

Information Generation and Use Under Proposition 65: Model Provisions for Other Postmarket Laws?

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INTRODUCTION

California's Proposition 65, The Safe Drinking Water Act of 1986,¹ a voter-passed initiative, possesses unusual information-generation and use features, together with some burdens of proof not usually seen in typical postmarket statutes. After placing Proposition 65 within the context of other kinds of statutes, this paper describes the features of Proposition 65 and then analyzes what contributes to its efficacy as an environmental health statute. I argue that Proposition 65 has a number of characteristics that make it reasonably effective in reducing exposures to toxicants: its automatic provisions, its provision shifting the burden of proof to firms that expose the public to toxicants, its meaningful sanctions, its "responsibility" attribute and its adaptability to address new toxicants.

I. HUMAN HEALTH REGULATION

The laws for protecting human health can be roughly classified into three categories: (1) premarket testing and approval statutes, (2) premarket notification statutes, and (3) postmarket statutes. Premarket *testing and approval* statutes require the testing, screening, and agency approval of products before they enter commerce in order to prevent adverse consequences occurring from exposures. Typical premarket screening laws in the United States include the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),² as well as the Food, Drug, and Cosmetic Act (FDCA)³ concerning drugs and new food additives. Premarket *notification* laws, such as the premarket notification provisions of the Toxic Substances Control Act (TSCA)⁴, require firms to notify the U.S. Environmental Protection Agency (EPA) of their intent to manufacture a product and to provide any data they have about it. However, unlike premarket screening laws, the TSCA's premarket notification provision does not impose any legally required testing provisions on a firm (although the agency can demand this if it finds evidence of toxicity) and no explicit approval provisions analogous to those under the drug or pesticide laws. *Postmarket* statutes permit substances to enter commerce, typically with no legally required testing, and they are only subject to regulation if an agency can provide the requisite data and demonstrate sufficient risk or harm from exposure to the substance in question to justify regulation.

Ordinarily, certain kinds of burdens of proof are matched with certain kinds of laws. Premarket testing and approval laws place burdens on manufacturers to conduct testing, provide data about safety, and demonstrate some degree of safety or level of minimal risk to the satisfaction of a governmental agency. Premarket notification laws

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1. CAL. HEALTH & SAFETY CODE §§ 25249.5–13 (2007).

2. 7 U.S.C. § 136 (2000).

3. 21 U.S.C. §§ 301–399. (2000).

4. 15 U.S.C. §§ 2601–2692 (2000).

place a burden on a manufacturer to notify the EPA that it is seeking to manufacture a product and to provide any data it has about the product. By contrast, postmarket laws tend to place burdens on governmental regulatory agencies to establish a case for regulation after a product has entered commerce by showing risks or harms, and sometimes then to specify ambient levels of exposures to minimize risks, or impose a technology regulation to reduce exposures. California's Proposition 65 is a more complex mixture: it is postmarket law with some information-use and information-generation provisions possessing one burden of proof feature that is more characteristic of premarket laws.

Before turning to Proposition 65, however, it may be helpful to imagine what a more health-protective law might look like in outline. Elsewhere, I have argued that one possible model would have several features to better protect the public health and the environment, many of which would increase information generation by those who produce or use substances.⁵ It would require greater affirmative knowledge generation by manufacturers of potentially toxic substances than postmarket laws typically do. In this it would resemble the features of U.S. drug or pesticide laws. It would also require appropriate premarket review and assessment of the safety of substances and products before they were permitted into commerce.⁶ Moreover, a health-protective regime would require ongoing monitoring of a product's effects on the public with legally required reporting of adverse effects of products to an agency. Finally, it would provide for more timely, and less legally burdensome, responses to any early warnings of adverse health effects in order to reduce or eliminate exposures to toxic substances faster rather than slower, once there is appropriate evidence of risk or harm. Where full-fledged premarket laws were impractical or unworkable, there could be limited testing of some products and more minimal testing of others for which there was lesser concern for their toxicity. If postmarket laws were utilized, they would aim to replicate as many of these features as were plausible within a postmarket framework (for example, better monitoring of the public health and products that could cause adverse effects, as well as more rapid responses to reduce exposures when early warnings were received).

Unfortunately, for the most part we do not live in such a health-protective world. For example, a National Research Council (NRC) report documents how little health and safety data there are for the vast majority of substances.⁷ This, it seems to me, is a direct consequence of post-market laws. The NRC found that there were:

- 12,860 substances produced in volumes exceeding one million pounds per year for which 78% had no toxicity information available, and 11% had minimal toxicity information;

5. Carl F. Cranor, *Some Legal Implications of the Precautionary Principle: Improving Information Generation and Legal Protections*, in 2 EUROPEAN JOURNAL OF ONCOLOGY LIBRARY 31-51 (2003).

6. For example, there might be features of substances that would indicate that some would require greater testing and scrutiny and some less. Thus, there might be a "tiered" review system, with greater or lesser degrees of scrutiny.

7. NAT'L RESEARCH COUNCIL, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 12, 84 (1984).

- 13,911 chemicals produced in volumes of less than one million pounds of which 76% had no toxicity data, and 12% had minimal toxicity information;
- 8627 food additives, of which 46% had no toxicity data, 34% had some toxicity information (but it was below the minimal level), and 1% had minimal toxicity information;
- 1815 drugs, 25% of which had no toxicity data, 36% had some toxicity data (but below the minimal level), and 3% had minimal toxicity information;
- 3410 cosmetics, 56% of which had no toxicity data, 18% had some toxicity data (but below the minimal level), and 10% had minimal toxicity information;
- 3350 pesticides of which 36% had no toxicity data, 26% with some toxicity data (but below the minimal level), and 2% had minimal toxicity information.

The upshot is that substances typically enter commerce without any legally required testing and then remain there until several events occur: There is sufficient scientific evidence (generated by an agency) to make a case for harms or risks of harm; there is political will to follow the science; any scientific and legal standards of proof have been met; the regulatory process is completed; and legal appeals have been exhausted. This is not a legal structure that works well to protect human health and the environment.⁸

II. PROPOSITION 65

Proposition 65 is a postmarket law that has some features that assist public health protection and that resembles several different kinds of regulatory statutes outlined above, and which employs several sorts of burdens of proof. It also has information-generation and use characteristics that differ somewhat from standard patterns. In outline Proposition 65 consists of the following major features.

First, it specifies 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.”⁹ This provision applies to all kinds of exposures, such as environmental, workplace, and consumer products. There is a related provision prohibiting the contamination of land or drinking water with chemicals known to the state to cause cancer or reproductive toxicity.¹⁰

Second, it states that certain substances are known to cause cancer or reproductive toxicity because they have been *listed* by a designated legal agency, the Office of

8. See CARL F. CRANOR, TOXIC TORTS: SCIENCE, LAW AND THE POSSIBILITY OF JUSTICE 337–91 (2006).

9. CAL. HEALTH & SAFETY CODE § 25249.6 (2007).

10. *Id.* § 25249.5 (2007).

