A Guide for Pesticide Registrants

California Department of Pesticide Regulation

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On the cover: *Diabrotica*. In the twentieth century, *Diabrotica* became a major pest of maize in North America as maize growing areas increased. The practice of continuous maize growing was largely responsible for the expanding range of *D. virgifera virgifera*. Photo: Alex Wild, www.alexanderwild.com.

Chapter 1

Introduction to Pesticide Registration

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- Authority to Regulate

Does My Product/Device Require California Registration?
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Introduction

Overview

The purpose of this manual is to provide guidance to the Department of Pesticide Regulation's (DPR) stakeholders on applying for pesticide product registration and amendments. Topics include:

- Guidance on determining if a product requires registration.
- Types of product registrations.
- Submitting an application for registration of a new product or amendment of a currently registered product.
- The internal registration process at DPR.
- Maintaining a product registration.
- Other related topics such as mill assessment, enforcement, and product inactivation/discontinuance.

Authority to Regulate

There are both federal (U.S.) and state laws that govern the manufacture, sale, distribution, and use of pesticide products.

The *federal* authority to regulate pesticides is found in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Code of Federal Regulations Title 40 (40CFR), Parts 150 to 189. The U.S. Environmental Protection Agency (EPA) is responsible for regulating pesticides at the federal level.

A *State*'s authority to regulate pesticides is found in FIFRA, section 24(a) and reads, "A State may regulate the sale or use of any Federally-registered pesticide or device in the state, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act." DPR is given further authority in the following sections of California law and regulations:

California Food and Agricultural Code (law), Division 6, sections 11401 - 12408

California Food and Agricultural Code (law), Division 7, sections 12500-14155 and 15300-15340

California Food and Agricultural Code (law), Division 13, sections 29000-29103

Business and Professional Code (law - structural) Division 3, Chapters 14-14.5

California Code of Regulations, Title 3, Division 6, sections 6000-6960

California Code of Regulations, Title 16, Division 19, sections 1900-1999.5

Note: In the field of pesticides, FIFRA clearly states that only the federal government has authority over pesticide labeling. In other words, no state or local government can dictate what is on a pesticide product label. However, a state can refuse to allow registration of a product and therefore the possession, sale and use of any pesticide not meeting its own health or safety standards. States can also adopt regulations more protective of health and the environment than on a product label.

Does My Product/Device Require California Registration?

What is a Pesticide?

California Food and Agricultural Code (FAC) section 12753 defines a pesticide as any of the following:

(1) Any substance or mixture of substances which is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest, as defined in FAC Section 12754.5, which may infest or be detrimental to vegetation, man, animals, or households, or be present in any agricultural or nonagricultural environment whatsoever.

(2) Any spray adjuvant.

Further, a "pest" is defined in FAC section 12754.5 as any of the following that is, or is liable to become, dangerous or detrimental to the agricultural or nonagricultural environment of the state:

- Any insect, predatory animal, rodent, nematode, or weed.
- Any form of terrestrial, aquatic, or aerial plant or animal, virus, fungus, bacteria, or other microorganism (except viruses, fungi, bacteria, or other microorganisms on or in living man or other living animals).
- Anything that the director, by regulation, declares to be a pest.

A product requires registration in California if:

(1) The U.S. Environmental Protection Agency (U.S. EPA) Office of Pesticide Programs requires registration of the product (excluding Plant Incorporated Protectants) and the product is sold, distributed, or used in California.

(2) California law requires registration of the product even if U.S. EPA does not (e.g., spray adjuvants, structural pest control devices, certain FIFRA 25(b) products).

Types of Products

Certain products require both federal and state registration while others require only state registration. The following information will help determine which products require registration in California:

Products that require U.S. EPA and DPR registration

- **Technical grade active ingredient (TGAI) and manufacturing use products (MUPs):** Defined as any federally registered product that is distributed or sold for manufacturing, formulation, reformulation, or repackaging into other pesticide products must be registered.

  California requires the registration of TGAI products and MUPs that are:

  Manufactured in California (excludes products manufactured solely for export out of California), or

  Used in California to manufacture or formulate an end-use product (excludes products manufactured or formulated for export out of California).

  If the raw material is registered at U.S. EPA as a pesticide, then it must be registered in California before being delivered or sold into California for use in the formulation of any pesticide (MUP or End Use) within the state.

  Spray adjuvants labeled solely for manufacturing use or repackaging into end-use spray adjuvants are not required to be registered, but spray adjuvants products with labels that include both manufacturing/repackaging and end-use directions require registration with DPR.

40 CFR 152.3

- **End-use products:** products sold, used, or distributed in California (e.g., disinfectants, sanitizers, agricultural chemicals, certain pheromones, home and garden products, etc.) for pesticidal purposes that are not TGAIs or MUPs.

  Note: End-use products manufactured in California for sole shipment outside the state do not require DPR registration.

  40 CFR 152.3

- **California Master Labels:** A California Master Label is defined by DPR as a pesticide product label bearing most or all U.S. EPA accepted uses for that product, but that the company does not intend to market for sale or use in California. Master label products cannot be sold or distributed in California. To sell, use or distribute the product in California, the registrant must also register the end-use product, even if the labels are virtually identical. For more information, see http://www.cdpr.ca.gov/docs/registration/guides/master_labels.pdf or Appendix G.

  40 CFR 152.3

Additional products that require California registration

- **Additional/alternate brand names:** pesticide products sold under alternate brand names in California require separate registrations.

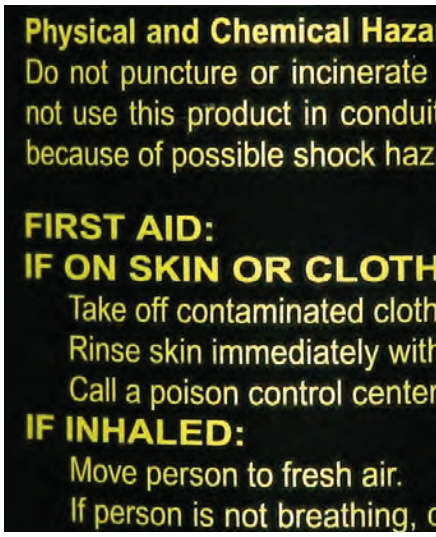
  Note: Applicants must notify U.S. EPA of all alternate brand names through their notification process (see U.S. EPA form 8570-1).

  FAC 12821
  3 CCR 6152

- **Supplemental distributor products:** products distributed or sold under another company's name and address (also known as supplemental registrations or subregistrants; must have the same formulation, label, and packaging as the basic manufacturer).

  Note: Supplemental distributors must submit to U.S. EPA a statement (U.S. EPA form 8570-5) signed by both the registrant and the distributor acknowledging their agreement.

  40 CFR 152.132



- **Spray adjuvants** (often referred to as "adjuvants"): products that are intended to be used with other pesticides to aid the application or enhance the effect of that pesticide (e.g., wetting agents, pH modifiers, stickers, spreaders, etc.). As previously noted, spray adjuvants labeled solely for manufacturing use or repackaging into end-use spray adjuvants do not require registration. However, spray adjuvant products with labels that include both manufacturing/repackaging and end-use directions require registration with DPR.

FAC 12758

- **Structural pest control devices:** any device or method used to mitigate any wood destroying pest.

CA Notice 2000-7
FAC 15300

- **Certain FIFRA 25(b) products:** FIFRA section 25(b) products must be registered unless they meet the exemption requirements outlined in California Code of Regulations section 6147 (e.g., > 1% citronella products for topical use, products not labeled according to California regulation, etc.). For more information, see http://www.cdpr.ca.gov/docs/registration/guides/section25b.pdf or Appendix H.

FIFRA 25(b)
(136w.(a)2[b])
3 CCR 6147

Products that do not require DPR or U.S. EPA registration

- **Fertilizers and soil amendments:** Products intended solely for use as fertilizers are regulated by the California Dept. of Food and Agriculture (CDFA).

Note: Products labeled or intended for use as both fertilizers and pesticides must be registered by both DPR and CDFA.

- **Devices** (not including structural pest control devices for wood destroying pests in California): physical or mechanical means to trap, destroy, or mitigate a pest which do not include a pesticidal substance (e.g., fly traps, glue boards, mouse traps, sound generators, ozone generators, water treatment devices,* etc.).
  ***In addition, water treatment devices are regulated by the California Department of Health.**

  Note: Other requirements *do* apply to pest control devices. U.S. EPA *requires* companies that manufacturer pest control devices to obtain U.S. EPA establishment numbers for their products –for more information go to http://www.epa.gov/pesticides/factsheets/devices.htm.

FIFRA 2(h)
(136 ([h])

- **Human/Animal Drugs**: products intended to control viruses, bacteria, microorganisms or pests regulated by another agency, on or in living man or other animals (e.g., lice control, internal parasite control, athlete's foot products, etc.). **Note:** These products are regulated by a number of different agencies (FDA, CDFA, etc.).

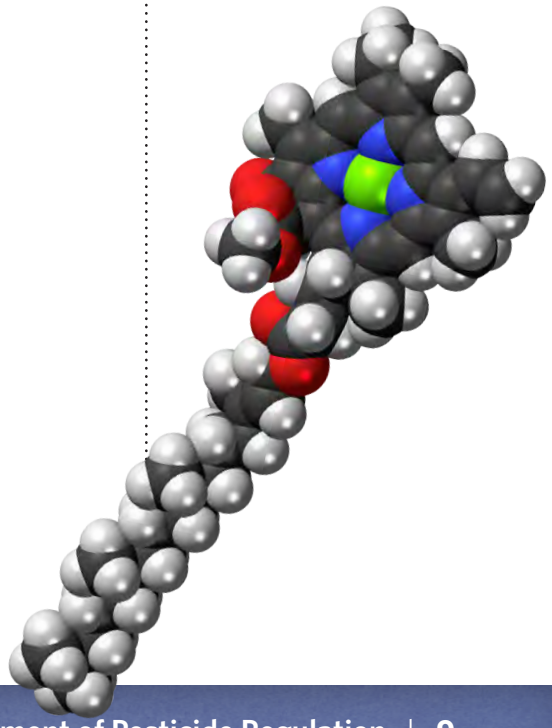
40 CFR 152.6

- **Products** that are not considered pesticides and are specifically exempted in 40 CFR Parts 152.8, 152.10, and 152.20, that also meet the criteria for exemption under 3 CCR section 6147.

- **Treated articles:** articles treated with a registered pesticide to protect the article itself (e.g., paints treated with a pesticide to protect the paint coating, plastics or other materials treated to prevent mold from affecting the material itself). For additional information, see U.S. EPA Pesticide Registration Notice 2000-1.

40 CFR 152.25

Note: Pesticide treated clothing (e.g., permethrin treated clothing) or other pesticide treated materials that claim to protect the user are not considered treated articles and **must** be registered as pesticides by both U.S. EPA and DPR.



Types of Registrations

Product registrations and exemptions from registration in California fall into the following types:

- **Full registration** – is one that has fulfilled all California registration requirements (known federally as a FIFRA section 3 registration).

  Note: Most products are registered under this section.

- **Conditional registration** is a registration conditioned upon the completion of certain specified data requirements. Examples might be a 1-year storage stability study or additional efficacy data. Once conditions of registration have been met, the conditions are removed and a full registration can be granted.

- **Experimental Use Permit** (known federally as a FIFRA section 5 registration).

  An Experimental Use Permit is a permit issued by U.S. EPA that allows a person/company to test an unregistered pesticide product or an unregistered use of a currently registered product, to develop the data necessary to register the product under Section 3 of FIFRA.

- **FIFRA** section 18 - Emergency Exemption from registration.

  FIFRA section 18 authorizes use of an unregistered pesticide in a state for a limited time if U.S. EPA determines that emergency conditions exist.

- **FIFRA** section 24(c) - Special Local Need (SLN) registration.

  FIFRA section 24(c) allows states to register new products or an additional use of an existing product to address a pest situation that is existing or imminent, and that a Section 3 product cannot currently mitigate.

- **FIFRA** section 25(b) – Exemption from registration.

  Exempts certain pesticide products from registration.

Note: the fact that a product is conditionally registered federally does not automatically mean it will be given a conditional registration in CA.

Chapter 2

How to Obtain a New Product Registration

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- Cover Letter
- California Application for Pesticide Registration
- Six Copies of the Proposed Marketing/Production/Container Label, or if Only Registering a Master Label, the Master Label
- Data to Support Registration
- U.S. EPA Documentation
- Application Fees
- Designated Agents/Representative Letter

How to Obtain a New Product Registration

The following submission requirements apply to:

- New products not currently registered with DPR that contain new active ingredients.
- New products not currently registered with DPR that contain active ingredients found in other products currently registered with DPR.
- Products currently registered with DPR but are intended to be sold under additional/alternate brand names in California.
- Supplemental distributor (sub-registrant) products not currently registered with DPR.
- California Master Label products.

Quick Guide

To apply for a ***new product*** registration, the following are required:

- Cover letter (strongly recommended).
- California Application for Pesticide Registration.
- Six copies of the proposed marketing/production/container label, or if only registering a master label, the master label, printer's proof, or copies thereof.
- Data to support registration.
- U.S. EPA documentation.
- $1,150 application fee.
- Designated agent letter (when applicable).

Mail applications to the assigned Regulatory Scientist (if none has been assigned, address your application to Pesticide Registration Branch) at:

(Packages sent via UPS, DHL, Fed-Ex, etc.)

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

(Packages sent via U.S. Postal Service)

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

Detailed Information

Cover letter

Each submission should be accompanied by a detailed cover letter. DPR suggests the following information be included:

- The registrant's (company) name, address, and contact information (e.g., telephone number, e-mail address).
- Note if the package has been submitted by a designated agent on behalf of the registrant.
- The product name.
- The EPA registration number (if applicable) or a statement that the product does not require federal registration.
- The reason for submission of the package (e.g., request for new end-use product registration, master label, supplemental distribution, etc.).
- Requests for data waivers or references to data waivers included with the package (if applicable).
- For supplemental distributors – note if the basic registrant's product is currently registered with DPR.
- Whether data are being submitted to support the product registration, data were previously submitted by the registrant or another registrant/ trade group, or if the registration will rely on data submitted by another registrant/trade group.
- If referencing data on file with DPR include the DPR Study ID#, Document ID#, Tracking ID#, or other DPR identification numbers (if known to the applicant).
- If the applicant plans to rely upon data on file with DPR to support a substantially similar product(s), include the product name(s) and U.S. EPA or DPR registration number(s). See Appendix B for guidance on determining "substantially similar."
- Whether or not additional items (e.g., CSF or supporting data) will or have been sent separately by a third party.
- Note if requesting to submit the product concurrently with submission of an application to U.S. EPA for federal registration, include a justification for the concurrent submission (most products require federal registration prior to submission at DPR). **See California Notice 2015-03** (http://www.cdpr.ca.gov/docs/registration/canot/2015/ca2015-03.pdf).
- If only a draft label is submitted, note that container labels (or copies) will be submitted to DPR prior to final acceptance.

