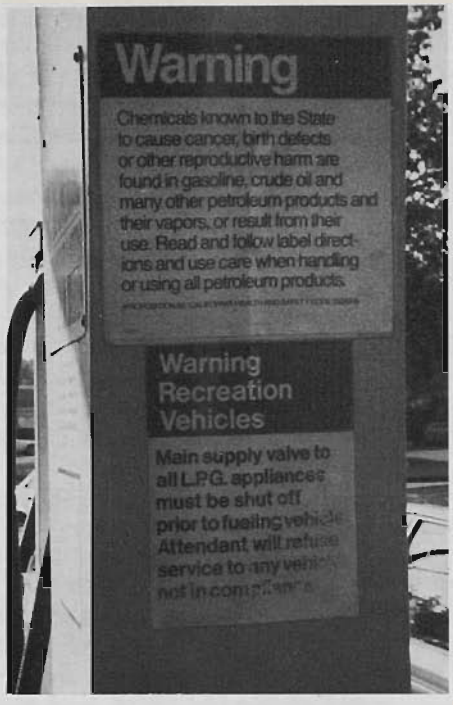
Toxics Regulation Under California's Proposition 65

A State Law with National Effects



➢ **When California voters approved Proposition 65 in 1986, some thought its novel approach to regulation of hazardous substances was going to ruin California's economy; others argued that it would significantly improve the environment and people's health. Both claims were greatly exaggerated. While Proposition 65 has contributed to environmental improvement, it also appears to be a law with which Californians and national businesses, including farmers, can live.**

In this discussion, we use "no significant risk" sometimes to mean the risk standards for both carcinogens and reproductive toxicants. This is not strictly correct. However, this approach simplifies the discussion.

by Gloria E. Helfand, Brett W. House, and Douglas M. Larson

Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, is a remarkably simple law. The Governor, in consultation with the state's qualified experts, must publish a list of chemicals which cause cancer or reproductive harm. A business entity is prohibited from "discharging" a listed chemical into drinking water unless (1) the chemical poses "no significant risk" of cancer or (2) produces "no observable effect" on reproduction (the "NOEL" level) at one thousand times the level in question, and (3) the discharge conforms with all other applicable standards.

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In addition, if a business, such as a farmer, exposes someone to a chemical (including workplace exposure, additives in food, or air emissions), it has to provide a "clear and reasonable warning" to those being exposed, unless the exposure poses no significant risk to them. Importantly, Proposition 65 effectively puts the burden of proving the safety of these substances on farmers, institutions and companies using the chemicals, unless those exposed are warned about the danger.

Proposition 65 can be enforced by anyone who wishes to bring suit. However, the state attorney general and local district attorneys have 60 days to take over any suit brought by a private party. This so-called "bounty hunter" provision gives 25 percent of assessed fines, which can range up to $2500 per day, to the person bringing the suit.

Proposition 65 does not override existing laws, but does com-

plement them. If other laws have more stringent safety requirements, those requirements stand. Any penalties from enforcement of Proposition 65 are in addition to those tied to other existing and future environmental laws.

Implementation

Tremendous confusion reigned after the law's passage. Businesses were frightened that almost everything they did would be regulated in ways they could not foresee. Much of the confusion related to one of the law's innovations: the absence of a large new bureaucracy to implement it. In theory, the state had little role in implementing Proposition 65. Once qualified experts were named to the Scientific Advisory Panel (SAP) that would identify and list hazardous chemicals, lawsuits would become the principal enforcement mechanism. Nevertheless, then-Governor Deukmejian designated the California Health and Welfare Agency (CHWA) to take the lead in interpreting its provisions to promote its orderly implementation. The first chemicals were listed February 27, 1987; one year later the first warnings would be required for exposures to those chemicals, and 20 months later discharges of those chemicals would be prohibited, unless they posed no significant risk. By January 1, 1991, 369 chemicals were considered carcinogenic, and 111 were considered developmental or reproductive toxicants, with at least 22 considered both carcinogenic and reproductive toxicants (Figure 1).

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How this law has been implemented is in large part responsible for its successes, its failures, and its accomplishments to date. The main features include:

Listing of Chemicals. Prior to passage of Proposition 65, farmers and industry groups worried about which chemicals would be listed by the SAP. Because "listing" a chemical automatically triggers the law's provisions, the only place delay can benefit chemical users is in forestalling listing itself. This arena became the law's first battleground.

In February 1987, 26 carcinogens with clear evidence of causing cancer in humans and 3 reproductive toxicants were listed; an additional 200 chemicals were to be further studied. A coalition of environmental and labor organizations brought suit against the Governor, claiming that he violated Proposition 65 by listing so few chemicals. A Court of Appeals concurred, ruling in July 1989 that the initial list did not fulfill the law's requirements. Though the SAP had listed most of the 200 disputed chemicals before the suit was concluded, this listing delay bought time for users of those chemicals.

