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**INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**DRAFT- PROPOSED NEW SECTIONS 25506 AND 25507
EXPOSURES TO HUMAN AND PLANT NUTRIENTS IN HUMAN FOOD**

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 ballot initiative on November 4, 1986, and is codified as 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 requirement that businesses warn individuals before they knowingly and intentionally expose individuals to chemicals known to cause cancer or reproductive toxicity.

Section 25506 – Exposures to Human Nutrients

Certain chemicals such as vitamins and minerals are necessary to promote human health. Excessive exposures to some of these same chemicals have the potential to cause cancer or adverse reproductive effects. However, the recommended doses for optimum human nutrition sometimes may be high enough to require a Proposition 65 warning. Providing a warning for cancer or reproductive effects for exposures to a listed chemical in a food (including dietary supplements) that is at or below the recommended level necessary for good health does not further the purpose of Proposition 65.

Proposed Section 25506 states that an “exposure” to a listed chemical does not occur for the purposes of the warning requirements of the Act if the exposure results from the consumption of a food, and the exposure does not exceed the level set by OEHHA.¹ OEHHA will determine which listed chemicals to include in this new regulation, giving

¹ Under existing regulations, if the person causing the exposure can prove the chemical is naturally occurring in the product pursuant to Title 27, Cal. Code of Regs., section 25501, no warning is required. This proposed regulation addresses situations in which the nutrient cannot be shown to be naturally-occurring or is intentionally added to a food product.

priority to chemicals that are generally recognized by the scientific community as essential for human health. For example, a listed chemical with a Recommended Daily Allowance established by the National Academies' Institute of Medicine, Food and Nutrition Board may be considered a nutrient for purposes of this section and OEHHA may adopt an exposure level for that chemical.

By establishing the level of a listed chemical that does not constitute an exposure within the meaning of the Act, the proposed regulation would further the purposes of Proposition 65 by ensuring that a warning is not required for beneficial intakes of dietary nutrients contained in conventional foods and dietary supplements. Manufacturers or other businesses would not be required to provide a warning for exposures to listed chemicals in food that are nutrients beneficial to human health, as long as exposure from that food is at a level that will not cause harm. Consumers will benefit from this regulation by not having warnings placed on food items that provide them with levels of listed nutrients that are beneficial to their health.

Section 25507 – Human Exposures to Plant Nutrients

In agriculture, soil is typically depleted of some chemicals that are essential for optimal plant growth. Consequently, growers apply fertilizers to supply these nutrients for food crops. These essential plant nutrients are taken up by the plant and can remain in plant tissue and become constituents of foods consumed by people. Some nutrients that are necessary for healthy plant growth and are present in food may, at certain levels of exposure, have the potential to cause cancer or adverse reproductive effects, and may therefore be listed under Proposition 65. There is the possibility that Proposition 65 warning requirements may be triggered for a nutrient in a plant-based food when the expectation of harm is non-existent. As in the case of food nutrients, it is not in the interest of public health to warn the public away from foods that are beneficial to their health and safe to consume. This regulation is intended to address this concern.

Proposed Section 25507 states that an “exposure” to a listed chemical through consumption of a food does not occur for purposes of the warning requirements of the Act, to the extent that the chemical is present due to its use to promote plant growth² and as long as it is ingested at or below the level set by OEHHA in the regulation. OEHHA will determine which listed chemicals to include in this section, giving priority to chemicals that are generally recognized by the scientific community as essential for healthy plant growth. In order to take advantage of this regulation, the person causing the exposure would have to be able to show that the chemical was added to the soil or to other growing media in an amount necessary to maintain healthy plant development.

NECESSITY

² Under existing regulations, if the person causing the exposure can prove the chemical is naturally occurring in the product pursuant to Title 27, Cal. Code of Regs., section 25501, no warning is required. This proposed regulation addresses situations in which the nutrient cannot be shown to be naturally-occurring or is intentionally added to a food crop.

