



April 20, 2022

Office of Environmental Health Hazard Assessment

Re: **Notice Second 15-Day Modification of Text for Proposed Amendment: Clear and Reasonable Warnings – Short Form**

<https://oehha.ca.gov/proposition-65/cnr/notice-second-15-day-modification-text-proposed-amendment-clear-and-reasonable>

Dear Director Zeise:

I am providing these comments on behalf of the Almond Alliance of California, in cooperation with the Almond Board of California. The Almond Alliance is an association which serves as the almond industry's advocacy voice, promoting the interests of its members. The Almond Board of California administers the almond industry's grower-enacted federal marketing order. Under the supervision of USDA, the Almond Board represents the 7,600 growers and 100+ processors of almonds in California.

**The almond industry is concerned over the implications that the Office of Environmental Health Hazard Assessment's (OEHHA) Notice Second 15-Day Modification of Text for Proposed Amendment ("the Notice") will have for almonds.**

OEHHA has recognized the challenges industries, including almonds, face to meet Proposition 65 requirements. Almonds are widely recognized by regulatory, scientific and health organizations as a **wholesome and healthy food** which is included in numerous consumer diet recommendations and federal dietary guidelines. While implementing Proposition 65, OEHHA has long recognized that food is different and therefore requires balancing the many requirements of the law with the need to provide ongoing nutrition. The agency further understands that chemicals are unavoidably created by cooking or heat processing and many require special treatment under the regulations. Unlike other consumer products subject to Proposition 65, the purchase and consumption of food is universally necessary for human health.

We believe the Short Form does not address the more significant consideration – the obligation to warn consumers in the first place for foods that would have been exempted from such through OEHHA's prior proposed action.

As noted in the Notice:

*The proposed amendments were modified in Section 25602(a)(4) to reference the Section 25601(c) to make clear the existing requirement "to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use".*



Attempts to eliminate or to warn consumers about listed chemicals in cooked and heat-processed foods will have unintended and detrimental public health consequences. This includes creating **consumer confusion** if one government agency is recommending consumption, while another is requiring warnings.

## Background

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The California almond industry represents virtually 100% of almond production in the U.S. California is also the source of over 80% of global production. In 2019, almonds were California's #2 agricultural commodity, with a farmgate value of \$6.09 billion. California almonds support over 104,000 jobs, the majority of which are in the Central Valley which has faced considerable economic pressures due to overall challenges to agriculture, as well as the ongoing COVID-19 battle that has fallen particularly hard on the ability to protect communities and agricultural workers.

Like many plant-based foods, almonds have come to be associated with health and nutrition – a nutrient dense source of protein, fiber, and Vitamin E. FDA granted nuts, including almonds, a qualified health claim in 2003 based on significant scientific research. In the past two decades, 185 papers have been published related to almond nutrition and health. Almonds have been among the foods contained in federal dietary guidelines, recommended for daily consumption in diets to address health issues including cardiovascular disease, diabetes, weight management, etc. There have also been a number of research studies/publications demonstrating positive associations between nut (including almonds) consumption and reduced cancer incidence. One 2016 systematic review and dose-response meta-analysis demonstrated that higher nut intake is associated with reduced risk of total cancer mortality, in addition to mortality from other chronic diseases and infections.

The purpose of Proposition 65 is not to overly burden industry, or confuse consumers related to a food that is recommended by other government bodies for its nutritional benefit and contribution to a healthy lifestyle.

## General Comments

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We recognize that OEHHA's efforts to find a solution to ongoing questions related to acrylamide's presence in many foods and Proposition 65 have been considerable. Obviously, there is no single solution that will fit all situations.

AAC has previously provided OEHHA with comments related to the feasibility of meeting levels established through prior settlements, as well as the economic burdens incurred to adapt practices to control highly variable formation of acrylamide. The Notice will not address the floodgates that will be reopened and the continued enforcement actions that are likely, if there is no alternative. In fact, we anticipate a renewal of silly, frivolous warnings and potential litigation given the existence of prior settlements. Given that OEHHA's prior proposal to address this recognized problem was not supported by the judgment, we need to find a workable option.



