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California's Toxics Initiative: Making It Work

by Judith A. DeFranco*

On November 4, 1986, California voters overwhelmingly1 approved Proposition 65, the Safe Drinking Water and Toxic Enforcement Initiative of 1986 (Act).2 Proposition 65 requires the Governor to publish a list of chemicals known by the state to cause cancer or reproductive toxicity.3 Next, it prohibits businesses4 from discharging listed chemicals to sources of drinking water.5 Prohibited discharges are exempt from the Act if the business can prove that the discharge took place less than twenty months after the chemical was first listed, or that the discharge complies with other applicable laws and requirements and does not release a significant amount of the chemical.6 Furthermore, Proposition 65 requires businesses subject to the Act to give a clear warning to anyone whom they knowingly and intentionally expose to a listed chemical.7 The Act exempts from the warning requirement exposures to carcinogens that the business can show do not cause a significant risk,8 and exposures to reproductive toxicants9 that the business can show do not have an observable effect at 1000 times the exposure level.10 Finally, specified officials or, under certain circumstances, anyone acting in the public interest may bring suit to enforce the provisions of the Act.11

* Member, Second Year Class.
2. CAL. HEALTH & SAFETY CODE §§ 25180.7, 25189.5, 25192, 25249.5-13 (West Supp. 1988).
3. Id. § 25249.8. See infra notes 52-60 and accompanying text.
5. § 25249.5. See infra notes 66-79 and accompanying text.
6. § 25249.9.
7. § 25249.6. See infra notes 80-86 and accompanying text.
8. § 25249.10.
9. Id. Reproductive toxicants are chemicals which cause harm to unborn children. The effects include malformation, functional impairment, altered growth, and lethality. See EPA Guidelines for the Health Assessment of Suspect Developmental Toxicants, 51 Fed. Reg. 34,028, 34,029 (1986) [hereinafter Developmental Toxicants].
10. § 25249.10(c).
11. § 25249.7. See infra notes 87-91 and accompanying text.
Business interests vigorously opposed passage of Proposition 65 on several grounds. First, they argued the Act was unnecessary because existing laws provided adequate protection to the public.\(^{12}\) They also argued that the exemptions would be unusable both because the Act was unclear and because they could not scientifically prove that any exposure is safe.\(^{13}\) Finally, businesses feared, as a consequence, they would be required to warn about most ordinary products and activities or face enforcement of the Act by anyone who wished to sue.\(^{14}\)

Both the environmental groups that sponsored Proposition 65 and the business community opposing it recognized that the Act would not work without clarifying regulations.\(^{15}\) The California Health and Welfare Agency, the lead agency charged with implementing Proposition 65, began to develop implementing regulations shortly after its passage. The Agency first issued interpretative guidelines defining some of the terms in the Act.\(^{16}\) They then proposed regulations and held public meetings and workshops.\(^{17}\) Ten days before the effective date of the warning provisions, the Agency issued a series of emergency regulations, addressing some of the problems of implementation.\(^{18}\) Some questions still remain, and some of the issues resolved by the regulations face challenges from environmental groups.\(^{19}\)

This Note examines the problems of implementing Proposition 65. Part I examines the objectives of Proposition 65 and explains its major provisions. Part II explains the objections of business to the provisions regulating carcinogens. Section A discusses the exemption for insignificant risks from exposure to carcinogens.\(^{20}\) It explains that estimating

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14. Id.
15. Id.
18. Id. §§ 12101-12901. The regulations and supporting documents are available from the California Health and Welfare Agency, 1600 Ninth Street, Room 450, Sacramento, CA 95814.
20. The exemptions from the discharge prohibition and warning requirement for reproductive toxicants do not include an exemption for insignificant risks. Rather, the business must show that "exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question." Cal. Health & Safety Code § 25249.10(c) (West Supp. 1988). This standard is more restrictive than the standard for carcinogens, since reproductive toxicants usually have a threshold, and an insignificant level of exposure might otherwise be found at a much higher exposure than allowed by the Act. See Developmental Toxicants, *supra* note 9.
risk from exposure to carcinogens necessarily involves a great deal of uncertainty. Further, no level of risk from carcinogens is generally recognized as insignificant.\textsuperscript{21} Thus, the only alternative Proposition 65 leaves businesses is to reduce discharges below detectable levels and give warnings whenever any exposure may occur. A barrage of warnings for trivial risks, however, may reduce the public's awareness of truly significant hazards and cause unnecessary fear.

Section B examines several shortcomings of the exemption for undetectable amounts of a chemical. First, the exemption does not apply at all to the warning requirement.\textsuperscript{22} Hence, businesses will often have to warn about chemicals which they know are present in products but which are not detectable nor harmful at such low levels. Second, the Act and its implementing regulations do not adequately specify how to determine whether a detectable amount of a listed chemical is present.\textsuperscript{23} Without adequate guidelines, a business cannot monitor its own compliance.

Section C demonstrates how the enforcement provisions of the Act increase the businesses' uncertainty by making them potentially subject to suits for exposures and discharges that would be deemed unworthy of action by government.\textsuperscript{24}

Part III examines the response of the environmental groups who sponsored the initiative to the criticisms raised by business.\textsuperscript{25} First, in response to the contention that the exemption for insignificant risks is meaningless, they argue that the data needed to show that risks are insignificant are developed as part of the listing process itself. Environmental groups also argue that warnings can be avoided because businesses can eliminate the chemicals from their products, discharges, and processes. This section concludes that while both arguments have merit, neither is entirely correct.

Part IV evaluates possible solutions to the concerns of business. Section A examines the emergency regulations on risk assessment and the insignificant risk exemption of Proposition 65. The regulations establish standards for performing risk assessments and define an insignificant level of risk.\textsuperscript{26} They also exempt exposures from foods, drugs, cosmetics, and medical devices if such exposures comply with other state and federal laws.\textsuperscript{27} Section A concludes that these regulations effectively meet

\begin{itemize}
\item \textsuperscript{21} See infra notes 97-160 and accompanying text.
\item \textsuperscript{22} See \textit{CAL. HEALTH \\& SAFETY CODE} § 25249.10 (West Supp. 1988); infra notes 168-79 and accompanying text.
\item \textsuperscript{23} See infra notes 181-90 and accompanying text.
\item \textsuperscript{24} See § 25249.7(d); infra notes 191-203 and accompanying text.
\item \textsuperscript{25} See \textit{L.A. Times}, Oct. 13, 1986, Part I, at 20, col. 1.; infra note 205 and accompanying text.
\item \textsuperscript{26} \textit{CAL. ADMIN. CODE} tit. 22, §§ 12701-12721 (1988).
\item \textsuperscript{27} \textit{Id.} § 12713.
\end{itemize}
the goal of adequately protecting the public without overburdening businesses and therefore should be retained.

Section B argues for a discharge regulation specifying that the detectability of a chemical be determined in the body of water that is designated as a source of drinking water. Although the emergency regulations do not directly address this question, one alternative is to make the determination at the point where the chemical is released. Section B argues that this interpretation of the regulations is neither logical nor intended by the language of the Act.

Section C proposes that the Act be amended to exempt undetectable amounts of carcinogens from the warning requirement—to promote public policy considerations as well as to further the purposes of the Act.

I. The Objectives and Provisions of the Initiative

A. The Twin Objectives: Elimination of Unsafe Chemicals from Drinking Water and Warning of Potential Exposures

Two major motivations prompted adoption of the initiative. The first was the public's desire to avoid unsafe amounts of chemicals. Although at the time the initiative was placed on the ballot, numerous federal and state laws dealt with water quality and with toxics exposure, many felt these laws were inadequate. As proof that California

28. Id. § 12201(d) (defining discharge or release to water or land); § 12901 (acceptable methods of detection in various media).

29. See, e.g., Federal Water Pollution Prevention and Control Act, 33 U.S.C.A. §§ 1251-1376 (West 1986) (Section 1317(a) requires the Administrator to publish a list of toxic pollutants and to establish effluent standards or prohibitions—the maximum level of permissible discharge from a site. Effluent standards must be set at a level which provides an adequate margin of safety); the Federal Safe Drinking Water Act, 42 U.S.C. §§ 300f to 300j-10 (1982 & Supp. 1988) (requiring standards to be set for maximum contaminant levels in drinking water at a "level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety"); Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C.A. § 9621 (West Supp. 1987) (directing that remedial actions be taken to clean up site, with preference given to permanent corrective actions); California's Porter-Cologne Water Quality Act, Cal. Water Code §§ 13000-13806 (West 1971 & Supp. 1988) (providing a comprehensive system for protection of the beneficial uses of water).

