

May 13, 2010

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P.O. Box 4010, MS-19B
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Re: Request for Public Hearing Re Bisphenol-A

Dear Ms. Oshita:

The Grocery Manufacturers Association (“GMA”) – whose members produce, process, and prepare foods consumed by virtually all Californians – is pleased to provide these comments on the Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A (the “Request”), published by the Office of Environmental Health Hazard Assessment (“OEHHA”) on February 12, 2010.

The use of Bisphenol-A (“BPA”) in epoxy resin coatings has for over 30 years helped improve the safety and quality of food and beverages by protecting the integrity and performance of cans and metal closures for glass jars. The unique properties of these coatings assure that fruits, vegetables, fish, and other foods can be canned and stored safely over long periods of time, providing a relatively low-cost source of nutrients to consumers and delivering an important health benefit to Californians.

Many consumers face economic and logistical obstacles limiting their access to fresh fruits, vegetables, and proteins. Product packaging employing BPA allows them to obtain the benefits of those foods. Moreover, because epoxy resins keep foods safe for extended periods of time, canned foods are critical to emergency preparedness; they also are essential for persons who are elderly or otherwise unable to do frequent food shopping. Although research continues on alternative materials that would serve the same function as BPA, at present there are no commercially viable substitutes that will work for all food uses. Any decision that has the consequence of discouraging consumers from buying canned foods whose liners contain very low levels of BPA could, therefore, have a material adverse impact on consumer well-being.

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For all these reasons and others described below, the prospect of adding BPA to the Proposition 65 list raises numerous public health issues of great importance to food manufacturers, retailers, and consumers. It is essential, therefore, that OEHHA have as robust a record as possible for any decision that may profoundly impact public health from changes in consumers' purchasing and food consumption decisions, and we had requested a short additional time period to respond to OEHHA's Request. We reiterate our request for an additional 30 days to comment on this subject.

Given the benefits delivered every day by protective linings in food packaging, it is critical that OEHHA use the resources available to it to be sure that its decision is (1) scientifically supported and (2) consistent with the language, purpose, and intent of the statute and its implementing regulations. Based on the extensive record currently before OEHHA, it is clear that a decision to list BPA administratively – through the authoritative bodies mechanism – does not pass either test.

I. DISCUSSION

OEHHA is poised to take an unprecedented step in interpreting and applying Proposition 65. Specifically, OEHHA proposes to allow its staff to overrule a determination by the Developmental and Reproductive Toxicant Identification Committee ("DART IC") that BPA is not "known to the state" to cause reproductive toxicity.

The DART IC's unanimous vote not to list BPA rested on a full body of scientific evidence from a number of different sources, including the 2008 monograph prepared by the National Toxicology Program ("NTP"). The DART IC expressly requested that OEHHA bring the chemical back for further review by the DART IC should new information come to light.

Instead, OEHHA now proposes to list BPA under the authoritative body criterion of subdivision (b) of section 25249.8 of Proposition 65, based on a narrow slice of the scientific record considered by the DART IC. Such an application of subdivision (b) is flatly inconsistent with the language, structure, and intent of the statute; it also exceeds OEHHA's authority to implement the statute.

If there were new evidence supporting listing, OEHHA should have referred BPA back to the DART IC for further consideration. Where, as here, the more recent scientific evidence supports the DART IC's unanimous decision *not to list*, OEHHA should simply put BPA back into the pool of candidate chemicals in accordance with its Prioritization Procedures.

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A. OEHHA May Not Use the Authoritative Bodies Criterion to Overrule the State's Qualified Experts.

When Proposition 65 was presented on the November 1986 ballot, voters were told that the new statute would include only those chemicals “known — not merely suspected, but known — to cause cancer and birth defects,” and that Proposition 65 would require the application of more rigorous science than any other toxics law.¹ To ensure this high degree of scientific integrity, Proposition 65 requires the Governor to appoint a panel of scientific experts and, “only after full consultation” with that panel, to update the list.²

Section 25249.8, subdivision (b), provides that “[a] chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if

in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or

if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or

if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.”

