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Susan Luong
Office of Environmental Health Hazard Assessment ("OEHHA")
Proposition 65 Implementation
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Re: April 8, 2005 Notice to Interested Parties Re: Proposed Rulemaking, Title 22, California Code of Regulations; Amendments to Section 12601, Clear and Reasonable Warning: Acrylamide, and Section 12705(e), Specific Regulatory Levels Posing No Significant Risk: Acrylamide.

Dear Ms. Luong:

These comments are submitted on behalf of a coalition of associations whose members produce, process, prepare, serve, and sell the foods consumed by virtually all Californians.[1]

During the nearly three years that OEHHA has been considering the regulation of acrylamide in foods under Proposition 65, there have been numerous workshops and hearings, a Cancer Identification Committee Meeting, and voluminous written public comments that have provided OEHHA with scientific data and the views of a wide array of government, academic, independent, and food industry experts. Virtually *all* of these experts recommended *against* cancer warnings about acrylamide in food where acrylamide is present

[1] Members of the coalition include the California Chamber of Commerce, California Restaurant Association, California Retailers Association, American Bakers Association, American Frozen Food Institute, Chocolate Manufacturers Association, Grocery Manufacturers of America, Institute of Shortening and Edible Oils, National Confectioners Association, Food Products Association, National Potato Council, National Restaurant Association, Snack Food Association, Wheat Foods Council, California League of Food Processors, and the California Manufacturers and Technology Association.

as an unintended byproduct of cooking and heating. That record shows nearly unanimous agreement by independent testifying experts – including the United States Food and Drug Administration – that such warnings 1) are not supported by existing scientific evidence, 2) are not recommended by the vast majority of health regulatory agencies throughout the world who have scrutinized the potential risks of acrylamide, as well as other byproducts of cooking, 3) would have adverse health consequences, and 4) are not warranted by the minimal risk involved.

In the course of OEHHA's consideration of acrylamide, we have urged OEHHA to adopt a narrowly tailored exemption for acrylamide and other Proposition 65 chemicals that are created as the unintended byproduct of heating the natural constituents of food. We continue to believe that this approach should be considered and decided, in a rulemaking proceeding, before the Agency proceeds to make a decision on the three proposed rules that are the subject of these comments and others submitted today on behalf of the Coalition.

Should the Agency nonetheless decide to proceed with the current rulemaking, the record before OEHHA leaves no doubt that **sound considerations of public health support the conclusion that, at this time, there should be no cancer warnings on food based solely on the presence of acrylamide that is the unintended byproduct of cooking or heating the natural constituents of the food**. Otherwise stated, the best information currently available supports an alternative risk level for acrylamide at a level higher than that produced by cooking. (Such an alternative risk level may be qualitative/descriptive, or a specific NSRL may be calculated.) This conclusion and the corresponding regulations may change, of course, if existing information changes materially.

Others will be submitting written comments on the Coalition's scientific and technical concerns about the "safe harbor" levels in the proposed rules discussed in the May 24, 2005 hearing. This letter primarily addresses legal and policy issues raised during the hearing pertaining to the establishment of an alternative risk level and the proposed amendment to the warning provisions of section 12601. We ask that our comments of June 6, 2005 be incorporated into this rulemaking record as they are relevant both to how the Agency proceeds and to the substance of the three proposed regulations.

I. SOUND CONSIDERATIONS OF PUBLIC HEALTH REQUIRE AN ALTERNATIVE RISK LEVEL FOR ALL FOODS AT THE LEVEL AT WHICH ACRYLAMIDE IS PRESENT AS THE RESULT OF COOKING.

We agree with OEHHA that it is both appropriate and necessary, given existing information, to establish alternative risk levels that would not require warnings regarding acrylamide in food where sound considerations of public health support that conclusion. We disagree, however, with OEHHA's proposal to limit such an alternative risk level to a single food category, based on a single health consideration, while ignoring the substantial testimony by

FDA and other experts on the adverse health consequences of acrylamide cancer-risk warnings on *any* foods at this time. OEHHA has suggested that it views its ARL proposal as a "first step" toward considering alternative risk levels for other food categories.[2] Far from supporting such a piecemeal approach, the extensive record compiled over the past three years from government, academic, and industry food science experts points in the opposite direction.