Environmental Health Hazard Assessment.¹¹ Two scientific committees assist in this task: the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant Identification Committee (DART).¹² There are several routes by which substances or products may be listed under Proposition 65:

- (1) They may be listed as a result of statutory incorporation by reference to California's Labor Code sections 6382(b)(1) and 6382(d) which in turn refer to "human or animal carcinogens" identified by the International Agency for Research on Cancer (IARC), or the National Toxicology Program (NTP) and "carcinogens or potential carcinogens" identified by IARC in its monograph series or NTP.¹³ Thus, even if a substance has only been identified as a carcinogen in animal tests by the NTP or IARC, it can become a "listed" substance via incorporation of the Labor Code.
- (2) One of the early scientific advisory panels, the Carcinogen Assessment Committee,¹⁴ recommended an interpretation of additional "authoritative bodies" (other than the IARC and NTP) who would identify carcinogens or reproductive toxicants that California would also recognize for listing purposes, provided that substantial evidence in the "authoritative" agencies' records shows that the chemicals meet Proposition 65 criteria.¹⁵ Other authoritative bodies include the U.S. Food and Drug Administration (FDA), the EPA, and the National Institute of Occupational Safety and Health (NIOSH).¹⁶ When California's CIC or DART have a substance that is listed as a result of being incorporated by reference, they provide a thirty-day notice of intent to list during which anyone affected by the listing may comment. If there are comments, the agencies will respond and then continue the listing procedure, unless the comment calls attention to a problem that needs to be addressed before listing.
- (3) Independently, the CIC or DART Identification Committee may identify carcinogens or reproductive toxicants for listing if they are "clearly shown" to cause cancer or reproductive toxicity.¹⁷
- (4) If another governmental agency "formally require[s]" the substance to carry a cancer or reproductive toxicity warning, it is subject to Proposition 65.¹⁸

11. CAL. CODE REGS. tit. 22, § 12102 (2007).

12. CAL. HEALTH & SAFETY CODE § 25249.8(b) (2007); CAL. CODE REGS. tit. 22, §§12301–12305 (2007).

13. CAL. HEALTH & SAFETY CODE § 25249.8(a) (2007).

14. This was a precursor committee to the Carcinogen Identification Committee.

15. CAL. HEALTH & SAFETY CODE § 25249.8(a); CAL. CODE REGS. tit. 22, § 12306 (l)–(m) (2007); *W. Crop Prot. Ass'n v. Davis*, 95 Cal. Rptr. 2d 631 (Cal. Ct. App. 2000).

16. CAL. CODE REGS. tit. 22, § 12306 (l)–(m).

17. CAL. HEALTH & SAFETY CODE § 25249.8(b); CAL. CODE REGS. tit. 22, §§12301–12305.

18. Edward Weil, Deputy Attorney Gen., State of Cal., Lecture at the University of California, Berkeley (Feb. 2, 2005) (citing CAL. HEALTH & SAFETY CODE § 25249.8(a); CAL. CODE REGS. tit. 22, § 12902) (lecture notes on file with the Indiana Law Journal).

Third, once substances have been “listed,” businesses that expose the public have several options open to them; they may: (1) issue clear and reasonable warnings about exposures; (2) generate more information to show there is *no significant risk*,¹⁹ or to show there is no exposure; (3) reduce exposure from the substance so there is no significant exposure or risk; or (4) phase out the product.²⁰

That is, once substances are listed, then those who expose the public must issue “clear and reasonable warnings” unless they are exempt.²¹ With clear and reasonable warnings on consumer products, or occupational labels, that comply with the Federal Hazard Communication Standard,²² firms are protected.

If a firm does not issue a warning, it may show that it is in compliance with the law by showing that exposure causes “no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer [or reproductive toxicity]”²³ For carcinogens, a firm must show that exposure does not cause a greater than 1/100,000 lifetime risk of exposure.²⁴ For reproductive toxicants, it must show that exposures will be lower than 1/1000 of an ambient level with no observed effects.²⁵ The firm has the burden of proof to show by a preponderance of the evidence²⁶ the current level of exposure and that the current level is lower than exposures requiring warnings.²⁷ In addition, a firm does not need to provide a warning for an “exposure for which federal law governs warning in a manner that preempts state authority.”²⁸

Finally, a firm can reduce exposure to the product (for example, by reducing fugitive emissions from an oil refinery so that exposures were below levels that required warnings). For products for which exposures cannot be reduced, a firm may phase out the product. This could mean creating pottery without lead, or reformulating a product without a toxic substance in it, as when 3M apparently reformulated “White Out” so that it no longer contains a toxic product.

In effect, once a substance has been listed as a reproductive or carcinogenic toxicant, a firm can make its own self-interested, cost-benefit choices to issue warnings (and live with the public relations consequences); develop new information to show that exposure is below the level requiring warnings; reduce exposure; phase out the product; or replace it with a less hazardous product. Thus, a firm has considerable

19. CAL. HEALTH & SAFETY CODE § 25249.10(c) (2007).

20. Interview with Lauren Zeise, Chief of Reprod. & Cancer Hazard Assessment, Office of Env'tl. Health Hazard Assessment, Cal. Env'tl. Prot. Agency (Feb. 2000) (summarizing Proposition 65 options open to a firm that exposes the public to a listed toxicant).

21. CAL. CODE REGS. tit. 22, § 2601(a) (2007). “Whenever a clear and reasonable warning is required under Section 25249.6 of the Act, the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm.” *Id.*

22. CAL. CODE REGS. tit. 22, § 12601(c)(1)(A)–(C) (2007).

23. CAL. HEALTH & SAFETY CODE § 25249.10(c).

24. CAL. CODE REGS. tit. 22, § 12703(b) (2007).

25. CAL. HEALTH & SAFETY CODE § 25249.10(c).

26. *Baxter Healthcare Corp. v. Denton*, 15 Cal. Rptr. 3d 430, 453 (Cal. Ct. App. 2004).

27. *Consumer Cause, Inc. v. SmileCare*, 110 Cal. Rptr. 2d 627, 635 (Cal. Ct. App. 2001).

28. CAL. HEALTH & SAFETY CODE § 25249.10(a).

leeway to decide what is the best alternative from its point of view. However, the listings together with the automatic permissible exposure levels that are set by statute provide considerable incentives to firms to serve the public interest.