30. Toxic substances, including carcinogens, were regulated under a number of statutes which either banned them outright or required warnings. These included:

(1) The Occupational Safety and Health Act, 29 U.S.C. §§ 651-678 (1982), under which standards have been set for occupational exposure to 24 human carcinogens. 29 C.F.R. § 1910.1001-.1043 (1987). Additionally, employers are required under this Act to provide workers with information on the health effects of chemicals to which they are exposed, including exposure to known or suspected carcinogens. Id. § 1910.1200.

(2) The Hazardous Substances Information and Training Act, Cal. Lab. Code §§ 6360-6399.5 (West Supp. 1988), also requires information on the presence of carcinogens in the workplace to be made available to workers.

(3) The Delaney Clause of the Food, Drug, and Cosmetic Act forbids the addition of any
needed tougher laws, the ballot argument cited instances in which children were exposed to toxics in Fullerton, Riverside, McFarland, Sacramento, and San Jose. In addition, in the year immediately preceding the initiative, the public had read of pesticides in wells in the central valley, trichloroethylene and dichloroethylene in wells in the Silicon Valley, and trichloroethylene in wells in the San Fernando Valley. The initiative promised to eliminate chemicals in drinking water and ensure that businesses would warn the public of all exposures not proven safe. Additionally, the authors assured the public that studies used to place a chemical on the list would provide the necessary data for determining safety levels.

The second motivation behind the initiative was a desire to speed up regulatory control of carcinogens and reproductive toxicants. Traditionally, regulatory agencies have been responsible for risk management—the process of controlling risk. Risk management balances risk, as determined by a risk assessment, legislative directives, and sociological, political, and technological considerations, to decide how much to control exposure to toxic agents. This is usually done through notice and comment rulemaking, a process which may take many years, even decades.

amount of a food additive which has been shown to be a carcinogen in appropriate tests in humans or animals. 21 U.S.C. § 348(c)(3)(A) (1982).


(8) The Toxic Substances Control Act, 15 U.S.C.A. §§ 2601-2654 (West 1982 & Supp. 1988). The Act bans the manufacture and distribution of polychlorinated biphenyls unless they are totally enclosed. Id. § 2605(e). It also authorizes the Administrator of the Environmental Protection Agency to prohibit or regulate the distribution and use of chemicals which present an unreasonable risk to health or the environment. Id. § 2605(b).


37. Id.

38. For an explanation of notice and comment rulemaking, see F. HEFFRON & N. McFEELEY, THE ADMINISTRATIVE REGULATORY PROCESS 237-41 (1983). Examples of stat-
The environmental groups sponsoring the initiative blamed industry for most of the delays in setting acceptable standards. They argued that the initiative, by placing the burden on businesses to prove an exposure is safe, would “turn the current system around”; industry would be forced to use its influence to encourage the setting of standards or face the alternative of having to prove in court that a chemical release did not present a significant risk.


The Safe Drinking Water and Toxic Enforcement Act of 1986 promises citizens the following rights:

(a) To protect themselves and the water they drink against chemicals that cause cancer, birth defects, or other reproductive harm.
(b) To be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm.
(c) To secure strict enforcement of the laws controlling hazardous chemicals and deter actions that threaten public health and safety.
(d) To shift the cost of hazardous waste cleanups more onto offenders and less onto law-abiding taxpayers.

To ensure these rights, Proposition 65 requires the Governor to develop a list of chemicals known by the state to cause cancer or reproductive toxicity. It also prohibits businesses from knowingly discharging listed chemicals to sources of drinking water, and requires businesses to give a clear warning before knowingly and intentionally exposing anyone to a listed chemical. The Act provides both injunctive

utes requiring the notice and comment process include the Administrative Procedure Act, 5 U.S.C. § 553 (1982), and the Clean Air Act, 42 U.S.C. § 7601 (1982).

39. An example of promulgation of a rule taking more than a decade is the Food and Drug Administration regulation of the migration of vinyl chloride into food from food packaging. The problem was recognized in 1973. Although some uses of vinyl chloride polymers in food packaging were eliminated quickly, rules setting safe use conditions are still not final. See FDA, Vinyl Chloride Polymers, 51 Fed. Reg. 4173 (1986) (to be codified at 21 C.F.R. pts. 172, 175, 176, 177, 179, 181) (proposal withdrawn Jan. 27, 1986) [hereinafter Vinyl Chloride]; Proposed Uses of Vinyl Chloride Polymers, 51 Fed. Reg. 4177 (1986) (to be codified at 21 C.F.R. pts. 172, 175, 176, 177, 179, 181) (proposed 1986) [hereinafter Proposed Uses].

43. CAL. HEALTH & SAFETY CODE § 25249.8 (West Supp. 1988); see infra notes 56-64 and accompanying text.
44. § 25249.5.
45. § 25249.6; see infra notes 84-90 and accompanying text. The Act also requires designated government employees who learn of illegal discharges or threatened illegal discharges to disclose the discharges to specified persons. § 25180.7 This provision applies to all illegal discharges of hazardous waste, not just to discharges of listed chemicals. See CAL. ADMIN. CODE tit. 22, § 12201(f) (1988). These provisions are beyond the scope of this Note.
relief for violations. Certain public officials or any person acting in the public interest may bring action to enforce the Act's provisions.

To implement its provisions, the Act requires the Governor to designate a lead agency to adopt regulations, standards, and permits to further the purposes of the Act. The Governor chose the California Health and Welfare Agency as the lead agency to implement Proposition 65.

(1) The List of Substances Known by the State to Cause Cancer or Reproductive Toxicity

The Act required the Governor to publish, by March 1, 1987, a list of chemicals known to the state to cause cancer or reproductive toxicity. The list was to include, at a minimum, substances listed as carcinogens by the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), and the Occupational Safety and Health Administration. Additionally, the list was to include a chemical if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.

46. CAL. HEALTH & SAFETY CODE § 25249.7(a) (West Supp. 1988).
47. Id. § 25249.7(b).
48. Id. § 25249.7(c).
49. Id. § 25249.7(d). Persons acting in the public interest may only bring this action following at least 60 days notice to the designated public officials and only if the public officials have not diligently pursued the matter themselves. Id.
50. Id. § 25249.12.
52. CAL. HEALTH & SAFETY CODE § 25249.8(a).
54. CAL. HEALTH & SAFETY CODE § 25249.8(b). The Governor's Scientific Advisory Panel has declined to recognize the Federal National Toxicology Program as an authoritative body for purposes of the Act. CAL. ADMIN. CODE tit. 22 § 12305, at 39 (1988) (Final Statement of Reasons). The California Health and Welfare Agency believes that the Act does not require the Panel to recognize any particular body as authoritative. Id. Although this appears correct for chemicals qualifying on the basis of qualified expert opinion under CAL. HEALTH & SAFETY CODE § 25249.8(b), the provisions of § 25249.8(a) appear to require the initial list to
Backers expected the list to contain over 200 chemicals.\textsuperscript{55} When the initial list was released on February 27, 1987, however, it contained only twenty-six known human carcinogens plus three reproductive toxicants.\textsuperscript{56} The AFL-CIO filed suit the same day seeking to require the Governor to expand the list to about 250 chemicals.\textsuperscript{57} On April 24, 1987, the court ordered the addition of all but one of the carcinogens proposed by the AFL-CIO and all but two reproductive toxicants to the list.\textsuperscript{58}

Once a substance is placed on this list, businesses subject to the Act must comply with the discharge prohibition within twenty months,\textsuperscript{59} and with the warning requirement within twelve months.\textsuperscript{60}

\textit{(2) Persons Subject to the Discharge and Warning Requirements}

The discharge and warning provisions of Proposition 65 apply to "person[s] in the course of doing business."\textsuperscript{61} Under the regulations, a business need not operate for profit. Any person with ten or more employees on the day of the discharge or exposure is subject to the provisions of the Act.\textsuperscript{62} The number of employees is determined by counting all paid, full- and part-time employees on the date the event occurs.\textsuperscript{63}

The Act excludes cities, counties, the state and federal government, and entities operating public water systems.\textsuperscript{64} Federal, state, and local include carcinogenic substances identified by the National Toxicology Program. This section does not require the NTP to be designated as an authoritative body in order to have its list of carcinogens included in the Governor's list.

\textsuperscript{55} San Francisco Chron., Oct. 28, 1986, at 8, col. 2 (consensus existed on both sides that approximately 200 chemicals were known to be carcinogens).


