Complying with Proposition 65: An Industry Overview

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VVV 000008690

California's Safe Drinking Water and Toxic Enforcement Act of 1986[1] *popularly known as "Proposition 65," took effect on Feb. 27, 1988, requiring exposure warnings for 29 chemicals on the Governor's list of substances "known to the state to cause cancer or reproductive toxicity." On Oct. 27, 1988, the law's provision prohibiting the "knowing" discharge of listed chemicals into any source of drinking water will take effect. Within the next two years, more than 200 substances, including lead, benzene, asbestos, and even tobacco smoke, will become subject to the warning and discharge provisions of this controversial ballot initiative.*

One source of controversy is Proposition 65's sweeping and often ambiguous language. In an attempt to clarify certain terms, the California Health and Welfare Agency, the lead agency charged with implementation, issued a set of final and emergency regulations shortly before the law took effect on Feb. 27. This article will provide a brief overview of Proposition 65, the implementing regulations, and enforcement and compliance issues.

Overview

Proposition 65 was based on the proponents' belief that neither the federal nor the state government was adequately protecting the people of California from hazardous chemicals.[2] In response to this perceived problem, the law established two relatively simple causes of action under the discharge and warning provisions. It allows citizen suit enforcement, and shifts the burden of proof to defendants.

The Discharge Prohibition. Sec. 25249.5 of the California Health and Safety Code states that, with limited exceptions, "[N]o person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, notwithstanding any other provision or authorization of law." The prohibition does not apply to persons employing fewer than 10 employees, to public agencies, or to operations of public water systems.[3]

A chemical is "known to the state to cause cancer or reproductive toxicity" if the state's "qualified expert" finds that the chemical has been "clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity."[4] A chemical automatically falls into this category if an organization considered by the state's experts to be authoritative has formally identified the chemical as a carcinogen or reproductive toxicant, or if a state or federal agency has formally required that the chemical be labeled as a carcinogen or reproductive toxicant. The law directs the Governor to publish annually a list of chemicals identified in accordance with these criteria.

There are two exemptions from the discharge prohibition. There is a 20-month grace period following the listing of any chemical. In addition, a specific discharge is exempt if it will not result in any "significant amount" of the discharged chemical entering any source of drinking water *and* the discharge is in compliance with all applicable regulations, permits, and orders.[5] This specific exemption offers little relief, however. In any enforcement action the burden is on the defendant to show that a discharge satisfies these criteria.[5] Furthermore, a "significant amount" is "any detectable amount" unless the defendant can show that exposure to the discharged chemical in drinking water poses "no significant risk" of cancer, assuming lifetime exposure at the level of discharge, or that the exposure will have no observable reproductive effect assuming exposure at 1,000 times the level of discharge.[6]

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The law fails to define either "significant risk" or "detectable amount" and thus creates practical difficulties for businesses attempting to demonstrate a lawful discharge. Fortunately, the Health and Welfare Agency's emergency regulations address "no significant risk" and "no observable effect level," which should ease the burden to prove that exposures meet the exemption criteria.

The Warning Requirement. The second major provision of Proposition 65 requires that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."[7] Warnings need not be given to exposed persons individually, but may be disseminated generally by means such as product labels, mailings, signs, and media announcements.[8] The law places the burden to provide a warning primarily on manufacturers, packagers, and producers rather than on retailers.[8] The Health and Welfare Agency's emergency regulations also address the warning provision.

The law offers three limited exemptions from the warning requirement.[9] The first applies to exposures where federal law governs warnings "in a manner that preempts state authority." The second applies to exposures occurring within 12 months of the date the chemical is added to the Governor's list. The third requires a defendant to show that the exposure will pose "no significant risk" of cancer, assuming lifetime exposure, and will result in no observable reproductive effects at 1,000 times the level of exposure.

The Penalties. Proposition 65 permits private citizens as well as public enforcement officials to sue for violations of both the warning and the discharge provisions.[10] Plaintiffs may seek injunctive relief and/or civil penalties. Violation of either the warning or the discharge provision of the law carries a maximum penalty of $2,500 per day per violation. Plaintiffs in failure-to-warn cases will attempt to maximize penalties by asking that penalties be assessed on a "per day per individual exposed" basis. The law's "bounty hunter" provision awards one-fourth of any assessed penalties to the office or citizen bringing the action. These penalty provisions are expected to result in vigorous private enforcement of Proposition 65.