The FDA and other health agencies agree that *no change in dietary advice is warranted* by existing knowledge concerning acrylamide.[3] Current scientific evidence is that the risks from acrylamide produced as the result of heating the natural constituents of *any* food are hypothetical and low, while the risk of adverse consequences to public health from widespread warnings is real. Furthermore, since research into strategies for the reduction or elimination of acrylamide in foods has not yet produced a workable means of doing so, a warning requirement will not lead to "reformulation" but simply to the change in advice regarding diet or cooking methods against which FDA and other experts have warned.

Based on this record, sound considerations of public health justify establishing safe harbor levels that – like the proposed alternative risk level for breads and cereals – exceed the levels of acrylamide produced as the unintended byproducts of heating the natural constituents in foods. Until evidence emerges to the contrary, OEHHA should avoid piecemeal regulations and act in accordance with the record by establishing such an ARL for cooking-related acrylamide in all foods.

A. Evidence on the Record Supports a Uniform ARL for Acrylamide Produced as an Unintended Byproduct of Cooking.

1. There are currently no reliable means of reducing acrylamide levels in food outside the laboratory.

The record before OEHHA is clear that, while research continues on a number of fronts, there is as yet no commercially feasible means to reduce or eliminate acrylamide that is formed when the asparagines and sugars naturally present in plant-based foods are heated. OEHHA has acknowledged as much in its initial statement of reasons: "Although

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[2] Transcript of May 24, 2005 Hearing on Proposed Acrylamide Rulemaking ("May 2005 Tr.") at 103:6-104:3 (comments of Carol Monahan indicating that the Agency views the proposed rulemaking as a "first step" toward identifying foods that qualify for an ARL).

[3] There is certainly nothing in the record that supports the view that it would be advisable to substitute bread and cereal for prunes, fried potatoes and chips, roasted almonds, coffee, grilled asparagus, and the many other foods containing acrylamide.

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."[4]

While modest reductions have been achieved under laboratory conditions, methods for reducing or eliminating acrylamide on a commercially feasible scale while maintaining the palatability, quality, and nutritional profile of existing products have eluded researchers.[5] Dr. Terry Troxell of FDA testified in 2003 that several strategies for reducing acrylamide levels have been studied – including removal of the precursors to acrylamide before the reaction occurs, disruption or redirection of the process that causes acrylamide to form, and removal of acrylamide from foods after formation.[6] However, Dr. Troxell and others testified that each of these strategies comes at a cost in terms of the quality and/or safety of the food:

> It should be pointed out, also, that we recommend that we look at ways to reduce acrylamide formation in food products, but we must be careful in how we look at doing that because it can . . . come at the expense of the desired flavor, color, safety and overall digestibility of food products.[7]

Without a viable means for lowering acrylamide to levels that fall below the current or proposed NSRL, manufacturers, distributors, restaurateurs, and grocers would be left having to make complex product-by-product analyses to decide whether or not a warning on each particular product – or each specific cookie or prune – is required, analyses that have, thus far, proven difficult for even government and industry experts. In the technical document supporting the proposed ARL, the Agency acknowledges the high degree of variability in

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[4] Initial Statement Of Reasons, Title 22, California Code of Regulations, Section 12705(e), Specific Regulatory Levels Posing No Significant Risk (April 8, 2005) ("ARL ISOR") at 3.

[5] Transcript of May 9, 2005 Workshop Concerning Natural Constituents in Food ("Exemption Workshop Tr.") at 81:13-83:19; Transcript of May 12, 2003 Public Workshop, Proposition 65 Regulatory Options Regarding Acrylamide in Food ("May 2003 Tr.") at 23:24-25:12.

[6] May 2003 Tr. at 23:24-25:12; *see also* Exemption Workshop Tr. at 82:2-6 (comments of Dr. Dan Tallmadge) ("These mitigation approaches are specific to the unique food type, process and raw material source. Single approaches have not been found to be universally applicable due to large variation in global raw material compositions, food formulation and production practices."); May 2003 Tr. at 57:7-10 (comments of Dr. Takayuki Shibamoto) ("It is very difficult to say – or I think the increase of the precursors during storage may not have too much impact to the final formation of acrylamide.").

