INITIAL STATEMENT OF REASONS
TITLE 22, CALIFORNIA CODE OF REGULATIONS

PROPOSED SECTION 12900
USE OF SPECIFIED METHODS OF DETECTION AND ANALYSIS FOR LISTED CHEMICALS FOR VOLUNTARY COMPLIANCE TESTING
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 originally adopted in 1989 to clarify and make more specific what is meant by "any detectable amount" in Proposition 65. 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 as originally adopted, particularly in the context of consumer products exposures. Recent court 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 had 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. In response, OEHHA proposed amendments to Section 12901 it believed conformed more closely with the California Evidence Code and case law in a Notice of Proposed Rulemaking issued on June 4, 2004. Comments on the proposal found that the amendments did not respond to the regulated community's needs nor add clarity to the statute and thus, garnered minimal support. Rather than to move forward with the June 4 proposal, OEHHA determined the best approach was to repeal Section 12901 in its entirety, an expressed alternative within the proposal. A 15-day Notice of Intent to Repeal Section 12901 was issued on

[1] All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

September 17, 2004. The rulemaking package repealing Section 12901 was submitted to the Office of Administrative Law on February 8, 2005 and is currently under review for approval.

In addition to the required 15-day notice period on the Notice of Intent to Repeal Section 12901, OEHHA took the additional step of inviting all those who commented on the September 17 Notice 12901, to meet with the Director and other staff from OEHHA in order to discuss the concerns that were raised in the written comments and to develop a reasonable solution. The stakeholder meeting was held in Sacramento on November 15, 2004. More than a dozen individuals attended the meeting representing a variety of interested parties including the metals industry, grocery manufacturers, environmental groups and the Attorney General's Office. The group met for two hours to discuss the various issues raised in the written comments. Following the meeting, OEHHA drafted a proposed regulation, more limited in scope than the existing regulation that could replace Section 12901 if it were repealed. OEHHA attempted to address the key issues raised by the various stakeholders in the November 15 meeting. OEHHA circulated the "unofficial" working draft of a new regulation to the individuals who had attended the meeting. The draft was acceptable to some of the meeting participants, with minor changes, and was rejected entirely by others. While not reaching the point of consensus, the meeting with stakeholders produced a new, more focused regulation, which OEHHA is proposing as a new Section 12900 that it believes will meet the basic needs of the various stakeholders, further the purposes of the Act, and be consistent with California evidentiary law.

In summary, the proposed Section 12900 is intended to accomplish the following goals that were identified at the stakeholder meeting noted above:

1. Expressly provide business with the ability to rely on test results they have obtained using analytical test methods already in use or that are required for compliance with other regulatory programs to show that they are in compliance with Proposition 65.
2. Identify the primary governmental sources for test methodologies that could be used by businesses for compliance testing.
3. Require businesses to use the most sensitive of available testing methodologies listed in item number 2.
4. Require businesses to follow all testing procedures and protocols for the selected method in order to invoke the affirmative defense offered by the regulation.
5. Provide that any admissible evidence could be offered in litigation to prove or disprove an allegation that a prohibited discharge, release or exposure had occurred, except for situations in which an appropriate method of detection and analysis has been applied and the chemical has not been detected in a given discharge, release or exposure.
6. Provide that the regulation does not affect the normal burdens of proof for plaintiffs or defendants in Proposition 65 enforcement cases.
7. Specifically provide that an alleged discharge, release or exposure cannot be proven solely through the application of a scientific presumption that a chemical is present at one-half the detection limit for a particular testing method.
8. Specify that the new regulation is effective immediately and should be applied to any enforcement action pending at the time it is adopted.

OEHHA believes that the proposed regulation accomplishes these goals. Each provision of the proposed regulation is discussed in greater detail 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 relied on oral and written comments from interested parties that were offered as part of the regulatory action on Section 12901. These items are included in the rulemaking record for both Section 12901 and this proposed regulation. 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

An alternative proposal for amending Section 12901 of the regulations was offered by certain business representatives, but OEHHA believes that the alternative amendments to Section 12901 would increase the complexity of the regulation and would likely not further the purposes of the Act. Moreover, OEHHA believes that the alternative would be more burdensome to the affected parties than the proposed action. OEHHA therefore chose to initiate a new rulemaking action that proposes a new Section 12900 be added to Title 22 that addresses the core issues raised by the interested parties in the rulemaking action on Section 12901, without further attempting to amend that regulation.

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 address core needs for clarity and certainty that were specifically requested by regulated businesses. The proposed regulatory action does not impose any new requirement upon any business, including small business. Instead, it provides for an affirmative defense, under specified circumstances, to allegations that a person doing business may have violated the Act.

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 is intended to provide an

affirmative defense, under specified circumstances, to allegations that a person doing business may have violated the Act.

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 Section 12900

The purpose of new Section 12900 is two-fold. First, the regulation will provide a "safe harbor" for persons subject to the discharge prohibition or warning requirements of the Act, by allowing those businesses that conduct tests of their discharges, releases or exposures to rely on the results of those tests, in certain circumstances, as a defense to an allegation that they are violating the discharge or warning provisions of the Act. Second, the regulation is intended to encourage businesses to pro-actively test their discharges, emissions or releases and their products for the presence of listed chemicals. This new regulation is intended to be narrowly focused on these two objectives and does not attempt to address other scientific and evidentiary issues that may arise in a particular enforcement action. When OEHHA proposed repeal of Section 12901 of the Proposition 65 regulations, those opposing the repeal expressed that these two issues needed to be addressed through a regulatory action in order to provide business with a level of certainty and predictability they felt would be lost through repeal of Section 12901, and in order to encourage business to continue with their Proposition 65 compliance programs.