The law is backed by monetary sanctions—\$2500 per exposure without “clear and reasonable warnings.”²⁹ Since the fine is for each exposure to each person, the total fine can become quite large. The law may be enforced by the Attorney General, but also by private parties, who have a private right of action. The private enforcement provision may be utilized only after the state has taken no action after having been informed of violations. A private enforcement action concerning acrylamide has been brought³⁰ following the discovery that French fries and potato chips contain amounts of acrylamide, a probable human carcinogen according to the IARC,³¹ that exceed the Proposition 65 mandated risk levels. When there is private enforcement, the private party receives 25% of the penalties assessed for violation, with the remainder going to the state’s Office of Environmental Health Hazard Assessment.³²

The state is not obliged to establish ambient exposure levels (which are quite difficult to implement). This is a substantial improvement over statutes that require agencies to set ambient exposure levels. No significant risk levels are specified by statute, and firms responsible for exposing individuals should ensure that any exposures they pose are below the statutorily set levels. On the face of the statutory provisions, one might be concerned about how protective of the public health it is, since under Proposition 65 a governmental agency does not necessarily reduce exposures or authorize the removal of a product from market, or mandate ambient exposure levels. Instead, it leaves that decision to individual businesses shaped by legal and various private incentives. Nonetheless, California has had considerable success in lowering exposures to carcinogens and reproductive toxicants. One would need to investigate whether such reductions in environmental exposure are greater than those accomplished by other states or by federal agencies. The drivers and motivators for this success are the results of private parties seeking to avoid the monetary costs of noncompliance with the statute or to avoid the stigma of a warning label attached to their products or property (more on this below).

California has had successful enforcement litigation concerning lead, tobacco smoke (especially second-hand smoke), engine exhaust, toluene, methylene chloride, mercury, ethylene oxide, di(2-ethylhexyl)phthalate (DEHP) (a plasticizing chemical), trichloroethylene, and perchlorethylene. In general, “companies have learned that if you keep a chemical off the list, you save a lot of headaches.”³³ These enforcement actions have resulted in “product reformulation [for example, mercury removed from nasal spray, lead reduction in power cords, lead in calcium supplements, lead in dishes and glassware],” have enabled “people to choose to avoid exposure [for example,

29. CAL. HEALTH & SAFETY CODE § 25249.7(b) (2007).

30. Council for Educ. and Research on Toxics v. McDonald’s Corp., No. BC280980 (L.A. Super. Ct. Mar. 23, 2005).

31. Int’l Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 60: Some Industrial Chemicals*, available at <http://monographs.iarc.fr/ENG/Monographs/vol60/volume60.pdf>.

32. CAL. HEALTH & SAFETY CODE § 25249.12(b) (2007).

33. Edward Weil, Deputy Attorney Gen., State of Cal., Presentation to the Northern California Society for Risk Analysis (2005) (lecture notes on file with the Indiana Law Journal).

mercury in fish, alcoholic beverages, community exposure warnings, second-hand smoke],” and have provided “useful educational information.”³⁴ Dow Chemical is reported to have conducted a reassessment of its California facilities as a result of Proposition 65.³⁵

III. INFORMATION USE AND GENERATION UNDER PROPOSITION 65

On the dimensions of information *use* and *generation*, California’s Proposition 65 has a number of innovations. First, it automatically (or nearly automatically) utilizes available data that have been generated by other authoritative bodies. If one of the authoritative bodies recognized by California formally identifies a carcinogen or reproductive/developmental toxicant, the California Environmental Protection Agency (“Cal EPA”) can quickly incorporate the toxicant into its list under Proposition 65. Moreover, California is required to review the actions of other authoritative bodies at least every two years and update its Proposition 65 lists (adding or excluding agents as is appropriate).³⁶ This greatly accelerates the identification process since each new substance does not have to be identified *de novo* on a substance-by-substance basis as a result of a time-consuming literature review and science advisory panel determination. Other agencies and scientific advisory panels’ efforts that are presumed sufficiently accurate can be utilized quite quickly. Thus, if any authoritative body identifies a substance as a carcinogenic or reproductive/developmental toxicant, it can be quickly listed under the law.

Second, under Proposition 65 it appears that the Cal EPA can act more quickly in most instances than other agencies authorized to act under other statutes. There is no need for rule making, because once the CIC or DART Identification Committee has recommended the listing of a substance (and made it subject to the other legal requirements), the Cal EPA may act. Since the inception of Proposition 65, the state has listed about 502 carcinogens and 277 reproductive or developmental toxicants.³⁷ Once listed, these substances become subject to the other provisions of the law requiring either an appropriate warning or an accompanying assurance that risks from the listed substances do not exceed legal levels. It is not clear that any other agencies have a comparable record over a twenty-year period; this question would need to be researched.

Third, in 1991 the Carcinogen Assessment Committee (a precursor of the CIC) recommended the creation of potency numbers for carcinogens in order better to serve both the business community and the public.³⁸ The potency numbers indicate the

34. *Id.*

35. Zeise, *supra* note 20.

36. CAL. LAB. CODE § 6382(c) (2007).

37. These numbers were supplied to the author by a Cal EPA employee. Communication from Sara Hoover, Research Scientist, Office of Env'tl. Health Hazard Assessment, Cal. Env'tl. Prot. Agency, to author (Sept. 9, 2006) (on file with the *Indiana Law Journal*). Because of Proposition 65's provisions, this list is continually updated and is something of a moving target; a frequently updated link to the latest list of substances is available at http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html.

38. The author was a member of the Carcinogen Assessment Committee. The original data analysis was conducted during 1991–92. See Carl F. Cranor, *The Social Benefits of Expedited*

amount of a substance it would take over a lifetime of exposure to increase the risk of cancer in humans by one in 100,000.³⁹ If a firm creates an exposure to a listed substance at less than this level, then it has a “safe harbor” for those exposures; it is not subject to the warning requirement or other legal action under Proposition 65.⁴⁰ If exposures from a listed substance pose carcinogenic risks greater than one in 100,000, a firm is subject to the requirements of the law.⁴¹ By issuing potency numbers and the accompanying safe harbors, the Cal EPA provides some approximate guidance to the public concerning risks or the absence thereof from exposures to the listed carcinogenic or reproductive toxicants. The upshot is that as a result of administrative action the state has expedited one step of a typical risk assessment to assist firms in finding “safe harbors” for exposures (saving them from spurious lawsuits) and to provide the public with (somewhat esoteric) guidance about exposure levels. Potency numbers, together with a firm’s knowledge about the concentrations of a toxicant to which the public is exposed, permit a firm to titrate ambient exposure levels of carcinogenic and reproductive toxicants to comply with the law. It is important to note that the firm causing the exposure has the legal responsibility to ensure that risks from ambient exposures do not exceed the statutory limits.

