CHAPTER 3 *(excerpted from AB780 report)*

ROLES AND RESPONSIBILITIES

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Periodically over the past 20 years, criticism has been voiced by regulated industries that California's pesticide program is unnecessarily duplicative of other state or federal government programs, increasing costs and resulting in delays in registering pesticide products. (In 1990, after this criticism was renewed during legislative debate on changing the mill assessment rate, the Legislature requested a formal report "to determine which program components can be modified or eliminated in order to avoid duplication of any other State or federal requirements.")

A particular focus of this criticism has been California's pesticide registration program. California is unique among states for the breadth and depth of the evaluation it conducts before allowing the sale and use of pesticides. The program's closest parallel is that of U.S. EPA. However, while both DPR and U.S. EPA evaluate and license pesticides for sale and use, the two programs fill separate though complementary roles. The State fulfills a specific function under federal pesticide laws. In addition, California regulators are subject to specific State mandates, not the least of which is the CEQA requirement that DPR consider the potential impact of a pesticide on California's unique environment, under California use conditions.

In response to these critiques, DPR embarked on a decade-long self-examination that has resulted in significant progress in eliminating unnecessary duplication and overlap, increasing programmatic efficiency and service to the public and regulated industries. *(See Chapter 12 for discussion of these initiatives.)* At the same time, one must recognize there will always be some *necessary* duplication and overlap with U.S. EPA. The requirements of State law – and the generally

higher expectations of the citizens of California (including State legislators) regarding implementation of health and environmental standards in the nation's most populous and top agricultural state – demand no less.

THE ROLE OF U.S. EPA

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, the omnibus federal pesticide statute) *specifically* authorizes state regulation of the sale and use of federally registered pesticides as long as state regulations are at least as restrictive as federal standards. Under FIFRA, for example, states may prohibit the distribution and sale of a federally registered pesticide or restrict pesticide use locally to protect ground water, wildlife, or human health. (Acknowledging the realities of interstate commerce, FIFRA does prohibit states from imposing their own requirements on pesticide labeling or packaging.)

Generally, U.S. EPA enforces FIFRA requirements. However, FIFRA Section 26 gives states that have adequate enforcement procedures, laws, and regulations, primary authority for enforcing state laws and regulations related to pesticide use in their own jurisdictions. In 1975, California became the first state in the country to receive such designation, and today virtually all states manage their own enforcement programs under cooperative agreements with U.S. EPA.

The pivotal role of the states in regulating the use of pesticides is a result of lobbying by the states, who have argued successfully that their level of control is more knowledgeable, precise, and reliable. The federal role, by design, is not intended to substitute for the authority of any state to pursue a regulatory approach best suited to local conditions.

THE ROLE OF THE STATES

Charges of programmatic redundancies are not unique to California. Those who register and distribute pesticides nationally complain to Congress that – given federal standards – local and state pesticide use restrictions are unnecessary and make it difficult to conduct business from state to state. The criticism prompted this response in a 1996 U.S. Senate staff analysis of FIFRA amendments:

"Throughout history, States traditionally have had the fundamental responsibility of protecting health and safety. Over time, as some health and safety issues have become more complex and national in scope, some of these responsibilities have been shifted to the Federal government. In general, Federal authority has not increased at the expense of State authority. Even when it has, existing statutes have allowed States to set more stringent standards than Federal standards, if so desired and needed. We should permit States to set separate safety standards. States can set these standards more quickly than the U.S. EPA in response to an emergency. They can also set a standard that provides more comprehensive protection than a federal standard. Some states, for example, have formulated standards that are more stringent than federal standards and are better designed to protect individual groups of citizens.

"If states are no longer able to act independently to protect health, they will lose their access to the federal process, and the balance of the current system will be lost. It remains a question of policy, of wise interpretation of the Constitution, which recognizes that the federal government should not move in with a heavy foot and stomp on the rights of individual states to pass judgment on products that have a direct effect on the health and safety of their citizens," the Senate analysis concludes.

DIFFERENCES IN DPR AND U.S. EPA ROLES

Thus, while there are parallels in U.S. EPA's and DPR's pesticide regulatory programs, there are significant differences as well. That is, even in arenas where there appears to be significant overlap, there may be little duplication.