\textsuperscript{57} AFL-CIO v. Deukmejian, No. 348195 (Sacramento Super. Ct. filed Feb. 27, 1987), noted in \textit{17 Env't Rep. (BNA)} 1861 (Mar. 6, 1987).


\textsuperscript{60} Id. § 25249.10(b).

\textsuperscript{61} Id. § 25249.5-6.

\textsuperscript{62} \textit{Cal. Admin. Code} tit. 22, § 12201 (1988). This regulation makes caterers at cocktail parties, if the caterer employs ten or more people, or the host, if he hires enough assistants, responsible for warning the guests of the danger of alcohol. Other types of exposure which an employer might be required to warn about include dioxin in bleached paper, and polynuclear aromatics in toners. The regulation also makes public interest groups, such as the Environmental Defense Fund, subject to the provisions of the Act.

\textsuperscript{63} Id. § 12201(b).

\textsuperscript{64} \textit{Cal. Health & Safety Code} § 25249.11(b).
governments, however, may also cause widespread pollution through the operation of facilities such as landfills, military facilities, water treatment plants, or even from water chlorination. The legislature is currently considering removal of this exemption.65

(3) Ban on Discharge of Listed Chemicals

Proposition 65 bans businesses from knowingly discharging or releasing listed chemicals in a manner that may allow their entry into sources of drinking water.66 A business is exempt from the ban only if it shows that the discharge conforms with all other laws, and with every applicable regulation, permit, requirement, or order;67 and that the discharge will not result in a significant amount of the chemical entering a source of drinking water.68

The Act defines a significant amount as any detectable amount.69 If there is a detectable amount of a carcinogen present, however, a business still may show that the amount is not significant by proving that the discharge does not pose a significant risk over a lifetime of exposure at the level in question.70 Discharges of reproductive toxicants may be exempt if the business shows that the chemical would cause no observable effect71 at 1000 times the actual exposure.72 Figure 1 illustrates Proposition 65's regulatory scheme for both types of discharges to drinking water.

The provisions of Proposition 65 were vaguely written, causing the business community considerable concern about the implementation of the ban on listed chemical discharges. In an attempt to clarify the requirements, the California Health and Welfare Agency first issued interpretative guidelines73 that defined the terms "in the course of doing

66. CAL. HEALTH & SAFETY CODE § 25249.5. (West Supp. 1988) provides:
No 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 except as provided in Section 25249.9.
67. Id. § 25249.9(b).
68. Id.
69. Id. § 25249.11(c).
70. Id. § 25249.10(c), 25249.11(c).
71. Id. § 25249.9(b), 25249.10(c). The "no observable effect" level for a chemical is the maximum dose at which the expected effect is not observed. CAL. ADMIN. CODE tit. 22, § 12801 (1988).
72. CAL. HEALTH & SAFETY CODE § 25249.10(c).
Is a listed chemical released?  

- **No**  
  - Discharge prohibition does not apply

- **Yes**  
  - May any reach a source of drinking water?

  - **No**  
    - Discharge permitted

  - **Yes**  
    - May a detectable amount enter a source of drinking water?

      - **No**  
        - Does the discharge or release conform with applicable requirements?

          - **Yes**  
            - Discharge permitted

          - **No**  
            - Discharge banned

      - **Yes**  
        - Can the business demonstrate that the risk is insignificant (carcinogens) or less than 1/1000th the no effect level (reproductive toxicants)?

          - **Yes**  
            - Discharge permitted

          - **No**  
            - Discharge banned

Figure 1. Discharge prohibition
business,"74 "knowingly,"75 "passes or probably will pass into any source of drinking water,"76 and "significant risk."77 The Agency then held public meetings throughout 1987 to consider regulations. The guidelines were later withdrawn and emergency regulations were issued on February 27, 1988.78 The regulations resolve much of the ambiguity of the Act, but face challenge by environmental groups.79

(4) The Warning Provisions of the Act

Under the second major provision of Proposition 65, businesses subject to the Act must give a clear and reasonable warning before intentionally and knowingly exposing any person to a listed chemical:80

"Warning" . . . need not be provided separately to each exposed individual and may be provided by general methods such as labels on cont-

74. The Agency determined that the Act applied to any person who "has ten or more employees and who is not otherwise excluded by . . . HEALTH & SAFETY CODE Section 25249.11(b)." Id. at Supp. 11-12.
75. According to the Agency definition, "knowingly" encompasses only knowledge of the act of discharge, release, or exposure. Id. at Supp. 12.
76. The Agency has determined that a chemical will pass or probably will pass into a source of drinking water if it is deposited into water or onto land which is in hydraulic continuity with a source of drinking water whether or not it is upstream from the source. CAL. ADMIN. CODE tit. 22, § 12201(d) (1988). A release onto land includes a release into the air if the chemical will be immediately deposited onto land or into water. Id.
77. Safe Drinking Water and Toxic Enforcement Act of 1986 Interpretative Guideline, CAL. ADMIN. CODE tit. 26, Supp. 13 (1987). The Agency initially defined significant risk as "an unacceptable risk which shall be determined after the evaluation of a scientific risk assessment of a chemical's inherent toxicity and potential human exposure." The regulations abandoned this definition and instead established procedures that a business may use to determine whether exposure to a listed chemical poses no significant risk, CAL. ADMIN. CODE tit. 22, §§ 12701-12721 (1988), or is less than 1/1000th of the no observable effect level. Id. §§ 12801-12803.
78. Id. §§ 12101-12901 (1988).
80. CAL. HEALTH & SAFETY CODE § 25249.6 (West Supp. 1988).
sumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. The California Health and Welfare Agency defines "expose" as "causing to ingest, inhale, contact via bodily surfaces or otherwise come into contact with a chemical." Once in effect, the warning requirement has three exemptions. First, the Act does not require warnings for "exposure for which federal law governs warning in a manner that preempts state authority." Second, it does not require warnings for exposures to carcinogens which can be shown to pose no significant risk. Finally, exposures to reproductive toxicants which have no significant effect at exposures one thousand times the level in question are also exempt from the warning requirement. Notably absent is an exemption for exposures to undetectable amounts of a chemical. Figure 2 illustrates Proposition 65's regulatory scheme for warning of chemical exposures.

(5) Enforcement

Designated government officials or, under certain circumstances,

81. Id. § 25249.11(f). The remainder of this section provides:
In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

82. CAL. ADMIN. CODE tit. 22, § 12201(e). Exposure could be through "water, air, food, consumer products, and any other environmental exposure as well as workplace exposures."

83. The warning requirement becomes effective 12 months after the Governor places a chemical on the list. CAL. HEALTH & SAFETY CODE § 25249.10(b).


85. § 25249.10(c).
86. § 25249.10.
87. The Attorney General, any district attorney, any city attorney of a city having a
Is Exposure to a Listed Chemical Possible?  

Yes

Can the Business Demonstrate that the Risk is Insignificant (Carcinogens) or Less than 1/1000th the No Effect Level (Reproductive Toxicants)?

No

Does Federal Law Preempt?

Yes

Exemption Applies

No

Warning Required

Warning Requirement Does Not Apply

No Warning Required

Figure 2. Warning Requirement
any person bringing suit in the public interest may bring an action to enforce the discharge prohibition and warning requirements of the Act. The Act provides both injunctive relief and civil penalties of up to $2,500 dollars per day of violation. As an incentive, a person bringing an action in the public interest is entitled to twenty-five percent of the penalty collected.

The provisions of Proposition 65, taken together, represent a dramatic shift in the approach to toxics control. The Act places on those responsible for the exposures the burden of showing the exposures are safe. At the same time, it circumvents the discretion regulatory agencies have traditionally had in setting standards and deciding whether to initiate enforcement actions. Understandably, business interests were concerned about the potential impact of the Act.

II. Objections to the Act

Business interests opposing Proposition 65 argued that without definitions of crucial terms in the Act, the exemptions would be meaningless, and doubted that definitions and standards could be readily established. They also argued that the Act would require them to warn about ordinary and safe products which would, in turn, cause warnings about truly significant hazards to get lost among the warnings for trivial risks.

A. The Problem with the No Significant Risk Exemption

Entities seeking exemption from the warning requirement under the no significant risk exemption objected strongly to Proposition 65’s lack of definitions and standards. Since the burden of proving that a particular exposure to a carcinogen presents no significant risk is on those responsible for the exposure, businesses wanted to know precisely what they had to prove. The evidence used to show that the risk is not significant is to be of comparable scientific validity to that used for placing the chemical in excess of 750,000, or, with the consent of the district attorney, a city prosecutor in any city or city and county having a full-time city prosecutor may enforce the Act. CAL. HEALTH & SAFETY CODE § 25249.7(c) (West Supp. 1988).

