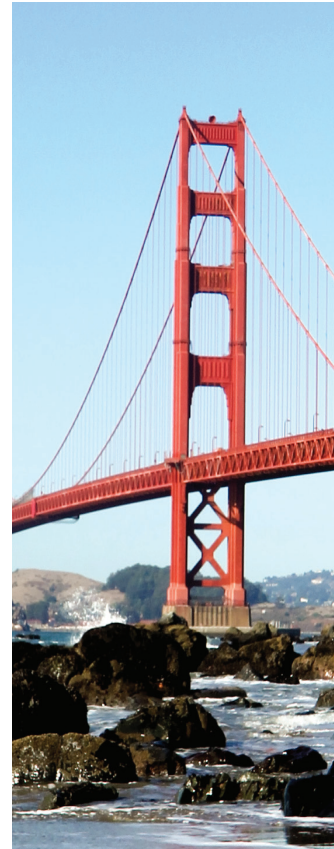



REMOVING UNCERTAINTY:



Proposed Standards-Based Reforms to California's Proposition 65

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Introduction



In November 1986, California voters passed a ballot initiative, “The Safe Drinking Water and Toxic Enforcement Act of 1986,” known colloquially as “Proposition 65.” In part, the initiative requires businesses operating in California to warn customers of possible exposure to chemicals known to the state of California to cause cancer or reproductive harm. To determine when a business must post a sign or label a product, the law requires California’s Office of Environmental Health Hazard Assessment (OEHHA) to maintain a list of chemicals that it finds cause either cancer or reproductive harm.

While the law was passed with the intention of improving public health, the regulations and litigation stemming from the law’s enactment have created a massive burden for businesses operating in California. Because the law was enacted through a voter-approved ballot measure, most substantive reforms to the law require a two-thirds majority of the legislature or voter approval. However, there are achievable regulatory and legislative changes that could alleviate some of the burden for businesses and improve the effectiveness of warnings for California citizens.

The greatest challenge for businesses trying to comply with Proposition 65 is the degree of uncertainty surrounding whether or not they are in compliance with the law. This paper outlines three major problems with the regulatory framework governing Proposition 65, particularly a lack of scientific basis for listing determinations, and offers recommended solutions. The main problems are the:

- Lack of clearly defined, objective standards for determining which scientific literature is considered by OEHHA before opting to list or de-list a particular chemical;
- Lack of standardized testing to determine:
 - a. “Safe harbor levels” for listed chemicals, and
 - b. Whether a chemical should be listed or de-listed;
- Lack of clear federal preemption.

Since Proposition 65 allows private citizens to bring action against businesses they suspect of violating the law’s provisions, the law has generated substantial litigation. **Citizen-initiated, so-called “bounty hunter” lawsuits, cost businesses more than \$17.4 million in 2013 alone, and nearly three-quarters of that total was paid to plaintiffs’ attorneys.** This doesn’t even include legal fees, time lost, and cost of compliance by the businesses. By creating clear standards and increasing transparency, OEHHA can help businesses more easily comply with Proposition 65’s requirements, substantially reducing their risk of litigation.

Primary Problems

Listing Chemicals: How OEHHA Determines Relevant Literature

OEHHA does not do any original research on chemical safety. Instead, the agency relies on the research of other scientists and the opinions of “authoritative bodies.”

Authoritative bodies include:

- U.S. Environmental Protection Agency
- U.S. Food and Drug Administration
- National Institute for Occupational Safety and Health
- National Toxicology Program
- International Agency for Research on Cancer

OEHHA is supposed to take a “weight of the evidence” approach to listing chemicals,¹ but the agency has an enormous amount of leeway to determine which research it will consider and how much weight to give each paper when determining a chemical’s potential as a carcinogen or reproductive toxin.

The process by which the “state’s qualified experts” determine whether a particular chemical has been clearly shown to cause cancer or reproductive toxicity is severely flawed.

These flaws include, but are not limited to:

- **Relying on abstracts rather than full studies to determine candidates for listing:** For instance, in the cases of benzo(a)pyrene, uranium, methyl parathion, deltamethrin, and Xylene, DART IC stated it only reviewed abstracts and/or titles of relevant studies.² Yet, each of those chemicals was selected (based on abstracts of studies and study titles) as a candidate for listing under Proposition 65.
- **Lack of recent research:** Recently, OEHHA reconsidered whether Hexafluoroacetone³ should remain listed under Proposition 65. The studies considered by OEHHA were dated: 1979,1982,1983,1984,1985, 1988,1991. Every study considered was more than two decades old. This is typical of the research reviewed by OEHHA—the agency itself says: “It is unlikely that chemicals will be proposed for CIC or DART IC review that have been recently reviewed by an authoritative body and found to have insufficient evidence of carcinogenicity or reproductive toxicity, respectively.”⁴ As the CSPA pointed out in regulatory comments to the agency, “The lack of recent research or review would generally indicate that a chemical is not likely a concern.”⁵