The expedited potency procedures decreased the amount of time for determining the potency of a subset of carcinogens to one chemical per day, down from one chemical every one-half to five person-years⁴² (one chemical every 180–1725 person-days,⁴³ the previous pace at Cal EPA for potency assessments). Thus, the determination and assessment of many potency numbers can be relatively quick compared with other laws. This reduces the time it takes for a potency assessment that is part of a full risk assessment that would be required for setting ambient exposure levels. Businesses that potentially expose the public to toxicants can be guided by safe-harbor potency assessments, if they are available, and can ensure that exposures do not exceed legally mandated risk levels. This protects these firms from governmental or private legal action and protects the public as required by law.

In effect the expedited potency procedures might be seen as part of a social division of responsibility for a full risk assessment. Recall that a full risk assessment for setting ambient exposure levels would consist of identification of a substance as a toxicant, determination of its potency or dose-response (the amount of substance that would cause some adverse effect), exposures to which people would be subject, and then an overall risk characterization (an estimate of “the magnitude of the public-health problem”⁴⁴) to establish which representative exposures would cause adverse effects

Risk Assessments, 15 RISK ANALYSIS 353, 354 (1995).

39. CAL. CODE REGS. tit. 22, § 12703(b) (2007).

40. See REPROD. & CANCER HAZARD ASSESSMENT BRANCH, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CAL. ENVTL. PROT. AGENCY, PROPOSITION 65 SAFE HARBOR LEVELS: NO SIGNIFICANT RISK LEVELS FOR CARCINOGENS AND MAXIMUM ALLOWABLE DOSE LEVELS FOR CHEMICALS CAUSING REPRODUCTIVE TOXICITY (2005), available at <http://www.oehha.ca.gov/prop65/pdf/Aug2005>StatusReport.pdf>.

41. CAL. CODE REGS. tit. 22, § 12703(b) (2007).

42. A “person-year” is calculated by multiplying the number of people working on a potency assessment by the number of years they work.

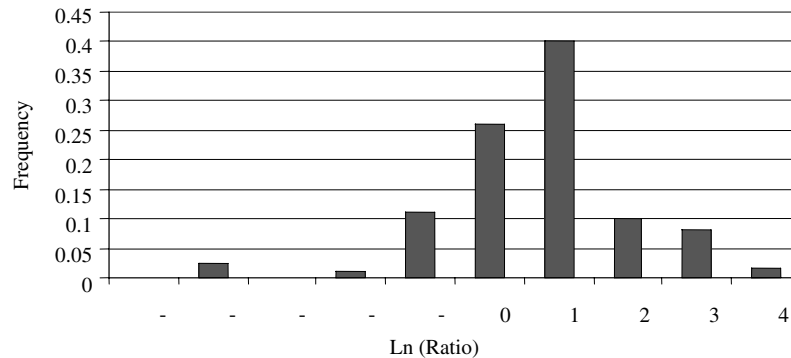
43. A “person-day” is calculated by multiplying the number of people working on a potency assessment by the number of days they work.

44. NAT’L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 28 (3d prtg. 1984).

and how extensive they might be.⁴⁵ Under Proposition 65 the state identifies (and lists) carcinogenic and reproductive toxicants and, when it has the resources available, provides potency assessments to guide the public and affected firms. (It is not obliged to do so; that burden is legally on firms exposing the public.) Affected firms (not the state, as under postmarket statutes that require ambient exposure levels) then have the responsibility to conduct exposure assessments and must characterize the risk sufficiently to ensure that the public is not exposed to ambient levels that exceed statutory risk requirements.⁴⁶ Firms have the final burden of proof to ensure that legally specified risk levels are not exceeded.

In 1994 the state issued about 140 expedited potency assessments as a group.⁴⁷ Firms could appeal a decision about the potency value of a particular substance, if the state's expedited potency assessments disagreed with the state's science-intensive potency assessments by more than a factor of four. There were no appeals.⁴⁸

Comparison of Expedited to Conventionally Calculated Cancer Potency



Source: Sara M. Hoover, Lauren Zeise, William S. Pease, Louise E. Lee, Mark P. Henning, Laura B. Weiss & Carl Cranor, *Improving the Regulation of Carcinogens by Expediting Cancer Potency Estimation*, 15 RISK ANALYSIS 267, 276 (1995).

The accuracy of the expedited potency assessments is partially captured in the above graph. In 1994 when the 140 expedited potency assessments were issued, there were seventy-four for which a comparison could be made between California's new expedited potency calculations and previous science-intensive calculations from California. The graph above shows that 86% of the substances assigned expedited

45. *See id.*

46. *See supra* text accompanying notes 20–27.

47. In the late 1990s an additional eight expedited potency assessments were issued, when there were data available (a particular database of animal studies), and the state had resources to issue the potency assessments. Interview with Sara Hoover, Sara Hoover, Research Scientist, Office of Env'tl. Health Hazard Assessment, Cal. Env'tl. Prot. Agency (Sept. 9, 2006).

48. Interview with Lauren Zeise, Chief of Reprod. & Cancer Hazard Assessment, Office of Env'tl. Health Hazard Assessment, Cal. Env'tl. Prot. Agency (June 2000).

potency numbers are within a factor of 7.4⁴⁹ of potency numbers assigned by time-consuming, science-intensive processes. Moreover, the concordance between the expedited and science-intensive potency assessments was more accurate than if two agencies (U.S. EPA and Cal EPA) had conducted science-intensive potency assessments on an identical list of substances. The latter comparison (or, more accurately, difference) was illustrated by comparing a list of forty carcinogens that had been assessed by time-consuming and science-intensive procedures by both the Cal EPA and the U.S. EPA.⁵⁰

Moreover, there appear to be considerable social cost savings from the expedited procedures. If one compares the social costs of two separate procedures in which a hypothetical universe of 400 known carcinogens receive a potency number by means of the expedited procedures and people have protection from the carcinogens versus a circumstance in which a few substances have a potency number to guide protections, but most would still be awaiting regulatory action, a reasonable modeling of social costs appears strongly to favor expedited potency assessments. In the graph below, the modeled savings are represented by the cost “gap” between conventional science-intensive procedures and expedited potency assessments. Analogous procedures are compared with each other.⁵¹ The social cost “gap” represented by the diagonal cross-hatching assumes that conventional science-intensive potency assessments result in about 81% false negatives, because substances likely to cause cancer in humans go unregulated, but also result in ten percent major overregulation of substances that are regulated. It also assumes 100% concordance between positive tumor results in animal tests and positive tumor results in humans. These results are compared with expedited procedures, which have 12.5% major overregulation, 0% underregulation because all substances are assigned potency assessments and regulated, and 100% concordance between animal and human results.⁵²

The vertical cross-hatching compares conventional science-intensive procedures with expedited procedures that have different assumptions. These conventional science-intensive potency assessments are assumed to result in 10% overregulation, have 49% false negatives, and sixty percent concordance between positive results in animal studies and positive results in humans. The expedited potency assessment procedures with which they are compared assume 2% underregulation, 60% major overregulation, and 60% concordance between animal and human results.