88. Id. § 25249.7(d). A person bringing suit under this provision must give notice of the violation 60 days prior to filing suit to the Attorney General, the district attorney, any city attorney where the violation is alleged to have occurred and the alleged violator. She may then bring suit if “neither the Attorney General, nor any district attorney nor any city attorney or prosecutor has commenced and is diligently prosecuting an action against such violation.” Id.

89. Id. § 25249.7(a).
90. Id. § 25249.7(b).
91. Id. § 25192(a).
Opponents of the Act feared that proving the safety of any exposure to a carcinogen would be impossible unless the lead agency established clear standards. 96

(1) Determining How Much is Safe: The Limitations of Scientific Risk Assessment

The limitations of scientific risk assessment are a fundamental problem facing businesses trying to comply with Proposition 65. 97 Built into the “no significant risk” exemption for discharges of and exposures to listed chemicals are assumptions that science can accurately determine risk and that people can agree that some level of risk is not significant. Unfortunately, science is not yet able to accurately determine the amount of risk associated with various modes of exposure to most carcinogens. 98 Faced with the need to decide which exposures should be regulated, government agencies have used additional assumptions to fill the gaps in their knowledge. They base these assumptions upon supposed mechanisms of carcinogenesis and public policy considerations. 99 This combination of science and policy and the resulting assumptions is scientific risk assessment.

A variation in the assumptions adopted can dramatically affect the estimate of risk. 100 Regulatory agencies and others performing risk assessments recognize this limitation 101 and often include information about the underlying assumptions and uncertainty in the assessment. Despite its limitations, some form of risk assessment is necessary to the

95. Id. § 25249.10(c).


97. See Stenzel, The Need for a National Risk Assessment Communication Policy, 11 HARV. ENVTL. L. REV. 381 (1987) ("‘Risk’ is a conditional probability of suffering harm which is often expressed in quantitative terms.").

98. See Chemical Carcinogens, 50 Fed. Reg. 10,372, 10,375 (1985) (final document) ("Often a choice must be made among several different scientifically plausible options"); Risk Assessment, supra note 36, at 34,001 (risk assessment requires judgments when available information is incomplete); Ruckleshaus, Risk, Science, and Democracy, 1 ISSUES SCI. & TECH. 19, 26 (1985) (risk assessment is a device used to avoid the paralysis of waiting for definitive data).

99. Public policy in performing a risk assessment has traditionally used conservative methods of estimating risk. Agencies consider this policy to be prudent because of the serious effects and the uncertainties in the estimates. See, e.g., Risk Assessment, supra note 36, at 33,997-99 (recognizing that in most cases procedures do not exist for making a “best” estimate of risk, so one should choose in most cases a method of extrapolating to low doses which gives an upper-limit risk estimate). See generally CALIFORNIA DEP'T OF HEALTH SERVICES, GUIDELINES FOR CHEMICAL CARCINOGEN RISK ASSESSMENTS AND THEIR SCIENTIFIC RATIONALE B-6 (1985) [hereinafter GUIDELINES] (implications for the identification of carcinogens).


101. See, e.g., Risk Assessment, supra note 36, at 33,994 (guidelines necessarily include judgmental positions based’ on the regulatory mission of the Agency).
development of regulations. The regulations implementing Proposition 65's no significant risk provisions adopt conservative risk assessment assumptions similar to those contained in the state and federal guidelines.

Risk assessment procedures are designed to separate estimates of the potential harm from a particular exposure from the policy decision on how to control the exposure. Estimating the harm from exposure to a chemical requires assessing the hazard posed by the chemical and the level of exposure likely to occur. An estimate of the hazard includes hazard identification and dose-response assessment. Depending upon the purpose of the risk assessment and the results of various steps, an assessment may contain one or more of the possible steps.

Each step in this process requires assumptions to bridge the gaps where scientific knowledge is lacking. An examination of the uncertainties inherent in each step of risk assessment demonstrates why it would be so difficult to scientifically prove an absence of significant risk in defending an action under the Act.

a. Hazard Identification

Under Proposition 65 the Governor's experts are required to de-

102. See Ruckelshaus, supra note 98, at 27 (some form of risk assessment is necessary to determine if there is any basis for regulatory action).
104. See, e.g., GUIDELINES, supra note 99.
105. For general principles of estimating risk from chemical carcinogens used in the federal government, see Chemical Carcinogens, 50 Fed. Reg. 10,372 (1985) (final document). Principles contained in the Office of Science and Technology document are adapted by agencies that must perform risk analyses as part of their regulatory programs. See, e.g., Risk Assessment, supra note 36, at 33,993 (adopting guidelines for EPA, using principles of the OSTP report).
106. Risk Assessment, supra note 36, at 33,993. The assumptions themselves may be the product of agency policy and thus value laden. An example of this is the policy of ignoring negative results. Whittemore, Facts and Values in Risk Analysis for Environmental Toxicants, 3 RISK ANALYSIS 23, 27 (1983).
107. See infra notes 110-27 and accompanying text.
108. See infra notes 128-46 and accompanying text.
109. Risk Assessment, supra note 36, at 33,993. If the purpose is simply to identify chemicals that are carcinogens, a hazard identification is all that is required. Under Proposition 65 the state's experts are generally responsible for the identification of chemicals for placement on the list. CAL. HEALTH & SAFETY CODE § 25249.8(b) (West Supp. 1988). The regulations expand the role of the Science Advisory Panel, allowing it to determine specific levels of exposure posing no significant risk. CAL. ADMIN. CODE tit. 22, § 12705 (1988). Under the federal Food, Drug, and Cosmetic Act chemicals which have been shown to be carcinogens may not be added to food. An assessment of the potency of a carcinogen is not necessary for a decision on its use as a food additive. See 21 U.S.C. § 348(c)(3)(A) (1982). If the hazard identification fails to demonstrate a hazard there is no need to estimate risk. Conversely, if there is no potential for exposure, a hazard assessment may be unnecessary.
develop a list of chemicals subject to the Act. The Act also requires the list to include chemicals formally identified as carcinogens or reproductive toxicants by state or federal agencies. Hazard identification procedures are used by the Governor's experts and various agencies to determine whether a particular chemical can increase the incidence of disease in humans. The procedures used ultimately determine which chemical will be included in the list.

A Scientific Advisory Panel (SAP), created pursuant to the Act, reviews the standards and procedures for determining carcinogenicity and reproductive toxicity. The SAP has not adopted standards for designating chemicals as carcinogens or reproductive toxicants, and the regulations do not require it to do so. Undoubtedly, however, the panel will follow hazard assessment guidelines similar to those developed by the California Department of Health Services or by the U.S. Environmental Protection Agency (EPA) for identifying human carcinogens.

The principles of hazard identification under the federal and state guidelines are quite similar. Neither system requires evidence in humans before a chemical may be designated a probable human carcinogen; the designation can be based on two animal bioassays or on human evidence. The EPA guidelines classify a chemical as a probable human carcinogen even if a well-designed and well-conducted epidemiologic study shows no association between exposure to the chemical and increased cancer risk. The state's guidelines permit a chemical that...

110. CAL. HEALTH & SAFETY CODE § 25249.8(a); see supra notes 52-54 and accompanying text.
111. Section 25249.8(a).
112. See Risk Assessment, supra note 36, at 33,993.
114. Id. § 12305(d).
116. See supra note 105.
117. See Risk Assessment, supra note 36.
118. Although animal studies commonly form the basis for human carcinogenic risk determinations, the assumption that a chemical, found carcinogenic in one or more species of animals, is also a human carcinogen is not free of controversy. Chemical Carcinogens, 50 Fed. Reg. 10,372, 10,375 (1985).
119. Risk Assessment, supra note 36, at 33,999-34,000; GUIDELINES, supra note 99, at A-12, A-13. Bioassays involve exposure of small numbers of animals to multiple high doses of a chemical for extended periods and looking at their response. See, e.g., EPA, Health Effects Testing Guidelines, Oncogenicity, 40 C.F.R. § 798.3300 (1987) (minimum standards for testing set by rules promulgated under the Toxic Substances Control Act require 100 animals per test group and at least three test levels including one at the highest tolerated dose).
120. Risk Assessment, supra note 36, at 34,000; GUIDELINES, supra note 99, at A-13. Only known human carcinogens were on the Governor's initial list. 17 Env't Rep. (BNA) 1861 (Mar. 6, 1986). Later additions have included chemicals shown to be carcinogenic in animal studies. 18 Env't Rep. (BNA) 748 (July 3, 1987).
121. Risk Assessment, supra note 36, at 33,999-34,000.
would be classified a probable human carcinogen on the basis of animal
tests to be removed from that category on the basis of a properly con-
ducted epidemiological study.122 The experts who wrote the state guide-
lines, however, found no study which met this standard.123 Thus, in
practice, data from humans that show no association between exposure
to a chemical and increased cancer rates will not change a determination
based on animal studies that a chemical causes cancer. This practice in-
creases the chance of labelling a chemical a human carcinogen at the cost
of controlling and eliminating valuable chemicals that do not in fact
cause cancer in humans. The agencies of the federal and state govern-
ment that use this system for identifying hazards claim that it represents
prudent policy in the absence of scientific proof.124

