

**INITIAL STATEMENT OF REASONS**  
**22 CALIFORNIA CODE OF REGULATIONS**  
**TITLE 22, CALIFORNIA CODE OF REGULATIONS**  
**AMENDMENT TO SECTION 12104**  
**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. Included among the mandates of the statute is a prohibition against contaminating sources of drinking water with chemicals known to the state to cause cancer or reproductive harm (Health and Safety Code Section 25249.5) and a requirement upon businesses to provide warnings before exposing individuals to chemicals known to the state to cause cancer or reproductive harm (Health and Safety Code Section 25249.6). Failure to comply with these provisions may subject a business to a civil lawsuit and subject it to civil penalties of up to \$2,500 per day for each violation pursuant to Health and Safety Code Section 25249.7.

Businesses need to know whether they are in compliance with the provisions of the Act relative to the specific discharge or exposure circumstances of their business. Many businesses would like to seek the assurance and advice of the Office of Environmental Health Hazard Assessment (OEHHA) regarding the lawfulness of the business’s discharge or exposure activities under the Act. The safe use determination (SUD) process serves that purpose. The SUD process is a tool the regulated community may use to help them determine compliance with the discharge prohibition or warning requirement of the Act. Based upon the specific set of facts presented by the requester, OEHHA will issue a decision representing its best judgment on whether the discharge or exposure in question was “safe” (i.e., does not trigger the discharge prohibition or warning requirement) in light of the application of the Act. The proposed amendments clarify the manner and circumstances under which a SUD request would be considered.

Thus far, few requests for a SUD have been submitted to OEHHA. Although many businesses would have liked to seek the assistance of OEHHA, many have been hesitant to apply. Among the reasons OEHHA has received for this hesitancy has been business’s apprehension that submission of a SUD request may invite service of a 60-day notice of violation upon the requester by a private party. Under the current regulations, service of such a notice precludes OEHHA from issuing a SUD. Under the proposed regulations, this prohibition would no longer apply. However, under the current regulations, pending civil or criminal litigation on the subject matter of the safe use determination request is grounds for OEHHA to terminate the request. This remains the rule under the proposed regulations unless the request was accepted before litigation was initiated.

A related concern that has been expressed is the issue of confidentiality of the request and the supporting data and information submitted. To address these concerns and, in turn, enhance the usefulness of the SUD process, OEHHA is proposing to amend the regulations as described below.

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

No other 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

OEHHA held a public workshop to solicit suggestions for the clarifying regulations concerning safe use determinations in advance of preparing the proposed rulemaking package. Several suggestions were incorporated in the proposed regulatory amendments. Some suggestions that were not incorporated include: (1) elimination of the "advisory only" limitation placed on the SUD decision; (2) allowance for the submission and issuance of a SUD after a 60-day notice violation has been served or a complaint is filed; and (3) creation of an expedited SUD process subject to a higher fee schedule. The reasons for rejecting these suggestions are explained below: (1) A SUD is defined as a "written statement issued by the lead agency ... which interprets and applies the Act to a specific set of facts." (Title 22, California Code of Regulations, Section 12102(c)) As such, a SUD should not be considered as a blanket assurance that a business will not incur liability or be a party in future litigation concerning Proposition 65. The Act does not give OEHHA the authority to grant immunity from liability or from private or public prosecution. A SUD is advisory to the particular requester based upon the specific set of facts presented. It is not a binding determination, but may be used as evidence by the requester in the event of future enforcement action. Only the judicial branch may make a binding determination whether or not failure to provide a Proposition 65 warning is a violation of the Act. (2) OEHHA has partially accommodated the suggestion to allow issuance of a SUD despite the service of a 60-day notice of violation or if a complaint is filed. OEHHA believes that it is appropriate to proceed with the review and evaluation of a SUD request, if the SUD was submitted in good faith before a notice of violation is sent or formal complaint is filed. The SUD process was not intended to be used as a means for business to prepare for litigation or other types of enforcement actions. (3) OEHHA does not have the resources to provide expedited service. OEHHA's ability to issue a SUD is limited by staff and time resources. In most instances, OEHHA could not respond any faster even if the requester paid additional fees. Therefore, an expedited process would not be feasible.

## 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. The safe use determination provision is voluntary, not obligatory, and does not impose any requirement upon any business, including small business. In fact, the proposed regulations make it more likely that a small business may apply for a safe use determination.

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

The proposed regulation is voluntary, not obligatory, and does not impose any requirement upon private persons or business. There is no significant adverse economic impact on any business.

## AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

Proposition 65, formally known as the Safe Drinking Water and Toxic Enforcement Act of 1986, 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.

### Section 12104

The term, “Act” is defined to mean the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code Section 25249.5 et seq.) and for purposes of consistency of references, all references to Health and Safety Code Section 25249.5 et seq. are amended to refer to the “Act.” The phrase “of the Act” is added as appropriate throughout the section.

### Section 12104(b)

In the past and again during the public workshop, OEHHA held on March 18, 2002 to solicit public input on proposed amendments to the SUD regulations, businesses have commented on their reluctance to request a SUD. To address the concern that submitting a request for a SUD may initiate service of a 60-day notice of violation upon a business and then perhaps cause litigation to ensue either by the public prosecutors or a private party, OEHHA is proposing to adopt an amendment to paragraph (1) of subsection (b) which would allow for the continuation of the SUD process as long as the SUD request was received and accepted before service of the 60-day notice of violation or before a complaint by the public prosecutor had been filed on the same subject matter. OEHHA believes that it is appropriate to proceed with the issuance of a SUD, if a business had, in good faith, submitted a request before a notice of violation or formal complaint had been filed. In the existing regulations, if the subject matter of the SUD request is at issue in any pending civil or criminal case, OEHHA would not proceed with the issuance of the SUD. OEHHA proposes to amend the regulations to clarify what is not meant by “pending” litigation, identifying circumstances under which OEHHA could consider a SUD request. More specifically, the proposed regulation clarifies that if a contested case has settled, but the parties want to obtain additional guidance from OEHHA regarding whether or not a given exposure circumstance triggers the warning requirement under Proposition 65, they may still seek a SUD.

