[CHAPTER 1]

California's First Century of Pesticide Regulation

California has regulated pesticides for a century. Its citizens — through their Legislature — have established a comprehensive body of law to control every aspect of pesticide sales and use, and to assure that the state's pesticide regulators also have the tools to assess the impacts of that use. The first pesticide-related law was passed in this state in 1901, and since the 1960s, a whole body of modern, increasingly science-based pesticide law and regulation has come into being.

The California Department of Pesticide Regulation (DPR) protects human health and the environment by regulating pesticide sales and use and by fostering reduced-risk pest management. DPR's strict oversight begins with product evaluation and registration, and continues through statewide licensing of commercial applicators, dealers and consultants, environmental monitoring, and residue testing of fresh produce. In 2001, DPR had an annual budget of approximately $60 million, with a staff of about 460, including scientists from many disciplines. Their work is augmented by approximately 400 biologists working for County Agricultural Commissioners in all 58 counties on local pesticide enforcement.

Putting the Ladybird to Work: colonizing beneficial insects in an orange orchard; 100 ladybirds [ladybugs] to each container.
— Caption on this 1919 Department photograph

The 19th Century: Pests Flourish, New Pesticides Developed

The Industrial Revolution of the mid-19th century made mechanized farming possible. With tractors to plow, farmers could cultivate larger acreages. The availability of machinery promoted intensified, specialized agriculture, with crops bred to a uniformity that made for easier machine processing. But this monocultural mass production provided an ideal environment for insect pests to flourish. At the same time, remarkable new transportation systems made possible both the commercial transport of harvested crops and hitchhiking by insect pests to new homes where no natural predators existed. As migration opened up the American West, farmers cleared forests to garner cultivable lands, and native pests often adapted to the change by acquiring a taste for domestic crops. Moving a crop to a new area can transform a previously unimportant insect into a serious pest. The Colorado potato beetle was a local insect with another name and an appetite limited to wild grasses until potatoes were introduced to the American West from South America and their acreage increased throughout the mid-1800s. To confront the escalating pest problem, the federal government in the 1880s helped establish a system of land-grant colleges to teach the agricultural sciences and research new ways to control insects, weeds and other pests.

Few chemicals were available at the time to fight pests. A number of insecticides had been in use for centuries, primarily mineral, herbal or animal preparations. The most popular were hellebore (a poisonous herb of the lily family), quassia (distilled from various tropical trees of the ailanthus family), lime, and tobacco, all applied in water-based solutions; various types of oils; copper compounds; and of course, sulfur (whose earliest recorded use was by the Summerians well before 2500 BC). In the Middle East, pyrethrum flowers (a member of the chrysanthemum family) were dried, powdered, and sold worldwide as a powerful insecticide, but attempts failed to grow the flower in the U.S. and produce economical amounts of insecticide.

Arsenic, used against insects and rodents for millennia, was typically mixed with food bait to fight household pests. In the mid-1800s, farmers found they could use Paris green, a common, arsenic-containing paint pigment, to kill insects in their fields. Then as now, farmers were searching for pest control that was inexpensive, quickly applied,

and effective. Paris green was swiftly followed by London purple (calcium arsenite), lead arsenate and calcium arsenate. In the 1880s, French grape growers accidentally discovered that Bordeaux mixture, a combination of hydrated lime and copper sulfate, could fight powdery mildew fungus.

The use of pesticides grew tremendously into the 1900s, but the materials used did not change radically. The active ingredients in most pesticides were compounds of arsenic, antimony, selenium, sulfur, thallium zinc, copper, or plant-derived alkaloids. Hydrogen cyanide gas was also used for fumigation, and various oils applied to fight pests. The first selective herbicide was discovered in 1896 when iron sulfate was found to kill broadleaf weeds but not cereal crops. Over the next decades, many other simple inorganic compounds (e.g., sodium nitrate, ammonium sulfate and sulfuric acid) were put into very limited use as herbicides. However, since labor for weed removal was cheap and readily available, farmers were not generally interested in using herbicides. Instead, they used a combination of clean cultivation, tillage, crop rotation with weed-competitive crops, and hand-weeding to keep their weed problems under control.

Likewise, even in the early decades of the 20th century, use of insecticides and fungicides was not widespread, and confined largely to high-value tree fruit crops. Although a few scientists expressed concerns over arsenic residues remaining on sprayed fruits and vegetables, the consensus was that wind and rain removed most residues and in any case, arsenic was not considered harmful in the small amounts present on sprayed produce. Little thought was given to the potential hazard of repeated exposure to small amounts of arsenic present all around, for the chemical was also used to color paper, candles, artificial flowers, fabrics, toys, plates, carpets and clothing.

California's first pesticide law, one of the first in the nation, was passed in 1901.

Early Pesticide Regulation: Focus on Consumer Fraud

With the relatively small number of pesticides in use in the early 20th century, pesticide regulation was a matter of low priority at both the state and federal levels. There was little concern about their long-term effects on health or the environment. The focus of regulation was on protecting pesticide users from fraud by ensuring product quality. Pesticides, like many products of the time (including foods and drugs), were often adulterated or mislabeled. It was not unusual for manufacturers to make extravagant claims for products that were useless at best, and sometimes destructive to the plants on which they were used.

The nation's first pesticide law was passed in New York in 1898. Oregon and Texas followed in 1899, and California and Washington in 1901. California's law (Act of February 28, 1901, Chapter 53) was entitled "An act to prevent fraud in the sale of Paris green used as an insecticide," and charged the Director of the University of California Agricultural Experiment Station with ensuring the quality of a single arsenic-based product, Paris green, the most widely used insecticide. Dealers were required to submit samples of their products to the Experiment Station with a written statement describing brand names, number of pounds contained in each package, name and address of manufacturer, and percentage of Paris green contained. "The statement so furnished," the law declared, "shall be considered as constituting a guarantee to the purchaser that every package . . . contains not less than the amount . . . set forth in the statement." The Agricultural Experiment Station was tasked with analyzing samples. Sellers of deficient products were guilty of a misdemeanor and according to the new law, "shall be fined not less than fifty dollars nor more than two hundred dollars, together with the costs of the suit."

The commercial success of Paris green spurred the development of other arsenic-based pesticides and Congress responded in 1910 by passing a pesticide product quality law, the Federal Insecticide Act, essentially a labeling law concerned with protecting consumers from ineffective pesticides or deceptive labeling. The statute, applauded for its inclusiveness, applied to a large class of products — insecticides and fungicides — not previously covered by any laws. However, the new law contained neither a federal registration requirement nor any significant safety standards.