Hazard identification, whether based on epidemiological studies of
humans or studies of laboratory animals,125 involves numerous assump-
tions and uncertainties. If the data comes from human epidemiological
studies, uncertainties exist because the level of exposure is seldom known
and because there may be differences in exposures to other chemicals
between the exposed and control groups.126 If the data comes from stud-
ies of laboratory animals, assumptions must be made about whether the
animal used is a good model for the chemical's effect on humans,
whether benign tumors are indicative of carcinogenic potential, and
whether animal response to the chemical at high doses indicates a hazard
at low exposure levels.127

The process of identifying a chemical as a probable human carcino-
gen does not yield an estimate of the degree of risk associated with a
particular level of exposure. This requires a dose-response assessment
and an exposure assessment.

b. Dose-Response Assessment

A dose-response assessment defines the relationship between the
dose of a chemical and the probability of the harmful effect.128 A
number of assumptions, however, must be made in performing a dose-
response assessment129 because of the methods used in determining

123. Id.
124. Id. at B-24. But see E. EFRON, THE APOCALYPTICS 310-333 (1984) (arguing that it is
difficult to establish a correlation between the results of animal studies and the probability of
similar results in humans).
125. Risk Assessment, supra note 36, at 34,000; GUIDELINES, supra note 99, at A-12, A-
13.
126. See Risk Assessment, supra note 36, at 33,995.
127. Id. at 33,994-95.
128. Id. at 33,993.
129. Id. at 33,779.
whether chemicals are carcinogens, and our limited knowledge of cancer mechanisms.

Although scientists prefer to use data from human studies for dose-response assessments, most chemicals are listed as probable human carcinogens on the basis of animal studies. In these studies, researchers expose small numbers of animals, usually rodents, to high doses of a chemical. Extrapolation of data from animal studies to humans requires assumptions because of species differences, differences in routes of exposure, and differences in level of exposure. Agencies that develop regulatory programs usually require a description of all assumptions made in arriving at a risk estimate because differences in assumptions can lead to dramatically different risk estimates. For example, depending on the assumptions used, estimates of lifetime risk from ingestion of saccharine at 0.12g/day range from 0.001 to 5,200 lifetime cases per million exposed, a five million fold variation.

130. Id. at 33,997; Orloff, supra note 100, at 6.

131. For example, in 1985, 23 substances were listed by the International Agency for Research on Cancer (IARC) as human carcinogens on the basis human studies; approximately 200 were listed as probable human carcinogens on the basis of animal studies. GUIDELINES, supra note 99, at B-24, B-27 to B-31.

132. Orloff, supra note 100, at 7.

133. Differences among species in responding to a particular chemical may result from differences in metabolic pathways (the way the animal's body changes and eliminates the chemical), and in susceptibility to particular tumors. Risk Assessment, supra note 36, at 33,997. There is also a need to adjust data to reflect differences in size and lifespan. Id. at 33,998.

134. Most animal studies are done by feeding the chemical to the animals. Orloff, supra note 100, at 7. The exposure to humans, however, may occur at work, where skin contact or inhalation are more likely. The differences in the uptake of the chemical and distribution by the different route of exposure must be accounted for in determining risk. Risk Assessment, supra note 36, at 33,997.

135. Animal studies use high doses of the chemical to maximize the chance of detecting an effect. Risk Assessment, supra note 36, at 33,994. Because the mechanisms of carcinogenesis are largely unknown, scientists are not sure which method of extrapolation from high to low doses is likely to give the best estimate of risk. Id. at 33,997. The method usually preferred is the linear multistage procedure which assumes that the response is directly proportional to the exposure. Id. This procedure gives a higher estimate of risk than other methods, such as a quadratic model which assumes that the response increases with the square of the exposure. Id. at 33,998. At very low doses, the linear model gives a higher risk estimate. Id.

136. See, e.g., id. at 33,996 (uncertainties should be included in a risk assessment); FDA, Sponsored Compounds in Food Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues, 50 Fed. Reg. 45,530, 45,542-43 (1985) [hereinafter Sponsored Compounds] (discussing the use of risk assessment procedures for carcinogenic residues in meat).

The regulations implementing Proposition 65 establish assumptions that a business may use in performing a quantitative risk assessment. The regulations call for conservative assumptions, including use of the most sensitive study deemed to be of sufficient quality for risk assessment, a no-threshold model for carcinogens, and use of the upper ninety-five percent confidence limit and a linearized multistage model for extrapolation.

Under the no-threshold model, any exposure to a carcinogen, no matter how small, is presumed to present a risk. Thus, a low dose, perhaps even a single molecule, of a carcinogen is assumed unsafe. Other regulatory agencies also use no-threshold models in risk assessment. For instance, the EPA used a no-threshold model in a rule promulgated under the Safe Drinking Water Act to set a maximum contaminant level of zero for five known or probable carcinogens reasoning that, since no threshold could be established, any exposure would be a health risk. The District of Columbia Circuit upheld the zero level, concluding that the "final rule . . . evidences a reasoned determination . . . that known and probable carcinogens have no safe threshold."

c. Exposure Assessment

An exposure assessment identifies the populations exposed, and esti-
mates the duration, types, and magnitude of exposure to a chemical. 147 Like hazard identification and dose-response assessment, exposure assessment requires assumptions to fill gaps where data is not available. 148

Unlike hazard assessment and dose-response assessment, in which the data are generated by a few researchers and are chemical specific, exposure assessment is product or activity specific; it is characteristic of use. For this reason, individual businesses are usually in a better position than governmental agencies to generate the information needed for an exposure assessment of their activities. For example, permits issued to businesses under the Clean Water Act require them to monitor discharges. 149 When monitoring is required, the business knows how much of a chemical it releases. Similarly, businesses often monitor workplace exposures. When a chemical is intentionally added to a product, its concentration is usually known. In other cases, however, such as when a chemical is an unintended contaminant of a product, the amount present may not be known.

Even when a business knows the amount of a chemical present, other factors necessary to perform an exposure assessment may not be easily determined. For example, if the chemical is released from the business property, an exposure assessment must account not only for the amount which leaves the site, but also for the routes by which it migrates, its physical properties related to mobility, the number of people who may contact it, and the duration and route of their exposures. 150 In practice, the exposure assessment is based on a combination of data and reasoned estimates, 151 and, therefore, provides an additional source of uncertainty in a risk assessment.

The regulations implementing Proposition 65 include exposure assumptions that businesses must use in performing quantitative risk assessments in the absence of more specific and scientifically verifiable data. 152 The assumptions are very general, including the amount of air breathed, water consumed, and hours worked. 153 The regulations also require the business to incorporate into the assessments any estimates developed by government agencies. 154

147. Risk Assessment, supra note 36, at 33,993.
148. Id. at 33,993-94. See also Orloff, supra note 100, at 10-11. (Scientists often cannot monitor actual concentrations. When they must use assumptions, the choice of a model can vary the risk estimate by a factor of several hundred).
150. Risk Assessment, supra note 36, at 33,998.
151. Id.
153. Id.
154. Id.
d. Risk Characterization: Is the Risk Significant?

A risk characterization is used to judge the significance of the risk.\textsuperscript{155} It combines hazard identification with the numerical estimates of dose-response and exposure assessment to give an estimate of the carcinogenic risk of a chemical.\textsuperscript{156} As with the other types of risk estimation, risk characterization will vary according to the assumptions used.\textsuperscript{157}

We have seen that estimating the risk from exposure to a chemical is highly uncertain. Moreover, it is impossible to demonstrate that any level of exposure is completely safe or poses no risk. While the Act's no significant risk exemption suggests that some risks are not significant, federal agencies that have considered the problem have been reluctant to adopt any particular level of risk as a threshold for significance.\textsuperscript{158} This reluctance is due to the subjectivity of the risk determination.

