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Proposition 65 Implementation
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Re: April 8, 2005 Notice to Interested Parties Re: Workshop on Potential Regulatory Action Exempting from the Proposition 65 Warning Requirements, Exposures from Chemicals that Form from Natural Constituents in Food During Cooking or Heat Processing.

Dear Ms. Oshita:

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] We appreciated the opportunity to participate in OEHHA's May 9th 2005 workshop, which considered expressly exempting from Proposition 65 chemicals in food formed as the by-products of heating the natural constituents of food.

During that workshop, as well as other workshops and hearings in the nearly three years that OEHHA has been considering the regulation of acrylamide in foods under Proposition 65,

[1] Members of the coalition include the California Chamber of Commerce, California Grocers Association, 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.

the Agency has heard from a wide array of government, academic, independent, and food industry experts. Virtually *all* of these experts expressed serious concerns about the high risks and relatively low benefits associated with widespread warnings about foods that contain by-products of heating natural constituents of foods. The substantial record compiled by OEHHA on this issue is truly one-sided, with nearly unanimous agreement by the 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 numerous health regulatory agencies throughout the world who have scrutinized the potential risks of acrylamide (as well as other by-products of cooking), and 3) unduly risk adverse health consequences.

This substantial record requires regulatory action to exclude acrylamide from Proposition 65 warning requirements, as well as other chemicals in food that are unintended by-products of heating natural constituents in foods. Such an exemption is consistent with and necessary to further the purpose of Proposition 65 – informing the public about dangerous chemicals to which they are exposed. Such an amendment will also avert a mass of pointless lawsuits and/or misleading warnings on a large part of our food supply – warnings that would not only misinform but also have serious adverse public health and economic consequences for Californians.

I. An Express Exemption for the Unintended By-products of Heating the Natural Constituents of Food Would Further the Purposes of Proposition 65.

OEHHA has specifically requested comments on the "threshold" legal issue of the Agency's statutory authority to exempt by-products of heating and cooking natural ingredients in food.[2] As further explained below, it is plain from the face of Proposition 65 that furtherance of the statute does not require warnings about *every* circumstance in which a person ingests, breathes or touches Proposition 65 chemicals – not even when those chemicals are present in amounts above the "no significant risk" levels set forth in the statute. That, in fact, has always been how the statute is interpreted by the lead agency to which the Governor has delegated authority to implement Proposition 65. The lead agency has consistently interpreted the statute as allowing – possibly requiring – the creation of exceptions to a universal warning requirement by regulation in addition to those spelled out in the statute. And the judiciary has approved such regulatory action.

OEHHA unquestionably has the authority to adopt the regulation at issue here in order to assure that the purposes of the statute are served, and not impeded by meaningless and confusing warnings about the foods Californians consume. An administrative agency acts within its statutory authority when it adopts implementing regulations that are "consistent,

[2] *See* Transcript of May 9, 2005 Workshop ("May 2005 Tr.") at 140:19-141:4; 180:22-23.

not in conflict with the statute, and reasonably necessary to effectuate its purpose."[3] To withstand a challenge, the agency's actions need only be found reasonable.[4] In fact, the agency is owed considerable deference in this regard, and its "rules and regulations are *presumed* to be reasonable in the absence of proof to the contrary" and will be upheld "unless it is *clearly shown* that the regulation is so unreasonable as to be arbitrary or capricious, or in excess of the authority vested in the agency."[5] These widely accepted rules regarding the scope of regulatory authority also apply to OEHHA's authority under Proposition 65.[6]

Proposition 65 expressly authorizes OEHHA, as the lead agency charged with implementation of the statute, to "adopt and modify regulations, standards, and permits as necessary to conform with and implement this chapter and to further its purposes."[7] To determine whether the proposed exemption falls within this authority, a court would first look at the language of the statute.[8]

The preamble to Proposition 65 spells out the rights of Californians it is intended to further, only one of which is relevant to the issue at hand: the right of Californians to be informed about exposure to dangerous chemicals.[9] One commenter at the May 9th workshop asserted that this requires a warning for listed chemicals in every instance, no exceptions.[10] That view ignores and conflicts with the plain text of the statute as adopted by the voters, the views of the lead agency as reflected in the regulations it has adopted, and judicial interpretation, all of which recognize that this statutory purpose does *not* require – and may, in fact, be inconsistent with – providing consumers with warnings about every chemical exposure under every circumstance.

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[3] Cal. Govt. Code § 11342.2; *Mooney v. Pickett*, 4 Cal.3d 669 (1971); *Nicolle-Wagner v. Deukmajian*, 230 Cal. App. 3d 652, 659 (1991).

[4] *County of Santa Cruz v. State Bd. Of Forestry*, 64 Cal. App. 4th 826, 835 (1998).

[5] *Bess v. Park*, 144 Cal. App. 2d 798, 804 (1956) (emphasis added).

[6] *Nicolle-Wagner*, 230 Cal. App. 3d at 658.

[7] Cal. Health & Safety Code § 25249.12(a).

[8] *County of Santa Cruz*, 64 Cal. App. 4th at 835 ("The first of the two criteria for regulatory validity set out in *Government Code section 11342.2* requires judicial construction of the claimed source of the agency's rulemaking authority . . . .").

[9] Cal. Health & Safety Code § 25249.5, Historical Note § 1.

[10] May 2005 Tr. at 69:14-17.