California Application for Pesticide Registration

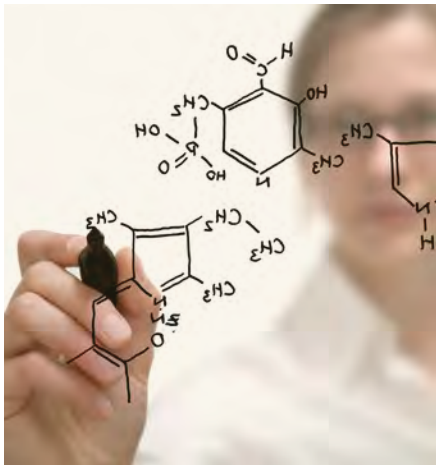
To apply for registration of a pesticide product in California, a California Application for Pesticide Registration (DPR-REG-030) must be filled out and submitted to DPR.

General information on submitting an application:

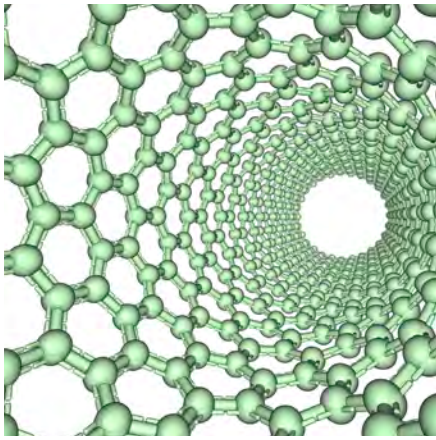
- The application must be signed and dated by the registrant or a designated agent.
- The registrant's company name and address must be consistent with the company's information on file with U.S. EPA.
- In lieu of the California Product Formulation Information sheet (page 3 of the California application), the applicant may substitute a copy of the U.S. EPA Confidential Statement of Formula (CSF).
- All alternate formulas/CSFs must be submitted to DPR even if the only difference in the formula is a fragrance, varied paint color, or the addition of fertilizer components.
- If the applicant is a supplemental distributor and does not have access to the basic registrant's CSF, they may note the following in their cover letter and on the formulation sheet:

  The basic registrant's product formulation is currently on file with DPR and should be referenced, or

  A copy of the basic registrant's product formulation has been requested by the applicant and will be provided directly by the basic registrant.



Six Copies of the Proposed Marketing/Production Container Label



General Guidance on Submitting Marketing/Production/Container, or if Only Registering a Master Label, the Master Label:

- Submitted label must be identical to that on record at U.S. EPA and must include all revisions identified in the U.S. EPA letter of acceptance or formal correspondence, with the following exceptions:

  The address on the label may differ.

  Use sites may be deleted.

  Bilingual text added to the federal label by non-notification may appear on the label (but is subject to DPR review).

- If a label is resized before it is submitted, it must be legible and the applicant must indicate the percentage reduction or enlargement.
- U.S. EPA provides guidelines for label formatting (applicable to products that require federal registration), however, exceptions are made at their discretion. See the U.S. EPA Label Review Manual for details.

Note: DPR requires six copies of the proposed **marketing/production/container label, or if only registering a master label, the master label** be submitted for review and acceptance. The six copies may be printer's proof labels, final printed labels, or copies thereof. As noted, if the submitted labels are not final printed or printer's proof, the applicant should acknowledge in a cover letter that printer's proof or final printed labels will be submitted to DPR prior to the license being issued.
A license will not be issued until final printed labels, printer's proof labels, or copies thereof have been submitted.

Multiple Container Sizes

Many pesticide products are sold in more than one container size. If the label language varies on the different size containers (e.g., precautionary or storage and disposal statements), six labels for each representative size that has different language must be submitted if different sizes will be sold, used or distributed in California. For example, a product may be sold in 2, 5, 10, and 50-pound bags. The label language may be identical for the 2 and 5-pound bag, but the 10 and 50-pound bags require different disposal or precautionary statements. In this case, the applicant should submit six copies of either the 2 or 5-pound bag and six copies of either the 10 or 50-pound bag.

Colors, Dyes, Fragrances, and Fertilizers

Many pesticide products are sold with varying colors, dyes, fragrances, or as combination pesticide/fertilizer products. A registrant must submit six copies of printer's proof, final printed labels, or copies thereof for each representative color, dye, fragrance, or fertilizer variation they intend to sell, use or distribute in California. They must also submit a separate confidential statement of formula or product formulation sheet for each color, dye, fragrance or fertilizer variation, since each will have minor differences in the inert ingredients. It should be noted that pesticide/fertilizer products are regulated by both DPR and the California Department of Food and Agriculture.

In all cases, the labels require review and acceptance by DPR but no fee is required for the additional labels as long as the size, color, dye, fragrance, or fertilizer component are not considered part of the brand name (**some exceptions apply to antimicrobial products**). They are not considered separate registrations.

Note: If the size, color, dye, fragrance, or fertilizer component is included as part of the brand name, the submission is considered an additional/alternate brand name and must be registered as a separate product per FAC section 12821. A separate application and registration fee are required.

Data to support registration

All products proposed for registration in California must be supported by scientific data. Information on California's data requirements can be found online at http://www.cdpr.ca.gov/docs/registration/manual/chapter_03.pdf.

FAC 12824

All data required by 40 CFR, Part 158 or 161 for federal registration, regardless of submission to U.S. EPA, must be submitted to DPR. In addition, any study not identified in federal regulations, but required by U.S. EPA to support registration of the pesticide product, is also required by DPR. For example, federal regulations require that all registrants generate product performance data, but U.S. EPA does not generally require this data be submitted to support registration of non-public health products. DPR requires submission of product performance data for all products.

3 CCR 6170

3 CCR 6159

In addition, DPR may require supplemental data to support the registration or amendment of a pesticide product (e.g., hazards to bees, indoor exposure).

3 CCR 6176-6199.7

In lieu of relying on data submitted with an application, DPR may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. **If an applicant *does not* supply a complete data set, and intends for DPR to rely on another company's data to support its registration application, the applicant may be required to offer to pay the data owner a share of the cost of producing the data.** For information, see http://www.cdpr.ca.gov/docs/legbills/ab1011/resource.htm. This does not apply to applicants that rely upon their own data that is currently on file with DPR.

FAC 12811.5

CA 2004-7

Applicants are reminded to specify in their cover letter if they intend for DPR to rely upon the evaluations of previously submitted data. DPR does not require certain residue data. See CA Notice 2004-7 for federally-required studies that are not required by DPR .

Formatting data

DPR requires that data submitted for review be organized and bound in a specific manner. Improperly bound data will be returned or shredded, and ***will not be reviewed***. See California Notice 2006-06 for format guidelines.

Note: DPR requires that data submitted for review be organized and bound in a specific manner. Improperly bound data will be returned or shredded, and **will not be reviewed**. See California Notice 2006-06 for format guidelines.

U.S. EPA documentation

This does not apply to adjuvants or other products that do not require federal registration! See Chapter 1 for information on products that do not require federal registration.

U.S. EPA stamped-accepted label and accompanying letter of acceptance

Applicants must submit a copy of the most current U.S. EPA stamped-accepted label and accompanying letter of acceptance.

Note: If a product is being reviewed concurrently by U.S. EPA, proof of federal registration must be provided before the product will be registered in California. If a U.S. EPA stamped-accepted label and accompanying letter is not provided with the application, an explanation must be provided in the cover letter. To determine if the product qualifies for concurrent review, see FAC sections 12836 and12836.5, and California Notices 2015-03.

Additional correspondence to/from U.S. EPA

Once a product label is stamped-accepted by the U.S. EPA, any documents relevant to that label (i.e. federal amendments, notifications, etc.) should be submitted to DPR. In addition, any written (e-mail or hard copy) correspondence between the registrant and U.S. EPA pertinent to the current stamped-accepted label or cover letter should also be submitted. Examples include:

- Amendments submitted through the federal notification process that are not included on the most current stamped-accepted U.S. EPA label (applicant should submit a copy of completed notification form).
- Removal of restrictions or requirements outlined in the cover letter accompanying the stamped-accepted label.

Additional/alternate brand name form

Registrants are required to notify U.S. EPA using form 8570-1, when distributing a product under an additional/alternate brand name. A copy of this completed form must be submitted to DPR. However, U.S. EPA's return response to the company is not required.

Supplemental distributor form

If the applicant is a supplemental distributor, U.S. EPA's Notice of Supplemental Distribution of a Registered Pesticide Product form (8570-5) must be signed and dated by both the basic registrant and the supplemental distributor and submitted to DPR. This form is required whether or not the basic registrant is registered in California.

Application fees

All new products	$1,150 (new and currently approved active ingredients)
Interim registrations	$5,000 (in addition to the $1,150 application fee)
Structural devices	$200

All application fees are processing fees, are non-refundable, and do not guarantee registration of the product.

Make check or money order payable to "Cashier, State of California."

Payment cannot be made by credit card at this time.

Designated agents/representative letter

A "designated agent" is a designated member of a firm, an independent consultant, or similar representative authorized to make business decisions on behalf of the registrant. Designated agents must submit a designated agent letter to DPR with their submission. For details see California Notice 2009-5.

Chapter 3

Pesticide Product Registrations - General Review Procedures

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Processing the Application

All application submissions are received by the California Environmental Protection Agency (CalEPA) mailroom (CalEPA is comprised of six boards and departments including DPR), regardless of shipping method. On average it takes 3-14 days before they are received by DPR's Pesticide Registration Branch (PRB) Regulatory Scientists. Once received from the mailroom, application packages are processed by Intake staff.

Upon receipt, Intake staff enter information into DPR's Tracking Database. At this point, three critical things occur:

(1) A Tracking Identification Number (Tracking ID#) is assigned to the application submission. A Tracking ID# is a unique identifier that allows DPR to track a product submission throughout the review process. The Tracking ID# remains in the database indefinitely so that general information about the submission can always be retrieved. This number should be referenced when contacting the Regulatory Scientist regarding the application package.

(2) E-mail notification – Once the Tracking ID# is generated, an automatic e-mail response is sent to the e-mail address provided on the application form, notifying the applicant that DPR is in receipt of their submission (provided a correct e-mail address was supplied). This is the first e-mail notification the applicant will receive.

(3) Data submitted to support the application are sent to indexing where the volumes are assigned document numbers, individual studies are assigned study identification numbers, and the study information is cataloged. Data must be formatted according to the guidelines in California Notice 2006-6 or the application submission will be returned. Once the indexing process is complete, the applicant will receive a second e-mail notification.

Evaluation Process

Each company that registers pesticide products in California is assigned a Regulatory Scientist who will coordinate that company's registration activities in California. Unlike U.S. EPA, DPR does not distribute products according to active ingredient and/or use type. Special submissions (e.g., new active ingredient, major new use, FIFRA section 24c Special Local Needs, FIFRA section 18 Emergency Exemptions) may be assigned to other DPR staff, but the assigned Regulatory Scientist remains the registrant's point of contact. Once assigned, it is important to note the contact information for the Regulatory Scientist and their supervisor, which is available online at http://www.cdpr.ca.gov/docs/registration/reg_org.pdf.

Once received, the Regulatory Scientist will review the application submission for completeness and determine if it must undergo scientific evaluation. If the application submission requires scientific evaluation, the Regulatory Scientist then decides which of the following evaluation stations need to review the data:

- Pesticide Registration Branch
  - Chemistry
  - Fish and Wildlife
  - Microbiology
  - Pest and Disease Protection
  - Plant Physiology
- Medical Toxicology Branch
- Worker Health and Safety Branch
- Environmental Monitoring Branch
- Enforcement Branch

For a description of the different evaluation stations and their corresponding responsibilities, see http://www.cdpr.ca.gov/docs/registration/manual/appendices/appendix_e.pdf.

A description of the process used for common registration actions is provided below.

Products that contain active ingredients found in currently registered products

Time frames for requests to register products containing active ingredients found in currently registered products vary based on staffing, the number of submissions received, and the complexity of the submission. Data are routed consecutively in no particular order to applicable evaluation stations for review. For example, once chemistry completes its evaluation, the submission may be routed to the Medical Toxicology Branch for review or vice versa. DPR's e-mail notification system will indicate when a submission enters and exits an evaluation station, thereby allowing the applicant to know where their submission is at a given point in time.

Products that contain new active ingredients

As noted in Chapter 1, DPR considers an active ingredient to be "new" if it is not found in a currently registered product in California.

Application submissions to register products containing new active ingredients are subject to extensive data requirements that take more time to evaluate than products with currently registered active ingredients. Multiple scientific evaluations are typically required, and unlike products that do

not contain new active ingredients, the submission is typically routed to evaluation stations simultaneously. For example, toxicologists in the Medical Toxicology Branch may be reviewing toxicology studies at the same time as chemists are reviewing environmental fate data. However, it is important to note that some evaluations cannot take place until other stations have completed their reviews. For example, the Environmental Monitoring Branch's ground water evaluation cannot take place until the Registration Branch chemists have found submitted environmental fate studies to be acceptable. Likewise, Fish and Wildlife scientists cannot complete their evaluation of ecotoxicology data until the Registration Branch chemists have completed their evaluation of the submission.

Amendments

Products frequently undergo changes to the label, either at the initiative of the registrant or as required by U.S. EPA or other regulatory authorities. Most label revisions must be submitted to the department before they can be sold in California. To determine if your label amendment requires review by DPR, see http://www.cdpr.ca.gov/docs/registration/guides/notification_factsheet.pdf or Appendix I. In addition, Chapter 4 contains details on how to submit a label amendment.

Additional/Alternate Brand Name Products

Additional/alternate brand name products sold in California require separate registrations. Additional/alternate brand name products contain active ingredients already found in currently registered products. Therefore, they are processed as products that contain active ingredients found in currently registered products.

Requirement to post for public comment

3 CCR 6253

California law requires a 30 calendar day public posting period of all proposed and final DPR decisions to register or deny registration of pesticide products that may cause foreseeable direct or indirect physical change in the environment. DPR accepts public comments on all proposed decisions to register or deny registration of pesticide products. These decisions can be found on our Web site under Notice of Decisions. DPR must respond to all public comments received on a proposed decision before taking a final action with regard to a product's registration.

Comments should be addressed to:
Pesticide Registration Branch, Chief
Department of Pesticide Regulation
1001 I Street, P.O Box 4015
Sacramento, California 95812

Licensing

Once the 30-day posting period is complete and DPR has responded to all comments received, the product can be licensed. A "license" is a certificate of registration issued by DPR that grants the registrant permission to sell their product in California for up to one calendar year. All products licensed in California are assigned internal "alpha codes" to distinguish alternate or additional brand name products that are registered under the same U.S. EPA Registration Number. **The alpha code is not required on the printed label but will appear on DPR's databases, quarterly mill assessment reports, and the product license/renewal.** For example, the first product to be registered is assigned alpha code "AA." If DPR registers additional brand name products with the same U.S. EPA Registration Number, the additional products are assigned alpha codes "ZA," "ZB," "ZC," etc.