### **Impact on Food Safety**

In 2007, a USDA regulatory requirement was put in place that almonds consumed in the U.S. be subjected to a validated treatment which results in a minimum 4-log reduction of Salmonella. There are **multiple treatments that have been validated** – some are more appropriate to retain the “raw” characteristics of almonds (such as steam/heat treatments or chemical/fumigation treatments) while other validated treatments include blanching, oil roast, dry roast, etc. All treatments involve a degree of heating the almond.

Dry or light roasting can result in considerable variability in achieving the required 4-log reduction. It is sometimes necessary to first pre-pasteurize the almonds in order to roast at these lower temperatures and still comply with the 4-log reduction mandated by the almond industry’s USDA Federal Marketing Order.

OEHHA cited Almond Board of California (ABC) data showing that roasting almonds at or below 265 degrees will result in minimum acrylamide formation – but this was based on a single lab study in 2011, not commercial practices. In fact, roasting above 290 degrees is often needed to pasteurize almonds. It is important to note, too, that a treatment such as chemical/fumigation as a “pre-pasteurization” step is not allowed for organic production – putting an even greater burden on that sector to comply with these requirements.

### **Alternative Defense**

Subsection (b) provides that Section 22505 “*does not preclude businesses from using evidence, standards, risk assessment methodologies, principles, assumptions or levels in articles 7 and 8 of the Proposition 65 regulations to establish whether a warning is required for a listed chemical in a food that is created by cooking or other heat processing.*” It further confirms that business may choose to rely on other provisions including “*...the alternative risk level described in Section 25703(b)(1) or food intake calculations pursuant to Section 25721, or a combination of these....to show a warning is not required.*”

Certainly, most companies have chosen settlement rather than pursue litigation due to the excessive costs associated with a prolonged legal battle. **The Proposed Notice will have no impact on that situation.** The almond industry has evaluated consumption levels of almonds in the U.S., based on shipments and an analysis of CDC’s National Health and Nutrition Examination Survey (NHANES) data. It was assumed that 100% of the almonds consumed were roasted and therefore contained some level of acrylamide, which would overestimate potential exposure. According to the analysis, almonds are present in a wide range of food categories (snack, crackers, cereals, milk, butter, etc.) and consumed across all age populations.

### **In Conclusion**

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Warning labels, whether a short form or long, are concerning for products that are safe and healthful. As noted, if it is not feasible for a company to implement processing parameters to achieve a 225 ppb level, their only choice is to mount a costly NSRL (or alternative NSRL) defense, or to put a warning label on the product. Consumers will see *the same product on*



*the retail shelf – some with warnings, others without.* This is likely to undermine confidence in the product with a warning label, putting those companies at a direct competitive disadvantage with greater economic consequences.

Moreover, creating an impression that almonds are unhealthy directly conflicts with the message from key health and nutrition authorities – including USDA and FDA – that almonds should be consumed as part of a healthy diet. Creating this type of consumer confusion is exactly the result OEHHA is trying to avoid.

As noted in our opening comments, almonds are widely recognized by regulatory, scientific and health organizations as a wholesome and healthy food which is included in numerous consumer diet recommendations. Almonds are further subject to strict food safety requirements, regulated by USDA, which necessitate a pasteurization treatment. While there are multiple treatments available, not all validated 4-log reduction treatments work for all products or industry segments (i.e., conventional vs organic).

We believe the only solution is to revisit the option to **establish an ARL for almonds** based on NHANES consumption data which was already shared with OEHHA, as well as the fact that acrylamide formation is unavoidable in light of other regulatory requirements related to food safety (pasteurization).

The AAC and ABC appreciate this opportunity to provide comments, and welcome further discussions with OEHHA.

Sincerely,

A handwritten signature in black ink, appearing to read "Aubrey Bettencourt".

Aubrey Bettencourt  
President/CEO