A. The Language of Proposition 65 Contains Exemptions that Further the Purposes of the Statute.

It is plain from the face of the statute that the voters contemplated – and that the purposes of the statute are served by – *not* applying a warning requirement to all exposure scenarios.[11] Proposition 65 is not a robotic warning provision disconnected from common sense; it contains a number of limitations or exemptions to a universal disclosure mandate. For one, the obligation to warn does not extend to products containing listed chemicals at levels below the "no significant risk" level, a limitation that, by cutting back (at least in theory) on the number of warnings regarding inconsequential levels of chemicals, furthers the purpose of "informing" consumers.[12]

There are other statutory provisions – particularly those that reflect competing policy considerations, or that are necessary to make the regulatory scheme practical, enforceable, or simply acceptable – that represent exemptions to a universal disclosure mandate and that arguably conflict with the limitless application of the right-to-know language in the Proposition 65 preamble. The exemptions for governments, small businesses, and large public water systems, for example, arguably undermine the right to know – resulting, among other things, in warnings to consumers about some exposures (those caused by businesses of ten or more employees, for example) but no warnings about identical exposures (caused by government or small businesses).[13] Also excluded from Proposition 65 warning requirements are unintentional exposures to listed chemicals – even though these exposures pose the same risk to those exposed as those that are intended.[14]

Many regulations already have been adopted by OEHHA and its predecessor to implement the statute and its purposes by reasonably interpreting key words in the statute to avoid unnecessary or impractical warning requirements. Viewing the statute as a whole, it is clear that a rigid and indiscriminate application of the warning requirement is inconsistent with the statute itself. Indeed, this view has been endorsed both by the Agency and the judiciary.

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[11] *See, e.g.*, *Yeroushalmi v. Miramar Sheraton*, 88 Cal. App. 4th 738, 748 (2001) (statutory language must be construed "in the context of the statute as a whole and the overall statutory scheme").

[12] Cal. Health & Safety Code § 25249.10. *See also Nicolle-Wagner v. Deukmajian*, 230 Cal. App. 3d 652, 666 (1999); Final Statement of Reasons for Section 12501 ("12501 SOR") at 5.

[13] Cal. Health & Safety Code § 25249.11(b).

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

B. Regulatory Precedent Exists for Exemptions that Further the Purposes of the Statute.

OEHHA has already adopted regulations that depart from the literal language of the statute itself. These include several regulations identifying certain circumstances that are not "exposures" – regardless of the levels of the chemicals involved and even though the chemicals are listed.[15] With one exception, these exemptions have never been challenged in court. That one exception, *Nicolle-Wagner v. Deukmajian,* leaves no doubt that the exemption at issue here furthers the purpose of Proposition 65 and is fully within OEHHA's regulatory authority.

C. The Court has Approved OEHHA's Authority to Create Regulatory Exemptions in Furtherance of Proposition 65: *Nicolle-Wagner.*

Nicolle-Wagner was a challenge to the regulation providing that "naturally occurring" chemicals in food do not constitute "exposures" under Proposition 65. The question before the court was whether, as the plaintiff argued, the regulation was in conflict with Proposition 65 and/or was not reasonably necessary to effectuate its purpose.[16] More specifically, the plaintiff argued that excluding natural chemicals from the term "exposure" conflicted with Proposition 65 because the statute approved by voters regulated "all chemicals" known to the state to cause cancer or reproductive toxicity and did not distinguish between man-made chemicals and those that occur naturally.[17] The State argued that, because the term "exposure" is not defined by the statute, the lead agency has delegated authority to interpret the term in a way that furthers the statutory purpose.[18]

The Court of Appeal agreed with the State both as to its authority and on the issue of whether the regulation furthers the purposes of Proposition 65. As *Nicolle-Wagner* is the Court of Appeal decision most relevant to the regulation here under consideration, it bears detailed scrutiny on several points.

1. Scope of OEHHA's authority

The court first identified the standard for determining the scope of the agency's regulatory authority: A regulation is within OEHHA's authority if "the Agency 'reasonably interpreted its legislative mandate' in adopting the regulation."[19] The court went on to say that where, as

[15] Cal. Code Regs. tit. 22, §§ 12501-504.

[16] *Nicolle-Wagner,* 230 Cal. App. 3d at 657.

[17] *Id.*

[18] *Id.* at 658.

[19] *Id.* at 657.

here, "a statute empowers an administrative agency to adopt regulations, such regulations must be consistent, not in conflict with the statute . . . ."[20] In deciding whether that standard is met, the court noted that it would "defer, to some extent to the technical skill and expertise of the rulemaking agency in interpreting the statutes at issue."[21]

2. Consistency with Proposition 65

In *Nicolle-Wagner*, the Court concluded that applying some common sense and practicality to what constitutes an "exposure" by excluding naturally occurring chemicals from the warning requirement is not in conflict with the statute, and hence within the agency's authority, for at least two reasons. First, inasmuch as the term "exposure" is not defined in the initiative, the implementing agency has the authority, and arguably the obligation, to define it.[22] Second, "the language of the statute, as well as the ballot arguments both for and against the proposition . . . indicate that Proposition 65 sought to regulate toxic substances which are *deliberately* added or put into the environment by human activity."[23] The court acknowledged that the ballot arguments and language of the statute contained support for plaintiffs' position that no exception was intended, but concluded that "the better view is that the electorate did not intend naturally occurring substances to be controlled by Proposition 65," and further noted that the ballot arguments talked of the statute's effect as *limited to man-made chemicals*.[24]

3. Reasonable necessity to effectuate the statutory purpose

The *Nicolle-Wagner* court next turned to the question of whether section 12501 was reasonably necessary to effectuate the statutory purpose.[25] The agency, in its final statement of reasons for the regulation, justified the exemption as necessary to further the "clear and reasonable warning" language found in section 25249.6.[26] By avoiding a flood of warnings on nearly all foods containing small amounts of listed chemicals, the court held that the

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[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.* at 659 (emphasis added).

[24] *Id.* at 660.

