

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

PROPOSED AMENDMENTS TO:

**SECTION 25305, SCIENCE ADVISORY BOARD, POWERS AND DUTIES
SECTION 25701, NO SIGNIFICANT RISK LEVELS, GENERAL
SECTION 25705, NO SIGNIFICANT RISK LEVELS, SPECIFIC REGULATORY
LEVELS POSING NO SIGNIFICANT RISK
SECTION 25801, NO OBSERVABLE EFFECT LEVELS, GENERAL**

MARCH 23, 2012

SUMMARY

The proposed amendments clarify that two specified Science Advisory Board Committees¹ provide scientific peer review of the scientific basis for regulations proposed for Articles 7² and 8³ that are developed by the Office of Environmental Health Hazard Assessment (OEHHA). The Carcinogen Identification Committee (CIC) provides peer review for proposed No Significant Risk Levels (NSRLs) for carcinogens and other regulations proposed for Article 7 - No Significant Risk Levels. The Developmental and Reproductive Toxicant Identification Committee (DARTIC) provides peer review for proposed Maximum Allowable Dose Levels (MADLs) for reproductive toxicants and other regulations proposed for Article 8 – No Observable Effect Levels. This regulation clarifies OEHHA’s existing peer review procedures.

BACKGROUND

Proposition 65⁴ requires the Governor to maintain a list of chemicals known to cause reproductive toxicity or cancer, and requires businesses to provide a warning when they cause an exposure to a listed chemical. Proposition 65 also prohibits businesses from knowingly discharging or releasing a listed chemical

¹ Title 27, Cal Code of Regs., section 25302 *et seq.*, all further references are to sections of Title 27, unless indicated otherwise.

² Section 25701 *et seq.*

³ Section 25801 *et seq.*

⁴ The Safe Drinking Water and Toxic Enforcement Act of 1986, enacted by voters’ initiative on November 4, 1986, codified at Health and Safety Code section 25249.5 *et seq.* and commonly known as “Proposition 65”.

into water or onto or into land where it passes or probably will pass into a source of drinking water. Proposition 65 creates limited exceptions to these warning and discharge requirements when the person responsible for the exposure can show that exposure to the listed carcinogen poses no significant risk, or that there will be no observable effect at an exposure 1000 times the level in question when the exposure is to a listed reproductive toxicant.⁵

OEHHA is the state entity responsible for the implementation of Proposition 65, and has the authority to adopt and amend regulations to further the purposes of Proposition 65.⁶ To assist businesses in complying with Proposition 65's discharge prohibition and warning provision, OEHHA develops "safe harbor" exposure levels in Sections 25705 and 25805, no significant risk levels for carcinogens and maximum allowable dose levels for reproductive toxicants. OEHHA also updates, as needed, the regulations first adopted in February 1988, which establish the methods and principles used for calculating safe harbor levels, and for calculating exposure under Proposition 65. These regulations can be found in Sections 25701 through 25721 and 25801 through 25821.

Peer Review of the Scientific Basis for Proposed Regulations by the Science Advisory Board

Two committees of the Science Advisory Board are appointed by the Governor to be the "state's qualified experts" to advise and assist in the implementation of Proposition 65.⁷ The CIC provides expertise regarding carcinogenicity, and the DARTIC provides expertise regarding reproductive toxicity.

Section 25305 sets out the powers and duties of the two committees. Subsection 25305(a) applies to the CIC, and 25305(b) applies to the DARTIC. Pursuant to these regulations, the committees may "[r]eview or propose standards, procedures and definitions related to the implementation, administration or interpretation of Proposition 65 ...upon request by the lead agency." When OEHHA adopts or amends the Article 7 and 8 regulations it follows the rulemaking procedures established in the Administrative Procedure Act. Health and Safety Code section 57004 requires peer review of the scientific basis for OEHHA's proposed regulations prior to their final adoption. Health and Safety Code section 57004 specifically provides that scientific peer review of regulations proposed under Proposition 65 can be accomplished through a process that is

⁵ Health and Safety Code section 25249.9 and 25249.10

⁶ Health and Safety Code section 25249.12(a)

⁷ Section 25302

similar to that required for other regulations.⁸ The state's qualified experts provide scientific peer review for regulatory actions under Proposition 65, therefore providing a peer review process that is similar to that described in the statute.

The proposed regulatory amendments would add Subsections 25305(a)(6) and 25305(b)(6) to the existing regulations to clarify that the CIC and DARTIC are provided with the scientific basis for NSRLs and MADLs, respectively, as well as other proposed amendments to the regulations in Articles 7 and 8, for their review and comment. These amendments would not change OEHHA's existing practices.

