

INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS
PROPOSED AMENDMENTS TO TITLE 27, CALIFORNIA CODE OF
REGULATIONS SECTION 27000
CHEMICALS REQUIRED BY STATE OR FEDERAL LAW TO HAVE BEEN
TESTED FOR POTENTIAL TO CAUSE CANCER OR REPRODUCTIVE
TOXICITY, BUT WHICH HAVE NOT BEEN ADEQUATELY TESTED AS
REQUIRED.

Summary

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65¹ and has the authority to promulgate and amend regulations to implement and further the purposes of the Act. OEHHA is proposing to amend Title 27, of the California Code of Regulations, section 27000², to update this regulation and incorporate 2016 amendments to the federal Toxic Substances Control Act.

Background/Problem to be Addressed by the Proposed Rulemaking

A. Proposition 65

Proposition 65 was a ballot measure that Californians approved in November 1986 with 63 percent of the popular vote. Proposition 65 is a right-to-know law based on the concept that members of the public have a right to know when they are being exposed to listed carcinogens or reproductive toxicants. Proposition 65 requires the Governor of California to publish a list of chemicals known to the state of California to cause cancer or reproductive toxicity.

B. Section 27000

Health and Safety Code section 25249.8(c) provides as follows:

“On or before January 1, 1989, and at least once per year thereafter, the Governor shall cause to be published a separate list of those chemicals that at the time of publication are required by state or federal law to have been tested for potential to cause cancer or reproductive toxicity but that the state’s qualified experts have not found to have been adequately tested as required.”

¹ Health and Safety Code Section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as “Proposition 65”. Hereafter referred to as “Proposition 65” or “the Act”.

² All further references are to sections of Title 27, Cal. Code of Regs., unless indicated otherwise.

Title 27, California Code of Regulations, section 27000 is the regulation adopted by OEHHA to implement this requirement. This regulation contains a list that is updated annually of chemicals that are required by state or federal law to be tested for carcinogenicity or reproductive toxicity, but have been deemed to need further testing.

C. Federal Toxic Substances Control Act (TSCA) amendments of 2016

Subsection (c) of Section 27000 includes chemicals that require testing under former Section 4(a) of TSCA. Under Section 4(a) testing of a chemical is required when that chemical may present an unreasonable risk, or is produced in substantial quantities and enters the environment in substantial quantities, or may have significant or substantial human exposure³.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law. This Act updated the Toxic Substances Control Act, changing some of the language and causing most of the language that was not changed to be renumbered. Because of this update, the language in section 4(a) in the previous version of TSCA was moved to section 2603(a) of the new TSCA. OEHHA is therefore proposing to revise Section 27000 to reflect the changes in TSCA and make other non-substantive amendments and clarifications in order to update this regulation.

Purpose

The purpose of the proposed amendments is to update and clarify Section 27000. Sections of this regulation have become outdated, some due dates have expired and some federal statutes cited in it have been renumbered.

Subsection 27000(a)

The proposed amendments would remove some language from the regulation language to the Initial Statement of Reasons because it is an explanatory statement, not a regulatory requirement, thus it belongs in the Initial Statement of Reasons (ISOR):

“A chemical that already has been designated as known to the state to cause cancer or reproductive toxicity is not included in the listing as requiring additional testing for that particular toxicological endpoint. However, the ‘data gap’ may continue to exist, for purposes of the state or federal agency’s requirements.”

³ 15 U.S.C.A. §2603(a).

Subsection 27000(b)

The proposed amendments would slightly modify subsection (b) to provide more clarity. Paragraphs were numbered and the term “non-200” was deleted. “Non-200” refers to the original language of the Birth Defect Prevention Act of 1984 (SB950) which required that, no later than December 31, 1985, the Department of Pesticide Regulation (DPR) would identify 200 pesticide active ingredients which DPR determined to be hazardous to people and to have the most significant data gaps. DPR identified those 200 pesticide active ingredients in 1985 and thus this provision is outdated.

Subsection 27000(c)

The proposed amendments in subsection (c) would change the title of the the US Environmental Protection Agency (USEPA’s) “Office of Toxic Substances” to the “Office of Pollution Prevention and Toxics” to reflect the newer nomenclature used by the federal Agency.

“Section 4(a)” would be changed to “Section 2603(a)” to reflect the 2016 amendments and renumbering of TSCA.

The following statement would also be removed from the regulatory text.

NOTE: The testing of the above chemicals is being carried out under “Enforceable Consent Agreements” (or ECAs) under Section 4 of TSCA. In addition, there are a number of ongoing TSCA testing action development activities that may be of interest in the context of Proposition 65. When promulgated, these TSCA Section 4 Test Rules and/or ECAs will require industry to conduct reproductive toxicity, developmental toxicity, and/or cancer studies on a number of 1) hazardous air pollutants (or HAPs), 2) chemicals frequently found at Superfund sites, and 3) U.S. high production volume (or HPV) chemicals. As these, and possibly other, TSCA Section 4 Test Rules/ECAs become effective, this table will be revised to reflect those additional chemical substances for which developmental toxicity, reproductive toxicity, and/or oncogenicity testing is currently being required under Section 4 of TSCA.

This change is proposed for two reasons: (1) It is explanatory language and not necessary in the body of a regulation; and (2) this statement may no longer be accurate, since the US EPA has not yet released any changes to testing procedure based on the 2016 amendments to TSCA.

Necessity

These proposed amendments are necessary to add clarity and avoid potential confusion due to outdated information and incorrect citations in the existing regulation.

Economic Impact Assessment Required by Gov. Code section 11346.3(b)

In compliance with Government Code section 11346.3, OEHHA has assessed all the elements pursuant to sections 11346.3(b)(1)(A) through (D):

Creation or elimination of jobs within the State of California

This regulatory action will not impact the creation or elimination of jobs within the State of California, it simply updates and provides clarification of an existing regulation without changing its effects.

Creation of new businesses or elimination of existing businesses within the State of California

These proposed amendments will not impact the creation of new businesses or the elimination of existing businesses within the State of California. The proposed amendments to the regulation simply provide updates and clarification of an existing regulation without changing its effect.

Expansion of businesses currently doing business within the State of California

This proposed regulatory action will not impact the expansion of businesses within the State of California. The proposed amendments to the regulation simply provide updates and clarification of an existing regulation without changing its effect.

Benefits of the proposed regulation to the health and welfare of California residents, worker safety, and the state's environment

The proposed update of this regulation will benefit the health and welfare of the public by providing current information and correct citations in this regulation.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

No technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

No reasonable alternatives to this proposed amendment have been proposed to OEHHA. Not promulgating these amendments would leave outdated regulatory language uncorrected.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the proposed action, or would be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small business. In addition, OEHHA has determined that the proposed regulatory action will not impose any mandatory requirements on small businesses. Proposition 65 expressly exempts businesses with less than 10 employees⁴ from the requirements of the Act.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed amendments are simply updates and clarifications of the existing regulation and cause no changes in its effect. Therefore, there is no significant adverse economic impact on 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. OEHHA has determined that the regulations do not duplicate and will not conflict with federal regulations.

⁴ Health and Safety Code section 25249.11(b).