On February 16, 1988, the California Health and Welfare Agency issued emergency regulations that withdrew the proposed definition of significant risk, but established the standard for insignificant risk—a risk of one additional incidence of cancer in a population of one hundred thousand.\textsuperscript{159} It is likely that these regulations will be challenged in court.\textsuperscript{160} The major provisions of the regulations, however, should withstand court challenge as they are reasonable in light of the public's concerns and the limitations of science. They are also necessary because without a well-defined standard, the subjective nature of risk assessment

\textsuperscript{155} Risk Assessment, \textit{supra} note 36, at 33,998.
\textsuperscript{156} \textit{Id.}
\textsuperscript{157} \textit{Id.} at 33,998-99.
\textsuperscript{158} Cross, \textit{Beyond Benzene: Establishing Principles for a Significance Threshold on Regulatable Risks of Cancer}, 35 \textit{EMORY L.J.} 1, 44 (1986) (claiming that many experts have tried and failed to establish an unambiguous level of acceptable risk for society). William Ruckelshaus, former administrator of the Environmental Protection Agency, described the problem regulators face when they present quantitative risk estimates to the public: "It is hard to describe, say, one cancer case in 70 years among a population of a million as an 'acceptable risk' when such a description may too easily summon up for any individual the image of some close relative on his deathbed." Ruckelshaus, \textit{supra} note 98, at 26-27. There has been some movement towards defining insignificant levels of risk for specific types of exposure. For example, the Occupational Safety and Health Administration declined to specify an insignificant level of risk in its final rule on occupational exposure to formaldehyde, but found that a lifetime risk of one in one thousand was significant. OSHA, Occupational Exposure to Formaldehyde, 52 Fed. Reg. 46,168, 46,233 (1987) (to be codified at 29 C.F.R. pts. 1910, 1926). A recently promulgated Food and Drug Administration (FDA) rule allows the use of carcinogenic drugs in food animals provided that the residue of the drug in the meat product would pose an insignificant risk. The FDA's rule provides that a lifetime risk of one in one million is insignificant, finding clear consensus that this was insignificant, but acknowledged that a higher level of risk may also be insignificant. Carcinogenic Residues; \textit{supra} note 141, at 49,578.
\textsuperscript{159} \textit{CAL. ADMIN. CODE}, tit. 22, §§ 12701, 12703 (1988).
\textsuperscript{160} San Francisco Chron., Feb. 22, 1988, at A4, col. 2.
makes it unlikely that businesses could prove their activities qualify for Proposition 65's no significant risk exemption.

(2) Universal Warnings Are Not in the Public's Interest

Since a business may not be able to prove the absence of significant risk, it might choose to warn the public about any product, process, or release that may contain only trace amounts of a listed substance. This course could lead to the labelling of an enormous number of ordinary products. The list could include chemicals naturally present in soil, meat, vegetables, and other substances widely dispersed in the environment.

Such warnings, however, may do more harm than good. First, with a huge increase in the number of warnings, the public may become indifferent. Because the Act requires only a warning of the presence of a carcinogen, not of the magnitude of the risk, people will be unable to differentiate between small and large risks. As a result, serious dangers may be unnoticed or ignored. Indeed, when each product or exposure is labelled as "possibly" containing "small" amounts of carcinogens, the public arguably will be in greater danger than it is currently, because specific requirements for hazard labelling draw attention to known risks.

Second, widespread labelling could increase fear of the risks in using these products, resulting in tort actions for cancerphobia. This cause of action is recognized in New Jersey, where emotional distress caused by fear of contracting cancer is compensable provided the fright is reasonably foreseeable and substantial bodily injury or sickness occurs as a re-

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161. For example, arsenic is present in soil and in trace amounts in food. In answering the food industry's concerns about the lack of exemptions in the Act for these trace contaminants, some have insisted that unless the food industry can prove the amount of a dangerous chemical present and the amount which is safe, it must warn the public of the chemical's presence. D. Roe & C. Pope, San Francisco Examiner, Jan. 31, 1988, at A18 (letter to the editor). The emergency regulations give an interim exemption for foods from the warning requirements, CAL. ADMIN. CODE 22, § 12713, but this provision has been challenged. AFL-CIO v. Warriner, No. 359223 (Super. Ct. Sacramento filed May 31, 1988).

162. Testosterone and progesterone, both natural hormones on the list, are found in animal tissue. R. DERFMAN & F. UNGAR, METABOLISM OF STEROID HORMONES 22 (1965).

163. Aflatoxin is a mold found on peanuts and grain. Merrill & Schewel, FDA Regulation of Contaminants of Food, 66 VA. L. REV. 1357, 1403 (1980); Orloff, supra note 100, at 7.

164. See CAL. ADMIN. CODE tit. 22, § 12601. Placing a duty on businesses to estimate and communicate the size of the risk would have problems as well because such estimates are inherently uncertain. See supra notes 97-102 and accompanying text.

165. Examples include the required warnings on cigarettes and workplace warnings required by the OSHA Hazard Communication Standard, 29 C.F.R. § 1910.1200 (1987). The latter regulation requires material safety data sheets to list any carcinogen present in concentrations of 0.1% or more and requires worker training and access to the information. Id. § 1910.1200(d)(9)(ii), (e), (f).
sult of the fright.166

B. The Exemption for Undetectable Amounts

Discharges containing an undetectable amount of a listed chemical are exempt from the discharge prohibition. Because the exemption for insignificant risks is difficult to apply, the exemption for undetectable amounts is even more attractive to businesses. However, this exemption is problematic because it does not extend to the warning provision.167 Additionally, its provisions are not well defined, making compliance difficult.

(1) The Exemption for Undetectable Quantities Does Not Apply to the Warning Requirement

The current warning provision does not include an exemption for products or discharges containing undetectable amounts of listed chemicals.168 Yet, based upon consideration of the sources of raw materials, the chemistry involved, and basic physics, the presence of a chemical can often be predicted. Thus, it is possible to "know" that a chemical is present and that people will be exposed to it without being able to detect it. Under the Act, however, once a manufacturer "knows" the chemical is present he must either warn those who may be exposed to it or prove that the risk of exposure is not significant.169

Regulation of chemicals known to be present on the basis of theoretical considerations already exists. The theoretical presence of vinyl chloride in food prompted a Food and Drug Administration (FDA) proposal to regulate the use of polymers and copolymers of vinyl chloride for food packaging.170 Vinyl chloride, which has been linked to liver cancer in humans,171 is of special interest because it is one of the chemicals that was included in the initial list of carcinogens under the Act.172 Polymers made from vinyl chloride were used for packaging food and beverages prior to the Food Additive Amendments of 1958.173 Vinyl chloride monomers are used to form the polymers—chains of several hundred vinyl chloride units. The polymers are not toxic, however,
small amounts of the monomer that remain unreacted are carcinogenic.\textsuperscript{174}

In January 1973, the FDA learned from a bottler that as much as twenty parts per million (ppm) of vinyl chloride monomer were found in alcoholic beverages stored for up to nine months in bottles made of vinyl chloride polymers.\textsuperscript{175} The FDA subsequently banned the use of vinyl chloride polymers in alcoholic food or beverage packaging.\textsuperscript{176} In 1974, it proposed an extension of the ban to all food contact articles.\textsuperscript{177} Before 1975, polymers made from vinyl chloride commonly contained 1000 ppm of residual vinyl chloride monomer.\textsuperscript{178} Manufacturers reduced that amount to 10 parts per billion (ppb) or less by use of new processing techniques.\textsuperscript{179}

While this reduction is significant, migration of the carcinogenic monomer from the packaging material to the food remains a concern. Such migration is measurable when the monomer is present in the packaging material at high levels, but current analytical techniques cannot detect vinyl chloride in food packaged with the low residual materials now available. Nevertheless, the FDA has concluded, based upon data obtained at higher concentrations of vinyl chloride and upon the laws of diffusion, that there will be some migration to food whenever any monomer is present in the food packaging.\textsuperscript{180} The FDA reasoned that even if vinyl chloride cannot be measured in the food, its presence is known, but proposed to permit its use because of the low risk.\textsuperscript{181}

This same reasoning may be applied to a variety of business activities regulated under Proposition 65. A business that releases a listed chemical to the air could be required to warn downwind neighborhoods exposed to an undetectable amount of the chemical. Similarly, crops grown in soil known to contain traces of arsenic could be known to contain arsenic based on knowledge of plant uptake mechanisms, even if it is not detectable. Unless an exemption for undetectable, otherwise permitted exposures is added to the Act, businesses will need to warn in these and similar circumstances.