In less technical language the major differences in comparing science-intensive potency assessments with expedited assessments is that the first social cost “gap”

49. That is, on a natural log scale they are within +1 or -1 of being completely accurate. A natural log value of +1 translates into a multiplicative number no greater than 7.4.

50. See Sara M. Hoover, Lauren Zeise, William S. Pease, Louise E. Lee, Mark P. Henning, Laura B. Weiss & Carl Cranor, *Improving the Regulation of Carcinogens by Expediting Cancer Potency Estimation*, 15 RISK ANALYSIS 267, 272, 277 tbl.4, 278 tbl.5 (1995). Identical substances that were independently assessed for their potency by means of science-intensive and time-consuming procedures by the two different agencies differed in the potency calculations by a greater amount than the expedited and science-intensive potency assessments completed by California EPA. See *id.* These comparisons provide a measure of the accuracy of the expedited potency assessments.

51. See Cranor, *supra* note 38, at 355–57.

52. For more details of this model, see *id.*

comparison assumes that animal studies predict with 100% accuracy that substances will cause cancer in humans, while the second social cost “gap” comparison assumes that animal studies are only 60% accurate in predicting tumors in humans. The actual rate of accuracy is likely to be somewhere between sixty and 100%. The take-home message, however, is that whether the animal studies are 100% accurate or only 60% accurate (or somewhere in between) in predicting substances that will cause cancer in humans, basing the expedited potency assessments on animal studies and expediting them is much better from a social-cost and health-protective perspective than time-consuming, science-intensive potency assessments that leave many substances without potency numbers (and to some extent unregulated).

The two modeling comparisons between science-intensive and expedited procedures show that society appears to be well ahead on a social cost basis utilizing faster, expedited potency assessments (even at some cost of less than full accuracy per substance) rather than utilizing quite slow, science-intensive procedures for the same purpose. In short, it appears that it is better to provide quick but possibly less accurate potency assessments than to go for long periods of time without any potency assessments, leaving the public at risk without reducing exposures or without giving firms information so they can reduce exposures and the public can avoid them.

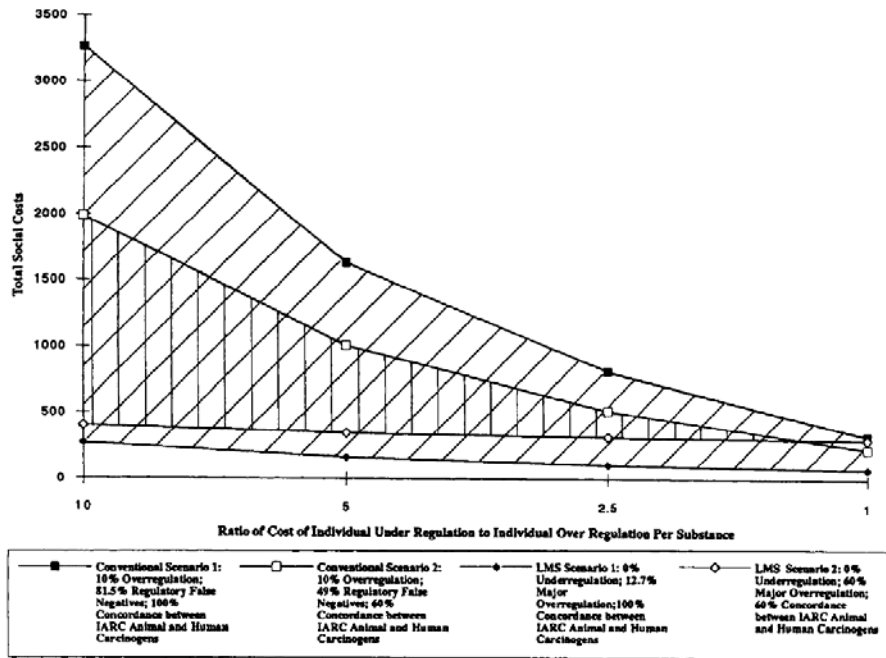


Fig. 1. Comparison of total costs for conventional vs. expedited Potency assessments for a universe of 400 substances.

Source: Cranor, *supra* note 38, at 356.

Finally, it is important to note that in the spirit of other features of Proposition 65, the adoption of expedited potency assessments makes use of readily available data

(from an independently established database⁵³) and other expedited procedures that utilize animal studies and calculated carcinogenic potency based on them.⁵⁴

IV. WHY DOES PROPOSITION 65 WORK?

Several features of Proposition 65 make it work as well as it does, especially in comparison with laws superficially similar to it (such as some “listing” statutes considered below and other more conventional postmarket laws). To understand why it works better than most statutes in providing public health protections, one should look to the automatic procedures contained within it, to the requirement that a firm seeking to avoid the warning requirements has a burden of proof to make certain showings, to its meaningful sanctions in response to violations, to the fact that firms will be specifically identified and have to post warnings of exposures unless they reduce them, and finally to its ability to address new toxic threats.

A. Automatic Provisions

The listing of individual chemicals by the governor’s expert committees could be relatively quick in principle, but in practice it has gradually become somewhat more time consuming because political pressures have caused modifications in the legal processes leading to the listing of individual substances. Despite this, many substances are listed through nearly automatic procedures that incorporate the results of other agencies and scientific bodies that have identified carcinogens and reproductive/developmental toxicants. Other postmarket statutes could utilize analogous provisions to contribute to a list of toxicants that might be regulated by technology-forcing laws or listing statutes; additionally, such provisions could even provide candidate substances for other postmarket actions.

Once substances are listed, there are some further automatic features in the statute that quickly achieve results that can take years when agencies bear the burden of proof under other statutes.

First, there are automatically specified and statutorily imposed risk levels that must not be exceeded by exposures to carcinogenic, reproductive, or developmental toxicants. Affected parties may not dispute the legislatively mandated risk levels in the same way they might argue against ambient exposure levels or the use of particular technologies under other postmarket statutes that provide incentives for firms to argue that high costs should modify the required exposure levels or to dispute the costs and feasibility of mandated technologies. The reduction of pressure points between regulated parties and agencies better serves public health protections. Other postmarket

53. This is a database of animal studies on carcinogenic substances created by Lois Gold and her associates at the University of California, Berkeley, from which the potency assessments may be calculated. See Lois Swirsky Gold, Charles B. Sawyer, Renae Magaw, Georganne M. Backman, Margarita de Veciana, Robert Levinson, N. Kim Hooper, William R. Havender, Leslie Bernstein, Richard Peto, Malcolm C. Pike & Bruce N. Ames, *A Carcinogenic Potency Database of the Standardized Results of Animal Bioassays*, 58 ENVTL. HEALTH PERSP. 9, 22–305 (1984).

