

**NOTICE OF PROPOSED RULEMAKING
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**PROPOSED AMENDMENT TO
SECTION 25707(b), ROUTE OF EXPOSURE**

**THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65**

September 16, 2011

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to amend Title 27, California Code of Regulations section 25707. The proposed amendment to Section 25707¹ removes the reference to hexavalent chromium in Section 25707(b)(4) as posing no significant risk when ingested, based on recent scientific findings that establish that chromium (hexavalent compounds) can be carcinogenic by the oral route. The primary document relied upon for this amendment is the OEHHA document, Public Health Goals for Chemicals in Drinking Water: Hexavalent Chromium (VI),² which was released on July 27, 2011.

PUBLIC PROCEEDINGS

OEHHA is requesting public comment concerning this proposed amendment to the regulation. A public hearing to present oral comments will be scheduled only upon request. Such a request must be submitted in writing no later than 15 days before the close of the comment period on October 31, 2011. The written request must be received by OEHHA at the address listed below no later than October 17, 2011. A notice for the public hearing, if one is requested, will be posted on the OEHHA web site at least ten days in advance of the hearing date. The notice will provide the date, time, location and subject matter to be heard. Notices will also be sent to those individuals requesting such notification.

If you have any special accommodation or language needs, please contact Monet Vela at (916) 323-2517 or mvela@oehha.ca.gov by October 17, 2011. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

Any written statements or arguments, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on October 31, 2011, which is hereby designated as the close of the comment period.

¹ All further references are to Title 27 of the California Code of Regulations unless otherwise indicated.

² Office of Environmental Health Hazard Assessment (OEHHA), Public Health Goals for Chemicals in Drinking Water: Hexavalent Chromium (VI), Pesticide and Epidemiology and Toxicology Branch, OEHHA, California Environmental Protection Agency, July 2011. Available online at <http://www.oehha.ca.gov/water/phg/072911Cr6PHG.html>

Written comments regarding this proposed action may be sent by mail or by e-mail addressed to:

Fran Kammerer
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, California 95812-4010
Telephone: 916-445-4693
E-mail: fkammerer@oehha.ca.gov

Comments sent by courier should be delivered to:

Fran Kammerer
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
Sacramento, California, 95814

CONTACT

Inquiries concerning the substance and processing of the action described in this notice may be directed to Fran Kammerer, in writing at the address given above or by telephone at (916) 445-4693. Monet Vela is a back-up contact person for inquiries concerning processing of this action and is available at (916) 323-2517.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Proposition 65 was enacted as a voters' initiative on November 4, 1986, and codified at Health and Safety Code section 25249.5 et seq. OEHHA is the lead state entity responsible for the implementation of the Act. OEHHA has the authority to promulgate and amend regulations to further the purposes of the Act.³ The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water.

Section 25707

Title 27, section 25707(b)(4) of the California Code of Regulations provides that five listed chemicals pose no significant risk by the route of ingestion: (1) Asbestos, (2) Beryllium and beryllium compounds, (3) Cadmium and cadmium compounds, (4) Chromium (hexavalent compounds), and (5) Nickel and nickel compounds.

³ Health and Safety Code section 25249.12(a).

While hexavalent chromium has long been recognized as a potent carcinogen by the inhalation route of exposure, there is now sufficient evidence that hexavalent chromium is also carcinogenic by the oral route of exposure.⁴ This proposed amendment will remove the reference to hexavalent chromium from Section 25707(b)(4) to reflect the current scientific information concerning this chemical.

AUTHORITY

Health and Safety Code section 25249.12.

REFERENCE

Health and Safety Code sections 25249.5, 25249.6, 25249.7, 25249.9, 25249.10, and 25249.11

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

OEHHA has determined the proposed regulatory action would not impose a mandate on local agencies or school districts; nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action. Proposition 65 expressly does not apply to federal, state or local governmental agencies (Health and Safety Code section 25249.11(b)).

COSTS OR SAVINGS TO STATE AGENCIES

The OEHHA has initially determined that no savings or increased costs to any State agency will result from the proposed regulatory action. Proposition 65 expressly does not apply to federal, state or local governmental agencies (Health and Safety Code section 25249.11(b)).

EFFECT ON FEDERAL FUNDING TO THE STATE

OEHHA has initially determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

EFFECT ON HOUSING COSTS

OEHHA has initially determined that the proposed regulatory action will have no effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

⁴ OEHHA, Public Health Goals for Chemicals in Drinking Water: Hexavalent Chromium (VI), July 2011, <http://www.oehha.ca.gov/water/phg/pdf/Cr6PHG072911.pdf>.

OEHHA has made an initial determination that the adoption of the proposed amendment will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS/BUSINESSES

OEHHA has initially determined that the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The OEHHA is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

EFFECT ON SMALL BUSINESSES

OEHHA has determined that the proposed regulatory action will not impose any new or additional requirements on small business. Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code section 25249.11(b)).

