

# American Bakers Association

*Serving the Baking Industry Since 1897*

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June 23, 2005

Ms. Susan Luong  
Office of Environmental Health Hazard Assessment  
Proposition 65 Implementation Program  
P.O. Box 4010  
Sacramento, CA 95812-4010

Re: Proposed Rulemaking Updating the Dose Response Assessment for Acrylamide and Proposing a Revised No Significant Risk Level, Proposing an Alternative Risk Level for Acrylamide in Breads and Cereals, and Proposing Warning Language for Acrylamide in Food

Dear Ms. Luong:

These comments are submitted on behalf of the American Bakers Association (“ABA”) regarding three proposed regulatory actions under the Safe Drinking Water and Toxic Enforcement Act of 1986 (“Proposition 65” or the “Act”) with respect to acrylamide in foods: (1) updating the dose response assessment for acrylamide and amending Section 12705(b) by revising the no significant risk level (“NSRL”) for this chemical; (2) adding a new Section 12705(e) establishing an alternative risk level for acrylamide in breads and cereals, pursuant to Section 12703(b); and (3) amending Section 12601 to add new “safe harbor” provisions specific to warnings for acrylamide exposures from food.

ABA is the national trade association representing the wholesale baking industry. Our membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. As such, ABA has a substantial interest in these proposed rulemakings because they would affect potential warning requirements regarding acrylamide for nearly all baked goods. ABA appreciates this opportunity to comment on these significant proposals and provide the Office of Environmental Health Hazard Assessment (“OEHHA”) with insights gleaned from the breadth and depth of its members’ long experience in the production and sale of baked goods. ABA is also part of a coalition of major food associations that has formed to address the issue of acrylamide (“Industry Acrylamide Coalition”) and endorses the comments submitted by that coalition. ABA’s individual comments touch upon the general issues implicated by the proposed rulemakings but are focused primarily upon the issues affecting the warning requirements for baked goods.

ABA remains fundamentally committed to ensuring that consumers have a safe, wholesome, and nutritious food supply, and that labeling and other health communications about food products are grounded in sound science to ensure that information is truthful and not misleading. Towards that end, ABA strongly supports OEHHA’s earlier proposal to establish a limited exemption from Proposition 65 warning requirements for exposures to listed chemicals that form in food as a result of naturally occurring constituents in the food being cooked or heat processed, for the reasons articulated in ABA’s comments to that proposal, submitted on June 6, 2005. Such an exemption would encompass acrylamide in food and would obviate the three proposed

rulemakings addressed in these comments. If OEHHA does not proceed with that exemption and acrylamide in food remains subject to the warning requirements of Proposition 65, then ABA considers some aspects of the three proposed rulemakings at issue to be a step in the right direction, but has serious concerns about the scientific basis for and practical implications of the regulations as proposed.

## **It is Premature to Establish Any NSRL for Acrylamide Exposure Through Food**

Across the globe, public health organizations are actively examining acrylamide formation in food, human exposure levels, and potential human carcinogenicity, and the body of scientific evidence is rapidly evolving. Yet, not a single one of those organizations, other than OEHHA, has concluded that the evidence to date supports the establishment of a level above which a significant risk of cancer exists. To the contrary, national and international public health authorities have emphasized that the data do not yet support the establishment of such a level. The United States Food and Drug Administration (“FDA”) has made plain that “it is premature to set a level for acrylamide in food.”<sup>1</sup> The World Health Organization (“WHO”) also emphasizes that the current scientific evidence cannot reliably support a demarcation between “significant” and “insignificant” risk. In its 2005 document, “Frequently Asked Questions – Acrylamide in Food,”<sup>2</sup> WHO explains,

The theoretical models to predict whether cancer would develop in humans as a result of ingesting acrylamide in food are not reliable enough to develop firm conclusions about risk. . . . The important pre-requisite for any decision [about acceptable risk level] is, however a clear picture of the nature and level of the risk, as well as the potential for lowering this level. This clear picture does not exist for acrylamide at present.

