

The Pesticide
Registration
Branch

Desk Manual
Chapter 1

2013

California Department of Pesticide Regulation

Overview

Pesticide Registration Process

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Note from the editor:

This Desk Manual is a guidance document for our Regulatory Scientists concerning the pesticide registration process. To maintain accuracy, periodic updates will be incorporated into the manual. Not all links within this document are accessible to outside viewers.

The manual is to be used in conjunction with other reference documents, including the [“A Guide for Pesticide Registrants”](#), and is intended to reflect the California laws and regulations. As with any guide, variations may occur. Please direct any questions or suggested changes regarding this manual to your supervisor. Please see the Appendix for a list of reference materials including a glossary of terms.

It should also be noted that the acronym “RS” (Regulatory Scientist) is used throughout this manual.

I. What is a Pesticide?

The term pesticide is defined by federal law in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), by federal regulation in the Code of Federal Regulations (CFR) Title 40, by California law in the Food and Agriculture Code (FAC), and by California regulations in Title 3 California Code of Regulations (CCR) section 6000. U.S. EPA and DPR define the term pesticide and products covered under those definitions differently. It is important to recognize those differences as certain products are not considered pesticides under federal law but are under California law.

[FIFRA Sec. 2](#)
[40CFR](#)
[152.3,152.5](#)
[FAC](#)
[12753,12754.5,](#)
[12758](#)
[3 CCR 6000](#)

II. Authority to Regulate (Federal and State)

California law cannot preempt federal law. 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 following sections of FIFRA refer to types of federal registrations and exemptions from registration:

Section 3 authorizes full or conditional registration

Section 5 authorizes issuance of an Experimental Use Permit (EUP) Section 24(c) authorizes the states to issue a Special Local Needs (SLN) registration

Section 18 authorizes the issuance of an emergency exemption from registration

Section 25(b) authorizes the exemption of certain pesticide products from registration requirements

These terms will be discussed in more detail in future chapters.

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." The Department of Pesticide Regulation is given further authority in the following sections of California law and regulations:

California Food and Agricultural Code (law), Division 6 & 7, sections 11401 through 14155

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

California Food and Agricultural Code (law), Division 13, sections 2900-29103.

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

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

III. Pesticide Programs Division Functions

- A. Pesticide Registration Branch
- B. Enforcement Branch
- C. Worker Health and Safety Branch
- D. Medical Toxicology Branch

E. Environmental Monitoring Branch

F. Pest Management and Licensing Branch

G. Product Compliance Branch

A. Pesticide Registration Branch

The Pesticide Registration Branch coordinates and communicates with stakeholders and scientific staff regarding the pesticide registration process, though other Branches other may be involved in the evaluation process. This branch is responsible for processing over 6,000 registration actions per year, coordinating reevaluations, and processing data call-ins for existing products. The process ensures the protection of human health and the environment by regulating pesticide sales and use, and by fostering reduced-risk pest management.

The branch performs the following functions:

1. General Functions

- Process and track new pesticide product registration applications to ensure labeling complies with federal and state requirements
- Process label amendments and other revisions to currently registered products.
- Act as liaison between DPR, applicants, U.S. EPA, and other stakeholders
- License pesticide products
- Process, track, and license devices used in structural pest control for wood-destroying organisms
- Renew product registrations
- Coordinate and track data call-ins, reevaluations, risk assessments, and mitigation requirements
- Process and review adverse effects disclosures [FIFRA, section 6(a)(2)]

- Process public records requests concerning registration actions
- Issue California Research Authorizations
- Maintain an accurate and complete label database for both internal staff and the public

2. Registration Resource Center

The Registration Resource Center maintains the official product files. Access is limited to authorized personnel. Staff members respond to information requests from a variety of sources and coordinate the following activities:

- Maintains currently active pesticide product and license files, FIFRA, section 24(c), FIFRA, section 18 emergency exemptions, denial, and inactive files
- Acts as information source for state and county staff and other stakeholders concerning registered products, their labels, and use patterns
- Provides product label file documents and other information from our databases in response to information requests

The Registration Resource Center is also a reference source for "protected" data used by authorized DPR personnel. Information about protected data and other confidential information is found in DPR's procedural memo [PPMM 1-71](#). Note: U.S. EPA uses the term Confidential Business Information (CBI) for this type of information. The majority of data volumes are housed at the State Records Center. Volumes may be accessed upon request.

