CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65

Notice Of Proposed Rulemaking

Title 27, California Code Of Regulations

Proposed Amendment Of Section 25703(A)(6)
Quantitative Risk Assessment

JULY 29, 2011

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to amend Title 27, Cal. Code of Regulations, section 25703(a)(6)[1], to modify the calculation used to convert estimates of animal cancer potency to estimates of human cancer potency. Cancer potency estimates are used to calculate No Significant Risk Levels for carcinogens listed under Proposition 65[2]. This modification will bring the Proposition 65 program interspecies conversion calculations into uniformity with the other OEHHA programs such as the drinking water public health goal and air toxics programs. The text of the proposed amendment is attached to this notice.

PUBLIC PROCEEDINGS

OEHHA is requesting public comment concerning these proposed amendments 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 September 12, 2011. The written request must be received by OEHHA at the address listed below no later than August 29, 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.

Any written statements or arguments, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on September 12, 2011, which is hereby designated as the close of the written comment period. Written comments regarding this proposed action may be sent by fax, mail or by e-mail addressed to:

Fran Kammerer
Office of Environmental Health Hazard Assessment

[1] All further references are to Title 27, California Code of Regulations, unless otherwise indicated.
[2] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq.

P. O. Box 4010
Sacramento, California 95812-4010
Telephone: 916-445-4693
Fax: 916-323-2610
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Comments sent by courier should be delivered to:

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

It is requested, but not required, that hard-copy statements or arguments be submitted in triplicate.

CONTACT

Inquiries concerning the action described in this notice may be directed to Fran Kammerer, Staff Counsel via e-mail at fkammerer@oehha.ca.gov, or via mail at OEHHA, P.O. Box 4010 Sacramento, California 95812-4010. Monet Vela is a back-up contact person for inquiries concerning processing of this action and is available at (916) 323-2517 or mvela@oehha.ca.gov.

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, within the California Environmental Protection Agency, is the 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[4]. The Act also prohibits the discharge of listed chemicals to sources of drinking water[5].

For chemicals known to cause cancer, an exemption from the warning requirement is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which the person is responsible produces no significant risk or that a discharge which otherwise complies with all applicable requirements would not cause any significant amount of the discharged or released chemical to enter any source of drinking water[6]. A determination that a level of exposure poses no significant risk may be made

[3] Health and Safety Code section 25249.12
[4] Health and Safety Code section 25249.6
[5] Health and Safety Code section 25249.5
6 Health and Safety Code sections 25249.9 and 25249.10

utilizing regulations that have previously been adopted by OEHHA (sections 25701-25721).

Section 25703 provides the guidance for conducting quantitative risk assessments to establish “No Significant Risk Levels,” or “NSRLs.” Subsection (a) provides certain default assumptions or principles which OEHHA considers to be “generally accepted” that can be used to calculate NSRLs. NSRLs are calculated from estimates of human cancer potency, a measure of the carcinogenic activity of the chemical. When data from experiments in animals are used as the basis of the calculation, an animal cancer potency estimate is derived. This animal cancer potency estimate is then converted to a human cancer potency estimate, using an interspecies scaling factor. Subsection (a)(6) provides a formula for interspecies scaling for making this conversion. However, Section 25703(a) also provides that other assumptions, principles or data sets should be used where scientifically more appropriate. The proposed regulation aims to update the approach to interspecies scaling to be consistent with practices of other OEHHA programs and of the U.S. Environmental Protection Agency.

AUTHORITY

Health and Safety Code section 25249.12.

REFERENCE

Health and Safety Code sections 25249.5, 25249.6, 25249.10(c), 25249.11, and 25249.12

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

OEHHA has initially determined that no significant 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

OEHHA has made an initial determination that the adoption of the amendments to the regulation 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. The proposed regulation does not impose any new requirements upon private persons or business.

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

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 businesses. Proposition 65 exempts businesses with less than 10 employees.

CONSIDERATION OF ALTERNATIVES

Pursuant to 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 regulatory amendments, all the critical information upon which the regulation is based, and the text of the proposed amendments to the regulation. A copy of the Initial Statement of Reasons and a copy of the text of the proposed regulation 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 proposed 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 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 OEHHA's web site at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: July 19, 2011