[CHAPTER 3]

Pesticide Registration

Pesticide registration is how the Department of Pesticide Regulation (DPR) examines the ingredients of a pesticide product; the site or crop on which it is to be used; the amount, frequency and timing of use; and its potential effect on human health and the environment.

The 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 must evaluate 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 must review the pesticide product label and scientific data and 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. (A small subset of low-risk pesticides may be granted an exemption from registration. *See* 25(b) exemptions *below.*)

A *registrant* is a business or individual that holds the certification of registration and is therefore responsible for the product. In essence, registrants guarantee the accuracy and validity of all language and claims on the label. A registrant can be a chemical company, government agency, importer or any person wishing to market a pest control 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 evaluation. Their role is to assure that, when a product is used under the restrictions and protective measures (that is, mitigation) on the U.S. EPA-registered label, it will cause no harm (that is, significant adverse effect) on human health, nontarget 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 and various other substances used to control pests. *(See in this chapter,* 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. The rest of 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 there for reasons other than pesticidal activity. Pesticides are regulated to control the effect of both the active ingredient and other ingredients in the formulated product.

Data needed to evaluate a registration application. The law requires prospective registrants to send DPR data on potential human health and environmental effects associated with use of their product, including:

The control of pesticides in California is obtained through registration. Manufacturers intending to sell pesticides must register their products and fully comply with the law.

— 1939 department annual report

What Is a Pesticide?

Pesticides are chemicals designed to be harmful to a target pest and purposely introduced into the environment to do their job of managing insects, bacteria, weeds, rodents or other pests. 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 animals (like insects or mice), unwanted plants (weeds) or organisms that cause plant diseases. In addition, both state and federal law include as pesticides products that regulate plant growth, cause plants to drop their leaves or dry plant tissue.

Therefore, 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 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.)

- 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 nontarget organisms.
- Effects on fish and wildlife.
- Worker exposure.

The Registration Branch manages the pesticide data studies collection. Staff catalogs and maintains data received from pesticide registrants. In 2011, the library housed more than 75,000 volumes of data containing about 212,000 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 Branch also manages the Label Resource Center, which maintains all product files for pesticides registered in California, including Section 24(c) and Section 18 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. Label Resource Center staff makes nonconfidential information available to the public, registrants, county agricultural commissioners (CACs), DPR staff, Poison Control Centers, the Legislature and other government agencies.

Categories of Pesticides

DPR registers these 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, 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 nonpesticide material used with a pesticide product or pesticide spray mixture to improve the pesticide's performance or the physical properties of the spray mixture.)

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 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 toxicologists 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

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- Antimicrobials.
- Spray adjuvants.

Birth Defect Prevention Act

In 1984, the Legislature passed the Birth Defect Prevention Act (BDPA, Chapter 669[1], SB 950). The law mandated that registrants of pesticides registered before 1984 bring health effects data on their chemicals up to current scientific standards. It also required that the Department of Pesticide Regulation (DPR) not register new active ingredients without a full complement of health effects studies. The required studies (primarily done on experimental animals) were chronic toxicity, mutagenicity, neurotoxicity, oncogenicity, reproductive effects and teratology. The BDPA required DPR to use these and other data to determine if a pesticide would cause human health problems. If continued use of a pesticide presents a significant health hazard that cannot be adequately mitigated, DPR is required to cancel the registration of products containing that active ingredient.

The BDPA mandated that DPR begin by developing a list of 200 active ingredients that would be the first focus of enforcement. These were chemicals with the most significant data gaps, widespread use, and which were suspected of being of greater health concern. (A data gap means that DPR lacks adequate health effects studies in any one of the required categories noted above.)

