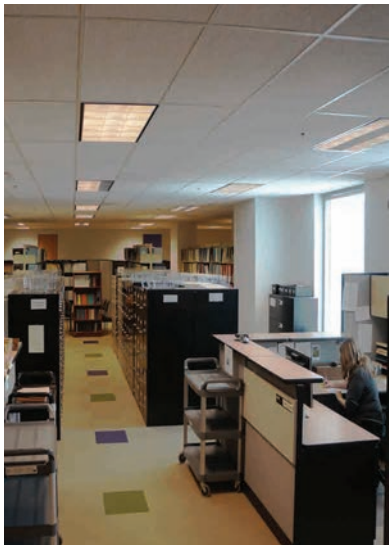


Product registration by the numbers:

- **1,200: new products registered in 2015.**
- **2,300: amendments to registered products.**
- **4,000-5,000: registration submissions per year processed by the Pesticide Registration Branch.**
- **13,600: Number of registered products as of the summer of 2016.**
- **1,050: Active ingredients registered in California.**

Pesticide Registration

The Department of Pesticide Regulation (DPR) performs a scientific evaluation of the ingredients of a pesticide product; the proposed site or crop on which it is to be used; the amount, frequency and timing of use; and its potential effects on human health and the environment. This evaluation is called the pesticide registration process.

THE PESTICIDE REGISTRATION PROCESS

Before a pesticide can be registered (licensed) in California, it must be registered with the U.S. Environmental Protection Agency (U.S. EPA). After receiving an application for registration, DPR evaluates the product thoroughly under guidelines of the Food and Agricultural Code (FAC) to ensure that it is effective and will not harm human health or the environment when used according to label directions.

DPR scientists review the pesticide product label and scientific data and must find it acceptable before the product can be registered. The product must be labeled properly and found suitable for its intended use. Pesticides that pass this scientific, legal and administrative process are granted registration that allows their distribution, sale and use in California. A small subset of low-risk pesticides are granted an exemption from registration if they meet certain criteria. (*See 25(b) Exemptions on Page 33*).

A registrant is a business or individual that holds the certification of registration and is therefore responsible for the product. A registrant can be a chemical company, government agency, importer or any person wishing to market a pesticide product in California. It may include manufacturers of technical-grade pesticidal chemicals used to prepare end-use products. It also includes formulators who prepare the end-use products, and distributors who put their own labels on pesticide products purchased from formulators. The registrant's name and address must appear on the product label.

Several DPR branches take part in the preregistration scientific evaluation. Their role is to ensure that, when a product is used under the restrictions and protective measures on the U.S. EPA-registered label, it will cause no harm (that is, significant adverse effect) on human health, non-target organisms or the environment. The Pesticide Registration Branch coordinates this process and serves as liaison to registrants.

Pesticides are substances or mixtures of substances intended for preventing, destroying, repelling or mitigating any pest. Though often misunderstood to refer only to insecticides, the term pesticide also applies to herbicides, fungicides, antimicrobials, and various other substances used to control pests. (*See Page 24, What is a Pesticide?*). The active ingredient is the chemical or substance component of a pesticide product that can kill, repel, attract, mitigate or control a pest or the chemical that acts as a plant growth regulator, desiccant or nitrogen stabilizer. In addition to the active ingredient(s), a formulated pesticide product consists of one or more inert ingredients, such as water, solvents, emulsifiers, surfactants, clay and propellants. While these other ingredients may be chemically or biologically active (and therefore not inert), they are included in the product for reasons other than pesticidal activity. Pesticides are regulated to control the effect of both the active ingredient and inert ingredients in the formulated product.

The law requires prospective registrants to send DPR data on potential human health and environmental effects associated with use of their product, including:

- Product composition and chemistry.
- Acute and chronic toxicity—that is, the capacity of the chemical to harm humans either in limited (acute) or long-term (chronic) exposures.
- How the pesticide behaves in the environment.
- Effectiveness against targeted pests (efficacy).
- Hazards to non-target organisms.
- Effects on fish and wildlife.
- Worker exposure.

The Registration Branch manages the pesticide data studies collection. Staff catalog and maintain data received from pesticide registrants. In 2016, the Registration Resource Center housed more than 85,900 volumes of data containing about 237,000 studies. This includes studies that have been submitted to U.S. EPA, additional efficacy, safety and environmental data required by DPR, and registration-related correspondence and evaluation memoranda.

The Registration Resource Center also maintains all product files for pesticides registered in California, including Section 24(c) (Special Local Needs registrations) and Section 18 (Emergency Exemptions from registration) files. Only authorized persons may directly access these files since they contain proprietary information—primarily formulas of pesticide products, which are considered confidential business information under federal law. The Registration Resource Center responds to requests for non-confidential information from the public, registrants, county agricultural commissioners, DPR staff, Poison Control Centers, the Legislature and other government agencies.

The Registration Resource Center contains nearly 86,000 volumes of information about registered pesticides.

CATEGORIES OF PESTICIDES

DPR registers the following categories of pesticides:

- **Conventional pesticides**.
- **Biochemicals and microbials (biopesticides)**. Biochemical pesticides are naturally occurring substances that control pests by a mechanism other than toxicity—for example, sex pheromones used as mating disrupters for insect pests. A microbial pesticide is one in which the active ingredient is a living pathogen (for example, a bacterium) that infects a pest and then kills or inhibits it.
- **Antimicrobial pesticides**. These are substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms such as bacteria, viruses or fungi on inanimate objects and surfaces.
- **Spray adjuvants**. California law requires registration of adjuvants, which are not considered pesticides under federal law. (An adjuvant is broadly defined as any non-pesticide material used with a pesticide product or pesticide spray mixture to improve the pesticide's performance or the physical properties of the spray mixture.)
- **Plant growth regulators.** These are substances that accelerate or slow the rate of growth or maturation of a plant, or otherwise alter behavior through physiological action.

