

OEHHA Program Descriptions

The mission of the individual sections within OEHHA

Executive Office

The Executive Office provides the direction and leadership necessary to plan, develop and administer programs and activities in OEHHA. Other functions provided by the executive office include legal support to various programs, legislative analysis and liaison, communication and public information, and administrative functions relating to OEHHA's Proposition 65 activities.

Administrative Services Division

The Administrative Services Division carries out the various administrative tasks necessary to support the Office, including contracts and business services, human resources, fiscal services, and information technology.

Air, Community, and Environmental Research Branch (ACERB)

The Air, Community, and Environmental Research Branch (ACERB) has wide-ranging responsibilities that include assessing the health effects of criteria air pollutants and toxic air contaminants; conducting epidemiological studies of the health effects from air pollution; conducting innovative research of public-health issues relating to climate change and identifying the impacts of climate change in California; identifying California communities with the highest burdens and vulnerabilities to pollution; and assisting state and local agencies in the review of hazards and ecological risks posed by contaminated sites.

Specific Program Activities within ACERB

Air Toxics "Hot Spots" Program

 Developing and updating guidance on the preparation of health risk assessments for major industrial facilities.

- Developing health guidance values for contaminants found in air. These include unit risk factors for carcinogens and Reference Exposure Levels (RELs) for noncarcinogens.
- Providing assistance on health-related air toxics issues to the Air Resources Board, air quality management/pollution control districts, local health officers, and environmental health officers.

Children's Environmental Health Protection

- Advancing health risk assessment methods focused on infants and children.
- Implementation for CalEPA's Children's Environmental Health Program, including
 organizing annual symposia on the health effects of environmental pollution on
 children, outreach to medical professionals on children's environmental health,
 consultation with other CalEPA boards and departments, and local agencies on
 children's environmental health.
- Assessment of the adverse impacts of air pollution on children's health.

Climate Change

- Conducting epidemiological studies on mortality and morbidity of heat exposure in California.
- Developing environmental indicators that track climate change and its impacts on California.

Criteria Air Pollutants

- Developing health-based recommendations for Ambient Air Quality Standards for criteria air pollutants.
- Conducting epidemiological studies on the health effects from exposure in the general population to criteria air pollutants.

Contaminated Site Risk Assessment

- Providing consultation services to California's Regional Water Quality Control Boards and local governmental entities on health risks from exposure to hazardous materials at contaminated sites undergoing cleanup.
- Developing soil and soil-gas values for screening assessments at contaminated sites.

 Maintainance of a searchable online database of toxicity values developed or adopted by OEHHA.

Environmental Justice

 Development, updating, and use of California Communities Environmental Health Screening Tool (CalEnviroScreen) to identify California communities highly burdened by multiple pollution sources and vulnerable (due to poverty and other socioeconomic factors) to the adverse effects of pollution.

Environmental Research

 Conducting research and consultation, as requested, on emerging environmental issues, such as guidance addressing exposures to cyanotoxins in surface water.

Toxic Air Contaminant Program

 Developing chemical-specific health effects assessments for air contaminants proposed as "Toxic Air Contaminants."

Reproductive and Cancer Hazard Assessment Branch (RCHAB)

The Reproductive and Cancer Hazard Assessment Branch (RCHAB) has responsibilities that include administering the scientific aspects of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65); operating the California Environmental Contaminant Biomonitoring Program (Biomonitoring California) in collaboration with the California Department of Public Health and the Department of Toxic Substances Control; and conducting exposure and health risk analyses for reproductive and developmental toxicants and carcinogens.

Specific program activities within RCHAB

Proposition 65 Scientific Activities

- Compiling and evaluating scientific information to develop hazard identification materials in support of the evaluation and listing of chemicals as causing cancer or reproductive toxicity under Proposition 65.
- Evaluating whether authoritative federal and international entities have made formal identifications of carcinogens and reproductive toxicants that meet the criteria for listing under Proposition 65.
- Developing safe harbor levels that provide guidance for when warnings are required for listed carcinogens (No Significant Risk Levels, NSRLs) and reproductive toxicants (Maximum Allowable Dose Levels, MADLs).

