

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

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

**AMENDMENT TO SECTION 25705
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK:**

**AMENDMENT TO SECTION 25805
SPECIFIC REGULATORY LEVELS:
CHEMICALS CAUSING REPRODUCTIVE TOXICITY**

POLYCHLORINATED BIPHENYLS

April 13, 2012

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt an updated No Significant Risk Level (NSRL) for polychlorinated biphenyls (PCBs), of 0.35 micrograms per day by amending Title 27, California Code of Regulations, section 25705.¹ OEHHA also proposes to adopt a specific regulatory level having no observable effect for PCBs, and amend Section 25805.

PUBLIC PROCEEDINGS

Any written comments concerning this proposed action, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on **May 28, 2012**, the designated close of the written comment period. All comments received will be posted on the OEHHA website at the close of the public comment period.

The public is encouraged to submit written information via e-mail, rather than in paper form. Send e-mail comments to P65Public.Comments@oehha.ca.gov. Please include "PCBs MADL/NSRL" in the subject line. Hard-copy comments may be mailed, faxed, or delivered in person to the appropriate address below.

Mailing Address: Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-25B
Sacramento, California 95812-4010
Fax: (916) 323-2610
Street Address: 1001 I Street
Sacramento, California 95814

A public hearing on these proposed regulatory amendments will be scheduled upon request. To request a hearing send an e-mail to Monet Vela at monet.vela@oehha.ca.gov or to the address listed above by no later than **May 11, 2012**, which is 15 days before the close of the comment period. OEHHA will mail a notice of the hearing to the requester and interested parties on the Proposition 65 mailing list for regulatory public hearings. The notice will also be posted on the OEHHA web site at least ten days before the public hearing date. The notice will provide the date, time, and location of the hearing.

If a hearing is scheduled and you have special accommodation or language needs, please contact Monet Vela at (916) 323-2517 or monet.vela@oehha.ca.gov at least one week in advance of the hearing. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT

Please direct inquiries concerning the proposed regulatory actions described in this notice to Monet Vela, in writing at the address given above, or by telephone at (916) 323-2517. Susan Luong is a back-up contact person for inquiries concerning processing of this action and is available at susan.luong@oehha.ca.gov or (916) 327-3015.

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

Proposition 65² prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity, without first giving clear and reasonable warning to such individual (Health and Safety Code section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water (Health and Safety Code section 25249.5).

No Significant Risk Level

For carcinogens, an exemption from the warning requirement is provided by the Act when the exposure for which the person is responsible can be demonstrated to produce no significant risk, or when a discharge that otherwise complies with all applicable requirements would not cause any significant amount of the chemical to enter any source of drinking water (Health and Safety Code sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk may be made utilizing regulations that have previously been adopted by OEHHA (Sections 25701-25721).

¹ All further regulatory references are to sections of Title 27 of the 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., commonly known as Proposition 65 and referred to herein as "Proposition 65" or "The Act."

Section 25701 describes alternative methods for making such a determination. Section 25705 sets forth the process for determining “no significant risk” levels for purposes of Proposition 65 and establishes those levels for certain listed chemicals.

Details on the bases for the proposed levels are provided in the initial statement of reasons for these regulatory amendments, which is available on request from Monet Vela and is posted on the OEHHA web site at www.oehha.ca.gov.

This proposed amendment to section 25705 would update the existing NSRLs for PCBs by amending Section 25705(b) as follows:

Chemical	NSRL, in units micrograms per day
Polychlorinated biphenyls (PCBs)	0.35 (food chain exposures)

The proposed updated NSRL for PCBs is based upon a risk assessment performed by the U.S. Environmental Protection Agency (U.S. EPA) that OEHHA has reviewed and determined to be consistent with Section 25703. The cancer potency values developed in the U.S. EPA risk assessment provide the basis for calculating the proposed NSRL (food chain exposures). This is discussed in more detail in the initial statement of reasons for this proposed regulatory amendment.

Maximum Allowable Dose Level

For chemicals known to the state to cause reproductive toxicity, 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 observable reproductive effect, assuming exposure at 1,000 times the level in question (Health and Safety Code sections 25249.9, 25249.10 and 25249.11). The maximum dose level at which a chemical has no observable reproductive effect is referred to as the no observable effect level (NOEL). The Act also provides an exemption from the prohibition against discharging a listed chemical into sources of drinking water if the amount discharged does not constitute a “significant amount,” as defined, and the discharge is in conformity with all other laws and regulatory requirements (Health and Safety Code sections 25249.9 and 25249.11). Thus, these exemptions apply when the exposure or discharge in question is at a level that does not exceed the NOEL divided by 1,000.

Regulations previously adopted by OEHHA provide guidance for determining whether an exposure to, or a discharge of, a chemical known to cause reproductive toxicity meets the statutory exemption (Sections 25801-25821). These regulations provide three ways by which a person in the course of doing business may make such a determination: (1) by conducting a risk assessment in accordance with the principles described in Section 25803 to derive a NOEL, and dividing the NOEL by 1,000; or (2) by application of the specific regulatory level adopted for the chemical in Section 25805; or

(3) in the absence of such a level, by using a risk assessment conducted by a state or federal agency, provided that such assessment substantially complies with Section 25803(a). The specific regulatory levels in Section 25805 represent one one-thousandth of the NOEL.