Although all pesticides are regulated under the same state statutory standards, the different categories pose different levels of risk and exposure. As a result, antimicrobial, biochemical and microbial pesticides are subject to fewer data requirements for registration than conventional chemicals. Data requirements for

What Is a Pesticide?

Under state and federal law, a pesticide is any substance intended to control, destroy, repel, or otherwise mitigate a pest. Any organism that causes damage or economic loss, or transmits or produces disease, may be the target pest. Pests can be insects or animals (e.g. mice), unwanted plants (weeds) or organisms that cause plant diseases. In addition, state and federal laws consider products to be pesticides if they regulate plant growth, cause plants to drop their leaves or dry plant tissue.

Therefore, the word "pesticide" is an umbrella term that includes many kinds of chemicals—not only insecticides, herbicides and other agricultural and lawn-and-garden chemicals, but also many industrial, institutional and home-cleaning products, such as algaecides (used to control algae in swimming pools and water bodies), disinfectants, sanitizers, mildew removers and insect repellents.

California also regulates adjuvants as pesticides. This class of chemicals, exempt from federal registration, must be registered in California. Adjuvants are emulsifiers, spreaders, water modifiers and other compounds added to improve the effectiveness of a pesticide.

Many products, ranging from toothbrushes to children's toys, are treated with antimicrobial pesticides to get rid of bacteria. The antimicrobial pesticides are usually added to the product during manufacture (for example, plastic shower curtains) but may be added afterwards (for example, mixing a mold-preventing pesticide into paint). If a treated product makes public health claims—that is, it claims to "fight germs" or "control fungus"—the article must be registered as a pesticide. If no public health claims are made, the product is exempt from federal or state regulation. However, the product label must make clear that the benefits of pesticide treatment do not extend beyond the article itself.

Some products, while considered pesticides, are exempt from the registration process in California. These include certain products that contain low-risk ingredients, such as garlic and cedar; as well as plant-incorporated protectants, which are pesticidal substances produced by genetically modified plants.

Excluded from California's definition of pesticides are:

- Over-the-counter and prescription treatments for head lice, which are regulated by the U.S. Food and Drug Administration.
- Cosmetics and similar products intended to be applied to the human body, including antibacterial soaps and lotions, and antifungal creams. (Insect repellents applied to the human body, however, are pesticides).
- Fertilizers, nutrients and other substances used to promote plant survival and health.
- Biological control agents, except for certain microorganisms. (Biological control agents include beneficial predators such as birds or ladybugs that eat insect pests).

antimicrobial pesticides and biopesticides are organized into a tier-testing system with specified extra studies at higher tiers required if unreasonable adverse effects are seen in lower-tier studies. The lower-tier studies are a subset of those required for conventional pesticides and the studies overall are generally selected from those required for conventional pesticides. Examples of lower-tier studies are acute toxicity, developmental toxicology, mutagenicity, efficacy, and effects on fish and wildlife. Proposed uses on food generally require more studies than nonfood uses.

DATA EVALUATION

DPR scientists review toxicology and other studies from the registrant for adequacy and potential adverse effects. If scientists conclude there are potential adverse health effects, they study the pesticide's risk potential and prepare a risk evaluation. If the pesticide is a new active ingredient (that is, never registered in California), it is prioritized for risk assessment. (*See Chapter 5 for more information on risk assessment.*)

In addition, DPR scientists with expertise in chemistry, microbiology, plant physiology, pest and disease prevention, ecotoxicology, or environmental fate review data to determine the effects of pesticides on target pests and non-target effects (that is, effects on species not considered the target pest). The latter includes:

- Non-target effects on plants (phytotoxicity).
- Ecotoxicology.
- Effects on endangered species.
- Effects on the environment, including soil, ground and surface water.
- Pest protection (entomology).
- Plant pathology.
- Harmful effects on integrated pest management (IPM) systems.

Included is a review to ensure that product residues on harvested commodities will not exceed legal limits (tolerances set by U.S. EPA) when the pesticide is used according to label directions.

DPR scientists also review product labels to ensure:

- They comply with U.S. EPA labeling standards and clarity.
- They accurately reflect human health hazards suggested by toxicology data.
- They accurately reflect environmental hazards suggested by environmental data.
- The label requirements are practical and can be enforced in the field.
- Use instructions are adequate to protect pesticide users and others from overexposure.

If any changes to the label are necessary, DPR staff work with the registrant and U.S. EPA to recommend revisions that will satisfy California's health or environmental concerns. According to federal law, pesticide label language is controlled exclusively by U.S. EPA, which must approve any changes. A state cannot require manufacturers to change labels. However, states can refuse to allow registration and therefore the possession, sale or use of any pesticide not meeting its own standards.

DPR also consults with other public agencies on proposed pesticide registrations and, more broadly, on regulatory policies through routine daily contacts

Scientific studies submitted to support an application for registration of a pesticide product.

The Pesticide Registration and Evaluation Committee meets at least every other month at the CalEPA building in Sacramento.

and, more formally, through its Pesticide Registration and Evaluation Committee (PREC). Chaired by the Registration Branch chief, the PREC usually meets every two months. It brings together public agencies that have legal jurisdiction on pesticides or whose activities or resources may be affected by use of pesticides. (In 2000, the department's Pesticide Advisory Committee, whose role overlapped that of the PREC, was merged with the latter committee.)

The PREC includes representatives of the state Departments of Public Health, Food and Agriculture, Industrial Relations, CalRecycle, and Fish and Wildlife; the Structural Pest Control Board; CalEPA's Office of Environmental Health Hazard Assessment (OEHHA), State Water Resources Control Board, Air Resources Board, and Department of Toxic Substances Control; the University of California, Department of Environmental Toxicology; U.S. EPA, Region 9; University of California, Department of Environmental Toxicology, IR-4 Program; and the California Agricultural Commissioners and Sealers Association. The PREC advises DPR on regulatory development and reform initiatives, public policy and program implementation, and science issues associated with evaluating and reducing risks from the use of pesticides. It fulfills a critical interagency consultation role mandated by DPR's certified regulatory program under the California Environmental Quality Act (CEQA).