Cal. Health & Saf. Code § 25249.8(b).

In OEHHA's Request announcing its consideration of listing BPA under the authoritative body criterion, and again at the April 20, 2010 public forum, OEHHA argued that the criteria set forth in section 25249.8 of Proposition 65 for adding chemicals to the list are “co-equal” and independent of one another, and that no single criterion takes precedence over another.³ However, as explained below, this view is inconsistent with the context and purpose of

¹ California Secretary of State, Restrictions on Toxic Discharges into Drinking Water; Requirement of Notice of Persons' Exposure to Toxics. Initiative Statute (1986) (“Ballot Pamphlet”), at p. 55.

² Cal. Health & Saf. Code § 25249.8, subd. (d); Ballot Pamphlet at p. 54.

³ OEHHA, Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A (Feb. 12, 2010), available at http://www.oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html, visited May 3, 2010.

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section 25249.8 and its implementing regulations, and is not consistent with OEHHA's actual practices.⁴

1. The state's qualified experts criterion is the "primary approach to listing."

Regulations implementing the authoritative body criterion were promulgated in 1990.⁵ The final statement of reasons explaining the regulations makes clear that it was not intended to replace, let alone *contradict*, work already done by the science panels. Indeed, the state's qualified experts criterion under subdivision (b) of section 25249.8 was intended to serve as the "*primary approach to listing*."⁶

⁴ For example, OEHHA has prioritized the listing criteria according to its view of how much process is required prior to listing under various listing criteria. In 2006, for example, OEHHA publicly articulated a new legal theory (the validity of this theory has been challenged and is the subject of a lawsuit currently pending in the Court of Appeals) that an incorporation provision used to create the initial version of the Proposition 65 list in 1987 creates an ongoing current mandate for OEHHA staff to list chemicals identified by reference to California Labor Code section 6382, subdivisions (b)(1) and (d), automatically and with no opportunity for the SAB or the public to present contrary scientific evidence or for the SAB or OEHHA staff to consider such evidence. *See, e.g.*, OEHHA, Request for Comments on Chemicals Proposed for Listing by the Labor Code Mechanism (June 12, 2009), at p. 2, available at http://www.oehha.ca.gov/prop65/docs_admin/pdf/LCDART061209.pdf (visited May 3, 2010). Thus, on August 7, 2009, OEHHA listed 20 such chemicals at once. OEHHA, Chemicals Listed Effective August 7, 2009 As Known to the State of California to Cause Cancer Or Reproductive Toxicity, available at http://www.oehha.ca.gov/prop65/docs_admin/LClist080709.html. Many of these chemicals were listed because they had been identified by NTP and would therefore be subject to additional process (including scientific challenges by the public or a member of the SAB) under OEHHA's own regulations had they been proposed for listing under the authoritative body criterion. *See* Cal. Code Regs., tit. 27 § 25306(h), (i). Chemicals listed pursuant to the "state's qualified expert" criterion under subdivision (b) of section 25249.8 are subject to the most process – including public meetings of the Committees, consideration of written comments, and quorum voting. Cal. Code Regs., tit. 27 § 25302(d)-(f). As a practical matter, OEHHA has used all three rationales to consider various NTP chemicals, without any explanation for how it chooses one over the other.

⁵ These regulations were promulgated by the Health & Welfare Agency, which was the lead agency for implementing Proposition 65 until 1991, when OEHHA assumed the role. (*People ex rel. Lungren v. Super. Ct.* (1996) 14 Cal.4th 294, 309-310; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333, 346, fn. 2.) For simplicity, all references to the lead agency (without regard to dates) are to OEHHA.

⁶ Final Statement of Reasons for Rule 25306 (formerly 12306) (hereinafter "25306 FSOR"), at 8 (emphasis added). The Court of Appeal for the Second Appellate District recently echoed this view of the purpose and intent of section 25249.8, subdivision (b). *Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment*, 169 Cal. App. 4th 1264, 1282 (2009).