[25] *Id.*

[26] *Id.* at 661.

exemption was reasonably necessary to safeguard the effectiveness of the statute's warning provision.[27]

D. The Same Logic that Supports Existing Statutory and Regulatory Exemptions also Supports the Proposed Exemption.

As described below each of the concerns that led to the adoption and approval of the "naturally occurring" exemption applies with at least equal force to chemicals produced as the unintended result of heating the natural constituents of food. In fact, there is no relevant toxicological, health or policy difference between a chemical formed as a by-product of cooking and the chemical as a product of other human activities that are an integral part of producing food and are exempted from regulation under section 12501.[28] For each of the reasons discussed below, the logic applied by the lead agency in adopting the naturally occurring exception and by the *Nicolle-Wagner* court in sustaining it supports – indeed compels – the conclusion that exposure to a chemical that is the unintended by-product of cooking or heating natural constituents of food should not be regulated under Proposition 65.

1. The "cooking" exemption is consistent with Proposition 65.

a. Because cooked food is safe, the proposed exemption is consistent with Proposition 65's "no significant risk" requirement.

An important basis for the original naturally occurring exemption was the lead agency's conclusion, based on long human experience with the "general safety" of consuming foods with low levels of such chemicals, that warnings are *unnecessary* for these chemicals in food.[29] The *Nicolle-Wagner* court agreed:

> We all presume, to some extent, that foods that have been eaten for thousands of years are healthful, despite the presence of small amounts of naturally occurring toxins.[30]

The same is true for cooked foods, despite the presence of low levels of chemicals produced by heating. For example, although scientists have only recently learned that acrylamide is present in "*almost all foods of plant origins*" it has undoubtedly been in the human food

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[27] *Id.*

[28] *See* June 6, 2005 letter from Dr. David R. Lineback of the University of Maryland, Director, Joint Institute for Food Safety and Applied Nutrition.

[29] 12501 SOR at 4.

[30] *Nicolle-Wagner*, 230 Cal. App. 3d at 660.

supply for thousands of years.[31] We now know that when foods whose natural constituents include sugars and certain amino acids (as is true of an overwhelming number of foods) are baked, broiled, grilled, fried or toasted, acrylamide is "formed normally."[32] It is not surprising, therefore, that acrylamide has been detected in grilled asparagus and other vegetables, potato products, coffee, vegetarian burgers, bagels, bread crumbs, pizza crust, tortillas, breakfast cereals, almonds and other nuts, peanut butter, chocolate, baked beans, soups, macaroni and cheese, dips and onion rings, to name but a few.[33] It is also undisputed that the list is likely to grow.[34] When other chemical by-products of cooking natural constituents in foods are included, the list extends to meats and covers nearly all cooked foods.

Human beings have been consuming these foods and the chemical by-products of cooking that they contain since our prehistoric ancestors discovered that cooking turns plant and animal matter into food. As Professor Michael Payne of U.C. Davis testified:

> The use of cooking to make foods safer extends back long before recorded history, perhaps as far back as the pre-human Peking man some three-quarters of a million years ago.[35]

This is not an industrial phenomenon, but simply the natural result of cooking – whether in a factory or a restaurant, at home or over the campfire.[36]

A similarly long human history was sufficient evidence for the lead agency in 1987 and for the *Nicolle-Wagner* court thereafter to conclude that "naturally occurring" chemicals posed little risk to consumers. The agency's 1987 conclusions about the safety of unprocessed foods were expressly "not based on controlled clinical studies."[37] Rather, the agency said, its

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[31] Transcript from May 12, 2003 Public Workshop, Proposition 65 Regulatory Options Regarding Acrylamide in Food ("May 2003 Tr.") at 64:8-12 (Comments of Dr. Henry Chin) (emphasis added).

[32] *Id.* at 13:12-15 (Comments of Dr. Terry Troxell of FDA).

[33] *Id.* at 64:8-12; *see also* 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), available at http://www.oehha.ca.gov/prop65/law/pdf_zip/acrylamideintakeReport.pdf.

[34] *See, e.g.*, May 2005 Tr. at 136:5-7 ("[Y]ou must agree, the FDA has tested some products. They have not tested the universe.") (comments of Alise Cappel, Environmental Law Foundation).

[35] May 2005 Tr. at 56:18-21 (comments of Dr. Michael Payne).

[36] May 2003 Tr. at 14:5-25, 51:12-52:13.

[37] 12501 SOR, at 4.

"scientific underpinnings [are] the extent that consumer experience over time has demonstrated that [such foods] are safe to consume."[38]

This is true as well of cooked foods and the chemicals they contain, as the record established by OEHHA regarding acrylamide amply demonstrates. That record suggests that the human body may have adapted to safely eliminate these constituents or that such low levels are not, in fact, harmful.

Moreover, evidence suggests that chemicals such as acrylamide that are present in foods at low levels result in "very low exposures" and pose very small risks.[39] In fact, the only published health studies of acrylamide from cooking and processing found *no increase* in cancer rates associated with acrylamide intake.[40] Sir Paul Nurse, the co-winner of the 2001 Nobel Prize in Physiology or Medicine, and Chief Executive of Cancer Research UK, which published the first study, suggested that an explanation for this result is that while "we know that acrylamide can be carcinogenic to animals, . . . this study suggests that either levels in food are too low to affect cancer risk, or that the body is able to deactivate the chemical in some way."[41]

Other chemical by-products of cooking natural constituents – such as heterocyclic aromatic amines and polycyclic aromatic hydrocarbons formed when meats are grilled – are present at comparable or even lower levels than acrylamide.[42] Given the FDA and World Health

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[38] *Id.*

[39] *Id.* at 19:25-20:4, 21:17-19.

[40] *See Dietary Acrylamide and Cancer of the 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 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. While no increase in cancer attributable to acrylamide was found in any of these dietary studies, an inverse trend was found for large bowel cancer, with a 40% reduced risk in the highest compared to lowest quartile of dietary exposure to acrylamide (Mucci et al., 2003).