¹ Guidance Criteria For Identifying Chemicals For Listing As “Known To The State To Cause Cancer”, March 2001

² http://www.oehha.ca.gov/prop65/public_meetings/pdf/DARTprior071211.pdf

³ Reconsideration of Three Chemicals Listed under Proposition 65 as Known to Cause Reproductive Toxicity 2014

⁴ Office of Environmental Health Hazard Assessment. (2004). Process for prioritizing chemicals for consideration under Proposition 65 by the “State’s Qualified Experts”. Retrieved from California Environmental Protection Agency website: http://www.oehha.ca.gov/prop65/CRNR_notices/state_listing/pdf/finalPriordoc.pdf

⁵ Law, B. L. (2012). Comments on “Announcement Of Chemicals Selected By OEHHA For Consideration For Listing By The Developmental And Reproductive Toxicant Identification Committee And Request For Relevant Information On The Reproductive Toxicity Hazards Of Deltamethrin And Xylene”. Retrieved: http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/pdf_zip/040412gencoms.pdf

- **Failure to recommend specific animal species used for testing:** Within the Proposition 65 guidelines are recommendations as to the type and numbers of animals used, yet there are no specific recommendations requiring specific species used. As an example, two of the most commonly used rats in medical studies are the Wistar Rat and the Sprague-Dawley strain of rat. Numerous studies over the years have demonstrated differential responses of these rats in the same experimental design, (Beije B, Möller L. 1988, García-López, et.al. 1996, Zmarowski, et.al. 2012, Irving, 1975). Measurements of tumor growth in rats or mice may be very different depending on husbandry, and whether or not these animals were inbred or outbred. For a detailed review of the responses of different rat strains to pharmaceutical agents and naturally occurring substances see S. Kacew, and M. F. W. Festing, 1996.

Other regulatory agencies have a much more detailed set of criteria for evaluating literature. Though page length in and of itself is not an indication of the thoroughness of OEHHA's guidance, it's a helpful comparison of the amount of detail given by the agency. For example, the cancer guidelines published by OEHHA on the Proposition 65 website are merely five (5) pages long. In contrast, the EPA's "Guidelines for Carcinogen Risk Assessment"—the guidance document used by the agency for developing risk assessments and weighing evidence of carcinogenesis and other health effects—is 166 pages in length.⁶

Case Study: SuperNutrition

SuperNutrition is a family-owned small business that produces nutritional supplements sold around the globe. The company was targeted by a bounty hunter who identified lead in one of its supplements. In addition to paying a \$220,000 fine and over \$100,000 in legal fees, the company lost approximately \$1 million per year in sales due to reformulating products which long term customers loved and stopped buying due to the changes. So far, the company has lost a total of approximately \$3 million in sales that will never be regained.

The company produces roughly 30 supplements. To test each product on an annual basis is roughly \$5,000 each year. Testing is no guarantee a business will be safe from lawsuits—different labs can come back with vastly different chemical readings.

Proposition 65 has devastated SuperNutrition's business, which has struggled to recover from the effects of the lawsuit.

The lack of clear regulatory guidance as to how OEHHA evaluates literature to place a chemical on the Proposition 65 warning list leaves manufacturers and retailers who sell products that may contain potentially listed chemicals in the dark as to how to evaluate the safety of their own products in accordance with California law.

Identifying "Safe Harbor Levels" for Listed Chemicals

Businesses are not required to provide a Proposition 65 warning if they can show that chemicals used fall within the No Significant Risk Levels (NSRLs) for cancer-causing chemicals or Maximum Allowable Dose Levels (MADLs) for chemicals causing reproductive toxicity.⁷ However, such levels have only been established for a tiny fraction of the over 800 chemicals listed under Proposition 65. Businesses hoping to avoid a lawsuit have the responsibility to test and establish safe harbor limits themselves—and then hope that the court agrees with their determination in the event that the businesses are sued for failure to warn under Proposition 65. This testing is extremely expensive for businesses, particularly small businesses, and the guidelines for establishing this safe harbor amount are vague.

⁶ Environmental Protection Agency. (2005). Guidelines for carcinogen risk assessment (EPA/630/P-03/001F). Retrieved from http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF

⁷ Office of Environmental Health Hazard Assessment. (2013). Most current proposition 65 no significant risk levels (NSRLs) maximum allowable dose levels (MADLs). Retrieved from <http://www.oehha.ca.gov/prop65/getnsrls.html>

Consider the nutritional supplement industry—these companies often produce hundreds of different products, each of which have to be tested for Proposition 65-listed chemicals. That’s why the industry’s trade association has advised its members: “Given finite economic resources, absolute assurance of Prop 65 compliance is nearly impossible. The best a supplement company can do is prioritize which Prop 65 chemicals to test for, conduct chemical testing as appropriate, and make sure that strong quality control processes are in place.”⁸

For the chemicals that do have a safe harbor limit established by OEHHA, the threshold is not necessarily based on sound science. Levels set by the FDA and World Health Organization for daily intake of many of the chemicals listed by OEHHA are much higher than those set by the state of California.

