

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

**NOTICE OF MODIFICATIONS TO  
TEXT OF PROPOSED REGULATIONS**

**AMENDMENT TO TITLE 22, CALIFORNIA CODE OF REGULATIONS  
SECTION 12805. SPECIFIC REGULATORY LEVELS:  
CHEMICALS CAUSING REPRODUCTIVE TOXICITY**

**[Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity  
for Di(2-ethylhexyl)phthalate (DEHP) by Intravenous Injection]**

**OAL RULEMAKING FILE No. 05-1027-05 S**

**March 3, 2006**

Pursuant to the requirements of Government Code Section 11346.8(c), and Section 44 of Title 1 of the California Code of Regulations, the Office of Environmental Health Hazard Assessment (OEHHA) is providing notice of changes made to the proposed regulations, Title 22, California Code of Regulations, Section 12805. These proposed regulations were originally the subject of a Notice of Proposed Rulemaking issued on October 29, 2004. A public hearing was held on December 13, 2004. Written and oral testimony was accepted at the hearing. In addition, written comments were received during the 45-day public comment period that ended on December 13, 2004. OEHHA reviewed the comments and, on June 24, 2005, proposed to revise proposed Maximum Allowable Dose Levels (MADLs) for di(2-ethylhexyl)phthalate (DEHP) (by intravenous injection). Another public hearing was held on August 8, 2005. OEHHA reviewed the written comments submitted. On August 23, 2005, OEHHA was requested to publish a written explanation of the manner in which it is relying on new documents and to extend the commenting period. In response to the request, OEHHA issued a Clarification of Notice of Addition of Documents and Information to Rulemaking file, OAL FILE Z-01-1019-06, on August 30, 2005 and extended the comment period from September 1 to September 15, 2005. One further set of comments was received. OEHHA submitted the proposed regulation to Office Of Administrative Law (OAL) on October 29, 2005. On December 13, 2005, OAL disapproved the proposed regulation for failing to comply with the "clarity" standard and for failing to follow certain procedures required by the Administrative Procedure Act.

OAL noted in its rejection of the rulemaking that the age groups for neonatal boy and infant boy specified in the regulations did not have a meaning generally familiar to those directly affected, and that the terms were defined neither in the regulation nor in the governing statute. OAL also noted that the proposed MADLs did not show levels

applicable to ages between infant and adult. OAL further noted that one document cited in the rulemaking was omitted from the rulemaking file, while another document that was not cited was included in the file.

OEHHA has addressed these issues by renaming the “neonatal” as “neonatal infant,” by specifying ages for “neonatal infant” and “infant,” and by providing guidance for calculation of MADLs for males in the age groups between infant and adult. To address the procedural issue, OEHHA substituted the cited document for the document that was not cited in the rulemaking file.

This notice announces the availability of the modified proposed regulatory text for public comment. In addition, the supporting document “Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di(2-ethylhexyl)phthalate (DEHP) by Intravenous Injection”, has been revised as described above and is also available for public comment. This revised document provides the rationale for the modifications to the proposed regulatory text. Following this public comment period, the revised regulation will be re-submitted to OAL with any needed responses to comments.

Comments regarding the proposed changes to the text of regulations or the inclusion of the specified document, will be accepted by OEHHA between March 3, 2006 and March 20, 2006. All written comments must be submitted to OEHHA by e-mail, mail, fax, courier or hand-delivery, no later than 5:00 p.m. on **March 20, 2006**, and addressed to:

Susan Luong  
Office of Environmental Health Hazard Assessment  
Mailing Address: P. O. Box 4010  
Sacramento, California 95812-4010  
Street Address: 1001 I Street, 19<sup>th</sup> Floor  
Sacramento, California 95814  
Fax No.: (916) 323-8803 Telephone: (916) 445-6900

Comments transmitted via email should be addressed to: [sluong@oehha.ca.gov](mailto:sluong@oehha.ca.gov).

If you have special accommodation or language needs, please contact Susan Luong at (916) 445-6900 or [sluong@oehha.ca.gov](mailto:sluong@oehha.ca.gov) by July 25, 2005. 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 **March 20, 2006**, which is hereby designated as the close of the written comment period.

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

A copy of the revised proposed regulatory text is attached. Text that was not amended [from how it is currently set out in regulation] is shown in plain text. Amendments to the text are shown in the following manner: regulation language that was originally proposed and was the subject of the December 13, 2004, public hearing is shown in single-underlined or strike-out; deletions from and additions to the proposed language that were the subject of the August 8, 2005 public hearing are shown in bold single strikeout and single underline, and further amendments to the proposed language made in response to the issue of clarity raised by OAL December 2005 are shown in double underline and double strikeout. The supporting document “Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di(2-ethylhexyl)phthalate (DEHP) by Intravenous Injection” has been revised with the first set of changes in underline and strikeout and the second set in double underline and strikeout. Inquiries concerning the action described in this notice may be directed to Susan Luong, in writing, at the address given above, or by telephone at (916) 445-6900.