- Providing additional scientific support and compliance assistance for Proposition 65, including conducting exposure assessments, developing interpretive guidance, and evaluating requests for and developing Safe Use Determinations that provide guidance for when warnings are required.
- Developing information for the general public on chemicals listed under Proposition 65, including information on exposure sources and pathways, and ways to reduce exposures.

Biomonitoring Program

- Implementing OEHHA's scientific activities under Biomonitoring California, which involve:
 - Developing hazard evaluation documents to support selection of chemicals for biomonitoring.
 - Translating complex toxicological information into plain-English materials, such as chemical fact sheets, for individual participants in biomonitoring studies.
 - o Developing materials to aid in interpreting biomonitoring results.
 - Providing scientific and administrative support to the program's Scientific Guidance Panel.
- Managing the Biomonitoring California website, including developing chemicalspecific content and maintaining the biomonitoring results database.

Safer Alternatives Assessment Program

 Reviewing chemical hazard traits and safer alternatives to toxic chemicals to support the DTSC's novel Safer Consumer Product's program.

Pesticide and Environmental Toxicology Branch (PETB)

The Pesticide and Environmental Toxicology Branch (PETB) is composed of five sections performing various activities pertaining to different aspects of pesticide toxicity and epidemiology, drinking water contaminants, contaminants in fish and shellfish, and the potential health effects of synthetic turf.

Specific Program Activities within PETB

Pesticide Risk Assessment

- Performing statutorily mandated peer reviews of pesticide Risk Characterization Documents (RCDs) and Exposure Assessment Documents (EADs) prepared by the Department of Pesticide Regulation (DPR).
- Evaluating pesticide toxicity data for use in DPR's regulatory decisions.
- Preparing documents on the toxicity of and exposure to pesticides used by the invasive species program of the California Department of Food and Agriculture (CDFA).
- Communicating toxicity and exposure information of the pesticides and chemicals used in the CDFA invasive species program to the public.

Pesticide Epidemiology Program

- Tracking and maintaining records of pesticide-related illnesses.
- Preparing and updating Guidelines for Physicians who Supervise Workers
 Exposed to Cholinesterase-Inhibiting Pesticides, which describes the statewide
 program to monitor the health of pesticide handlers and the responsibilities of
 physicians in the Medical Supervision Program.
- Evaluating the effectiveness of the Medical Supervision Program by analyzing pesticide handlers' blood-cholinesterase test results.
- Providing education to physicians and other health care providers on
 - o The Recognition, Management, and Reporting of Pesticide Illness
 - The California Medical Supervision Program.
- Working mutually with DPR to develop regulations to protect agricultural workers who handle or come into contact with pesticides.
- Providing assistance to local health officers in the event of pesticide poisonings.

Public Health Goal Program

 Performing human health risk assessments and toxicity evaluations for the development of Public Health Goals (PHGs) and notification levels for chemical contaminants in drinking water. The State Water Resources Control Board uses OEHHA's PHGs to develop California's regulatory drinking-water standards.

Fish, Ecotoxicology, and Ambient Water Program

- Evaluating chemical contaminants in fish and wildlife, and developing fish consumption advisories, which are published in the California Sport Fish Regulations handbook and are posted on OEHHA's website.
- Making recommendations to the California Department of Fish and Wildlife (CDFW) on the closure and reopening of fisheries following oil spills in state waters.
- Working with CDPH, DFW, and the Fish and Wildlife Commission to determine fishery closures and re-openings due to marine toxins.

Special Investigations

 Studying the potential human health hazards posed by chemicals released from recycled tire material in synthetic turf and playground mats.