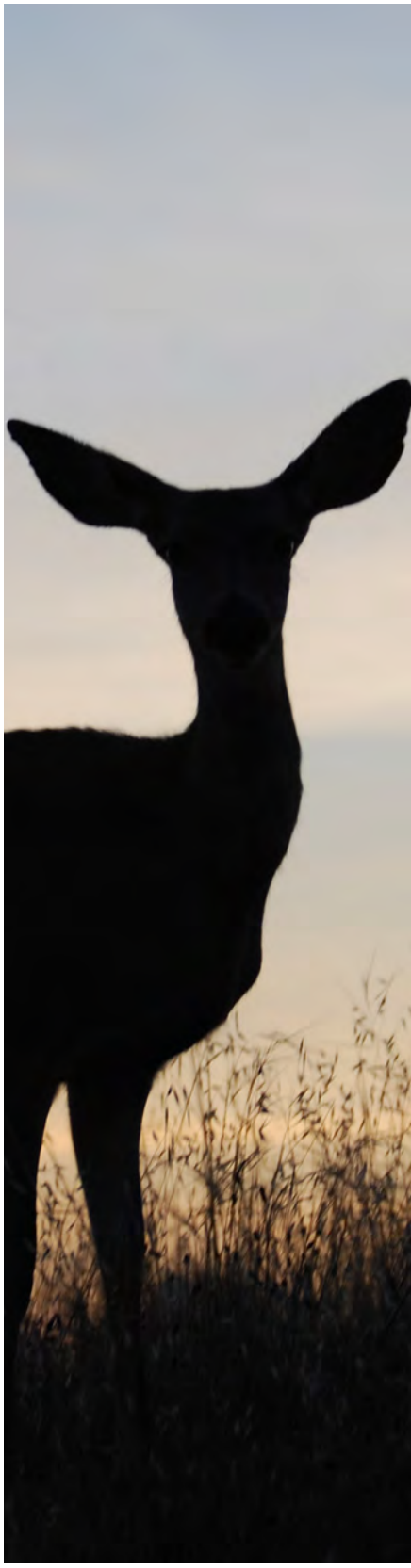
There are two types of product registrations (excluding interim registrations that are rare and will not be discussed in this manual) - full and conditional:

- Full product registration - A full (unconditional) certificate of registration (license) is issued when all DPR data and administrative requirements have been met.
- Conditional product registration - A conditional certificate of registration (license) is issued for a product that has met all of the administrative requirements, and most, but not all of the data requirements required by law. Data deferred at the time of registration must be generated and submitted within the time frame designated by DPR, not to exceed three years from the date of registration. Many restrictions apply. For information, see 3 CCR section 6200.

The registrant must receive a copy of the license (hard copy or e-mail) before their product can be sold, used, or distributed in California!

Ombudsman – Point of Contact

The Pesticide Registration Branch has an Ombudsman to provide a central point of contact for the regulated community, the public, and other government agencies on pesticide registration issues and general aspects of pesticide regulation. On a day-to-day basis the Ombudsman answers questions and acts as a troubleshooter in the investigation and resolution of disputes. By serving as an interface to interpret and clarifying policy issues and identifying problem areas, the Ombudsman assists DPR management internally and streamlines efforts to increase efficiency and timeliness. The current Registration Branch Ombudsman's contact information can be found online at http://www.cdpr.ca.gov/docs/registration/funcmenu.htm.



Chapter 4

How to Maintain a Product Registration

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How to Maintain a Product Registration

Several regulatory actions can occur once a new pesticide product is registered with DPR. Examples include:

- Label amendments.
- Formula revisions.
- Company name and/or ownership changes and product ownership transfers.
- Registration Renewal.
- Product inactivation/discontinuance.
- Mill assessment.
- Risk assessment.
- Reevaluation.
- Adverse effects reports.

Actions may be initiated by the registrant, U.S. EPA, or DPR. This chapter describes general processes that follow the registration of a product.

Label Amendments

There are two different ways by which a registrant can revise their label with DPR: label amendment and revision by notification. All types of label revisions may be submitted to DPR through the amendment process, a limited number of actions may be submitted through the notification process, and a few actions do not require any notification to DPR. To determine the correct process for submission, see http://www.cdpr.ca.gov/docs/registration/guides/notification_factsheet.pdf or Appendix I.

It should be noted that the California amendment and notification processes differ from those used by U.S. EPA. In most cases, the applicant must first amend their product label with U.S. EPA before it can be submitted to DPR for acceptance.

Note: If a label is resized before it is submitted, it must be legible and the applicant must indicate the percentage reduction or enlargement with a minimum 6-point font

Label Amendment Process

Label amendments that require submission through the label amendment process **must be reviewed and accepted by DPR prior to release for shipment in California**. A $25 application fee is required if data are required to support the amendment (whether the data referenced are already on file at DPR or are being submitted with the amendment).

Applicants must submit the following:

- A cover letter explaining the reason for submission and detailing the changes made.
- A completed Application to Amend Pesticide Product (DPR-REG-035) must be submitted if the amendment requires the $25 fee.
- 6 copies of the proposed marketing/container/production label (Note: If a label is resized before it is submitted, it must be legible and the applicant must indicate the percentage reduction or enlargement with a minimum 6-point font).
- U.S. EPA documentation (this may include a U.S. EPA stamped-label and accompanying letter or a copy of the U.S. EPA notification form), if required.
- Data to support the amendment (if applicable).

Note: In lieu of relying on data submitted with an application, DPR may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. **If an applicant does not supply a complete data set, and intends for DPR to rely on another company's data to support its registration application, the applicant may be required to offer to pay the data owner a share of the cost of producing the data.** For information, please visit our website at http://www.cdpr.ca.gov/docs/legbills/ab1011/resource.htm. This does not apply to applicants that rely upon their own data that is currently on file with DPR.

Note: If the amendment involves foreign language text, the change must be submitted through DPR's label amendment process!

Notification Process

Revising a label through California's notification process allows the registrant to release for shipment the revised product label/formulation once the notification is received by DPR. For this reason, revisions allowed through this process are limited. However, labels submitted by notification are subject to review. See the DPR vs. U.S. EPA Non-notification, Notification,and Amendment Comparison Char t (Appendix I) to determine if the revision qualifies for submission through the notification process.

- If the revisions meet the notification criteria, the notification will be processed and the revised label stamped – "Accepted by Notification." If an e-mail address was provided with the application, the applicant will be notified by e-mail. However, the applicant will not receive an acceptance letter or copy of the accepted label. A copy of the label may be obtained through a public record request.
- If the revisions are not in compliance with the notification requirements, a letter is sent to the applicant advising that the package has been either (1) returned because it cannot be processed or (2) it will be processed as a label amendment. **A non-compliant product released for sale into California prior to the review and acceptance as a label amendment is considered misbranded and is subject to penalties.**

Applicants must submit the following:

- A cover letter explaining the reason for submission and detailing the changes made.
- A completed Notification of Minor Changes form (DPR-REG-031).
- 3 copies of the proposed marketing/container/production label.
- U.S. EPA documentation if applicable (this may include a copy of the U.S. EPA notification form if required).
- $25 application fee.

Changes that do not require submission to DPR

- Changes to U.S. EPA establishment numbers.
- Changes to the source of an inert ingredient.
- Changes to the source of an active ingredient, provided there is no change in inert ingredients and the new source product is federally registered.
- Changes to the source of 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).
- Changes in the formulation process of a product made by a "non-integrated system" (a non-integrated system is a blending or dilution of product components involving no chemical reaction-distinguished from a reaction process).
- Changes in package size or net contents (restrictions apply – see http://www.cdpr.ca.gov/docs/registration/guides/notification_factsheet.pdf (Appendix I) for details).
- Changes to the materials safety data sheet (MSDS) unless it is specifically referenced on the product label.
- FIFRA section 2ee recommendations – DO NOT submit these to DPR.

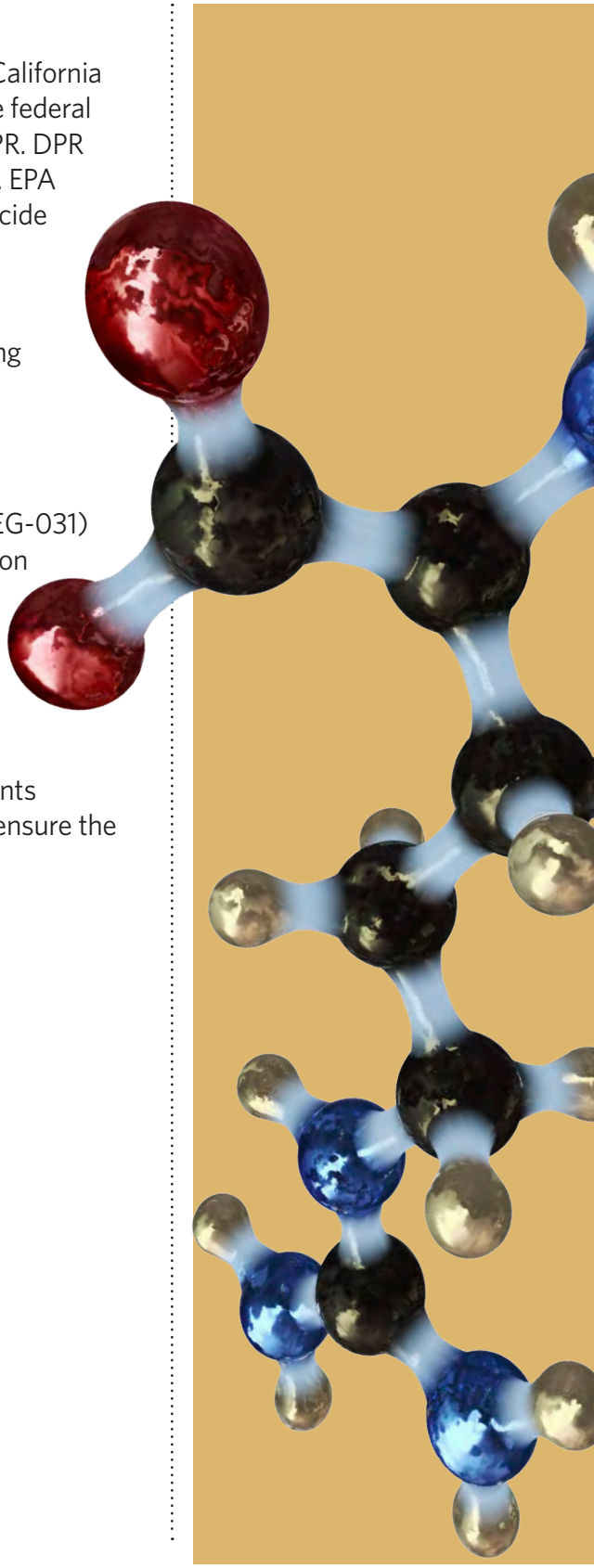
Formula Revisions

New or alternate product formulations sold, used or distributed in California must first be submitted and accepted by DPR. Products that require federal registration must receive federal approval prior to submission to DPR. DPR accepts confidential statements of formula (CSFs) accepted by U.S. EPA or DPR product formulation information sheets (page 3 of the pesticide application form).

Applicants must submit the following:

- A cover letter explaining the reason for submission and detailing the changes made.
- A copy of the revised or alternate formula(s).

If the formula revision can be submitted through the notification process, a completed Notification of Minor Changes form (DPR-REG-031) must also be submitted. For all other formula revisions, no application is required, provided there are no changes made to the product label.



Formula revisions that require label revisions

If the formula change requires revisions to the currently accepted label, the two actions will be processed separately by DPR. Registrants should reference instructions on submitting a label amendment to ensure the proper documentation is included.

Company Name and/or Ownership Changes and Product Transfers

Company change in ownership

A certificate of registration (product license) in California cannot be transferred if there is a change of business ownership (see 3 CCR section 6153). A change in business ownership is the transfer of a U.S. EPA company number from one legal entity to another, even if the same company owns both entities. A new application and $1,150 application fee are required per product. This applies to basic manufacturing companies and all supplemental distributor companies when the basic manufacturer changes ownership.

Applicants must provide DPR with written confirmation that U.S. EPA has accepted the name/ownership change, new applications for each product affected, and a $1,150 application fee for each product. Registrants have one year to submit revised labels to DPR (as a label amendment) once the product is licensed under the new company name. Note: If a company's firm number is transferred by U.S. EPA from one legal entity to another, but there is no change in company name or EPA Registration Number associated with that company name, the purchasing company must submit written confirmation from U.S. EPA that the ownership change has been accepted, but is not required to submit to DPR new application forms, labels, other documents, or fees. For example, if Company Y purchases Company Z with EPA Reg. No. 123-1234, but allows Company Z to continue to operate as Company Z with EPA Reg. No. 123-1234), Company Y must submit confirmation that the ownership change has been accepted by U.S. EPA, but no new application, label, or fee is required.

Products may be possessed and sold by a dealer/distributor for two years from the last date of registration. Persons who legally obtained the product during this time can continue to use the product indefinitely (provided no action has been taken by U.S. EPA or DPR that would affect existing stocks).

Note: The new registrant can continue to sell the previous registrant's existing stock provided the old product continues to be registered. However, unlike U.S. EPA, DPR does not allow a grace period for the registrant to exhaust existing stock once the product is no longer registered. **Therefore, it is important for a registrant to continue registration of the old company's product if they wish to exhaust the existing stock.**

Company name change without a change in ownership

If a company changes its name but there is no change in ownership, the registrant must submit paperwork to reflect the new company name. **There is no fee required for a change in company name when there is no change in ownership.** The following items must be submitted:

- A new complete Application for Registration Pesticide Product form (DPR-REG-030). Note: a CSF may be submitted in lieu of the California Product Formulation Sheet.
- 6 copies of the proposed marketing/production/container label, or if only registering a master label, the master label reflecting the new company name.
- U.S. EPA stamped-accepted label and approval letter, and a copy of U.S. EPA form 8570-5 if the applicant is a supplemental distributor.
- Additional correspondence to/from U.S. EPA including the name change approval.
- A copy of DPR's Declaration of No Change in Ownership form.

Note: if the product name changes in addition to the company name, this is not considered a company name change but a new product registration under the new company name. All paperwork and fees relating to a new product apply.

Product transfers

A registrant may choose to sell one or more products to another registrant. This is sometimes referred to as a product transfer. The product transfer is specific and does not involve the sale or purchase of the company itself. Since a certificate of registration cannot be transferred in California, it is subject to registration as a new product (see Chapter 3).

Renewals

A pesticide product certificate of registration (license) expires on December 31 of each year. **A $1,150 annual renewal fee is required for each product registered in California.** On October of each year, DPR mails to each registrant an Application for Renewal of Registration with a list of their currently registered pesticide products. DPR does not have the capability of sending or receiving renewal notices online.

Once the Application for Renewal of Registration is received, the registrant must complete and return the renewal form in accordance with the following instructions:

(1) The signed renewal form and renewal fee(s) should be returned to DPR as soon as possible, and no later than January 31 of the following year. To avoid unregistered product sales penalties, the registrant must be in possession of the new license before any product can be sold the upcoming year. ***Do not substitute another form for the renewal form. DPR will return incomplete or incorrect renewal forms.***

(2) Labels must not be submitted with the renewal. Applications for new products, amendments and/or company name/ownership changes must be sent separately to the assigned Regulatory Scientist.

(3) A single line shall be drawn through any product on the form that the company no longer wishes to register for the following year and any product no longer registered with U.S. EPA. Products that are no longer registered with the U.S. EPA may not be renewed in California. However, if U.S. EPA allows the sale of existing stock for a limited time period, the products may remain registered in California during that time period.

(4) The company's current telephone number shall be written in the space provided on the renewal form.

(5) The registrant should verify that the company address is correct. Unless the company resides outside of the United States the company address must be that of the ***registrant***, **NOT** a consultant or another firm. Company address changes may be made directly on the renewal form.

