

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

NOTICE OF PROPOSED RULEMAKING

TITLE 22, CALIFORNIA CODE OF REGULATIONS

AMENDMENT TO SECTION 12805
SPECIFIC REGULATORY LEVELS:
CHEMICALS CAUSING REPRODUCTIVE TOXICITY

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment proposes to establish a specific regulatory level having no observable effect for di(2-ethylhexyl)phthalate (DEHP) and amend Title 22, California Code of Regulations, Section 12805.

PUBLIC PROCEEDINGS

A public hearing will be held on **August 8, 2005**, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. The public hearing will commence at 10:00 a.m. in the Byron Sher Auditorium, California Environmental Protection Agency Building, 1001 I Street, 2nd Floor, Sacramento, California and will last until all business has been conducted, or until 5:00 p.m. This public hearing will also provide opportunity for presentation of statements or arguments orally or in writing pertaining to the proposed MADL for DEHP by intravenous exposure which is noticed separately [available on the OEHHA website at <http://www.oehha.ca.gov/prop65/law/dehpivnote.html>].

Any written statements or arguments regardless of the form or method of transmission must be received by OEHHA by 5:00 p.m. on **August 8, 2005**, which is hereby designated as the close of the written comment period.

Written comments regarding this proposed action can be sent by mail or by fax addressed to:

Susan Luong
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation Program
P. O. Box 4010
Sacramento, California 95812-4010
FAX: (916) 323-8803
Telephone: (916) 445-6900

Comments sent by courier should be delivered to:

Susan Luong
Office of Environmental Health Hazard Assessment
1001 I Street, 19th Floor
Sacramento, California 95814

Comments may also be transmitted via email addressed to: (sluong@oehha.ca.gov).

It is requested but not required that written statements or arguments be submitted in triplicate.

If you have special accommodation or language needs, please contact Susan Luong at (916) 445-6900 or sluong@oehha.ca.gov by July 25, 2005. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT

Please direct inquiries concerning the substance and processing of the action described in this notice to Susan Luong, in writing at the address given above, or by telephone at (916) 445-6900. Ms. Cynthia Oshita is a back-up contact person for inquiries concerning processing of this action and is available at the same telephone number.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq. and commonly known as Proposition 65 (hereinafter referred to as “Proposition 65” or “the Act”), 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 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 such persons from knowingly discharging a listed chemical into water or onto or into land where such chemicals pass or probably will pass into any source of drinking water (Health and Safety Code section 25249.5).

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 he or she is responsible produces no observable reproductive effect, assuming exposure at 1,000 times the level in question (Health and Safety Code section 25249.10). 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). The term “significant amount” is defined in a manner that equates to the level that triggers the warning requirement. Thus, these exemptions apply

when an exposure or discharge does not exceed the NOEL divided by 1,000. One method by which a person in the course of doing business may determine whether an exposure or a discharge is exempt from the Act is by application of the specific regulatory level for the chemical in Title 22, California Code of Regulations Section 12805¹. The levels in Section 12805 represent the maximum dose level at which the chemical has no observable reproductive effect, given an exposure at one thousand (1,000) times the level in question. Regulations previously adopted by the Office of Environmental Health Hazard Assessment (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 12801-12821). 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 12803 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 12805; 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 12803(a). The specific regulatory levels in Section 12805 represent one one-thousandth of the NOEL. This proposed regulation sets forth a maximum allowable dose level (MADL) for adoption into Section 12805 using scientific methods outlined in Section 12803.

Details on the scientific basis for the proposed number are provided in the reference cited below, which is also 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 amendment to Section 12805 would adopt the following regulatory level for the chemical known to the state to cause reproductive toxicity:

| Chemical | MADL, in units micrograms per day | Reference |
|----------------------------------|--|--------------|
| Di(2-ethylhexyl)phthalate (DEHP) | <u>410 (oral exposure of adults)</u> <u>58 (oral exposure of infant boys)</u> <u>20 (oral exposure of neonatal boys)</u> | OEHHA (2005) |

The risk assessment which was used by the OEHHA to determine the stated level is as follows:

Office of Environmental Health Hazard Assessment (OEHHA, 2005). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di(2-ethylhexyl)phthalate (DEHP) by Oral Exposure. OEHHA Reproductive and Cancer

¹ All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

Hazard Assessment Section, California Environmental Protection Agency, Sacramento, June 2005.

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.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

OEHHA has determined the proposed regulatory action would not pose 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. The Office of Environmental Health Hazard Assessment 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

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

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.

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

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.

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

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 regulation will not impose any requirements on small business. Rather, the proposed regulation will assist small businesses subject to the Act in determining whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition.

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 regulation, all the critical information upon which the regulation is based, and the text of the regulation. A copy of the Initial Statement of Reasons, a copy of the text of the regulation and a copy of the risk assessment which was used by OEHHA to determine the MADL are available upon request from OEHHA's Proposition 65 Implementation Program 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 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 changed regulations and the full text will be mailed to individuals who testified or submitted 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 changes.

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 Proposition 65 Implementation Program at the address and 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

Joan E. Denton, Ph.D.
Director

Dated: June 24, 2005