INITIAL STATEMENT OF REASONS
TITLE 22, CALIFORNIA CODE OF REGULATIONS

SECTION 12705(e). SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK

The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65[1] (hereinafter referred to as "the Act"), prohibits a person in the course of doing business from knowingly and intentionally exposing an individual to a chemical that has been listed as known to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code section 25249.6). The Act also prohibits such persons from knowingly discharging a listed chemical into water or onto or into land where such chemicals pass or probably will pass into a source of drinking water (Health and Safety Code section 25249.5).

For chemicals known to the State to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure poses no significant risk, or that the exposure would not cause any significant amount of the discharged or released chemical to enter any source of drinking water, and which otherwise complies with all applicable laws and requirements (Health and Safety Code sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk can be made using regulations that have previously been adopted by the Office of Environmental Health Hazard Assessment (OEHHA) (Title 22, California Code of Regulations, Section 12701-12721[2]). Section 12703(b) provides for the use of an alternative risk level in certain situations.

Pursuant to Section 12703(b), because OEHHA has determined that breads and cereals are important sources of dietary fiber and nutrients and cooking such foods is necessary in order to render them palatable, sound considerations of public health support the establishment of an alternative risk level for acrylamide in breads and cereals. Acrylamide in grain-based breads and cereals that comply with all relevant federal standards (including Title 21, Code of Federal Regulations (CFR) section 104.20) will be considered to pose no significant risk of cancer if 1) consumption of the food poses a risk from acrylamide calculated to result in no more than one excess case of cancer in an exposed population of 10,000, assuming lifetime exposure at the level in question; or 2) the concentration of acrylamide in the food is less than 200 ppb. OEHHA proposes to adopt subsection (e) to Section 12705.

Section 12705(e)

In July 2003, OEHHA received comments from the federal Food and Drug Administration (U.S. FDA) concerning OEHHA's proposed work plan for acrylamide in foods. U.S. FDA expressed concern that setting a level for acrylamide that would be applicable to food could negatively impact public health by causing consumers to avoid certain healthy foods. Specifically, U.S. FDA stated that "[c]onsumers who avoid eating some of these foods, such as breads and cereals, may encounter greater risks because they would have less fiber and other

[1] Health and Safety Code section 25249.5 et seq.
[2] All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

beneficial nutrients in their diets." U.S. FDA currently recommends that consumers eat 6-11 servings of grain products per day.

OEHHA is aware of the public health importance of promoting healthy eating choices, and the important role a balanced diet plays in promoting and maintaining optimal health. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats, maintenance of desirable body weight, and increased consumption of fruits and vegetables, and grain products. For example, the U.S. FDA recommends that individuals eat a balanced diet, choosing a variety of foods low in trans fat and saturated fat, and rich in high-fiber grains, fruits and vegetables. Breads and cereals are grain-based foods that generally have a high-fiber content, and are generally low in trans fat and saturated fat. In addition, whole grain and enriched and fortified breads and cereals are a good source of vitamins and other important nutrients. OEHHA also notes that breads and cereals are dietary staples for most of the U.S. population.

Acrylamide is present in breads and cereals and OEHHA estimated acrylamide intake from these foods using U.S. FDA measurements of acrylamide levels and food consumption survey data (OEHHA, 2005). With regard to breads, as explained in more detail in the supporting technical document, OEHHA believes that the acrylamide intake of average eaters of white breads does not exceed the no significant risk level (NSRL) of 1.0 µg/d. (The NSRL is defined as the daily intake associated with a cancer risk of approximately one in 100,000 (i.e., 1×10^{-5} cancer risk)). However, for average eaters of whole grain and wheat breads it is less clear whether daily acrylamide intake is less than the NSRL.

OEHHA calculates that consumption of breads with acrylamide content of 20 ppb corresponds approximately to a 1×10^{-5} cancer risk. Therefore, OEHHA has determined that breads with acrylamide content of 200 ppb will likely result in acrylamide intakes with a cancer risk level of approximately one in 10,000 (i.e.1×10^{-4} cancer risk.) These levels include both toasted and untoasted breads.

Consumption of ready-to-eat cereals with acrylamide content of 20 ppb will likely result in approximately a 1×10^{-5} cancer risk. OEHHA has determined that the acrylamide intake of the average eaters of most cereals exceeds this risk. OEHHA calculates that ready-to-eat cereals with acrylamide content of 200 ppb correspond to acrylamide intakes associated with a 1×10^{-4} cancer risk.

Given the recognized nutritional health benefits associated with consumption of breads and cereals, OEHHA proposes that an alternative cancer risk level of 1×10^{-4} for acrylamide in breads and cereals be applied, based on significant public health considerations regarding the consumption of these foods. Thus, breads and cereals with acrylamide content below 200 ppb, which corresponds to a cancer risk level not greater than 1×10^{-4}, will not require warning for acrylamide as causing cancer under Proposition 65.

