

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

PROPOSED AMENDMENTS TO
SECTION 25302, SCIENCE ADVISORY BOARD
SECTION 25304, FINANCIAL DISCLOSURE

May, 2013

SUMMARY

These proposed regulatory amendments¹ would make two changes to the current regulations governing the state's qualified expert committees:

- The required level of education and training for appointment to either committee would be a completed doctoral degree, research experience in specific areas of expertise, and ongoing expert scientific work. These requirements would add more specificity to the general provisions currently in the regulation.
- Remove certain portions of Section 25304 that were made redundant when Committee members were added to the Office of Environmental Health Hazard Assessment's (OEHHA) Conflict of Interest Code.²

BACKGROUND

OEHHA is the state entity responsible for the implementation of Proposition 65.³ OEHHA has the authority to adopt and amend regulations to further the purposes of Proposition 65. OEHHA maintains a list of chemicals known to cause reproductive toxicity or cancer. The law requires businesses to provide a warning when they cause an exposure to a listed chemical, and prohibits the discharge of listed chemicals into sources of drinking water. Proposition 65 states that one of the four ways a chemical can be identified as "...known to the state to cause cancer or reproductive toxicity within the meaning of this chapter [is] if in the opinion of the state's qualified experts it has been clearly shown through

¹ Title 27, Cal. Code of Regs., sections 25302 and 25304, all further references are to sections of Title 27, Cal. Code of Regs., unless indicated otherwise.

² Title 2, Cal. Code of Regs, section 54700

³ The Safe Drinking Water and Toxics Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., commonly referred to as "Proposition 65".

scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity....”⁴

Two committees serve as the “state’s qualified experts” for identifying chemicals for the list and to further advise and assist the Governor in the implementation of Proposition 65: the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant Identification Committee (DARTIC).⁵

Currently, Sections 25302(b)(1) and (2) describe the required areas of expertise for the members of the two committees. These are:

- For the CIC: epidemiology, oncology, pathology, medicine, public health, biostatistics, biology, toxicology, and related fields.
- For the DARTIC: epidemiology, developmental toxicology, reproductive toxicology, teratology, medicine, public health, biostatistics, biology, toxicology, and related fields.

PURPOSE

Section 25302(b), Expertise of Committee Members

The proposed amendments to Section 25302(b) specify that committee members must have completed a doctoral degree in a specified area of expertise, have conducted scientific research in a specified area of expertise, and have demonstrated ongoing knowledge and expertise through the conduct of advanced scientific work using scientifically valid and generally-accepted test methods related to their areas of specialization. These proposed amendments would ensure that committee members possess expertise that is the most relevant to the committees’ work.

For purposes of clarity, the proposed amendments would modify Section 25302(b)(2), to remove certain sub-specialties in the area of toxicology (i.e., developmental toxicology, reproductive toxicology) that are included in the existing identification of toxicology as a relevant field. This removes an inconsistency between section 25302(b)(1), where sub-specialties of toxicology are not specified and section 25302(b)(2), which mentions them. The areas of expertise in which a doctoral degree is required are specified in amended Subsections 25302(b)(1)(i) and 25302(b)(2)(i). The new Subsections 25302(b)(1)(ii) and 25302(b)(2)(ii) require that Committee members must also

⁴ Health and Safety Code section 25249.8(b)

⁵ Title 27, Cal. Code of Regs., section 25302

have demonstrated ongoing expertise, and conduct scientific work of relevance to the identification of chemicals for listing under Proposition 65. The relevant sub-specialties of ongoing expertise for CIC members include cancer epidemiology, cancer pathology, biostatistics, chemical carcinogenesis, cancer mechanisms and related fields; and for DARTIC members include reproductive or developmental epidemiology, developmental toxicology, male reproductive toxicology, female reproductive toxicology, teratology, biostatistics, and related fields.

Section 25304, Financial Disclosure Requirements

This proposed amendment would repeal the redundant portions of Section 25304 but retain the existing provisions that require all Committee members to be in compliance with the requirements of the Fair Political Practices Act⁶ before they are allowed to cast votes on committee actions.

Section 25304 currently requires that the members of both the CIC and DARTIC make a public disclosure of their investments in, income from or business positions in any partnership, corporation, or other entity that imports, manufactures, distributes, sells, buys, or uses chemicals that are or may be considered carcinogens or reproductive toxicants.

However, DARTIC and CIC Committee members are covered by the OEHHA Conflict of Interest Code⁷, therefore the provision in Section 25304 is duplicative and should be repealed.

PROBLEMS BEING ADDRESSED BY THIS PROPOSED RULEMAKING

Section 25302(b), Expertise of Committee Members

The existing regulation specifies that the members of the committees must be experts in the designated specializations, but does not indicate what constitutes expertise or educational requirements. To ensure that members of the committees are indeed the “State’s Qualified Experts” as required by Proposition 65, OEHHA is proposing amendments to the regulation that would clarify the required education and experience.

The amended regulation requires a doctoral degree and research experience in named specialized areas. It also requires demonstrated ongoing expertise in the conduct of advanced scientific work relevant to identifying chemicals as carcinogens or reproductive toxicants using generally accepted and scientifically

⁶ Government Code sections 81000 through 91015

⁷ Title 2, Cal. Code of Regs, section 54700

valid principles and methodologies. For the CIC members this includes ongoing work in one or more of the following areas: cancer epidemiology, cancer pathology, biostatistics, chemical carcinogenesis, cancer mechanisms and related fields. For the DARTIC members this includes conduct of ongoing advanced scientific work in one or more of the following areas: reproductive or developmental epidemiology, developmental toxicology, male reproductive toxicology, female reproductive toxicology, teratology, biostatistics, and related fields.