[7] Exemption Workshop Tr. at 40:11-17 (comments of Dr. A. Larry Branen, Professor of Food Science and Toxicology at the University of Idaho); May 2003 Tr. at 24:5-25:13.

acrylamide levels and consumption rates for many foods.[8] Indeed, virtually every participant in the acrylamide rulemaking process – including attorneys who file enforcement actions – has acknowledged the complexity of dietary, health, and scientific issues concerning exposures to chemicals produced by heating foods.[9]

> [A]t this point the relationship between cooking temperatures and product composition is so complex that looking at an approach that focuses on either – on storage or just on cooking temperature is pretty – is unwarranted and could lead to consequences which we all don't want to see.[10]

FDA's testing shows that levels of acrylamide vary from lot to lot and may differ depending on which day the product is tested or even within a single day and single batch.[11] This uncertainty assures warnings that constitute a change in advice to consumers regarding diet, a result that nutritionists and the FDA agree is unwarranted and potentially dangerous.

2. Low risks associated with acrylamide formed during cooking are far outweighed by risks associated with warnings.

The Agency has before it ample evidence that the risks associated with small amounts of acrylamide formed when natural constituents of plant materials are heated during cooking are hypothetical and low, and do not warrant recommendations for a change in dietary advice.[12]

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[8] Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, *Characterization of Acrylamide Intake from Certain Foods* (March 2005) ("Acrylamide Intake Document") at 8, available at http://www.oehha.ca.gov/prop65/law/pdf_zip/acrylamideintakeReport.pdf (visited July 5, 2005). Neither the proposed ARL regulation nor its supporting technical document provides a precise definition of the products that would qualify for the proposed ARL. For example, would a blueberry muffin be considered a "grain-based" bread? What about a bran muffin or a toasted bagel? Is a granola bar a "cereal"? These sorts of line-drawing exercises will almost certainly take place in courtrooms if the Agency continues in the piecemeal manner it has set forth.

[9] May 2003 Tr. at 14:16, 53:3-5, 63:4, 64:24-65:1, 68:1, 68:14, 137:4-8, 146:24-147:4, 147:12-13, 160:22-161:2, 180:22-25.

[10] *Id.* at 68:13-18 (comments of Dr. Henry Chin).

[11] *Id.* at 23:6-10; 26:14-19, 65:10-66:12, 67:3-5, 67:19-23; *see also infra* n.12.

[12] May 2003 Tr. at 19:25-20:4, 21:15-19 (comments of Dr. Terry Troxell of the United States Food and Drug Administration) ("Epidemiology could provide interesting information, but it may be very difficult to detect small risks with this method such as risks associated with the relatively low exposures to acrylamide that occur through food."); *see also Dietary Acrylamide and Cancer of the*

Indeed, U.S. and international organizations that have been sponsoring, conducting, and reviewing emerging research have declined to revise existing advice that consumers eat a balanced diet but need not change those diets to avoid foods containing acrylamide.[13]

By contrast, virtually every nutrition expert who has provided evidence to the Agency on this issue, including food scientists from FDA, have warned that widespread warnings on food products will be uninformative, misleading and may have unintended, adverse health consequences. Dr. Terry Troxell explained:

> [I]t's something we have to be very careful about because, if you're talking about tipping, if you tip the nutritional – the food eating behaviors and food cooking behaviors a little bit here, you can probably encounter much greater risk than the reductions you're going to achieve in acrylamide exposure.[14]

Large Bowel, Kidney, and Bladder: Absence of an Association in a Population-based Study in Sweden, L.A. Mucci et al., British Journal of Cancer 88: 84-9, Jan. 13, 2003; Sir Paul Nurse, Chief Executive of the Cancer Research UK organization, commented on this study in a January 28, 2003 press release, available at http://www.cancerresearchuk.org/news/pressreleases/acrylamide; *Fried Potatoes and Human Cancer;* C. Pelucchi et al., International Journal of Cancer 105:558-560, July 1, 2003; *Dietary Acrylamide and Risk of Renal Cell Cancer*, L.A. Mucci et al., International Journal of Cancer 109(5):774-6, May 1, 2004; *Acrylamide Intake and Breast Cancer Risk in Swedish Women*, L.A. Mucci et al., Journal of the American Medical Association 293(11):1326-7, March 16, 2005.