PURPOSE

1. Subsection 25705(b)(2) currently provides that the notice of proposed rulemaking and the Initial Statement of Reasons for that regulatory action be provided to each member of the CIC during the public comment period prior to the lead agency's adoption of an NSRL pursuant to Subsection 25705(b)(1). One of the proposed amendments revises and moves this provision from Subsection 25705(b)(2) to Subsection 25701(e) to clarify that rulemakings initiated under all provisions of Article 7 are to be sent to the CIC for scientific peer review.
2. Article 8 does not expressly require the lead agency to send the notice of proposed action and Initial Statement of Reasons for proposed MADLs or other regulations to the DARTIC. One of the proposed regulatory amendments adds Subsection 25801(f) to clarify that rulemakings initiated under Article 8 are to be sent to the DARTIC for scientific peer review.
3. The proposed amendments add Subsections 25305(a)(6) and 25305(b)(6) to clarify that the committees' powers and duties include scientific peer review of regulatory proposals developed for Articles 7 and 8.

PROBLEM BEING ADDRESSED BY THIS PROPOSED RULEMAKING

The Proposition 65 regulations do not clearly specify the procedure that OEHHA follows to satisfy Health and Safety Code section 57004's requirement for a peer review of scientifically based regulations. These proposed amendments describe this procedure.

⁸ Health and Safety Code section 57004(b)

NECESSITY

OEHHA is proposing these amendments to clarify and make specific its current practices concerning requesting peer reviews by the CIC and DARTIC of the scientific basis for proposed safe harbor levels and other amendments to sections of Articles 7 and 8. The proposed amendments also specify that this practice complies with Health and Safety Code section 57004.

BENEFITS OF THE PROPOSED REGULATION: See "Benefits of the Proposed Regulation" under ECONOMIC IMPACT ANALYSIS below.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS

OEHHA relied on the attached Economic Impact Analysis in developing this proposed regulation.

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

One alternative to the committee members conducting these reviews would be to establish a contract for scientific peer reviews with the University of California or a similar institution of higher learning, but this would increase the cost and time taken for the reviews significantly, and would be inefficient. The committee members are the state's designated experts on carcinogens and reproductive toxicants, and as such are an exceptional resource for peer review of documents on these subjects. The committee members have experience reviewing such documents and can provide a more experienced and expedited review, which is helpful to businesses and individuals who need these safe harbors to determine if they must provide a warning for exposures to listed chemicals or if they are prohibited from discharging a listed chemical into a source of drinking water.

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

The proposed regulatory action will not adversely impact small business because it is simply a clarification of OEHHA's current practice. Further, Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code section 25249.11(b)).

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS

The proposed regulatory action 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 because the proposed amendments to the regulations do not impose any new requirements upon private persons or business.

EFFORTS TO AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS ADDRESSING THE SAME ISSUES

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.

ECONOMIC IMPACT ANALYSIS
Gov. Code section 11346.3(b)

OEHHA finds there will be no economic impact related to these minor proposed regulatory amendments. The amendments do not impose any costs because they are simply a clarification of a process that OEHHA already uses related to peer review of the scientific basis for the adoption of NSRLs and MADLs. These levels provide compliance assistance to businesses subject to Proposition 65, and their use is entirely voluntary.

Problem being addressed by this proposed rulemaking:

The existing regulations do not clearly specify the procedure that OEHHA follows in order to obtain scientific peer review for proposed Proposition 65 regulations that satisfy Health and Safety Code section 57004's requirement for a peer review of scientifically based regulations.

How this regulation will address the problem:

These proposed amendments describe and explain the procedure OEHHA uses to obtain scientific peer review for regulations proposed under Articles 7 and 8 of its regulations.

Impact on the Creation, Elimination, or Expansion of Jobs/Businesses in California

These minor regulatory amendments will not affect the creation or elimination of jobs within the State of California. The proposed amendments clarify an existing process for obtaining scientific peer reviews for proposed safe harbor levels.

Benefits of the Proposed Regulation

These regulatory amendments will provide clarity concerning OEHHA's current practice for requesting scientific peer review for Proposition 65 regulatory proposals that comply with the requirements of Health and Safety Code section 57004. Safe harbor levels provide needed compliance assistance for businesses subject to the Act and provide relevant information to consumers who may choose to avoid or limit their exposure to listed chemicals. Ensuring the scientific basis for the safe harbor regulatory levels is critical in order to ensure the scientific integrity of the process.

