



# OEHA

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Risk Assessment Guidelines

Children's Food Dyes

Toxic Air Contaminants

Public Health Goals

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Proposition 65

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Safe Harbors

AB 617

California

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Medical Supervision

Harmful Algal Blooms

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CalEnviroScreen

Emergency Response

Biomonitoring California

Fish Advisories

Biogas

Risks

Hazard

Traits

Fishery Closures

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Domoic Acid

Green Chemistry

1983





## 1983 Red Book Framework

- Two distinct actions –  
risk assessment and risk management

### NAS 1983 “Red Book”



# 1983 “Red Book”

## 4 Elements of Risk Assessment

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**Hazard identification**  
(Does the agent cause the adverse effect?)

**Dose response Assessment** (What is the relationship between dose and incidence in humans?)

**Exposure Assessment**  
(What exposures are currently experienced or anticipated under different conditions?)

**Risk Characterization**  
(What is the estimated incidence of the adverse effect on a given population?)







# 1986 Ballot Initiative: Proposition 65



65

## Restrictions on Toxic Discharges into Drinking Water; Requirement of Notice of Persons' Exposure to Toxics. Initiative Statute

Official Title and Summary Prepared by the Attorney General

**RESTRICTIONS ON TOXIC DISCHARGES INTO DRINKING WATER; REQUIREMENT OF NOTICE OF PERSONS' EXPOSURE TO TOXICS. INITIATIVE STATUTE.** Provides persons doing business shall neither expose individuals to chemicals known to cause cancer or reproductive toxicity without first giving clear and reasonable warning, nor discharge such chemicals into drinking water. Allows exceptions. Requires Governor publish lists of such chemicals. Authorizes Attorney General and, under specified conditions, district or city attorneys and other persons to seek injunctions and civil penalties. Requires designated government employees obtaining information of illegal discharge of hazardous waste disclose this information to local board of supervisors and health officer. Summary of Legislative Analyst's estimate of net state and local government fiscal impact: Costs of enforcement of the measure by state and local agencies are estimated at \$500,000 in 1987 and thereafter would depend on many factors, but could exceed \$1,000,000 annually. These costs would be partially offset by fines collected under the measure.

### Analysis by the Legislative Analyst

#### Background

Currently, the state has a number of programs designed to protect people against possible exposures to harmful chemicals. The major programs involve the regulation of:

- **Waste Discharges.** The State Water Resources Control Board and the regional water quality control boards regulate the discharge of wastes into state waters, including rivers, streams, and groundwater that may be used as sources of drinking water. The Department of Health Services regulates the disposal and cleanup of hazardous waste, including hazardous waste that may contaminate drinking water.
- **Drinking Water.** Current law prohibits local water agencies from supplying drinking water to the public that contains dangerous levels of certain harmful chemicals. Local water agencies must inform customers when the level of these chemicals exceeds certain limits. The Department of Health Services enforces these limits.
- **Workplace Hazards.** The Department of Industrial Relations regulates exposure to cancer-causing materials and other harmful substances in the workplace. Current law also requires employers to inform workers of possible exposure to dangerous substances.
- **Pesticides.** The Department of Food and Agriculture regulates the use of pesticides in agriculture and in other business applications, such as maintenance of landscaping and golf courses.

These regulatory agencies must make judgments about the amounts of harmful chemicals that can be released into the environment. In doing so, they try to balance what it costs to prevent the release of chemicals against the risks the chemicals pose to public health and safety. As the level of allowable exposure goes down, the cost of prevention typically goes up. The risk that some substances pose to health is not always known. Often, scientists cannot determine precisely the health impact of low-level exposures that occur over 20 or 30 years.

#### Proposal

This measure proposes two additional requirements for

businesses employing 10 or more people. First, it generally would prohibit these businesses from knowingly releasing into any source of drinking water any chemical in an amount that is known to cause cancer or in an amount that exceeds 1/1,000th of the amount necessary for an observable effect on "reproductive toxicity." The term "reproductive toxicity" is not defined. Second, the measure generally would require those businesses to warn people before knowingly and intentionally exposing them to chemicals that cause cancer or reproductive toxicity. The measure would require the state to issue lists of substances that cause cancer or reproductive toxicity.