Once reviews by DPR scientists and technical specialists are complete, DPR management decides whether to propose product registration or deny the application. Under law, denial of registration must be based on:

- Serious uncontrollable adverse effects on the environment.
- Greater harm than benefit to the environment.
- Harm to vegetation, domestic animals, or public health and safety.
- Uses considered to have little or no value.

If any reviewing DPR branch recommends against registration because of inadequate data, unacceptable studies or unmitigated adverse effects, DPR will not register the product until these questions are resolved and concerns raised by other state agencies are considered. DPR posts proposed decisions to register or deny applications weekly, beginning a 30-day period for public comment.

Before the decision can be finalized, DPR responds to public comments. Should DPR decide to proceed with registration, it issues a license for product sale and use to the registrant.

DIFFERENCES BETWEEN STATE AND FEDERAL REGISTRATION PROCESS

While California's pesticide registration parallels its federal counterpart in most respects, there are differences in application. For example, DPR and U.S. EPA may review the same group of toxicology studies sent with an application for registration. However, they may rely on different studies from the data package to reach a registration decision. Often, the two agencies reach the same conclusion. Sometimes, the conclusions differ, in part because DPR focuses on California-specific effects. For example, DPR may refuse to register a product because of potential effects on workers in California's labor-intensive agriculture.

U.S. EPA has broad authority to waive submission of some studies or to not complete data evaluations before granting conditional registrations. DPR's authority to grant conditional registration is more limited. For example, if a registrant submits preliminary efficacy data indicating that the product is effective for its proposed use, DPR may conditionally register the product for a limited period to allow the registrant to complete and submit final efficacy studies. However, if the product contains a new active ingredient, in most instances, the department

is precluded from conditionally registering the product unless the registrant has submitted a complete toxicology data package that has been reviewed by DPR scientists.

Further, DPR may require more or different studies not required by U.S. EPA. These added studies include, but are not limited to, data on worker exposure, foliar residue, indoor exposure potential, hazards to bees, and dust hazard of powdered products to workers.

There are also significant differences in how U.S. EPA and DPR consider data. In California, more than 350 different kinds of specialty crops are grown, including fruits, nuts, vegetables and horticultural crops. Most are considered "minor-use crops" for pesticides and are high in harvested value but planted on relatively small acreage compared to field crops such as corn, soybeans and wheat. These uses are not always economically attractive to the pesticide industry because the amount of pesticides sold is limited while the costs to obtain and maintain registration are substantial. Because of the state's cropping patterns, DPR focuses more resources than U.S. EPA on these minor uses.

Field crops also require little cultural care during the growing season and are primarily harvested mechanically by tractor workers in enclosed cabs. On the other hand, California's fruit, vegetable and horticultural crops require extensive cultural care before harvest and are harvested by hand. These activities typically result in high worker contact with foliage. (The U.S. Department of Labor's National Agricultural Worker Survey estimates that a little more than a third of all farmworkers in the U.S. work in California agriculture. That would translate to roughly 648,000 individuals working on California farms each year.)

DPR gives specific attention to how a pesticide will be used under California climatic and cultural conditions. Some crops, such as rice, may be grown with different water and land management practices in California than in other areas of the country. California agriculture is irrigated, changing how pesticides are applied and how workers (irrigators moving pipe, for example) are exposed. For example, DPR field studies have found that pesticides that may decay rapidly elsewhere under warm, humid conditions in summer can persist longer under the hot, dry conditions typical of many of California's agricultural areas. Algaecides and other pesticides used in swimming pools must reflect the outdoor, year-round use typical in many areas of the state.

California is also unique in that tens of thousands of its residents live in homes near the nation's most intensively farmed acreage. The effect of pesticide use at this agricultural-urban boundary is a key evaluation factor in California. DPR, for example, has traditionally placed more emphasis than U.S. EPA on evaluating the potential for off-site movement of pesticides, and on taking steps to prevent it.

DPR sometimes denies registration to products approved by U.S. EPA. DPR has based denials on such factors as a lack of appropriate or acceptable toxicology or environmental data or an inadequate margin of safety under the label instructions. DPR has also denied state registration for federally registered products that could not show reasonable effectiveness under California conditions or which did not meet labeling claims.

Another difference between the U.S. EPA and DPR registration process is that federal pesticide law (the Federal Insecticide, Fungicide and Rodenticide Act, FIFRA) requires U.S. EPA to balance risk considerations with economic benefits. During registration and, more formally, during cancellation proceedings, U.S. EPA must determine not only whether there are "unreasonable adverse effects on the environment," but must also consider the "economic, social, and environmental costs and benefits of the use of any pesticide." The risk-benefit provisions of FIFRA were modified in 1996 to ensure health-based safety standards for dietary residues. However, federal law mandates U.S. EPA consider economic benefits of pesticides.

DPR scientists consider the effects of pesticide use near agricultural-urban boundaries when making registration decisions.

Pesticide products can be conditionally registered, before a full unqualified registration is granted, if health and environmental studies are completed and there is "a clear need for the use of the product in California."

California law does not allow consideration of economic benefits unless it is not possible to mitigate any significant adverse effects, and there is no feasible alternative that would substantially reduce any significant adverse effect. Only then may DPR consider registration if the benefits clearly outweigh the risks. The department has never used this discretion. Instead, it has followed clear, legal mandates to ensure that pesticide use in the state poses no significant risk to the public, farmworkers and the state's environment and wildlife. The basic decision rule is that DPR may approve a pesticide registration application or, if already registered, allow continued use, if it decides the pesticide can be used safely according to label directions and any DPR regulatory and permitting requirements. DPR can adopt regulations to place an active ingredient on the state's restricted material list. Restricted materials require a permit from the county agricultural commissioner, who has broad discretion to impose site-specific control measures based on local conditions. DPR recommends conditions to be included in the permits.

