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Fran Kammerer
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Sacramento, CA 95812

Re: Comments on Beneficial Nutrients Regulatory Concept, Proposition 65 Regulatory Update Project

Dear Ms. Kammerer:

These comments on the above-referenced proposed regulatory action[1] are submitted on behalf of the Grocery Manufacturers Association ("GMA"), an association of companies whose members produce, process, prepare and otherwise sell foods consumed by virtually all Californians. The Office of Environmental Health Hazard Assessment ("OEHHA" or the "Agency") has proposed a revised "conceptual" regulation under Article 5 of Proposition 65's implementing regulations regarding foods that contain chemicals listed under Proposition 65 that are human and plant nutrients (the "Proposal").

I. INTRODUCTION

The Proposal is a continuation of a process begun on March 21, 2008, when OEHHA published a notice requesting public participation in an April 18, 2008 workshop to discuss similar – but more specific – conceptual language.[2] Participants in the April 18 workshop, including representatives appearing for GMA, offered substantial testimony, addressing both

[1] OEHHA, Proposition 65 Regulatory Update Project Regulatory Concepts For Exposures To Human And Plant Nutrients In Human Food, Opportunity For Public Participation, Notice Of Second Public Workshop (November 3, 2008) ("November Notice"), available at http://www.oehha.ca.gov/prop65/public_meetings/Regupdate110308.html.

[2] OEHHA, Request for Public Participation, Notice of Public Workshop - Proposition 65 Regulatory Update Project, Beneficial Nutrients Regulatory Concept ("March Notice") (March 21, 2008), available at http://www.oehha.ca.gov/prop65/law/regs032108.html.

the concept of an exemption or defense of some kind for such foods, and the specific language proposed.[3] The response was universally negative. None of the participants believed that the conceptual regulation was necessary at this time.[4] There was also substantial criticism of the specific language proposed.

Notwithstanding this unanimous feedback, eight months later, OEHHA issued its November Notice, announcing revised conceptual language and a December 12, 2008 workshop to discuss it.[5] OEHHA also issued a Draft Initial Statement of Reasons, setting forth its rationale for the revised proposal.[6] For the reasons described in both workshops, and for all of the reasons set forth below, pursuit of this regulation still appears to represent an unnecessary expenditure of OEHHA's limited resources; because the conceptual regulation is unworkable as written, the continuation of this process would also require the continued expenditure of private resources in pursuit of a regulation for which there is no current need.

II. DISCUSSION

A. There is no apparent need for this regulation.

As discussed at length in the April workshop and in the written comments that followed, Vitamin A is currently the only chemical listed under Proposition 65 that is also known to be a human nutrient. When Vitamin A was listed, the Science Advisory Panel ("SAP") considered the countervailing concerns of subjecting a human nutrient to Proposition 65's warning requirements and resolved the issue by an appropriate qualification to the listing.[7] If

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[3] *Id.* (linking to audio recording of April 18, 2008 workshop).

[4] Written comments voicing objections to the conceptual regulation are posted on the webpage with the March Notice, at http://www.oehha.ca.gov/prop65/law/regs032108.html.

[5] November Notice, available at http://www.oehha.ca.gov/prop65/public_meetings/Regupdate110308.html.

[6] OEHHA, Initial Statement of Reasons Title 27, California Code of Regulations, Draft- Proposed New Sections 25506 and 25507, Exposures to Human and Plant Nutrients In Human Food ("Draft ISOR"), available at http://www.oehha.ca.gov/prop65/public_meetings/pdf/draftisor111908.pdf.

[7] Vitamin A is listed as "retinol/retinyl esters, when in daily dosages in excess of 10,000 IU, or 3,000 retinol equivalents..." Cal. Code Regs., tit. 22, § 12705; OEHHA, *Safe Drinking Water and Toxic Enforcement Act of 1986, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity* (hereinafter, the "List"), at 15, (March 21, 2008) available at http://www.oehha.ca.gov/prop65/prop65_list/files/032108list.pdf. At the April 18, 2008 workshop held to discuss the Proposal, OEHHA identified two listed chemicals—chromium and vitamin A—as beneficial nutrients. OEHHA, Slideshow Presentation by OEHHA staff, at slide 5, available at (April 18, 2008) http://www.oehha.ca.gov/prop65/law/pdf_zip/041808wkshpslides.pdf. However, chromium hexavalent, the only form of chromium on the list, is not a nutrient. The List at 4; *see also,*

and when boron or manganese, the two nutrients now cited by OEHHA, are considered for addition to the Proposition 65 list, the appropriate SAP committee can and should address any conflict between nutritional benefits and potential risks posed by such chemical in food, and make its listing recommendation accordingly.

B. The issue is best addressed, if at all, on a nutrient-by-nutrient basis in the context of a specific listing decision taken by the SAP.