Ongoing scientific work that meets the requirements of Subsections 25302(b)(1)(ii) and 25302(b)(2)(ii) includes: writing scientific papers and technical reports, serving on scientific advisory panels, conducting experimental and other studies, and peer-reviewing scientific work. "Ongoing" generally means that the work has occurred within the last four years. These requirements will ensure an individual's expertise in a designated specialization matches the needs of the committee.

Section 25304, Financial Disclosure Requirements

After Section 25304 was adopted, OEHHA amended its Conflict of Interest Code to expressly include members of all OEHHA advisory committees, including the CIC and DARTIC. The committee reporting requirements are the same in both regulations. Therefore Section 25304 is redundant. The proposed amendments would repeal these portions of the existing regulation.

NECESSITY

The proposed amendments to Sections 25302(b)(1)(i) and (2)(i) specify that a doctoral degree is required for service on the committees, and define the types of doctoral degrees that are acceptable. They include doctoral degrees in medicine and relevant areas of science. This is to ensure that the appointed members have the relevant education to determine whether chemicals can cause cancer or reproductive toxicity. Sections 25302(b)(1)(ii) and (2)(ii) define the relevant expertise members must acquire after they have attained their doctoral degrees. This proposed amendment is to ensure that committee members attain and maintain the expertise needed for these committees.

The ongoing conduct of scientific research and analysis and interpretation of research results are essential to maintaining scientific expertise, and demonstrate the ability to comprehend and interpret information on hazard identification. Service on expert scientific panels, peer-reviewing scientific work,

and publishing in the scientific literature or submitting a peer-reviewed study to a government agency (generally within the past four years), are indications of the depth and breadth of understanding of recent scientific developments in the fields pertinent to the evaluation of reproductive or cancer hazards. This understanding is important in evaluating chemicals for potential listing under Proposition 65.

The proposed amendments to this section also remove an inconsistency between the two committees in terms of the required areas of expertise, in that the general field of toxicology was specified as relevant for both committees, while certain subspecialties of toxicology were identified only for the DARTIC.

Section 25304 – Since OEHHA’s Conflict of Interest Code was amended to include all committee members, certain aspects of the existing regulation is redundant and should be repealed.

BENEFITS OF THE PROPOSED REGULATION

These regulatory amendments will provide the following benefits:

- Ensure that the members of both committees are fully qualified to serve as the “state’s qualified experts”⁸.
- Eliminate redundant regulatory language.

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

OEHHA used Title 2, California Code of Regulations, section 54700, OEHHA’s Conflict of Interest Code (see appendix) as a basis for proposing the amendments to Section 25304. OEHHA also 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

OEHHA is not aware of any reasonable alternatives to the proposed regulatory action. An alternative to the proposed revisions would be to retain the existing regulations. OEHHA has rejected that alternative because updating these regulations is in the best interest of both the regulated and enforcement communities and will further the health protective purposes of the Act.

⁸ Health and Safety Code section 25249.8(d)

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

Because the proposed amendments simply clarify certain an existing regulation that applies to expert committees, make the regulation more specific and eliminate redundancies, they will have no adverse impact on small businesses.

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

Because these proposed regulatory amendments relate to the qualifications for expert committees and related procedural issues for those committees, 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. The proposed regulation does 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)

Because these proposed regulatory amendments relate to the qualifications for expert committees and related procedural issues for those committees, the proposed regulatory action will not have a significant statewide adverse economic impact.

Problems being addressed by this proposed rulemaking:

Section 25302(b), Expertise of Committee Members – The existing regulation specifies that the members of the committees must be experts in the designated specializations, but does not indicate what constitutes such expertise. To ensure that members of the committees are indeed the “State’s Qualified Experts” as required by Proposition 65, OEHHA is proposing amendments to the regulation that would clarify the education and ongoing scientific work that establishes an individual’s expertise in a designated specialization.

Section 25304, Financial Disclosure Requirements – After Section 25304 was adopted, OEHHA amended its Conflict of Interest Code to expressly include members of all OEHHA advisory committees, including the CIC and DARTIC. The committee reporting requirements are the same in both regulations. The addition of the Committee members to OEHHA’s Conflict of Interest Code renders portions of Section 25304 redundant. The proposed amendments would repeal these portions of the existing regulation.

How this regulation will address the problem:

Section 25302(b), Expertise of Committee Members – The proposed amendments would specify that committee members must have completed a doctoral degree in a specified area, and conduct ongoing advanced scientific work of relevance to the identification of chemicals as carcinogens or reproductive toxicants using generally accepted and scientifically valid principles and methodologies.

Section 25304, Financial Disclosure Requirements – This proposed amendment will repeal the redundant portion of Section 25304.

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

This regulatory proposal will not directly affect the creation or elimination of jobs within the State of California. The committees are statutorily required to provide advice and identify chemicals known to the state to cause cancer or reproductive

toxicity. The economic impact, if any, of their future decisions would be speculative. Further, listing decisions under Proposition 65, including those of the committee, are expressly exempted from the requirements of the Administrative Procedure Act.⁹

Because the proposed regulatory amendments are procedural in nature and do not impose any mandatory requirements on businesses subject to the Act, 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.

Benefits of the Proposed Regulation

These regulatory amendments will provide the following benefits:

- Ensure that the members of both committees are fully qualified to serve as the “state’s qualified experts.”¹⁰
- Eliminate redundant regulatory language.

⁹ Health and Safety Code section 25249.8(e)

¹⁰ Health and Safety Code section 25249.8(d)