INITIAL STATEMENT OF REASONS
TITLE 22, CALIFORNIA CODE OF REGULATIONS

AMENDMENTS TO SECTION 12901
METHODS OF DETECTION
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 is 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. Included among the provisions of Proposition 65 is a prohibition against contaminating sources of drinking water with chemicals known to the state to cause cancer or reproductive harm and a requirement that businesses provide warnings before exposing individuals to chemicals known to the state to cause cancer or reproductive harm. Health and Safety Code section 25249.11, subsection (c) defines "significant amount" of a listed chemical to mean "any detectable amount," other than an amount which poses no significant risk for carcinogens, or would have no observable effect assuming exposure at one thousand times the level in question with regard to chemicals known to cause reproductive harm. Proposition 65 does not specify what analytical test methods must be used to determine whether a discharge, release, or exposure contains a detectable amount of a chemical listed under the Act.

California Code of Regulations, Section 12901[1], was adopted in 1989 to clarify and make more specific what is meant by "any detectable amount" in Proposition 65. The current version of the regulation provides that where specified state or local governmental agencies have adopted or employed a method of analysis, that method must be used for purposes of the Act. Where these specified state or local government agencies have not adopted a method of analysis, but where a federal governmental agency has, the federally adopted method must be used. Where no governmental (local, state, or federal) agency has adopted a method of analysis, a method of analysis that is generally accepted in the scientific community must be used. Where no such method is available, a scientifically valid method must be used. Where more than one method of analysis had been adopted in a given tier, then any method within the tier could be used. The structure of the current regulation, therefore, created a tiered hierarchy of acceptable methods of analysis. The existing regulation also provides that generally accepted standards and practices for sampling, analyzing, and interpreting the data must be observed when using a particular method of analysis and that no discharge, release or exposure occurs under Proposition 65, unless a listed chemical is detectable as provided in the regulation.

[1] All further references are to the California Code of Regulations, unless otherwise indicated.

Although one of the original purposes of the regulation was to allow regulated industries to rely on analytical test methods and procedures they were already using to comply with other environmental laws, in recent years, litigants and courts have had difficulty interpreting and applying Section 12901, particularly in the context of consumer products exposures. Recent cases such as *Mateel Environmental Justice Foundation v Edmund Gray et al.* (2004) 9 Cal.Rptr.3d 486: 4 Cal. Daily Op. Serv. 569; 2004 Daily Journal D.A.R. 717, and various trial court decisions have highlighted issues with the application of the regulation to particular types of products as well as the difficulties some litigants encounter in identifying the proper method of analysis for a given chemical in a particular medium. Therefore, OEHHA has determined that amendments to the regulation are necessary to provide more certainty for persons subject to the provisions of the Act. OEHHA staff have informally solicited input from representatives of the plaintiff and defense bar, the Office of the Attorney General and various members of the public, staff has reviewed decisions and pleadings from various court cases, decided and pending, that address the application of this regulation and have developed these proposed amendments to the regulation for public comment and discussion. OEHHA will also consider alternatives to the proposed amendments that may include potentially repealing some or all of the section.

In summary, the proposed amendments to Section 12901 would conform more closely with the California Evidence Code and case law by removing the current hierarchy among the various acceptable methods of detection; would add a definition for the word "medium" as used in the regulation; and would make various other technical changes to the regulation in an attempt to add clarity and flexibility in the application of the regulation to various types of scenarios, in particular consumer products alleged to be causing exposures to chemicals listed under Proposition 65. Each substantive proposed amendment to the regulation is discussed below.

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

As noted above, OEHHA reviewed public records from cases filed under Proposition 65 including *Mateel Environmental Justice Foundation v Edmund Gray et al.* (2004) 9 Cal.Rptr.3d 486: 4 Cal. Daily Op. Serv. 569; 2004 Daily Journal D.A.R. 717, the California Evidence Code and case law interpreting the Evidence Code. OEHHA also consulted the American Heritage Dictionary (1989, based on the Second New College Edition) for common word usage related to the term "medium." 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 is considering repeal of the regulations in whole or in part as a possible alternative to the proposed regulatory action amending the Section 12901. OEHHA welcomes public comment on this possible alternative and will consider all comments provided.

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 amendments are intended to address ambiguity in the current regulations concerning methods of detection related to the discharge of or exposure to listed chemicals. The proposed regulatory action does not impose any new requirement upon any business, including small business.

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 amendments do not impose any new requirements upon private persons or business. In fact, the proposed regulatory action is intended to simplify and add clarity to the regulation and provide greater flexibility for litigants and courts faced with interpreting the regulation and the Act while providing a level of certainty for persons subject to the provisions of Proposition 65.

AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

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.

Proposed Amendments to Section 12901

The proposed amendments to Section 12901 are discussed in detail below:

Subsection (a) – this subsection has been amended to clarify that the term "any detectable amount" means a level actually detected or detectable using a method of analysis provided in this section. In certain circumstances, for example where an exposure is anticipated from a particular consumer product, a violation may be shown either through actual test results (from the product in use or in a simulated laboratory setting), or by showing that an analytical test method is available that could have been employed by the person causing the alleged exposure or discharge. Conversely, a product manufacturer may use a Section 12901 analytical test method to test its product in advance to determine its potential to cause an exposure to a listed chemical in order to determine whether a warning notice may be required under the Act.

