Changes in mixing directions which do not affect the dilution ratio or the minimum or maximum use dilutions. b. Addition of tables, charts, or other graphics which present the same use directions already approved by U.S. EPA in narrative form. c. Additional application methods permitted under FIFRA Sec. 2(ee)(3) may be added to the label by notification as long as: 1) the method results in exposure no greater than the currently registered method(s); 2) the new method results in no change in dosage, concentration, timing, or frequency of application; and 3) the product is not registered for public health uses or termiticides. d. Use directions may be modified by notification to include mixing with a fertilizer, if the dosage, concentration, and frequency of the pesticide application do not change. <p>See PR Notice 98-10 for more details on changes a-d. All other changes must be made by amendment.</p>

Type of Change

Comment

DPR Amendment
 DPR Notification
 DPR Non-Notification
 U.S. EPA Amendment
 U.S. EPA Notification
 U.S. EPA Non-Notification

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LABEL STATEMENT CHANGES (continued)

<p>Add risk reduction statements related to “non-flammable” claims, closed systems, and water soluble packaging</p>	<p>•</p>				<p>•</p>	<p>U.S. EPA: The following statements can be added through U.S. EPA's notification process:</p> <p>a. A “non-flammable” claim may be added by notification if a product meets the following based on the statement of formula: 1) if it contains or becomes a gas, it must not ignite when exposed to a lighted match; or 2) it is a liquid and has a flash point greater than 350°F; and 3) no test of any kind demonstrates the product is flammable.</p> <p>b. If a product has already been approved for use in a closed system for transfer during mixing and loading, or during application, a 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.</p> <p>c. A phrase like “water soluble packaging” may be added by notification, if applicable.</p>
<p>Add product composition statements related to pesticide category type, botanical claims, fragrance, "water-based," or claims such as "new"</p>	<p>•</p>				<p>•</p>	<p>U.S. EPA: The following statements can be added through U.S. EPA's notification process:</p> <p>a. The following pesticide categories: “fungicide,” “insecticide,” “rodenticide,” “herbicide,” “defoliant,” “repellent,” “desiccant,” “microbicide,” “antimicrobial,” “disinfectant,” “sanitizer,” “biochemical,” “microbial,” “plant regulator,” “nematicide,” and “plant-pesticide.” Other terms are not acceptable by notification.</p> <p>b. If a product is acute toxicity category III or IV, then: 1) statements such as “rotenone, a botanical insecticide” may be added if it is derived from plant extracts; 2) botanical claims may be added for inert ingredients if ALL inerts are listed in the ingredients statement. Broad, non-specific terms like “natural” or “organic” are not acceptable.</p> <p>c. If a product has been amended to add/change a fragrance, terms such as “lemon scent” may be added by notification, as well as terms like “unscented” ONLY if the product is odorless/nearly odorless and contains no odor-masking ingredient such as perfume. “Descented” may be added if the product contains an odor-masking ingredient. These terms may also be added to the product name, but need to be specified as either an additional brand name or change to primary brand name.</p> <p>d. “Water-based” may be added by notification if the product contains at least 50% water by weight, is acute toxicity category III or IV, and presents no physical/chemical hazards that require a warning statement. All ingredients must be in an aqueous solution.</p> <p>e. Truthful statements about alternate or minor formulation changes (e.g., “new”) approved by U.S. EPA may be added by notification for six months after U.S. EPA's approval of a revised or alternate formula beginning when the product with this claim is first sold or distributed. “Improved” is allowed by notification only if it indicates how the product has been improved such as “improved wettability” or “improved pouring spout.” Safety related or other false or misleading claims are not permitted (e.g., “less toxic,” “worker safe”).</p>

Type of Change

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DPR Amendment
 DPR Notification
 DPR Non-Notification
 U.S. EPA Amendment
 U.S. EPA Notification
 U.S. EPA Non-Notification

LABEL STATEMENT CHANGES (continued)

Minor FIFRA-related changes	•						<p>U.S. EPA: Minor FIFRA-related label changes may be made through U.S. EPA's notification process if they are: consistent with or specified by a PR Notice; consistent with 40 CFR Part 156; and involve no change in the ingredients statement, signal word, use classification, precautionary statements, first aid statements, physical/chemical/biological properties, storage and disposal, or directions for use.</p>
Revise storage and disposal statement	•	•					<p>DPR: Changes may be submitted through DPR's notification process if the revised label language matches U.S. EPA PR-Notice 2007-4. Any deviations from this language must be submitted as an amendment to DPR.</p> <p>U.S. EPA: Changes to storage and disposal statements can be submitted through U.S. EPA's notification process if the exact language set forth in 40 CFR 156.140 to 156.159 and U.S. EPA PR-Notice 2007-4 is used.</p>
Remove redundant labeling statements		•					<p>Statements may be combined to remove redundancy anywhere on the label through both notification processes if required label statements are not removed, changed, or moved.</p>
Change in warranty statement		•					<p>Statements may be added, revised, or deleted through both notification processes if consistent with all requirements and they do not disclaim the performance or safety of the product when used according to directions.</p>