(6) As an alternative to mailing a hard copy of the license to the registrant, DPR will e-mail the license. If this is preferred, the appropriate box on the renewal form shall be marked and the email address written in the space provided.

(7) The renewal application must be signed and dated.

Note: Applications for Renewal of Registration are sent directly to the registrant and not to their designated agents unless the registrant of record is located outside the U.S. Agents who coordinate California renewals should obtain the Application for Renewal of Registration from the registrant(s) for which they act as agent. In the event that an Application for Renewal of Registration is not received by the registrant by November 15th, they should contact the DPR Registration Branch's Licensing Unit at PRBlicensingmail@cdpr.ca.gov.

(8) The renewal application with the required payment of $1,150 per product to be registered (make checks payable to Cashier, State of California), shall be mailed to:

DEPARTMENT OF PESTICIDE REGULATION
PESTICIDE REGISTRATION BRANCH
ATTN: LICENSING
1001 I STREET, P.O. BOX 4015
SACRAMENTO, CA 95812-4015

Late renewal/procedure for reinstatement of registration

If, by April 1, a registrant does not submit its pesticide product renewal application to DPR, the Pesticide Registration Branch Licensing Unit will issue a letter informing the registrant that DPR has not yet received its renewal application, and that as a result, its product(s) registration(s) is considered lapsed as of January 1 of the current calendar year. Once a product registration lapses it is illegal to sell the product in California. The letter will advise the registrant that they must inform DPR by June 1 if it intends to renew the registration(s) of its product(s). If the registrant does not respond by June 1, DPR will amend the database to list the company's product(s) as "inactive" effective December 31 of the previous year.

If, after the product's registration is inactivated, the registrant decides to reactivate the registration, the registrant may request a reinstatement. DPR will accept requests for reinstatement of pesticide product registrations only until December 31 of the current renewal year.

A request for either late renewal or reinstatement of a pesticide product's registration must be accompanied by a $1,150 renewal fee and $230 late fee for each product. DPR will issue a Supplemental License, listing the product brand name, EPA Reg. No., and the date of renewal. The Licensing Unit will amend the database to list the product as "active." The date of the Supplemental License will reflect the lapse in registration. However, the lapse will not show in DPR's database.

Lapsed registration

A registrant cannot legally sell a product once the renewal or registration of that product has lapsed.

> Products whose registration has lapsed (become inactive) shall not be sold by the registrant, but may be possessed and sold by a dealer for two years after the last date of registration. It should be noted that products may not be sold or shipped into California once they are inactive; even to a licensed dealer. Therefore, the product must be shipped or sold into California prior to its inactivation to be legally possessed or sold by a dealer.
>
> If acquired while legally registered or within two years after the date of last registration, such products may be possessed and used according to the directions on the label.

3 CCR 6301

Conditional registrations

Referenced in Chapter 3, a conditional product license (registration) is issued for a product that has met all of the administrative requirements, and most, but not all, of the data requirements required by law. Data deferred at the time of registration must be generated and submitted within the time frame designated by DPR, not to exceed three years from the date of registration.

Registrants are required to submit status reports at the same time as their license renewal application if their data waiver extends past January 1 of the next calendar year. Although the status report and the license renewal application must be sent at the same time, they are sent to different staff members within the Pesticide Registration Branch. **The status report must be addressed to the company's assigned Regulatory Scientist. The license renewal application must be addressed to Licensing, as these two documents are processed separately.** If the time frame given for the data waiver has expired or cannot be met prior to the end of the year, the registrant must request a deadline extension or their product will not be renewed. Extension requests must be addressed to the company's assigned Regulatory Scientist.

If DPR reviews submitted data and determines the conditions have been fulfilled, the conditional registration will be changed to a full registration. If the submitted data do not fulfill the conditions, the registrant will be notified and a determination on how to proceed will be made at that time.

Further, a conditionally registered product will not be renewed if the registrant has not complied with the conditions. If the registrant does not "line out" the product on their renewal application form, the product will be inactivated by DPR.

Frequently Asked Questions

Can I be fined if I submit my renewal by December 31 but do not receive my license by January 1?

No. Your renewal is considered "on time" if it is post marked prior to January 1. DPR has 60 days to process an application for renewal (3 CCR 6215). Depending on when the application was received, the registrant may not receive their renewal license by January 1. Applications that are not received by January 31 are subject to penalties.

Can I be fined if I submit my renewal application after February 1, but continue to sell my product in the interim?

Yes. Renewal applications submitted after January 31 are subject to late fees and the license becomes effective on the date stamped on the license. Product released for shipment by the registrant between January 1 and the date on the renewal license, is considered the sale of an unregistered product.

If I'm late to submit my renewal, am I responsible for paying the mill assessment on products for the period of time my products aren't registered?

Yes. Mill assessment must be paid on product that is sold, even if there was a lapse in registration. In addition, applications that are not received by January 31 are subject to renewal penalties.

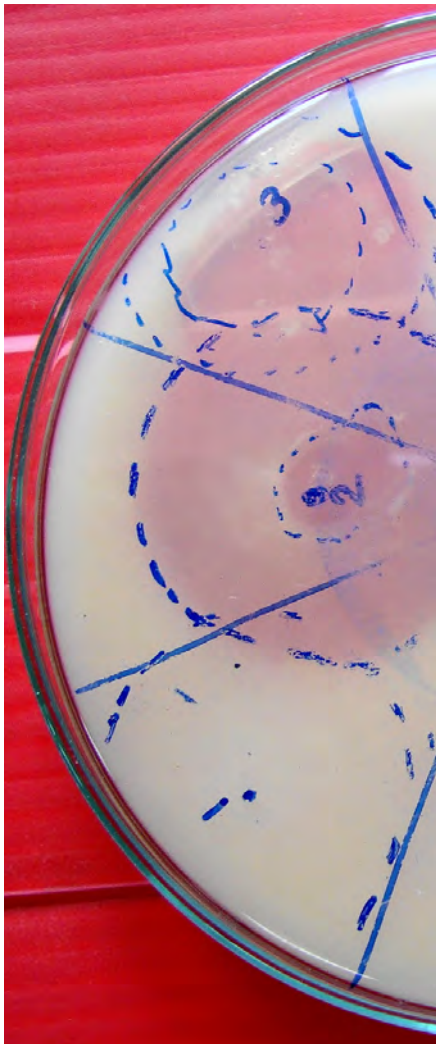
Product Inactivation/Discontinuance

Unlike many other states, California does not have a formal discontinuance process that requires the registrant to continue registration of a product until existing stocks have been depleted. Once a product is no longer shipped or sold into California, it is not required to be registered. There are two ways in which a product registration can be inactivated by the registrant:

(1) Voluntary cancellation during the year – At any time, a registrant may request that the registration of any of its pesticides be voluntarily canceled. A Voluntary Cancelation form must be filled out and submitted to DPR.

(2) Request for inactivation during the renewal period – A registrant may request that DPR inactivate any product registration for the upcoming year by drawing a line through the product name on their renewal form as described previously.

DPR has the authority to cancel or suspend a product registration, after a hearing, if the product has demonstrated any of several adverse effects listed in FAC 12825-12827.



Mill Assessment

Registrants must, on a quarterly basis, pay an assessment per dollar sales on each registered pesticide product sold into California.

Exempted from this requirement are:

- Manufacturing-use only.
- Pesticide products listed under 3 CCR 6384 (active ingredient is a pesticide but is for a non-pesticidal use).

If another person, not the registrant, is the first person to sell the pesticide in California, they are required to have a broker or dealer license and are subject to payment of mill assessment. For more information, refer to the Product Compliance Web page on Mill Assessment.

Risk Assessment

Risk assessment is a process designed to answer questions about the toxicity of a chemical, exposure resulting from its various uses, the likelihood that use will cause harm, and how to characterize that risk. Risk assessment plays a critical role in DPR's evaluation of the potential human health hazards associated with pesticide exposure. DPR's comprehensive approach assesses potential dietary (food and drinking water), workplace, residential, and ambient air exposures.

Risk assessment is often the driving force behind new regulations and other use restrictions. DPRs Medical Toxicology Branch manages the risk assessment process with exposure assessments developed by Worker Health and Safety Branch, environmental fate reviews by Environmental Monitoring Branch, and supporting information from other branches. DPR initiates risk assessments for a number of reasons, focusing on pesticides that pose the greatest potential risk. For example, the identification of possible adverse health effects during review of toxicology data may trigger a risk assessment. Similarly, DPR may initiate a risk assessment when use of a pesticide can result in ambient air exposures of concern. Once the risk has been fully characterized, regulators develop a strategy for responding to that risk. This is called *risk management,* and is separate from risk assessment.

For more information, see DPR's Web page on Risk Assessment.

Reevaluation

3 CCR 6220-6228

FAC 12824

California law requires DPR to continuously evaluate registered pesticides. DPR established the reevaluation process to implement this requirement. A number of factors may result in a registered pesticide product or group of products being reevaluated:

- Public or worker health hazard.
- Environmental contamination.
- Residue over tolerance.
- Fish or wildlife hazard.
- Lack of efficacy.
- Undesirable phytotoxicity.
- Hazardous packaging.
- Inadequate labeling.
- Disruption of the implementation or conduct of pest management.
- Other information suggesting a significant adverse effect.

Upon receipt of information indicating that use of a pesticide may have caused or is likely to cause an adverse effect to people or the environment, DPR is required to investigate. If, based on that investigation, DPR finds that the pesticide has caused or may have caused a significant adverse effect, reevaluation is triggered. When a pesticide enters reevaluation, DPR reviews existing data and may require registrants to provide more data. The goal is to determine the extent of the potential hazard and to identify ways to reduce or eliminate problems. For more information, please see DPR's Web page on Reevaluation.

Adverse Effects Reporting Requirements

If, during the registration process, or any time after registration, the registrant (or applicant) has evidence of an adverse effect or risk to human health or the environment, the registrant (or applicant) must immediately submit the information to DPR. This information includes, but is not limited to, that required by federal law FIFRA Section 6(a) (2).

Registrants must submit adverse effects disclosures in a cover letter with a citation referencing FAC section 12825.5 or 3 CCR section 6210. If there is reason to believe that use or continued use of the pesticide constitutes an immediate substantial danger to persons or to the environment, the director may, after notice to the registrant, suspend the registration pending a hearing and final decision.

Chapter 5

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Pesticide-Related Areas of Interest

Broker License

A company must have a pesticide broker license if it is (1) the first to sell, offer to sell, distribute into, or bring into California for sale any pesticide product, AND (2) it is not the registrant or a licensed pest control dealer.

For more information concerning this topic, see http://www.cdpr.ca.gov/docs/license/broker.htm.

Prop 65 List

Proposition 65 (Prop 65), officially known as the "Safe Drinking Water and Toxic Enforcement Act," was approved by California voters in 1986. It requires the State to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list has grown to include approximately 800 chemicals since it was first published in 1987. Prop 65 requires businesses to notify Californians about significant amounts of listed chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment. Proposition 65 also prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water.

Businesses are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone, including workers, to a listed chemical. This warning can be given by a variety of means, such as by labeling a consumer product, posting signs at the workplace, distributing notices at a rental housing complex, or publishing notices in a newspaper. Once a chemical is listed, businesses have 12 months to comply with warning requirements.

While federal law controls pesticide labeling and federal law supersedes state law, registrants may opt to add a warning to their label based on their understanding of Prop 65 and the liability associated with not warning. For more information about Prop 65, see http://www.oehha.ca.gov/prop65/

"Doing Business as," "A Division of," or "A Subsidiary of"

If a registrant identifies their company name as "a division of," "a subsidiary of," or "doing business as (DBA) another company," this must be reflected in their name on record at both U.S. EPA and DPR. All documents submitted to both agencies must include the company name as, "Company A, doing business as

Company B," except, the product label may identify the company as "Company B" or the phrase "Company A, doing business as Company B."

Two Products with the Same Brand Name

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

(1) Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B).

(2) Registrants assigned more than one company number (e.g., 1234 and 567 both issued to Company X).

Note: this does not apply to a registrant that registers both a California Master Label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

Federal law does not prohibit two different registrants from using the same product brand name. California regulations allow two different registrants to use the same brand name, provided the products:

(1) Are the same chemical composition, or

(2) Do not have different physical conditions sufficient to affect their pesticidal properties.

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This regulation applies to California master labels!**

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name.

Acceptable – A basic manufacturer and their supplemental distributor register their products under the same brand name.

Not acceptable – One 41% glyphosate product registered to Company A, and one 20% glyphosate product registered to Company B, both registered under the same brand name.

ATCC Numbers for Antimicrobial Product

American Type Culture Collection (ATCC) numbers: ATCC is a private, nonprofit biological resource center and research organization whose mission focuses on the acquisition, authentication, production, preservation, development and distribution of standard reference microorganisms, cell lines and other materials for research in the life sciences. In other words, ATCC obtains or produces different strains of microorganisms, cell lines, and other materials such as bacteria, assign them specific numbers (ATCC numbers), and sells them to researchers and other organizations.

ATCC numbers must appear in one of the following locations for antimicrobial products:

- On the data matrix provided to U.S. EPA.
- On the California Master Label (as optional text) with the listing of the organisms claimed.
- As the final page of the California Master Label (as optional text).

Section 18 Emergency Exemptions

Section 18 of FIFRA authorizes use of an unregistered pesticide for a limited time if U.S. EPA determines that emergency conditions exist. For information on Section 18s, see http://www.cdpr.ca.gov/docs/registration/guides/section18.pdf (Appendix C). The Section 18 Emergency Exemption web page also provides information on current Section 18s in California.

Section 24(c) Special Local Needs

Section 24(c) of FIFRA allows states to register new products or an additional use of an existing product to address a pest situation that is existing or imminent, and that a Section 3 product cannot currently mitigate. For more information on Section 24(c) registrations, see http://www.cdpr.ca.gov/docs/registration/guides/section24c (Appendix D). The Section 24(c) Special Local Needs web page also provides information on current Section 24(c) in California. (http://www.cdpr.ca.gov/docs/registration/sec24/sect24intro.htm)

Pesticide Products Prohibited from Schools and Child Care Facilities

Under the California Education Code, Section 17610, the use of a pesticide on a school site is prohibited if that pesticide is granted a conditional registration, an interim registration, or an experimental use permit by DPR, or if the pesticide is subject to an experimental registration issued by the U.S. EPA, and either of the following is applicable:

> The pesticide contains a new active ingredient.
>
> The pesticide is for a new use. This paragraph does not apply to a conditionally registered pesticide that is approved for other uses that has fulfilled all registration requirements that relate to human health, including, but not limited to, the completion of mandatory health effect studies pursuant to the Birth Defect Prevention Act of 1984 (Art. 14 (commencing with Sec. 13121), Ch. 2, Div. 7, F. & A.C.). The requirements of this section are not intended to impose any new labeling requirements.

The use of a pesticide on a school site is also prohibited if DPR cancels or suspends registration, or requires phase out of use, of that pesticide.

Vendors or manufacturers of pesticides that are prohibited for use on a school site pursuant to subdivision (a) are prohibited from furnishing those pesticides to school districts or school sites either by sale or by gift.