[41] *Id.*

[42] May 2003 Tr. at 14:9-14.

Organization conclusions that the acrylamide levels do not warrant a change in dietary advice, it follows that the same is true for these other chemicals.[43]

Finally, it must be remembered that foods produced and sold to consumers are subject to state and federal regulations that safeguard California consumers from exposures to harmful substances.[44] We would have it no other way. Our livelihood depends on providing consumers with foods that are safe and on their confidence that the food supply is safe. FDA and other food health agencies do research and adopt regulations to make sure that this occurs. The scope and reach of these food safety regulatory schemes will be unaffected by the exemption contemplated here. As is true of natural constituents in foods, an exclusion for the by-products of heating these constituents will not pose a health risk to consumers.

b. The proposed exemption is consistent with Proposition 65's "knowing and intentional" requirement because neither chemicals produced by cultivation (exempt from Proposition 65) nor those unintentionally produced by heating (presently covered by Proposition 65) are deliberately added.

In *Nicolle-Wagner*, the court found that the intent of the electorate in passing Proposition 65 was to regulate "toxic substances which are *deliberately* added or put into the environment by human activity . . . . [T]he electorate did not intend naturally occurring substances to be controlled by Proposition 65."[45] The court further recognized that, unless such naturally occurring substances are excluded from the warning requirements, there will be warning labels on most foods, thereby *conflicting* with the purposes of the statute.[46]

There is simply no legal, policy, or scientific distinction between chemicals formed in cultivation of crops and those formed when crops are cooked or processed so that they can be consumed as food. Alice Waters does not intentionally "*put*" into the environment chemicals produced by cooking, any more than does a farmer whose seedlings produce plants containing naturally occurring Proposition 65 chemicals.[47]

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[43] May 2003 Tr. at 30:7-16.

[44] 21 U.S.C. § 342 et seq.; *see also* 21 C.F.R. § 110 et seq; Cal. Health & Safety Code § 109935 et seq.

[45] *Nicolle-Wagner,* 230 Cal.App.3d at 660 (upholding § 12501, the naturally occurring regulation).

[46] *Id.* at 661.

[47] Indeed, the National Academy of Sciences has drawn a definitional distinction between naturally occurring chemicals that are "constitutive" or "derivative" from chemicals naturally present in plants (including furano coumarins, isoflavanoids, phytoalexins, cutins, alkaloid, polycyclic hydrocarbons,

Human interaction with plants and other food materials is best viewed as a continuum. It includes the preparation of the seed or bulb, selection of growing location, preparation of soil to optimize absorption of nutrients and minerals, planting to optimize exposure to sunshine and nutrients, and irrigation. Plants are then harvested, distributed, purchased and cooked to render the nutrients available to humans. All of these are human activities necessary to allow people to convert seeds to energy: "If you can't grow it, if you can't plow it, if you can't irrigate it, then it's not going to be edible . . . ."[48]

Most of the constituents of concern are not present in the seed or bulb from which the seed is grown, but rather are by-products of sunshine, water, and absorption of minerals in the soil. In fact, the formation of Proposition 65 chemicals may occur at any point along this continuum. The selection of a single moment of human interaction with the food supply to define "human activity" relevant to the formation of Proposition 65 chemicals is arbitrary. There is no toxicological (or statutory) distinction between cultivation-related sources, which are exempted from regulation, and the unintended production of chemicals from heating foods, which is not. They do not pose different health risks. They do not pose different scientific issues. They do not pose different right-to-know issues.

A restaurant owner testifying at the May 2003 acrylamide workshop expressed it this way: "I'm not adding anything to my food. I'm not changing the way the food is presented other than preparing it. . . . Nonetheless . . . it seems that practically every item on my menu contains acrylamides in some way, shape or form. There's really nothing that I can do about this because I'm practicing the cooking methods that have been going on in the world for hundreds and thousands of years, from grilling to frying to roasting to open flame grilling."[49]

It is quite likely that most people would concur with this view. This is critical to a determination of what furthers the purposes of Proposition 65 because the intent of voters is to be discerned by interpreting the words of a ballot initiative *as they would be used and understood by the electorate.*

> The words must be understood, not as the words of the civil service commission, or the city council, or the mayor, or the city attorney, but as the words of the voters who adopted the

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pyrazines, and heterocyclic amines) on the one hand and those that are extracted from one food material and "added" to another food (including sucrose, glucose, isolated soy protein used in infant formulas, flavors extracted or distilled from spices, numerous gums and starches) on the other. *Carcinogens and Anticarcinogens in the Human Diet: A Comparison of Naturally Occurring and Synthetic Substances*, National Academy Press, (1996) Tbl 1-1.

[48] May 2005 Tr. at 76:11-13.

[49] May 2003 Tr. 51:12-19, 52:4-8 (remarks by Sam Manolakas, California restaurant owner).

> amendment. *They are to be understood in the common popular way*, and, in the absence of some strong and convincing reason to the contrary, not found here, they are not entitled to be considered in a technical sense inconsistent with their popular meaning.[50]

The fact that courts may define "intentional" broadly enough in other contexts to include all consequences that flow from a person's actions is irrelevant. This distinction did not escape the court in *Nicolle-Wagner*, which rejected a legalistic view of the statute for the common-sense meaning conveyed in the ballot pamphlet.[51] Thus, in holding the "naturally occurring" exemption consistent with the intent of the voters, the court concluded that voters would draw a distinction between a person who intentionally grows, distributes, or sells foods with Proposition 65 chemicals and one who *deliberately adds* those chemicals to food or otherwise *puts* them into the environment.[52]