California's parallel legislation, the State Insecticide and Fungicide Act of 1911 (Chapter 653), was also primarily concerned with mislabeling and adulteration. The

State Legislature had appointed a committee of California pesticide users and manufacturers to draft the new law, and they recommended taking wording from the California Fertilizer Act of 1903. The State's new statute went beyond the 1910 federal pesticide control law in that it required all manufacturers, importers and dealers in insecticides and fungicides to register their products (for a $1 fee) with the Secretary of the Board of Regents of the University of California, submitting a statement on "the component parts of the substances which they proposed to offer for sale." Proper labeling was also required, stating the name of the product, name and address of the manufacturer, place of manufacture, and chemical analysis showing "the percentage of each substance claimed to have insecticidal value, the form in which each is present and the materials from which derived, and the percentage of inert ingredients." The purpose of this latter provision "was to enable the user to know the insecticidal value of the material, and also to make the manufacturer more careful as to the composition of his products." This section was described at the time as the "most radical of any of the requirements, and was the one most seriously objected to by those who wished to oppose the law . . . Practically the only serious objections came from the makers of 'secret' remedies who had been profiting by the use of fictitious names."

The law also required that the Agricultural Experiment Station sample and analyze all registered pesticides annually. However, the number of registered brands in the first two years after passage of the law grew "well toward 10,000," and it became quickly apparent that annual analysis would be impossible. The law was amended to remove that requirement in 1914. At the same time lobbying by manufacturers and dealers prompted the Legislature to eliminate the requirement for detailed pesticide labeling, requiring instead a "general" statement of the contents. A second amendment exempted a number of products from the registration requirements, including several household insecticides (for example, flypaper, mothballs, ant poison), as well as sheep dip, lice killer, and sulfur. In 1916, further amendments provided for an additional registration fee and for issuing certificates of registration. In 1917, new rules required pest control businesses to have a certificate of qualification from the County Horticultural Commissioner (later to be called County Agricultural Commissioner).

A 1911 California statute required registration of pesticide products and "a statement of component parts."

In 1919, the California Department of Agriculture (CDA) was created from the State Commission on Horticulture. In 1920, legislation brought "the several County Horticultural Commissioners in California, a total of 52, and their deputies . . . under the direction of the Director of Agriculture, in the performance of their duties pertaining to the standardization of fruits, vegetables and other plant products, and in the prevention of the illegal introduction into the state of plant diseases, noxious weeds and insects and other animal pests . . . This cooperation is appreciated and fills a long-felt want in the Department," the Department said in its annual report. "It is a means by which the Department is kept in touch with the undertakings and accomplishments of the horticultural commissioners in their endeavor to serve the fruit growers and farmers of the state."

The new Department of Agriculture, in its first annual report in 1920, declared the need for a new law to regulate pesticide manufacture and sale, to "accomplish the following purposes:

- *Encourage the manufacture and sale of standard and well-tried remedies.*
- *Discourage the sale of poorly compounded or low-grade remedies prepared in a poorly equipped factory, or by the careless manufacturer.*
- *Prohibit the sale of worthless preparations placed on the market either through ignorance or with intent to defraud.*
- *Prohibit the sale of preparations which are injurious to cultivated plants or domestic animals, or are a menace to the public health.*
- *Restrain the activities of the clever fakir who profits by falsely claiming some new discovery or some mysteriously acting poison, and in reality is selling some common and well-known substance under camouflage of coloring matter or odor."*

With the 1921 passage of the Economic Poisons Act (Act of June 3, 1921, Chapter 729), regulatory authority over pesticides was transferred from the University of California to CDA. ("Economic poison" was a synonym used for "pesticide."

Legislation in the 1990s substituted statutory references to "economic poison" with the more commonly understood "pesticide.") The1921 law also expanded CDA's authority beyond insecticides and fungicides. The statute was described in a 1921 Department report as "a novelty in legislation of this type, there being no other law, state or national, regulating the manufacture and sale of rodent poisons and weed poisons." The legislation gave CDA authority to control not only the manufacture and sale but also the use of pesticides. However, the Department recognized that "the State is a large one and to attempt to distribute a corps of inspectors large enough to detect fraudulent practices would be a hopeless task . . . (Therefore) arrangements are now being made for the appointment of five or six County Horticultural Commissioners to act as collaborators in the enforcement of the Economic Poison Act."

The new Economic Poison Act also required manufacturers when registering their products to supply information on how a product was formulated, as well as a product sample to assure quality standards. Cancellation or denial of registration was authorized for products found detrimental to agriculture or public health. Throughout the 1920s, CDA used its in-house labs to "test the efficacy of insecticides and fungicides for which it appears extravagant claims have been made." Evidence gathered was used to file misdemeanor charges against the manufacturer if the product was already registered, or to cancel or refuse registration.

Enforcement of the law protects the manufacturer against unfair competition and the consumer against an army of unscrupulous individuals, lying in wait to get the consumer's dollar without giving value received. The industries themselves are responsible for passage of the agricultural chemical laws and cooperate in their enforcement.
– 1933 Department annual report

The right of the CDA Director to refuse to register or to cancel the registration of a firm "attempting to sell fraudulent or worthless insecticides" was upheld in a 1925 Appellate Court decision, overturning an earlier Superior Court decision that had held the 1921 Economic Poison Act unconstitutional *(A.R. Gregory v. CDA).*

Although CDA had the authority to refuse to register a pesticide if it was proven ineffective, without data in hand, there was no way of determining efficacy before a product was registered and used in the field, forcing the Department into a situation where it had to grant a registration. This loophole was closed by the Legislature in 1929 when it gave the Department authority to require "practical demonstration as may be necessary" to determine that products were effective and that they were not "generally detrimental or seriously injurious to vegetation." Although the statutes allowed cancellation based on health or environmental problems, the acknowledged focus of programs of the time was adulteration and misbranding. CDA's 1934 annual report said that its program "affords protection to the consumer as to quality and quantity and to the manufacturer by preventing unfair competition." Hundreds of product samples were analyzed each year, and about 30 percent were routinely found "extensively deficient." (By the 1940s, that percentage had dropped to about 10 percent, and deficiencies were attributed more to "irreducible error in manufacturing technique and not to an attempt to defraud.")

The 1920s: Food Residues Become a Concern

Adulteration of food by dishonest merchants — a centuries-old problem — worsened in the 19th century as a rapidly urbanizing America became more dependent on faraway sources of food. Poisonous adulterants were not uncommon, and people were sickened and even died as a result. In 1906, Congress passed the Pure Food and Drug Act, putting the U.S. Bureau of Chemistry (later to be reorganized as the U.S. Food and Drug Administration) in charge of protecting consumers against adulterated, misbranded, or impure food and drugs. Pesticide residues on food were not a significant concern until the 1920s, when the issue was pushed to the forefront with increasing pesticide use by farmers, and by a series of reported illnesses and several well-publicized seizures of fruit with high arsenic levels by health officials in major American cities.