New Proposition 65 Warnings

What is Proposition 65?

In 1986, California voters approved Proposition 65, an initiative to address their growing concerns about exposure to toxic chemicals. That initiative is officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986. The law requires California to publish a list of chemicals known to cause cancer or reproductive toxicity, and for businesses with 10 or more employees to provide warnings when they knowingly and intentionally cause significant exposures to listed chemicals.

This list currently includes more than 850 chemicals. Proposition 65 does not ban or restrict the sale of chemicals on the list. The warnings are intended to help Californians make informed decisions about their exposures to these chemicals from the products they use and the places they go.

The Office of Environmental Health Hazard Assessment (OEHHA) administers the Proposition 65 program.

What Are the Most Significant Changes to the Proposition 65 Warnings For Consumer Products?

Since the original warning requirements took effect in 1988, most Proposition 65 warnings simply state that a chemical is present that causes cancer or reproductive harm, but they do not identify the chemical or provide specific information about how a person may be exposed or ways to reduce or eliminate exposure to it.

New OEHHA regulations, adopted in August 2016 and that will take full effect in August 2018, change the safe harbor warnings which are deemed to comply with the law in several important ways. For example, the new warnings for consumer products will say the product "can expose you to" a Proposition 65 chemical rather than saying the product "contains" the chemical. They will also include:

- > The name of at least one listed chemical that prompted the warning
- The Internet address for OEHHA's new Proposition 65 warnings website, www.P65Warnings.ca.gov, which includes additional information on the health effects of listed chemicals and ways to reduce or eliminate exposure to them
- A triangular yellow warning symbol on most warnings

What Are Other Highlights of the New Warnings System?

The new warning regulation also:

- Adds new "tailored" warnings that provide more specific information for certain kinds of exposures, products, and places.
- > Provides for website warnings for products purchased over the Internet

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- > Provides for warnings in languages other than English in some cases
- Clarifies the roles and responsibilities of manufacturers and retailers in providing warnings.

How Do the New Warnings Compare to the Current Warnings?

A typical current Proposition 65 warning states, "WARNING: This product contains a chemical known to the State of California to cause cancer." A sample new warning would look like this: "AWARNING: This product can expose you to chemicals including arsenic, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov."

Why are Proposition 65 Warnings Changing?

In 2013, Gov. Edmund G. Brown Jr. proposed reforms to strengthen Proposition 65. The Governor called for changes to "require more useful information to the public on what they are being exposed to and how they can protect themselves." He added, "This is an effort to improve the law so it can do what it was intended to do – protect Californians from harmful chemicals."

In 2015, UC Davis researchers interviewed more than 1,500 randomly selected Californians and asked them to compare the new specific warnings to the current generic warnings. The results were dramatic – 77 percent said the new warnings would be more helpful than the current system.

What Are the Goals of the New Warnings?

The new warning system has several main goals. These include:

- Making warnings more meaningful and useful for the public
- > Reducing "over-warning" in which businesses provide unnecessary warnings
- Giving businesses clearer guidelines on how and where to provide warnings.

When Will the Changes Take Effect?

In August 2016, the Office of Administrative Law approved the new regulations for improved Proposition 65 warnings. Businesses can currently choose whether to provide the old warning or the new warning as part of the regulation's two-year phase-in period. Beginning August 30, 2018, the old warning system will expire and businesses that want "safe harbor protection" that deems them in compliance with Proposition 65 will use the new warning system.

What is the Purpose of the New Proposition 65 Warnings Website?

In 2016, OEHHA launched a new website, www.P65Warnings.ca.gov, to provide the public with more information on chemicals, products, and locations associated with Proposition 65 warnings. The website is part of the state's effort to provide Californians with more useful information on chemicals they are being exposed to and ways to protect themselves.