54. See generally Cranor, *supra* note 38; Hoover et al., *supra* note 50.

laws could incorporate legislatively specified risk levels in order to protect the public health and remove some pressure from agencies.

Second, further implementation of the statute is also automatic. Firms are automatically required to post clear and reasonable warnings, or they may take other steps to reduce or eliminate exposure levels below the statutory trigger.

Proposition 65's automatic exposure levels bear some resemblance to the legislatively created "hammers" that were part of the Resource Conservation and Recovery Act (RCRA) amendments of 1984⁵⁵ and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980.⁵⁶ RCRA specified certain deadlines for EPA action and provided automatic bans on land disposal for certain kinds of toxic wastes,⁵⁷ while CERCLA "put requirements in the statute itself; it specified toxic substances that were to be listed for CERCLA regulation by incorporating previously established lists, and it set reportable quantities for many of these substances at one pound until EPA issued more appropriate reportable quantities."⁵⁸

Thus, CERCLA set rebuttable legal presumptions about the quantity of a substance that had to be reported to the EPA and that warranted an emergency response. These legislatively specified quantities could be changed by rule making (but had not been by as late as 1987). By comparison, Proposition 65 sets nonrebuttable risk levels for each substance found to be a carcinogenic or developmental toxicant. Firms must comply with them unless they choose to take a different course of action. They can choose to comply with the law in other ways, but they must take action by posting clear and reasonable warnings, or legally justifying why the law should not apply to the exposure levels that they create.

Third, the statutory provisions of Proposition 65 automatically apply to all firms that employ fewer than ten employees and who expose the public to listed substances. In-depth discussion is unnecessary, as this feature is not much different from language in other statutes.

B. Burden Shifting

I indicated at the outset that the burden of proof has been shifted on some issues under Proposition 65 compared with other postmarket statutes. There is some explicit burden shifting, but other provisions functionally accomplish similar ends.

Firms explicitly have the burden to show that there is no significant risk or no observable effect from an exposure.⁵⁹ The defendant must show by competent scientific evidence (not general assertions of safety) that both the existing level of exposure and that the existing exposures are below the level for which a warning is required by the statute.⁶⁰

55. 42 U.S.C. §§ 6901–6992 (2000).

56. 42 U.S.C. §§ 9601–9675 (2000).

57. See U.S. OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, IDENTIFYING AND REGULATING CARCINOGENS 134–35 (1987), available at http://www.theblackvault.com/documents/ota/Ota_3/DATA/1987/8711.PDF.

58. *Id.* at 136.

59. CAL. HEALTH & SAFETY CODE § 25249.10(c) (2007).

60. See *Consumer Cause, Inc. v. SmileCare*, 110 Cal. Rptr. 2d 627, 633–36 (Cal. Ct. App.

Moreover, firms are automatically required to do certain things if they expose the public to listed toxicants. They can meet their legal obligations under Proposition 65 in various ways, but they must take some action or offer certain justifications for their choices. They are legally required to post warnings or are given a limited number of legally constrained choices about other possible courses of action (one of which requires them to bear the burden of proof).⁶¹ However, there are substantial legal limits on what they can do, and they must take some affirmative action to pursue alternative courses of action. The alternatives open to them do provide choices, but those choices must be within limited legal constraints. Although some of these other choices do not explicitly require the firm to bear the burden of proof, the firm must make an argument for some of them (for example, presenting a case that warnings on their products are preempted by federal statutes, or reduce exposures from their products, and so on).

Burden shifting also places some of the social responsibility for any needed risk assessments partially on affected firms. They can receive assistance from the state if it has calculated a safe harbor value for a substance, but otherwise they have substantial burdens of proof. This avoids leaving all the responsibility for determining appropriate exposures on the state, to be resisted by affected firms at every stage of the process.

C. Meaningful Sanctions

Although most statutes have sanctions in case their provisions or regulations issued under the authority of the statute are not complied with, the seemingly minimal sanctions of Proposition 65 can be quite substantial. There is a fine of \$2500 for each person exposed per day during which there are not clear and reasonable warnings for carcinogenic and reproductive toxicants.⁶² When individual exposures are in the thousands and the exposures occur over any significant period of time, the total fines can run into the millions of dollars. This increases the urgency for a business to be sure that it is not in violation of the statute.

D. The Identification/Responsibility Feature

Proposition 65 has a feature that increases its efficacy; this is what one might call its “identification” or “responsibility” feature. Once a substance is identified as a carcinogenic or reproductive toxicant, a firm must issue warnings regardless of the circumstances of the exposure. Thus, *all* firms that create exposures for the public would have to post warnings, unless they could offer some defense within the limited legal choice of alternatives. When a firm has to post a warning, this identifies it as a source of toxicity in the community. Such identification in effect calls attention to the firm’s responsibility for (one might say *ownership of*) the exposure (whether it is lead from an industrial facility, lead in earthenware, or lead in wiring, if these exceed statutorily imposed exposure levels). It is likely that this attention and responsibility are unwanted by most firms. Avoiding unwanted attention as a source of toxic products in the community and responsibility for exposing the public (as well as avoiding potentially substantial fines) then provides a motivation for firms to eliminate exposures or to pursue alternatives that reduce exposures. Unwanted publicity is a

2001).

61. See *supra* notes 20–27 and accompanying text.

62. CAL. HEALTH & SAFETY CODE § 25249.7(b)(1) (2007).

great motivator. Even postmarket statutes that required agencies to set ambient exposure levels (the most onerous of laws from a public health perspective) could be amended to have listing and warning provisions for toxicants pending more elaborate regulatory action. That is, there could be a provision calling attention to the identification of a toxicant sourced within the community that requires a warning, while the agency engages in a further rule making to reduce exposures.

E. Adaptability

Finally, Proposition 65 has a surprising adaptability feature that can be a substantial strength when new toxicants appear or toxicants pose heretofore unexpected risks (even at lower exposure levels). A major scientific conference has recently revealed that prenatal and immediate postnatal exposures to low levels of carcinogens, neurotoxicants, endocrine disrupters, and so on can have substantial effects on developing fetuses or newborns.⁶³ Moreover, some of these adverse effects can last a lifetime, affecting the neurological, reproductive, immune, and cardiovascular systems. Thus, low-level, prenatal exposures can produce adverse effects lasting into adulthood and even old age. Some exposures to known toxicants at much lower levels may pose risks, or there may be newly identified products that pose such risks. I have argued elsewhere that existing legal structures can have substantial difficulties responding to new sources of toxic effects and new exposures.⁶⁴ However, within current legal structures, Proposition 65 is something of an exception.