The Chemical List. On Feb. 27, 1987, California's Governor George Deukmejian published a list of 29 chemicals "known to the state to cause cancer or reproductive toxicity." This first listing triggered the warning requirement as of Feb. 27, 1988, and the discharge prohibition as of Oct. 27, 1988, for these 29 chemicals. At the same time, the Governor published a list of 202 "candidate" chemicals that the Governor's Scientific Advisory Panel (SAP) is in the process of reviewing.[11] From the candidate list and elsewhere, the panel has added approximately 200 more chemicals to the Governor's original list. The warning and discharge provisions affecting these chemicals take effect 12 months and 20 months, respectively, from the date of their publication.

Implementation of the Law

During the past year, the Health and Welfare Agency issued numerous draft interpretative guidelines and proposed regulations under Proposition 65 in order to "test the waters." Finally, on Feb. 17, 1988, the agency issued final and emergency regulations defining key terms such as "knowing" and "discharge into drinking water" and addressing, among other issues, the statutory terms "clear and reasonable warning" and "no significant risk."

Definitions. The final regulations clarify that a "knowing" discharge, release, or exposure requires the person responsible to be aware both that the act is occurring and that the chemical is listed.[12] Knowledge that the release or exposure is unlawful is not required.[12] Another key phrase, "discharge or release into water or onto or into land," includes releases to air that are "directly and immediately deposited into water or onto land."[13] In addition, the term includes transfers of listed chemicals to third parties for purposes of discharge or release in an unlawful manner. The term does not include the sale, exchange, or other transfer of a chemical to a solid waste disposal facility or a hazardous waste facility owned by a third party, provided that the disposal complies with all applicable state and federal laws.[13] Nor does the term include the sale, exchange, or other transfer of the chemical to any publicly owned treatment works.[13]

The regulations also establish a rebuttable presumption that any discharge or release into water or onto or into land which is in "hydraulic continuity" with a source of drinking water "probably" will pass to that source regardless of whether it is upgradient or downstream.[13] Unfortunately, the regulations failed to define the term "hydraulic continuity." Moreover, the law defines "source of drinking water" by reference to regional water quality control plans.[14] In their current form, those plans are too general to provide meaningful guidance under Proposition 65; they reference virtually all surface and ground water. The State Water Resources Control Board is in the process of finalizing a definition of "source of drinking water," and has held several hearings on that issue.

General Provisions. The Health and Welfare Agency's final rules also address procedures for obtaining guidance from the agency in the form of interpretative guidelines, safe use determinations, and information letters.[15]

Anyone who is unsure whether a current or potential business activity is in violation of Proposition 65 may seek a "safe use determination."[16] Trade associations also may request safe use determinations on behalf of their members.[16] A safe use determination "represents the State's best judgment concerning the application of the Act to the particular facts presented in the request."[16] A request for a safe use determination must be submitted in writing to the agency, and should contain as much detailed information as possible regarding the use of the chemical, exposure, and toxicity.[17] However, safe use determinations are subject to public notice and comment, and are advisory only. They do not preclude an enforcement action under the law.[18]

Interested parties also may request interpretive guidelines.[19] The agency defines an interpretive guideline as a "draft regulatory proposal."[19] The request must state the nature of the guideline requested and the reason for the request.[19] If an interpretive guideline is published pursuant to a request, the agency may later rescind the guideline, propose that it be formally adopted, or modify it and either republish it as an interpretive guideline or a proposed regulation.[20]

Clear and Reasonable Warnings. Under its emergency regulations, the agency interprets "clear and reasonable warnings" as those "reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure."[21] The warning must "clearly communicate" that the chemical in question is known to the state to cause cancer or reproductive effects.[21] The agency has defined three categories of exposure—consumer products exposures, occupational exposures, and environmental exposures—and prescribes acceptable methods of transmitting warnings for each category. Businesses need not adhere to the specific warning language or transmittal method set forth in the regulations, but are free to develop their own warning statements.[21]

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Consumer product exposures are defined as exposures resulting from the acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.[22] Consumer product warnings may be transmitted by either labeling on or accompanying the product; identification of the product at the retail outlet by means of shelf labeling, signs, menus, or some combination of the three; or a system of signs, public advertising, and toll-free telephone information services or any other system providing a clear and reasonable warning.[22]

Primary responsibility for providing consumer product warnings rests with the manufacturer, producer, or packager. Nevertheless, the regulations make it clear that anyone in the chain of commerce who sells or otherwise transfers a consumer product with knowledge that the product requires a warning is responsible for providing that warning.[23]