For example, DPR and U.S. EPA may review the same group of toxicology studies submitted 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. In some cases, the conclusions differ, in part because DPR focuses on California-specific impacts. DPR may refuse to register a product because of potential impacts on workers in California's labor-intensive agriculture, or because the only potential use of the product in California would be in areas that are also home to an endangered species that would be harmed by the pesticide.

Moreover, U.S. EPA has broad authority to waive submission of some studies, or to not complete data evaluations, before granting conditional registrations. As a result, U.S. EPA often allows products to be sold and used while studies and reviews are being completed. On the other hand, DPR's authority to grant conditional registration is much more limited. In most cases the Department is precluded from registering a product containing a new active ingredient without having finished its review of a complete data package. Applicants for California registration of a new pesticide product must either submit all required data, or specifically cite relevant data currently on file with DPR. If the registration applicant does not own the cited data, they must obtain a letter of authorization from the data owner.

Furthermore, DPR may require additional or different studies not required by U.S. EPA for federal registration of a specific product. These additional studies may include data on worker exposure, foliar residue, indoor exposure potential, hazards to bees, and dust hazard of powdered products to workers.

In addition, under federal regulations, applicants for U.S. EPA registration of a pesticide product containing the same active ingredient as products already registered (even though the formulation may differ) are not required to submit data, and can instead simply cite "all" data on file with U.S. EPA that was previously submitted by other registrants. U.S. EPA does not determine whether relevant studies are on file to support all registered pesticide products until some later date when the active ingredient goes through the federal reregistration process.

Additionally, DPR requires that efficacy data be submitted with all applications for registration. U.S. EPA requires that manufacturers develop but not necessarily submit such data, except for products that have public health impacts such as disinfectants. DPR's evaluation of product effectiveness data protects California pesticide users from the consequences of ineffective products.

Differences in Data Evaluation Procedures

There are also significant differences between U.S. EPA and DPR in how pesticide data are considered. In California, more than 350 different kinds of crops are grown, primarily fruits, nuts and vegetables. Most are considered "minor crops" for pesticide sales, unlike the field crops of the Midwest and South (corn, soybeans and wheat, for example) which, with their extensive national acreage, are the major market for pesticides and thus the natural focus of U.S. EPA.

Field crops require little cultural care during the growing season and are primarily harvested mechanically, by workers driving in enclosed cabs. This is in contrast to California's fruit, nut and vegetable crops, which often require extensive cultural care before harvest, with accompanying worker contact with foliage. Many California crops are hand-harvested. Between a quarter and a third of all farm workers in the U.S. work in California. (Estimates of the number of farm workers in California vary but are on the order of 750,000.)

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. DPR's own field studies have found that pesticides that may decay rapidly under warm, humid conditions can persist longer under hot, dry conditions typical of many of the State's agricultural areas. Algaecides and other pesticides used in swimming pools must reflect the outdoor, year-round use that is typical in many areas of California.

California's Unique Focus

California is also unique in that tens of thousands of its residents live in suburbs adjacent to the nation's most intensively farmed acreage. The impacts of pesticide use at this agricultural-urban interface are 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's fumigant program also has no parallel at U.S. EPA. DPR has extensive rules and regulations designed to reduce of off-site movement of three widely used fumigants, methyl bromide, 1,3-dichloropropene and metam-sodium. U.S. EPA has focused on methyl bromide's ozone-depleting characteristics, and on 1,3-dichloropropene primarily because of its potential to contaminate ground water. Similarly, U.S. EPA has no special restrictions on metam-sodium beyond those on the product label.

These and other differences affect the evaluation of safety and effectiveness of pesticide products in California. DPR has expertise in evaluating California-specific impacts on environment and health that U.S. EPA – a federal agency – cannot have.

DPR on occasion denies registration of products that have obtained federal registration. These denials have been based on such factors as a lack of appropriate or adequate studies, label instructions that do not provide sufficient mitigation of product hazard, and an insufficient margin of safety in the projected use. As a result of registration review, the Department also may impose use restrictions and mitigation measures in addition to those on pesticide labels, assuring that valuable pest control technologies are made available to California consumers while potential risks to the public, workers and the environment are minimized.