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People who read Proposition 65 warnings and want to learn more can go to the website to find additional information about chemicals and best practices for reducing or eliminating exposures. The website contains fact sheets about Proposition 65 chemicals and specific types of exposure, such as from furniture products or enclosed parking facilities. It also answers frequently asked questions about Proposition 65 and includes a glossary of Proposition 65 terms.

Will Businesses Be Required to Provide the New Warnings?

No. The regulation states that a business is not required to use the new safe harbor warning system to comply with the law. However, using the safe harbor warnings is an effective way for businesses to protect themselves against Proposition 65 enforcement actions. Businesses that use the safe harbor warnings are deemed compliant with the law's requirement for clear and reasonable warnings.

Businesses have the option to provide different warnings if they believe they comply with the law. Additionally, small businesses with fewer than 10 employees are exempt from Proposition 65's warning requirements.

Will Products Manufactured Before August 2018 Need to Use the New Warnings?

No. Products manufactured before August 30, 2018 will not need new warnings if they meet the requirements that were in effect at the time of their production.

Will Special Warnings Approved by Courts in Previous Legal Settlements Remain in Effect?

Yes. The regulation states that OEHHA recognizes court-ordered settlements and judgments that impose specific Proposition 65 warnings.

What Circumstances Will Require Warnings in Languages Other Than English?

When a consumer product sign, label or shelf tag used to provide a warning includes consumer information in a language other than English, the warning must also be provided in that language in addition to English. Facilities that provide signage in non-English languages would also have to provide any required warnings in those languages, in addition to English.

For Internet purchases, warnings can be provided by including a clearly marked hyperlink using the word WARNING on the product display page.

Which Exposures, Products, and Places Have Specific Tailored Warnings?

In addition to the warnings for chemical exposures from consumer products, the new regulation provides specific warnings for exposures from:

Alcoholic beverages, food and non-alcoholic beverages, prescription drugs, dental care, wood dust, furniture products, diesel engines, vehicles, and recreational vessels

OEHHA

Enclosed parking facilities, amusement parks, petroleum products, service stations and vehicle repair facilities, and designated smoking areas

Can Businesses Request Additional Tailored Warnings?

Yes. The regulation allows businesses to request new tailored warnings pursuant to Government Code sections 11340.6 and 11340.7 (Petition for Rulemaking). OEHHA will consider these requests and can amend the regulation to add tailored warnings as appropriate.

What Are the Warning Responsibilities for Manufacturers and Retailers?

The new system clarifies that manufacturers have the primary responsibility for providing Proposition 65 warnings. Manufacturers can choose whether to put warning labels on their products or to provide notices to their distributors, importers or retail outlets that a product may cause an exposure to a listed chemical that requires a warning provide warning signs or other warning materials. Manufacturers can also enter written agreements with retailers to modify this allocation of responsibility as long as the consumer receives a clear and reasonable warning before her or she is exposed to a Proposition 65 chemical.

Retailers must confirm that they received the notice and must use the warning signs or other materials provided by the manufacturer.

Are There Other Regulations to Assist Businesses with Warning Requirements?

Yes. In addition to other forms of compliance assistance, OEHHA has regulations that set procedures for requesting advice from the agency including Interpretive Guidelines and Safe Use Determinations.

In some cases, OEHHA may issue an interpretive guideline that clarifies warning requirements with regard to specific facts. Current Interpretive Guidelines apply to consumption of sulfur dioxide in dried fruits, chlorothalonil in tomato products, consumption of methanol from pectin that occurs naturally in fruits and vegetables, and hand-to-mouth transfer of lead through exposure to consumer products and fishing tackle. For more information on Interpretive Guidelines, see https://oehha.ca.gov/proposition-65/interpretive-guidelines-proposition-65.

There is also a procedure for requesting a Safe Use Determination. A Safe Use Determination is a written statement issued by OEHHA that interprets whether specific sets of exposures require warnings. For example, in recent years, OEHHA has issued several Safe Use Determinations related to exposures from diisononyl phthalate (DINP) in vinyl flooring and outdoor furniture products. For more information on the Safe Use Determination Process, see https://oehha.ca.gov/proposition-65/proposition-65-safe-use-determination-sud-process.