Accordingly, if OEHHA were to finalize its proposal to establish an NSRL of 1.0 µg/day for acrylamide, it would stand alone among its national and international peers in attempting to fix a risk threshold based upon the unsettled nature of the currently available scientific data.

The risk assessment document accompanying OEHHA’s notice of its proposed amendment of the NSRL for acrylamide does not provide adequate scientific support for the proposed level. As discussed in detail in the comments of the Industry Acrylamide Coalition, serious deficiencies in that assessment undermine its value in providing a scientific basis for the proposed NSRL. In particular, the assessment is based upon unrealistically conservative assumptions such as linearity, and OEHHA’s conclusions concerning genotoxicity as the mechanism for cancer cannot be supported at such low doses. OEHHA also has not accounted for new studies indicating that acrylamide in food is not bioavailable, and the animal studies upon which OEHHA relied overestimate cancer potency. Further, OEHHA’s conclusions are contrary to the results of epidemiology studies, which have not borne out any human cancer risk from acrylamide ingestion through food.

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<sup>1</sup> See Letter from Lester M. Crawford, DVM, PhD, Deputy Commissioner, to Joan E. Denton, M.S., Ph.D., OEHHA, July 14, 2003, at 1 (“Crawford Letter”).

<sup>2</sup> Available at [http://www.who.int/foodsafety/publications/chem/acrylamide\\_faqs/en/print.html](http://www.who.int/foodsafety/publications/chem/acrylamide_faqs/en/print.html).

Accordingly, while ABA appreciates OEHHA's willingness to revisit the currently unsupportable 0.2 µg/day acrylamide NSRL, the acknowledged need for revision of the acrylamide level set in 1990 should serve as a cautionary tale against the establishment of an NSRL where the evidence cannot yet legitimately and reliably support such a level. To set a new NSRL for acrylamide at this time would be, in large measure, arbitrary and speculative, and would surely commit OEHHA to future rulemaking to revise the level when the scientific evidence regarding human cancer risk from acrylamide ingestion becomes more settled. For these reasons, ABA requests that OEHHA refrain from establishing a revised NSRL for acrylamide that would reflect exposure through food consumption. Rather, at this time, OEHHA should revise the acrylamide listing at Section 12705(c)(2) to clarify that the current NSRL does not relate to acrylamide exposure through ingestion of food.

## **Any Proposed Alternative Risk Level Must Extend to All Food**

The scientific uncertainty that precludes establishing an NSRL for acrylamide similarly renders any alternative risk level arbitrary and unsupportable. However, if OEHHA proceeds with the establishment of its proposed NSRL, then ABA strongly supports an alternative risk level not only for bread and cereal, but for cooked food generally. While ABA particularly appreciates the alternative level for bread and cereal, there is no statutory or regulatory basis for distinguishing among categories of cooked food when establishing such levels. The plain language of Section 12703(b)(1) makes clear that "sound considerations of public health" support the establishment of alternative levels for the entire category of food in which chemicals are produced by cooking necessary to render the food palatable or to avoid microbiological contamination. The regulation does not allow for the parsing of food categories based upon "public health" considerations, as the proposed regulation purports to do. Nowhere in the Final Statement of Reasons for Section 12703(b)(1) are such distinctions among cooked food even contemplated. To the contrary, OEHHA's predecessor, the Health and Welfare Agency, made clear that the intended "public health" benefit is simply cooking the food:

In light of the offsetting public health benefit that the cooking of food provides, the Agency takes the position that businesses which utilize cooking necessary for the processing or preparation of food should not be strictly held to the  $10^{-5}$  standard.

Subsection (b)(1) of this regulation specifically includes cooking necessary to avoid microbiological contamination or to make food palatable as an example of a public health consideration which supports the use of a no significant risk level other than  $1 \times 10^{-5}$ . Under the previous version of the regulation, cooking was arguably an example of a public health consideration.

Specifically including necessary cooking as an example dispenses with the need for argument.<sup>3</sup>

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<sup>3</sup> Final Statement of Reasons, Title 22, Cal. Code of Regs. Section 12703 at 5-6.