Federal and state agricultural officials responded with reassurances that arsenic residues were not a concern if the pesticide was properly applied, and embarked on educational campaigns to persuade farmers not to overspray. In December 1925, a handful of illnesses among British consumers of American-grown fruit prompted the English authorities to warn against consumption of foreign-grown apples, and sales of California apples plummeted. In response, State pesticide regulators the next year began analyzing small quantities of fresh produce for residues and in 1927, the California

Legislature passed the Chemical Spray Residue Act. This law made it illegal to pack, ship, or sell fruits or vegetables with harmful pesticide residues. It also established allowable arsenic residues that mirrored those that had been established by the federal government that same year. These allowable residues (called tolerances) were set by the U.S. Bureau of Chemistry for apples and pears in interstate commerce and for export.

California's Spray Residue Act established monitoring programs designed not only to safeguard the consumer against harmful residues, but also to certify California-grown fruit as free of excess residues. The Department operated a voluntary, fee-based certification program until the 1940s. The goal was to ensure that no shipments of California fruit were confiscated by other states or nations because of excess residues. When illegal residues were found, the lots of produce were quarantined and growers were instructed on how to remove residues with an acid wash. However, growers whose crops repeatedly had residues over allowable levels faced hefty fines and even jail sentences.

In 1934, the Economic Poison Act was amended to prohibit pesticide sales in anything other than the registrant's container, with "name and percent of every ingredient . . . intended for use on or sold for application to any food crop in such a way as to leave a residue deleterious to health must be plainly stated on label." *Deleterious residues* were defined as residues of arsenic, fluorine, and lead, the only chemicals for which the federal government had tolerances established. CDA expanded its monitoring program to sample for these residues, and by 1935 was taking 25,000 samples a year, 22,000 under the voluntary certification program and 3,000 as part of the Department's use enforcement program.

With the introduction of many new synthetic organic pesticides in the late 1930s and 1940s, residue sampling expanded to test for DDT and other organic compounds. In 1949, the Spray Residue Act was amended to expand the definition of potentially harmful spray residues beyond those of arsenic, fluorine and lead to encompass "any pesticide or constituent thereof which on produce is harmful to human health in quantities greater than a maximum amount or permissible tolerances established by rules and regulations of the Director." The amendments also gave the Director authority to set tolerances. Laws passed in 1967 and 1983 reinforced the right of California's Agriculture Director to review federal tolerances and adopt them in the State, or to set more stringent tolerances. With the creation of the Department of Pesticide Regulation (DPR) in 1991, that authority was transferred to the DPR Director. The federal Food Quality Protection Act of 1996 preempted states from setting their own tolerances.

In 1953, the Legislature amended the Spray Residue Act to include grains used to feed livestock or poultry. This was in response to the Department of Agriculture's concerns that it could not take legal action in cases where pesticide misuse contaminated anything other than fruits or vegetables.

At the federal level, the Food, Drug, and Cosmetic Act was amended in 1954 to prohibit registration of any food-use pesticide that left residues until and unless the U.S. Food and Drug Administration (U.S. FDA) issued a tolerance that sanctioned "safe" residue levels.

The Department has had a produce testing program since the 1920s.

New Pesticides and the "Green Revolution"

By the mid-1930s, a wider variety of pesticides were being used, including pyrethrins, rotenone-containing preparations, zinc and iron sulfate, petroleum oils, and the new products of organic chemistry. The new products included agents that controlled nematodes and weeds, that defoliated plants and preserved wood, and that stimulated or retarded plant growth. In addition, as CDA reported in 1944, "chemists (have) synthesized emulsifiers, wetting agents, solvents and similar adjuvants or accessory substances which . . . greatly facilitate accomplishment of pest control."

That same year, the Department expressed concern about what it called the "hazards of new products. The rapid increase in the use of synthetic organic chemicals," the Department said in its annual report, "illustrates the need for study to provide for intelligent handling of products of this nature. Possible industrial health hazards of new products should be anticipated. Problems constantly arise as to hazards to workers not only in mixing of chemicals but in making field applications. When a chemical is not acutely poisonous, generally little is known as to the extent of its injuriousness.

Information should be at hand with regard to insidious chronic poisoning of newly developed materials, as well as to their acute toxicity." (It would be another 40 years before the State's pesticide regulators received legal authority and developed the scientific expertise to begin the task of collecting data and analyzing the potential long-term effects of pesticide exposure.)

The Department took note of these "remarkable advances and unprecedented developments in the chemistry of pest control," which along with new, high-yield plant varieties, chemical fertilizers, irrigation technology, and mechanization, helped prompt the so-called "Green Revolution." By the late 1940s, the use of inorganic arsenic-, lead- and fluorine-based compounds had significantly decreased. New, organic compounds like DDT, 2,4-D and ethyl parathion were revolutionizing agriculture, increasing yields and reducing the need for higher-priced, labor-intensive weed and insect control methods and pest-reducing practices.

The number of registered products continued to grow as manufacturers rushed to market the new products of organic chemistry. A 1945 Department report noted the increase in product registrations, stating that in 1925, "only 1,700 products were on the market for pest control purposes in California." In 1935, "the total had doubled to about 3,500 products, and (in 1945) over 7,000 different (pesticides were) registered for sale in this State." By 1950, there were 9,070 registered products, and by 1956, there were 11,904. (The number of registered products continues to change from year to year within a narrow range; in 2000, it was about 11,500 products.)

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

Pesticide applications by aircraft increased as well. In 1934, 65,479 acres were treated by aircraft, by 1939 it was 296,000 acres, in 1947, 614,348 acres and by 1953, 3.5 million acres. With this technological development came increasing concerns about and problems with aerial drift.

In 1947, Congress responded to the increasing use of pesticides by enacting the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This law governing the registration, sale, possession and use of pesticides required that pesticides distributed in interstate commerce be registered with the U.S. Department of Agriculture (USDA). The law also contained a rudimentary labeling provision. Like its 1920 predecessor, FIFRA in 1947 was more concerned with product quality and efficacy than with safety. However, the statute declared pesticides "misbranded" if they were harmful to man, animals or vegetation (except weeds) when properly used.

Major defects in the new law soon became apparent. The registration process was largely a hollow formality since the U.S. Secretary of Agriculture had no power to refuse registration, even for a chemical considered highly dangerous. The Secretary could register a formal protest against registration but this did not prevent the registrant from manufacturing or distributing the product. The only way the Secretary could deal with a hazardous product was to take legal action for misbranding or adulteration, with the burden of proof on the government. Congress did not deal with this aspect of FIFRA until it revised the law to strengthen regulatory authority in 1964.