Activities include the following:

- Provide authorized persons access to the pesticide data volumes and product files
- Archive data and check out data volumes to authorized staff
- Maintain an updated list of personnel approved to access

Memo:
[1-31-91](#),
[2-16-93](#),
[3-14-97](#)

PRB 00-05

Memos:
[1-31-91](#),
[3-14-97](#)

Memo:
[5-19-92](#)

FIFRA Sec.
[10](#)

the data and product files

- Maintain the "completed binders" that contain the evaluation reports for each product and are filed by product name, chronologically, with recent material in front
- Maintain online index of DPR rulemaking files (files that contain the record of a regulation change, adoption, amendment, or repeal) and other documents
- Maintain online catalog records of all books and serials in DPR
- Process book and subscription orders for DPR

Complete up-to-date information is available on the DPR [Registration Resource Center](#) web page.

B. The Enforcement Branch

The Enforcement Branch is responsible for enforcing state and federal laws concerning pesticide sales and use. The branch is responsible for the following activities:

- Inspect wholesalers and retailers to determine whether pesticide products are registered and if labels are identical to registered labels
- Conduct pesticide product compliance inspections
- Coordinate with the County Agricultural Commissioners who, in turn, are largely responsible for enforcing California pesticide use laws and regulations in their counties
- Ensure uniform enforcement with due process and provide training and assistance for County Agricultural Commissioners and their staff
- Sample raw agricultural commodities throughout California for laboratory analysis of pesticide residues
- Oversee illness report investigations conducted by the County Agricultural Commissioner's offices

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- Review product labels upon request to ensure enforceability of label statements

C. Worker Health and Safety Branch

The Worker Health and Safety Branch is responsible for human safety (including the general public as well as workers) during and after pesticide use. The Branch conducts pesticide exposure research and pesticide illness surveillance, participates in the pesticide risk assessment process, and develops mitigation measures in response to risk assessment findings. The branch communicates with the County Agricultural Commissioners, the Office of Environmental Health Hazard Assessment, the Department of Public Health, and other related agencies. Specific branch activities include the following:

- Review scientific data relating to exposure of persons to pesticides
- Conduct research on human exposure to pesticides
- Conduct dislodgeable foliar residue studies to investigate the degradation of pesticides and determine safe reentry times for workers and the public
- Develop exposure assessments in conjunction with the Medical Toxicology Branch as part of the risk assessment process
- Develop methods to reduce excessive pesticide exposure
- Hold public meetings to receive input on mitigation measures
- Evaluate reports of pesticide illnesses and compile into a surveillance database
- Identify health effects of pesticides on persons who mix, load, and apply pesticides or who are otherwise exposed to pesticide applications or residues
- Participate in human illness episode investigations
- Conduct epidemiologic research on pesticide-related illnesses
- Provide information to physicians, emergency medical care facilities, and poison control centers during illness

investigations

- Provide safety information and consultations to pesticide users through the [Pesticide Safety Information Series leaflets](#)
- Prepare research reports on pesticide exposure incidents, exposure monitoring studies, and epidemiology research projects
- Conduct industrial hygiene workplace evaluations

D. Medical Toxicology Branch

The Medical Toxicology Branch reviews acute and chronic toxicology studies that are submitted in support of new product registration or to maintain the registration of existing active ingredients. Branch activities include:

- Review of acute toxicology data submitted to support product registrations and FIFRA, section 18 emergency exemptions
- Review of chronic toxicology data submitted to support new active ingredient product registrations
- Review of chronic data submitted for Birth Defects Prevention Act of 1984 (SB950)
- Coordinate [Proposition 65](#) information on pesticides with OEHHA
- Conduct risk assessments in conjunction with the Worker Health and Safety Branch and OEHHA
- Review applicable adverse effects disclosure reports

E. Environmental Monitoring Branch

The Environmental Monitoring Branch reviews pesticides found in the environment (including ground and surface water), and develops strategies to minimize their impact. Branch activities include the following:

- Review all new products, label amendments, and FIFRA, section 24(c) products applied to water or rice, or that

meet certain environmental criteria (with or without data)

- Perform ground and surface water analysis
- Develop data to assess environmental contamination from pesticide use and develop mitigation measures to minimize environmental impact

F. Pest Management and Licensing Branch

The Pest Management and Licensing Branch activities include the following:

- Assemble information and data on [Integrated Pest Management](#) (IPM) and promote its implementation
- Recognize California organizations that emphasize pest prevention, favor least-toxic pest control, and share their successful strategies with IPM Innovator Awards
- Award Pest Management Alliance Grants that support projects to increase implementation and adoption of effective pest management practices that reduce risks to human health and the environment
- Facilitate voluntary establishment of IPM policies and programs in public schools throughout California, while assisting school districts with implementation of requirements of the Healthy Schools Act
- Conduct IPM education and outreach for licensed child-care centers in California, providing training for child care providers about reduced-risk pest management
- Conduct pest management assessments of commodities, including [alternatives](#) to the use of methyl bromide, and [pesticide use trends analyses](#) to provide an overview of pesticide use in California
- Collect, error check, and analyze pesticide use reporting data from the County Agricultural Commissioners
- Produce the annual [Pesticide Use Report](#), which lists the amount of reported pesticide applied and acreage treated for each commodity and active ingredient, and provides a pest management analysis of the trends in pesticide use in

the major crops

- License and certify pesticide dealers, pesticide brokers, agricultural pest control advisers, pest control businesses, and pesticide applicators
- Develop and update study materials and examinations to test the competency and responsibility of licensees to advise, use or supervise the use of pesticides
- Approve continuing education courses to ensure license and certificate holders keep their knowledge current in the areas of pest management and pesticides
- Identify, map, and maintain the Endangered Species database as part of the Endangered Species program

G. Product Compliance Branch

The Product Compliance Branch (PCB), formerly known as the Mill Assessment Branch, has two primary roles:

- Pesticide Product Compliance
- Mill Assessment Collection and Disbursement

PCB is charged with ensuring all pesticides products sold for use in California are registered and that the sellers are in compliance with sales reporting and mill assessment payments. When violations pertaining to pesticide sales or labeling are observed, PCB takes the lead in directing the investigation, collection of evidence, and documentation of findings that will serve to substantiate the violation. PCB compliance activities include:

- Conducting audits of pesticide registrants, brokers, and dealers
- Investigating reports of unregistered/misbranded sales
- Conducting marketplace inspections wherever pesticides are sold and market place surveillance inspections
- Consult with the Registration Branch and U.S. EPA to determine whether a product can be legally sold and meets the definition of a pesticide

- Working closely with DPR’s Office of Legal Affairs in developing and proposing enforcement actions and settlement agreements
- Establishment Inspections
- Collects product samples for laboratory analysis

Mill Assessment - DPR assesses a fee on all sales of pesticides, levied at the point of first sale into California. A “mill” is equal to one-tenth of a cent. Currently the mill assessment rate is 21 mills, or 2.1 cents per dollar. Mill assessment funds support more than two-thirds of the State's total pesticide regulatory system including, enforcement, health and safety, and environmental monitoring programs. In addition, mill assessment revenues are disbursed to the County Agricultural Commissioners (CACs) to reimburse them for pesticide use enforcement activities at the local level. The PCB's mill assessment activities include:

- On a quarterly basis, collect reports of pesticide sales in California and reports of pesticide mill assessments paid
- Disburse 7.6 mills (approximately \$17 million) of the collected mill assessment fees to the CACs on an annual basis.

For more information:

<http://www.cdpr.ca.gov/docs/mlassess/masesmnu.htm>.

IV. Introduction to the Pesticide Regulation Process

A. Overview

DPR is the lead agency responsible for a comprehensive pesticide regulatory program in California.

Before a pesticide can be sold, offered for sale, or used in California, it must be registered with DPR. The purpose of the registration process is to determine that the product can be used safely and effectively in accordance with its label directions. The pesticide product label and scientific data must be reviewed and found acceptable before the product can be

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[12824](#),
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registered. The pesticide product must be properly labeled and found appropriate for its intended use.

With certain exceptions, pesticide products must be registered by the U. S. Environmental Protection Agency (U.S. EPA) before being submitted to California for registration. Certain products may be submitted for registration in California concurrently with U.S. EPA as described in Chapter 4. Additionally, California law requires registration of spray adjuvants, which are not considered pesticides under federal law.

Note: Certain pesticide products that have been determined not to pose unreasonable risks to public health or the environment are exempt from registration. See Chapter 4 for more information on FIFRA, section 25(b) products.