Accordingly, any alternative risk level for acrylamide established pursuant to Section 12703(b)(1) must apply to all food that is cooked to render it palatable or to avoid microbiological contamination.

Moreover, even the proponents of the federal dietary guidance upon which OEHHA purports to rely in establishing an alternative risk level for bread and cereal would not condone the proposed disparate treatment of food categories. Federal dietary guidelines, as well as nutrition experts, have consistently emphasized that all food can have a role in a healthy diet, and that “good food/bad food” distinctions do not promote sound dietary recommendations. The FDA comment upon which the alternative risk level for bread and cereal is based was plainly intended to highlight these foods merely as examples of foods that provide fiber and other beneficial nutrients.<sup>4</sup> The comment cannot reasonably be construed to categorize bread and cereal as fundamentally and qualitatively different from or superior to other food that also plays a beneficial role in the diet.

Further, the “bread” and “cereal” categories are neither meaningful nor nutritionally significant. For example, in OEHHA’s report of acrylamide intake estimates for various foods, the agency established separate categories for “bagels,” “biscuits,” “bread,” “quickbreads and muffins,” “toast,” and “tortillas,” and acrylamide levels varied widely among these categories.<sup>5</sup> It is unclear, however, whether the proposed alternative risk level for “breads” would apply only to “bread” as categorized in OEHHA’s report or to all of the foregoing categories that consumers, food manufacturers, and retailers might reasonably consider to be “bread” within the general understanding of that term. Within the “cereal” category, products range from high fiber, low sugar cereals to cereals that provide almost no fiber and whose nutrient profiles differ little from cookies or candy, and yet all of these cereals would come within the proposed regulation establishing an alternative no significant risk level on “public health” grounds. Meanwhile, low-fat, whole grain crackers would not be eligible for the alternative level. Such arbitrary distinctions among food categories make no sense as a matter of nutrition or public health policy.

At a minimum, any alternative risk level should extend to all grain products. As OEHHA expressly recognized in its Initial Statement of Reasons for the proposed amendment, the FDA recommends the consumption of grain products. That recommendation is not limited to bread and cereal. Moreover, the Dietary Guidelines for Americans 2005 (“Dietary Guidelines”), issued jointly by the U.S. Department of Health and Human Services (“HHS”) and U.S. Department of Agriculture (“USDA”), and ensuing revised USDA Food Guide Pyramid continue to emphasize the importance of grain-based food products as a foundation of a healthy diet. In particular, the Dietary Guidelines encourage increased consumption of whole grain products for their fiber content and other nutritional benefits, but also recognize the importance of enriched grain products in helping consumers achieve adequate nutrient intake, including folic acid for women of childbearing age to reduce the risk of neural tube defects. While bread and cereal can certainly play a part in helping consumers achieve the recommended servings of grain products, other grain products can similarly fill this nutritional role, and indeed the Dietary Guidelines

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<sup>4</sup> See Crawford Letter, at 2.

<sup>5</sup> See “Characterization of Acrylamide Intake from Certain Foods,” March 2005, Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Table 1, at 6.

emphasize flexibility and variety in making food choices. For example, a consumer could select a whole grain waffle topped with fruit for breakfast, rather than cereal. These foods are interchangeable as a matter of dietary guidance. Consequently, there is no public health justification for treating them differently with respect to an alternative risk level for acrylamide.

Notably, a well-established benefit of consuming fiber-rich grain products is the reduction in cancer risk. Indeed, FDA promulgated a health claim for fiber-containing grain products, fruits and vegetables and reduced risk of cancer based upon significant scientific agreement supporting the diet/disease relationship.<sup>6</sup> Unless the alternative risk level is extended at least to all grain products, however, a product other than bread or cereal that is eligible to bear this fiber/cancer health claim would also need to be the subject of a warning that the product contains acrylamide which may *increase* the risk of cancer. This illogical result seems even more egregious when one considers that the health claim is based upon extensive scientific evidence proving the health benefit, whereas studies to date have not shown an increased cancer risk with acrylamide exposure.<sup>7</sup>

If OEHHA proceeds with an alternative risk level for only bread and cereal, then the language of the proposed regulation must be changed to delete reference to compliance with federal *standards*. In the context of the bread industry, the term “standards” generally refers to federal food standards of identity. The use of this term in the proposed regulation implies that the alternative risk level applies only to products for which federal food standards of identity have been established. ABA recommends that the language be changed to refer to compliance with “all relevant federal *requirements*.”