It is important to note that this regulation would not apply to circumstances in which a listed chemical is detected in the discharge, release or exposure. In that case, the person responsible for the discharge, release or exposure would need to look to other portions of the regulations to determine whether the discharge or release contained a significant amount of the chemical or whether an exposure creates a risk significant enough to require a warning (see for example sections 12401-12504 of the regulations concerning discharges and sections 12701-12821 concerning levels of exposure to listed chemicals.)

The specific purpose for each of the provisions of the new regulation is discussed below:

Subsection (a) of the proposed regulation provides that no prohibited discharge, release or exposure to a listed chemical will be deemed to have occurred if the person otherwise responsible for the discharge, release or exposure, can show that he or she has properly conducted an appropriate test using a method of detection and analysis that meets the criteria in Section 12900(b) and determined, based upon the test results that the chemical is not present. This would allow a person otherwise responsible for a discharge release or exposure to a listed chemical to avoid liability for alleged violations of the discharge prohibition or warning requirements under the Act by providing test results showing that the chemical(s) at issue had not been detected, thus avoiding protracted and potentially expensive litigation in those situations in which the person routinely conducts such testing and consistently obtains test results that show the chemical is not detected.

Subsection (a) requires that in order to rely on the results of a particular test, the person otherwise responsible for the discharge, release or exposure, must have conducted a test using a method of detection and analysis that is described later in the regulation. The test must be in the same medium (i.e. air, water, soil, food) in which the alleged discharge, release or exposure is alleged to have occurred. In the event such testing has occurred more than once over the year prior to the notice or complaint concerning an alleged discharge release or exposure, each and every test result must show that the chemical at issue is not present. This provision is included in order to avoid situations in which more than one test has been conducted and one or more of these tests show that the chemical is present in the discharge, release or exposure. In that case, the person responsible for the discharge release or exposure would not be allowed to rely on a test result test showing the chemical had not been detected to avoid liability, if in fact other test results during the same time period showed the chemical was present.

Subsection (b) provides a definition for the term "method of detection and analysis" which is used throughout the regulation. The purpose of this provision is to require that the test methodology and procedure used by a business to determine whether a listed chemical is present in a discharge, release or exposure for which they are responsible, be one that is appropriate for the particular factual situation. For example, if lead may be present in a discharge of water, then the test method and analysis used to detect it should be one that is intended and designed to measure lead levels in water. The same method may not be appropriate to measure the level of lead in a food product.

Subsection (b) specifies that in order to rely on the test results from a given method of detection and analysis for purposes of Section 12900, the method of detection and analysis must be one that is required or sanctioned, as evidenced by the issuance of a permit, regulation, guideline or other official action that specifies or requires the use of the method of detection and analysis for a chemical in a medium. For example, a local air district may require the use of a specified test method and procedure for chemical air emissions from a particular site. Therefore, a regulated business that uses the test method required or specified by its permit for detecting and measuring a chemical could use test results showing that the chemical was not detected for purposes of this section. The subsection also identifies the federal, state and local agencies that may require or sanction a method of detection and analysis that can be used for purposes of this section.

Finally, subsection (b) states that a method of detection and analysis may be required or sanctioned by an agency if it requires or specifies a particular method for a particular chemical in a permit, regulation, guidance document or other official action on the part of the agency. This provision was included in this regulation to help clarify the terms "required or sanctioned."

Subsection (c) of the proposed regulation provides that where more than one method of detection and analysis exists that meets the criteria in subsection (b) then the person doing business may only rely on the test results of the most sensitive method. The person doing business, therefore, must determine which of the federal, state and local agencies listed in subsection (b) have jurisdiction over the business itself and the chemical at issue, it must then determine whether a method of detection and analysis is required or sanctioned by any one of those agencies, and then it must use the most sensitive test among those when determining compliance under the Act if the business wishes to take advantage of the affirmative defense provided in subsection (a) of the proposed

regulation. This provision is included to ensure that a person doing business uses the most accurate and up-to-date methods of detection and analysis available that meet the criteria in subsection (b).

Subsection (d) provides that a person doing business has the burden of proving the all the elements of and the factual basis for the affirmative defense that is provided in subsection (a), including proof that in all instances in which the method of detection and analysis was used, that all required protocols and procedures have been followed. This subsection is not intended to change the normal burdens of proof in a civil action. The subsection merely states what OEHHA believes is the existing state of the law.

Subsection (e) provides that the proposed regulation is not intended to affect the ability of a plaintiff or defendant to prove or disprove that a prohibited discharge, release or exposure has or is occurring, except that the defendant may assert the affirmative defense contained in subsection (a) if all the criteria in the proposed regulation has been met and the person doing business has a test result or results that show that no amount of the chemical in question has been detected in the discharge, release or exposure that is at issue in the enforcement action. Subsection (e) also provides that the scientific assumption that a chemical is present at half the limit of detection for that method of detection and analysis may not be the only evidence offered to prove that a listed chemical is present in a discharge, release or exposure. This provision is included to avoid a situation in which a person doing business is required to defend an action based solely on a scientific presumption concerning a testing procedure. Additional evidence should be required in such situations and would be necessary in any event to prove that the discharge or release consisted of a significant amount of the chemical in question, or that the alleged exposure was to an amount of the chemical that would pose a significant risk of cancer or reproductive harm.

Subsection (f) explains that the provisions of the proposed regulation are not mandatory and that they should not be construed to require that any person in the course of doing business conduct compliance testing. Use of the proposed regulation is voluntary.

Subsection (g) is included to provide that the proposed regulation will become effective immediately upon its adoption and will apply to any enforcement action pending at that time. This is intended to encourage businesses subject to the Act to conduct testing and to provide them with the opportunity to assert the affirmative defense provided at the earliest opportunity.