

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

**AMENDMENTS TO SECTION 25204
SAFE USE DETERMINATIONS
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986**

PURPOSE

The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65 (hereinafter referred to as “Proposition 65” or “the Act”), was enacted as a voters’ initiative on November 4, 1986, and codified at Health and Safety Code section 25249.5 et seq. The Office of Environmental Health Hazard Assessment (OEHHA), within the California Environmental Protection Agency is the state entity responsible for the implementation of the Act. OEHHA has the authority to promulgate and amend regulations to further the purposes of the Act.¹ The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water. The law and regulations provide exceptions to these requirements in certain circumstances. One way an affected business can determine whether a warning is required for a specific exposure, or whether a discharge of a chemical to a source of drinking water is prohibited, is by asking for a formal opinion from OEHHA.

Section 25204 of the California Code of Regulations, Title 27², sets out the procedures and criteria for requesting that OEHHA issue a formal written opinion known as a “Safe Use Determination” (SUD). Currently, section 25204(a) states that OEHHA’s SUDs are advisory only and not binding in any enforcement proceeding. This undervalues OEHHA’s technical expertise and knowledge, providing little incentive for a business to invest the time and expense needed to obtain one. SUD requests often deal with very technical scientific and legal issues that are best resolved in the open and public process afforded by OEHHA, rather than on a case-by-case basis through private litigation.

A SUD represents OEHHA’s best judgment concerning the application of Proposition 65 to the facts presented in a request and should carry due weight in an enforcement proceeding. The purpose of this proposed amendment to the regulation is to remove the “advisory only” language in the regulation and replace it with language providing that the SUD has presumptive effect in an enforcement proceeding.

In addition, subsection 25204(d)(1) currently establishes a nonrefundable processing fee of \$500 to be paid when a SUD request is submitted to the agency. The proposed

¹ Health and Safety Code section 25249.12(a)

² Formerly Title 22, Cal. Code of Regulations, section 12204, all further references are to sections of Title 27 (formerly Title 22) of the California Code of Regulations unless otherwise indicated.

amendment would increase the processing fee established in the regulation from \$500.00 to \$1000.00 to better cover the minimum initial costs of processing and reviewing the SUD application.

Subsection 25204(g) of the Act states that the lead agency or any other state agency may ask for additional information or explanation from the SUD applicant at any time while an accepted request for a SUD is pending. In order to ensure that these requests are responded to in a timely manner so that OEHHA can efficiently complete its work on the request, OEHHA is proposing an amendment that would add a requirement that any information requested be provided to the agency within 60 days, unless otherwise agreed by the agency.

NECESSITY

Subsection 25204(a) - Several interested parties representing both business subject to the Act and entities involved in enforcement have requested that OEHHA's SUDs carry more weight in court proceedings. The process of obtaining a SUD can require considerable time and expense. OEHHA wants to encourage businesses to use the SUD process to resolve the often difficult legal and scientific issues that arise under the law and regulations, rather than wait to have these issues addressed by the courts on a case-by-case basis. Therefore, OEHHA is proposing amendments to subsection 25204(a) that will delete the existing language making the determinations advisory only and instead give OEHHA's determinations presumptive effect in an enforcement proceeding.

Subsection 25204(d)(1) - The processing of a SUD request requires thorough analysis of the requester's facts and materials by OEHHA scientists and legal staff. The original processing fee of \$500 has not changed since the regulation was adopted in 1989 although agency costs have increased, as have the complexity of the issues presented in the requests. This amendment more accurately reflects these cost increases by raising the initial processing fee to \$1,000 to more adequately cover OEHHA's cost in initially reviewing the application.

Subsection 25204(g) - OEHHA at times needs to ask for additional information or explanations after a SUD has been accepted, but before a decision has been reached. It sometimes has taken considerable time, and repeated requests, before this information is provided. This can make the SUD process unnecessarily long and arduous. By limiting the time to provide this information to 60 days, the SUD process will be more efficient for both OEHHA and the SUD applicant.

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

OEHHA reviewed summaries of the November 2, 2007 OEHHA Regulatory Update Scoping Workshop (discussed below). OEHHA did not rely upon any technical,

theoretical, or empirical studies, reports or documents in proposing the adoption of this regulation.

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

In 2007, OEHHA initiated a renewed effort to review and update its regulations dealing with Proposition 65. During the process of prioritizing potential regulatory actions for the Project, comments were solicited and received from interested parties by way of written and oral comments at a public workshop held November 2, 2007. This workshop was attended by many interest groups from a wide range of areas such as manufacturers, retailers, agriculture, environmental non-profit organizations, and enforcement groups. At this workshop, suggestions were requested for regulatory amendments or developments that were needed under Proposition 65. One concept that received support from a variety of groups was the suggestion that OEHHA's SUDs be made "binding" rather than being just "advisory". In an unusual agreement between normally conflicting groups, environmentalists and industry both agreed that this was an important step. Because the SUDs are developed by a neutral state agency, not by paid advocates, this was considered to be a reasonable way to solve problems that normally would have to be resolved in private litigation, through often lengthy procedures.

OEHHA considered adopting regulatory language making the SUDs binding. However, that alternative was rejected as beyond the scope of the agency's authority. The other alternative is to leave the existing language intact in the regulation. This alternative does not respond to the issues raised by interested parties or further OEHHA's objective to resolve difficult issues of scientific, technical and legal nature in an open and public process rather than through protracted litigation.

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. Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code §§ 25249.5, 25249.6, and 25249.11(b)). Further, the proposed regulation is intended to increase the weight of OEHHA's legal and technical determinations in an enforcement proceeding, thereby providing businesses and enforcement groups with greater certainty and clarity concerning the applicability of the Act and the implementing regulations to specific factual situations. The proposed regulatory action does not impose any new requirement upon any business, including small businesses. Instead, it provides for an affirmative defense, under specified circumstances, to allegations that a person may have violated the Act or its implementing regulations.

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. The proposed regulation does not impose any new requirements upon private persons or business. In fact, the proposed regulatory action will provide an affirmative defense, under specified circumstances, to allegations that a person may have violated the Act.

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.