Finally, ABA observes that an alternative no significant risk level even for bread and cereal will be irrelevant, as a practical matter, under the proposed warning scheme. If warnings about acrylamide formation in “starchy” food are posted at the point of sale in retail outlets, consumers will naturally assume that the warnings relate to bread and cereal, even if such products fall below the alternative risk level. There would be no way to distinguish these foods from those about which a warning is provided. This reality further reflects the intrinsic lack of soundness of the proposed scheme that would require warnings about a chemical found in a vast array of healthful food important to the diet and for which a human cancer risk has not been established.

## **The Proposed Warning Language Must Be Revised to Accurately Reflect the Range of Food in Which Acrylamide is Formed**

ABA continues to believe that warnings about acrylamide are not justified by the scientific evidence at this time, and would be so pervasive as to be either misleading or meaningless. Given the enormous range of food in which acrylamide has been detected –including in coffee, potato chips, peanut butter, bread, olives, and prune juice – warnings would need to address a substantial proportion of food consumers are accustomed to purchasing. Warnings relating to such an abundance of food would diminish the overall significance of Proposition 65 cancer warnings. Moreover, as the California Health and Welfare Agency recognized when establishing

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<sup>6</sup> 21 C.F.R. § 101.76.

<sup>7</sup> See FDA Action Plan for Acrylamide in Food, March 2004, at 2, available at <http://www.cfsan.fda.gov/~dms/acrypla3.html> (“FDA Action Plan”).

an exemption for chemicals “naturally occurring” in food, “[o]ne of the purposes of the Act is to inform the consumer about the presence of toxic chemicals and to facilitate the ability of the consumer to choose among exposures. Food is a basic daily necessity of life on a par with the water that we drink and the air that we breathe.”<sup>8</sup>

The Agency acknowledged that “warnings for naturally occurring chemicals in food would not significantly enlighten the consumer about his or her options.”<sup>9</sup> The same logic holds true for warnings relating to the extensive breadth of food containing acrylamide; that is, warnings would not significantly inform consumers about their options because they would relate to so many foods that consumers could not choose among exposures without compromising the nutritional quality of their diets.

Warnings about acrylamide in food could also mislead consumers into thinking acrylamide is only a hazard in store-bought food. In fact, the FDA has expressed concern that consumer exposure to acrylamide may be greatest through home cooking.<sup>10</sup> At a minimum, consumers scared by warnings into substituting home baked goods for purchased varieties would be exposed to the same level of acrylamide, and therefore the warning would fail to accomplish any reduction in exposure.

Again, not a single other national or international public health authority has recommended warnings about acrylamide in food. To the contrary, and as incorporated into the proposed “safe harbor” warning, FDA advises consumers to continue to eat a balanced diet, choosing a variety of foods that are low in trans and saturated fat and rich in high-fiber grains, fruits and vegetables. While ABA appreciates OEHHA’s inclusion of FDA’s advice in its proposed “safe harbor” warning, it is virtually certain that consumers will be confused by a message that combines a cancer warning with federal dietary advice to consume some of the very foods that are the subject of the cancer risk warning. The incongruity of the warning and incorporated dietary guidance highlights the inappropriateness of providing acrylamide warnings based upon the current body of evidence.

If OEHHA insists upon requiring acrylamide warnings at this time, then ABA supports the general approach proposed but urges significant clarification to ensure accuracy of the message and delineation of warning responsibilities. With respect to the location of a warning, ABA agrees that warnings on product labels are inappropriate in light of the vast number of foods that contain acrylamide when cooked. Moreover, on-product labels could not include information sufficient to avoid confusing, misleading, and misinforming consumers, leading them to avoid consuming food that is necessary for a healthful and nutritionally complete diet. ABA supports requiring acrylamide warnings, if at all, only in one location, e.g., at the point of sale in retail outlets or in a single notice for food served or sold for immediate consumption in food facilities.