Section 25506

Nutrients such as vitamins and minerals are sometimes intentionally added to conventional food products, or marketed in dietary supplements. They can be added to food products to help satisfy nutritional requirements as defined by the National Academies' Institute of Medicine, Food and Nutrition Board's Recommended Dietary Allowances (RDAs) or sold as health supplements at a variety of different doses, sometimes many fold above the RDA. The current statutory and regulatory structure of Proposition 65 does not differentiate between exposures to nutrients and exposures to other chemicals. Therefore, a business may have to provide a Proposition 65 warning for a listed chemical that is a nutrient at an exposure level that is actually beneficial to human health. It is contrary to the health-protective intent of Proposition 65 to require a warning for food nutrients at such exposure levels, as it could discourage the consumption of healthy foods and diminish the overall credibility of Proposition 65 warnings for chemical exposures through foods.

OEHHA is considering the listing under Proposition 65 of certain chemicals that are necessary for human health at recommended levels, but at higher levels appear to have the potential to cause reproductive toxicity. As a hypothetical example, a chemical could have an RDA of 800 micrograms per day established by the Institute of Medicine's (IOM) Food and Nutrition Board. The IOM may also have established a Tolerable Upper Intake Level for the chemical of 4,000 micrograms per day, indicating that this is the "maximum level of daily nutrient that is likely to pose no risk of adverse effects" with a notation of developmental toxicity as an outcome of concern. Under Proposition 65, businesses do not have to provide a warning if their product causes an "exposure [that] will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity." However, if this showing could not be made, a warning would be required. In this hypothetical example, exposures above 4 micrograms per day would require warning. This is because the maximum no-adverse-effect-level is 4,000 micrograms per day, and dividing this by 1,000 results in a maximum daily exposure level of 4 micrograms per day. However, the RDA for this chemical is 800 micrograms, a factor of 200 greater than the level that would require warning. Thus a warning for developmental toxicity would be required for virtually every supplement providing this nutrient,³ since in order to have a human health benefit, a dose significantly greater than 4 micrograms per day – that is 0.5% of the RDA - would be needed.

Section 25507

Fertilizers can contain one or more essential plant nutrients that are added to the soil or applied to plant foliage for the purpose of supplementing the plant's nutrient needs. A deficiency of any one nutrient might limit plant growth or crop development. In the cultivation of food crops, essential plant nutrients that are insufficient in the soil or other growing media are added by the grower through fertilizers. These nutrients are absorbed

³ If the person causing the exposure can prove the chemical is naturally occurring in the product pursuant to Title 27, Cal. Code of Regs., section 25501, no warning is required.

by the plants, and they can be retained in plant components that are consumed by humans. OEHHA is considering the Proposition 65 listing of certain chemicals that are sometimes added to the soil to supplement the nutrient needs of plants cultivated for human consumption, and which appear to have the potential to cause reproductive toxicity. If, as in the example given above for human nutrients, exposures to a listed plant nutrient through human consumption of a plant-based food trigger the warning requirements of the Act at levels that may be considered safe, consumers could be discouraged from consuming healthy and nutritious foods because they believe the foods pose a risk when in fact they do not.

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

OEHHA reviewed summaries of the of the April 18, 2008, pre-regulatory workshop comments (discussed below). Except for a review of the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine, 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.

On April 18, 2008, a public pre-regulatory workshop was held in Sacramento, California. Proposed draft regulatory language was presented, and comments were invited. At the workshop the following possible regulatory language was used to help explain the regulatory concept and to initiate and focus the discussion:

“Section 1250X. Exposure to Beneficial Nutrients in a Food

(a) Human consumption of a food shall not constitute an “exposure” for purposes of Section 25249.6 of the Act to a listed chemical in a food if the person causing the exposure to the chemical can show that the chemical is a nutrient that is beneficial to human health and that the total amount of the chemical consumed in a food, whether naturally occurring, intentionally added to the food, or otherwise present, does not exceed the level established in subsection (c).

(b) For purposes of this section, a chemical is beneficial to human health if a daily value or allowance has been established for the chemical or compound by the Food and Nutrition Board of the Institute of Medicine, National Academies.