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Regulations implementing the qualified expert criterion established a Scientific Advisory Board (“SAB”) consisting of two committees, the DART IC and the Carcinogen Identification Committee (“CIC”). Cal. Code Regs., tit. 27 § 25302(a). The SAB committees conduct a thorough review of the scientific evidence and determine “whether a chemical has been clearly shown, based upon scientifically valid testing according to generally accepted principles, to cause cancer or reproductive toxicity.” Cal. Health & Saf. Code § 25249.8 (subd. b); Cal. Code Regs., tit. 27 § 25305(a)(1), (b)(1).

The SAB committees are required to receive and consider written materials and oral comments from interested members of the public. Once all such comments are considered, the committee has three choices on how to proceed:

The Committee may render an opinion that the chemical has been clearly shown to cause cancer or reproductive toxicity, may fail to reach such a conclusion, or may defer the decision to a later meeting.⁷

Where the committee decides to defer, it is required to present an action plan and set a timetable for completion and reconsideration at a future meeting.⁸ Otherwise, the chemical will not be added to the list.

2. The authoritative body criterion was not intended to bypass a decision already made by the DART IC.

Unlike the qualified experts criterion, the purpose of the authoritative body provision of section 25249.8, subdivision (b), was to conserve the panel’s limited resources: “The apparent purpose of the authoritative bodies provision is to establish a streamlined process for the Panel.” *Exxon*, 169 Cal. App. 4th at 1282 (citing 25306 SFOR, at 8). This approach “takes full advantage of the resources available through the Agency, *and conserves the energies of the Panel as the Act apparently intended.*” 25306 FSOR at 8 (emphasis added).

Further evidence of the primacy of the SAB is found in the regulations implementing the authoritative body criterion. Under both the statute and its implementing regulations, the

⁷ OEHHA, *Procedure for Prioritizing Candidate Chemicals for Consideration under Proposition 65 by the “State’s Qualified Experts” Reproductive and Cancer Hazard Assessment Section Office of Environmental Health Hazard Assessment California Environmental Protection Agency*, at p. 13 (May 1997), available at <http://oehha.ca.gov/prop65/pdf/priodoc.pdf>, visited May 3, 2010 (“Prioritization Procedure”).

⁸ *Id.*

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SAB retains control over which bodies are considered authoritative. Cal. Health & Saf. Code § 25249.8, (subd. b); Cal. Code Regs., tit. 27 §§ 25305(a)(2), (b)(2); 25306 (b).

Thus, the regulations also reserve to the SAB the right to set conditions on designations. 25306 FSOR at p. 27 (“If the Panel has discretion in designating authoritative bodies, it may condition its designation.”). This was deemed necessary to guard against “uncontrolled” listings based on stale or invalid science:

The science of hazard identification is not static. Studies relied upon today may, in the light of new data, be unreliable tomorrow. The identification of chemicals under the Act was intended by the voters to be based on scientific testing. It would make little sense to have chemicals listed under the Act where the data relied upon by an authoritative body is outdated and clearly contradicted by newer data. . . . [T]he regulatory implications of listing under the Act require a consideration of new data.

25306 FSOR at p. 20; see also *id.* at 22, 26-28. Therefore, at the recommendation of the SAB, the regulations establish procedures intended to ensure against the “uncontrolled listing” of chemicals that do not satisfy the statutory criteria. (25306 FSOR at 22, 26-28.)

Among these controls is a reservation of the SAB’s authority to review of a chemical being considered for listing under the authoritative body criterion:

Within 30 days following the publication of the notice, interested parties, including any member of the appropriate Committee, shall submit to the lead agency their written objections to the addition of the chemical to the list of chemicals known to the state to cause cancer or reproductive toxicity, along with any supporting documentation.