U.S. EPA's Risk-Benefit Mandate

Another difference between the U.S. EPA and DPR registration process is that FIFRA requires U.S. EPA to balance risk considerations with economic benefits. During the registration process 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 take into consideration the "economic, social, and environmental costs and benefits of the use of any pesticide." In suspension proceedings (as opposed to registration decisions), U.S. EPA is not required to balance environmental risks and benefits, although it has been U.S. EPA's policy to conduct such an analysis.

The differences between federal and state laws in this regard, while subtle, are critical. U.S. EPA is charged by FIFRA to register a pesticide upon determining that "its composition is such as to warrant the proposed claims for it; its labeling and other material required to be submitted comply with the requirements of FIFRA; it will perform its intended function without unreasonable adverse effects on the environment; and, when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." (FIFRA, Section 3[c][5])

Although the risk-benefit provisions of FIFRA were modified in 1996 to ensure health-based safety standards for dietary residues, federal law mandates U.S. EPA consider economic benefits of pesticides, defining unreasonable adverse effects on the environment to mean "any unreasonable risk to man or to the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard" set in 1996 of a "reasonable certainty" of no harm. (FIFRA, Section 2[bb])

Similarly, U.S. EPA may cancel the registration of a pesticide if it finds that "when used in accordance with widespread and commonly recognized practice, (it) generally causes unreasonable adverse effects on the environment." (FIFRA, Section 6[b])

California law does not require consideration of economic benefits and DPR does not register products with unmitigated, significant adverse effects, no matter the benefit. California law provides a clear mandate to assure that pesticide use in the state poses as little risk as possible to the public, farm workers, and the State's environment and wildlife.

The basic decision rule is simple: DPR may approve a pesticide registration application (and, if already registered, allow continued use) if it is convinced that the pesticide can be used safely, assuming the product is applied according to label directions, and in accordance with any additional permitting requirements DPR might implement under certain circumstances. California law instructs DPR to "…endeavor to eliminate from use in the state any pesticide which endangers the agricultural or non-agricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented." (F&A Code 12824)

Other Key Differences

There are also significant differences in other aspects of the State and federal pesticide programs. For example, when U.S. EPA in 1989 proposed a new national endangered species protection program, it would have prohibited the use of certain pesticides in large areas throughout California. U.S. EPA's approach to habitat mapping and hazard assessment, necessarily national in scope, was particularly unsuitable for California conditions. For example, some habitats were overestimated by factors of 10 to 10,000 times the actual area.

With the cooperation of federal, state, and local agencies, DPR in 1989 began developing its own, highly respected endangered species program. DPR's program is customized to the state's unique microhabitats and varied cropping patterns to make sure local conditions are examined and local concerns are met when U.S. EPA makes decisions on pesticide use in endangered species habitats. California's program is based on accurate habitat maps and on mitigation measures tailored to allowing needed pest control while providing protection to endangered species.

DPR has strong, formal programs that U.S. EPA does not for post-registration evaluation of pre-registration conclusions. In registering a product, both DPR and U.S. EPA rely on various data to conclude that a product can be used safely. However, DPR's environmental monitoring of air and water, illness surveillance program, exposure monitoring studies, and ground water reporting system each help determine if that conclusion is borne out by real-world use, and if not, how use practices can be changed to mitigate adverse effects.

Focusing on Expertise

While criticisms of redundancy overstate the case, and critical differences in law and methodology exist between U.S. EPA and DPR, there is nonetheless ample room for coordination and collaboration. Over the past decade, the two agencies have made significant strides in worksharing as they explore their respective

procedures, methods, and areas of special expertise, with the mutual goal of eliminating unnecessary duplication. *(See discussion, Chapter 12, on U.S. EPA-DPR worksharing project.)* However, DPR must continue to focus on areas of interest to California: that is, the State's particular mix of food and fiber crops, and more broadly, the unique concerns of California residents, particularly at the agricultural-urban interface.