For the very reasons cited by OEHHA as motivating this Proposal, any beneficial nutrient proposed for listing under Proposition 65 should be submitted to the appropriate SAP committee, so that it can consider how to weigh and balance the benefits and risks. The SAP's analysis should include, among other things:

- Whether the nutrient should be listed at all, in light of its offsetting benefits;
- If it is listed, whether and how the listing should be qualified to reflect the health benefits of the chemical;
- Whether, and, if so, how, a maximum daily exposure level should be established; and
- Any other relevant considerations necessary to assure that Proposition 65 warnings do not adversely affect the health of California consumers and that the purpose of the statute is effectuated.

Given the very small number of beneficial nutrients that appear to be potential Proposition 65 chemicals, this approach should not be unduly burdensome for the SAP.

C. Before proceeding with a regulation addressing beneficial nutrients, OEHHA should address other, more pressing regulatory issues.

If the regulatory update project is to yield any useful outcome, GMA believes that the Agency must focus its resources on regulatory actions that will address the most pressing needs and offer the most promising solutions. In its comments on OEHHA's November 2, 2007 workshop to discuss its regulatory update project, GMA identified several such

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e.g., May 2, 2008 Letter from F. Jay Murray to Fran Kammerer, posted with the March Notice, at http://www.oehha.ca.gov/prop65/law/regs032108.html.

priorities—all aimed at serving the purposes of Proposition 65 while avoiding the crush of unnecessary litigation that results from ambiguous and difficult-to-implement provisions.[8]

1. The "Naturally Occurring" exemption must be revised.

This Proposal highlights the importance of one of the areas GMA originally suggested be a high priority for the Update Project: revision of the so-called "naturally occurring" exemption to the definition of "exposure" under Proposition 65.[9] As GMA pointed out in its prior comments, there is a pressing need to revise the exemption to make it meaningful and understandable to those developing compliance programs and enforcing the law.[10]

The current Proposal incorporates the naturally occurring exemption to address the tension between the need to consume foods that contain beneficial nutrients and the alleged cancer or reproductive risks posed by such chemicals. The link between the existing exemption and the Proposal is logical, since both are aimed at preserving important health benefits associated with food. However, as a practical matter, the naturally occurring exemption has, because of its formulation, been virtually meaningless to most businesses. Thus, as it exists, it does nothing to address the balancing that would be required were additional beneficial nutrients to be listed. *Before* the naturally occurring exemption is incorporated into a new regulation, that exemption must be revised to make it achieve its intended purpose.

When the naturally occurring exemption was adopted, both OEHHA's predecessor and the Court of Appeal that upheld the regulation assumed that it would alleviate the need for grocers and food manufacturers to put defensive warnings on food to avoid the expenses of trial and the difficult burdens of proving that an exposure to chemicals in food presents "no significant risk" defense.[11] As written and implemented, the current regulation does not serve this purpose. In fact, 20 years of experience with Proposition 65 litigation has demonstrated that, as it exists, the exemption is irrelevant and of no value to the vast majority of foods and the businesses that grow, sell, process, prepare, serve or otherwise sell them. At best, it simply substitutes an equally expensive, time-consuming and far more difficult and uncertain factual showing that must be made in litigation, for the existing affirmative defenses.

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[8] Letter from Michèle B. Corash to Dr. Joan Denton (November 17, 2007) ("GMA Update Comment Letter"), available at http://www.oehha.org/Prop65/public_meetings/pdf/GMAcomments111607.pdf.

[9] Cal. Code Regs., tit. 27 § 25501.

[10] GMA Update Comment Letter, at 3.

[11] *Nicolle-Wagner*, 230 Cal. App. 3d 652, 660-61 (1991); Cal. Health & Saf. Code § 25249.10(c).

Most of the critical terms in the exemption are ambiguous, thereby inviting lengthy, burdensome litigation. The burden of proving that a chemical is "naturally occurring" in food is born by the defendant.[12] To qualify, the defendant must make several showings, including that (1) the chemical is not added to the food by any human activity and that (2) the amount of the chemical present in the food is reduced to the lowest level currently feasible.[13] Because these are intensely factual questions, the sufficiency of the defendant's showing may only be resolved at trial, after discovery, expert depositions and, almost certainly, the expenditure of millions of dollars.[14] Moreover, these showings call for information that is unknown and unobtainable for many sellers in the chain between grower and consumer.