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Where Can I Find More Information On Proposition 65 Warning Requirements?

Proposition 65 and its regulations are posted at https://oehha.ca.gov/proposition-65-law-and-regulations.

For a side-by-side comparison of the current and new warning regulations, see https://oehha.ca.gov/media/downloads/crnr/side-sidearticle6090116.pdf.

For More Information:

Sam Delson Deputy Director for External and Legislative Affairs

Office: (916) 324-0955 Cell: (916) 764-0955

Sam.Delson@oehha.ca.gov

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OEHHA's Amended 2016 Warnings Regulations



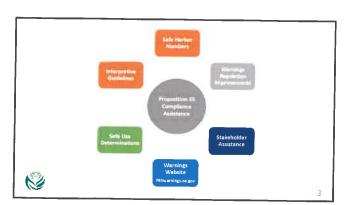
Lauren Zeise, Director Carol Monahan-Cummings, Chief Counsel

Office of Environmental Health Hazard Assessment California Environmental Protection Agency

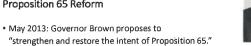
Introduction

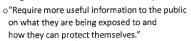
- OEHHA is the designated lead agency for Proposition 65
 OEHHA implements but does not enforce the law
- Warning requirement is an essential element of P65
 Warnings required prior to exposure to listed chemicals
- OEHHA original warning regulation established in 1988
- The entire warning regulation was repealed and reenacted August 2016





Proposition 65 Reform





oProposals intended to address frivolous/nuisance lawsuits.



Timeline of New Regulations

- July 2013 Public Workshop to collect ideas
- April 2014 Pre-regulatory workshop with draft regulations
- 2015 Formal Regulatory Proposals
- 2016 Final Regulations adopted o New warning regulations (Cal. Code of Regs. Title 27, Article 6) o Proposition 65 warnings website regulation (Cal. Code of Regs. Title 27, Article 2)
- Dozens of stakeholder meetings held throughout the process (ongoing)
- August 2018 New warnings fully effective (Title 27, Article 6)



To meet the requirements of Proposition 65, it is our responsibility to inform you of the following: Some products sold in this store contain chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

2016 Clear and Reasonable Warnings Regulation

Motivation for Change

- Make warnings more meaningful to the public
- Reduce over-warning
- Resolve conflict between manufacturer/retailer responsibilities to provide warnings
- Provide more product/place specific warnings
- Update methods to take into account technological advances (Internet, smart phones)
- Provide increased clarity regarding compliance o How and where to provide warnings



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Overview of Regulation

- Phase-in period of two years
- Effective date of regulation: August 30, 2018
- Consumer products manufactured prior to the effective date will not require new warnings if they meet existing safe harbor requirements
- Court-approved warnings expressly recognized and considered "clear and reasonable" for parties to litigation.



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Overview of new regulation - continued

- Clarifies responsibilities to provide warnings
 Manufacturer vs retailer
- Retains "safe harbor" approach for warnings to provide flexibility for businesses
 - o Includes changes to warning methods and content o More specificity and clarity in warnings
- Added "tailored" warnings for specific kinds of exposures.
 Examples: dental care, furniture, diesel engines, automobiles, recreational vessels, amusement parks.
- Fully effective August, 2018
- Can use the new safe harbor provisions now



Subarticle 1

25600. General.

- Mandatory provisions applicable throughout Article 6
- Subsection (b) allows for warnings to be provided in accordance with the revised Article 6 prior to the two-year effective date of 8/30/2018
- Subsection (c) allows for businesses to request "tailored warnings" through a Petition for Rulemaking, and provides that Interpretive Guideline Requests and Safe Use Determinations are available under other OEHHA regulations.
- Subsection (e) restates that OEHHA recognizes court ordered settlements and final judgments as to parties to those settlements and judgments



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Subarticle 1, continued

25600. General, cont.

 Subsection (f) makes clear that a business is not required to use the "clear and reasonable" warning methods and content in Subarticle 2 in order to comply with the Act.