Occupational exposures are those occurring "in the work place of the employer causing the exposure, to any employee."[24] Occupational warnings may be transmitted by product labeling, signs in the workplace, or warnings that comply fully with all information, training, and labeling requirements of the Federal Occupational Health and Safety Act (OSHA) hazard communications standard (29 C.F.R. Sec. 1910.1200), the California Hazard Communications Standard (8 C.C.R. Sec. 5194) or, for pesticides, the pesticide and worker safety requirements authorized in the California Food and Agriculture Code Sec. 12980 *et seq.*

Finally, the regulations define an "environmental exposure" as any exposure which is neither an *occupational nor a consumer* product exposure.[25] Specifically, it is one "which may foreseeably occur as the result of contact with an environmental medium," including air, water, soil, vegetation, man-made or natural substances, through inhalation, ingestion, skin contact, or otherwise.[25] Appropriate warning methods for environmental exposures include signs in the affected area, notices mailed or delivered every three months to each occupant in the affected area, or public media announcements once every three months.

No Significant Risk Levels. In another set of emergency regulations, the agency established several possible means of determining that a particular exposure poses "no significant risk of cancer."[26] The agency has adopted a

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risk level of one excess cancer in an exposed population of 100,000 as representing no significant risk.[27] Pursuant to the emergency regulations, a determination of no significant risk may be made: by performing a quantitative risk assessment in accordance with the standards described in the regulations; by showing that a listed chemical poses no significant risk by a particular route of exposure; or by reference to a chemical specific regulatory level of no significant risk established by the agency in conjunction with the SAP. To date, the agency has established no risk levels under this provision.

No significant risk also may be determined by reference to a level adopted by the agency based on existing federal and state standards.[28] A list of these is included in the regulations, and covers the 29 chemicals for which warnings currently are required. The agency also has promulgated specific risk levels for the trace elements arsenic (inorganic), beryllium, and cadmium.[29]

Finally, as an interim measure, the agency has determined that exposure to listed chemicals in foods, drugs, cosmetics, and medical devices regulated under federal and state safety laws poses no significant risk of cancer.[30] The agency reserves the right, however, to adopt superseding regulatory levels under this section, following its own quantitative risk assessment of each listed chemical.

No Observable Effect Levels. In addition to defining no significant risk levels for carcinogens, the agency has promulgated emergency rules addressing no observable effect levels (NOELs) for reproductive toxicants.[31] NOELs for such exposures may be based upon either a maximum dose level determined in accordance with prescribed standards (and divided by 1,000 to arrive at a maximum allowable dose), or by reference to a specific regulatory level for the listed chemical. The agency already has established levels for ethylene oxide (20.0 micrograms/day) and lead (0.5 micrograms/day). In addition, NOELs may be established by reference to assessments by state or federal agencies which are conducted in a manner substantially equivalent to the assessment methods prescribed in the regulations.[32]

Regulations issued to date have helped to clarify the warning requirements, but many issues relating to the discharge prohibition remain unclear. In anticipation of the Oct. 27, 1988 effective date for the discharge provision, the agency has published draft regulations addressing levels of no significant risk for regulated chemicals in drinking water and measurement of listed chemicals in discharges or releases to sources of drinking water. The agency proposes to identify as levels of no significant risk: drinking water maximum contaminant levels established by the California Department of Health Services; drinking water action levels for chemicals for which maximum contaminant levels have not been established; and levels of discharge or release of chemicals which are permitted by a Regional Water Quality Control Board in a water quality control plan or waste discharge requirements when such levels are based on consideration of carcinogenic risks associated with such discharge or release.

With regard to measuring listed chemicals in discharges or releases to sources of drinking water, the agency proposes that the amount of a listed chemical in a discharge or release be determined by procedures used or prescribed by the State Water Resources Control Board or the Regional Water Quality Control Board, including procedures concerning the number of samples and the frequency and site of sampling. Additional draft regulations addressing discharge issues are likely to circulate in the next few months.

Compliance and Enforcement: The Warning Requirement

Proposition 65 clearly authorizes enforcement actions by the State Attorney General, district attorneys, city attorneys, and private citizens.[33] The citizens suit provision requires 60 days' notice

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to public enforcement officials and the alleged violator. The suit may proceed only if public enforcement officials fail to "diligently prosecute" the alleged violator within those 60 days.

In a failure-to-warn case, plaintiffs' evidentiary burden for establishing a *prima facie* case is minimal. Plaintiffs need only demonstrate a knowing and intentional exposure of an individual to a listed chemical, with no warning. If a warning is provided, the sole issue will be the adequacy of that warning. There is no need for a plaintiff to show physical harm from exposure, nor is there any injury requirement for an individual to bring suit. Organizational plaintiffs as well as individual citizens have the opportunity under Proposition 65 to bring an action.