In January 1986, DPR notified registrants of data gaps for pesticide products containing any of the 200 priority active ingredients. DPR found that much of the data submitted in response to the data call-in notice did not meet U.S. Environmental Protection Agency guidelines. Because these studies had been performed years earlier, many registrants were unable to get the data necessary to upgrade the studies from the laboratories that did the original work. Although registrants contracted with laboratories for new studies, most failed to complete and submit new chronic health effects studies within the time frames set by law. The BDPA required submission of data on priority-list pesticides by March 1991, a deadline the Legislature later extended to March 1996 (Chapter 1228, Statutes of 1991, SB 550). Later legislation (Chapter 1, Statutes of 1995-1996, SB 1XXX) extended until December 1997 the deadline for submission of final studies on two pesticides, methyl bromide and pentachlorophenol.

In 2001, DPR presented its final report to the Legislature on the status of the chronic health effects studies required by the BDPA. The department reported that of the priority 200 active ingredients, 143 remained subject to the data call-in and no data gaps existed for any of these compounds, including methyl bromide and pentachlorophenol. DPR had granted exemptions for products containing two active ingredients. (Under the BDPA, a pesticide may be exempted from the data requirements if it is determined the chemical has only limited use and there is insignificant exposure to workers or the public.) Of the remaining priority pesticides, 47 had been withdrawn from the market by their manufacturers and DPR had suspended 8 for failure to submit required data. Product registrations are suspended if data for any active ingredient cannot be upgraded with additional information or if data were not submitted. Once a pesticide registration is suspended, registrants must halt all sales. Retail dealers may continue selling affected products for two years and consumers may continue to use products on hand.

In 1992, DPR began calling in data for the 703 registered active ingredients that were not on the priority list, as required by 1991 legislation (Chapter 1227, AB 1742).

By the end of 2010, there were 429 active ingredients no longer subject to data requirements. These active ingredients had been withdrawn from the market by the manufacturers, were suspended by DPR, or were spray adjuvants and not subject to BDPA data requirements. Of the remaining 274 active ingredients, 198 had complete data on file and five were exempt. Another 58 were at various stages in the process; requests were received for waivers or exemptions, which the BDPA allows for those chemicals with insignificant exposure potential. The remaining 13 active ingredients are subject to suspension.

[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 deleted or superseded by later legislation have been omitted.

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.*)

Staff scientists with expertise in chemistry, microbiology, plant physiology, pest and disease prevention, fish and wildlife biology, or environmental fate review data to determine the effects of pesticides on target pests and nontarget effects (that is, effects on species not considered the target pest). The latter includes:

- Nontarget effects on plants (phytotoxicity).
- Fish and wildlife hazards (ecotoxicity).
- Effects on endangered species.
- Effects on the environment, including soil, ground and surface water.
- Pest and disease 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 works 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 make changes in 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 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, Resources Recycling and Recovery, and Fish and Game; the Structural Pest Control Board; Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA), State Water Resources Control Board, Air Resources Board, and Toxic Substances Control Department; the University of California; U.S. EPA, Region 9; U.S. Department of Agriculture; 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.

A decision as to what constitutes adequate directions for use on labels of the many different types of pest control products … requires careful study on the part of all concerned.

— Economic Poisons: California Law and Its Administration (1944)

Results from use of a particular product in another state are not always acceptable evidence of its vales in California. There are cases where a regional difference may influence the effectiveness of an economic poison.

— Economic Poisons: California Law and Its Administration (1944)

- 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 all questions are resolved, including concerns raised by other state agencies. 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 may include 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, mainly fruits, nuts, vegetables and horticultural crops. Most are considered "minor-use crops" for pesticide sales, high in harvested value but planted on relatively small acreage in the United States 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 farm workers in the United States work in California agriculture. That would translate into 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.

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 assure 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 CAC, who has broad discretion to impose site-specific control measures based on local conditions. DPR recommends conditions to be included in the permits.)

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 department annual report

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 deferred after consultation with OEHHA). 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[1], 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 ground water studies if the Pest Management and Licensing Branch confirms the product would reduce risks

[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.

A number of hearings have been held on applications for registration of materials which appears to be of little or no value for the purposes recommended or which were generally detrimental, with the result that such licenses were either refused, the application withdrawn, or the recommendations so modified as to remove objectionable features.