The lead agency appeared to make this distinction as well when it promulgated section 12501, drawing the "naturally occurring" concept from FDA regulations that distinguish between an: "inherent natural constituent of a food," and "the result of environmental, agricultural, industrial, or other *contamination*."[53] Dr. Terry Troxell (who leads the FDA effort in this area), testifying at the 2003 acrylamide workshop commented that acrylamide "[i]s *not added but formed normally* in certain cooking foods . . . It's formed from *nutrients* in our food; *not from contaminants*."[54] Another food safety expert testifying at the same workshop agreed that a chemical formed during cooking does not fit "the classical definition of a chemical contaminant."[55]

When the "naturally occurring" exception was adopted in 1987, the lead agency declined to extend it to all chemicals formed during cooking or "customary methods of food processing,"[56] That was a broader exclusion than the one being considered by OEHHA

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[50] *Creighton v. City of Santa Monica*, 160 Cal. App. 3d 1011, 1018 (1984) (emphasis added)

[51] *Nicolle-Wagner*, 230 Cal. App. 3d at 659 (rejecting the argument that "furnishing foods to consumers which are known to contain naturally occurring carcinogens or reproductive toxins might constitute a 'knowing and intentional' exposure of individuals to the chemicals" in favor of the plain-language explanation in the ballot materials).

[52] *Id.* at 660.

[53] 12501 SOR, at 6; OEHHA has since confirmed the connection to FDA regulations. *See* May 2005 Tr. at 14:21-22, 15:24-16:3.

[54] May 2003 Tr. at 13:12-15, 14:18-25 (comments of Dr. Terry Troxell) (emphasis added).

[55] *Id.* at 62:24-63:1 (comments of Dr. Henry Chin).

[56] 12501 SOR at 9.

today. The exemption we support is narrow and, consistent with the existing naturally occurring exception, limited to *unintended* by-products of heating *natural constituents* already in foods.

However, even if that were not the case, OEHHA has the authority to adopt a regulation identical to one it has previously rejected where it is supported by changes in the information available to the Agency (such as more experience with the effects of the existing regulation or new scientific information) or other changed circumstances. Among other things, the agency did not know in 1987 that acrylamide is formed naturally in thousands of food products when they are heated or cooked; nor did it know that failure to include acrylamide and similar by-products of cooking in the exclusion would lead to litigation and undermine the clear and reasonable warning objectives of the statute – the very result the naturally occurring exception was intended to avoid.[57]

Courts will defer to agency discretion even where an agency changes its mind after determining that a departure from an earlier interpretation is necessary to further the purposes of the statute.[58] In *Californians for Political Reform Foundation v. Fair Political Practices Commission*, the court found that changed circumstances had caused the Fair Political Practices Commission to reconsider an earlier regulation that was no longer serving the purposes of the Political Reform Act of 1974:

> Accordingly, the Commission was forced to take a hard look at its regulations, and to amend those regulations relating to administrative expenses, in order to harmonize the regulations with a purpose of the Act, i.e., to ensure that everyone is allowed to participate fairly and equally in the elective process.[59]

Thus, the court found that the basis for the agency's change in position was "sound, and because the regulation is fully consistent with the Act, it is entitled to deference from this court."[60] Similarly, faced with the new information concerning the low risks associated with the unintended by-products created by heating the natural constituents of food and the potential consequences of widespread warnings, OEHHA would be well within its authority to revisit its original conclusions concerning cooking.

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[57] See *Nicolle-Wagner*, 230 Cal.App.3d at 661.

[58] *Californians for Political Reform Found'n v. Fair Political Practices Comm'n.*, 61 Cal. App. 4th 472 (1998).

[59] *Id.* at 489.

[60] *Id.*

2. The proposed exemption is necessary to further the purposes of Proposition 65.

Just as the court in *Nicolle-Wagner* determined that the "naturally occurring" exemption was reasonably necessary to safeguard the effectiveness of the statute's warning provision, the proposed exemption is calibrated to avoid confusion and uncertainty.

a. Avoiding widespread warnings on cooked foods is necessary to further the statute's "clear and reasonable warnings" requirement by avoiding consumer confusion.

A primary purpose of Proposition 65's warning provision is to provide information "to facilitate the ability of the consumer to choose among exposures."[61] The preamble to current section 12501 and the *Nicolle-Wagner* decision both concluded that, rather than enlightening consumers, broadly applicable food warnings were "more likely to cause confusion for the consumer who would be unable to differentiate between risks."[62] This conclusion applies equally to chemicals formed by cooking. In fact the exception must be broadened to include such by-products of natural constituents if the objectives of the original naturally occurring exception are to be achieved.

Virtually *all* of the experts who have participated in the acrylamide proceedings before OEHHA shared FDA's concern that widespread warnings on food products will be uninformative, misleading and may have unintended, adverse health consequences. As Dr. Terry Troxell warned:

> "[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."[63]

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[61] 12501 SOR at 5; *see also, e.g.*, May 2003 Tr. at 104:22-25, 116:1-5.

[62] 12501 SOR at 5.

[63] May 2003 Tr. at 72:11-16; *see also* OEHHA Background Materials for the 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); May 2005 Tr. at 40:11-22 (comments by Dr. A. Larry Branen) ("Caution must also be taken in the potential 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.").

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.[64]

She 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.[65] In the case of certain canned vegetables, for example, undercooking could lead to botulism poisoning.[66]

These unintended adverse consequences of warnings are real. Consumer research confirms that warnings about acrylamide in processed foods may lead consumers to conclude that buying fresh vegetables and cooking them at home will reduce or eliminate the risks of acrylamide.[67] The fact is, however, that the chemical reactions that produce acrylamide are the same whether the cooking occurs in a food-processing plant or at home.[68]

Food safety experts also warned OEHHA that consumers might globalize reactions to acrylamide warnings and undercook foods other than those identified as containing acrylamide. "For example, if we give advice for consumers to not overcook foods, some consumers may react broadly to it and not cook meat adequately, potentially resulting in a greater risk for food-borne disease that has very serious consequences for susceptible populations."[69] Such fears are justified given the diverse audience who would receive the warnings:

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[64] May 2003 Tr. at 118:3-15, 122:6-23.