For example, lead. OEHHA lists lead as both a carcinogen and a reproductive toxin.⁹ The established MADL is 0.5 µg/dL—an extremely low limit. Meanwhile, the World Health Organization has referenced a total level of intake ranging from 106 to 206 µg/dL. (Castellino 1995).

Case Study: Mercury in Tuna

Methyl mercury was listed as a developmental toxin by OEHHA in 1987. In 2001, a Proposition 65 lawsuit was filed against several tuna canning companies claiming that their products contained an unacceptable level of methyl mercury—mercury can bioaccumulate in tuna.

Though the federal Food and Drug Administration (FDA) is aware that tuna often contains mercury, it has concluded that the risks are outweighed by the benefits of tuna and advises the public, particularly pregnant women, about the benefits of eating tuna in safe levels. In dismissing the case against the tuna manufacturers, the trial court ruled that OEHHA’s warning requirement with respect to mercury in tuna fish conflicted with the FDA’s policy of advising consumers about both the benefits and risks associated with fish consumption.

The judge in the case advised (People of the State of California vs. Tri-Union Seafoods, LLC et al. 2006):

Consistent with its mission and practice, FDA has studied carefully the issue of methylmercury in fish for more than twenty-five years and has developed substantial expertise in analyzing both the scientific and consumer education aspects of the issue. Accordingly, FDA is uniquely qualified to determine how to advise consumers on the issue of methylmercury in fish.

Though the suit dismissal was upheld by an appellate court, the court declined to rule specifically on the preemption argument.



⁸ Alliance for Natural Health USA). (2012). A Guide to California’s Proposition 65 for the Nutritional Supplement Industry. Retrieved from <http://www.anh-usa.org/wp-content/uploads/2013/04/Prop-65-manual.pdf>

⁹ Office of Environmental Health Hazard Assessment. (2015). Chemicals known to the State to cause cancer or reproductive toxicity. Retrieved from http://oehha.ca.gov/prop65/prop65_list/files/P65single012315.pdf

In fact, one can reach the OEHHA-established threshold of .5 µg/dL just from consuming a few servings of fruits or vegetables.¹⁰ It's therefore baffling that OEHHA has established such a low safe harbor limit.

Lack of Clear Federal Preemption

The federal government regulates chemicals under the Toxic Substances Control Act, and various federal agencies already prescribe labeling rules for products like packaged foods and pharmaceuticals. Subjecting manufacturers to more than one system of labeling, it creates a clear problem for manufacturers and retailers attempting to sell the same product in California and other states.

Businesses in California can't count on federal preemption to save them from costly litigation—the courts haven't ruled on the issue clearly enough for businesses to judge whether federal law may trump Proposition 65 in their case. Instead, litigants are free to bring cases against businesses for failure to issue a warning under Proposition 65, even if those businesses are in full compliance with existing federal regulations.

Proposed Solutions

Authoritative Bodies

As we've previously noted, OEHHA is bound by the decisions of "authoritative bodies." When these bodies determine a chemical is a potential carcinogen or reproductive toxin, there is a rather straightforward administrative procedure to list that chemical on the Proposition 65 warning list. **But while OEHHA is bound to defer to authoritative bodies when a chemical is identified as harmful, it is not bound to defer to authoritative bodies that identify a chemical as safe.**

Proposed Solution: In cases where an authoritative body has ruled a chemical as safe, OEHHA should defer to the authoritative body.

The Recognition of Consensus Standards by the Federal Government

In 1995 Congress passed the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113. This law directs all federal government agencies to use for regulatory, procurement, and other agency activities, wherever feasible, standards and conformity assessment solutions developed or adopted by voluntary consensus standards bodies in lieu of developing government-unique standards or regulations. The NTTAA also encourages government agencies to participate in standards development processes, where such involvement is in keeping with an agency's mission and budget priorities. Recently the OMB issued a Circular (A-119) on the use of voluntary consensus standards, including recommendations on how and to what extent federal agencies must support voluntary consensus standards activities. Though there are some clarifications articulated in this circular, the basic tenets for the use of non-governmental consensus standards by Federal agencies remains intact.