[13] May 2003 Tr. at 30:7-16; *see also, e.g.*, World Health Organization, *Frequently Asked Questions – Acrylamide in Food*, available at http://www.who.int/foodsafety/publications/chem/acrylamide_faqs/en/ (visited July 7, 2005) ("The information available on acrylamide so far reinforces general advice on healthy eating, including moderating consumption of fried and fatty foods. There is not enough evidence about the amounts of acrylamide in different types of food to recommend avoiding any particular food product."); United Kingdom Food Standards Agency, *Analysis of Total Diet Study Samples for Acrylamide* (January 11, 2005) available at http://www.food.gov.uk/science/surveillance/fsisbranch2005/fsis7105 (visited July 7, 2005) ("More than 200 research projects have been initiated around the world and this survey has been conducted as part of that international effort. The results of the survey form part of the wider international body of evidence and will be fed into the February 2005 Joint FAO/WHO Expert Committee on Food Additives safety evaluation of acrylamide in food. The results of this survey do not affect Agency advice on what people should eat.")

[14] May 2003 Tr. at 72:11-16; *see also* OEHHA Background Materials for CIC Consultation on OEHHA Proposed Acrylamide Workplan, Sept. 9, 2003, available at http://www.oehha.ca.gov/prop65/docs_state/acrylback.html ("Background Materials"), at Tab 5; May 2003 Tr. at 71:25-72:9; 31:5-9, 68:8-11, 13-18, 70:25-71:14, 71:18-24, 72:20-23, 113:21-25, 116:1-5 (comments by Drs. Barbara Schneeman, Barbara Petersen, and Henry Chin); Exemption Workshop Tr. at 40:11-22 (comments by Dr. A. Larry Branen) ("Caution must also be taken in the potential

Dr. Barbara Schneeman (then on the faculty of the University of California at Davis and now head of FDA's Center for Food Safety and Applied Nutrition's Office of Nutritional Products, Labeling, and Dietary Supplements) testified in 2003 that recommending reduced consumption of particular foods could adversely affect nutrition because there is no assurance that replacement foods chosen by consumers would provide the same benefits and nutritional balance.[15]

Dr. Schneeman, Dr. Troxell, and other food safety experts who testified were also concerned that, if it were believed that acrylamide could be reduced by lowering cooking temperatures, attempts to do so could lead to food safety issues or dietary imbalances due to undercooking.[16] In the case of certain canned vegetables, for example, undercooking could lead to botulism poisoning.[17]

B. The Potential Adverse Consequences of Piecemeal Adoption of Alternative Risk Levels are Not Justified Based on the Record.

The record is replete with admonitions from nutrition experts – including the sources from FDA that the Agency has relied upon for its conclusions about the benefits of bread and cereals – concerning the risks posed by establishing piecemeal safe harbor values.[18] These experts have cautioned against creating the types of "good food/bad food" distinctions that result from singling out certain categories of foods.

In fact, the expert testimony before OEHHA is clear and one-sided on the subject of utilizing such distinctions to devise public advisories that will affect dietary choices. Nutrition experts agree that sound dietary recommendations do not make a "good food/bad food"

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labeling. Again, as I said, unwarranted consumer fears could lead to avoidance of foods that contribute significantly to the nutritional and satiety value of the American diet.").

[15] May 2003 Tr. at 118:3-15; *see also id.* at 122:6-23 (comments of Drs. Troxell and Schneeman).

[16] May 2003 Tr. at 71:18-24. Even absent the risk of undercooking, advising people not to overcook foods raises the risk of other adverse effects, such as a higher rate of fat absorption from foods fried at a lower temperature. *Id.* at 31:16-18.

[17] *Id.* at 70:25-71:14.

[18] *See, e.g.*, May 2003 Tr. at Tr. at 72:10-16 (comments of Dr. Terry Troxell); 145:20-146:9 ("The second question that we need to consider is, how much will consumers reduce their consumption of foods that contain acrylamide if we do begin trying to get a message across that will reduce consumption of these foods. And closely related to this is, what foods will consumers substitute for the foods that they avoid. . . . You cannot view the diet – a piece of the diet in isolation. When you start making a change in one piece of the diet, it's going to cause effects in the rest of the diet. There are trade-offs in people's food choices.") (comments of Dr. Richard Forshee).

distinction, but emphasize that each food must be considered within the context of a balanced diet.