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DPR Amendment
 DPR Notification
 DPR Non-Notification
 U.S. EPA Amendment
 U.S. EPA Notification
 U.S. EPA Non-Notification

PACKAGING CHANGES

<p>Change in packaging and related label statements</p>		•			•	<p>Changes in shape, color, or composition of packaging/labeling statements due to package size and type changes may be submitted through both notification processes only if all of the following apply:</p> <ul style="list-style-type: none"> a. The dosage, concentration, frequency or method of application do not change; b. Exposure is not increased (e.g., adding non-water soluble packaging to a product only registered for water-soluble packaging; protective clothing/equipment required because of the proposed package change; and new data requirements triggered for increased exposure); c. Before or after the proposed change, the product is not subject to CRP (including voluntary CRP); d. The product is not a rodenticide; e. No WPS labeling statements are changed; f. Package size 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; g. Package size or other characteristics are not changed to violate DPR or U.S. EPA restrictions on a product (e.g., size limitations may be imposed on a product to limit homeowner use only); and h. No changes made to stations (bait, control, attractant, etc.) housing the pesticide during its use.
<p>Change in package size or net contents</p>		•	•		•	<p>DPR: For products that meet the following:</p> <ul style="list-style-type: none"> a. Dosage, concentration, frequency, and method of application are not changed; b. Exposure is not increased; c. Product is not a rodenticide; d. WPS wording is not affected; e. Package size is not reduced to the point that the net contents are smaller than the dosage in the directions for use; f. Changes do not violate U.S. EPA or other restrictions (i.e., size limits for homeowner products); and g. No changes made to stations (bait, control, attractant, etc.) housing the pesticide during use. <p>--Package size and net contents for products not subject to CRP (or not voluntarily adopting CRP) can be revised without notifying DPR. --Package size and net contents for products subject to CRP (including voluntarily) can be submitted through DPR's notification process.</p> <p>U.S. EPA: Package size/net contents may be revised without notifying U.S. EPA except for:</p> <ul style="list-style-type: none"> a. Products subject to or which voluntarily adopt CRP requirements under 40 CFR Part 157 (either before or after the package size change); b. Products subject to other special U.S. EPA-mandated size-related requirements; and c. Rodenticide products; or d. Changes modifying the product's toxicity category or chemical properties.

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 U.S. EPA Notification
 U.S. EPA Non-Notification

INGREDIENT CHANGES

Increase or decrease percentage of <u>active</u> ingredient on label	•			•		This is considered an alternate formula. Submit through both amendment processes.
Change nominal concentration of <u>inert</u> ingredient		•			•	A registrant may change the stated nominal concentration of any inert ingredient through both notification processes if the nominal concentration falls within the certified limits for that ingredient as listed on the statement of formula. U.S. EPA also requires that the composition of the ingredient be known to the registrant.
Change in certified limits of <u>inert</u> ingredient		•			•	A registrant may change the certified limits of any inert ingredient(s) in a formulation through both notification processes, if the certified limits fall within the standard certified limits in 40 CFR 158.350 . Certified limits may not be changed via notification if: a. U.S. EPA has previously determined that alternative certified limits will apply; or b. The registrant has already changed the nominal concentration
Change source of <u>active</u> ingredient			•	•	•	DPR: The source of active ingredient can be changed without notifying DPR if there is no resulting change in inert ingredient and the new source product is registered by U.S. EPA. U.S. EPA: A registrant may change the source of an active ingredient through U.S. EPA's notification process, if 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). All other revisions require submission through U.S. EPA's formal amendment process. U.S. EPA: The following active ingredient related changes MUST be made by amendment: -Results in a change in the nominal inert ingredient total or change in toxicological category or chemical property. -Use of an unregistered source of an active ingredient. -Results in a new formulation. -Changes the stated nominal concentration of any active ingredient or certified limits from that shown on the previously submitted statement of formula. -If the new source is not registered for at least the same uses as the existing source, the unsupported uses must be deleted from the formulated product or data must be submitted to support the additional uses.