Subsection (a) has also been amended to clarify that any evidence admissible under California Law can be offered to prove or disprove a violation of the Act, thus clarifying that Section 12901 does not require a plaintiff or defendant to employ any particular method of analysis or present any particular type of evidence to prove or disprove a violation of the Act. This clarification will

provide flexibility so that any analytical test method that is appropriate, feasible and available may be used to prove or disprove an alleged exposure or discharge. OEHHA also proposes adding "frequency," "site," and "type of media" to the elements that must be included in the procedures for a method of analysis to be acceptable under Section 12901.

Finally, a provision has been added to subsection (a) stating that "[t]he medium tested must be the same medium in which a discharge or exposure may occur or is alleged to have occurred." The term "medium" is defined in the next subsection. This provision was added to clarify that where a discharge or exposure is alleged to have occurred through a particular medium such as air, water, soil, food or a consumer product, that medium must be the subject of any testing that is offered to prove the violation.

In the proposed amendments, a new subsection (b) has been added. The new subsection provides a definition for "medium," a term used throughout Section 12901. The definition is being proposed to add clarity to the regulation in response to OEHHA's observation that the regulated community, courts and litigants have expressed confusion as to the meaning of the term in the context of Section 12901. The new definition clarifies that the term "medium" refers to the substance, or mixture of substances, that creates the exposure (i.e. water, air or soil, food mixed with or containing the chemical in question) or that closely duplicates the actual exposure conditions. The new subsection also provides that where the exposure may be caused through the use of a consumer product, the "medium" is the portion of the product causing the exposure (i.e. the surface of the product that is causing a dermal exposure). This definition is consistent with the common usage definition of the term "medium" as the "intervening substance through which something is accomplished, conveyed or transferred" (American Heritage Dictionary (1989, based on the Second New College Edition) Page 423). The term "medium" is separate and distinct from the term "expose" which is defined in Section 12102(i).

In the case *Mateel Environmental Justice Foundation v Edmund Gray et al.* (2004) 9 Cal.Rptr.3d 486: 4 Cal. Daily Op. Serv. 569; 2004 Daily Journal D.A.R. 717 the court found that under Section 12901, the term "medium" was sufficiently broad enough to allow for the use of a test for lead in "water," for example, and did not require that the test be performed on "California drinking water." OEHHA finds the Court's holding to be reasonable and consistent with the existing regulation and general usage of the term "medium." The proposed amendments to the regulation are intended to clarify the fact that the medium to be tested must be analogous to the item causing the real world exposure or discharge, but that the test need not be performed on a sample obtained during an actual exposure situation or from the actual discharge. Thus, the analytical test method must be applied to the substance causing the alleged exposure or discharge, not the receiving substance or surface. In other words, one may simulate, in a controlled laboratory setting, the alleged exposure or discharge and apply an analytical test method acceptable under Section 12901 to a sample of the medium at issue (i.e. water, air, soil, food, consumer product). It is not necessary that the actual water, air, soil or consumer product that is alleged to have caused the exposure or received the discharge be used in the test.

New subsection (c) in the proposed amendments defines the term "generally accepted in the scientific community" as used in subsection (a). The proposed amendment would clarify the types

of entities or procedures that can be used to identify an appropriate method of detection for a given chemical. The new subsection incorporates provision from the deleted subsections (b), (c) and (d), collapsing the former "tiers" or hierarchy associated with the sources of the various analytical test methods.

In the proposed amendments, current subsections (b), (c) and (d) have been collapsed into a new subsection (c) that includes each of these methods of analysis, but removes the hierarchy that was established in the current regulation. The proposed amendments would allow a court to consider all admissible evidence in an enforcement action and would allow both sides to use whatever testing method is available and feasible for a particular situation. This amendment would allow a regulated business, a plaintiff or defendant to choose any method of analysis that is acceptable under Section 12901 to test a given material, emission, item or product. This change in the regulation would eliminate the current practice of requiring a test proponent to prove that the method of analysis selected is from the highest "tier" available under the regulation. Such a requirement does not further the purposes of the Act because it requires an often cumbersome and time consuming search of all state, local and federal sources for possible test methodologies, followed by literature searches and other procedures in order to locate and verify the efficacy of a given analytical test method before a person is able to conduct testing and rely on the results of the test. The proposed amendment recognizes the fact that there is no federal or state data base for methods of analysis for given chemicals in a given medium and, therefore, it is often difficult to determine what method has been adopted or employed by a given entity to use in testing for a specific chemical in a given medium. It is anticipated that this proposed amendment would eliminate unnecessary litigation over the method of analysis "tier," and more appropriately focus the question on whether the method of analysis is appropriate for the given medium and type of exposure or discharge being alleged, and whether the test was properly conducted.

The proposed amendments would add a new subsection (e) that explicitly provides that in the event a method of detection has been employed consistent with all the requirements of Section 12901 in which the chemical in question is not detected or is below the standard detection limit for that test method, the test results will create a rebuttable presumption that no unlawful discharge or exposure has occurred. OEHHA believes that this provision is simply a statement of current California law. The new subsection (e) also provides that the subsection does not impose any requirement that a person conduct any test. It is intended to provide a level of certainty for a regulated business where a valid test result has been obtained showing that no detectable level of a chemical is present or that the level detected is below the standard detection limit for the method of detection used, the burden shifts to the other party to provide evidence that would rebut the test results. This would allow businesses that otherwise are required to conduct periodic testing of their emissions or products, to rely on those test results when making a determinations as to whether a warning is required or a particular discharge is prohibited. Subsection (e) also states that the regulation does not require any person to conduct testing.

Former subsections (f) and (g) have been renumbered to new subsections (d) and (f) respectively but retain all their original provisions.