INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED AMENDMENTS TO SECTIONS 25801, 25803 AND 25805
NO OBSERVABLE EFFECT LEVELS
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,[1] was enacted as a voters' initiative on November 4, 1986. 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.[2] 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 Act provides exceptions to these requirements in certain circumstances. For chemicals known to cause reproductive toxicity, an exemption to the warning and discharge provisions is provided if there would be no observable effect given an exposure one thousand (1,000) times the level of exposure in question.

OEHHA is proposing amendments to Sections 25801, 25803, and 25805 of the California Code of Regulations, Title 27.[3] These sections, which fall within Article 8 of the Proposition 65 implementing regulations, set out the procedures and criteria for determining an exposure level where there would be no observable effect. This level divided by 1000 results in a maximum allowable dose level (MADL). The MADL is the highest level of exposure at which a warning is not required or a discharge not prohibited.

Section 25801(a) provides the scientific standard that is applied in determining the "no observable effect level," namely that the determination "be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing." However, it also provides that: "[n]othing in this article shall preclude a person from using evidence, standards, assessment methodologies, principles, assumptions or levels not described in this article to

[1] Codified at Health and Safety Code section 25249.5 et. seq., hereafter referred to as "Proposition 65" or "The Act"
[2] Health and Safety Code section 25249.12(a)
[3] All further references are to sections of Title 27, of the California Code of Regulations, unless otherwise noted.

establish that a level of exposure has no observable effect at one thousand times the level in question." Thus a defendant in an enforcement action may request that a court adopt an alternative "no observable effect level" to that established in regulation. This regulatory proposal seeks to remove that provision in order to establish consistently-applied standards in Proposition 65 enforcement. The current provision gives equal status to guidance levels developed by OEHHA that are established in regulation and those developed by other parties using alternative methods that meet the minimum scientific standard. OEHHA adopts MADLs through an open, public regulatory process that allows any member of the public to provide input into the process. On the other hand, MADLs developed by a court are not. These court adopted levels also only apply to the parties involved in the particular action so they are not uniformly applied.

Similarly, if OEHHA has not adopted a safe harbor level, a court cannot simply apply the procedures set out in the regulation to determine a level. Instead, a court is asked to determine whether a proposed alternative approach and the resulting level are appropriate in a given situation. A court would be required to make a factual determination as to whether the minimum scientific standard has been met and whether the methods used are appropriate without the benefit of an open, public process as is required under the Administrative Procedure Act.

OEHHA is proposing this change to establish that the methods and procedures, as well as the levels adopted through their application will be the standards in all situations, thus bringing clarity and consistency to this issue.

A sentence has also been added to Section 25805(a) to clarify that the values provided in that section are the maximum allowable dose levels for evaluating Proposition 65 exposures.

Section 25801(c) defines a no observable effect level, or "NOEL," to mean the maximum dose level at which a chemical has no effect. The more specific term "dose" is currently described in two different ways in the article – first, as an amount per bodyweight (units milligram per kilogram) in section 25803(b)(1) and second, as an amount in units milligrams in section 25803(a)(2). To remove this inconsistency, section 25801(c) and 25803 (b)(1) will use the more general term "maximum" or "highest" exposure level for the "no observed effect level" and reserve the term "dose" for amounts such as the "maximum allowable dose level;" that is, the "MADL."

Section 25803(a)(2), adopted in 1989, emphasizes a practice used at the time to establish drinking water health advisories, air reference exposure levels, clean-up levels at hazardous waste sites and other regulatory guidance levels. The practice was widely used by expert scientific organizations and regulatory agencies, including the National Academy of Sciences, U.S. Environmental Protection Agency (U.S. EPA) and the California Department of Health Services. The practice involved selecting the empirical no observed effect level – the highest exposure level in a study observed to have no effect - as the point of departure. This was the most common accepted

procedure for establishing a regulatory standard in 1989.

The current regulation explains that the default procedures in the regulation are to be used "in the absence of principles or assumptions scientifically more appropriate based upon the available data." Thus, the regulation takes into account the fact that other procedures may be more scientifically appropriate for certain data sets. One such procedure that has become commonly accepted is the benchmark dose methodology. This is currently the preferred method for establishing guidance levels. In California, this method is used to establish reference exposure levels for air pollutants and public health goals for drinking water. The U.S. EPA and the National Academy of Sciences (Science and Decisions: Advancing Risk Assessment 2009) have accepted this method. The proposed change to Section 25803(a)(2) of the regulation specifically recognizes the benchmark dose methodology as an acceptable means of deriving a no observed effect level. This change does not preclude use of other generally accepted scientific methodologies, if they are more appropriate to the data in question.

OEHHA is also proposing to amend Section 25803(a)(2) to give guidance on the valuation of a NOEL in the case where the exposure may be reported as a range rather than a single value, as occurs with epidemiology studies and certain animal studies.

The proposed changes to Section 25803(a)(3) and 25803(a)(8) are corrections of terminology and revisions of phrasing to more clearly express the intent of the regulation.

The proposed change to Section 25803(b) would provide default body weights for children and infants. The current regulations specify default bodyweights to be used in calculation of the MADL: When the MADL is based on female or male reproductive toxicity, bodyweights of 58 and 70 kg, respectively, are identified as the defaults. These bodyweight are relevant to reproductive effects occurring in adults, where the relevant period of exposure is in adulthood. In some instances, however, female or male reproductive toxicity can result from exposures occurring after birth but prior to adulthood. In such cases, default bodyweights relevant to the developmental period during which the exposure resulting in reproductive toxicity occurred are required. The revision to Section 25803(b) provides such age-specific default bodyweights. OEHHA also proposes revisions to this Section to clarify that the earlier provision in Section 25803(a) governing "principles or assumptions scientifically more appropriate based upon the available data" is also applicable to this Section.

NECESSITY

Subsections 25801(a) and 25805(a) - The current regulation allows private parties to challenge or establish a regulatory value for a given chemical and therefore leaves it to the courts to resolve questions on a case-by-case basis. Such questions are best resolved in an open public forum such occurs in a rule making which allows all interested parties to participate and insures certainty and consistency for all parties

since the resulting standards will be generally applicable.

Subsection 25803(a)(2) – The procedures specified in Section 25803 have always explicitly been defaults, with the use of principles or assumptions scientifically more appropriate based upon the available data specifically permitted. Despite this explicit authorization of the use of alternative procedures, it has been argued successfully that use of the benchmark dose methodology, for example, is not permitted under the regulation. Since the benchmark dose approach is now generally accepted, and scientifically preferred where data permit, as a methodology for quantitative risk assessment, this proposed change will clarify the original intent of the regulation and allow for the most current and appropriate methodology to be applied.

Subsection 25803(b) – In order to calculate appropriately protective levels at which warnings must be provided for certain chemicals that cause reproductive toxicity, OEHHA has had to use body weights for males and females that differ from the default weights currently specified in the regulation. This is because the reproductive effects resulted from exposures prior to adulthood, with concomitantly lower body weight at the time of exposure. The addition of age-specific default body weights to this Section will clarify the approach to be applied in such cases.

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

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.

All of the changes to the regulations are either clarifications of existing terminology or expansions of specific aspects of provisions already contained in the regulations. An alternative to the proposed revisions would be to retain the existing language of the regulations. OEHHA has rejected that alternative because of the present and future potential misinterpretation of those broad provisions. The proposed revisions will provide more specificity and clarity to the regulations.

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)). The proposed revisions to the regulations may assist small businesses if they have concerns over how MALDs are established, by clarifying some existing provisions of the 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.

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.