[65] 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.

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

[67] Cogent Research, *Consumer Behavioral Shifts: Understanding Consumer Response To Acrylamide & Other Food/Health Issues* (April 2003) (conducted for the International Food Information Council).

[68] May 2003 Tr. at 14:5-25, 51:12-52:13.

[69] *Id.* at 31:5-9; May 2005 Tr. at 58:6-17 ("A general fear of heat processing could stimulate interest in the fetish of raw milk consumption, a process proven to be associated with increased morbidity and mortality in consumers. Similarly, I have a genuine concern that a vilification of cooking could lead to home undercooking of hamburger, resulting in increased cases of E. coli, especially in children.") (comments of Dr. Michael Payne).

> While people will argue that people can distinguish between not overcooking – not overtoasting their toast versus not overcooking their – not undercooking their hamburger, frankly, we have an extremely diverse population, and I think there's going to be a significant cohort of the population that are going to take that message broadly and stop cooking, you know, everything kind of as well if they were to worry about acrylamide.[70]

As one commenter reminded OEHHA, such misunderstandings concerning food-related health information are not unprecedented: "When frozen raspberries were recalled due to health concerns, many consumers failed to recognize the issue was solely linked to frozen raspberries and stopped buying fresh raspberries . . . ."[71]

Of course we know that even if acrylamide is not formed in meats and certain other foods, cooking these foods produces benzo(a)pyrene or other chemical by-products of heating natural constituents in those foods. It is particularly important, therefore, that the exception not be limited to acrylamide and, thereby, create further confusion and risk.

b. The proposed exemption is necessary because warnings on foods about unintended by-products of cooking natural constituents would create uncertainty and conflict with the purposes of the Proposition 65.

The "naturally occurring" regulation was also based on the concern that the widespread presence of several Proposition 65-listed chemicals as natural constituents of foods would "lead to unnecessary warnings, which could distract the public from other important warnings on consumer products."[72]

> [D]ue to the abundance of foods which . . . inherently contain low levels of carcinogens or reproductive toxicants, *warnings could appear on a large number of food products, and consequently, diminish the overall significance of food warnings.*[73]

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[70] May 2003 Tr. at 72:1-9.

[71] May 2003 Tr. at 48:21-49:1.

[72] 12501 SOR, at 4.

[73] *Id.* at 3 (emphasis added).

This rationale was subsequently upheld by the Court of Appeals. Commenting that the dearth of evidence about risks and the litigation burden on defendants would result in a flood of defensive warnings by businesses to protect themselves from lawsuits, the court concluded:

> Since one of the principal purposes of the statutes in question is to provide "clear and reasonable warning" of exposure to carcinogens and reproductive toxins, such warnings would be *diluted to the point of meaninglessness if they were to be found on most or all food products.*[74]

The situation confronting those who grow, process, sell or serve food is no different in terms of the litigation risks. Virtually every participant in the acrylamide rulemaking process – including attorneys who file enforcement actions – has acknowledged the complexity of scientific issues concerning exposures to chemicals produced by heating foods.[75]

> [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.[76]

Consequently, bright-line conclusions about the levels of unintended by-products of cooking in any particular serving of a food have thus far eluded government, academic and industry experts alike. FDA's evidence is that levels of acrylamide, for example, vary from lot to lot and that test results may differ depending on which day the product is tested: "FDA found substantial day-to-day variability for chips *made on the same production line and with the same potato cultivar grown on the same farm all from a recent harvest.*"[77] The primary basis for the variance is that the experiments were "done on a different day."[78] Industry experts obtained similarly variable results in such foods as gravy, bread, and snack foods.[79]

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[74] *Nicolle-Wagner*, 230 Cal. App.3d. at 661 (emphasis added).

[75] 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.

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

[77] *Id.* at 23:6-10 (emphasis added).

[78] *Id.* at 26:14-19

[79] *Id.* at 65:10-66:12, 67:3-5, 67:19-23.

Given this difficulty by the nation's most qualified food and nutrition experts, California's grocers and restaurateurs stand little chance of being able to predict which products would expose them to liability for failure to warn, and will likely, therefore, have to resort to the very types of blanket prophylactic warnings that section 12501 was promulgated to avert – warnings that the *Nicolle-Wagner* court found would undermine the purposes of Proposition 65.

> Were these substances not exempted from [Proposition 65's] warning requirements, the manufacturer or seller of such products would bear the burden of proving, under subdivision (c) of [Proposition 65], that the exposure poses no 'significant risk' to individuals. The administrative record in this matter indicates that such evidence largely does not exist. Thus, grocers and others would be required, in order to avoid liability under these statutes, to post a warning label on most, if not all, food products. [80]

Indeed, these companies have every reason to fear litigation; several Proposition 65 lawsuits based on acrylamide produced by cooking have already been filed.

Nicolle-Wagner found that "over 300 types of foods" would be subject to the warning requirement without the exemption for naturally occurring substances, but noted evidence presented at the public hearings on Section 12501 that "*most food products* contain at least trace amounts of carcinogens and reproductive toxins which appear on the Governor's list."[81] The same is true of foods that contain Proposition 65 listed chemicals as the result of heating or cooking. Foods already identified by FDA as containing acrylamide, just one such chemical, account *for approximately 40% of the energy consumed in the typical diet*, and the list of such foods will continue to grow.[82] In fact, the record before the agency indicates that acrylamide alone may be formed in "*almost all foods of plant origins*," given the right conditions.[83]

Moreover, looking just at acrylamide grossly underestimates the potential explosion of pointless warnings and litigation. Many other chemicals are known to be the unintended result of cooking. A few examples include: benzo(a)pyrene, benzo(a)anthracene,

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[80] 230 Cal. App. 3d at 660-61.