CONDITIONAL AND INTERIM REGISTRATIONS

DPR may conditionally approve an application for registration if it determines that, while a registration decision can be made, further data from the registrant are needed for an unconditional registration. All required health and environmental studies must be submitted (although certain mandatory health-effects data can be waived after consultation with Office of Environmental Health Hazard Assessment). The data already on file with DPR must substantiate that use of the pesticide is not expected to cause any significant effect on health or the environment while the rest of the data are being developed.

Evidence is also needed that there is "a clear need for the use of the product in California." Studies that are deferred are typically supplemental requirements such as final efficacy data and storage stability. Registrants must report yearly on progress made toward development of waived data. Conditional registrations are limited to no more than three years.

Legislation in 1993 (Chapter 963, AB 771) set up an interim registration that allowed DPR to defer certain data requirements for federally registered pesticides that meet specified criteria. DPR can defer efficacy data and some environmental fate studies if the Pest Management and Licensing Branch confirms the product would reduce risks when used in a pest management system. The product must reduce risks to workers, public health or the environment, lessen the risk of pest resistance problems, or reduce a substantial risk of economic loss as a result of a pest infestation for which there is no other feasible control. The registrant must agree to produce the required data within three years and DPR must consult with the PREC before approving the application. DPR charges a $5,000 fee to cover added costs. If granted, uses are limited to those within a pest management system. DPR may require extra controls, such as a restricted material permit or a written recommendation from a pest control adviser, or a limitation on the application location, amount or method. Interim registration has seldom been requested by registrants.

Another type of provisional registration was established by 1995 legislation (SB 283, Chapter 608[1]). It allows DPR to issue a certificate of emergency registration to products that previously had been used in California under a Section 18 emergency exemption (*see Page 34 for a discussion on Section 18 registration*) and which have since been granted federal registration. As of 2016, there had been no instances when DPR used a certificate of emergency registration as allowed by SB 283.

[1] Appendix A lists this and other statutes noted in this chapter and shows the related code section it amended or added. Statutes and related code sections that have been deleted or superseded by later legislation have been omitted.

ADVERSE EFFECTS DISCLOSURE

Adverse effects reports are an important supplement to the data generated by registrants in support of registration. If a registrant has additional information on an adverse effect or risk of a pesticide to human health or the environment during the registration process or at any time after, the registrant must immediately report that to DPR. At a minimum, the registrant must submit all of the information required to be sent to U.S. EPA under parallel provisions of FIFRA Section 6(a)(2).

This information may come in the form of studies that the registrant undertakes or learns about, or reports of incidents of adverse effects resulting from the use of pesticide products. Adverse effects may include product defects, lack of product efficacy or exposure incidents where individuals become ill or die from pesticide exposure. Thus, this reporting requirement provides an after-the-fact check on registration decisions.

No proof of a cause-and-effect relationship is required for an incident to be reportable because both U.S. EPA and DPR primarily use the reports to look for patterns of concern. Adverse effects information may lead DPR to request additional information from registrants and, in some cases, reevaluate uses of a pesticide. As a result, DPR may impose additional restrictions or even cancel the registration of the pesticide. (*See Chapter 4 for more information on continuous evaluation and reevaluation.*)

Each application for registration renewal must include a statement that the applicant has complied with adverse effects disclosure requirements.

SUSPENSION AND CANCELLATION

DPR can take action to suspend or cancel a pesticide registration if it determines that existing risks related to use of the pesticide are unacceptable and registrants either have not or cannot make necessary changes to address the unacceptable risks. DPR can also cancel a product registration when a registrant fails to submit required data for a product in reevaluation or when a registrant "repeatedly violates" provisions of the Food and Agriculture Code.

In all instances, the registrant can request a hearing. The product may be sold and distributed until DPR makes a final decision on cancellation. If no hearing is requested, DPR cancels the registration of the product or products. Once a registration is canceled, the registrant can no longer sell the product. DPR has authority to allow continued retail sales of products in the channels of trade for a specified period. If acquired when registered, or when sales were allowed, personal use of cancelled products in the possession of an individual is allowed indefinitely.

A suspension is an immediate ban on the sale and use of a pesticide product. DPR may suspend the registration of a product when it determines the "use or continued use of a pesticide constitutes an immediate substantial danger to persons or to the environment." The suspension must be followed within 10 days by an action to cancel the registration or the suspension is lifted. DPR must conduct a hearing before making a final decision on cancellation.

Registrants may also request to voluntarily cancel the registration of a product or amend the registration to delete selected uses. Requesting voluntary cancellation sometimes reflects a registrant's conclusion that the cost of producing more studies required by DPR is not worth the expected return from sales. When a registrant voluntarily cancels a registration, retail sales of the product in the channels of trade in California may continue for two years. Use of voluntarily cancelled products already in the possession of an individual is allowed indefinitely.

Whether a substance is a pesticide and under the jurisdiction of that law depends not only upon the nature of the substance and the information on the label, but also upon intended uses and upon printed, written, or oral claims. For example, petroleum oil sold for use solely as a fuel or lubricant is not a pesticide, but the same material is a pesticide when sold or intended for application to plants to control scale insects, or as a spray to control weeds, or for application to ponds to control mosquitoes.

— 1944 department annual report

While this department does not permit experimentation with new materials by allowing unproven materials to be sold to growers or users, it does not wish to offer any obstacle to the development of such materials.

— 1944 California Department of Agriculture annual report

STREAMLINING REGISTRATION

The process of evaluating and registering pesticide products is complex, involving interaction of several DPR branches and thousands of individuals and businesses. This core business activity is therefore a natural focus of process improvement efforts that DPR began in the early 1990s and, building on early successes, continued well into the next decade.

Among the conclusions of a 1993 study DPR commissioned of its registration process (*Challenge and Change: A Progressive Approach to Pesticide Regulation in California*) was that the department could expedite registration of reduced-risk products by greater coordination with U.S. EPA. In 1994, DPR and U.S. EPA began a "harmonization" project to more closely coordinate their registration processes. The goals were to reduce needless duplication, develop complementary, specialized expertise tailored to the capabilities of each agency, get reduced-risk products to market faster, and more quickly remove products from use that posed unacceptable risks.