More recently, another lawsuit has forced the SAP to consider other agencies—the Environmental Protection Agency (EPA), the International Agency for Research on Cancer, the National Toxicology Program, the National Institute of Occupational Safety and Health, and the Food and Drug Administration (FDA)—as "authoritative bodies." If an authoritative body or a state or federal agency determines that a chemical is a carcinogen or a reproductive toxicant, then it is added to the Proposition 65 list. A number of chemicals have recently been added to the list by this method.

Though the rate of addition of carcinogens has dropped since 1988, the listing of reproductive toxicants has increased. Unlike the case for carcinogens, no standard protocol exists for determining when a chemical causes reproductive harm. As research into these chemicals grows, their listings could continue to increase.

No Significant Risk. Since this phrase was not defined for carcinogens in the Proposition, some guidance was necessary. CHWA interpreted "no significant risk" as the risk level calculated to result in 1 excess cancer in an exposed population of 100,000 people (the so-called 10^{-5} standard) over a 70-year lifetime of exposure.

This level may be less conservative (depending on a number of factors, such as the data, assumptions, and principles used in the study) than that used by other regulatory agencies; the EPA and FDA typically use a standard of 1 excess cancer in a population of 1 million. As a result, if a substance is regulated to this standard by another agency, then it falls under the no significant risk exemption of Proposition 65. However, many uses of listed chemicals, such as those in paints, are not subject to federal regulation; their effects on consumers may be controlled primarily by Proposition 65.

While the 10-5 standard seems settled, that standard must then be translated into a specific use level for each chemical. Under other environmental laws (though not under food safety laws), the chemical cannot be significantly regulated without determining a safety standard to show what level of use poses a risk to health and welfare. This has provided companies the incentive to delay determination of these safe use levels. Proposition 65, in contrast, has turned the tables on this regulatory disincentive. If a chemical has no determined safe use level, then under Proposition 65, a business must itself be able to demonstrate that its level of use poses "no significant risk." Firms now have a strong incentive to discover the danger of the substances they use and the significance of the exposures associated with them. CHWA has so far determined safe use levels for 70 chemicals. In addition, some firms are commissioning their own risk assessments.

Reproductive Toxicants. Proposition 65 covers reproductive toxicants unless the exposure or discharge involves less than 1/1000 of NOEL. Since reproductive toxicants, when regulated (though often they are not), are frequently controlled at levels of 1/10 of NOEL, this level is more stringent than some other laws and regulations.

This added stringency can lead to regulatory problems. For instance, vitamin A is dangerous in high doses but is necessary for human reproduction at levels higher than 1/1000 of NOEL. To get around this problem, vitamin A is listed only for daily doses exceeding safe levels.

While carcinogens have been regulated under many laws, reproductive toxicants have not previously been controlled as a class. There is much uncertainty about which toxicants will be listed and the degree of safety which will be prescribed.

Discharges into Sources of Drinking Water. Under the Federal Clean Water Act, discharge permits allow emissions at certain levels, and a firm has to be proven in vi-

olation of its permit before it is guilty. In contrast, someone bringing suit under Proposition 65 need only show that a business discharged a listed substance into drinking water; the business has the burden to show that the discharge did not pose a significant risk.

While the differences between these approaches can be substantial, they are partially overridden by the relative liberality of the 10^{-5} standard. The State Water Resources Control Board claims that discharge permits are almost always more conservative than the Proposition 65 standards for the substances included in the discharge permits. If a firm is complying with its permits, it will probably be well within the "no significant risk" exemption for those chemicals. However, the large number of listed chemicals not included in the discharge permits is still subject to the proposition's requirements.

The Warning Requirement. Proposition 65 does not prohibit the use of hazardous chemicals; instead, it simply requires that businesses provide a "clear and reasonable warning" to anyone being exposed to a listed chemical beyond the "no significant risk" level. This provision is intended to give consumers, workers, and others exposed to these hazardous substances the information to make better-informed decisions: Do they wish to bear the risks for the benefits they will receive, or are the risks too high? At the same time, Proposition 65 did not repeal other laws and regulations which protect exposed people from many hazards.

Affected Parties:
Private businesses employing 10 or more people.

Regulated Substances:
Carcinogens and reproductive toxicants. A list of those substances is developed by the Governor with input from the Scientific Advisory Panel.

Restrictions:
A business cannot knowingly discharge or release listed chemicals into sources of drinking water (either surface or groundwater).

A business must provide a "clear and reasonable warning" if it otherwise knowingly and intentionally exposes someone to a listed chemical.

Exemptions:
Carcinogens: If the level of use poses "no significant risk" (defined by regulation as posing less than 1 excess cancer in a population of 100,000).

Reproductive toxicants: If the level of use is less than 10-3 times the "no observable effect level" (NOEL).