> If you go to what nutritionists recommend, the dietary guidelines recommend, the American Dietetic Association recommends, they constantly come back to avoiding the concept of good food/bad food.
>
> It's how one puts food together in a diet that determines whether or not something is associated with promoting health, preventing disease. It's not individual foods. So one encourages moderation, but rarely would you tell a person that a food is bad and it can't have a place in a normal healthy diet.
>
> So – and implying if you label one food bad, that consumers are going to automatically choose something that's good, I think, is an assumption that is not borne out by consumer behavior.[19] (Dr. Barbara Schneeman)

As explained by the American Dietetic Association, such distinctions lead to consumer confusion:

> The value of a food should be determined within the context of the total diet because classifying foods as "good" or "bad" may foster unhealthy eating behaviors. . . . Nutrition confusion can be reduced by emphasizing moderation, appropriate portion size, balance and adequacy of the total diet over time, the importance of obtaining nutrients from food, and physical activity.[20]

Moreover, as the following exchange illustrates, FDA's Dr. Terry Troxell agreed with Dr. Schneeman (and virtually every other nutrition expert who has testified in this matter) that a "good food/bad food" strategy rests on invalid assumptions about consumer behavior:

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[19] May 2003 Tr. at 114:20-115:8 (comments of Dr. Barbara Schneeman).

[20] Jeanne Freeland-Graves, Susan Nitzke, *Position of The American Dietetic Association Total Diet Approach to Communicating Food And Nutrition Information*, 102 Journal of the American Dietetic Association 100, 100 (January 2002), available at http://www.adajournal.org/scripts/om.dll/serve?action=searchDB&searchDBfor=art&artType=full&id=as0002822302900301#rs0002822302900301004.

> DR. TROXELL: We did do "what ifs" in our exposure assessment. . . . It wasn't: "What if" you didn't eat fries and eat something else? Okay?" And that's a totally different scenario. Because if you don't eat fries, you're going to eat something else. And, I think, you know, as people will, they're going to eat something else that will have more or less acrylamide –well, not more necessarily, but they're going to have – they're going to have some acrylamide . . . .
>
> DR. SCHNEEMAN: They won't necessarily substitute an apple.
>
> DR. TROXELL: Right. That's the point.[21]

Excluding all categories of foods besides breads and cereals from consideration for an ARL risks all of the potential adverse consequences identified by Dr. Schneeman and others on the record.

The Initial Statement of Reasons indicates that the proposed ARL springs from comments by FDA citing breads and cereals as examples of foods whose nutritional benefits could be lost as the result of consumer confusion concerning acrylamide:

> 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 beneficial nutrients*** in their diets."[22]

OEHHA's rationale for singling out breads and cereals (and focusing only on dietary fiber in those foods) is based on this single portion of a sentence of testimony. However, implicit in the remainder of the testimony, and explicit in the FDA testimony as well as the rest of the

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[21] May 2003 Tr. at 122:8-122:23.

[22] ARL ISOR, at 1-2 (emphasis added).

record, is that precisely the *same* conclusion can be reached about other foods, other health benefits and even about acrylamide in food in general.[23]

Indeed, Dr. Schneeman testified that acrylamide warnings will likely impact nutritionally valuable foods at virtually *every* level of the food guide pyramid.[24] For example, evidence on the record suggests that acrylamide may be found in a wide variety of cooked fruits and vegetables, including potatoes, prunes and prune juice, roasted asparagus, and potentially, "*almost all foods of plant origins*."[25]

Thus, while we agree with the concept that alternative risk levels should be established for acrylamide, based on sound considerations of public health, it is arbitrary and ill-advised to cherry-pick the benefits of grains and ignore the many nutritional benefits of other foods that contain acrylamide.

In sum, we appreciate the Agency's recognition that warnings concerning acrylamide have the potential to adversely affect consumer foods choices. We also agree with OEHHA that section 12703(b) could provide a mechanism to resolve this problem, even if the Agency chooses not to adopt the proposed exemption for all chemicals produced as the unintended result of cooking and heating the natural constituents of food. However, the record is clear that piecemeal rulemaking such as that proposed will produce confusion, distort dietary choices, and result in adverse health consequences. Accordingly, if the Agency intends to proceed with setting an ARL under section 12703(b), it should be an alternative risk level for acrylamide at levels exceeding those created as the unintentional byproduct of heating foods.

II. TO PROVIDE A TRUE "SAFE HARBOR," THE PROPOSED AMENDMENTS TO SECTION 12601 MUST CLEARLY IDENTIFY THE OBLIGATIONS OF EACH ENTITY IN THE CHAIN OF DISTRIBUTION.