For the list of current pesticide products prohibited from use in schools or child care facilities, please visit DPR's web page at http://apps.cdpr.ca.gov/schoolipm/school_ipm_law/prohibited_prods.pdf.

Research Authorizations

With the exception of those exempted by Title 3, California Code of Regulations (3 CCR) section 6268, a written authorization for research must be obtained from DPR before any experimental, unregistered use of a pesticide in California. A research authorization (RA) allows researchers to collect field data under California use conditions to support California registration of a pesticide product. To apply for a RA, see http://www.cdpr.ca.gov/docs/registration/regforms/ra/ramenu.htm (Appendix E).

If the product and the proposed use are federally registered, there is no limit on the field size for the RA. However, any RA request for more than 100 acres per crop requires specific justification. If the product or proposed use is NOT federally registered, the RA is limited to ten acres or less on land or one surface acre or less of water. If the product or proposed use is on more than 10 acres of land or one surface acre of water, the researcher must obtain a federal experiment use permit (EUP) from the U.S. EPA If a federal EUP is obtained, researchers have the option of either applying for an RA or registering the federal EUP in California on a conditional basis. Please note these are separate processes with different requirements and limitations. See http://www.cdpr.ca.gov/docs/registration/guides/research_authorizations.pdf (Appendix E) and 3 CCR section 6260 – 6272 for more information on RAs. For information on EUPs, see http://www.cdpr.ca.gov/docs/registration/guides/experimental_use.pdf (Appendix F).

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Appendix A

Glossary of Terms

Note: Many additional terms can be found in Title 3 California Code of Regulations (CCR), section 6000 and Title 40 Code of Federal Regulations (CFR), part 152.3

Active ingredient(s): Active ingredient means any substance (or group of structurally similar substances if specified by U.S. EPA) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desicant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in 40 CFR part 174.3.

FIFRA Sec. 2 40 CFR 152.3 152.125

Acute dermal LD_{50}: A statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

40CFR 152.3

Acute inhalation LC_{50}: A statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

40CFR 152.3

Acute oral LD_{50}: A statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

40CFR 152.3

Adjuvant: see Spray Adjuvant.

Agricultural use: The use of any pesticide or method or device for the control of plant or animal pests, or any other pests, or the use of any pesticide for the regulation of plant growth or defoliation of plants. It excludes the sale or use of pesticides in properly labeled packages or containers that are intended for any of the following:

a. Home use.

b. Use structural pest control.

c. Industrial or institutional use.

d. The control of an animal pest under the written prescription of a veterinarian.

e. Local districts or other public agencies that have entered into and operate under cooperative agreement with the State Department of Health Services pursuant to section 116180 of the Health and Safety Code, provided that any exemption under this subdivision is subject to the approval of the director as being required to carry out the purposes of this division.

Note: California law defines agricultural use differently than U.S. EPA. For U.S. EPA's definition, please see 40 CFR part 170.3.

Algaecide: Substance intended to kill algae in various settings including swimming pools, industrial water cooling towers, and agricultural sites.

Antifouling product: Pesticide intended for use on boat and ship bottoms, pier and dock pilings, and similar submerged structures to prevent attachment or damage and destruction by marine invertebrates.

Antimicrobial product: Pesticide intended to inhibit growth of any bacteria, fungi or viruses declared to be a pest and which exist in any environment, except in or on living man or animals. This includes the following:

FIFRA Sec.2mm

i. Sanitizer and disinfectant used on inanimate surfaces.
ii. Sterilizer intended to kill virus and all bacteria, fungi and their spores, on inanimate surfaces, except liquid sterilants used to sterilize critical and semicritical medical equipment that are exempt from registration
iii. Bacteriostat intended to inhibit growth of bacteria in the presence of moisture.
iv. Fungicide and fungistat intended to inhibit the growth of, or destroy fungi (including yeasts).
v. Commodity preservative and protectant intended to inhibit the growth of, or destroy bacteria and fungi.
vi. Preservative and protectant used in manufacturing processes.

Applicant: A person who applies for a registration, amendment, or renewal of a pesticide product registration.

Attractant: Substance which, through its property of attracting certain animals, is intended to help in mitigating pests. Attractants include sensory stimulants such as pheromones, synthetic attractants, and certain extracts from naturally occurring organic materials. Attractants can be used alone or they can be used in combination with toxicants to kill pests.

Avicide: Substance intended to prevent, destroy, repel, or mitigate pest birds. Bird toxicants and repellents also include sensory agents utilizing taste, sight, touch, or other means, intended to repel certain bird species or populations from certain sites, and reproductive inhibitors intended to reduce or otherwise alter the reproductive capacity.

Bacteriostatic water filter: This is a water filter unit containing a substrate such as activated charcoal, with a bacteriostatic agent, used for terminal (end) processing of potable (drinking) water.

Basic registrant: A term used to describe a company that manufactures a product. Also known as the basic manufacturer or primary registrant.

Biopesticide: Certain types of pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals. There are three major classes of biopesticide: 1) Microbial, 2) Plant-Incorporated-Protectants, 3) Biochemical.

Biochemical pesticide: Naturally occurring substances that control pests by non-toxic mechanisms and include substances of such things as insect sex pheromones and scented plant extracts. Please see Chapter 8 for more information.

Carbamate: group of organic compounds sharing a common functional group with the general structure -NH(CO)O-.

Chemigation: Applying pesticide through an irrigation system or mixing with irrigation water before the water is applied to the soil or crop.

CCR 6000
FAC 13142 40
CFR 170.3

Chronic toxicity: The property of a substance or mixture of substances to cause adverse effects in an organism, upon repeated or continuous exposure over a period of at least one-half the lifetime of that organism.

Closed system: A procedure for removing a pesticide from its original container, rinsing the emptied container, and transferring the pesticide and rinse solution through connecting hoses, pipes, and couplings that are sufficiently tight to prevent exposure of any person to the pesticide or rinse solution. Rinsing is not required for undiluted pesticide. System design and construction must meet DPR criteria.

CCR 6000-6746

Co-pack: Also known as a multi-pack, a co-pack is 1) registered pesticide product, in one container, that is packaged with a non-pesticide component, in a separate container and sold as a single unit or 2) two or more pesticide products packaged in separate containers but sold together.

Conditional registration: A time-limited product registration granted to a registrant where specific data requirements are waived, provided the company agrees to submit that data within three years or less.

CCR 6200

Confidential business information (CBI): Information that is considered trade secret under federal law and not releasable under the Public Record Act (section 6254.2) See FIFRA section 10.

Concurrent submission: A product application submitted to California concurrently with the product application submission to U.S. EPA. (See FAC sections 12836).

Defoliant: A substance which causes leaves or foliage to drop from plants such as harvest-aid agents for cotton to facilitate harvesting.

FAC 12752
FIFRA Sec. 2

Degradation Product: A substance resulting from the transformation of a pesticide by physicochemical or biochemical means.

Desiccant: A substance or mixture of substances intended for artificially accelerating the drying of plant tissue. Desiccants include harvest aid agents that result in accelerated drying and death (maturation) of certain crop plants, such as cotton and soybeans.

FIFRA Sec. 2

Device: Any instrument or contrivance (other than a firearm) as described in FIFRA Section 2(h) which traps, destroy, repels, or mitigates a pest. A device is not considered a pesticide, with the exception of certain structural uses requiring California registration under FAC 15300.

40CFR 152.500

Diluent: A substance that is mixed with a pesticide to adjust the concentration of the final finished spray prescribed on the pesticide label. A diluent is added in the field by the end user. Water is generally used as a diluent. We do not regulate diluents.

Disinfectant product: Disinfectants are used on hard inanimate surfaces & objects to destroy or irreversibly inactivate infectious fungi & bacteria but not necessarily their spores. Disinfectants are divided into two groups: hospital and general use. (See label review manual).

Distributor registration: The distribution or sale of a registered product under another company's name or address. Also referred to as a subregistration or supplemental distribution. The distributor is considered an agent of the registrant under FIFRA. (See 40 CFR 152.132).

Drift: Movement of pesticide, during or immediately after use, through air to a site other than the intended site of application. See substantial drift (3 CCR 6000).

CCR 6000

Dual use: Term used by DPR to define a pesticide that is labeled for both agricultural and home use, or other non-ag uses.

Economic Poison: Term no longer used for "pesticide".

Efficacy: The ability of a pesticide product when used according to label directions to control, kill, repel, or induce the desired action in the target pest as claimed.

Emergency exemption: The term for a FIFRA Section 18 exemption from registration. The four types are: (1) specific, (2) quarantine, (3) public health, and (4) crisis. An emergency exemption is issued in response to an emergency pest problem, where no registered alternatives are available.

Emergency registration: A time-limited registration under California law FAC Section 12833 that authorizes registration of a product during the scientific evaluation process, if an emergency exists and there was a previous Section 18.

End-use product: A pesticide products whose labeling 1) Includes directions for use of the product for controlling pests or defoliating, desiccating, or regulating the growth of plants and 2) Does not state that the product may be used to manufacture or formulate other pesticide products. (See 40 CFR 152.3).

Environment: Includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

Establishment: Location where a pesticide or device or active ingredient used in producing a pesticide is produced or manufactured.

FIFRA Sec. 2 40 CFR 167

Final printed labeling: The label or labeling of the product when distributed or sold. It does not include the package of the product, unless the labeling is an integral part of the package. (See 40 CFR 152.3).

Fumigant: To apply smoke, vapor, or gas, especially for the purpose of disinfecting or destroying pests. (Merriam-Webster dictionary).

Fungicide: Substance intended to prevent or inhibit growth, or kill any fungus (including yeasts), except those on or in living man or animals, declared to be a pest. This includes both agricultural fungi, industrial fungi, and household fungi (not including mildew).

Herbicide: Substance intended to kill, prevent, or inhibit the growth of plants and plant parts declared to be a pest. An herbicide can act by direct contact, soil treatment, as a preemergent, as a root control, as a debarking agent on trees, as an aquatic herbicide, or as a biological weed-control agent. Herbicides can also be used in swimming pools and aquariums. The definition does not include plant growth regulators or slimicides.

Home use: Use of a product in the home or its immediate environment.

CCR 6000

Household use: The pesticide is applied directly to humans or pets in, on, or around all structures, vehicles, or areas associated with the household or home life. See also definition for residential.

Immediate container: The container which is in direct contact with the pesticide.

Industrial use: Use for or in a manufacturing, mining or chemical process, or use in the operation of factories, processing plants, and similar uses.

CCR 6000

Inert ingredient: Any substance (or group of structurally similar substances if designated by U.S. EPA), other than an active ingredient, which is intentionally included in a pesticide product, except at provided by 40 CFR part 174.3. Also known as "other" ingredients.

FIFRA Sec. 2 40 CFR 152.3

Ingredient statement: A statement that contains the name and percentage of each active ingredient and the total percentage of all inert ingredients in the pesticide.

Insect: Insects include beetles, bugs, bees, flies, and other allied classes of arthropods whose members are wingless and usually have more than six legs, (for example spiders, mites, ticks, centipedes, and wood lice), generally having the body more or less obviously segmented. Most belong to the Class Insecta, are six-legged, and usually winged.

FAC 12754
FIFRA Sec. 2

Insecticide: Substance intended to destroy, repel, prevent or inhibit the establishment, reproduction, development, or growth of, any member of the Class Insecta or other allied Classes in the Phylum Arthropoda declared to be pests. Insecticides are used in agriculture, home or home garden, and other settings such as on stored food and feed, raw or manufactured goods, or on buildings and building materials.

Institutional use: Any application of a pesticide in or around any property or facility that functions to provide a service to the general public or to public or private organizations, including but not limited to:

CCR 6000
CFR 152.3

(1) Hospitals and nursing homes

(2) Schools other than preschools and day care facilities

(3) Museums and libraries

(4) Sports facilities

(5) Office buildings.

Interim registration: A time-limited registration allowed by California law FAC Section 13161-13170 to allow extra time to generate certain data in support of the registration. The product must be part of a pest management system. An additional $5,000 application fee is required.

Label: Written, printed, or graphic material on, attached to, or accompanying the pesticide product container or wrapper at any time.

FIFRA Sec. 2
Label Review Manual

Labeling: All labels and all other written, printed, or graphic matter

(1) Accompanying the pesticide or device at any time or

(2) To which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the U.S. EPA, the U.S. Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

Leach: The process by which substances (pesticides) move through media, especially soil, or materials such as wood.

Letter of authorization: 1) Letter from a company authorizing use of their data on file to support another company's application for registration or 2) access to company information on file with DPR.

Manufacturing use product (MUP): Any pesticide product that is not an end-use product.

40CFR 152.3

Master label: As defined by DPR, a Master Label is a pesticide product label bearing most or all U.S. EPA-accepted uses for that product. However, the company does not intend to market that label for sale and use in California.

Maximum residue levels (MRL): Term used especially by the European countries to define residue tolerance levels.

Note: As defined by U.S. EPA, the "master label" is the label that contains all of the approved uses for a given product and all associated required labeling. (see label review manual).

Microbial pesticide: Pesticide that consists of a microorganism (e.g., a bacterium, fungus, virus or protozoan) as the active ingredient. Microbial pesticides can control many different kinds of pests, although each separate active ingredient is relatively specific for its target pests. (See Chapter 8).

Molluscicide: Pesticides intended to repel or kill organisms such as snails and slugs in the class of Mollusca or barnacles.

Multi-packs: Also known as a co-pack, a multi-pack is 1) registered pesticide product, in one container, that is packaged with a non-pesticide component, in a separate container and sold as a single unit or 2) two or more pesticide products packaged in separate containers but sold together.

Mutagenic: The property of a substance to induce changes in the genetic complement of either somatic or germinal tissue in subsequent generations.

Nematicide: Substance intended to prevent, repel, or destroy nematodes in or on plants, plant parts, soil, or certain infested agricultural commodities or articles. Not included are unsegmented round worms with elongated, fusiform, or sac-like bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts. Nematodes may also be called nemas or eelworms.

FIFRA Sec. 2

Neonicotinoids: A class of insecticides that is chemically similar to nicotine that acts as neurotoxins to insecticides. Examples include imidacloprid, thiamethoxam, and clothianidin.

New active ingredient: An active ingredient not currently registered in California.

New product: A pesticide product not currently registered in California. It can contain either a currently registered active ingredient or a new active ingredient.

Nominal concentration: The amount of an ingredient expected to be present in a typical sample of pesticide at the time the pesticide is produced. It is expressed as percentage by weight.

40CFR 158.153

Nontarget organisms: Plants, animals, and other organisms that are not intended to be controlled, injured, killed, or detrimentally affected in any way by the use of a pesticide.

Oncogenic: The property of a substance to produce or induce benign or malignant tumor formations in living animals.

Organophosphate: Compounds derived from phosphoric acid that inhibits acetylcholinesterase, an enzyme needed for proper nervous system function.

Outdoor application: Any pesticide application or use that occurs outside enclosed man-made structures or the consequences of which extend beyond enclosed man-made structures, including, but not limited to, crops, pulp and paper mill water treatments and industrial cooling water treatments.

Personal protective equipment (PPE): Apparel and devices worn to maximize human body contact with pesticides or pesticide residues that must be provided by an employer and are separate from, or in addition to, work clothing. Examples include coveralls, chemical resistant suits or gloves, respiratory protective equipment, protective eyewear.