Enforcement:
Suits can be brought by state or local officials, or by private citizens. Fines can be up to $2500/day.

While CHWA ruled that products regulated under Federal food, drug, and cosmetics laws are considered to meet the "no significant risk" level for carcinogens until it determines safe use levels for those substances, that rule has been struck down in court. However, to date, no suits have challenged the absence of a warning on an affected product. Again, because of the relative liberality of the CHWA standard, most FDA-regulated products are unlikely to require warnings once this exemption is gone.

National Concerns

After the law passed, a number of industries, including food processors and manufacturers of drugs and cosmetics, sought exemptions from Proposition 65's requirements. They claimed that the new law, though strictly speaking only applying to California, in fact imposed significant burdens on businesses across the country and infringed on areas in which federal law preempted state laws. The warning requirement was the focus of this anti-Proposition 65 effort.

Businesses have options, however. They can reformulate their product to avoid listed chemicals, provide warnings, eliminate production of the product, or abandon the California market.

Reformulation, arguably the goal of the act, almost certainly involves some expense to the firm, though it would probably make the product safer. Manufacturers of typewriter correction fluid, spot removers, cans with lead solder, and waterproofing spray for shoes have thus far adopted this approach. Many firms are said to be reformulating products quietly, without publicity, to avoid having the old product considered unsafe.

Providing a warning bypasses the expense of eliminating the chemical; however, it tells the consumer about the risk and could make the product less desirable. Additionally, if one brand of a product carries a warning but another brand does not, the unlabeled brand may "appear safer" and thus more desirable. The law uses competitive forces to encourage firms to reduce their use of listed chemicals.

Firms must also decide whether to meet the law's requirements outside California or to segregate their product lines. Warning customers outside California could raise concerns about the products where they were not legally required to be raised; reformulating the product only for California would permit the (presumably) less expensive original product to continue to be sold in other states. Segregating product lines, on the other hand, can involve major production and inventory expense. Segregation is not always difficult: for instance, gasoline stations in California carry warnings that stations outside the state are not required to post. On the other hand, in response to a suit requiring warnings on cigars and pipe tobacco, tobacco companies now provide warnings on these products nationwide.

Eliminating a product is simple if the product has close substitutes. Some product lines are probably no longer available in California because of Proposition 65. However, no such case has received significant public attention.

Finally, a business could bypass the California market. This option is not worthwhile for most goods and services: California is such a big market (13 percent of U.S. GNP in 1988) that a firm could lose a great deal of business if it abandoned the state. Anecdotal evidence suggests that some firms with possible air discharge violations are considering relocating to other states to avoid Proposition 65 and other environmental requirements.

Businesses now have a much greater incentive to know what hazardous substances they use, how hazardous they are, and what alternatives exist.

To date, no lawsuit seeking Federal preemption of aspects of Proposition 65 has been successful. Attempts at an override by White House Executive Order have also failed. Despite some claims that the law has been burdensome, a 1988 study by the Council of Economic Advisers found those claims greatly over-

stated. Politically, the preemption issue split President Reagan's Executive Branch. While industry backers supported preemption to reduce regulation, states' rights advocates argued that California should not be overridden by the Federal government. Ultimately, the law was left alone.

An Assessment

Has Proposition 65 had net benefits for the public, or have its costs outweighed whatever good it has done? The primary benefits of Proposition 65 can be put in two categories: (1) improvements to public health and safety due to increased regulation and monitoring of hazardous substances; and (2) more informed decisionmaking through increased awareness of the presence and nature of hazardous substances. For the most part, improvements to public health are thus far relatively small. Some product reformulation has taken place, and some firms have changed their practices, but most changes have not been radical. In part, if a firm is obeying other laws, it may need to do little to meet the "no significant risk" provisions. (The major exception so far is several suits over air discharges of ethylene oxide into residential neighborhoods; a large local population was suffering from a significant health risk before the lawsuits.) Additionally, enforcement actions to date have been limited. Neither private parties nor public agencies have the technical or economic capacity to bring large numbers of suits, even with the shift in the burden of proof and "bounty hunter" compensation.

The second benefit from Proposition 65, on the other hand, is probably more significant than originally anticipated. Businesses now have a much greater incentive to know what hazardous substances they use, how hazardous they are, and what alternatives exist. Greater understanding encourages businesses to reduce unsafe exposures. It can even lead them to improved production technologies and better compliance with other environmental laws. By ensuring safer business practices and environments, the law also should increase public confidence in the safety of products they buy.