A first step was to try to bridge the methodologies followed in reviewing registration actions. Beyond agreeing on acute toxicity reviews, however, this aspect of harmonization proved impractical. Beginning in 1999, DPR and U.S. EPA began a more structured "workshare" partnership to collaborate on specific product registrations. Included were three major elements: concurrent review, joint data review, and tolerance review for the fruit, nut, vegetable and horticultural crops that comprise the core of California's agricultural economy.

With concurrent review, DPR and U.S. EPA share data evaluations to reduce time needed to evaluate applications for registration. When conducting joint data review, the two agencies split the workload of evaluating data for a reduced-risk pesticide. The final workshare element is conducted with a third partner, the Interregional Research Project No. 4 (IR-4), a U.S. Department of Agriculture program that helps develop and register pesticides for minor crops. IR-4 develops pesticide residue data needed for pesticides to be used on California crops. DPR scientists review the data; these reviews help U.S. EPA set allowable residue levels on fresh produce, expediting minor-use registrations.

The 1993 Challenge and Change report also recommended that DPR focus on getting lower-risk products registered more quickly. In 1993, DPR began accepting applications for registration of products containing new microbial and biochemical active ingredients concurrently with their application to U.S. EPA. Before that time, a pesticide had to be registered federally before a company could apply to register it in California. In 1994, "to encourage the use of pesticides that are expected to pose reduced risk compared to alternative pesticides," DPR began accepting concurrent applications for products containing new active ingredients U.S. EPA classified as "reduced risk." In 1996, DPR expanded the concurrent-application program to include products containing biochemicals, microbials and U.S. EPA-designated reduced-risk active ingredients already in other California-registered products.

With the 1997 passage of SB 464 (Chapter 428), DPR began accepting new human health and public health antimicrobials concurrently. However, because of budgetary constraints between 2002 and 2005, DPR suspended most programs to accept concurrent registration applications. The two exceptions are products containing new active ingredients and new human health and public health antimicrobials. In 2016, these applications could still be submitted concurrently.

The department used recommendations in the Challenge and Change report, those of registrants and its own review of registration to make changes that reduced significantly the time needed for product approval, without altering California's safeguards. For example, in the 1990s, DPR made data review procedures more efficient and prioritized risk assessments to provide a more effective process for new, reduced-risk active ingredients. In 1999, working to remove bureaucratic

requirements that were not necessary to protect health and the environment, DPR began waiving the submission of some human health effects data and all data on fish and wildlife effects for certain low-risk pheromone products. In 2000, DPR adopted regulations exempting certain kinds of minimum-risk pesticides from registration, paralleling an earlier U.S. EPA action. Most exempt chemicals are low-risk substances that have a wide range of other, nonpesticidal uses as foods, medicines or household items.

In 2004, DPR also updated policies to no longer require submission of residue data with applications for registration, although the department can still request it. To improve tolerance-setting, DPR also worked with U.S. EPA, Health Canada and the European Union to develop a standardized statistical method for establishing tolerances.

The 2005 passage of AB 1011 (Chapter 612) removed a requirement that had essentially forced DPR to be the arbiter of business disputes over use of scientific data to support new registrations. Such disputes could delay registration actions for years. The bill created a California data-protection and cost-sharing system similar to the federal system.

Before the passage of AB 1011, DPR was prohibited from considering data sent by one company to evaluate another company's application to register a pesticide product or amend a registration without a letter of authorization from the company that originally sent the data. Data-generating companies could essentially keep competitors out of the California market by refusing to grant a letter of authorization. Many small companies could not afford to produce the required data themselves. AB 1011 did not change any of DPR's comprehensive requirements for health, safety and environmental data. However, with its passage, DPR could consider all data on file, regardless of the source. The legislation also authorized DPR to use previous evaluations of pesticide products when evaluating new registrations and label amendments.

The letter of authorization was replaced with data cost-sharing that is the responsibility of the applicant and data owners and does not involve DPR.

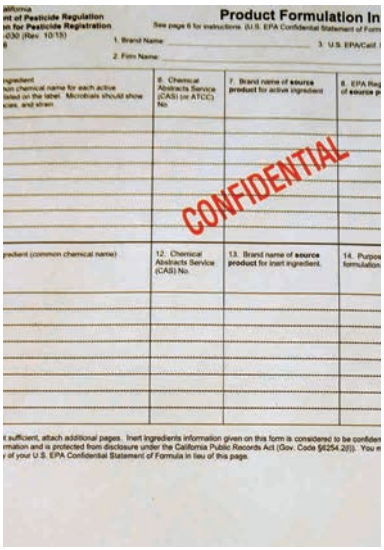
Applicants may still submit their own data in support of a registration application. If the applicant does not do so and wants DPR to instead use another company's data to support its registration application, the applicant may be required to offer to pay the data owner a share of the cost of producing the data. If the two parties cannot reach an agreement on the terms and amount of payment within 90 days after issuance of an irrevocable offer to pay, the applicant, source or data owner may begin or, with the consent of all parties, join a binding dispute resolution proceeding described in federal rules. If one of the parties fails to make an offer to pay or to take part in the proceeding to resolve disputes over the required offer to pay, they may ask DPR for a determination. If, after investigation, DPR finds a registrant has failed to make an offer to pay, to take part in the proceeding to resolve disputes, or to comply with an agreement, the department will cancel the registration of the product the data were used to support.

The new system resulted in a reduction in the number of applications for registration requiring scientific evaluation as well as a decrease in the average time that it takes DPR to process regular submissions from receipt to final action. Eliminating the need for DPR to evaluate duplicative data helped reduce the time to process a registration application by more than 25 percent.