U.S. EPA, in turn, has its own focus areas, in particular, cumulative risks posed by pesticides with common mechanisms of toxicity; endocrine disruptor screening and testing; identifying and developing new methods for complex ecological risk assessments; advancing the use of safer inert ingredients; and tolerance reassessment mandated by the Food Quality Protection Act (FQPA).

U.S. EPA also has made extensive use of California data gathered by DPR as it carries out the mandates of FQPA. California's pesticide use reporting data has assisted U.S. EPA by providing percent-of-crop-treated information necessary so as not to overstate cumulative risk. Moreover, U.S. EPA has acknowledged the high level of expertise and professionalism of DPR scientific staff by appointing a number of them to various panels that advise the federal agency on scientific policy and methodology. This also helps ensure that California's concerns are recognized in the formulation of federal scientific policies, and at that same time, that DPR policy development is informed by actions at the federal level.

Coordination with Other Agencies

There are several other programmatic areas where DPR activities and those of other state or federal agencies, or the university, appear to overlap. But the roles and responsibilities may differ considerably. For example, both the State Department of Industrial Relations and DPR oversee worker safety. However, Industrial Relations does not have programs that specifically address the safe use of pesticides, and neither does it investigate injuries or illnesses related to pesticide use. The County Agricultural Commissioners and DPR have the expertise and mandate in this arena, and investigate, evaluate and track every reported pesticide-related injury and illness.

The Air Resources Board (ARB) is the lead agency for implementation of the Toxic Air Contaminant Act, except for pesticides in air. In its smog-fighting role, the ARB also regulates the volatile organic content of consumer products, including many pesticides. (DPR has the lead with agricultural products.) Cal/EPA's Office of Environmental Health Hazard Assessment has the lead role for Proposition 65, including the listing of pesticides.

The State Water Resources Control Board (SWRCB) is the lead agency for coordinating and controlling water quality. DPR, as the lead pesticide agency, directly regulates the sales and use of pesticides, so its authorities also bear on the impact pesticides may have on water quality. DPR and the SWRCB have signed a management agency agreement to identify primary areas of responsibility and authority and to coordinate how local and State authorities work together in solving water quality problems related to pesticide use.

Coordination with the University

In pursuing DPR's mandate to encourage the development and implementation of reduced-risk pest management systems, DPR focuses on solving human health and environmental problems related to administration of pesticide regulations. DPR works cooperatively with the University of California (UC) and State University systems to identify where and how research, extension and education goals of the University can address pesticide regulatory issues through practical pest management.

DPR's programs focus on particular regulatory concerns in a way that the University does not. The Department emphasizes opening up dialogues with regulated industries to work together to implement feasible solutions to regulatory constraints. While the solutions frequently utilize the University's expertise, DPR's participation is critical to keeping this process focused on specific regulatory issues of primary concern and to providing analyses of the nuances of pesticide use in various situations.

In a 1994 report on the value of agricultural research programs, the University recognized the importance of addressing these concerns, saying: "Agricultural research on environmental and resource topics has become increasingly aimed towards helping agriculture respond to added regulations more efficiently. As the public demand for more environmental regulations continues, agriculture requires alternatives to current practices that will allow growers to maintain productivity in the face of changing and more restrictive regulations. Without ongoing research, it is difficult to maintain positive trends in productivity in the face of new regulatory constraints."

To eliminate overlap and improve coordination with the University and other organizations that fund pest management research, the Department in 2001 commissioned a study of its grant programs, and is now pursuing many of its recommendations. (The 98-page evaluation by the Center for Agricultural Partnerships is available on DPR's Web site.)

Other State departments such as Health Services, Fish and Game, or Industrial Relations are concerned with the identification of pesticide hazards that affect their operational sphere, but do not have the expertise to evaluate the impacts of entire cropping or pest management systems. They also lack authority to make changes in pesticide regulations. UC and the State University systems provide research, extension, and education, but have no regulatory authority.

The Department's Unique Role and Expertise

No other State program works more closely with agricultural and nonagricultural stakeholders and the public to provide information on and to promote pest management strategies that reduce pesticide hazards to health and the environment. DPR's is the only State program that evaluates an entire pesticide or pest management problem and coordinates implementation of corrective measures.