In California, regulators had clearer authority. Since the passage of the Economic Poison Act of 1921 and its 1929 amendments, the state's Director of Agriculture (and subsequently the Director of DPR) could cancel a registration, or refuse to register, any pesticide determined to be ineffective, damaging to non-target organisms, or detrimental to public health and safety when properly used. The Director also had authority to cancel or refuse registration to registrants who made false or misleading statements about their products.

Another defect in the 1947 FIFRA law was a lack of federal regulatory control on use of a pesticide in the field. That was not true in California, where the Director of Agriculture had some authority over use practices since the 1920s. Then came the dramatic increase in pesticide use in the late 1940s. Growers experimented with the new products, applying them in a variety of ways on a variety of crops, sometimes with insufficient knowledge of their effects or toxicity. Benefits were immediately apparent — healthy plants and increased yields. However, there were problems as well. Drift caused damage to non-target crops and killed livestock and honeybees. Improper applications caused injury and death to workers and others. Regulators realized they needed stronger, more targeted control measures.

Problems Prompt New Controls

A joint legislative committee was set up in 1947 to study the problems. Resulting 1949 legislation put a clear emphasis on safety in regulating pesticides, and led to the State's first regulations which governed pesticide handling and imposed restrictions on certain pesticides with the potential to cause injury to people, crops, or the environment. Permits were required to possess or use these pesticides.

With passage of this statute, regulation of professional applicators moved from the county level to become a responsibility shared by the State and the County Agricultural Commissioners. As far back as 1917, pest control businesses in California were required to obtain a certificate of qualification from the County Agricultural Commissioner. In 1935, the State Department of Agriculture was given the authority to adopt regulations, but the enforcement was left at the county level. In 1949, California made its first statewide effort to regulate pesticide application with legislation (Act of July 20, 1949, Chapter 1043) that required professional agricultural applicators and pilots be licensed by the State Department of Agriculture, with registration required in the county of operation. The new law also required applicators to keep certain records of applications and report this information to the County Agricultural Commissioner.

In 1949, state law was amended to expand state labeling requirements to adjuvants. In 1967, legislation gave the Department of Agriculture full authority to require registration and oversee the use of adjuvants. Adjuvants (emulsifiers, spreaders, wetting agents and other efficacy enhancers) are subject to registration in California but are exempt from federal registration requirements.

In 1949, California passed its first laws to regulate applications of pesticides statewide.

California's regulations continued to be fine-tuned throughout the 1950s, as an increasing number of newly developed but highly toxic chemicals were introduced to the market. Detailed regulations were adopted including buffer zones to protect adjacent crops and residences, and restrictions on nozzle sizes, wind velocities, and other factors to limit drift.

Silent Spring: Concerns About Long-Term Effects

The 1960s forever changed the way society viewed pesticides. Although problems had been apparent for some time — most notably, concerns about possible acute health effects and the increasing resistance of some pests to the new products — the signal event was the publication in 1962 of *Silent Spring*. Author Rachel Carson presented compelling arguments that pesticides and other chemicals were being used with little regard for their impact on either human health or the environment. *Silent Spring* is widely considered to have sparked the modern environmental movement.

Many changes in federal and state law have come about in the more than 40 years since *Silent Spring*. In 1969, Congress passed the National Environmental Policy Act (NEPA), which required federal agencies to consider environmental matters before undertaking new actions.

In 1970, the U.S. Environmental Protection Agency (U.S. EPA) was created to bring cohesion to the expansion of federal environmental activities. Both the USDA pesticide registration functions and the tolerance-setting authority that had been the province of the U.S. FDA were transferred to U.S. EPA (although U.S. FDA retained its residue monitoring program).

In 1969 and 1970, landmark legislation was enacted in California that required a "thorough evaluation" of pesticides before registration and gave the Department of Agriculture clearer authority to establish criteria for studies to be submitted by pesticide manufacturers. This legislation also gave the Department distinct authority to place restrictions on how pesticides may be used. The Director was also required to begin a program of orderly and continuous evaluation of pesticides and eliminate from use those posing a danger to the agricultural or nonagricultural environment. Two years later, the Department hired its first "in-house" evaluation scientists to review data submitted to support registration requests. The Department previously had relied on scientists at the University of California and in other state departments to evaluate data.

In 1971, a mill assessment (set at that time at $0.008 per dollar of pesticide sales) was enacted. Beginning in 1989, the Legislature approved a series of increases in the assessment level, and at the same time decreased the level of General Fund support for department activities. *(See Chapter 15 for a more detailed discussion of regulatory funding.)*

The Legislature changed the name of the Department in 1972 to the *Department of Food and Agriculture*. The name change acknowledged a widening of the Department's mission to include a statutory mandate not only to promote and protect California agriculture but also to protect public health, safety, and welfare. In 1991, the pesticide regulatory program was given departmental status as the Department of Pesticide Regulation (DPR), under the newly formed California Environmental Protection Agency (Cal/EPA).

In 1972, legislation transferred authority over the pesticide workplace to the State's pesticide regulatory program.

Legislation passed in 1972 (Chapter 794) made the development of pesticide worker safety regulations the joint and mutual responsibility of the California Department of Food and Agriculture (CDFA) and the Department of Health Services. (With the formation of Cal/EPA, DHS' consultation role was transferred to Cal/EPA's Office of Environmental Health Hazard Assessment.) The legislation also delegated pesticide use enforcement to CDFA and the County Agricultural Commissioners. With this, CDFA became the primary state agency responsible for the occupational safety of employees handling agricultural pesticides. CDFA's Worker Health and Safety program took a forceful role in making the workplace safer for pesticide users and workers. Regulations were adopted in the 1970s requiring pesticide handlers to receive safety training, that they be provided protective clothing and equipment, and mandating longer intervals before workers could re-enter fields treated with some pesticides. California also became the first state to require handlers to use closed systems when mixing and loading certain highly toxic pesticides into application equipment. The Department also established a pesticide illness reporting and investigation system still unique in the nation.

In 1972, FIFRA was extensively amended, virtually rewriting the law. The goal was primarily to strengthen its enforcement provisions and to shift its emphasis from labeling and efficacy to protection of health and the environment. The 1972 amendments also extended the scope of federal law to give U.S. EPA exclusive authority over pesticide labeling, establish standards for the certification of restricted pesticide applicators, and cover intrastate registrations to ensure states did not register pesticides that were not registered federally. The provisions were tested after California imposed additional data requirements as a condition of registration. The National Agricultural Chemical Association and other industry groups sued CDFA in 1980, arguing that federal law preempted states from imposing their own registration requirements and fees. A federal district court found in favor of the Department, ruling there was no federal preemption of state registration requirements. The litigants also tried unsuccessfully to persuade Congress to amend FIFRA to prevent states from requiring data that were different from or additional to data required by U.S. EPA.