The bill made it easier for generic pesticide products (typically lower in cost) to enter the California market. During legislative discussions, this raised concerns that more products containing older, more toxic ingredients would be registered and used. However, a 2009 DPR analysis found that while there was a slight increase in registration of these products, there was no correlation between this increase and the total pounds sold of these compounds.

"A vigilant and careful examination of all agricultural chemicals offered for sale in this State is necessary …"

— 1946 California Department of Agriculture annual report



DPR's Pesticide Registration Data Management System (PRDMS) will replace the current paper-based registration process.

ONLINE REGISTRATION PROCESS

In March 2013, DPR's Pesticide Registration Branch began an initiative to reengineer California's pesticide registration process. The Pesticide Registration Data Management System (PRDMS) will replace the current paper-based pesticide registration process and allow applications for registration, amendment and renewal of pesticide products to be submitted, evaluated and accepted electronically. In September 2015, DPR released a Request for Proposal (RFP) for bid for the PRDMS. It is anticipated that a vendor will be selected and development of PRDMS will begin in 2017.

REGISTRATION OF PEST CONTROL DEVICES

It is illegal to sell, own or use a structural pest control device in California unless it is registered by DPR, under state law that took effect in July 2001 (Chapter 651, AB 1134). Under the law, DPR must review device efficacy and safety before registration. These devices typically use microwave energy, electricity or heat to control termites, powder post beetles, carpenter ants and other wood-destroying pests. Devices that target decay-causing fungi, cockroaches and other household pests, and vertebrate pests such as mice and rats are exempt from device registration.

AB 1134 amended both the Food and Agricultural Code and the Business and Professions Code, placing regulatory authority for the program on DPR, CACs and the Structural Pest Control Board (SPCB). DPR has authority to make registration decisions regarding structural devices and CACs can levy civil penalties for violation of device statutes. In addition, the SPCB may take disciplinary action against its licensees for violations of device statutes. Applicants must pay DPR a $200 fee when submitting an application for device registration. These devices are exempt from pesticide renewal. Therefore, annual renewal fees are not required. As of early 2016, there were seven such devices registered for use in California: One electrical device, two microwave devices, and four heat devices.

EXPERIMENTAL USES AND RESEARCH AUTHORIZATIONS

Before federal or state regulators register a pesticide, they must have data on how it behaves under field conditions, including product efficacy, environmental fate and potential worker exposure. In addition, DPR requires these data be generated under California-use conditions. Because companies must conduct field studies to collect these data, federal and state law allows companies to apply for limited, experimental uses of pesticides.

Under FIFRA, U.S. EPA may grant registrants experimental use permits (EUPs) for new uses of registered or unregistered pesticides. DPR may grant research authorizations to federal EUPs if certain data requirements are met. If the test product contains an active ingredient already registered for other uses in the state, registrants must submit data on acute toxicity and on analytical methods to detect residues in the treated commodity. If the product contains a new active ingredient unregistered in California, DPR also requires studies on chronic health effects.

Federal EUPs are not required for most experiments on fewer than 10 acres unless they involve certain genetically engineered microbial pesticides. However, these small-scale experiments do require a research authorization (RA) from DPR. Most research authorizations are for 10 or fewer acres, although experimental plots may extend up to 100 acres provided the use is federally registered.

In applying for an RA, the applicant must specify the pesticide, treated crop or site, size of the trials, rates to be used, any existing residue tolerances and proposed disposition for the treated crop. If the pesticide is not registered for any use, the applicant must supply information on acute health effects. DPR may also

require data to assess potential adverse effects to workers, the public or the environment. If there is no applicable residue tolerance for the crop, the RA requires the crop be destroyed after harvest. DPR or the CAC may impose additional use controls to provide closer regulatory control. The CAC must be notified before an RA field trial begins. After the trial is complete, the researcher must send reports to the CAC and DPR.

Effective Jan. 1, 2016, DPR implemented regulatory changes pertaining to research authorizations. The changes included revisions to the forms used for the research authorization program, and revised the notification requirements. The changes were intended to ensure DPR and the CAC's have the necessary information to evaluate pesticides applied under the research authorization program. Researchers must provide the CAC with a copy of the approved research authorization and a notice of the intended pesticide application at least 72 hours prior to applying a pesticide requiring a research authorization, unless the CAC determines a shorter time period is adequate to evaluate the intended pesticide application. The notice of intended application must also include the location of each trial on a plot map, and a map or aerial photograph designating the location and identity of sensitive sites that could be adversely impacted by the pesticide application. The notice of intended application provided to the CAC must also be submitted to DPR at the same time.

EXEMPTIONS FROM REGISTRATION

Sterilants used in medical devices

The 1996 federal Food Quality Protection Act (FQPA) transferred jurisdiction of certain liquid chemical sterilant products used on critical or semicritical medical devices from U.S. EPA to the U.S. Food and Drug Administration. FQPA also exempted these products from registration under FIFRA.

Follow-up California legislation in 1997 (Chapter 530, SB 365) allowed DPR to exempt from state registration any liquid chemical sterilant product intended for use on critical or semicritical medical devices that had been exempted from federal registration.

Section 25(b) exemptions

In 1996, U.S. EPA exempted certain minimum-risk pesticides from registration under FIFRA Section 25(b) if they met specified criteria. State legislation that followed in 1997 (Chapter 691, SB 445) set up a similar category in California. Exempt chemicals are low-risk substances that have a wide range of other, non-pesticidal uses as foods, medicines or household items. They include substances such as garlic, peppermint, rosemary, cedar oil and castor oil.

To qualify for an exemption from registration in California, products must meet minimum requirements:

- The product must have qualified for exemption from federal registration under FIFRA Section 25(b).
- Each active ingredient in the product must be on DPR's list in regulation of exempted pesticides.
- The product must contain only those inert ingredients classified by U.S. EPA as "inert ingredients of minimal concern."
- All ingredients (both active and inert) must be listed on the label. The active ingredients must be listed by name and percentage by weight. Each inert ingredient must be listed by name.
- The label cannot include any false or misleading statements.