If either circumstance specified in paragraph (1) of subsection (b) occurs before the SUD is accepted by OEHHA, thus preventing issuance of the SUD, OEHHA would have no knowledge without proper notification by the requester. Timely notification is necessary because service of a notice of violation by a private party or filing of a complaint by a public prosecutor with jurisdiction before OEHHA has accepted the SUD would be grounds for terminating review and issuance of the request. A new paragraph (2) of subsection (b) is proposed to specify what should be done and when it should be done in the event that a notice of violation is served or a complaint is filed. OEHHA believes that 5 business days is sufficient time for the requester to prepare a short piece of correspondence advising OEHHA of receipt of the notice of violation or complaint. Written notice shall be given to OEHHA’s Deputy Director for Scientific Affairs because he and his staff will be the individuals within OEHHA responsible for reviewing the SUD request. Upon termination under the circumstances specified, all data and information submitted by the requester will be returned

observing full confidentiality. There is no need for OEHHA to retain the data or information if the request is terminated. Even though a request is terminated, if OEHHA began the process of reviewing the request for sufficiency of data and appropriateness as the subject matter of a SUD, costs would have been incurred and no refund should be made.

Existing paragraphs (2) – (5) of subsection (b) are renumbered to accommodate the addition of a new paragraph (2).

In newly renumbered paragraph (6) of subsection (b), a corresponding amendment is made to allow for the continuation of the SUD process if the request was received and accepted before the subject matter of the request became an issue in an administrative proceeding before another governmental agency. OEHHA is not aware of any such circumstance where this would apply, but this is a related change that logically parallels the change in paragraph (1) of this subsection.

#### Section 12104(c)

By amending this subsection to identify a SUD request as official information pursuant to Evidence Code Section 1040, OEHHA provides a certain level of limited confidentiality. In proposing this change, OEHHA does not intend to deny the public's access to public documents and information. Access is only limited during the time OEHHA is reviewing and determining acceptance of the request. During this time, OEHHA believes that disclosure of the information is against the public interest because there is a necessity for preserving the confidentiality of the information that outweighs the necessity for disclosure in the interest of justice. Upon acceptance of a SUD request by OEHHA, the "official information" privilege would no longer apply to the documents submitted by the requester to OEHHA. In particular, OEHHA does not want the submittal of a SUD request to initiate service of a 60-day notice of violation when OEHHA has not yet evaluated the request. The SUD request should be sent to OEHHA's Deputy Director for Scientific Affairs because he and his staff are the individuals responsible for reviewing the request. Also, direct mailing streamlines the process and limits access to the data and supporting information to essential OEHHA staff. OEHHA amends the existing regulations to enhance the likelihood that the regulated community would find the SUD process a more acceptable and useful regulatory tool. Over time as more businesses seek a SUD request, greater assurance can be felt that the warnings being given are for exposures situations that require a Proposition 65 warning.

In subparagraph (c)(7)(B), the statutory citation, "Government Code Section 6250 et seq.," is inserted for completeness of the reference for the Public Records Act.

#### Section 12104(d)

A new paragraph (2) to this subsection is proposed to clarify that a request for SUD and its supporting information would not be publicly disclosed until written acceptance of the request is sent. The notice of acceptance will be submitted to the Office of Administrative Law for publication in the California Regulatory Notice Register and sent to interested persons who are on the Proposition 65 mailing list. At that time, full disclosure of the request and information will be made. If a request is withdrawn before written acceptance is sent, then the request and all data and information submitted by the requester will be returned observing full confidentiality. If a request

is voluntarily terminated early in the consideration process and a SUD is not issued, OEHHA believes that the public interest in disclosure does not outweigh the public interest in retaining the materials as confidential. Even though a request is withdrawn, if OEHHA began the process of reviewing the request for sufficiency of data and appropriateness as the subject matter of a SUD, costs would have been incurred and no refund should be made. An amendment to this effect is proposed to specify these conditions.

#### Section 12104(e)

This subsection is revised to more specifically explain that if OEHHA asks for essential information that is lacking in order to complete the preliminary review of the SUD request, OEHHA will close the request if the requested information is not received within 30 days. The timeline is necessary to assure that the request remains active and that the requester is diligent in providing the information. Upon closure, all data and information submitted by the requester so far would be returned observing full confidentiality. There is no need for OEHHA to retain the data or information if the request is closed. Once again, if OEHHA began the process of reviewing the request for sufficiency of data and appropriateness as the subject matter of a SUD prior to closure, any costs that were incurred would be due and no refund would be made. The existing regulation states that a SUD request that is reopened is treated as a new request. This provision remains unchanged. This request for essential information is not intended to preclude OEHHA from asking for additional information or explanation as is deemed necessary to complete the consideration of the request as specified in existing subsection (g).

#### Section 12104(f)

This subsection is revised to clearly state what OEHHA will do if a SUD request appears to comply with the procedures of this section. Upon acceptance of the SUD request, a notice of acceptance will be submitted to the Office of Administrative Law for publication in the California Regulatory Notice Register and copies will be sent to all interested persons. This change is necessary to be in agreement with the new provision proposed in paragraph (2) of subsection (d) in which the request and supporting data and information would not be publicly disclosed until acceptance of the request has been published.

In existing subsections (f), (i), and (j), the title of the California Register is incomplete. The complete and proper title is the "California Regulatory Notice Register." The subsections are amended accordingly.