When substances are known by DART or an authoritative body to be reproductive/developmental toxicants—once they have been listed—they can be quickly addressed within the structure of Proposition 65. That is, once substances are listed, firms doing business in California must post clear and reasonable warnings so the public is aware that they are exposed to the products that may pose developmental threats.

A particular strength of Proposition 65 is that it requires warnings on exposures that cause developmental problems whether in the endocrine, neurological, or other organ systems, all of which appear to be affected by prenatal or immediately postnatal exposures to toxicants.⁶⁵ Moreover, listing a substance as a developmental toxicant is possible in principle as soon as the appropriate science is available. And it can address consumer products, a particular shortcoming of other areas of U.S. laws (the consumer product safety laws are not especially robust). More importantly, listing, and consequently enforcement, can be based on animal studies; human data are not required (there are frequently pressures under other postmarket laws for agencies to support their regulations by human data). Thus, for new toxicants, new adverse effects, or timing of toxic injuries, Proposition 65 offers the possibility of reasonably rapid

63. International Scientific Committee, International Conference on Fetal Programming and Development, *The Faroes Statement: Human Health Effects of Developmental Exposure to Chemicals in Our Environment*, May 24, 2007, 102 BASIC & CLINICAL PHARMACOLOGY & TOXICOLOGY 73, 73–75 (2008), available at <http://www.pptox.dk/Consensus/tabid/72/Default.aspx> [hereinafter *Faroes Statement*].

64. Carl F. Cranor, *The Legal Failure to Prevent Subclinical Toxicity*, 102 BASIC & CLINICAL PHARMACOLOGY & TOXICOLOGY 267, 267–72 (2008).

65. See *Faroes Statement*, *supra* note 63.

listing followed by imposition of Proposition 65's other legal requirements, including (depending upon how businesses respond to the notification requirement) relatively quick removal from commerce or reduction of exposure.

There are, however, some limitations on Proposition 65 for these purposes. As a postmarket law it does not have any provision for testing of products prior to entering the market (but this does not make it any worse than other postmarket laws). More seriously, at the present time it is limited by the restriction of evidence of developmental toxicity only to exposures occurring during development (not resulting from immediate postnatal exposures) and by what the relevant Developmental and Reproductive Toxicant Committee is prepared to act upon. Consequently, although it is a step forward in that it provides for reasonably rapid responses to new toxicants or new adverse effects from existing toxicants, it has some limitations. Nonetheless, it permits some state action when agencies under other statutory authorities would be nearly paralyzed. For example, the U.S. Endocrine Disrupter Screening Program, based on the 1996 Food Quality Protection Act and the 1996 amendments to the Safe Drinking Water Act,⁶⁶ has yet to screen any substances or take any other regulatory action in eleven years.⁶⁷

In many respects Proposition 65 is structurally similar to other laws that identify or list desirable environmental goals that the community seeks to achieve (or conversely, laws that identify or list adverse effects on the environment that the community seeks to avoid). However, Proposition 65 appears more effective in accomplishing its goals than some laws superficially similar to it.

Other laws concerning toxic substances that resemble Proposition 65 are those using various "lists," such as the Emergency Planning and Community Right-to-Know Act (EPCRA) that was embedded in the Superfund Amendments and Reauthorization Act.⁶⁸ To maintain the Toxics Release Inventory (TRI), a publicly accessible database containing information on toxic chemical releases and waste management activities required by the EPCRA,⁶⁹ the EPA issues a list of toxic substances, and then requires firms to provide information about chemicals that are being used, manufactured, treated, transported, or released into the environment. Communities can use the reported data to pressure firms to reduce exposures, or the mere production of data may cause firms to reassess practices and emissions to reduce exposures. Other provisions of Superfund set cleanup standards by reference to other statutes once there has been a toxic release. Such provisions reduce exposures, but there may also be cases in which reducing exposures to levels required by other statutes is not mandated by the cleanup plan that the EPA approves.

The TRI provides data that connect firms with releases of toxic substances (in this respect it resembles Proposition 65), but there is no legal recourse under that statute to citizens who are exposed, or to the EPA to regulate exposures (unlike the private enforcement provisions of Proposition 65). Such release information merely provides data communities can utilize to politically pressure firms into reducing community

66. See U.S. Environmental Protection Agency, Endocrine Disrupter Screening Program Background, <http://www.epa.gov/endo/pubs/edspoverview/background.htm>.

67. Cranor, *supra* note 64, at 270.

68. 42 U.S.C. §§ 11001–05, 11021–23, 11041–50 (2000).

69. *Id.* § 11023; see generally U.S. Environmental Protection Agency, Toxics Release Inventory Program, <http://www.epa.gov/tri/>.

exposures.⁷⁰ Moreover, there are no legally mandated exposure levels that firms cannot exceed; this is quite unlike Proposition 65. Thus, in contrast to Proposition 65 one might say that the Emergency Planning and Community Right-to-Know Act identifies firms as sources of toxic exposures, but they have no legal requirements (other than reporting) and no sanctions for exposing the public.

The National Environmental Policy Act (NEPA)⁷¹ requires governmental agencies (or perhaps private parties seeking governmental permits or other actions) to generate information about the environmental impact of major agency actions and alternatives to them. This law aims to improve decision making by ensuring that certain alternatives are considered and that environmental values are part of the decision making. In addition, agencies are required to use all “practicable means” to try to achieve various environmental and other goals in NEPA. Thus, one might think of NEPA as identifying (or possibly *listing*) environmental goals that agency actions cannot adversely impact and requiring agencies to develop alternative means to achieve their objectives.

The information generated and the alternatives considered are only *procedurally required*; that is, they appear not to aim at any substantive exposure or environmental protection standards. Moreover, NEPA permits citizens and other agencies to bring suits objecting to the *procedure* followed in pursuing agency objectives. The results of procedural suits might change how a government agency achieves its objectives and even reduce environmental damage, but there is no certain predictability and no guarantee of a particular substantive outcome. This law applies to governmental actions only and applies derivatively (if at all) to private actions. Unlike Proposition 65, there are no specified exposure levels for toxicants or specific violations that agencies must heed that would occasion legal action. It is also unclear whether there are any sanctions agencies (or, derivatively, private parties) would face other than being subject to procedural objections.