As discussed above and in more detail in our May 6, 2005 comments, we continue to believe that warnings about acrylamide and other byproducts of heating the natural constituents of

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[23] *See, e.g.,* June 2, 2005 Letter from Drs. Lorelei Mucci, Eric Rimm, and Kimberly M. Thompson to Cythia Oshita, at 2 ("[C]onsumers who feel compelled to reduce their exposures may determine that their only option is to forgo a large array of foods. It is noteworthy that several of the foods that contain acrylamide also contain micronutrients and fiber that are beneficial with respect to health."); May 2003 Tr. at 90:6-17 (comments of Dr. James Coughlin) (discussing antioxidents formed in foods as the result of Maillard reactions).

[24] *Id.* at 111:16-112:6.

[25] May 2003 Tr. at 64:8-12 (comments of Henry Chin) (emphasis added); *see also* Acrylamide Intake Document; May 2003 Tr. at 111:16-21, 65:10-66:12.

food are not justified.[26] Should the proposed warning regulations go forward nonetheless, we urge OEHHA to refine the current proposed amendment to Proposition 65's warning regulations to **define clearly what is required of each entity in the chain of distribution to satisfy *its* Proposition 65 obligation.** Unless each business knows what actions on its part suffice with respect to the signage in the proposed regulation, the amendment will not produce the intended result – a single, broad warning at the point of sale. Without such modifications, individual on-product warnings may remain the only way to avoid litigation.

The purpose of the "safe harbor" rules promulgated in section 12601 of Proposition 65's implementing regulations is to reduce uncertainty by identifying a course of conduct that complies with statutory obligations. Therefore, "[p]ersons using these 'safe harbor' messages and methods are assured that such warnings are in compliance with the Act."[27]

In this case, the scheme to provide consumers with information about acrylamide, as proposed by OEHHA, has another aim and additional potential advantages over ubiquitous on-product warnings: 1) to avoid overwhelming consumers with widespread warnings; 2) to provide a vehicle for more substantial information than can fit on a product package; 3) to reduce the likelihood that purchasers of cooked and processed foods will mistakenly conclude that they can avoid the risks warned of by cooking foods at home;[28] and 4) to avoid potential conflicts with FDA labeling requirements.[29] We support these objectives, and concur with OEHHA's conclusion that Proposition 65 does not require on-product labels.[30] We also agree with the Agency's objective of providing "the maximum level of flexibility for regulated businesses as they determine what is the most efficient and cost effective method to use in communicating the required warning," by providing that on-product labels are to be employed only "if the manufacturer chooses" to do so.[31]

Unless the proposed regulation is clarified, however, the choice and flexibility that the Agency envisions will not be achieved.

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[26] Letter from Michèle Corash to Cynthia Oshita, June 6, 2005.

[27] Initial Statement of Reasons, Title 22, California Code of Regulations, Section 12601, Clear & Reasonable Warnings ("12601 ISOR"), at 1.

[28] On this point, we believe the warning message is deficient in not clearly making the point that home cooking produces the same or greater levels of acrylamide as are found in processed or restaurant-cooked food.

[29] 12601 ISOR, at 2 (Point of sale warnings "will also ensure that the warning notice does not interfere with any mandatory labeling requirements for food that may be imposed by the FDA or other regulatory agencies").

[30] *Id.*

[31] *Id.*

Proposition 65 and existing implementing regulations require that the burden for providing signage should to "the extent practicable" be shouldered by manufacturers.[32] While providing for point-of-purchase warnings, however, the proposed regulation does *not* expressly provide – as it should – that a manufacturer discharges its obligations and obtains full benefit of the "safe harbor" by providing its customers with warning materials described and instructions for posting (or publication, if appropriate).

Proposition 65 imposes liability only for knowing and intentional failures to warn about exposures to listed chemicals.[33] A manufacturer who provides signs that are never actually posted or are later knocked down or stolen has not knowingly and intentionally exposed a customer to acrylamide without providing a clear and reasonable warning. However, unless the regulation spells this out, manufacturers may feel that they have to label all potentially affected foods to avoid having to litigate this issue on a case-by-case basis, the very outcome that the Agency has sought to avoid.[34]

The respective obligations of each person in the chain of distribution must be identified in the regulation. Specifically, the regulation must:

- Identify the information and material (e.g., signs or copy for publication specified in the regulation, instructions for posting or publishing, and mechanisms for obtaining additional signs) that each entity in the chain of distribution must supply to its direct customer; ***and***

- Specify that satisfying this requirement also satisfies that entity's obligations under Proposition 65.