Some low-risk substances used as pesticides are exempts from registration requirements.

Comparing Section 18 and 24(c) Exemptions

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 tho 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 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.

- The product labeling may not claim the product controls or mitigates microorganisms in a way that links the microorganism to a threat to human health, including disease-transmitting bacteria or viruses. The label may not claim to control rodent or insect pests in a way that links the pest to specific diseases.

DPR does not review or issue notices of exemption for products that meet the conditions for exemption. Sale of an unregistered pesticide product that meets the exemption criteria is not a violation of state law. However, if an unregistered product does not meet all exemption criteria, sale or distribution would be a violation of the Food and Agricultural Code.

Products exempted from registration under these criteria are not subject to pesticide use reporting or the mill assessment.

SECTION 24(C) AND SECTION 18

Federal law allows special registrations and emergency exemptions from registration under specific circumstances. Under criteria in FIFRA Section 18 (emergency exemptions) and Section 24(c) (special local need, or SLN, registrations), these uses can be approved outside the regular U.S. EPA registration process. Criteria include data to support the use, and justification that no other registered products are available to meet the emergency or special local need. These special registrations and emergency exemptions have limits on use and need special labeling.

A Section 24(c) can be requested either by the manufacturer as a first party, or by a third party such as a grower association. Only a third party such as a grower association or CAC can apply for a Section 18. The supporting documentation and justification for both are supplied by growers, pest control advisers, CACs, universities and other knowledgeable experts.

Section 24(c) of FIFRA allows states to register a new pesticide product not previously registered for any use, or an added use of a federally registered product, as long as there is a demonstrated "special local need" for such a product.

The special local need can be in a region of the state or can cover the entire state. If for a food or feed use, a residue tolerance or exemption from tolerance must already be established for the active ingredient on that commodity. Sometimes a group tolerance for similar kinds of crops is already in place. Residue data to support the proposed use rates and method of application must be available for review. Some reduced-risk active ingredients are exempt from the tolerance requirement.

Before issuing an SLN, states must determine that:

- The use will not cause unreasonable adverse effects on health or the environment if the product's composition is not similar to any federally registered product.
- Its use pattern is not similar to any federally registered use of the same or similar product.
- Other uses of the same or similar products have not been denied, suspended or canceled by U.S. EPA.
- The product does not contain a new active ingredient unregistered by U.S. EPA. Once issued, an SLN remains in effect until withdrawn by the registrant, manufacturer or DPR, or until U.S. EPA cancels the use. DPR issues about 100 SLNs each year.

Section 18 of FIFRA authorizes U.S. EPA to allow an unregistered use of a pesticide for a limited time if it determines that an emergency condition exists. U.S. EPA defines "emergency condition" as an urgent, non-routine situation that requires the use of a pesticide.

Requests are made for pesticides needed for pest problems affecting production of agricultural commodities when there are no alternatives to control the pest. Requests usually involve pesticides that have other approved uses so U.S. EPA and DPR scientists have prior knowledge and understanding of the requested chemical.

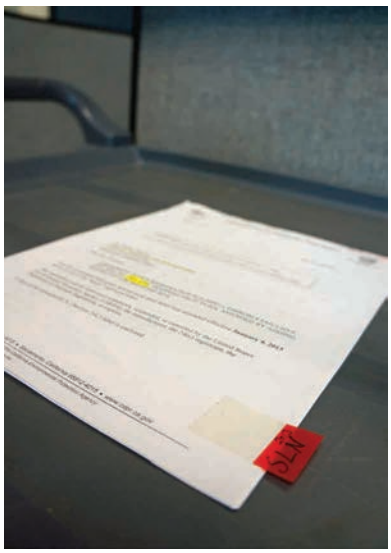
DPR forwards Section 18 requests to U.S. EPA only after a full evaluation and only for situations the department determines meet criteria for an "emergency condition." A chronic pest problem does not qualify as an emergency. The department works closely with commodity groups and other Section 18 applicants to help them develop the information needed to support the application. Significant documentation of the emergency pest problem must accompany a Section 18 request to DPR. This includes details on the nature of the emergency, costs of control, past yields, projected losses, a five-year economic profile for the crop, and evidence of the lack of registered, available alternative pest control practices.

California law requires an evaluation of the impacts of pesticide use on workers and a major focus of DPR's Section 18 review is on the potential effects of the proposed use in the state's labor-intensive agriculture. The request must also include any available residue chemistry data to support a residue tolerance.

If DPR confirms the emergency need and if its scientific review of the residue, chemistry, toxicology, ecotoxicology, phytotoxicity, and efficacy data demonstrates no unacceptable risks, the department forwards the request to U.S. EPA. If U.S. EPA determines the emergency to be valid and the risks are acceptable, it approves the emergency exemption. If the pesticide will be used on food or feed, U.S. EPA will establish a time-limited tolerance to cover any pesticide residues in food that may result.

In California, all uses under a Section 18 emergency exemption require a restricted materials permit from the CAC before purchase and use.

There are four types of Section 18s: specific, quarantine, public health and crisis. Most applications are for specific exemptions. They are 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 will not control. Specific exemp-



A Special Local Need exemption obtained to treat a fruit fly infestation.

tions may be approved for up to one year.

Quarantine exemptions are requested to control the introduction or spread of an invasive pest species not previously found in the United States. Quarantine exemptions may be authorized for up to three years.

Public health exemptions are requested to control a pest that will cause a significant risk to human health. The emergency is based on the risk to human health from the pest. Public health exemptions may be for up to one year.

Crisis exemptions may be issued only when there is an immediate need for a specific, quarantine or public health exemption and there is not enough time to have U.S. EPA review the request through normal time frames. DPR must receive verbal authorization from U.S. EPA before issuance. U.S. EPA performs a preliminary review to ensure there are no concerns and that the required safety findings 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. The applicant may follow with a request for a specific, quarantine or public health emergency exemption. This allows the use to continue until U.S. EPA decides on the corresponding exemption request.