In 1972, CDFA began licensing agricultural pest control advisers, with a later requirement for training and continuing education. Adviser licensing was directed at setting standards for professional conduct for those who advise growers on pest control methods and by requiring that pest control recommendations be in writing, making advisers legally accountable. In 1999, new regulations were adopted requiring that after 2002, prospective advisers must take more college courses related to integrated pest management and sustainable agriculture.

The 1970s saw an expansion of CDFA's pesticide enforcement focus. Federal grant money that followed the passage of the 1972 FIFRA amendments allowed the Department to upgrade its field offices with additional staff. This made possible more training and better supervision of the County Agricultural Commissioners, who have primary responsibility for field enforcement of the state's pesticide regulations.[1] Field inspection

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1 Rather than establishing a uniform system of regulation of pesticide use throughout the state, the Legislature has chosen a flexible system, adjusting local need and environmental concerns and placing wide discretion in County Agricultural Commissioners, manifesting its intent that local concerns and conditions be given paramount importance.

Preemption: Federal, State, and Local Jurisdiction Over Pesticide Use

Federal laws are always preeminent: once Congress passes laws that occupy an area, no government at a lower tier, i.e., at the state or local level, may pass laws that conflict with the federal laws. For example, FIFRA clearly states that pesticide labeling is regulated only at the federal level, by that preempting state or local laws in this arena. In other words, no state or local government can dictate what is on a pesticide product label. (However, a state can refuse to allow registration of a product and hence the possession, sale and use of any pesticide not meeting its own standards.)

The California Constitution also allows the State to preempt local jurisdictions. The Constitution states that local governing bodies (for example, City Councils or Boards of Supervisors) may pass laws (called "ordinances" at the local level) provided they do not conflict with state law. However, California State law (Chapter 1386, Statutes of 1984) states that no local government "may prohibit or in any way attempt to regulate any matter relating to the registration, sale, transportation, or use of pesticides, and any of these [local] ordinances, laws, or regulations are void and of no force or effect." (FAC Section 11501.1)

The 1984 legislation was passed in response to a State Supreme Court ruling that same year in *The People v. County of Mendocino*. In that case, the State Attorney General had sued the county, arguing that State law preempted a 1979 initiative approved by Mendocino County voters to prohibit the aerial application in the county of phenoxy herbicides. The herbicides were used by a forest products company to retard hardwood growth in favor of conifer growth. The initiative followed a 1977 incident in which an aerial herbicide application drifted nearly three miles onto school buses.

A lower court ruled in favor of the State, finding that California law preempted county regulation of pesticide use. However, in 1984 the State Supreme Court disagreed, ruling that "the Legislature has not preempted local regulation of pesticide use," that Mendocino's "initiative ordinance neither duplicates nor contradicts any statute," and that voters in any California county could prohibit the use of pesticides in that county, even if such use were authorized by state and federal law.

The Court stated, "The legislative history (of FIFRA) does not demonstrate a clear Congressional intention to preempt traditional local police powers to regulate the use of pesticides or to preempt state power to distribute its regulatory authority between itself and its political subdivisions."

In response, the State Legislature passed a bill adding Section 11501.1 to the Food and Agricultural Code, stating it is "the intent of the Legislature to overturn" the Supreme Court ruling, and that "matters relating to (pesticides) are of a statewide interest and concern and are to be administered on a statewide basis by the state unless specific exceptions are made in state legislation for local administration."

In an unpublished 1986 opinion, the Court of Appeal for the Third Appellate District found FAC Section 11501.1 constitutional and in so doing invalidated a Trinity County local pesticide ordinance.

(Local governing bodies may pass ordinances that regulate or restrict pesticide use in their own operations. For example, a City Council may pass an ordinance that restricts pesticide use in municipal buildings and in public parks, and a school district board can decree that certain pesticides cannot be used in schools.)

In 1991, in *Wisconsin Public Intervenor v. Ralph Mortier*, the U.S. Supreme Court ruled that, absent state law to the contrary, federal pesticide law does not preempt local regulations dealing with the use of pesticides. The U.S. Supreme Court ruled that FIFRA "leaves the allocation of regulatory authority to the absolute discretion of the states themselves, including the options of . . . leaving local regulation of pesticides in the hands of local authorities under existing state laws." Because California law clearly prohibits local ordinances, the 1991 U.S. Supreme Court decision had no effect in California.

In 1996, legislation (Chapter 361, AB 124) clarified but did not significantly alter DPR's preemption authority. The legislation required the Department to notify any local agency that promulgates an ordinance governing the sales, use, or handling of pesticides whenever the Department determines that the ordinance is preempted by existing State law. The bill also required the Department, if necessary, to file court action to have the ordinance invalidated and to prohibit its enforcement.

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procedures were standardized, their scope widened to include all aspects of pesticide use (with a particular emphasis on worker safety), record-keeping, storage, and disposal.

In 1977, CDFA recognized the increasing importance of pesticide regulation by elevating the program to Division status. From the 1920s through the 1950s, pesticide registration and regulation had been only one of the functions of the Department's bureau (later division) of chemistry. When the Department's various chemistry laboratories were consolidated, the regulation of both pesticides and fertilizers became the province of the Bureau of Agricultural Chemicals and Feed, within the Division of Inspection Services. In 1977, pesticide functions were split off to CDFA's new Division of Pest Management, Environmental Protection and Worker Safety.

California's Environmental Quality Act and Its Impact on Pesticide Regulation

In 1970, California passed its own version of NEPA with the enactment of the California Environmental Quality Act (CEQA). It is the State's principal statute mandating environmental impact review of development projects in California and applies generally to all state and local agencies and to private activities that the agencies finance or regulate. CEQA requires, among other things, that an environmental impact report be developed and subject to public review and comment before a permit is issued for a project that might impact environmental quality.

The 1980s were highlighted by an expansion of pesticide regulatory authority and passage of a number of statutory mandates.

In 1976, the State Attorney General issued an opinion that the State's pesticide regulatory program had to comply with CEQA when registering a pesticide or granting a license, permit or certificate. In other words, the opinion stated, under the terms of CEQA, the Department was required to prepare an environmental impact report (EIR) before registering any of the several hundred new pesticide products that come onto the market each year. In the same vein, County Agricultural Commissioners were required to prepare an EIR before approving several thousand permits issued annually to users of certain, high-hazard ("restricted") pesticides.