(c) This section applies only to exposures that do not exceed the Recommended Daily Allowance (RDA) established in the Dietary Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine, National Academies, current edition, if one is established. If no RDA is established, this section applies only to exposures that do not exceed 20 percent (20%) of the Tolerable Upper Intake Level established in the Dietary

Reference Intake Tables of the Food and Nutrition Board of the Institute of Medicine, National Academies, current editions

The original regulatory concept was to set the level for human nutrients at the Institute of Medicine's RDA, or a fixed 20 percent fraction of the Institute's Tolerable Upper Intake. OEHHA received written and oral comments that criticized the 20 percent criterion as arbitrary, and a number of commenters expressed concern that warnings could still be required for exposures beneficial for human health that happen to exceed 20 percent of the Upper Intake Level. One recommendation coming out of the pre-regulatory process was that the levels established by this regulation be based on the evidence for adverse effect and benefit for each individual chemical nutrient, rather than being based on a generic, automatic process. OEHHA accepts this recommendation. The new draft regulatory language for Sections 25506 and 25507 includes separately established levels for each nutrient.

To separately establish levels for these chemicals, OEHHA reviewed sources of dietary recommendations for the daily consumption of food nutrients. OEHHA has determined that the RDAs of the Institute of Medicine's Food and Nutrition Board along with supporting documentation are authoritative sources for nutritional requirements. There is an extensive volume of scientific literature available on nutritional requirements. This scientific literature will be reviewed in establishing levels in each of the proposed regulations. The Institute of Medicine Food and Nutrition Board also provides numerical values for no observed adverse effects for nutrients, and evidence supporting these levels. This authoritative information can be taken into account in establishing the "Maximum Daily Exposure from a Food," or MDEF for these regulations. However, because the evidence supporting these values can be for health effects not covered by Proposition 65 such as neurotoxicity, liver damage, or renal failure, these values do not directly translate into possible MDEFs, but can inform their development.

Existing regulations (Sections 25701(a) and 25801(a)) provide that the determination of a "safe harbor" level of exposure to a chemical that is known to the state to cause cancer or reproductive toxicity shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the State to cause cancer or reproductive toxicity. The proposed regulation is entirely consistent with and would not change this requirement.

In developing proposals for regulatory MDEFs for particular human and plant nutrients, OEHHA may opt at an early stage to request input from the public on the degree that a particular chemical may be considered a nutrient, and on possible MDEFs, along with supporting scientific documentation.

With regard to evaluating whether a chemical is essential for healthy food crops, there appears to be no official listing by the U.S. Department of Agriculture for essential plant nutrients or the levels of nutrients that are necessary for normal plant development. However, various organizations provide guidance to growers. For example, the California Fertilizer Association's *Western Fertilizer Handbook* and the North Carolina

Department of Agriculture & Consumer Service's publication *Essential Plant Nutrients* provide such guidance. There is also a large amount of research available on individual plant nutrients, performed at many academic and technical institutions. This information can be reviewed by OEHHA in evaluating whether a substance is a plant nutrient and in determining whether an amount in a food is present because it was necessary for the growth of the plant constituents in that food.

Another recommendation was that the exposure levels for each chemical nutrient be addressed at the time these chemicals come under consideration for listing under Proposition 65. A level will not be finally adopted for any chemical until it has been listed under the Act.

Another recommendation was that the regulatory level of each nutrient take into consideration specific forms of the chemical, for example the specific compound that carries the nutrient, and population groups that would be exposed to the nutrient. OEHHA agrees that these considerations are important and notes that the regulatory framework proposed for human and plant nutrients of Sections 25506 and 25507 accommodates this approach.

Finally, it was suggested that OEHHA simply issue a blanket exemption from the Proposition 65 warning requirements for all exposures to all chemicals considered to be nutrients. OEHHA believes this suggestion is beyond OEHHA's statutory authority and will not take the suggested action.

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 exempt determined levels of exposure to listed chemicals, an action that was specifically requested by regulated businesses. The proposed regulatory action does not impose any new requirement upon any business, including small businesses. Instead, it provides for an affirmative defense, under specified circumstances, to allegations that a person doing business may have failed to provide the required warning.

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 will provide an affirmative defense, under specified circumstances, to allegations that a person doing business may have failed to provide the required warning.

**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.