Shirts treated with an antimicrobial pesticide, later removed from store shelves because they were unregistered.

REGISTRATION REQUIREMENTS FOR PRODUCTS MADE OF PESTICIDE IMPREGNATED MATERIALS AND BEARING PESTICIDE CLAIMS

In December 2015, DPR notified stakeholders that each person/company with products made from pesticide-impregnated material sold into or within California under their own company name will require pesticide registration. Products made from pesticide impregnated material may include apparel (e.g. jackets, shirts, hats, socks, pants, shorts) or non-apparel (e.g. bedding, tents, seat covers, chopping blocks, shower curtains, mouse pads) which bear pesticide claims. DPR will require each company to obtain at least one registration for each use category (apparel or non-apparel) of product sold. If impregnated with different pesticides or different percentages of the same pesticide, separate registrations will be required. For additional information on pesticide impregnated materials, see DPR's website: http://cdpr.ca.gov/docs/registration/canot/2015/ca2015-13.pdf.

SECOND GENERATION ANTICOAGULANT RODENTICIDES

In 2014, to protect California's wildlife, DPR adopted regulations designating all second generation anticoagulant rodenticides (SGARs) containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone as California restricted materials, adding additional use restrictions, and revising the definition of a private applicator to refer to the federal definition of agricultural commodity found in Title 40 Code of Federal Regulations Section 171.2(5). Effective, July 1, 2014, SGARs could only be sold by licensed pest control dealers and purchased and used by certified applicators. Restricting the sale of SGARs to certified applicators is expected to significantly mitigate exposure to and protect California's non-target wildlife.

In addition, in 2014, Gov. Jerry Brown signed AB 2657 (Chapter 475) prohibiting the use of any anticoagulant pesticide containing the pesticides brodifacoum, bromadiolone, difenacoum, difethialone in any state park, state wildlife refuge, or state conservancy.

REGISTRATION FEES

By law, DPR's pesticide registration process must be funded by pesticide registration and renewal fees. Pesticide registration fees are paid at the time of

application for registration and annual renewal fees are paid at the end of each year. In January 2015, DPR held a public workshop to discuss an increase in registration fees for pesticide products, followed by a notice to stakeholders, and adoption of regulations. The impetus for the fee increase was to address increases in pesticide registration program costs and to fund the Pesticide Registration Data Management System—to convert the paper-based registration process into an electronic registration process. Effective Oct. 1, 2015, DPR adopted regulations to increase the application fees for pesticide registration from $750 to $1,150 per product. DPR also amended regulations to set an application fee of $25 for all amendments to currently registered products. The amendment fee applies to all types of amendments, including substantive and non-substantive label amendments, amendments to the formulation of pesticide products, notification of minor changes, and label changes required by the U.S. EPA or any other federal or state agency.

POLLINATOR PROTECTION

DPR is at the national forefront of the effort to protect bee health, taking proactive steps and a scientific approach to address concerns about the impact of pesticides on bees and pollinators health.

In 2009, DPR initiated the reevaluation of certain pesticide products containing four neonicotinoid chemicals: imidacloprid, thiamethoxam, clothianidin, and dinotefuran. Reevaluation is the legal mechanism that allows DPR to require the companies who have registered products for use in California to conduct tests and submit data for analysis by DPR scientists. The purpose of the reevaluation process is to provide DPR with a better understanding of the effects of neonicotinoids use on pollinators and provide a credible scientific basis for potential regulatory action to eliminate any significant impact resulting from their use on bee health.

DPR partnered with scientists at the U.S. EPA's Office of Pesticide Programs and Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that the required studies, and methods and procedures used to conduct studies on the effects of neonicotinoids provide useful and reliable information across the board to all three agencies for use in guiding their regulatory actions. A unified approach across jurisdictions is critical as bees and beekeepers are not limited by state borders, nor are their importance to agriculture and society.

A considerable volume of scientific research has been required to be conducted in specified ways as designed by DPR or in collaboration with its partners to elicit the most important and useful data for regulatory purposes. Much of this data has been submitted and evaluated. However, there is more work to be done in order to ensure that any actions taken actually address the perceived decline in bee health.

Each of the four neonicotinoid pesticides have different application rates for specific crops, requiring a substantial number of studies to understand the impact of the different pesticides using the application methods used for each crop group. Studies were required for each of the four neonicotinoids as used in the most relevant representative situations to determine the level of residue that remains in the pollen, nectar, and leaves of plants after multiple applications – residue if found in high enough levels, could result in lethal exposure to adult pollinators. Tests were then required to determine what levels of neonicotinoid pesticide would have lethal effects on pollinator larvae. Finally, U.S. EPA required higher-tiered honey bee studies with input from both DPR and PMRA Health Canada.

Tier II studies, or honey bee feeding studies, examine the effects on colonies following exposures to known concentrations of a pesticide in a food source fed to a bee colony. The registrant for imidacloprid voluntarily agreed to conduct a Tier III study, or full field study. This study looks at long-term effects under environmentally realistic exposure conditions.

In 2014, DPR made second generation anticoagulant rodenticides a restricted class of pesticide and limited their use.

DPR and U.S. EPA, as of 2016, were studying the possible effects of neonicotinoids on pollinators.

In 2015, U.S. EPA and DPR issued a Preliminary Imidacloprid Pollinator Risk Assessment. This assessment is the first of four preliminary pollinator risk assessments for neonicotinoid-containing insecticides. Preliminary pollinator-only risk assessments for the other compounds—clothianidin, thiamethoxam, and dinotefuran—will follow. Comprehensive risk assessments for all neonicotinoids will be completed in the future.

A GUIDE FOR PESTICIDE REGISTRANTS

DPR's "A Guide for Pesticide Registrants" contains systematic instructions for registering, amending and renewing pesticide products in California. To view this guide, please visit: http://www.cdpr.ca.gov/docs/registration/manual/guidance.pdf