After a specially convened Environmental Assessment Team determined this was not feasible, legislation was passed in 1978 (Chapter 308, AB 3765) which provided for an abbreviated environmental review procedure that would serve as the functional equivalent to a full-scale EIR. This meant that the State and the County Agricultural Commissioners did not have to prepare an EIR on each product or permit approved. Instead of an EIR, documentation of environmental impacts, mitigation measures, and alternatives were required. This necessitated expanding review of data before registration, a revision of Department regulations relating to pesticide registration and evaluation, public notice of proposed actions and decisions, and requiring site-specific permits to use certain restricted pesticides. The regulations also set up a mechanism for interaction between the Department and other State agencies which have responsibility for resources that may be affected by pesticides *(see Pesticide Registration and Evaluation Committee, Chapter 3)*. In December 1979, the State's pesticide regulatory program was certified by the State Resources Agency as functionally equivalent to CEQA. Any substantial changes in the certified regulatory program must be submitted to the Secretary of the Resources Agency for review, and the Secretary has the authority to determine whether the change alters the program such that it no longer meets the qualification for certification.

The 1980s: A Decade of Legislative Mandates

With the 1980s came far-reaching legislation that added authority and functions to the Division. In 1983, Governor Deukmejian issued Executive Order D-15-83, designating the pesticide regulatory program within CDFA as the lead agency in matters pertaining to pesticides. (Since its creation in 1991 by Governor's Reorganization Plan Number One [GRP-1], DPR has continued as the State agency with primacy over pesticide use and regulation.)

Increasing concern about air pollution resulted in the passage of 1983 legislation (Chapter 1047, AB 1807, sometimes called the Toxic Air Contaminant Act) to give the

State broader authority over airborne toxins. While most of the control measures were the responsibility of the Air Resources Board, industry concerns about CDFA primacy over pesticide regulation led to DPR being given the lead in evaluating pesticides in ambient air and developing control measures.

In 1984, the Legislature passed the Birth Defect Prevention Act (Chapter 669, SB 950) which required that all registered pesticides have complete and adequate chronic health effects studies. This increased the scope and responsibilities of CDFA's Registration functions and led to the creation in 1985 of a separate Medical Toxicology Branch to evaluate toxicological data and prepare health evaluations and risk assessments. California's is the only pesticide regulatory program in the country with a large and highly regarded scientific and technical staff that evaluates toxicology, environmental and other data required for pesticide registration, and conducts comprehensive risk assessments, including assessment of dietary risk.

The Pesticide Contamination Prevention Act (Chapter 1298, Statutes of 1985, AB 2021) focused on mitigating the effects of pesticides in ground water. The law required the Department to establish a database of wells sampled for pesticides, to collect data on the physical properties of pesticides that might lead to ground water contamination, and to control the use of and monitor for these pesticides.

The 1980s also marked the continued expansion of the Department's pesticide enforcement program. Enforcement Branch staffing was increased and legislation passed to enhance enforcement authority. AB 1614 (Chapter 943, Statutes of 1985) authorized the County Agricultural Commissioners to levy direct civil penalties on persons for violations of specified provisions relating to pesticides. Subsequent legislation (Chapter 843, Statutes of 1989, AB 1873) gave a more limited penalty authority to Department staff, and in 2000 (Chapter 806, SB 1970), DPR was given authority to levy civil penalties for serious cases resulting from high-priority investigations or multi-jurisdictional violations. AB 1142 (Chapter 908, Statutes of 1988) improved the Director's authority to seize and destroy a crop treated with a pesticide not registered for that crop.

In the 1980s, the U.S. EPA began developing a national Worker Protection Standard, initially modeling it on California's pioneering work in this area. Although the national worker protection standard that went into effect in 1995 differed in some respects from California's program, it had a common foundation and an essential similarity in purpose. Most elements of California's worker safety program exceeded the federal standard and where it did not, regulatory changes were made to bring those portions into compliance.

In 1988, Congress again amended FIFRA, strengthening U.S. EPA's authority in several major areas. The principal focus of the amendments was to accelerate the pesticide reregistration process and authorize the collection of fees to support re-registration activities. (To ensure that previously registered pesticides measure up to current scientific and regulatory standards, FIFRA requires the review and "re-registration" of all existing pesticides.)

During the 1980s, the decades-old residue monitoring program was enhanced with the addition of three new elements, including a program to test raw produce destined for processing (Produce Destined for Processing Program), and another to sample crops before harvesting (Preharvest Program). The most significant addition was the Priority Pesticide Program, designed to provide data useful for accurate assessments of dietary risk. With it, the Department began targeted sampling of commodities known to have been treated with pesticides of health concern. In the 1990s, the preharvest and processing programs were eliminated after several years of monitoring data demonstrated consistently lower percentages of detectable residues and lower rates of violations than in the Marketplace Surveillance Program. *(See Chapter 8 for more information on residue monitoring programs.)*

In 1990, responding to the public's concern about food safety, California expanded pesticide use reporting requirements to include all applications made to agricultural food crops and many non-agricultural applications as well. This replaced a system of limited use reporting that began in the 1950s. Farmers and pest control businesses now provide complete, site- and time-specific documentation of every pesticide application made to agricultural food crops, including post-harvest applications. In addition, reporting requirements also extend to applications by professional structural pest control companies, and to applications on parks, golf courses, cemeteries, rangeland and pastures, and

In 1990, California established the nation's first system for mandatory reporting of all agricultural pesticide use.

along roadside and railroad rights-of-way. *(See Chapter 10 for more information on pesticide use reporting.)*

What is a pesticide?

A pesticide is any substance or mixture of substances intended to control, destroy, repel, or attract a pest. Any living 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 microorganisms (like plant diseases and viruses). Though often misunderstood to refer only to insecticides, the term pesticide also applies to herbicides, fungicides, and various other substances used to control pests. Under U.S. and California law, a pesticide is also any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

Pesticide Regulation Given Departmental Status

In 1991, California's environmental authority was unified in a single Cabinet-level agency — the California Environmental Protection Agency (Cal/EPA). This brought the Air Resources Board, State Water Resources Control Board, and Integrated Waste Management Board under an umbrella agency with the newly created Department of Toxic Substances Control and Office of Environmental Health Hazard Assessment (OEHHA). As part of this reorganization, the pesticide regulation program was removed from CDFA and given departmental status as the Department of Pesticide Regulation within Cal/EPA. All pesticide-related statutory responsibilities and authorities were transferred to DPR with the exception of the Biological Control Program and the pesticide residue laboratory, which remained with CDFA, and local enforcement duties, which are under the County Agricultural Commissioners.

Cal/EPA was created with six primary goals. These are to: 1) focus on those activities, processes and substances presenting the greatest risk to public health and the environment; 2) set risk-based priorities using the best, most consistent science available; 3) provide vigorous and fair enforcement of the law, not only for public protection, but also to assure that law-abiding businesses are not undercut by unscrupulous competitors; 4) open the regulatory process for public participation; 5) view environmental protection and economic progress as complementary goals; and 6) prevent pollution from being created, rather than attempting to control it after the fact. The reorganization enhanced the State's effectiveness to protect the environment by giving Cal/EPA responsibility for coordinating issues which cross jurisdictional lines.