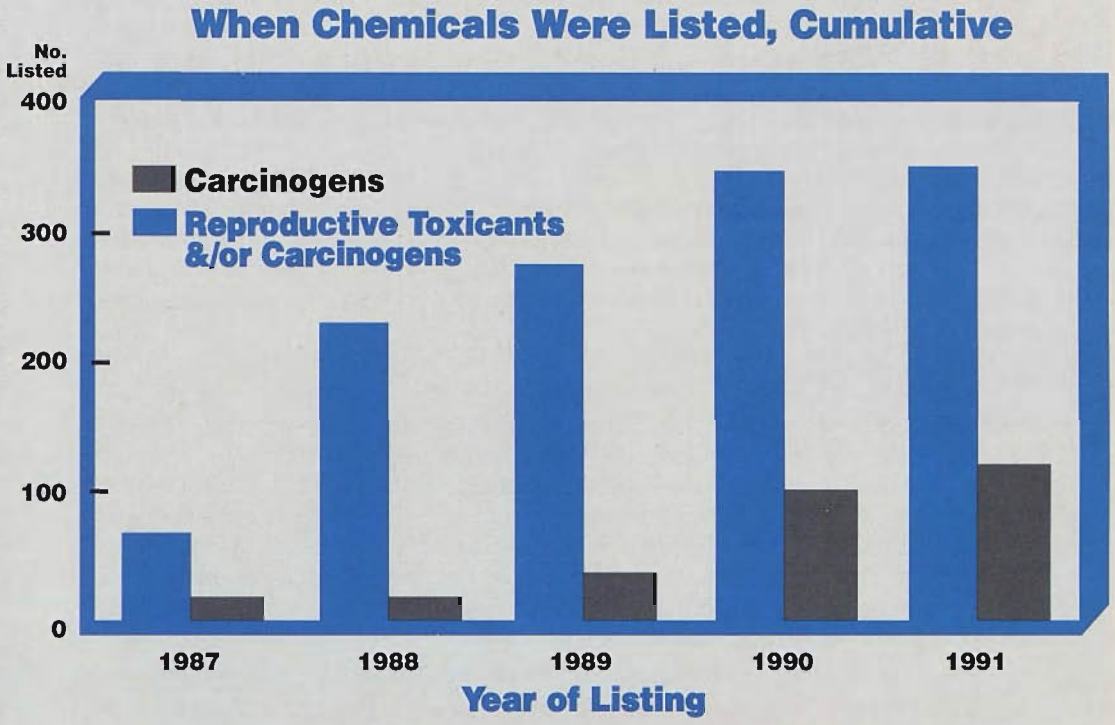
Of course, these benefits have not been achieved without cost. The first few years of Proposition 65 brought significant business expenditures, primarily to determine what the law meant and how to obey it. These expenditures largely went to lawyers and consultants to examine the implications of the law. Money was also spent to review production processes, to uncover uses of listed chemicals, reformulate products, post warnings, and make a closer study of discharges into water supplies.

Over time, these expenditures appear to have lessened. In part, businesses are developing a better understanding of what is necessary to comply with the law; they have taken many of the necessary actions and the continuing costs are lower than initial costs.

While these costs have declined, one area of remaining uncertainty is the costs arising from compliance suits. As of January 1, 1991, 11 of 23 enforcement suits brought have been settled out of court (5 by consent judgment). In all but one of those cases (which resulted in a confidential agreement), defendants agreed to change their warning practices and/or pay civil penalties. Ten cases are pending, and another was dismissed. In the last case, the law was not successful in halting aerial spraying of malathion to control the Mediterranean fruit fly, in part because listed chemicals fell under the "no significant risk" exemption.

Whether litigation costs will grow depends on whether enforcement suits over time increase in number, and whether the suits are successful. Two opposing forces seem to be at work. More enforcement suits were brought in 1990 than in all previous years. However, there is a substantial lag between the listing of a chemical and the bringing of an enforcement suit. The most common lag, 36 to 42 months, is not much less than the length of time since chemicals were first listed.

As time passes, litigation and associated costs could increase. On the other hand, as businesses learn from the early suits, the need for lawsuits might diminish. Still, both the compliance costs of the law and the number of suits brought under it are smaller than suggested in pre-election rhetoric.



Other costs and benefits of Proposition 65 are external to California. Because the law applies to products brought into California as well as those produced here, businesses outside the state incur compliance costs. On the other hand, because most businesses are not segregating their California products, the benefits to public health of reformulated products and better warnings are extended to citizens outside the state.

Perhaps one indicator of the burden imposed by Proposition 65 is the small number of active calls for its repeal. In fact, a recent unsuccessful ballot measure sought to extend its provisions to public as well as private entities. In retrospect, Proposition 65 has not been a "silver bullet" saving California's environment and protecting the health of its citizens, but neither has it been a death knell for businesses as many argued when it was proposed.

Moreover, there is the possibility that voters and consumers in other states will emulate Proposition 65 as they have so many other developments which were first initiated in California. Though no business person is likely to say so in public, Proposition 65 appears to be a law with which agriculture, food processors, and other industries can live.