This assessment is not theoretical – it has been playing out in courtrooms for years. In 2001, for example, a private plaintiff sued several chocolate manufacturers. After a thorough investigation of evidence presented by both parties, the Attorney General issued a highly unusual opinion letter concluding that the chemical at issue was naturally occurring and that the plaintiff's claims lacked merit:

> It is unusual for the Attorney General to publicly state that he has reviewed a matter under Proposition 65 and determined that it is not appropriate to proceed on the claim. . . . Nonetheless, because these products are consumed by so many Californians, we think it is important for the public to be aware that ***the Attorney General's decision not to commence a civil action in this matter is based on a conclusion that the action would lack merit, after thorough consideration by this office.***[15]

Notwithstanding, the plaintiff was able to pursue litigation all the way through fact and expert discovery, at a cost of millions of dollars to the defendants, *despite the fact* that defendants would almost certainly prevail if they were willing to bear the costs through trial. Indeed, the plaintiff dropped its claims only on the eve of trial, when it became apparent that the defendants would not back down.

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[12] Cal. Code Regs., tit. 27 § 25501(a).

[13] *Id.* § 25501(a)(3)-(4); The reference to Title 21 Code of Federal Regulations, Section 110.11 0, subdivision (c) of the FDA regulations is a particular mystery as a standard for the "lowest level currently feasible," even to FDA experts, as it seems to have no relevance to Proposition 65 issues.

[14] Cal. Civil Proc. Code § 437c(c) (summary judgment unavailable where triable issues of material fact are in dispute).

[15] September 28, 2001Letter from Supervising Deputy Attorney General Edward G. Weil to Roger Carrick and Michèle B. Corash, at 1-2, available at http://ag.ca.gov/prop65/pdfs/prop65chocolateltr.pdf (emphasis added).

Most companies simply cannot afford the cost or distraction of years of litigation required to resolve these factual issues. Even if they win at trial, they cannot recover any of the fees and costs they incurred; however, if they lose, they will be required to pay the plaintiffs' legal fees and usually a premium on top of those fees.[16] It is no wonder, then, that these issues have never been tried to judgment, even where it is clear that the chemicals in question are naturally occurring.

Another recent case involving balsamic vinegar illustrates the consequences to smaller companies. Based on peer-reviewed literature, it is undisputed that lead is naturally occurring in the region of Italy where balsamic vinegar is produced, and that the same lead naturally present in the soil is in the grapes used to make the vinegar. But most companies that import vinegar are too small to bear the cost of going to trial, even though they would have been able to prove that any lead present in their products was naturally occurring. The result of these flaws is that balsamic vinegar bottles now carry warnings for one reason only: the cost of litigation to prove the elements of the naturally occurring exemption is more than those small companies can afford.

The Proposal's reliance on the naturally occurring exemption provides one illustration of the need for this regulation to be workable and the exemption meaningful. Revising the exemption to achieve this goal must take precedence over a new regulation that, by incorporating the exemption in its current form, simply compounds the existing problems.

2. A Food Warnings System

The vinegar case also highlights the need for another important regulatory update project that OEHHA has undertaken – a workable system of warnings for foods, particularly those sold at retail. It had become common practice among private Proposition 65 enforcers to sue retailers, as well as manufacturers and importers. The results are predictable – even where manufacturer defendants are willing and able to litigate the underlying claims, suits against retailers (and the accompanying market pressures and indemnity demands) put pressure on the manufacturer to settle plaintiffs' claims without trial and to forgo their defenses. A practical and workable regulation setting forth warning systems for retailers and removing them from the litigation quotient would remove this obstacle to the full and appropriate application of the law and would be consistent with the voters' express intent.[17]

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[16] Cal. Health & Saf. Code § 25249.7(f)(4), (i), (j); Cal. Civil Proc. Code § 1021.5.

[17] Cal. Health & Saf. Code § 25249.11(f).

D. The Proposal provides no criteria for how the most significant part of the regulation—the MDEF—will be developed.

Although the drafting is unclear, is appears that the regulation is intended to work as follows:

For beneficial human nutrients, there is no exposure requiring a Proposition 65 warning, if

- the nutrient is "naturally occurring" as currently defined by regulations (this is not a change to the current regs); **or**
- it is below the "Maximum Daily Exposure from a Food (micrograms per day)."[18]

For beneficial plant nutrients, there is no exposure requiring a Proposition 65 warning, if

- the nutrient is "naturally occurring" as currently defined by regulations (this is not a change to the current regs); **or**
- "the nutrient is added to the soil in an amount necessary for healthy plant development" **and** it is below the MDEF. (As drafted, there is some confusion about what is actually intended, but that is how we understand what is intended.)[19]

The criteria for setting the MDEF are fundamental to the function and purpose of the Proposal. Because they are absent from the draft, the Proposal is simply too vague for GMA to provide meaningful comments.

E. The criteria for the plant nutrient exemption are too vague and unproveable to have any effect.

As a threshold matter, the plant nutrient provision in the draft section 25507 appears to be redundant to the exemption in section 25506. Since the goal of both is to set an outer limit on the amount of a nutrient that may be exempted from the definition of an "exposure" under Proposition 65, a provision that deals with plant nutrients separate from other sources is duplicative and unnecessary.