Because these new requirements would result in more stringent standards, the practical effect of the requirements would be to impose new conditions for the issuance of permits for discharges into sources of drinking water. In order to implement the new requirements, state agencies that are responsible for issuing permits would be required to alter state regulations and develop new standards for the amount of chemicals that may be discharged into sources of drinking water.

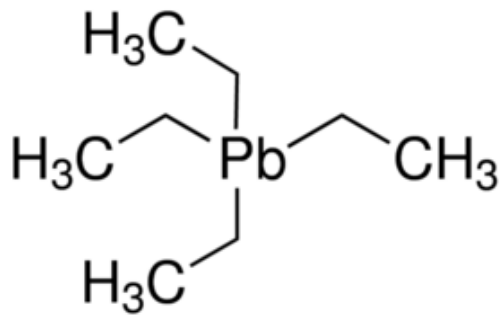
The measure also would impose civil penalties and increase existing fines for toxic discharges. In addition, the measure would allow state or local governments, or any person acting in the public interest, to sue a business that violates these rules.

#### Fiscal Effect

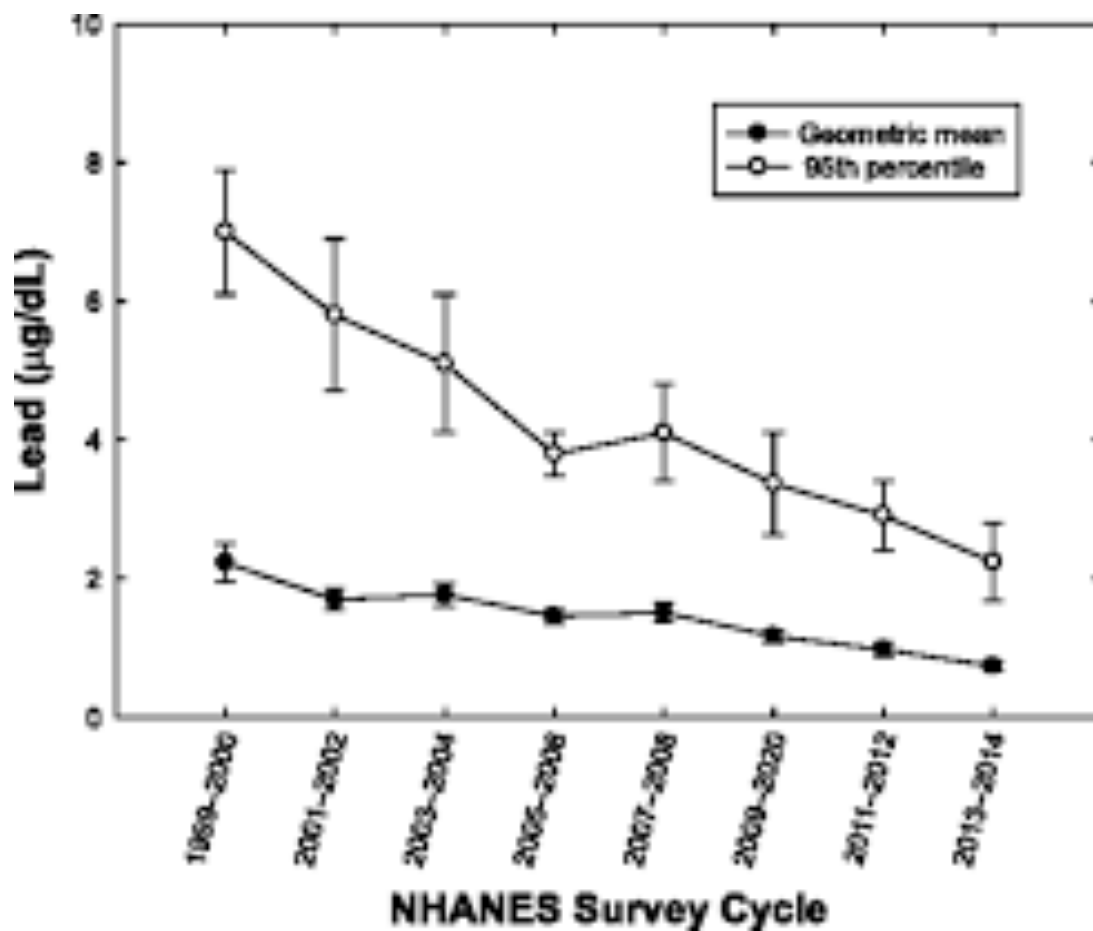
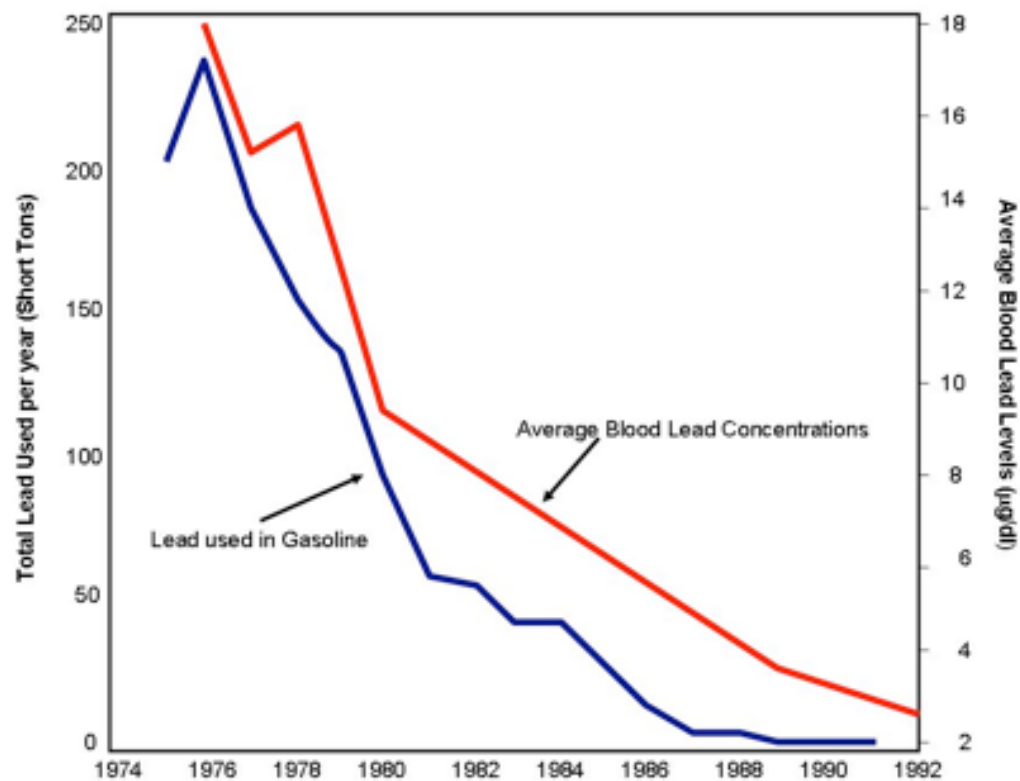
It is estimated that the administrative actions resulting from the enactment of this measure would cost around \$500,000 in 1987. Starting in 1988, the costs of these actions are unknown and would depend on many factors, but these costs could exceed \$1 million annually.

In addition, the measure would result in unknown costs to state and local law enforcement agencies. A portion of these costs could be offset by increased civil penalties and fines collected under the measure.

Beyond these direct effects of the measure, state and local governments may strengthen enforcement actions to ensure compliance with the new requirements. The costs of any additional enforcement could be significant.