[81] *Id.* at 655, 660 (emphasis added).

[82] FDA Food Advisory Committee Meeting on Acrylamide, Feb. 24-25, 2003; http://www.cfsan.fda.gov/~lrd/pestadd.html#acrylamide.

[83] May 2003 Tr. at 64:8-12 (emphasis added); *see also Id.* at 112:2-6, 51:12-19, 14:18-19.

dibenz(a,h)anthracene, benzo(b)fluoranthene, and indenopyrene created during smoking; benzo(a)pyrenes produced during the broiling of meat, and, along with benzo(a)anthracene, in dark roasted coffee; polynuclear (or polycyclic) aromatic hydrocarbons (PAHs) in cooked or processed potatoes, spinach and tea; canned chicken and beef broth, crackers, corn flakes, rice cereals, and cooked garlic and onion all have demonstrated mutagenic effects in the laboratory; and furans are formed during cooking from some of the same types of precursors as acrylamide.[84] The fact is that virtually *all foods* that are not boiled or consumed raw are likely to contain one or more of the nearly 800 Proposition 65-listed chemicals as the result of cooking or heating.[85]

Bombarding the public with the massive number of defensive warnings that will likely occur if OEHHA does not act to exempt by-products of cooking will result in the precise situation that HWA and the *Nicolle-Wagner* court sought to avoid – a profusion of warnings, blanketing the grocery shelves and restaurant menus, confusing and misleading consumers, and undermining the informational purposes of Proposition 65.

Under these circumstances, OEHHA would be acting well within its discretion and in furtherance of the statutory purpose in adopting today an exemption that is narrower than the one it previously considered, that is fully justified by policy, science and common sense, and that is consistent with the law as interpreted by the Court of Appeal.

II. Industry Has Incentives to Continue Working on Reductions of the Levels of Chemicals in Foods.

Director Denton requested comment on whether, in the absence of a Proposition 65 regulation requiring reductions of cooking by-products, industry would have incentives to reduce the presence of such chemicals in the food supply. The fact is that Proposition 65 regulations are not going to create those incentives – the incentives exist, but they are wholly independent of the Proposition 65 framework.

Not only is the food industry generally highly regulated at the state, federal, and even international levels, but unintended by-products of cooking natural constituents in foods have been the subject of particular, indeed virtually unprecedented, scrutiny by the FDA and by world health bodies for the past two to three years.[86] Among other things, these health

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[84] May 2005 Tr. at 100:11-13.

[85] May 2005 Tr. at 100:9-25, 139:21-140:1.

[86] *See http://www.slv.se/templatesHeatox/Heatox_Page____8547.aspx* (describing the HEATOX Project, an effort by 23 European institutional participants to identify "health risks recently discovered associated with hazardous compounds in heat treated carbohydrate-rich foods where substantial amounts of acrylamide and similar compounds can be formed. . . . Acrylamide is given

agencies are trying both to identify all of these unintended by-products of cooking and, where needed, find ways of reducing them. However, as Dr. Terry Troxell and several other food safety experts have testified at the various OEHHA hearings and workshops, the search for reduction approaches is time-consuming and difficult.

As Dr. A. Larry Branen (Professor of Food Science and Toxicology at the University of Idaho) testified at the May 9 workshop, efforts to date have produced conflicting results – results that, at best, would require an agency with food safety expertise to weigh feasibility, costs, and benefits and make a policy decision concerning the best approach:

> 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.[87]

FDA, in particular, has reviewed three basic strategies for reducing acrylamide levels in foods: (1) removing the precursors to acrylamide before the reaction occurs; (2) disrupting or redirecting the process that causes acrylamide to form; or (3) removing the acrylamide from foods after formation.[88]

Each potential strategy poses challenges. For example, with respect to measures aimed at preventing the reaction that causes acrylamide, Dr. Terry Troxell testified:

> We can reduce or remove precursors, the asparagines and sugars from foods, and it's likely to be near impossible to remove precursors as a broad approach. But it is possible, for example, to select cultivars with lower levels, and it may be possible to modify storage conditions to affect levels. It's

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particular emphasis, however, it is likely that also other compounds such as β-unsaturated carbonyl compounds and furans, representing potential health hazards, are formed during heating."); *see also* European Commission, *Food Contaminants – Acrylamide Information Base of Research Activities in the EU*, available at *http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/acryl_database_en.html* (a summary of EU efforts regarding acrylamide).

[87] May 2005 Tr. at 40:11-22.

[88] May 2003 Tr. at 23:24-25:13.

> possible, but is it feasible to control storage conditions broadly?[89]

Dr. Dan Tallmadge, the scientist-author of several peer-reviewed papers on acrylamide, commented at the May 9 workshop on the variability of acrylamide production and the limitations of current knowledge concerning agronomic reductions to acrylamide's precursors:

> 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.[90]

As Dr. Troxell testified, other strategies simply may produce unanticipated results that require further study:

> The other area is to disrupt the acrylamide-producing reaction. . . . [T]he research is starting to show that there might be some things to . . . make the reaction go on other pathways, and two things that were mentioned were cysteine and divalent cations. From what I've heard indirectly, it might take substantial amounts of these compounds, so it brings two issues up.
>
> What would the nutritional impact of adding a lot of . . . calcium, for example, as a divalent cation . . . ? That could actually be good; but if you do it broadly, it might be too much. But the other thing is, what other compounds are being formed that we don't know about? Sort of the devil you know versus the devil you don't here. [91]

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[89] *Id.* at 24:5-12; *see also, id.* 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."); 68:13-18 ("[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.").

[90] May 2005 Tr. at 82:2-6.

[91] May 2003 Tr. at 24:13-25:6.