The provisions of Section 12703(b) allow an alternative risk level for Proposition 65 carcinogens in foods where "sound considerations of public health support an alternative level." This allowance can be applied to acrylamide in breads and cereals. Breads and cereals are grain-

based foods that generally have a high-fiber content. Adequate intake of dietary fiber is widely recognized as an important part of daily nutrition. Recommendations to consume a high-fiber diet are based on several potential health benefits, such as the observations that increased intake of dietary fiber is associated with decreased risk of stroke and heart attack, decreased blood cholesterol levels, improved control of blood sugar levels in diabetics, and reduced risk of colorectal cancer. With regard to colorectal cancer risk and dietary fiber intake, the American Gastroenterological Association (2000) stated, "Currently available evidence from epidemiological, animal, and intervention studies does not unequivocally support the protective role of fiber against development of CRC [colorectal cancer]. However, when the whole body of evidence from these studies is analyzed critically, the overall conclusion supports an inverse association between dietary fiber intake and CRC risk." More recently, a study of 519,978 individuals from ten European countries found that individuals consuming 35 grams of dietary fiber per day had their colorectal cancer risk reduced by 40%, compared with individuals consuming only 15 grams of dietary fiber per day (Bingham et al., 2003). A second recent study compared the fiber intake of 33,971 individuals from the U.S. without distal colon polyps to 3,591 individuals from the U.S. with at least one adenoma of the distal colon, and found that intake of greater than 30 grams of dietary fiber reduced the risk of distal colon adenoma by 27% (Peters et al., 2003). A third study by Mai et al. (2003) did not find a protective role for dietary fiber intake associated with colorectal cancer risk among U.S. women, although women with the highest dietary fiber intake in this study had a much lower average daily intake (16.7 grams) than that associated with reduced cancer risk in the studies by Bingham et al. (2003) and Peters et al. (2003).

Whole grain or enriched breads and cereals are also rich in vitamins and other nutrients important for good health. Folate is one example of a vitamin present in both whole grain and enriched breads and cereals. Folate is a B vitamin needed both before and in the first weeks of pregnancy to reduce the risk of certain serious and common birth defects such as neural tube defects.

Cooking breads and cereals is necessary to render the foods palatable. Although adjustments to cooking temperatures and methods may help lower the levels of acrylamide in foods, research on this aspect of the issue has not been completed. It may be possible in the future for the U.S. FDA or another agency to develop guidance concerning appropriate methods for reducing acrylamide formation in cooked foods. At this time, however, OEHHA has determined that the provisions of Section 12703(b) allowing for the establishment of an alternative risk level for certain chemicals where sound considerations of public health warrant such action as, for example, where the chemical is formed through "cooking necessary to render the food palatable" have been met for breads and cereals.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES

An alternative to the proposed regulatory action would be to apply the NSRL of 1 μg/day to breads and cereals. Doing so would require warnings for the presence of acrylamide as a chemical known to the state to cause cancer in breads and cereals containing acrylamide at levels

of 20 ppb or higher. Given the recognized health benefits associated with consumption of high-fiber grain products, OEHHA has proposed an alternative risk level for acrylamide in breads and cereals, which are generally high in fiber, vitamins, or other nutrients. The proposed alternative risk level is one excess case of cancer in an exposed population of 10,000, which would result in no need to warn for the presence of acrylamide as a chemical known to the state to cause cancer, in breads and cereals containing acrylamide at levels less than 200 ppb.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES

The proposed regulatory action will not adversely impact small business. The proposed regulation identifies levels below which businesses are exempt from Proposition 65 warning requirements and the discharge prohibition. It reduces the Proposition 65 requirements on certain businesses, such as small bakeries and markets.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

The regulation 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 regulation identifies an alternative risk level for acrylamide in breads and cereals below which businesses are exempt from Proposition 65 cancer warning requirements and the discharge prohibition. The costs or expenses incurred by businesses to comply with the proposed regulation should be considerably lower than would be the case in the absence of the alternative risk level proposed in this regulation. Further, the proposed regulatory action makes it easier for affected businesses to comply with Proposition 65 by helping them determine when the warning requirements may apply.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF 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.

REFERENCES

American Gastroenterological Association (2000). American Gastroenterological Association medical position statement: impact of dietary fiber on colon cancer occurrence. *Gastroenterol* 118(6):1233-4.

Bingham SA, Day NE, Luben R, Ferrari P, Slimani N, Norat T et al. (2003). Dietary fibre in food and protection against colorectal cancer in the European Prospective Investigation into Cancer and Nutrition (EPIC): an observational study. *Lancet* **361**:1496-1501.

Mai V, Flood A, Peters U, Lacey JV, Schairer C, Schatzkin A (2003). Dietary fibre and risk of colorectal cancer in the Breast Cancer Detection Demonstration Project (BCDDP) follow-up cohort. *Int J Epidemiol* **32**:234-239.

Office of Environmental Health Hazard Assessment (OEHHA, 2005). Characterization of Acrylamide Intake from Certain Foods. California Environmental Protection Agency, OEHHA, Oakland, CA. available at: www.oehha.ca.gov

Peters U, Sinha R, Chatterjee N, Subar AF, Ziegler RG, Kulldorff M et al. (2003). Dietary fibre and colorectal adenoma in a colorectal cancer early detection programme. *Lancet* **361**:1491-1495.