DPR's pesticide expertise, and the fact that this expertise stretches across multiple media (air, water, soil, and impacts on human health and wildlife), prompted a 1983 gubernatorial executive order giving the State's pesticide program primacy over pesticide issues. This lead role has been reinforced by the Legislature, which in passing a variety of legislative mandates has given DPR the lead role in pesticide workplace safety, and in evaluating and controlling the impacts of pesticides on air, ground and surface water. This delegation has been supported during Legislative debate by the agricultural and chemical industries that were concerned about maintaining DPR's primacy over pesticides.

Therefore, although there are DPR functions that the Administration and the Legislature could theoretically transfer to other state agencies, accompanying cost savings to the State may be minimal, since these activities are for the most part not conducted by other agencies at this time. Transferring functions would necessitate assigning resources as well. Such a transfer would not only significantly dilute DPR's primacy in this arena but, over time, would adversely affect the efficiencies inherent in its cross-media pesticide expertise.

ABOUT SECTION 18 AND SECTION 24c

Section 18: A state can issue a Section 18, after approval by U.S. EPA, to meet an emergency pest problem for which no registered product is available. DPR maintains an extensive program to review Section 18 applications (named for the subsection of FIFRA that authorizes them). Under federal law, applications must be submitted by the authorized state agency (in California, DPR). The great number of crops grown here (more than 350 kinds of fruits, vegetables, nuts and grains), the diverse geography and weather, and the multiple growing seasons make the use of Section 18s important in California.

Federal law and policy requires that use of exemptions be kept to a minimum, Section 18 applications undergo intensive scrutiny by U.S. EPA and before that, by DPR. Each year, DPR rejects several Section 18 applications, usually for failure to document the emergency adequately. Extensive documentation of the emergency pest problem must accompany a Section 18 request, including detailed information 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.

DPR routinely contacts university researchers and other expert sources to verify the justification, and works closely with commodity groups and other Section 18 applicants to assist them in developing the information necessary to support the application. California law requires an evaluation of the impacts of pesticide use on workers, and a good part of DPR's Section 18 review focuses on the potential effects of the proposed use in California's labor-intensive agriculture. The request must also include any available residue data to support a tolerance (allowable residue level). For many Section 18 tolerances, DPR staff prepares the scientific evaluation needed by U.S. EPA to expedite its evaluation. After DPR's scientific review of the residue, chemistry, toxicology, and efficacy data – and confirmation of the emergency need – the request is forwarded to U.S. EPA with a proposed tolerance.

California Section 18 Applications, 1995-2001

Year	# Recv'd	# Issued	DPR denied	USEPA denied
1995	37	27	10	0
1996	32	24	6	2
1997	49	41	4	4
1998	63	41	22	0
1999	55	42	11	2
2000	43	34	8	1
2001	42	33	8	1

Note: Number of Section 18 applications increased nationwide after the 1996 passage of the Food Quality Protection Act.

U.S. EPA relies on California to know the local circumstances justifying the urgent, non-routine situation and the emergency need. DPR has a hard-earned reputation of submitting Section 18 applications to U.S. EPA that are well justified and on target in assessing risks. The professionalism of DPR's scientific staff is highly respected at U.S. EPA and has given California's science-based regulatory program a unique standing and credibility. The federal agency relies on DPR to have conducted a thorough review, thereby reducing the time it takes for U.S. EPA to issue a Section 18 to California.

Section 24c: These are state-specific registrations, through which states can register a new pesticide product for any use, or additional use of a federally-registered product, as long as there is both a demonstrated "special local need" for such a product, and a tolerance, exemption from a tolerance, or another clearance under the Federal Food, Drug and Cosmetic Act has been established. A Section 24(c) can be requested by either the manufacturer as the first party or by a third party such as a grower association. The special local need (SLN) can be in a region of the state or can cover the entire state, and can be for a food or nonfood use. 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.

The special local need must be justified and supported by knowledgeable experts and there can be no registered products available to meet the need. Once issued, an SLN remains in effect indefinitely until withdrawn by the registrant, manufacturer or DPR, or until U.S. EPA cancels the use. (DPR issues approximately 100 SLNs each year.)