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[12824,](#)
[12826](#)

40CFR
[152.15](#)

FIFRA
Sec.12

1. To register a product, an applicant must submit the appropriate documents and the required data

The Regulatory Scientist (RS) reviews each application submission for accuracy and completeness. This does not include review of data, which is reviewed by our evaluation staff. If incomplete, the submission may be returned. If complete, the submission may undergo scientific evaluation followed by a 30-day public comment period or be registered based on previously evaluated data. If the data and label are acceptable, recommendations are favorable, all possible adverse effects mitigated, and any comments received addressed, DPR licenses the product for registration.

Scientists in the Registration, Medical Toxicology, and Worker Health & Safety Branches perform scientific evaluation. For some products, the Environmental Monitoring and Enforcement Branches are also involved in the evaluation process. DPR may refuse to register any product that fails to meet the registration requirements.

After the product is registered, coding staffs enter information about the product and its label into the web accessible, product label database. A paper copy file is also maintained for each pesticide product.

2. Processing certain types of registrations

Supplemental distributors, additional brand names, changes of product ownership, and changes in company name are considered separate registration actions and must be reviewed, approved, and licensed before the product can be sold or offered for sale in California.

3. Significant label changes (substantive changes)

All significant changes made to the label of a registered product must be reviewed and approved (except those allowed through the DPR Notification process) before the product bearing the amended label can be sold or used in California. See Chapter 6 for details.

4. Once a product is registered, it is subject to data call-ins, reevaluations, and adverse effects reporting (see [Chapter 8](#))

Once a product is registered, it is subject to data call-ins, reevaluations, and adverse effect reporting and may result in the product's suspension or cancellation. In some cases, registrants may amend labels and formulations to mitigate hazards.

Registrants may voluntarily cancel their pesticide product registrations at any time. If a company chooses to voluntarily cancel (inactivate) their product at any time during the year other than the renewal period, a [voluntary cancellation](#) form must be signed and submitted to licensing. A registrant may cancel a product's registration during the renewal period by drawing a line through the product name on their renewal form.

5. Brief outline of the registration process

Below is a brief outline of the registration process for a new product

Intake Unit

**Receives submission
Enters information into mail log database
Assigns Tracking ID
Creates status sheet
Assembles submission into brown folder for assigned specialist**

Indexing Unit

Indexes and catalogs any data submitted by entering information into the appropriate database

Regulatory Scientist

**Reviews the submission for accuracy and completeness

Evaluates product for similarity to other products**

Reviews and evaluates the label

Returns incomplete submissions to the applicant

Forwards complete submissions to scientific evaluation (if required)

Evaluation Scientist

Evaluates the submitted data

Writes evaluation reports with registration recommendations

Regulatory Scientist

Reviews the evaluation scientists' recommendations when received and addresses any deficiencies

Program Manager

Reviews registration recommendations for final approval or denial of submission.

Regulatory Scientist

Posts the proposed registration recommendation for the 30-day public comment period.

Forwards to licensing technician after 30-day comment period is complete and all comments received have been addressed

Posts "Final to Register" on his/her action log or Denies registration and posts the submission "Final to Deny" on his/her action log

Licensing Technician

Issues Certificate of Registration (license)

B. Pesticide Registration and Evaluation Committee

The Pesticide Registration and Evaluation Committee (PREC) provides a discussion forum for California agencies that may be affected by the use of pesticides. It fulfills an essential role in DPR's certification for functional equivalency to the California Environmental Quality Act's Environmental Impact Report requirements. The committee was established in law, FAC, section 14103, and meets bimonthly to discuss registration issues.

The committee is chaired by DPR. Committee members include:

- Office of Environmental Health Hazard Assessment
- Air Resources Board
- California Department of Resources Recycling and Recovery (*CalRecycle*)
- State Water Resources Control Board
- Department of Toxic Substance Control
- Department of Fish and Game
- Department of Industrial Relations
- California Department of Food and Agriculture
- Department of Public Health
- Structural Pest Control Board in the Department of Consumer Affairs
- IR-4 Project University of California
- U.S. Department of Agriculture/Agricultural Research Service
- U.S. Environmental Protection Agency Region IX
- President of the County Agricultural Commissioner's Association

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[13150](#), [13165](#)**

Each week, PREC committee members receive a list of all products submitted into scientific evaluation by the Pesticide Registration Branch. Submitted scientific data and the product label are available for review by the committee members and their respective agencies. Committee member comments and recommendations are considered when the Pesticide Registration Branch proposes its registration decision.