DPR, with primary responsibility for regulating pesticide use and its potential impacts on water, air, soil, and biological organisms, had long had a cross-media program which develops and enforces mitigation measures that account for interactions across media. At the same time, several regulatory agencies have general jurisdiction and authority over specific media, such as the Air Resources Board (air), State Water Resources Control Board (water), and the Department of Fish and Game (fish and wildlife). In recognition of these roles, DPR has entered into a number of memoranda of understanding or agreements with such agencies to ensure a coordinated and effective approach to pesticide regulation regardless of the media impacted. In addition to these written cooperative agreements, DPR engages in frequent interagency consultations. Such consultations may be program-specific. For example, DPR is directed in statute to consult with OEHHA concerning the joint adoption of worker protection regulations as well as registration and risk assessment actions. In other cases, the consultation may be more systematic, such as a standing interagency advisory committee. DPR chairs advisory committees, including the Pesticide Registration and Evaluation Committee and the Pest Management Advisory Committee.

Accomplishments and Future Directions

DPR's primary mission is ensuring the safe use of pesticides. Since its creation in 1991, the Department has made significant strides in enhancing worker and environmental protections, strengthening uniformity of enforcement in the field while maintaining local discretion and flexibility, streamlining the regulatory process to encourage registration of safer materials, encouraging the development and use of reduced-risk pest management practices, and using existing and new statutory requirements to ensure the completion of an up-to-date toxicological database for all pesticide active ingredients.

Notable accomplishments in its first decade of existence as a full-fledged Department include:

- In 1990, California became the first state to require full use reporting of all agricultural pesticide use and structural pesticides applied by professional applicators. By the end of the decade, the Department had developed sophisticated analytical techniques to improve the quality and accuracy of the data collected and to ensure its usefulness and availability to a wide audience via the Internet.

- DPR established its "IPM Innovator" awards program in 1994 to aid in disseminating information on alternative methods of pest management. It recognizes growers and others who are already developing and using innovative ways of managing pests, and actively coordinates the formation of new "innovator" groups.
- As part of its commitment to encouraging voluntary, community-based, pollution prevention programs, DPR is one of the few government agencies in the nation awarding grants to help develop innovative pest management practices that reduce the risks associated with pesticide use. A grants program established in 1996 was expanded in 1998 with a complementary program of public-private alliances targeted at reducing pesticide risks to workers, consumers, and the environment. The grants program embodies DPR's approach of funding small, localized projects that help groups take research results and move them into the field via applied research and demonstration projects that, if successful, can be funded for broad geographic implementation
- In the late 1990s, DPR completed collection of required health effects data on a priority list of 200 pesticides of highest health concern. The mandate to collect data came with the 1984 passage of the Birth Defect Prevention Act. DPR is also completing risk assessments and risk mitigations on the highest-risk chemicals. By 2000, DPR had also completed collection of environmental fate data on pesticides required by the Pesticide Contamination Prevention Act of 1985; using this and other data, DPR scientists had developed methodology designed to put its ground water program on a more preventive basis.
- During the 1990s, requests for registration of new products increased as a result of the introduction of new chemical and biological agents. During the same period, budgetary constraints had led to reduced staffing to deal with the problem, and the average time to register a new pesticide increased from 200 days to more than 300 days. New staffing provided in the 1999-2000 budget allowed DPR to focus more resources on reducing the backlog. At the same time, increased staffing allowed the Department to reinvigorate an initiative begun in the 1990s to collaborate with the U.S. Environmental Protection Agency to share resources and expedite reviews and approvals of new pesticides, particularly those that pose lower risks to human health and the environment.
- In 1999, DPR also began to bring its wealth of information and various regulatory and nonregulatory tools to bear in developing solutions to water quality problems. With budget augmentations that began in the 1999-2000 fiscal year, DPR established a surface water protection program consistent with its longstanding ground water program. The goal of DPR's surface water program is to characterize pesticide residues in surface water bodies (including rivers, streams, and agricultural drains), identify the sources of the contamination, determine the mechanisms of off-site movement of pesticides to surface water, and develop site-specific mitigation strategies.
- Schools have been a special focus for DPR and its staff. In 1993, DPR staff began working with school districts across the state to implement reduced-risk pesticide programs. In 1994, DPR sent to each of the state's 1,000-plus school districts a 43-page booklet designed to encourage and assist school officials in setting up an IPM program. In 1996, DPR reported on its two-year survey of the State's school districts about their pest management practices, policies and programs. In 1998, a DPR grant enabled a consortium of school districts to develop a training curriculum for school IPM and a school pesticide record-keeping system. In 2000, another DPR grant is being used to develop model school IPM programs in five counties. In the 2000-01 fiscal budget cycle, DPR also received funding to establish a program to provide technical and logistical assistance to schools that wish to adopt IPM and reduce pesticide use.
- In response to an agency-wide directive, the Department in 1999 completed an in-depth assessment of its enforcement program. As part of this effort, input was solicited from the County Agricultural Commissioners, representatives of production agriculture, the pesticide industry, public interest groups, farm labor representatives, and other interested parties. The Department in early 2000 began implementing a variety of action items identified in the assessment, including expanding resources

In 1994, DPR presented its first "IPM Innovator" awards to recognize leadership and creativity in developing new reduced-risk pest management strategies.

for compliance assessment and county supervision; initiating a drift control initiative; improving enforcement planning and evaluating, and enhancing state and county authority to take action against pesticide violations. Fulfilling the challenges presented by the scope of the recommendations was expected to take several years.

- In the 1990s, to ensure uniform and effective compliance and enforcement, DPR and the County Agricultural Commissioners initiated three key projects: development and implementation in 1994 of enforcement guidelines to carry out a policy to foster consistent statewide enforcement responses; development and implementation of the "Pesticide Use Enforcement Prioritization Plan," a plan that prioritizes county activities based upon factors such as risk; and, finally, development and implementation of negotiated workplans for each county to assist them in more effectively planning activities and resource commitments. The Enforcement Initiative also made several recommendations to foster uniform and effective compliance and enforcement, including developing written guidelines for commissioners in the form of enforcement matrices or an enforcement or compliance policy manual.

To meet the expectations of stakeholders and the public for timely, responsive, friction-free access to government information and services, in 1999 DPR began to strategically re-engineer its website, and by extension, its business functions, to take advantage of the tremendous opportunities offered by advances in information technology. The goals are to make all databases fully accessible and searchable via the Internet, to ensure that DPR staff have access to timely, reliable information needed for decision-making, to develop a needs-guided delivery of information and services, and to transition business processes to take advantage of new technologies and make them Internet-capable.