40CFR 156.212
170.240 CCR 6000

Pest: Any undesired insect, rodent, nematode, fungus, bird, vertebrate, invertebrate, weed, virus, bacteria, or other microoganism (except microorganisms on or in living man or other living animals) which is declared to be injurious to health or environment.

FAC 12754.5
FIFRA Sec. 2 40 CFR 152.5

Pesticide: A pesticide includes the following:

FIFRA Sec. 2 40 CFR 152.3
FAC 12753
CCR 6000

(1) A substance, or mixture of substances, intended to defoliate plants, regulate plant growth, or prevent, destroy, repel, or mitigate any insects, fungi, bacteria, weeds, rodents, predatory animal, or any other form of plant or animal life declared to be a pest detrimental to vegetation, man, animal, or households, or any environment.

(2) Any spray adjuvant (DPR only). Spray adjuvants are not defined as pesticides by U.S. EPA.

Pheromone: A compound, produced by an arthropod, which modifies the behavior of the other individuals of the same species. Synthetic pheromones have also been manufactured.

40CFR 152.25

Plant growth regulator: The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Plant growth regulators include, but are not limited to, substances intended to cause stimulation or retardation of plant growth, stem elongation, abscission, sucker control, flower induction and fruit set, fruit thinning, altered sex expression, fruit growth and ripening, rooting of cuttings, seed and bud dormancy, and crop yield enhancement. FIFRA Sec. 2 FAC 12756

Plant-incorporated-protectants (PIPs): Pesticidal substances that plants produce from genetic material that has been added to the plant.

Postharvest: The application of a pesticide after harvest, usually to a stored commodity. This can also include seed treatments and treatment of a perennial crop after harvest of fruits, nuts, etc.

Precursor: A chemical without pesticidal action which is converted on-site, through chemical reaction, to a pesticide.

Preharvest interval: The period between the last application of a pesticide and the time of harvest of the treated commodity.

Printer's proof: A company label that has been reviewed and approved by an outside printing company.

Produce: Any food in its raw or natural state intended for consumer use with or without any further processing. FIFRA Sec. 2

Propellent: A gas or volatile liquid used in a pressurized pesticide product for the purpose of expelling the contents of the container.

Pyrethroid: Class of synthetic insecticides produced to duplicate or improve on the natural insecticide (pyrethrin) produced by chrysanthemum flowers. Examples include resmethrin, cypermethrin, and deltamethrin.

Registrant: A person or company who holds the registration of a pesticide and has obtained a certificate of registration (license) from the Department. FAC 12756

Research authorization (RA): The state-issued permit for experimental pesticide applications. This is a permit, not a registration action.

Residential: Use of a pesticide on pets, humans, or in, on, or around the area associated with a household. This also includes recreational vehicles and nonagricultural outbuildings and noncommercial greenhouses. 40CFR 152.3

Residue: The pesticide active ingredient, metabolite, or degradation product that is on a crop after a pesticide application.

Residue tolerance: see Tolerance

Restricted entry interval (REI): The time after the end of a pesticide application during which entry into the treated area is restricted.

CCR 6000 6182 6770~6778
CFR 170.3

Restricted materials: The term used for either California restricted or federally restricted materials.

CCR 6000 6400
FAC 14001~14015
FIFRA Sec.11

Rodenticide: Substance used to kill, repel, prevent, or inhibit reproduction of animals belonging to the Orders Rodentia and Insectivora and including all rabbits and hares. Rodenticides are usually used in conjunction with baits.

Rulemaking file: Copies of all correspondence relating to the adoption of a regulation.

Sanitizer: Substances which kill most of the vegetative bacteria on inanimate environmental surfaces. To qualify as a sanitizer, a 99.9% reduction of bacteria is required on non-food contact surfaces and 99.999% reduction on food contact surfaces after exposure to the substance for a defined contact time.

FIFRA sec.18

Section 18 Emergency Exemption: A time-limited exemption from registration for the use of an unregistered pesticide provided certain conditions are met.

CCR 6206

Service container: Any container, other than the original labeled container of a registered pesticide product provided by the registrant, that is utilized to hold, store, or transport the pesticide or the use-dilution of the pesticide.

FAC 12859 12757.5
CCR 6676 6678

Seed treatment: Protectants applied to seed as slurries or solutions, or as dry mixtures prior to planting. Usually insecticides, herbicides, and/or fungicides for control of soil insects, weeds, and preemergence damping of organisms.

Slimicide: Substance intended to prevent, inhibit the growth of, or destroy biological slimes composed of combinations of algae, bacteria or fungi declared to be pests. Slimicides include, but are not limited to, slime control agents for use in industrial water cooling systems and in pulp and paper mill wet-end systems.

Special Local Need (SLN): An existing or imminent pest problem for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally-registered pesticide product is not sufficiently available. Section 24(c) of FIFRA authorizes the state to issue the registration.

Split label: Also known as sub-labeling, a split label is a label that bears claims and directions for only a portion of the approved uses under a given Master label (as defined by U.S. EPA) but are a complete label in itself, containing all of the required labeling elements and placed on the container.

Spray adjuvant: Product used to enhance the activity of a pesticide and which is sold in a separate package. This includes any wetting agent, spreading agent, deposit builder, adhesive emulsifying agent, deflocculating agent, water modifier, or similar agent, with or without toxic properties of its own, intended to be used with another pesticide as an aid to the application or effect of the other pesticide. FAC 12758

Sterilant: Substance used to kill all bacteria, fungi, and viruses, including their spores.

Structural pest control: A use requiring a Structural Pest Control Board license.

Subregistration: A term used for the registration of a pesticide product by a distributor of the basic registrant's product.

Supplemental labeling: A term used to describe partial labels distributed separately from the container label, and may be distributed by the registrant or licensed distributor.

Teratogenic: The property of a substance to produce or induce functional deviations or developmental anomalies not heritable, in or on an animal embryo or fetus.

Tolerance, Residue: A residue tolerance is a commodity-specific federally established upper limit to the amount of a chemical's residue allowed on a commodity. This can be on a raw agricultural commodity at the time of harvest or, under certain circumstances, on a processed food or feed commodity. A chemical's residue includes the parent compound plus any degradates or metabolites. All substances intentionally applied to an agricultural crop must have a tolerance, or exemption from tolerance, established. 40CFR 180

ULV (Ultra Low Volume): A volume of one-half gallon or less total volume of spray per acre.

Use Dilution: The dilution specified on the label or labeling that produces concentration of the pesticide for a particular purpose or effect. FAC 12758.5

Vector: Any organism capable of transmitting the agent of human disease, discomfort, or injury. Included are mosquitoes, flies, fleas, cockroaches, ticks, mites, rats. FIFRA Sec. 2

Volatility: The property of a substance to convert into vapor or gas without chemical change.

Weed: Any plant that grows where not wanted. FIFRA Sec. 2 FAC 12759

Appendix B

Guide for Determining Substantially Similar

In order to be considered substantially similar, Registration Branch staff will confirm that the proposed and previously approved product(s):

- Contain the same active ingredient(s).
- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations.
- Contain the same or substantially similar inert ingredient(s).
- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s).
- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.
- Bear the same or substantially similar method(s) of application.
- Claim to control the same or substantially similar pests or site/pest combination(s).
- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination.

Note: this list should be viewed as guidance and does not represent regulatory requirements, nor should it be considered exclusive.

Fact Sheet: Section 18: Emergency Exemptions

A four-page fact sheet answers basic questions about Section 18.

Section 18

EMERGENCY EXEMPTIONS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is a Section 18 emergency exemption from registration?**
- **Who can apply?**
- **How do I apply?**
- **How do Section 18 emergency exemptions and Section 24(c) special local need registrations differ?**

What is a Section 18 emergency exemption from registration?

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the U.S. Environmental Protection Agency (U.S. EPA) to allow an unregistered use of a pesticide for a limited time if U.S. EPA determines that an emergency condition exists. The regulations governing FIFRA Section 18 (found in Title 40, Code of Federal Regulations (40CFR), part 166), define "emergency condition" as an urgent, non-routine situation that requires the use of a pesticide. It allows for the time-limited use of a pesticide product (not registered or not registered for that use) to control the emergency. Such uses are often referred to as "emergency exemptions," "Section 18s," or simply "exemptions."

FIFRA Section 18 also authorizes U.S. EPA to allow a federal or state agency the ability to grant the use of a pesticide product without registration, if an emergency condition exists. The issuance of a Section 18 is not the same as the issuance of a product license.

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Section 18

EMERGENCY EXEMPTIONS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

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- **Who can apply?**
- **How do I apply?**
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What is a Section 18 emergency exemption from registration?

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the U.S. Environmental Protection Agency (U.S. EPA) to allow an unregistered use of a pesticide for a limited time if U.S. EPA determines that an emergency condition exists. The regulations governing FIFRA Section 18 (found in Title 40, Code of Federal Regulations (40CFR), part 166), define "emergency condition" as an urgent, non-routine situation that requires the use of a pesticide. It allows for the time-limited use of a pesticide product (not registered or not registered for that use) to control the emergency. Such uses are often referred to as "emergency exemptions," "Section 18s," or simply "exemptions."

FIFRA Section 18 also authorizes U.S. EPA to allow a federal or state agency the ability to grant the use of a pesticide product without registration, if an emergency condition exists. The issuance of a Section 18 is not the same as the issuance of a product license.

Section 18 EMERGENCY EXEMPTIONS

There are four types of Section 18 emergency exemptions from registration:

SPECIFIC EXEMPTION

- These form the majority of requests.
- Requested to avert a significant economic loss or a significant risk to endangered or threatened species, beneficial organisms, or the environment.
- Growers or agricultural research scientists identify a pest situation that registered pesticides cannot control.
- May be authorized for up to one year.

QUARANTINE EXEMPTION

- Requested to control the introduction or spread of an invasive pest not previously found in the U.S.
- "Emergency" rests on the potential of an invasive species to cause a significant economic loss.
- May be authorized for up to three years.

PUBLIC HEALTH EXEMPTION

- Requested to control a pest that will cause a significant risk to human health.
- "Emergency" based upon the risk to human health from the pest to be controlled.
- May be authorized for up to one year.

CRISIS EXEMPTION

- May only be issued when there is an immediate need for a specific, quarantine, or public health exemption in situations involving an unpredicatable emergency situation when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of an exemption through normal means.
- DPR must confer with, and receive verbal authorization from, U.S. EPA before issuance. U.S. EPA performs a preliminary review to ensure there are no concerns, and whether the appropriate safety findings required by the Food Quality Protection Act (FQPA) can be made. If authorized by U.S. EPA, a state or federal agency may issue a crisis exemption allowing the use for up to 15 days.
- An applicant may follow up the crisis exemption with a specific, quarantine, or public health emergency exemption request. This allows the use to continue until U.S. EPA makes a decision on the corresponding exemption requested. This follow up request is usually done simultaneously in California.

Important To Note

- All uses under a Section 18 emergency exemption require a restricted materials permit from the appropriate county agricultural commissioner's office before purchase and use.
- Product uses under a Section 18 cannot be advertised unless criteria outlined in **40 CFR §168.22** are met.
- If the emergency use involves treatment of a food crop, U.S. EPA will establish a time-limited tolerance (maximum allowable residue levels) to cover any pesticide residues that may result. These are usually granted for two to three years.

Who can apply?

Applicants must be someone other than the product registrant. University of California (UC) Extension personnel, county agricultural commissioners, grower groups and others may apply. DPR recommends that applicants contact the designated Section 18 staff person at DPR before submitting an application to ensure all requirements are clearly understood.

How do I apply?

The applicant must submit the following information to DPR. If DPR approves the submission, it is then forwarded to U.S. EPA for review and approval.

❋ **DPR's application form PR-REG-003, *Application for Section 18 Emergency Exemption* (or go to the A-Z index on DPR's home page at www.cdpr.ca.gov and scroll to "Section 18"). No application fee is required. The application form must include:**

- A complete description of the emergency pest problem.
- Contact information for knowledgeable experts who can confirm the emergency.
- A detailed explanation of why currently registered pesticides or cultural practices are not adequate to address the situation.
- Product label instructions describing how to apply the product in order to control the pest problem.
- Documentation that a significant economic loss has occurred, or is about to occur, due to a pest problem.
- The economic history (typically three to five years worth of information) of the crop, including information on annual production, price of commodity, and cost of production before the pest problem occurred or became significant.

❋ **Scientific data to support the Section 18**

- Efficacy, residue chemistry, and phytotoxicity data.
- If pest resistance is the basis for the exemption, field data to demonstrate resistance to currently registered products is required. It is important that data be collected in the region where the pest problem is occurring.
- If the product is not registered in California, acute toxicology and product chemistry data are also required.

❋ **A letter of authorization from the product registrant.**

❋ **A draft product label and product formulation sheet if the product is not federally registered, or a copy of the U.S. EPA-accepted label and confidential statement of formula if the product is federally registered.**

How do Section 18 emergency exemptions and Section 24(c) special local need registrations differ?

SECTION 18	SECTION 24(c) Special Local Need
No tolerance yet established. U.S. EPA will establish a time-limited tolerance.	Tolerance or exemption already established.
For limited use to treat sudden and limited emergency pest infestations.	To meet a special local need (which may be a region of the state or the whole state).
Emergency situation must be well documented and not a historical pest problem. Economics and lack of alternatives must be verified.	Justification and lack of alternatives must be documented.
Can be used during the 30-day public comment period.	Must be posted for a 30-day public comment period before use is allowed.
Request made through DPR and issued after U.S. EPA approval, which includes the use, limitations on acreage and location, and the time-limited tolerance. DPR may issue "crisis" Section 18 after consultation with U.S. EPA.	DPR issues without U.S. EPA review, although U.S. EPA has 90 days to comment.
Expiration date not to exceed one year, except quarantine exemptions (up to three years). Renewable if the emergency recurs or persists, although renewal difficult after the third year.	Usually issued without expiration date. May be inactivated by applicant, DPR, or U.S. EPA.
Applicant must be third-party (someone other than the registrant).	Applicant may be first-party (the registrant) or third-party (someone other than the registrant).
Not subject to U.S. EPA maintenance fee. No DPR fee.	Subject to U.S. EPA maintenance fee. No DPR fee.
Use requires a restricted materials permit even if the product is not a restricted material.	Use requires a restricted materials permit only if the product is a restricted material.

Both Section 18s and Section 24(c) SLNs require scientific evaluation (efficacy, phytotoxicity, residue chemistry, and other data, as required) and a letter of authorization from the registrant.

For more information about Section 24(c) SLNs, see DPR's guide *Section 24(c) Special Local Need Registrations*.

For more information, please contact:

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May 2011

Fact Sheet: Section 24(c): Special Local Need Registrations

A three-page fact sheet answers basic questions about Section 24(c).

Section 24(c)

SPECIAL LOCAL NEED REGISTRATIONS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is a Section 24(c) special local need registration?**
- **Who can apply?**
- **How do I apply?**
- **How do Section 24(c) special local need registrations and Section 18 emergency exemptions differ?**

What is a Section 24(c) special local need registration?

Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Section 24(c) and Title 40, Code of Federal Regulations (40 CFR), section 162.152, authorize state pesticide regulators to register a new end-use product or an additional use of a federally registered pesticide product to address an existing or imminent pest situation. The pest situation must be a special local need within the state that cannot be mitigated by a currently registered product. To issue a special local need (SLN) registration, the following conditions must apply:

- If the pesticide is to be used on a food or feed commodity, the use is covered by the necessary tolerances or exemptions from tolerances.
- Registration for the same use has not previously been denied, disapproved, suspended, or cancelled by the U.S. Environmental Protection Agency (U.S. EPA), or voluntarily cancelled by the registrant.
- The pesticide product does not contain a new active ingredient unregistered by U.S. EPA.
- There is no federally registered product available to address the special local need.

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Section 24(c)

SPECIAL LOCAL NEED REGISTRATIONS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is a Section 24(c) special local need registration?**
- **Who can apply?**
- **How do I apply?**
- **How do Section 24(c) special local need registrations and Section 18 emergency exemptions differ?**

What is a Section 24(c) special local need registration?

Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Section 24(c) and Title 40, Code of Federal Regulations (40 CFR), section 162.152, authorize state pesticide regulators to register a new end-use product or an additional use of a federally registered pesticide product to address an existing or imminent pest situation. The pest situation must be a special local need within the state that cannot be mitigated by a currently registered product. To issue a special local need (SLN) registration, the following conditions must apply:

- If the pesticide is to be used on a food or feed commodity, the use is covered by the necessary tolerances or exemptions from tolerances.
- Registration for the same use has not previously been denied, disapproved, suspended, or cancelled by the U.S. Environmental Protection Agency (U.S. EPA), or voluntarily cancelled by the registrant.
- The pesticide product does not contain a new active ingredient unregistered by U.S. EPA.
- There is no federally registered product available to address the special local need.

An SLN may address a new pest, method or timing of application, different use rate, new crop/use site, or integrated pest management (IPM) practice in certain crops.

Who can apply?

There are two types of SLNs:

- A first-party SLN - the applicant is the registrant of the product.
- A third-party SLN - the applicant is someone other than the registrant, such as a grower, grower association, or University of California (UC) Extension personnel.

How do I apply?

Required items:

- The Department of Pesticide Regulation (DPR) **Form PR-REG-004**, *Request for a Special Local Need Registration (SLN), Section 24(c)*. No DPR application fee is required.
- Residue chemistry, efficacy, phytotoxicity, and any other data that may be identified during the review process to support the SLN use pattern.
- For a first-party SLN, six copies of the proposed label that addresses the SLN use pattern. Third-party SLN labels are developed from the state application form.
- For a third-party SLN, a letter of authorization from the registrant of the pesticide supporting the use of its product as an SLN.
- A completed and signed U.S. EPA **Form 8570-25**, *Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need*.
- Detailed letters or documentation from experts such as UC farm advisors or UC Extension specialists demonstrating the SLN pesticide/use pattern has been shown to address an existing or imminent pest problem and no federally registered pesticide product is sufficiently available to mitigate the pest situation.

How do SLNs and Section 18 emergency exemptions differ?

SECTION 24(c) Special Local Need	SECTION 18
Tolerance or exemption already established.	No tolerance yet established. U.S. EPA will establish a time-limited tolerance.
To meet a special local need (which may be a region of the state or the whole state).	For limited use to treat sudden and limited emergency pest infestations.
Justification and lack of alternatives must be documented.	Emergency situation must be well documented and not a historical pest problem. Economics and lack of alternatives must be verified.
Must be posted for a 30-day public comment period before use is allowed.	Can be used during the 30-day public comment period.
DPR issues without U.S. EPA review, although U.S. EPA has 90 days to comment.	Request made through DPR and issued after U.S. EPA approval, which includes the use, limitations on acreage and location, and the time-limited tolerance. DPR may issue "crisis" Section 18 after consultation with U.S. EPA.
Usually issued without expiration date. May be inactivated by applicant, DPR, or U.S. EPA.	Expiration date not to exceed one year, except quarantine exemptions (up to three years). Renewable if the emergency recurs or persists, although renewal difficult after the third year.
Applicant may be first-party (the registrant) or third-party (someone other than the registrant).	Applicant must be third-party (someone other than the registrant).
Subject to U.S. EPA maintenance fee. No DPR fee.	Not subject to U.S. EPA maintenance fee. No DPR fee.
Use requires a restricted materials permit only if the product is a restricted material.	Use requires a restricted materials permit even if the product is not a restricted material.

Both Section 24(c) SLNs and Section 18s require scientific evaluation (efficacy, phytotoxicity, residue chemistry, and other data, as required) and a letter of authorization from the registrant.

For information about Section 18s, see DPR's guide ***Section 18 Emergency Exemptions***.

For more information, please contact:

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Fact Sheet: Research Authorizations

A four-page fact sheet answers basic questions about Research Authorizations.

RESEARCH AUTHORIZATIONS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is a research authorization?**
- **How do I apply?**
- **How do research authorizations and experimental use permits differ?**

What is a research authorization?

With the exception of those exempted by Title 3, California Code of Regulations (3 CCR) section 6268 (see below), a written authorization for research must be obtained from DPR before any experimental, unregistered use of a pesticide in California. A research authorization (RA) allows researchers to collect field data under California use conditions to support California registration of a pesticide product.

If the product and the proposed use are federally registered, there is no limit on the field size for the RA. However, any RA request for more than 100 acres per crop requires specific justification.

If the product or proposed use is NOT federally registered, the RA is limited to ten acres or less on land or one surface acre or less of water. If the product or proposed use is on more than 10 acres of land or one surface acre of water, the researcher must obtain a federal experiment use permit (EUP) from the U.S. Environmental Protection Agency (U.S. EPA). If a federal EUP is obtained, researchers have the option of either applying for an RA or registering the federal EUP in California on a conditional basis. Please note these are separate processes with different requirements and limitations. See DPR's handout, *Experimental Use Permits*, for more information on EUPs.

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RESEARCH AUTHORIZATIONS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is a research authorization?**
- **How do I apply?**
- **How do research authorizations and experimental use permits differ?**

What is a research authorization?

With the exception of those exempted by Title 3, California Code of Regulations (3 CCR) section 6268 (see below), a written authorization for research must be obtained from DPR before any experimental, unregistered use of a pesticide in California. A research authorization (RA) allows researchers to collect field data under California use conditions to support California registration of a pesticide product.

If the product and the proposed use are federally registered, there is no limit on the field size for the RA. However, any RA request for more than 100 acres per crop requires specific justification.

If the product or proposed use is NOT federally registered, the RA is limited to ten acres or less on land or one surface acre or less of water. If the product or proposed use is on more than 10 acres of land or one surface acre of water, the researcher must obtain a federal experiment use permit (EUP) from the U.S. Environmental Protection Agency (U.S. EPA). If a federal EUP is obtained, researchers have the option of either applying for an RA or registering the federal EUP in California on a conditional basis. Please note these are separate processes with different requirements and limitations. See DPR's handout, ***Experimental Use Permits***, for more information on EUPs.

An RA is a permit and not a registration. Under an RA, the product cannot be sold for the experimental use but must be provided free to any cooperator whose property is being used for experimental trials.

The following should be noted:

- A special number is assigned to each permit by DPR.
- Commodities treated with the product may not be used for food or feed unless:
  (1) U.S. EPA has established a residue tolerance for the pesticide on the commodity and that tolerance has been met; **or**
  (2) The pesticide is exempt from a tolerance.
- All commodities treated with a product for which a tolerance has not been established must be destroyed.
- An RA is not under the jurisdiction of U.S. EPA.
- A Notice of Intent and a copy of the RA must be provided to the appropriate county agricultural commissioner's (CAC's) office at least 24 hours before an RA product application. See **3 CCR section 6434(b)** for more information about Notices of Intent.
- A plot map showing the exact location of the trial must be submitted to the CAC within seven days of trial initiation.
- An **Experimental Trial Report** must be submitted to the CAC at least 24 hours before a commodity treated under an RA is harvested or destroyed.
- After the last application, but within two weeks of the completion date of the RA, an **Experimental Pesticide Use Report** must be returned to DPR, whether or not trials were initiated.

These entities are exempt from an RA:

- A pesticide registrant, if it operates the property on which the research is to be conducted and continues to be the operator of the property until the treated commodity is destroyed or harvested.
- Personnel employed by colleges and universities and engaged in pesticide research, if they are operating according to an established pesticide use and experimentation policy of the college or university.

How do I apply?

A researcher may request an RA by submitting a completed DPR form **PR-REG-027**, *Pesticide Research Authorization*. There is no DPR application fee.

How do RAs and EUPs differ?

RA	EUP
Required for any experimental, unregistered use of a pesticide in California, regardless of the size of the test area. An RA is not under the jurisdiction of U.S. EPA.	Issued by U.S. EPA. DPR does not issue EUPs, but may conditionally register the EUP in California.
If product or proposed use is NOT federally registered, RA required on 10 acres or less on land or one surface acre or less of water. If used on more than 10 acres of land or one surface acre of water, must obtain a federal EUP. The EUP can be used under an RA or can be conditionally registered in California instead of an RA. Use on over 100 acres per crop requires specific justification.	Not required by U.S. EPA for research done on 10 acres or less of land, or one surface acre or less of water.
Effective for one year.	Effective normally one year, as specified by U.S. EPA. May be renewed, extended, or amended upon request and approval from U.S. EPA.
No DPR application fee.	$Σ̌h̆Σ50 DPR application fee for conditional registration.
Product cannot be sold for the experimental use and must be provided free to any cooperator whose property is being used for the trials.	Once conditionally registered by DPR, may be sold to specific researchers for use in research trials; not available to the public.
Treated commodities may not be used for food or feed unless U.S. EPA tolerance has been met or the pesticide is exempt from a tolerance. If no tolerance or exemption, treated commodities must be destroyed.	If there is no tolerance, U.S. EPA may establish a time-limited residue tolerance or exemption from tolerance before issuing. If no tolerance or exemption, treated commodities must be destroyed or fed only to experimental animals.
Exempt persons include: a registrant that is the operator of the property where research is conducted and continues to be operator until treated commodity destroyed/harvested; college and university personnel engaged in pesticide research.	Not required by U.S. EPA for laboratory or greenhouse tests; limited replicated field trials; or when the producer, applicator, or others conducting the test do not expect to receive any benefit in pest control.
The county agricultural commissioner (CAC) must be notified before initiation of the trial. Upon completion, an "Experimental Trial Report" must be submitted to the CAC and an Experimental Pesticide Use Report must be returned to DPR.	May be subject to DPR pesticide use reporting requirements, in addition to U.S. EPA reporting.

For more information, please contact:

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Appendix F

Fact Sheet: Experimental Use Permits

A four-page fact sheet answers basic questions about Experimental Use Permits.

EXPERIMENTAL USE PERMITS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is an experimental use permit?**
- **Is an experimental use permit valid for use in California?**
- **How do I register an experimental use permit?**
- **How do experimental use permits and research authorizations differ?**

What is an experimental use permit?

An experimental use permit (EUP) is a permit issued by the U.S. Environmental Protection Agency (U.S. EPA) that allows field testing of a pesticide product to gather additional data. The product may be unregistered (may or may not contain a new active ingredient) or may be a registered pesticide product being tested for an unregistered use. Under federal law, an EUP is not defined as a "registration" but it is considered a "license" to sell and use the product.

An EUP is not required when:

- The experimental use of the pesticide is limited to laboratory or greenhouse tests or limited replicated field trials as described in Title 40, Code of Federal Regulations (40 CFR), section 172.3(c); **and**
- The producer, applicator, or any other person conducting the test does not expect to receive any benefit in pest control from the use of the pesticide.

In addition, U.S. EPA does not require EUPs for research done on ten acres or less of land, or one surface acre or less of water. When testing more than one target pest at the same time and location, the acre limit must encompass all of the target pests.

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EXPERIMENTAL USE PERMITS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is an experimental use permit?**
- **Is an experimental use permit valid for use in California?**
- **How do I register an experimental use permit?**
- **How do experimental use permits and research authorizations differ?**

What is an experimental use permit?

An experimental use permit (EUP) is a permit issued by the U.S. Environmental Protection Agency (U.S. EPA) that allows field testing of a pesticide product to gather additional data. The product may be unregistered (may or may not contain a new active ingredient) or may be a registered pesticide product being tested for an unregistered use. Under federal law, an EUP is not defined as a "registration" but it is considered a "license" to sell and use the product.

An EUP is not required when:

- The experimental use of the pesticide is limited to laboratory or greenhouse tests or limited replicated field trials as described in Title 40, Code of Federal Regulations (40 CFR), section 172.3(c); **and**
- The producer, applicator, or any other person conducting the test does not expect to receive any benefit in pest control from the use of the pesticide.

In addition, U.S. EPA does not require EUPs for research done on ten acres or less of land, or one surface acre or less of water. When testing more than one target pest at the same time and location, the acre limit must encompass all of the target pests.

EXPERIMENTAL USE PERMITS

Although U.S. EPA authorizes states to issue EUPs under their own programs, the Department of Pesticide Regulation (DPR) does not do so. Instead, DPR requires a research authorization (RA) for any experimental, unregistered use of a pesticide in California, regardless of the size of the test area. The only exception to this requirement is when a federal EUP is required by U.S. EPA. Then, researchers may opt to register the federal EUP in California on a conditional basis instead of applying for an RA. See DPR's handout, ***Research Authorizations.***

TIME FRAMES

EUPs are effective for a period specified by U.S. EPA, normally one year, depending upon the crop or site to be tested and the requirements of the testing program. Permits may be renewed, extended, or amended upon request and approval.

USE RESTRICTIONS

EUPs are issued for test areas greater than ten acres for terrestrial use and one surface acre of water for aquatic use.

For aquatic use, waters which are involved in or affected by the EUP testing are not to be used for irrigation, drinking water, or body-contact recreational activities. Testing cannot be conducted in waters that contain or affect fish, shellfish, plants, or animals taken for recreational or commercial purposes and used for food or feed unless an appropriate tolerance or exemption from a tolerance has been established. This is also true for animal treatment tests.

Pesticides used under an EUP may not be sold or distributed other than to research participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the EUP. In addition, uses performed under an EUP cannot be advertised.

TOLERANCE REQUIREMENTS

If use of the product is on a food or feed crop (including animal treatments) and no tolerance has been established, U.S. EPA may establish a temporary residue tolerance or exemption from tolerance before issuing the EUP. If there is no tolerance or temporary tolerance (or exemption from tolerance), the food or feed derived from the experimental program must be destroyed or fed only to experimental animals.

Is an EUP valid for use in California?

DPR does not issue state EUPs. To use a federal EUP in California, the registrant must either obtain from DPR a conditional registration of the federal EUP or use the EUP under a California RA. California's registration of the EUP is conditional in terms of the parameters and restrictions of the EUP, such as the amount of active ingredient to be used, acres to be treated, and expiration date. For information on using an EUP under an RA, please see DPR's handout, ***Research Authorizations.***

How do I register an EUP?

Only the pesticide registrant may apply for an EUP. If a registrant does not apply for use of the product in California under an RA, it must conditionally register the EUP with DPR.