— 1926 department annual report

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). 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 Section 18 discussion below)* and which have since been granted federal registration. Once a pesticide is registered federally, it is no longer eligible for a Section 18. The legislation allows a temporary registration until full registration at DPR is granted. To issue the emergency registration, all required data must be submitted and DPR must determine that it is probable the product will be registered within a year. The emergency registration is for one year with a possible one-year renewal. DPR must also certify there are no indications the product would pose an unacceptable risk to worker safety and that the delay in completing a review of the data was beyond the registrant's control. When the legislation passed, there were often delays of a year or more between U.S. EPA registration and registration in California. In the 1990s, DPR focused on reducing those delays and by the end of the decade, delays were minimal. DPR was often issuing registration concurrently with U.S. EPA. As of 2011 there had been no instances when DPR used a certificate of emergency registration as allowed by SB 283.

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 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 FAC.

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. 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 is also allowed for two years.

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 safer 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

The department takes every opportunity to explain operation of the agricultural chemicals laws to manufacturers and to users, and cooperation and education has assured effective law enforcement.

— 1944 department annual report

The importance of California's excellent pesticides law is attested by the numerous requests for information concerning it which have been received from other states and countries where interest is evident in progressive legislation and control of agricultural chemicals.

— 1939 department annual report

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 2011, 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. Working to remove bureaucratic requirements that were not necessary to protect health and the environment, DPR in 1999 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. *(See 25(b) exemptions, below.)*

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.

Repeal of letter-of-authorization requirement. 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 in support of which the data were used.

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.

Registration of Pest Control Devices

The structural pest control industry sponsored 1998 legislation (Chapter 651, AB 1134) which created a program to require DPR registration of devices used to control wood-destroying pests. On July 1, 2001, it became illegal to sell, own or use a structural pest control device in California unless it is registered or under review by DPR. Under the law, DPR must review device efficacy and safety before registration. These devices typically use microwave energy, electricity or heat to control termites, powderpost 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.

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 as part of its certified regulatory program under CEQA. 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 give a conditional registration (limited to experimental uses) 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 acres or fewer 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

Continuous experimentation and investigation in the field of pest control by competent technical workers result in the appearance of many new insecticides, fungicides, and other agricultural chemical products, as well as improvements in older ones.

— 1939 department annual report

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.

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 certain 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, nonpesticidal uses as foods, medicines or household items. They include substances such as garlic, peppermint, rosemary, corn oil, cedar chips 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.
- 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) special local need (SLN) registrations and Section 18 emergency exemptions. 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) (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 table below compares Section 18s and Section 24(c)s.*

The agricultural chemical problems in California are more numerous and more complex than in most other states. Farmers of California produce more than 200 different commercial crops in a terrain that includes the highest and the lowest altitude in the United States. Many of these specialty crops are not produced elsewhere. The rainfall varies from less than two inches a year in dry interior regions to over 100 inches near the coast. The growing season varies from a full 365 days a year in some areas to less than 100 days in others. Some areas never have snow, others have as much as 37 feet.....

(see next page)

A Section 24(c) can be requested either by the manufacturer as the first party or 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.

Knowledgeable experts must justify and support the special local need and there can be no registered products available to meet the need. 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 cannot 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, nonroutine 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 data to support a residue tolerance.

If DPR confirms the emergency need and if its scientific review of the residue, chemistry, toxicology 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 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.

… Dense redwood forests grow in some parts of the State and other parts are desert wastelands. More than 1,100 separate and distinct soil types have been recognized and mapped in the soil surveys of California. It is evident that California farmers are faced with a complex problem in selecting and using fertilizing materials and pesticides intelligently and effectively. Materials and agricultural practices of value in other parts of the country may be of little or no value in California. A vigilant and careful examination of all agricultural chemicals offered for sale in this State is necessary ....

— 1946 department annual report

Comparing Section 18s and Section 24(c)s

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 expitration date. May be inactivated by applicant, DPR, or U.S. EPA.
Applicant must be thrid-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.

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 exemptions 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 means. 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.