# LEAD





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# Proposition 65 Hazard Identification

## Proposition 65 List of Chemicals Known to Cause Cancer or Reproductive Toxicity

Identified by

- State's Qualified Experts (SQE)  
Carcinogen Identification Committee  
Developmental and Reproductive  
Toxicant

Identification Committee

- Authoritative bodies named by the SQE
- State and Federal Labeling Requirements



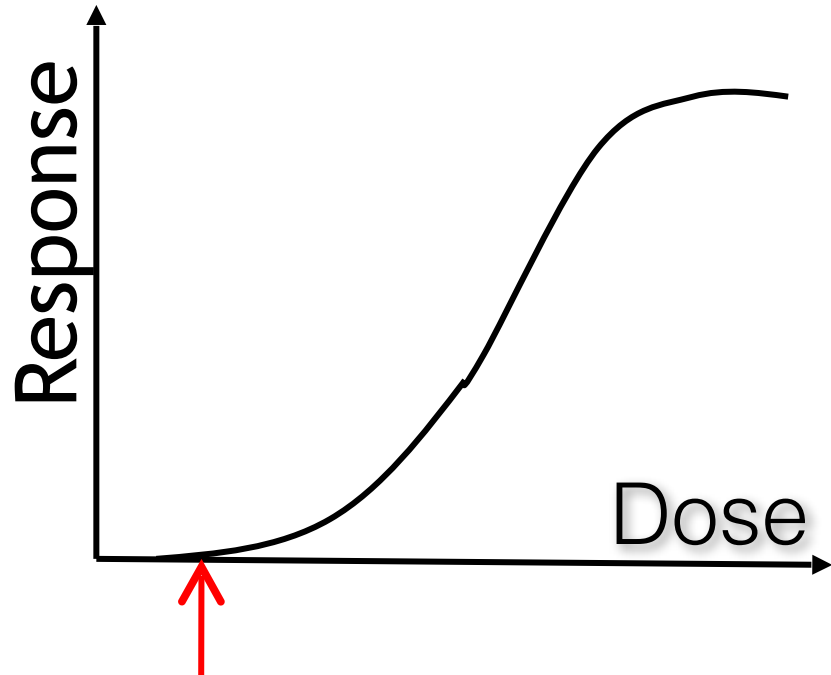


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# Proposition 65 Dose Response Assessment

**Safe Harbor Levels:** Exposures at or below which warning is not required

**Carcinogens:** No Significant Risk Levels (“NSRLs”) (Title 27 CCR § 25701, 25703, 25705)

**Reproductive Toxicants:** Maximum Allowable Dose Levels (Title 27 CCR § 25801, 25803, 25805)

Regulations spell out defaults that apply  
“in the absence of principles or assumptions scientifically more appropriate, based upon the available data...”