¹⁰ Reported Findings of Low Levels of Lead in Some Food Products Commonly Consumed by Children. (2012). Retrieved from <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm233520.html>

Since the passing of the National Technology Transfer Act, the Federal Government has established a mechanism to track and report the use of consensus standards by Federal agencies (Standards). According to the Standard.gov (Standards referenced in CFR) website there are, 11,081 records of Standards Incorporated by Reference (SIBR) in the Code of Federal Regulations (CFR). Of these, 6,538 standards listed in the Code of Federal Regulations have been developed by non-governmental ANSI accredited consensus standards organizations.

We recognize that the NTTAA only applies to the Federal Government and not the State, but California would do well to adopt a similar directive as it relates to Proposition 65. The perceived arbitrary nature of the policies and procedures of Proposition 65 are problematic for all parties involved. We request that the State of California take into consideration the following recommendations to improve the implementation of Proposition 65.

Development of Accredited Consensus Standards for Evaluating Chemicals

In cases where an authoritative body has not indicated a chemical is a carcinogen or reproductive toxin, more detail is needed to clarify what criteria OEHHA's committees will use to determine whether a chemical is listed under Proposition 65. Creating consensus standards for this process will make it much easier for California businesses to understand how the state plans to evaluate chemicals.

The use of consensus standards would allow all parties involved from academia, government, and industry to be working from the same protocols. Results can be easily compared by all parties with complete transparency and consistency of experimental design and implementation. Voluntary consensus standards are not static documents as the American National Standards Institute (ANSI) requires that approved consensus standards be reviewed and updated every 5 years.

Recommendations for Standardization (not all inclusive):

1. The State of California should engage an ANSI accredited Standard Development Organization (SDO) such as ASTM to develop consensus standards for all future testing.

- a. ANSI (American National Standards Institute) accreditation requires that all consensus standards developed have a broad range of stakeholders, ranging from government, academia, and industry.
- b. ANSI requires standards to be reviewed every 5 years and updated when necessary.

2. Standards can articulate, as examples:

- a. Specific animal species to be used
- b. Age of animals
- c. Quality of reagents
- d. Analytical techniques
- e. If cell lines are to be used:
 - i. Authenticated cell lines
 - ii. Age and number of passages of the cell lines
- f. Exposure conditions
- g. How population based studies should be conducted

h. All experimental conditions necessary to determine a chemicals carcinogenicity and/or reproductive toxicity

3. The development of the consensus standards should have the input by all the authoritative bodies that may submit chemicals for listing in Proposition 65.

a. This is particularly important since the listing of chemicals deemed to cause cancer or reproductive toxicity is a ministerial action when brought to the OEHHA by an authoritative body.

4. Toxicity levels for both carcinogens and reproductive toxicity should be harmonized by all stakeholders and codified in the standards.

5. Definitions for all critical terms should be harmonized and quantified.

6. These standards should be specific for both cancer causing and reproductive toxicity.

7. The standards should be sufficiently flexible to account for various types of experimental conditions such as; dermal exposure, inhalation, or ingestion as further examples.

8. These standards may not necessarily preclude the review of past publications but would be given significantly greater weight in the decision making process.

9. The consensus standards do not have to prohibit studies done outside the accepted protocols but these should be judged with the same scientific rigor in which the consensus standards were developed.

10. Recommendations that are counter to the results of these standardized studies would need to be justified.

11. All recommendations from outside sources to list or delist a chemical must cite studies using the consensus based standards.

Developing Safe Harbor Levels

We recognize that the State of California has established Safe Harbor Levels for a small number of the chemicals listed under Proposition 65. However, there are still an overwhelming number of chemicals that lack established safe harbor levels. To remove uncertainty, the OEHHA should also develop consensus standards establishing a clear process for businesses to determine safe harbor levels for such chemicals.

Creating this standard will allow businesses to ensure that their products do not contain amounts of Proposition 65-listed chemicals in a quantity that will require labeling and provide a clear baseline to protect themselves from bounty hunter lawsuits.

Federal Preemption

For industries that are subject to other federal labeling and ingredient requirements, federal law should preempt Proposition 65's labeling requirements. In addition to mercury in tuna fish, there are a number of instances where OEHHA requires a product to be labeled when federal regulatory bodies have ruled a product to be safe. To determine areas where federal law and Proposition 65 conflict, we recommend the establishment of a task force to identify areas of exemption from Proposition 65's requirements.

Conclusion

Industry works best when guidelines for doing business are clear, unambiguous, and perceived as fair, unbiased, and consistent. The current process for listing and delisting chemicals for Proposition 65 is too arbitrary to give credence to the results in either direction. The State of California needs to modify its procedures for listing and delisting chemicals to be more standardized, transparent, and comply with generally regarded principles of good science. Harmonization with authoritative bodies at the minimum for precise definitions would go a long way since their conclusions are accepted by Proposition 65 through ministerial action. Codification and standardization would make compliance with Proposition 65 less burdensome for industry and less controversial for the State of California.

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