This proposed regulation sets forth a maximum allowable dose level (MADL) for adoption into Section 25805 that was derived using scientific methods outlined in Section 25803.

Details on the basis for the proposed level are provided in the reference cited below, which is included in the rulemaking record. The reference is a risk assessment document prepared by OEHHA describing and summarizing the derivation of the regulatory level listed below.

The proposed regulation would adopt the following regulatory level for PCBs which are known to cause reproductive toxicity into Section 25805:

Chemical	MADL, in units micrograms per day	Reference
Polychlorinated biphenyls (PCBs)	2.3 (food chain exposures)	OEHHA (2012)

The risk assessment which was used by the Office of Environmental Health Hazard Assessment to determine the stated level is as follows:

Office of Environmental Health Hazard Assessment (OEHHA, 2012). Proposition 65 Proposed Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Polychlorinated biphenyls. OEHHA Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, Sacramento, February 2012.

Specific Benefits Anticipated by the Regulation: : The MADLs and NSRLs provide “safe harbor” values that aid businesses in determining if they are complying with the law. Some businesses may not be able to afford the expense of establishing or updating NSRLs and MADLs and therefore may be exposed to litigation for a failure to warn or for a prohibited discharge of the listed chemical. Adopting this regulation will save these businesses those expenses and may reduce litigation costs. By updating or establishing the safe harbor levels, this regulatory proposal does not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

PEER REVIEW

This notice and the initial statement of reasons are being provided to the OEHHA Science Advisory Board's Carcinogen Identification Committee and Developmental and Reproductive Toxicant Identification Committee for scientific peer review and comment.

AUTHORITY

Health and Safety Code Section 25249.12.

REFERENCE

Health and Safety Code Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

RESULTS OF ECONOMIC IMPACT ANALYSIS (Gov. Code section 11346.3)

By providing a MADL and an updated NSRL, this regulatory proposal spares businesses the expense of calculating their own MADL and updated NSRL and may also enable them to reduce or avoid litigation costs. In addition, the MADL and updated NSRL do not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

Impact on the Creation, Elimination, or Expansion of Jobs/Businesses: Because the proposed MADL and updated NSRL provide compliance assistance to businesses subject to the Act, but do not impose any mandatory requirements on those businesses, OEHHA has 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.

No Inconsistency or Incompatibility with Existing Regulations

OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations because it does not impose any mandatory requirements on those businesses, state or local agencies and does not address compliance with any other law or regulation

Specific Benefits of the Proposed Regulation: The MADLs and NSRLs provide "safe harbor" values that aid businesses in determining if they are complying with the law. Some businesses may not be able to afford the expense of establishing or updating NSRLs and MADLs and therefore may be exposed to litigation for a failure to warn or for a prohibited discharge of the listed chemical. Adopting this regulation will save these businesses those expenses and may reduce litigation costs. By updating or establishing the safe harbor levels, this regulatory proposal does not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a

level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

Because Proposition 65 expressly³ does not apply to 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.

COSTS OR SAVINGS TO STATE AGENCIES

Because Proposition 65 expressly⁴ does not apply to any State agency, OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

Because Proposition 65 expressly⁵ does not apply to any federal agency, OEHHA has 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 determined that the proposed regulatory action will have no effect on housing costs because it provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses.

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

Because the proposed MADL and updated NSRL provide compliance assistance to businesses subject to the Act, but do not impose any mandatory requirements on those businesses, OEHHA has made an initial determination that the adoption of 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.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

Since the proposed MADL and updated NSRL provide compliance assistance to businesses subject to the Act, but do not impose any mandatory requirements on those

³ See Health and Safety Code section 25249.11 (b)

⁴ See Health and Safety Code section 25249.11 (b)

⁵ See Health and Safety Code section 25249.11 (b)

businesses, the Office of Environmental Health Hazard Assessment 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 MADL and updated NSRL will not impose any mandatory requirements on small business. Rather, the proposed regulation will provide compliance assistance for small businesses subject to the Act because it will help them determine whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition of the Act.

CONSIDERATION OF ALTERNATIVES

Government Code Section 11346.5(a)(13) requires that 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, or would be more cost-effective in implementing the statutory policy or other provision of law.

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 regulation, all the information upon which the amendments are based and the text of the regulation. A copy of the Initial Statement of Reasons, the text of the regulation and the risk assessment which was used by OEHHA to develop the proposed regulation are available upon request from OEHHA at the address and 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 this 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 changed regulations and the full text will be mailed to individuals who testified or submitted written comments at the public hearing, if held, or whose comments were received by OEHHA during the public comment period, and anyone who requests notification from OEHHA of the availability of such changes. Copies of the notice and the changed regulation will also be available on the OEHHA Web site at www.oehha.ca.gov.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons for this regulatory action may be obtained, when it becomes available, from OEHHA at the address and telephone number indicated above, and on the OEHHA website at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: April 13, 2012