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), OEHHA must determine that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

OEHHA has prepared and has available for public review an Initial Statement of Reasons for the proposed amendments to these regulations, all the critical information upon which the regulation is based, and the text of the proposed regulations. A copy of the Initial Statement of Reasons and a copy of the text of the proposed amendments to these regulations are available upon request from Monet Vela at the telephone number indicated above. These documents are also posted on OEHHA's Web site at www.oehha.ca.gov.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on the changed proposed regulations and the full text will be mailed to individuals who testified or submitted oral or written comments at the public hearing, whose comments were received by OEHHA during the public comment period, and who request notification from OEHHA of availability of such change. Copies of the notice and the changed regulation will also be available at the OEHHA's Web Site at www.oehha.ca.gov.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons may be obtained, when it becomes available, from OEHHA's Monet Vela at the telephone number indicated above. The Final Statement of Reasons will also be available at the OEHHA's Web site at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: September 6, 2011

TITLE 27, CALIFORNIA CODE OF REGULATIONS

CHAPTER 1. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 7. NO SIGNIFICANT RISK LEVELS

Section 25707. Route of Exposure

Amend Section 25707(b) as follows:

(b) The following chemicals present no significant risk of cancer by the route of ingestion:

- (1) Asbestos
- (2) Beryllium and beryllium compounds
- (3) Cadmium and cadmium compounds
- ~~(4) Chromium (hexavalent compounds)~~
- ~~(5)~~ (4) Nickel and nickel compounds

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

**INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**PROPOSED AMENDMENT TO
SECTION 25707(b), ROUTE OF EXPOSURE**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65**

**PURPOSE AND BACKGROUND OF PROPOSED AMENDMENTS OF
REGULATION**

This proposed regulatory amendment removes the reference to chromium (hexavalent compounds) as a chemical that presents no significant risk of cancer by ingestion in Section 25707(b)(4). This proposed amendment is based on the currently available scientific information that shows oral exposures to this chemical can pose a cancer risk.

Proposition 65 was enacted as a voters' initiative on November 4, 1986.¹ The Office of Environmental Health Hazard Assessment (OEHHA) is the lead state entity responsible for the implementation of Proposition 65.² OEHHA has the authority to promulgate and amend regulations to further the purposes of the Act.³ The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water.

Section 25707 was originally adopted in 1990 to implement Health and Safety Code section 25249.10(c) of the Act. For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk. Section 25707 provides that when scientifically valid absorption studies conducted according to generally accepted standards demonstrate that absorption of a chemical through a specific route of exposure can be reasonably anticipated to present no significant risk of cancer at levels of exposure not in excess of current regulatory levels, OEHHA may identify the chemical as presenting no significant risk by that route of exposure.

Oral carcinogenicity of chromium (hexavalent compounds)

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et. seq., hereafter referred to as "Proposition 65" or "The Act"

² Cal. Code of Regs., Title 27, Article 1, subsection (a)

³ Health and Safety Code section 25249.12(a)

In 1987, chromium (hexavalent compounds) was listed as a carcinogen. At that time there was some uncertainty about whether this chemical posed a risk of cancer if ingested. Chromium (hexavalent compounds) was adopted into Section 25707 (b)(4) as having no significant risk of causing cancer by the route of ingestion. However, recent scientific data establish that chromium (hexavalent compounds) can be carcinogenic by the oral route. These data are reviewed in the recently released OEHHA document, Public Health Goals for Chemicals in Drinking Water: Hexavalent Chromium (VI).⁴ Based on a comprehensive review of the relevant scientific literature, the document found that hexavalent chromium is carcinogenic by the oral route of exposure. The document underwent two rounds of external public peer review by the University of California, beginning first in January 2008, and again in August 2009. The document was finalized on July 29, 2011.

PROPOSED REGULATORY AMENDMENT

Section 25707(b)(4)

The proposed change to Section 25707(b)(4) is provided below in underline and strikeout:

(b) The following chemicals present no significant risk of cancer by the route of ingestion:

- (1) Asbestos
- (2) Beryllium and beryllium compounds
- (3) Cadmium and cadmium compounds
- ~~(4) Chromium (hexavalent compounds)~~
- ~~(5)~~ (4) Nickel and nickel compounds

NECESSITY

This proposed regulatory amendment will conform the Proposition 65 implementing regulations to the currently available scientific knowledge about this chemical.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS.

The 2011 OEHHA document, Public Health Goals for Chemicals in Drinking Water: Hexavalent Chromium (IV), was relied upon for the amendment to 24707(b). In this document, OEHHA reviewed the available data on the toxicity of

⁴ Office of Environmental Health Hazard Assessment (OEHHA), Public Health Goals for Chemicals in Drinking Water: Hexavalent Chromium (VI), Pesticide and Epidemiology and Toxicology Branch, OEHHA, California Environmental Protection Agency, July 2011, available online at <http://www.oehha.ca.gov/water/phg/072911Cr6PHG.html>

hexavalent chromium and determined that there is sufficient evidence that hexavalent chromium is carcinogenic by the oral route of exposure. A copy of this document will be included in the regulatory file for this action. It is also available at: <http://www.oehha.ca.gov/water/phg/072911Cr6PHG.html>.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES

The alternative to the amendment to Section 25707(b) would be to maintain the current designation of hexavalent chromium compounds as determined to not be carcinogenic via the route of ingestion. This would be inconsistent with currently available scientific knowledge about this chemical.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES

OEHHA is not aware of any cost impacts that small businesses would incur in reasonable compliance with the proposed action. In addition, Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code section 25249.11(b)) so it has no effect on very small businesses.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and, thus, there is no duplication or conflict with federal regulations.