> 300 Safe Harbor Levels adopted by OEHHA in regulation

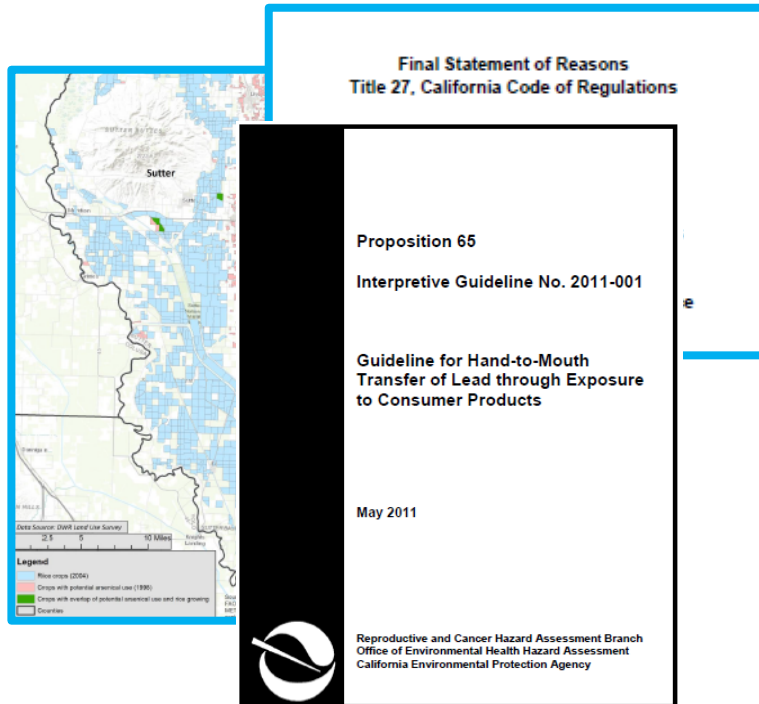


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# Proposition 65 Exposure Assessment

Estimating the exposure to a listed chemical that a consumer or by-stander is receiving

Guidance in regulation

Extent of exposure - Title 27 CCR § 25501 - 25505

Carcinogens - Title 27 CCR § 25721

Reproductive Toxicants - Title 27 CCR § 25821



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OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

#### Proposition 65

Interpretive Guideline  
No. 2018-01

Residential exposure to methyleugenol in bait stations and lures during invasive pest eradication program activities

August 2018



Pesticide and Environmental Toxicology Branch  
Reproductive and Cancer Hazard Assessment Branch  
Office of Environmental Health Hazard Assessment  
California Environmental Protection Agency

# Proposition 65 & Risk Characterization

**Proposition 65 Context:** Are exposures sufficiently high to require warning?

**Safe Use Determinations:**

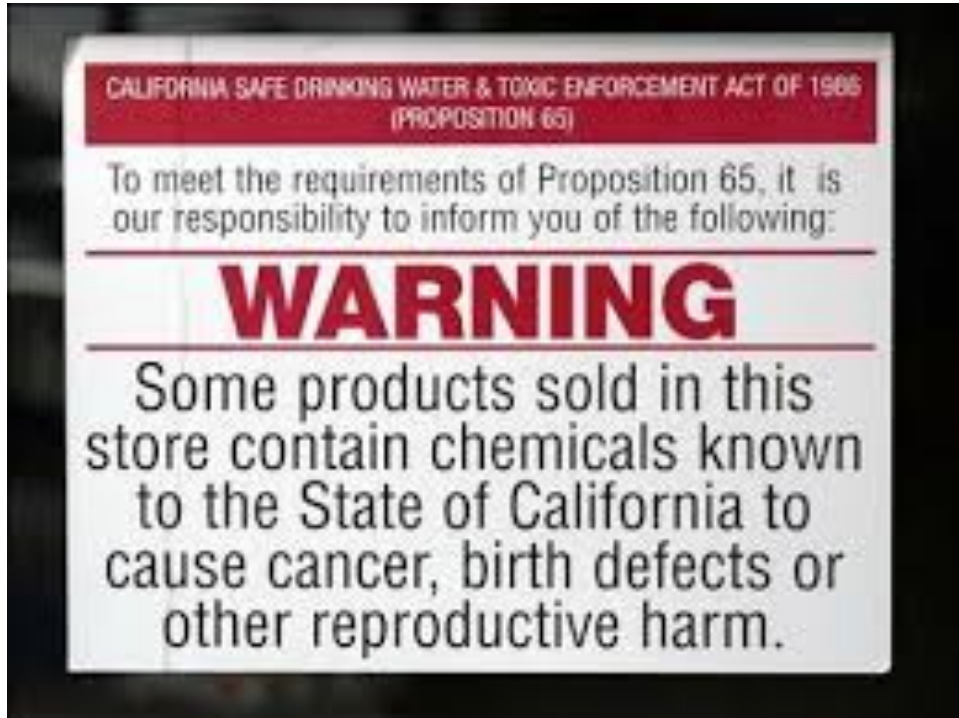
Exposure to a listed chemical use of a specific product is subject to the warning requirement

**Interpretive Guidelines:**

Proposition 65 and its implementing regulations interpreted for specific facts or circumstances

# New Warnings Effective August 30, 2018

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before



after





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