Required items:

- **DPR72%'-030**, *Application for Pesticide Registration*.
- $ΣĥΣ50 application fee.
- Method of analysis and analytical sample if the product contains a new active ingredient.
- A copy of the U.S. EPA-approved EUP label and accompanying letter if product was not submitted to U.S. EPA concurrently.
- A copy of the temporary tolerance approval letter, if applicable.
- All data required by U.S. EPA for an EUP pursuant to **40 CFR part 158**.
- All other information required for federal approval, including the proposed experimental program.

Important To Note

- EUPs may be submitted concurrently to DPR and to U.S. EPA for review.
- U.S. EPA requires applicants to submit the EUP package in a specific format, which differs from the typical format required for standard pesticide product registrations. The required information is divided into seven different sections (A-G). See **U.S. EPA form 8570-17**, Application for Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only for further details. This form can also be found on U.S. EPA's Web site at **www.epa.gov/opprd001/forms/**.

How do EUPs and RAs differ?

EUP	RA
Issued by U.S. EPA. DPR does not issue EUPs, but may conditionally register the EUP in California.	Required for any experimental, unregistered use of a pesticide in California, regardless of the size of the test area. An RA is not under the jurisdiction of U.S. EPA.
Not required by U.S. EPA for research done on 10 acres or less of land, or one surface acre or less of water.	If product or proposed use is NOT federally registered, RA required on 10 acres or less on land or one surface acre or less of water. If used on more than 10 acres of land or one surface acre of water, must obtain a federal EUP. The EUP can be used under an RA or can be conditionally registered in California instead of an RA. Use on over 100 acres per crop requires specific justification.
Effective normally one year, as specified by U.S. EPA. May be renewed, extended, or amended upon request and approval from U.S. EPA.	Effective for one year.
$ΣΗΣXP DPR application fee for conditional registration.	No DPR application fee.
Once conditionally registered by DPR, may be sold to specific researchers for use in research trials; not available to the public.	Product cannot be sold for the experimental use and must be provided free to any cooperator whose property is being used for the trials.
If there is no tolerance, U.S. EPA may establish a time-limited residue tolerance or exemption from tolerance before issuing. If no tolerance or exemption, treated commodities must be destroyed or fed only to experimental animals.	Treated commodities may not be used for food or feed unless U.S. EPA tolerance has been met or the pesticide is exempt from a tolerance. If no tolerance or exemption, treated commodities must be destroyed.
Not required by U.S. EPA for laboratory or greenhouse tests; limited replicated field trials; or when the producer, applicator, or others conducting the test do not expect to receive any benefit in pest control.	Exempt persons include: a registrant that is the operator of the property where research is conducted and continues to be operator until treated commodity destroyed/harvested; college and university personnel engaged in pesticide research.
May be subject to DPR pesticide use reporting requirements, in addition to U.S. EPA reporting requirements.	The county agricultural commissioner (CAC) must be notified before initiation of the trial. Upon completion, an "Experimental Trial Report" must be submitted to the CAC and an Experimental Pesticide Use Report must be returned to DPR.

For more information, please contact your assigned regulatory specialist or:

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Fact Sheet: California Master Labels

A two-page fact sheet answers basic questions about California Master Labels .

CALIFORNIA MASTER LABELS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is a California master label?**
- **Do California master labels require registration?**
- **How do I register a California master label?**

What is a California master label?

Some large manufacturing firms (basic manufacturers) develop products to be sold and marketed solely by supplemental distributors; these registrants do not intend to market these products under their own label in California. In these instances, the registrant may request a California master label for the product from the Department of Pesticide Regulation (DPR). The label will list most or all uses accepted by the U.S. Environmental Protection Agency (U.S. EPA). Registering the basic manufacturer's product in California as a master label enables DPR to review scientific data to support all use sites, rates, and other label information for subsequent supplemental distributor registrations at one time rather than individually for each supplemental end-use product. As a result, processing time is reduced and the registration process is streamlined for DPR staff and supplemental distributors. In addition, when a company has an approved California master label on file, it can readily market its products under sub-labels (a label which bears claims and directions for only a portion of the approved label). This is common for agricultural-use products that contain many uses directed towards different markets.

Do California master labels require registration?

Master labels are an option for registrants to streamline the registration process for sub-labels. Before the registrant's product can be sold in California, the sub-label must be registered.

Once a California master label is reviewed and approved in California, a license is issued. The registrant may submit California master labels for any type of product, such as agricultural, structural, biopesticide,

Important To Note

An approved California master label does not authorize a product to be sold, used, or distributed in California. California master labels are for reference only! They are not considered registered product labels.

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CALIFORNIA MASTER LABELS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **What is a California master label?**
- **Do California master labels require registration?**
- **How do I register a California master label?**

What is a California master label?

Some large manufacturing firms (basic manufacturers) develop products to be sold and marketed solely by supplemental distributors; these registrants do not intend to market these products under their own label in California. In these instances, the registrant may request a California master label for the product from the Department of Pesticide Regulation (DPR). The label will list most or all uses accepted by the U.S. Environmental Protection Agency (U.S. EPA). Registering the basic manufacturer's product in California as a master label enables DPR to review scientific data to support all use sites, rates, and other label information for subsequent supplemental distributor registrations at one time rather than individually for each supplemental end-use product. As a result, processing time is reduced and the registration process is streamlined for DPR staff and supplemental distributors. In addition, when a company has an approved California master label on file, it can readily market its products under sub-labels (a label which bears claims and directions for only a portion of the approved label). This is common for agricultural-use products that contain many uses directed towards different markets.

Do California master labels require registration?

Master labels are an option for registrants to streamline the registration process for sub-labels. Before the registrant's product can be sold in California, the sub-label must be registered.

Once a California master label is reviewed and approved in California, a license is issued. The registrant may submit California master labels for any type of product, such as agricultural, structural, biopesticide,

Important To Note

An approved California master label does not authorize a product to be sold, used, or distributed in California. California master labels are for reference only! They are not considered registered product labels.

antimicrobial, or adjuvant. California master labels are processed identically to other product registrations with these exceptions:

- The applicant is not required to submit printer's proof or final printed labels.
- Labels may include optional language or multiple sets of directions for use for various container sizes.
- The license does not entitle the user to sell, use, or distribute the product in California.
- The product name can be identical to that of the end-use label because the California master label cannot be sold, used, or distributed in California.

Important To Note

If it is the registrant's intent to distribute or sell the end-use product in California, even if the container label for the end use product is identical to the California master label, the registrant must seek an additional, separate registration for the end-use product.

How do I register a California master label?

To apply for registration of a California master label, the applicant must submit:

- DPR72%'-030, *Application for Pesticide Registration.*
- $ΣΗΣ50 application fee.
- Six copies of the proposed label.
- A copy of the U.S. EPA-approved label and accompanying letter (if applicable).
- Data to support registration or identification of a product previously approved by DPR that would be subject to the same data requirements as the applicant's product. The data requirements will differ based on the type of product being submitted.

For more information, please contact your assigned regulatory specialist or:

*ÏÌÙÎÎ - ÁÈ Í ÏÕÄÉZ(ÁÅÒÉ, Ombudsman
California Department of Pesticide Regulation
Pesticide Registration Branch
1001 I Street | P.O. Box 4015
Sacramento, CA 95812-4015
Telephone: (916) 32ΦZYXΦX
E-mail: 2ÅÇÉÓÔÒÁÔÉÏÎ8/ Í ÂÕÄÓ Í ÁÎ@cdpr.ca.gov

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Appendix H

Fact Sheet: Section 25(b) Pesticide Products Exempt from Registration

A two-page fact sheet answers basic questions about Section 25(b).

Section 25b (Exempt Products)

PESTICIDE PRODUCTS EXEMPT FROM REGISTRATION

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- **How do I determine if a product is exempt from registration in California?**
- **If a product qualifies for federal exemption, is it exempt from registration in California?**
- **Can a product be registered in California even if it is not required to be registered in California?**

How do I determine if a product is exempt from registration in California?

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 25(b) and California law exempt certain pesticide products from registration, provided they meet certain criteria. However, these products are still pesticides and individuals in the business of pest control for hire who apply exempt products are still subject to the Department of Pesticide Regulation's (DPR's) licensing requirements, but are exempt from pesticide use reporting.

The criteria and label requirements for products that are exempt from registration are outlined in DPR's California Notice to Registrants 2000-6. Because California exemption criteria are linked closely to U.S. Environmental Protection Agency (U.S. EPA) exemption criteria, U.S. EPA's PR Notice 2000-6 should also be used in conjunction with California's Notice 2000-6 as a reference. When U.S. EPA and California criteria differ, the California criteria must be followed.

A Guide To Understanding Pesticide Registration | 1

Section 25b (Exempt Products)

PESTICIDE PRODUCTS EXEMPT FROM REGISTRATION

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

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The criteria and label requirements for products that are exempt from registration are outlined in DPR's California Notice to Registrants 2000-6. Because California exemption criteria are linked closely to U.S. Environmental Protection Agency (U.S. EPA) exemption criteria, U.S. EPA's PR Notice 2000-6 should also be used in conjunction with California's Notice 2000-6 as a reference. When U.S. EPA and California criteria differ, the California criteria must be followed.

To qualify for exemption, products must meet the following minimum requirements:

- The active ingredient(s) must be listed by name and percentage (by weight) on the label. Each active ingredient in the pesticide product must be listed in Title 40, Code of Federal Regulations (40 CFR), section 152.25(f)(1). The approved list of active ingredients, along with California's specific requirements, can also be found in Title 3, California Code of Regulations (3 CCR), section 6147(a).
- All inert ingredients must be listed by name on the label. All inert ingredients must be on U.S. EPA's most current Inert Ingredients Eligible for Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 25(b) Pesticide Products list (formerly referred to as List 4A).
- The total percentage by weight must equal 100 percent.
- The label must not contain false or misleading statements as defined in 40 CFR section 156.10(a)(5)(i) through (viii).
- Additionally, products must also meet a series of exemption conditions described in 40 CFR section 152.25 and 3 CCR section 6147.

If a product qualifies for federal exemption, is it exempt from registration in California?

Not necessarily. For a product to qualify for exemption in California, it must meet federal exemption requirements and California exemption requirements outlined in 3 CCR section 6147.

Can a product be registered in California even if it is not required to be?

If a product is exempt from California registration but the registrant voluntarily elects to seek registration in California, the company is allowed to do so without seeking federal registration of its product with U.S. EPA. This product would be treated as a California-only registration.

For more information, please contact:

***ÏÌÙÎÎ - ÁÈ Í ÏÕÄÉZ(ÁÅÒÉ,** Ombudsman
California Department of Pesticide Regulation
Pesticide Registration Branch
1001 I Street | P.O. Box 4015
Sacramento, CA 95812-4015
Telephone: (916) 32ΦZYXΦX
E-mail: 2ÅÇÉÓÔÒÁÓÉÏ Î8 / Í ÂÕÄÓ Í ÁÎ@cdpr.ca.gov

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Fact Sheet: Amendment, Notification and Non-Notification Tables

A ten page set of tables comparing DPR and U.S. EPA policies for amendment, notification and non-notification.

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.

LIST OF ACRONYMS:
CFR: Code of Federal Regulations
CRP: Child-Resistant Packaging
CSF: Confidential Statement of Formula
DCI: Data Call-In
FDA: U.S. Federal 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

Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
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.

May 2011

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.

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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
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 does 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.

Revised March 2012

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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
ADD/DELETE USE SITES							
Add a use site other than a non-food antimicrobial site	•			•			
Delete a use site		•		•	•		**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. **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.
Add an indoor, non-food site for an antimicrobial product		•			•		May be added through both notification processes if: a. No additional data (e.g., efficacy, groundwater, ecological effects) are required for the added nonfood site; b. The site is within an already registered use pattern category for the product (as specified in 40 CFR Part 158); c. Exposure is not increased (e.g., adding broadcast treatment to a product registered for spot treatment); d. An agency decision or directive does not explicitly prohibit addition of the nonfood sites to particular products; e. The technical product label from which the product is formulated does not prohibit the proposed site; **and** f. 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				•		**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.

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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
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	•			•	•		**DPR**: Changes in directions for use must be submitted through DPR's amendment process. **U.S. EPA**: The following changes may be made through U.S. EPA's notification process: 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 §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. See PR Notice 98-10 for more details on changes a-d. All other changes must be made by amendment.

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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
LABEL STATEMENT CHANGES (continued)							
Add risk reduction statements related to "non-flammable" claims, closed systems, and water soluble packaging	•				•		**U.S. EPA:** The following statements can be added through U.S. EPA's notification process: 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. 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. c. A phrase like "water soluble packaging" may be added by notification, if applicable.
Add product composition statements related to pesticide category type, botanical claims, fragrance, "water-based," or claims such as "new"	•				•		**U.S. EPA**: The following statements can be added through U.S. EPA's notification process: a. The following pesticide categories: "fungicide," "insecticide," "rodenticide," "herbicide," "defoliant," "repellant," "dessicant," "microbiocide," "antimicrobial," "disinfectant," "sanitizer," "biochemical," "microbial," "plant regulator," "nematicide," and "plant-pesticide." Other terms are not acceptable by notification. 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. 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. 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. 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").

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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
LABEL STATEMENT CHANGES (continued)							
Minor FIFRA-related changes	•				•		**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.
Revise storage and disposal statement	•	•			•		**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. **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.
Remove redundant labeling statements		•			•		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.
Change in warranty statement		•			•		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.

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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
PACKAGING CHANGES							
Change in packaging and related label statements		•			•		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: 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.
Change in package size or net contents		•	•		•	•	**DPR:** For products that meet the following: 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. --Package size and net contents for products not subject to CRP (including voluntarily) 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. **U.S. EPA**: Package size/net contents may be revised without notifying U.S. EPA except for: 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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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
INGREDIENT CHANGES							
Increase or decrease percentage of active ingredient on label	•			•			This is considered an alternate formula. Submit through both amendment processes.
Change nominal concentration of inert 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 inert 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 active 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) &(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.

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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
INGREDIENT CHANGES (continued)							
Change source of inert ingredient			•		•	•	**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.
Change in source of starting materials for integrated systems products			•		•		**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). 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: 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: 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 non-integrated system products			•		•		**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: 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.

LIST OF ACRONYMS:
CFR: Code of Federal Regulations
CRP: Child-Resistant Packaging
CSF: Confidential Statement of Formula
DCI: Data Call-In
FDA: U.S. Federal 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

Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
NON-FIFRA RELATED CHANGES							
Change in the name or address of the registrant on the label	•				•	•	**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: 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. 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.
Add bilingual language	•					•	
Correct typographical or printing errors		•				•	**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.
Add symbols and graphics		•			•		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)). Examples include: a. Diagrams demonstrating how to open product containers; b. Graphics displaying application patterns such as aerial application; c. Pictograms displaying various exposure routes; d. Pictures of where the product can be used; or e. Pictures of persons wearing appropriate protective clothing
Redesign of label format		•				•	**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. **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.

LIST OF ACRONYMS:
CFR: Code of Federal Regulations
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Type of Change	DPR Amendment	DPR Notification	DPR Non-Notification	U.S. EPA Amendment	U.S. EPA Notification	U.S. EPA Non-Notification	Comment
NON-FIFRA RELATED CHANGES (continued)							
Modify non-pesticidal characteristics		•				•	**U.S. EPA**: Per PR Notice 98-10, these non-pesticidal claims can be modified without notification: 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		•				•	**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.
Revise EPA Establishment Number on label			•			•	

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