The Endangered Species Act (ESA)⁷² is also something of a “listing” statute. It requires that the Secretary of the Interior list endangered (and threatened) species and designate “their essential habitat.”⁷³ Federal agencies must not jeopardize these species or adversely modify their habitats. Moreover, plans must be prepared and implemented for species recovery where the habitat of endangered or threatened species is inadequate. Private parties “may not harm these species without undertaking remedial planning.”⁷⁴ In implementing the law, the Secretary of the Interior must use “the best scientific and commercial data available to him.”⁷⁵ This prohibits the Secretary from

70. This should not be underestimated as a form of regulation by social pressure, but it lacks the full effectiveness of Proposition 65.

71. 42 U.S.C. §§ 4331–4370 (2000).

72. 7 U.S.C. § 136 (2000); 16 U.S.C. §§ 1531–1544 (2000).

73. A species is endangered when it is “in danger of extinction throughout all or a significant portion of its range.” 16 U.S.C. § 1532 (2000). It is “threatened” when it “is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.” *Id.* Both are “scientific call[s] on how close the species is to the brink.” WILLIAM H. RODGERS, ENVIRONMENTAL LAW 1004 (2d ed. 1994).

74. Oliver A. Houck, *The Endangered Species Act and Its Implementation by the U.S. Departments of Interior and Commerce*, 64 U. COLO. L. REV. 277, 285 (1993).

75. RODGERS, *supra* note 73, at 1004 (quoting 16 U.S.C. § 1533(b)(1)(A) (1994)).

“disregarding available scientific evidence that is in some way better than the evidence he relies upon.”⁷⁶

The ESA resembles Proposition 65 in that it identifies (lists) something of considerable environmental value that must be protected (endangered or threatened species) and once a species is on the list, various legal requirements with which agencies (and citizens seeking to do business with them or seeking governmental approvals) must comply are triggered. This statute appears to have substantial impact on the behavior of agencies and the public alike. However, although it identifies individuals or agencies as being responsible for adversely affecting endangered or threatened species, it may result in less adverse publicity and consequently less public pressure on individuals or firms than Proposition 65 places on businesses that expose the public to carcinogenic and reproductive toxicants. In general the public is likely to react somewhat less strongly to governmental or private actions that jeopardize endangered or threatened species than it would to information that businesses in their communities were exposing them to toxic substances. Thus, it appears that the adverse publicity of Proposition 65 is likely to be a greater motivator for firms to modify their behavior than analogous consequences under the ESA. Indeed, since the consequences of a given individual action adversely affecting an endangered or threatened species may appear to be much less harmful to individuals in the community than threats to their health from toxic substances listed under Proposition 65, this is an additional strength of Proposition 65 that would motivate citizens to pressure firms to do the right thing and reduce exposures to toxicants.

Wetlands protection under section 404 of the Clean Water Act (CWA)⁷⁷ is a fourth law that appears to resemble some aspects of Proposition 65 and the ESA. Wetlands are designated by statute as meriting protection from dredging and filling. Section 404 of the CWA regulates the discharge of dredged or fill material into waters of the United States, including wetlands, requiring a permit before they can be filled or dredged.⁷⁸ Agencies have the burden of proof to ensure that proper permits are secured and that wetlands are protected. In order to receive a permit, a proponent must, to the extent practicable, meet three criteria: (1) take steps to avoid wetland impacts, (2) minimize potential impacts on wetlands, and (3) compensate for any remaining unavoidable impacts.⁷⁹ The burden to make these showings is on proponents of the activity. Finally, courts are authorized to take a “hard look” at the issuance of permits allowing such activities.⁸⁰

I cannot address the effectiveness of this law, but a few inferences can be made from the statutory requirements. Sometimes individual persons may be adversely

76. *City of Las Vegas v. Lujan*, 891 F.2d 927, 933 (D.C. Cir. 1989).

77. 33 U.S.C. § 1344 (2000).

78. *See id.*

79. *See Memorandum of Agreement Between the Department of the Army and the Environmental Protection Agency: The Determination of Mitigation Under the Clean Water Act Section 404(b)(1) Guidelines*, <http://www.epa.gov/OWOW/wetlands/regs/mitigate.html> [hereinafter *Guidelines*]. Proposed activities are regulated through a permit review process. An individual permit is required for potentially significant impacts. *See id.* Individual permits are reviewed by the U.S. Army Corps of Engineers, which evaluates applications under a public interest review, as well as the environmental criteria set forth in the *Guidelines*. *See id.*

80. RODGERS, *supra* note 73, at 339.

affected if section 404 is not properly enforced; for example, their personal water supplies might be damaged. However, because effects are likely to be delayed and diffusely spread among those potentially adversely affected, they become public “bads” (the opposite of public goods). Thus, individuals are unlikely to see substantial adverse effects. It will also be more difficult to connect any adverse effect to individual action when there is noncompliance with section 404. Consequently, citizens do not have narrow, self-interested, incentives to see that the law is properly enforced in the same way they likely have incentives to help enforce Proposition 65. There is too loose a connection between failure to enforce section 404 of the CWA and adverse effects on individual members of the public to generate enforcement pressure that can be effective under Proposition 65. There is also too loose a connection between the requirements of the law and how failure to abide by them can adversely affect individual members of the public.

None of the other laws with structures superficially similar to Proposition 65 appears to be as effective as Proposition 65 on a number of dimensions. None utilizes existing data to provide for public health or environmental protections. None uses expedited procedures to provide safe harbors for businesses and guidance to the public. None, to my knowledge, makes use of other expedited information procedures analogous to expedited potency assessments. And none has the ability to adapt to emerging toxicants or more subtle injuries, as Proposition 65 can address emerging developmental toxicants. All of these are substantial advantages of Proposition 65 in protecting the public health.

CONCLUSION

Many significant changes are due in environmental health laws (most of which are postmarket laws). Without change, we will have to rely upon “time-consuming, corroborative science in legally difficult circumstances to confirm on a case-by-case basis (against powerful political groups and difficult burdens and standards of proof) that there is actual harm, or sometimes risks of harm.”⁸¹ This is where we often find ourselves in the United States. This is not a paradigm of a protective agenda for the public, workforce, or the environment.

Proposition 65 goes some way toward better serving health protective goals for the public and the workforce. With its nearly automatic use of information generated by other agencies or consensus scientific bodies; its identification of and assignment of responsibility to particular firms as the sources of exposures; its shifting of the burden of proof (and legally constrained choices); its statutorily imposed exposure safety levels; its substantial fines for failure to comply with its legal provisions; and its comparatively rapid production of potency assessments, it appears to have considerable efficacy compared to many postmarket statutes. Aspects of this law would provide potential models for other health protective environmental laws. However, much more remains to be done to implement a better set of health protective laws in the United States.

81. Cranor, *supra* note 5, at 49.