DPR faces numerous challenges during the coming years. Because of the unique nature of the pesticide regulatory program, its first and foremost priority is to ensure that its pest management decisions are based on a solid scientific foundation, and that these decisions protect public health and the State's sensitive ecosystems. DPR's task is also to assure the continued supply of high-quality food and fiber products while encouraging reduced pesticide use and greater use of lower-risk pest control alternatives. DPR's operations must also be open, accessible, and accountable; the Department is working diligently to assure that the voluminous information that DPR collects on pesticides and their impact on human health and the environment is available in a timely and convenient manner. Critical to the Department's success will be building more partnerships with its stakeholders, piloting new approaches to environmental protection, and bringing more public involvement into the process.

> ***State government should take every opportunity to use information technology to make state services and programs more accessible and hassle-free.***
> *– Governor Gray Davis, September 2000*

The Rulemaking Process

Statutes are laws enacted by a legislature. Regulations are rules enacted by government agencies that have the same force of law as statutes. An agency receives its power to adopt regulations from statutes, and cites this authority at the end of each regulation. Regulations are rules adopted by a regulatory agency (like DPR) to carry out, interpret, or make specific the statutes enforced or administered by it, or to govern its procedures. The process of writing and adopting regulations is called rulemaking

The State Administrative Procedures Act (APA) prescribes the process for putting regulations into place (Government Code 11340-11359). Among other requirements, the APA requires state agencies to give public notice when proposing regulations, to provide extensive documentation to support the need and authority for the regulation, to receive and consider public comments, to submit regulations and rulemaking files to the Office of Administrative Law (OAL) for review to ensure compliance with the requirements of the APA, and to have the regulations published in the California Code of Regulations (CCR). The role of OAL is to ensure that state agency regulations are authorized by statute, consistent with other law, and written in a comprehensible manner.

A regulation typically takes six months to a year to complete. The APA also allows agencies to file emergency regulations, provided the rulemaking meets certain criteria. However, unlike permanent regulations, which stay on the books until revised or repealed, emergency regulations expire within 120 days, and therefore must be followed by proposal of permanent regulations.

The CCR contains the text of the regulations that have been formally adopted by State agencies, reviewed and approved by OAL, and filed with the Secretary of State. The CCR consists of 27 titles (including the Food and Agricultural Code, where most pesticide-related regulations reside). The CCR is available at offices of County Clerks, county law libraries, and many public libraries. The Food and Agricultural Code is available online on DPR's Web site <www.cdpr.ca.gov>. The CCR is available at <http://ccr.oal.ca.gov>.

External Scientific Peer Review: The purpose of peer review is to uncover any technical problems or unresolved issues in a draft document so that the final publication will reflect sound technical information and analyses. It is a process for enhancing the scientific or technical work product.

As a result of a legislative mandate (Chapter 295, Statutes of 1997, SB 1320), no Cal/EPA board, department, or office "shall take any action to adopt the final version of a rule [that establishes a regulatory level, standard, or other requirement for the protection of public health or the environment . . . without submitting] . . . the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer entity for its evaluation."

The legislation mandated peer review by the National Academy of Sciences, the University of California, California State University, any similar institution of learning, or by a group of individual scientists recommended by the UC President.

FAC Section 14023(b) mandates that toxic air contaminant (TAC) health evaluation documents be reviewed by the Scientific Review Panel. *(See Chapter 4 for description of DPR's TAC program)*. If regulations involve scientific documents already reviewed under the TAC program, the review by the TAC panel constitutes the legally required external peer review.

This external peer review process is in addition to the internal peer review that DPR typically conducts on its scientific documents. Also, the Food and Agricultural Code (Section 11454.1) directs OEHHA to provide scientific peer review of DPR risk assessments (including risk characterization documents and exposure assessment documents). In addition, DPR has chosen to submit risk assessments to U.S. EPA for peer review. *(See next page for flowchart of rulemaking process.)*

FLOWCHART OF RULEMAKING PROCESS

PREPARATION OF THE PROPOSED ACTION FOR PUBLIC COMMENT

The Legislature gives limited lawmaking power to a state agency or department when, by passing a statute, it gives the agency a task. An agency or department must have delegated authority from the Legislature to adopt, amend, or repeal a regulation, and must demonstrate the necessity for the proposed regulatory action by presenting substantial evidence in the rulemaking record.

DPR: Conducts preliminary rulemaking activities, such as research and stakeholder workshops, and prepares proposed action including notice, regulation text, reason for regulation, and costs to state and local government and the economic impact on business.

Consultation with other agencies: Depending on the issues addressed in proposed regulations, DPR may consult with the Office of Environmental Health Hazard Assessment, the Air Resources Board, the Department of Food and Agriculture, or other agencies.

External scientific peer review: *If the regulations are based on new scientific studies or methodology, that science (not the regulations themselves) must be peer-reviewed by the University of California, National Academy of Sciences or similar approved institutions. Peer review must be completed before adoption of final regulations.*

DPR: Submits proposed action to the State Office of Administrative Law (OAL).

OAL: Reviews notice for compliance with legal criteria and filing requirements. If approved, notice published in OAL's *California Regulatory Notice Register* and on DPR Web site [www.cdpr.ca.gov], and mailed to interested parties.

PUBLIC COMMENT PERIOD *(45-day minimum)*

Public Comment: Begins when proposed action published. All rulemaking documents must be available for public review and comment. Hearings may be scheduled by DPR or by request. Written comments may be submitted via mail and e-mail. DPR must consider public input relevant to the proposal.

FINAL REVIEW AND ADOPTION

After resolution of public comments and other issues, the regulation is adopted.

DPR: Reviews comments, plus any new information from other sources, and decides whether they warrant changes to proposed action.

Changes to proposed action are necessary

No changes or non-substantive changes

DPR: Changes that are "sufficiently" related require a 15-day notice for public comment on the revised text.

DPR: Major changes "not sufficiently" related require a new 45-day notice.

DPR: Completes rulemaking record, with extensive documentation, including regulation text, final statement of reasons, and responses to all comments relevant to proposed action. DPR must explain how proposed action was changed to accommodate comments, or reasons for no changes. Rulemaking record must be submitted to OAL within one year of publication of notice.

OAL: Typically has 30 working days to determine whether to approve proposed action based upon legal criteria and on adequacy of response to comments.

OAL disapproves

DPR: May be possible to revise and resubmit to OAL. DPR can also abandon proposed action, and the rulemaking record automatically closes one year after publication in the Register.

OAL approves

Filing: New regulation is filed with the Secretary of State and printed in California Code of Regulations. Regulation typically goes into effect 30 days after filing.