Type of Change	DPR Amendment DPR Notification DPR Non-Notification U.S. EPA Amendment U.S. EPA Notification U.S. EPA Non-Notification	Comment
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INGREDIENT CHANGES (continued)

Change source of <u>inert</u> ingredient			•		•	•	<p>U.S. EPA: If U.S. EPA has required that a registrant identify the source of an individual inert ingredient and the identity is known to the registrant, the registrant may change the source of that inert ingredient through U.S. EPA's notification process. However, if U.S. EPA has not required identification of the source of an inert ingredient, the registrant may change a source without notifying U.S. EPA.</p>
Change in source of starting materials for <u>integrated</u> systems products			•		•		<p>U.S. EPA: A registrant producing a product by an integrated system as defined in 40 CFR 158.300 that uses an unregistered source of active ingredient, is required to supply U.S. EPA with the sources of the starting materials for each ingredient (see 40 CFR 158.325).</p> <p>A registrant may change the source of the starting materials to other sources through U.S. EPA's notification process if the integrated systems product is:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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 significance (e.g., dioxins, furans, nitrosamines, arsenicals) that have not previously been reported to U.S. EPA or that occur above levels previously permitted by or reported to U.S. EPA.
Change in formulation process of <u>non-integrated</u> system products			•		•		<p>U.S. EPA: A registrant may modify the 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) through U.S. EPA's notification process, if:</p> <ol style="list-style-type: none"> 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 of the product will not change.

Type of Change	DPR Amendment DPR Notification DPR Non-Notification U.S. EPA Amendment U.S. EPA Notification U.S. EPA Non-Notification	Comment
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NON-FIFRA RELATED CHANGES

Change in the name or address of the registrant on the label	•				•	•	<p>U.S. EPA: The following is taken from U.S. EPA PR Notice 98-10 regarding revision to a registrant's company name and address on a product label:</p> <p>a. In accordance with 40 CFR 152.135, the transfer of ownership must be approved by U.S. EPA. Once a product's ownership has been approved by U.S. EPA, the registrant need not submit labeling reflecting the new registrant's company name and address.</p> <p>b. In accordance with 40 CFR 152.122, registrants are required to notify U.S. 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 U.S. EPA.</p>
Add bilingual language	•					•	
Correct typographical or printing errors		•				•	<p>DPR: Typographical and grammatical errors can be corrected through DPR's notification process provided that the phrasing does not change how the product will be used.</p>
Add symbols and graphics		•				•	<p>Symbols and graphics in conjunction with and in close proximity to explanatory label text may be added through both notification processes if 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)).</p> <p>Examples include:</p> <p>a. Diagrams demonstrating how to open product containers;</p> <p>b. Graphics displaying application patterns such as aerial application;</p> <p>c. Pictograms displaying various exposure routes;</p> <p>d. Pictures of where the product can be used; or</p> <p>e. Pictures of persons wearing appropriate protective clothing</p>
Redesign of label format		•				•	<p>DPR: A label may be redesigned/rearranged and submitted through the notification process if the approved text is not modified. Allowable changes include: color, type size, style, use of space, or configuration and placement of label elements.</p> <p>U.S. EPA: A label format change that does not modify approved label text and is consistent with the format requirements of 40 CFR 156.10 and U.S. EPA policy can be made without notifying U.S. EPA.</p>

Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
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NON-FIFRA RELATED CHANGES (continued)

Modify non-pesticidal characteristics			•				<p>U.S. EPA: Per PR Notice 98-10, these non-pesticidal claims can be modified without notification:</p> <ul style="list-style-type: none"> a. A non-pesticidal claim if it is not false or misleading, does not conflict with the pesticide labeling, and is consistent with other applicable laws 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 such non-pesticidal uses may be added by non-notification. For example, “Use at full strength (2 cups per gallon) to remove tough stains.” b. 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. c. Beneficial product attributes not related to pesticidal effect, such as “non-staining” and “non-corrosive to metals.” d. Claims regarding price/price-related marketing information such as “low price,” “25 cents off,” and “rebate available.” e. Factual statements about where the product was made (e.g., “Made in U.S.A.”) provided these comply with other regulatory requirements. f. Factual statements about uses approved by government agencies other than U.S. EPA if such statements do not imply endorsement by those agencies (e.g., “Approved for use in USDA-inspected meat and poultry plants.”) An unacceptable statement would be, “Contains materials that meet all FDA standards and regulations.” g. Per PR Notice 97-4, telephone numbers and internet addresses may be added without notification. h. Per PR Notice 97-6, the term “Other Ingredients” may be substituted for “Inert Ingredients” in the label ingredients statement without notification.
Other non-FIFRA related changes			•				<p>DPR: Non-FIFRA label elements (e.g., symbols or graphics required by other government agencies, date of manufacture, date of label approval, change in fertilizer analysis statement, and metric units in addition to standard units) may be added, revised, or deleted by notification. 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 as an amendment. If there is a resulting brand name change, the change must be submitted as an amendment.</p>
Revise EPA Establishment Number on label			•				