At a February conference sponsored by the Sierra Club, a representative from the Los Angeles District Attorney's office outlined

Compliance Checklist

To avoid either a public or a private enforcement action under the warning provision, businesses potentially subject to California's Safe Drinking Water and Toxic Enforcement Act should review the following checklist.

1. *Is the organization responsible for the exposure subject to Proposition 65?*

- Is the organization "doing business" in California?

It appears that anyone selling products or services within the State of California that could result in the exposure of California citizens to a listed chemical is subject to Proposition 65. The term "business" includes nonprofit activities.

- Does the business employ 10 or more people?

The term "employee" is broadly defined and includes part-time and unlawfully employed employees. Whether or not a business employs 10 or more people depends upon the number of employees on the date of the alleged violation.

- Is the business a "public entity"?

Pending legislative amendments that almost certainly will eliminate this exception, a "person in the course of doing business" excludes federal, state, and local agencies, and public water treatment systems.[26]

2. *Is a warning required under the law?*

- Is there an "exposure"?

The California Health and Welfare Agency defines the word "expose" as "causing to ingest, inhale, contact via body surfaces, or otherwise come into contact with the chemical." Companies should be aware of exposures that may occur outside the normal course of business, such as exposure to volatile organic compounds from leaking underground storage tanks. In addition, pesticide manufacturers should be aware of potential exposure to inert ingredients that are listed chemicals. Notwithstanding a possible preemption defense, exposure to listed inert ingredients in pesticides is likely to be one focus of citizen suit enforcement.

- Did the exposure occur in the course of doing business?

A person is considered as doing business regardless of whether an enterprise is conducted for profit.

- Was the exposure knowing and intentional?

"Knowing" is knowledge of the fact that exposure to a listed chemical will occur. It is important to note that receipt of a 60-day notice will trigger the "knowing" requirement. The regulations make it clear that exposures resulting from negligence are subject to the warning requirement.[28]

- Does the level of exposure exceed the levels for no significant risk and no observable effect set forth in the law and regulations?

If there is a question whether a current or potential business activity would cause an exposure in violation of the law, companies may consider seeking safe use determinations *in addition to* conducting in-house risk assessments. There are both advantages and disadvantages to this. The principal disadvantage is that safe use determinations are advisory only, and will not preclude an enforcement action under the law. In addition, a safe use determination is subject to public notice and comment. Consequently, safe use determinations may be most beneficial at the planning stages of an activity involving the use of a listed chemical.

3. *Does the person responsible for the exposure have a duty to warn others in the chain of commerce?*

The law states that the duty to warn should fall primarily on the manufacturer, packager, or processor, rather than on the retailer. Nevertheless, the implementing regulations require any person who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product with knowledge that a warning is required, to provide the warning to any person to whom the product is sold or transferred.[29] Consequently, any manufacturer, processor, or distributor with knowledge that a warning is required has a duty to provide the warning to all those following it in the chain of commerce.

4. *If a warning is required, is it "clear and reasonable"?*

A "clear and reasonable" warning is one reasonably calculated to make the warning message available to the individual prior to exposure. Whether a warning is clear and reasonable, of course, will depend on the particular circumstances of each case. It is likely, however, that proponents of Proposition 65 will challenge the agency's clear and reasonable warning regulations either in enforcement actions or in separate litigation against the agency.

5. *Is the warning requirement preempted?*

The Federal Insecticide, Fungicide and Rodenticide Act, the Federal Hazardous Substances Act, and the Occupational Safety and Health Act offer substantial preemption defenses. Furthermore, California already has acknowledged preemption at least on an interim basis under the Federal Food, Drug, and Cosmetic Act. Proponents of Proposition 65 plan to challenge the Agency's decision to exempt FFDCA-regulated products.

four factors that his office will examine in determining whether to bring a Proposition 65 enforcement action: the number people exposed to the chemical in the affected area; the health and safety risk posed by the specific release or exposure; the quality of available evidence; and the "outrageousness" of the alleged violators' conduct or activity.

David Roe, co-author of the law and senior attorney at the Environmental Defense Fund, listed the factors he considers important in determining whether to initiate a citizens suit: the seriousness of the exposure, based on exposure level, number, or susceptibility of population exposed and length of exposure; failure of the defendant to have conducted studies and quantified exposures in advance of the enforcement action; and absence of good faith compliance efforts (see Sidebar).