\textsuperscript{178} Proposed Uses, supra note 39, at 4178. Some of the vinyl chloride would leave the plastic bottle and migrate into the alcohol. The concentration in the alcohol was much lower than in the bottle itself.
\textsuperscript{179} Id. As much as a one million fold reduction in residual vinyl chloride levels has been achieved since the early 1970's. Vinyl Chloride, supra note 39, at 4174.
\textsuperscript{180} Proposed Uses, supra note 39, at 4179.
\textsuperscript{181} Id. at 4184-88.
A business claiming an exemption from the discharge prohibition must demonstrate that (1) the discharge or release will not cause any significant amount to enter a source of drinking water; and (2) the discharge or release conforms with all other laws and every applicable regulation, permit, requirement, and order.\(^{182}\) It may demonstrate that the amount is not significant by showing that the discharge is not detectable in a source of drinking water.\(^{183}\) The Act does not specify, however, at what location the drinking water should be sampled or what analytical methods should be used to establish detectability.

The implementing regulations also fail to indicate the reference point for determining whether a detectable amount of a chemical has entered or will enter a source of drinking water. Rather, the regulations broadly define discharge or release into water or onto land.\(^{184}\) This definition includes discharges into water or onto land in hydraulic continuity with sources of drinking water,\(^{185}\) discharges into air if the chemical is directly and immediately deposited into water or onto land,\(^{186}\) and transfer to another person for the purpose of releasing the chemical in a manner that violates the provisions of the Act.\(^{187}\) Transfers to solid waste treatment plants, hazardous waste facilities, and treatment works are excluded from coverage, provided the transfers comply with federal and state requirements.\(^{188}\)

Whether there is a distinction between a "discharge or release into water or onto land" and one "enter[ing a] source of drinking water"\(^{189}\) is critical to a business trying to determine if a discharge meets the undetectable amount exception. The regulations, however, do not indicate whether these two phrases are synonymous. The problem is greatest where the discharge is not to water. If detectability is determined at the point of release rather than at the source of drinking water, few releases would qualify for the exemption. Very small discharges would fail the detectable amount test even though the chemical could not be detected in


\(^{183}\) Id. § 25249.11(c). The alternative is to show that the discharge of a carcinogen does not pose a significant risk or that the discharge of a reproductive toxicant does not exceed 1/1000th of the no effect level. Id. § 25249.10(c).


\(^{185}\) Id. § 12201(e)(2). Interestingly, the regulations do not define hydraulic continuity. Presumably, hydraulic continuity exists when no barriers, either natural or man-made, block the movement of the water. See id. (if discharge is in hydraulic continuity with a source of drinking water it will probably pass to that source whether or not it is upstream or at a higher gradient).

\(^{186}\) Id. § 12201(d)(3).

\(^{187}\) Id. § 12201(d)(4).

\(^{188}\) Id. § 12201(d)(5)-(6).

the water supply. Even for direct discharges to water, small volume discharges might be detectable at the point of release but be undetectable in the body of water itself.

C. The Enforcement Provisions

Both businesses and regulatory agencies are concerned about the Act's bounty-hunter provision, which allows anyone to bring suit to enforce the Act and, if successful, to collect a reward of twenty-five percent of the penalty. One fear is that the provision will cause a rash of private litigation and in turn unduly influence the enforcement priorities of government officials. Since twenty-five percent of the penalty goes to the private prosecutor in an action under the Act, a district attorney or other designated official who receives notice of a violation has an incentive to act within sixty days to ensure that the entire penalty will go to his office. Moreover, although most litigation will probably be initiated by public interest groups, which are likely to consider the severity of the risk before filing suit, the Act could be used as a weapon in other legal disputes.

Other environmental statutes that allow citizen enforcement require the party enforcing them to claim personal injury, and none envision standard-setting as part of an enforcement proceeding against a discharger. For example, under the Federal Clean Air Act, the Water

190. Under this interpretation, a few milliliters of shampoo containing 1% formaldehyde as a preservative poured onto the ground outside a beauty salon would not qualify for the detectable amount exception since the formaldehyde is detectable at the point of discharge. Such a discharge would be highly unlikely to lead to detectable formaldehyde in any drinking water.

191. Edward Jagels, District Attorney for Kern County; Michele Corash, counsel for the Environmental Working Group; and Cathie Wright, member of the Assembly Committee on Environmental Safety and Toxic Materials argued that the proposition would take environmental regulation out of the hands of lawmakers and prosecutors and create a system of "vigilante justice with bounty hunters seeking awards." Rebuttal to Argument in Favor of Proposition 65, in CALIFORNIA BALLOT PAMPHLET, GENERAL ELECTION 54 (1986).

192. CAL. HEALTH & SAFETY CODE § 25249.7. A person acting in the public interest may bring suit 60 days after giving notice to the Attorney General, the local district attorney or city attorney, and the alleged violator. The suit may be commenced only if the officials do not commence or diligently prosecute an action against the violator. Id.

193. Id. § 25192(a)(3).


195. See § 25192. If this happens, the activities of the office may be disrupted, and more important hazards to public safety may be overlooked.

196. One commentator predicted the statute would be used by lawyers who scan the newspapers for potential cases, by relatives owed money, and by spouses in divorces. 18 Env't Rep. (BNA) 905, 928 (July 31, 1987).

Pollution Control Act,198 Safe Drinking Water Act,199 and Solid Waste Disposal Act,200 a citizen may bring suit on his own behalf to enforce a standard or permit.201 In each of these cases, however, the discharger has a standard established by regulation or permit and thus, clear guidelines. Proposition 65 does not provide comparable standards.

Aside from the specific problems presented by the Act’s enforcement provisions, general concerns have been voiced about citizen enforcement of environmental law, which are equally applicable to Proposition 65.202 The most serious criticism is that if such an enforcement mechanism becomes widespread, it will cause regulators to concentrate on those exposures getting attention from the courts rather than on the most serious problems.203

III. The Environmental Groups’ Contentions

Prior to its passage, environmental groups argued that the Act was not overly burdensome because it did not apply to safe exposures and because businesses would find substitutes for dangerous chemicals.204 They also contended that the studies used to place a chemical on the Governor’s list would provide the data needed to show what levels are safe.205

When the regulations implementing Proposition 65 were issued, environmentalists objected to some of the significant risk provisions and threatened to contest them.206 They particularly objected to the level of risk deemed insignificant and to the exemption for foods, drugs, cosmetics, and medical devices.207

Unfortunately, risk assessment is unable to scientifically prove that any level of a carcinogen is completely safe.208 Thus, if the regulations

200. Id. § 6972.
201. These laws do not permit a citizen to bring suit in the public interest. Rather, the person bringing suit in federal court must allege personal injury. See Sierra Club v. Morton, 405 U.S. 727 (1972) (discussing standing of environmental groups to bring action under the Administrative Procedures Act, 5 U.S.C. § 702 (1982)).
203. Id.
207. Id.
208. See supra notes 131-32 and accompanying text.
specifying levels of insignificant risk do not survive challenge, businesses may have to eliminate listed chemicals from their products and discharges. Substitutes can be found for some chemicals. Often, however, chemicals are present unintentionally—either because they are natural contaminants of raw materials or because they are byproducts of manufacture, and are not readily eliminated. When chemicals are intentionally included, it may be because substitutes are not available. In either case, elimination of the chemical is often impractical.

Totally eliminating a chemical can be very difficult. The EPA learned this when it began implementing a ban on the manufacture, processing, distribution, use, and disposal of polychlorinated biphenyls (PCBs). The Toxic Substances Control Act mandated the ban,209 allowing exceptions only when the EPA administrator finds that the activity does not present an unreasonable risk of injury to health or the environment.210 PCBs had a number of applications including use in capacitors, large transformers, and carbonless paper.211

Before the ban became effective, scientists discovered that PCBs were present in the environment not only because of the manufacture of Arochlor, but also as a byproduct of the manufacture of other products, such as pigments.212 The EPA and the Chemical Manufacturers' Association considered any process involving chlorine, aromatic organic molecules, and heat to be a potential source of PCBs.213 Complicating the regulatory problem was the fact that unintentional manufacture could yield any of the chemical structures included in the definition of PCB, and there was no reliable method to measure them. The EPA's solution was to require permits for continued manufacture while they sought ways to reduce or eliminate the unintended presence of PCBs in products214 and attempted to determine which situations did not present an unreasonable risk.

The list and the proposed list of substances known by the state to

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209. Substitutes, when available, may not be any safer than the chemicals they replace. Few chemicals have been tested for carcinogenicity or other chronic effects. Ames, Identifying Environmental Chemicals Causing Mutations and Cancer, JURIMETRICS J. 326, 331 (1980) (reports on only about 150 previously untested chemicals per year; there are about 50,000 untested chemicals).