25600.1. Definitions.

25600.2 Responsibility to Provide Consumer Product Exposure Warnings.

• Sets forth manufacturer/retailer responsibilities



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25600.2 Responsibility to Provide Consumer Product Exposure Warnings

Manufacturer/Retail Seller Responsibilities

- Product manufacturers have primary responsibility for warning New
- Manufacturer can label product or:
 - Provide notice to distributor/importer/retail seller that a product may cause an
 exposure to a listed chemical.
 - Provide warning signs, materials (unless they make other arrangements via contract).
 - Can modify allocation of responsibility by entering into written agreement with retail seller so long as consumer receives a warning prior to exposure.
- Retail sellers
- o 5 business-day opportunity to cure
- Confirm receipt of notice
- · Act as "pass-through" for warning
- Provide non-English language warnings in certain situations.

Subarticle 2. Safe Harbor Methods and Content

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Section 25601 Safe Harbor Methods and Content

. Sets forth methods and content for providing "safe harbor" warning

Section 25602 Methods of Transmission

 Point of display warnings, electronic device or process, labels, on-product ("short-form") warning, internet purchase warnings,

Section 25603 Consumer Product Exposure Warnings – Content

- "This product contains..." 👄 "This product can expose you to..."
- The name of at least one chemical in the warning.
 - o Warning required for chemicals A and B.
 Business can include the name of A or B, or both.
- · Named chemicals are those for which warning is being provided
- · Business selects which chemical(s) to include in warning
- Answers question: "What am I being exposed to?"

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Safe Harbor Warnings: Comparison of Current and New Content

WARNING: This product contains a chemical known to the State of California to cause cancer.

Ex. 1 Current safe harbor warning

A WARNING: This product can expose you to chemicals including arsenic, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Ex. 2 New safe harbor warning



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Subarticle 2. Safe Harbor Methods and Content

Section 25603. Consumer Product Exposure Warnings, cont.,

- OEHHA web site URL <u>www.P65Warnings.ca.gov</u>
- Warning symbol

Section 25604. Environmental Exposure Warnings – Methods of Transmission

Section 25605. Environmental Exposure Warnings - Content

Section 25606. Occupational Exposure Warnings.

Substantially retained provisions of September 2008 version of regulations

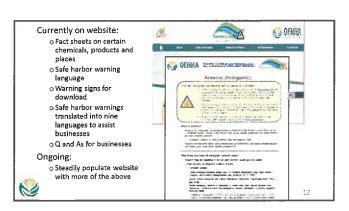


Subarticle 2. Safe Harbor Methods and Content

Section 25607. Specific Product, Chemical and Area Exposure Warnings.

- "Tailored warnings" for specific types of exposures
 - Food, alcohol, restaurants, prescription drugs, dental care, raw wood, furniture, diesel engines, vehicles, recreational vessels, enclosed parking facilities, service stations, vehicle repair facilities, smoking areas, (hotels – pending)
- Warnings about the exposures that can occur through these products and facilities
- Must use the tailored warning for the specific exposure type in order to meet the "safe harbor"
- Significant stakeholder input in development of tailored warnings
- · Will continue to develop tailored warnings





For more information:

- www.oehha.ca.gov
- https://oehha.ca.gov/media/downloads/crnr/side-sidearticle6090116.pdf
- <u>http://oehha.ca.gov/proposition-65/crnr/notice-adoption-article-6-clear-and-reasonable-warnings</u>
- www.p65warnings.ca.gov/

Carol Monahan-Cummings Chief Counsel OEHHA



(916) 322-0493 carol.monahan-cummings@oehha.ca.gov