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Litigation

There are several potential sources of litigation under Proposition 65. For example, proponents of the law already have stated that they intend to challenge several aspects of the agency's warning regulations, including the use of a toll-free number to warn of consumer product exposures, and the proposed wording of the warnings themselves. The first challenge to the law was filed by the Committee for Uniform Regulation in Labeling (CURL) in the U.S. District Court for the Northern District of California on Feb. 26, 1988. CURL, comprising a number of food-processing and packaging-related companies, challenged the law on a variety of federal and state constitutional grounds, including burden on interstate commerce, equal protection, due process, and violation of California's single issue initiative rule. The CURL lawsuit is likely to be but the first

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sumer must rely on professional services to replace the effectiveness and efficiency of aerosols. Jobs which the consumer had done inexpensively with aerosol products would cost much more since a professional would have to be hired to complete the job.

Even the professionals would find that aerosol alternatives cost more in labor and materials. Higher costs ultimately would be borne by the consumer.

Black Market

Although a state can stop retail sales of products in a particular locale, consumers could, and in all likelihood would, purchase these products by traveling outside the district. This encourages increased use of automotive transportation, the primary cause of ozone depletion, to obtain products elsewhere.

By inducing such behavior, a consumer product restriction would defeat the precise purpose of the SIP. If the proposed control measure prompts only a few additional automobile trips per day, the resultant hydrocarbon exhaust emission in the area could more than wipe out the most optimistic projections of hydrocarbon reductions.

Conclusion

Any attempt to reduce VOCs with a ban on aerosols or a reformulation requirement (in effect, a ban) will have little, if any, impact on hydrocarbon emissions or ozone depletion and indeed may even be counterproductive to the goal of pollution control. Furthermore, such a measure would not be cost-effective, placing an extraordinary financial burden on the consumer and on the industry, and would impose an undue burden on interstate commerce.

Therefore, states considering measures to reduce VOCs should apply a thoughtful, scientific approach and avoid a blind knee-jerk reaction to the deadline and political pressures of the Clean Air Act.

The solution for an effective approach to ozone attainment can be accomplished. Congress must legislate changes which do more than set a standard. Such changes must establish a reasonable, scientifically valid, risk-effective plan for attainment over a realistic period of time. This may even require reevaluation of the criteria for determining standards within the law.

Lawmakers who seek to use the CAA deadlines as leverage to reauthorize the law and, thereby, load it with draconian controls would better serve the public's interest in focusing on more realistic measures which can be reasonably expected to achieve compliance with NAAQS.

It is, however, unlikely that Congress will pass such CAA legislation before the current extensions runs out in August. In the interim, attempts by states to reduce VOCs without careful considerations are only adding to the Rube Goldberg confusion. The solution rests not only with the states but also with Congress in achieving a more realistic law.

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in a long line of court actions necessary to clarify the scope and requirements of this controversial law.

Footnotes

1. California Health and Safety Code §§25249.5–25249.11
2. The Safe Drinking Water and Toxic Substances Act of 1986, Sec. 1.
3. California Health and Safety Code §25249.11. Two bills, Assembly Bill No. 1028 and Senate Bill No. 269, have been introduced in the California legislature that would eliminate the public entity exemption. It is widely believed that such an amendment will pass the legislature this year.
4. Id. §25249.8 (a), (b).
5. Id. §25249.9.
6. Id. §25249.11(c).
7. Id. §25249.6.
8. Id. §25249.11(f).
9. Id. §25249.10.
10. Id. §25249.7.
11. The Agency has promulgated emergency regulations relating to the authority, duties and composition of the SAP. See Calif. Admin. Code Title 22, §§12301–12305 (1988).
12. Calif. Admin. Code Title 22, §12201(c).
13. Id. §12201(d).
14. See California Health and Safety Code §25249.11(d).
15. Calif. Admin. Code Title 22, §§12101–12305.
16. Id. §12104.
17. Id. §12104(c).
18. Id. §12104(a), (f).
19. Id. §12103.
20. Id. §12201(b).
21. Id. §12601(a).
22. Id. §12601(b).
23. Id. §12601(b)(5).
24. Id. §12601(c).
25. Id. §12601(d).
26. Id. §§12701–12713.
27. Id. §12703.
28. See Id. §12711.
29. Id. §12709.
30. Id. §12713.
31. Id. §§12801–12805.
32. Id. §12805(c).
33. Calif. Health and Safety Code §25249.7.
34. Id. §25249.11(b).
35. Calif. Admin. Code. Title 22, §12201(c).
36. Id. §12601(b)(5).