During the May 24 hearing on these proposed regulations, OEHHA expressed concern that this approach would mean that some consumers – those who shop in small grocery outlets that are not subject to Proposition 65, for example – would not receive warnings.[35] However, Proposition 65 does not require that warnings be provided to each individual consumer.[36] More general means, including posting notices in the public media, are allowed as long as the warnings are clear and reasonable.[37] To that end, we recommend that newspaper and

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[32] Cal. Health & Safety Code § 25249.11(f); Cal. Code Regs., tit. 22 § 12601(b)(2).

[33] Cal. Health & Safety Code § 25249.6.

[34] 12601 ISOR at 2.

[35] May 2005 Tr. at 134:7-135:4.

[36] Cal. Health & Safety Code § 25249.11(f).

[37] *Id.*

internet notices be expressly identified as warning methods that are equally acceptable as warnings at point of sale.

We also note that the ubiquitous nature of potentially affected products – already acknowledged by the Agency – assures that consumers will see the warning many times a day when they do their regular shopping or, if the change we recommend is made, read their newspapers. As the warning is not limited to food sold in a particular establishment, consumers will understand the warning applies to the same food products wherever they are sold.

III. FINAL CONSIDERATION OF ALL THREE PROPOSED AMENDMENTS MUST AWAIT THE AGENCY'S DECISION ON THE PROPOSED EXEMPTION FOR THE UNINTENDED BYPRODUCTS OF HEATING OR COOKING THE NATURAL CONSTITUENTS OF FOOD.

We renew the request that we made on June 6, 2005 – and that was joined by *all* who addressed the subject at the May 9 workshop and the May 24 hearing – that OEHHA not proceed with consideration of these three acrylamide regulatory proposals until it has settled on and implemented a course of action with respect to an exclusion for unintended byproducts of heating natural constituents in food. Doing otherwise would lead to public confusion:

> FDA suggests that California resolve the issue of a potential exemption before the warning language proposals are finalized. Otherwise, the possibility exists that warning signs could appear in stores after finalization of the proposals, only to be removed a relatively short time later. FDA believes that warning language for acrylamide in foods could confuse consumers by creating unnecessary public alarm about the safety of the food supply and by diluting overall messages about healthy eating. Some confusion resulting from the appearance of warning signs in stores will likely persist even if such signs later are removed.[38] (Dr. Terry Troxell)

Proceeding with the three acrylamide rules prior to deciding on the proposed exemption simply makes no sense.

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[38] May 31, 2005 comments of Dr. Terry Troxell, available at http://www.oehha.ca.gov/prop65/pdf/FDAcommentontheMay9,2005OEHHAworkshopwebversion.pdf.

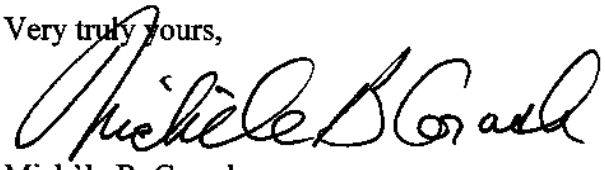
- Informed comment and decision-making regarding how to regulate acrylamide requires first knowing when, if at all, acrylamide will be regulated.

- An immediate regulation on when and how warnings are to be provided regarding acrylamide in food could be mooted by a subsequent decision to exclude from regulation acrylamide from cooking and heating. This would create both procedural problems (the Agency would have to go through a rulemaking to withdraw the regulation) and enforcement issues (If a restaurant failed to comply with the newly adopted acrylamide NSRL warning regulation the week before OEHHA adopts a regulation entirely excluding from the warning obligation acrylamide formed from heating, is the restaurant liable in a later-filed enforcement action? What about during the time period after the exclusion is adopted but before the prior regulation is rescinded?), thus producing even more litigation.

- Why would the Agency want to encourage, much less adopt, new warning requirements for acrylamide in food at the very time it is giving serious consideration to regulatory action premised on the view that such warnings do not serve the purposes of Proposition 65?

In sum, we once more urge OEHHA to use the information gathered in the past three years, including the May 24, 2005 hearing and all comments submitted to evaluate and identify the best approach in the near term to put a halt to litigation and the prospect of misleading warnings that are contrary to the purpose of Proposition 65.

Very truly yours,



Michèle B. Corash

cc: Joan Denton
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