Finally, Dr. Troxell testified that some alternatives may simply prove infeasible:

> The third strategy is remove acrylamide once it's formed, and this has been--a couple of things have been tried; UV, apparently, which didn't work; and secondly, supercritical CO2, which apparently stripped out enough flavor components to make the food inedible.[92]

Given the present state of knowledge, Proposition 65 regulations will not affect the incentives to reduce the levels. Thus far FDA's substantial effort to identify ways of reducing acrylamide has not identified a reliable, practical and effective means of doing so. When it does so, FDA is likely to require that these methods be adopted by industry and that will be done regardless of Proposition 65 requirements.

It should also be remembered that the chemicals we believe should be excluded from Proposition 65 are limited to *unintended* by-products of cooking. These chemicals are, by definition, of no value to the food industry as components of the food products they produce – they do not add value, taste, longevity, or any other benefit of which we are aware to the products. Thus, those who prepare and sell food have no vested interest in maintaining the levels of these chemicals – they did not mean for them to be there in the first place.

Finally, it is worth noting that OEHHA's very low NSRLs for most unintended by-products of cooking, combined with the limited information available concerning the actual level of exposure from the universe of potentially affected products, will quite likely result in companies simply choosing to participate in a warning program rather than continuing to chase reduction strategies.

However, recognizing OEHHA's concern that these efforts continue and be reflected in Proposition 65 requirements, we recommended at the May 9 hearing, that compliance with all applicable State and federal food safety regulations should be made a pre-condition for the regulatory exemption under consideration.[93] Thus, as the efforts of FDA and others evolve, the appropriate health regulatory agencies – be it the FDA or a California agency – may adopt regulations requiring particular processes for reducing one or more of these by-products of cooking. Such requirements would then be automatically incorporated into and become a condition for application of an exemption from the Proposition 65 warning requirement.

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[92] *Id.* at 25:9-13

[93] May 2005 Tr. at 51:5-11.

A vague and uncertain regulatory requirement that unintended by-products of cooking must be reduced to meet some narrative standard would not create incentives for reduction at all – they would simply leave companies with the choice of warning on the thousands of food products affected, or take the risk of litigation.

III. An Exemption Must Be Clear and Complete.

As discussed above, OEHHA is within its statutory authority to promulgate regulations exempting chemicals produced as the result of heating the natural constituents of food. A carefully crafted amendment will further the purposes of Proposition 65 and will achieve the objectives of the HWA and the court in *Nicolle-Wagner* by stemming the tide of excessive warnings and litigation.

In order to achieve this goal however, the language of an amendment must be clear and unambiguous. The public, the regulated community, and both public and private enforcers of Proposition 65 must be able to determine which chemicals and foods are exempt from regulation and which are not *without resort to litigation*. Thus, this determination must not rely on proof or resolution of complex factual analyses that must be decided at trial. Unless the application of an exemption can be clearly understood without need of litigation, the exemption will do nothing to stem the tide of litigation, which will in turn lead to a proliferation of "defensive" warnings – the very outcome that *Nicolle-Wagner* found undermines the purpose of Proposition 65 and that the exemption under consideration here is intended to avoid.

Those who commented on it at the May 9 workshop, including a commenter who brings private Proposition 65 enforcement actions, pointed out that OEHHA's "conceptual" exemption language contains vague and undefined terms concerning practices intended to reduce levels of listed chemicals in foods.[94] A regulation using the same language would make litigation over these terms inevitable, particularly in the absence of any existing, proven, well established and effective mitigation practices (as is currently the case with acrylamide and most other unintended by-products of heating and cooking).[95]

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[94] May 2005 Tr. at 161:12-22; 166:7-17. Indeed, the Agency has acknowledged that the regulation requires fine tuning. May 2005 Tr. at 170:18-22 ("[T]his is more of a conceptual thing, and is there information that you think that we need which would – that you could provide that would – would further inform us about how this – this conceptual regulation should be framed.") (comments of Dr. Joan Denton); *id.* at 174:10-12 ("I know we didn't want to pick apart this particular reg because it's not – it's not close to a point where it would be proposed in this form anyway . . . .") (comments of Carol Monahan).

[95] In fact, if such terms are included in a final regulation, it may be necessary for OEHHA to proceed with its proposed regulation establishing a safe harbor warning for acrylamide.

To advance the purposes of the statute in a manner wholly within OEHHA's authority, we urge that the Agency propose to adopt the following regulation:

> 22 CCR 12501(c) A person otherwise responsible for an exposure to a listed chemical in food does not "expose" an individual within the meaning of section 25249.6 of the Act to the extent the person can show that the chemical is an unintended by-product of heating or cooking natural constituents of foods, provided that the cooking or heating process complies with any requirements adopted (and in effect) by the United States Food and Drug Administration and/or the California Department of Health Services for the purpose of reducing the level of such chemical in food.

IV. A Decision Concerning the Exemption Must Precede Consideration of Proposed Acrylamide Rules.

Finally, because adoption of an extended exemption will have an impact on other matters before the agency, it is critical that OEHHA take an orderly approach to regulation in this area. At the May 24, 2005 hearing on the three pending and formally proposed acrylamide rules, OEHHA acknowledged that the proposed exemption would obviate the need for at least two of them. The Agency was less clear on whether or when it would proceed with consideration of its currently proposed revision of the no significant risk level safe harbor for acrylamide.

As voiced by *all* who addressed the subject at the May 9th and May 24th hearings, we urge OEHHA not to proceed with consideration of the three acrylamide regulatory proposals until it has decided what action to take with respect to an exclusion for unintended by-products of heating natural constituents in food and has implemented it. To proceed otherwise makes no sense.

- Informed comment and decision-making regarding how to regulate acrylamide requires first knowing when, if at all, it 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 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 urge OEHHA to use the information gathered in the May 9 workshop, along with these and other comments 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,

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