211. Id. § 2605(e)(2)(B).


213. Id. at 31,535.


215. Id.
cause cancer or reproductive toxicity include a number of chemicals that are also widely distributed in the environment, or that do not have substitutes for all of their uses. In these cases, businesses cannot simply eliminate the chemical.

IV. Making Proposition 65 Work

Given the current state of scientific knowledge, a business cannot show that a particular level of exposure to a carcinogen is completely without risk. Thus, for the Act to accomplish its purpose of protecting the drinking water supply and promoting warnings about exposure without imposing an impossible burden upon businesses, the following changes are needed. Regulations should be implemented to specify how the undetectable amounts exemption is to be applied. The Act should be amended to exempt undetectable amounts of listed chemicals from the warning requirements. The Science Advisory Panel should establish levels of exposure which are insignificant for each substance. Additionally, the recently enacted regulations should be upheld.

A. Significant Risk

The regulations defining certain risks and methods of determining risk are well reasoned and should be retained. The regulations allow businesses several ways of determining that their activities pose no significant risk. First, they list routes of exposure for certain listed chemicals that pose no significant risk. Second, they establish a conservative method of estimating risks. A risk calculated using the prescribed method is deemed not significant if the lifetime risk does not exceed one case of cancer attributable to the chemical exposure per 100,000 population. A business need not conduct a risk assessment itself, since the regulations recognize state and federal risk assessments. The California Health and Welfare Agency may set specific levels of exposure that pose no significant risk. Unless the Agency determines otherwise, exposure to listed chemicals in foods, drugs, cosmetics, and medical devices poses no significant risk provided the use conforms with state and federal safety laws. Finally, a business may choose to use any other evidence or standards to show that the exposure does not present a significant

218. See supra notes 137-46 and accompanying text.
219. § 12703(b).
220. § 12711(1).
221. See § 12705.
222. § 12713.
The most controversial provision of the regulations is the temporary exemption for foods, drugs, cosmetics, and medical devices. The Agency justified the exemption on the basis of the Food, Drug, and Cosmetic Act's comprehensive controls governing the safety of those products.

It was, however, distrust for government agencies' ability to carry out their responsibilities which motivated Proposition 65. Although the FDA reviews and must approve new food additives, drugs, and medical devices for safety prior to their sale to the public, many food additives and drugs which were marketed prior to the modern law were "grandfathered" and have not been thoroughly reviewed. Traditional foods are not subject to positive listing, nor are cosmetic ingredients except color additives. The substances listed would generally enter foods indirectly, either from pesticide use, as natural contaminants, as processing aids which are not fully removed or from packaging. The FDA requirements make it possible that some risks which are significant under Proposition 65's implementing regulations will escape immediate control. This concern should be balanced, however, against concern for the disruption that warning placement on all or most foods and drugs would cause. The DHS solution of a temporary exemption while levels of exposure which are significant are established properly balances these competing concerns.

B. Detectable Amount

Proposition 65 exempts discharges that will not cause a detectable amount of a chemical to enter a source of drinking water provided the discharge also conforms with other requirements.

There are three possible ways to apply the detectable quantity exemption. The Environment...
tal Working Group, a coalition of business, industry, and agriculture, proposes that the chemical be measured at the point where water is or could be withdrawn as a source of drinking water. The emergency regulations suggest that the detectable amount is to be determined at the point where the chemical is released from the control of the business. A third possibility is to determine whether a detectable amount is present at the point of entry into the drinking water, taking into account migration and dilution factors.

Since the purpose of the Act is to protect against harmful chemicals in water people drink, a logical focus for regulation is the point where drinking water is taken. Using this point to determine whether a detectable amount is present would place the regulation’s strictest controls on those discharges that most directly affect drinking water. Such a rule, however, would not adequately protect water that is not currently used and would make it difficult to attribute the pollution to its source.

If the detectable amount determination is made at the point where the chemical is released into the environment, low volume discharges will not qualify for the exemption. Activities such as spilling a few milliliters of gasoline on the ground would not qualify for the detectable amount exemption because of the presence of benzene traces even though the release would not cause detectable amounts of benzene to appear in any conceivable water supply. The language of the Act itself does not appear to require this stringent interpretation. It bans releases into water which pass or may pass to a source of drinking water but exempts discharges which are not detectable in a source of drinking water. This implies that the source of drinking water may be remote from the point of release. Further, the interpretation implied by the regulations would make businesses operating within release limits set by air or water discharge permits targets for suits by citizens seeking the bounty provided

232. Members of the Environmental Working Group are the American Electronics Association, the Beer Institute, the California Chamber of Commerce, the California Council for Environmental and Economic Balance, the California Farm Bureau Federation, the California League of Food Processors, the California Manufacturers Association, the California Mining Association, the California/Nevada Soft Drink Association, the Chemical Industry Council of California, the Santa Clara County Manufacturing Group, and the Western Agricultural Chemicals Association.

233. ENVIRONMENTAL WORKING GROUP, supra note 76, at §§ 10203, 10224.


236. Discharges are prohibited onto land if the chemical is likely to pass into a source of drinking water. CAL. HEALTH & SAFETY CODE § 25249.5. A discharger then has the burden of showing that the discharge is not detectable. Id. at 25249.9 Since the source of drinking water is now broadly defined by the statute, this type of discharge is arguably covered by the statute if the land involved is in hydraulic continuity with a source of drinking water.

237. Id. at § 25249.5, 25249.9.
in the act. Both knowledge of release and the fact of release could be shown by the permit and the required monitoring records. Because compliance with a permit is not sufficient to qualify for discharge exemption, businesses have the unenviable task of proving that a chemical release does not pose a significant risk.

The exemption will be more tailored to the concern addressed by the regulation if entry of the chemical into surface or ground water—whether an aquifer or surface water—is used as the reference point for determining whether a detectable amount has been discharged. The total volume released, the inherent mobility of the chemical in the medium into which it is released, its biodegradability, and the flow rate of the receiving body of water would be factors in determining whether the chemical could be detected in the source of drinking water. If data were not available on any factor, the business could use worst-case assumptions in its calculations.

One obvious concern is that the chemical will be undetectable at a concentration that poses a serious health risk. Measuring the concentration of the chemical at a point remote from its point of discharge makes it less likely that the chemical will be detected and thus controlled. The state can address this problem through restricting the business' NPDES discharge permit and through other regulations that restrict the amount released.

C. Amend the Act to Extend the Exemption for Insignificant Amounts to the Warning Requirement

Proposition 65 does not exempt undetectable amounts of a listed chemical from the warning requirements. Without this exemption, businesses that know a listed chemical is theoretically present must provide a warning label or perform an expensive and uncertain risk analysis. Extending the exemption to exposures that are undetectable using standard laboratory procedures and in compliance with health laws, permits, and regulations would give adequate protection to the public while reducing the danger of over-warning. Amending the Act to extend the exemption also would encourage businesses to monitor their own compliance with the Act, since test data showing no detectable amounts would provide the basis for an exemption, assuming the requirements of other laws are met.

238. The assumptions would be that the chemical migrated readily, was not biodegradable, or was not diluted by the receiving body.


Conclusion

The Safe Drinking Water and Toxics Enforcement Act of 1986 sent a clear message to businesses that the people of California wish to be protected from involuntary exposure to carcinogens and reproductive toxicants. Unfortunately, the Act leaves businesses throughout the state in a position of uncertainty due to the undefined terms, extreme standards, and potential for inconsistent enforcement by citizen bounty hunters. The California Health and Welfare Agency is attempting to alleviate the burden on businesses through regulations. The definition of significant risk contained in the regulations is a reasonable approach to implementation of the Act and should be retained. The first regulations clarifying the warning provisions of the Act, however, have been severely criticized by all parties and are likely to be challenged. Without sensible regulations, businesses must resort either to over-warning or totally eliminating discharges to comply with the Act. Hence, additional steps are needed to aid the implementation process.

First, the state should develop risk assessments for listed chemicals, and publish risk assessments already developed by agencies of the state or federal government.

Second, the Health and Welfare Agency should issue a regulation interpreting the undetectable amount exemption. Ideally, the definition would focus on whether the chemical is detectable at the point of entry into water designated as a drinking source.

Finally, the exemption for undetectable amounts of a listed chemical should be extended to the warning requirement. A need to avoid excessive warning and the problems and uncertainty inherent in risk assessment compel this conclusion. Public protection would be enhanced by extending the use of this exemption to exposures that comply with health-related requirements.