Moreover, just as uncertainties in the criteria for establishing a "naturally occurring" exemption create insurmountable obstacles to satisfying the defendants' burden of proof, the Proposal would create similar and even greater problems as regards plant nutrients. The defendant would have to prove, among other things, that the nutrient was "added to the soil

[18] Proposed Cal. Code Regs., tit. 27 § 25506, November Notice.

[19] Proposed Cal. Code Regs., tit. 27 § 25507, November Notice.

in an amount necessary for healthy plant development."[20] This burden and others created by this provision would render illusory any protections intended by the Proposal.

As an initial matter, the practical realities of food distribution in the 21st century would place the facts necessary to prove this exemption utterly out of reach for most businesses that manufacture or sell foods. Agricultural products are international commodities. In most cases, food manufacturers and distributors have little access to the exceedingly detailed (and possibly massive) information necessary to show where and under what conditions every particular batch of fruits and vegetables in their products was grown. Requiring a food manufacturer to prove such facts will create an insurmountable barrier to the use of this defense. Such unproveable burdens were central to the Court of Appeal's approval of the naturally occurring exemption:

> Were these substances not exempted from Health and Safety Code section 25249.6's warning requirements, the manufacturer or seller of such products would bear the burden of proving, under subdivision (c) of Health and Safety Code section 25249.10, 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.*[21]

Moreover, even where such information is available, the amount and identity of a nutrient "necessary for healthy plant development" will, no doubt, vary with the plant, the time of year, the part of the county or field in which the food is grown, the weather, the substitutes available and usable on any particular day or location, the views of the individual farmer and, in litigation, which expert is asked. As it is likely to be the subject of debate among qualified experts, a business wishing to rely on the exemption will, as with the existing naturally occurring exemption, face the certainty of having to hire experts and successfully litigate numerous contentious factual issues.

III. CONCLUSION

For all of the reasons above, GMA continues to believe that this Proposal is premature. However, as suggested in GMA's May 2, 2008 comments on the first "conceptual

[20] Proposed Cal. Code Regs., tit. 27 § 25507(a), November Notice.

[21] *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 660-61 (1991) (emphasis added).

regulation," *if* OEHHA nevertheless intends to proceed with a regulation along these lines, it should

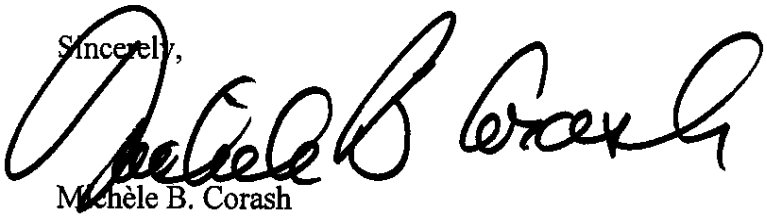
- proceed chemical by chemical, and
- absent specific and compelling reasons to the contrary, identify the nutrient and specify that its presence in food will be presumed to be naturally occurring and will not constitute "an exposure."

As OEHHA has recognized in past rulemakings, food is different from other consumer products for the very simple reason that human beings cannot do without it: "Food is a basic daily necessity of life on a par with the water that we drink and the air that we breathe."[22]

Therefore, regulations that affect foods – *particularly* those directly targeted at nutrients that are vital to the functioning of the body's systems – implicate important public health issues.[23] To further the purpose of the statute (thereby fitting within the Agency's authority), such regulatory provisions must be carefully crafted to provide meaningful information to consumers while avoiding a proliferation of warnings that would confuse, rather than enlighten, make certain foods unavailable, or worse still, actively discourage nutrient fortification of foods.[24] The approach recommended above is consistent with the purpose of Proposition 65 and is well within OEHHA's authority as described by the court of Appeal in *Nicolle-Wagner.*

In order to achieve these and other goals outlined by OEHHA at the November 2007 workshop on the regulatory update project, OEHHA must retain its focus and not be distracted by activities that address no current problem. GMA recommends that the Agency stay focused on these more fruitful pursuits and abandon the Proposal.

Sincerely,



Michèle B. Corash

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[22] Final Statement of Reasons, 22 California Code of Regulations Section 12501, at 5.

[23] Grocery Manufacturers Association, *Industry Guidance on Making Structure-Function Claims for Food*, available at http://www.fpa-food.org/upload/pdfs/guidance_claims.pdf (essential nutrients provide energy through macronutrients, supplying essential vitamins, minerals, and other micronutrients, providing moisture and hydration, or supplying other physiologically active components).

[24] *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 660-61 (1991).