Regarding the text of the warning, ABA supports the concept that warnings should provide general information and refer consumers who desire more details about acrylamide to websites where such information can be easily obtained and placed in context with respect to current dietary guidance and the scientific evidence concerning human cancer risk.

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<sup>8</sup> Final Statement of Reasons, Title 22, Cal. Code of Regs. Section 12501 at 4-5.

<sup>9</sup> *Id.* at 5.

<sup>10</sup> *See* Crawford Letter, at 2.

Further, ABA agrees that including FDA's dietary guidance may help counter the propensity of the warning to cause consumers to avoid foods that should be part of a healthful diet, although, as noted above, consumers may be confused by the fact that the proposed warning simultaneously warns about and encourages the consumption of some food, e.g., high-fiber grain products.

However, the first sentence of the proposed warning, referring to formation of acrylamide only in "starchy" food, is inaccurate and misleading in light of the current scientific evidence, and fails to satisfy the Act's requirement to provide clear and reasonable warning about exposures to listed chemicals unless otherwise exempted. Acrylamide has been found in a broad range of non-"starchy" food, including almonds, chile con carne, coffee, canned olives, peanut butter, Postum, prune juice, and sunflower seeds.<sup>11</sup> Yet, as currently worded, the proposed warning would not alert consumers to any of these potentially significant exposures. Rather, the reference to only "starchy" food falsely suggests that such food is the only food in which acrylamide is formed, and that consumers can rest assured that they will not be exposed to acrylamide if they simply steer clear of "starchy" food. Further, this inaccurate depiction of the scope of food in which acrylamide is formed could skew consumers' dietary choices away from grain-based food, the consumption of which is encouraged by the Dietary Guidelines as the foundation of a healthy diet. The challenge in crafting a warning that accurately characterizes the broad range of food in which acrylamide is found reflects the difficulty inherent in warning about a constituent that is so pervasive in the food supply and about which the human risk is not yet understood. Partly for these reasons, no warning about acrylamide in food should be mandated at this time, but if OEHHA chooses to go ahead, it should revise the first sentence of the warning to refer to "some food," consistent with the statement in the third paragraph of the proposed warning regarding reduction of acrylamide levels "by avoiding excessive browning or crisping of some foods." Information about the specific food in which acrylamide is formed could be obtained readily through the websites listed in the last paragraph of the warning.

Finally, ABA urges OEHHA to revise the proposed amendment to Section 12601 to identify the respective warning obligations of each person in the chain of distribution. The regulation must specify clearly what information and material each entity in the chain of distribution must supply to its direct customer, and must state clearly that by doing so, each entity fully satisfies its warning obligation under Proposition 65. If these obligations are not clarified in the language of the regulation itself, they will be determined through litigation that is sure to follow the promulgation of a regulation that is vague on this point.

As a defensive measure, manufacturers will likely resort to imposing warnings on product labels to ensure satisfaction of any warning obligation that may be attributed to them. Accordingly, the proposed regulation would have the practical effect of requiring on-product warnings – a result which the remainder of the proposed regulation has been carefully drafted to avoid.

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<sup>11</sup> See "Characterization of Acrylamide Intake from Certain Foods," March 2005, Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Table 1, at 6.

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ABA's principal concern remains the best interests of consumers and assuring the provision of safe, wholesome, and nutritious baked goods. For this reason, ABA believes that a warning for acrylamide formed in cooked food would be misleading and scientifically unjustified at this time. However, if OEHHA proceeds with its proposed warning scheme, including the establishment of an alternative risk level for only some food, then ABA strongly urges OEHHA to consider the revisions suggested above. ABA appreciates the opportunity to comment on these issues of substantial importance to the baking industry.

Respectfully submitted,



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