INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED AMENDMENTS TO SECTIONS 25801 AND 25803
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 ballot 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 and 25803 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 reproductive effect. This level divided by 1000 results in a maximum allowable dose level (MADL) for a listed chemical. The MADL is the highest level of exposure at which a warning is not required or a discharge not prohibited.

Section 25801(c) defines a no observable effect level, or "NOEL," to mean the maximum dose level at which a chemical has no observable reproductive effect. The more specific term "dose" is currently described in two different ways in the article – first, as an amount per bodyweight (milligram of chemical per kilogram of body weight) in section 25803(a)(1) and second, as an amount of daily exposure (milligrams of

---

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.

chemical per day) in section 25803(b). To remove this inconsistency, the proposed amendments will use the more general term “maximum” or “highest exposure level” in defining the NOEL and reserve the term “dose” for amounts such as 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 for 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 NOEL – the highest exposure level in a study observed to have no effect – as the point of departure. This was the most commonly accepted procedure for establishing a regulatory standard in 1989.

The proposed amendments to the current regulation explain 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 has accepted and uses this method, and established scientific advisory bodies such as its Science Advisory Board have endorsed it. The proposed amendments to existing Section 25803(a)(1) of the regulation specifically recognize the benchmark dose methodology as an acceptable means of establishing a NOEL. 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 existing Section 25803(a)(1) to give guidance on the valuation of a NOEL in the case where a study “reports a range of exposure levels associated with no observed effect,” for example, an air concentration of “1 to 10 parts per million” rather than a single value of “5 parts per million.” Exposures can be reported as ranges in epidemiology studies and animal studies. Methods for determining the NOEL may vary depending on the nature of the data reported. For example, where animals are exposed throughout gestation via drinking water to a given concentration of a chemical, the dose in milligrams per kilogram body weight may vary over the experimental period because of changes in body weight and drinking water intake. In the above example, the default NOEL is the lowest dose level in the range of doses for the animal group showing no adverse effect. Exposure at that level throughout the experimental period can be assumed to have no effect because exposure at or above that level has already occurred on every day, including any days when the conceptus is most sensitive to the chemical, without observable effect. Conversely, it cannot be assumed that a higher level of exposure throughout the experimental period would have had no effect because that could result in a higher

exposure of the conceptus on a day of greater sensitivity.

In a second example, where male reproductive toxicity is the endpoint and there is a range of doses among individuals grouped into assemblages such as quartiles, median dose level for the highest-exposure group showing no observable effect would be the default NOEL. If the median level is not available, the midpoint of the range or, alternatively, the mean dose could be used.

An alternative NOEL may be used if it is more scientifically appropriate than a default. For example, if data are available for individuals in a study, a statistical model could determine a benchmark dose as the NOEL. Or, where the range reflects uncertainty in the exposure level, statistical methods could be used to establish the NOEL. It should be noted that the above discussions are examples, and are not intended to limit the methodologies that can be applied. As science progresses, other methodologies may be developed, validated and accepted. The best generally-accepted methodologies should be used in each situation.

For ease in reading, the amended Section 25803(a)(1) has been divided in two (Section 25803(a)(1) and Section 25803(a)(2)).

The proposed amendments to existing Section 25803(a)(2) and 25803(a)(7) are corrections of terminology and revisions of phrasing to more clearly express the intent of the regulation.

The proposed amendments 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 needed in order to adequately calculate a MADL for these age groups other than adults. The proposed addition to Section 25803(b) provides age-specific default bodyweights.

OEHHA also proposes revisions to Section 25803(b) 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

Subsection 25803(a)(2) – The procedures specified in Section 25803 have always explicitly been defaults that permitted the use of principles or assumptions scientifically more appropriate based upon the available data. Despite this explicit authorization for

the use of alternative procedures, some have interpreted the regulation to prohibit the use of the benchmark dose methodology. Since the benchmark dose approach is now generally accepted (and scientifically preferred where data permit) as a methodology for quantitative risk assessment, this proposed amendment 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 exposures to listed chemicals that cause reproductive toxicity, the existing regulation only expressly identifies default bodyweights for adult males and females. This amendment to the regulation is necessary in order to clarify that the reproductive effects being evaluated resulted from exposures prior to adulthood. With concomitantly lower body weight at the time of exposure, the lower body weights are more appropriate for calculation of the MADL.

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

OEHHA is recognizing a current scientific consensus and did not rely upon any specific 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 proposed amendments to the regulations are either clarifications of existing terminology or explanations of specific aspects of provisions already contained in the regulations. An alternative to the proposed revisions would be to retain the existing regulations. OEHHA has rejected that alternative because clarifying these regulations is in the best interest of both the regulated and enforcement communities and will further the health protective purposes of the Act.

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 since they would clarify 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 amendments to the existing regulation merely clarify the purpose and intent of the existing regulation.

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.