Cal. Code Regs., tit. 27 § 25306(i). Thus, where the public or a member of the DART IC comes forward with scientific evidence demonstrating that there is no “substantial evidence” that a chemical causes reproductive toxicity, it must be referred to the DART IC for further consideration:

Objections shall be made on the basis that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied. The lead agency shall review such objections. If the lead agency finds that there is no substantial evidence that the criteria identified in subsection (e)

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or in subsection (g) have been satisfied, *the lead agency shall refer the chemical to the appropriate Committee* to determine whether, in the Committee's opinion, the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity.

Cal. Code Regs., tit. 27 § 25306(i) (emphasis added). Section 25306(g) of the regulations for authoritative bodies listing requires that the body in question has formally identified a chemical as "causing reproductive toxicity" based on one or both of the following criteria:

- (1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or
- (2) Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.⁹

In addition, OEHHA cannot list a chemical as a reproductive toxicant pursuant to the authoritative body criterion where "scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (g), paragraph (1) or subsection (g), paragraph (2)." Cal. Code Regs., tit. 27 § 25306(h).

These controls serve the resource conservation purpose of the listing criteria set forth in section 25249.8, subdivision (b), by limiting the SAB's review to only those chemicals that would not pass muster if reviewed by the DART IC or the CIC under its own regulations.

The administrative record is replete with scientific evidence demonstrating that the considerable body of scientific research on BPA – including, but not limited to, the studies cited in the NTP Monograph – provide "no substantial evidence" that the chemical is "known to cause" reproductive or developmental toxicity. Comments and testimony submitted by GMA, the American Chemistry Council, and many others have already set forth this

⁹ Cal. Code Regs., tit. 27 § 25306(g).

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evidence. If anything, the information emerging after the DART IC's decision not to list BPA offers stronger support for that decision.¹⁰ A decision to list BPA would flatly contradict this record.

B. Listing BPA Will Disrupt the Important Public Health Benefits that Canned Foods Deliver to Californians Every Day.

For all of the reasons above, interpreting the law to allow an administrative decision by OEHHA staff – which by its very nature is made without scientific input – to override the science-based decision of the experts on the DART IC is inconsistent with the language, purpose, and structure of the statute and its implementing regulations. Listing BPA also represents an indefensible public policy and health policy choice, placing such action even farther out of line with the intent of the California voters in adopting Proposition 65.

1. Cans made with epoxy resin liners provide frontline protection against food-borne illnesses.

Epoxy resins made with BPA have been used for over 30 years to improve the safety and quality of food and beverages by providing protective coatings for cans and the metal closures for glass jars. The use of these materials in can lining applications is necessary to protect public health. Without them, interactions between the metal and the can contents over time eventually leads to corrosion and contamination of the food by dissolved metals, and to formation of container defects that allow entry into the product of microorganisms that cause spoilage or illness.

Protective can linings slow down the rate of these interactions to such an extent that modern canned foods, even high acid foods like fruits and vegetables, can be counted on to retain their nutrition, quality, and consumer acceptability for years under a wide range of environmental and handling conditions. Epoxy resins promote safety because they stand up well to the temperatures necessary to sterilize foods and protect against microbes:

Microbes are killed by heat. If food is heated to an internal temperature above 160°F, or 78°C, for even a few seconds this [is] sufficient to kill parasites, viruses or bacteria, except for the *Clostridium* bacteria, which produce a heat-resistant form called a spore. *Clostridium* spores are killed only at temperatures above boiling. This is why canned foods must be

¹⁰ See, e.g., Richard M. Sharpe, *Is It Time to End Concerns over the Estrogenic Effects of Bisphenol A?*, *Toxicological Sciences* 114, no. 1, at pp. 1-4 (2010) (hereinafter, "Sharpe") (analyzing studies conducted on BPA after the NTP Monograph and concluding that further concerns about reproductive toxicity are unwarranted).

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cooked to a high temperature under pressure as part of the canning process.¹¹

As OEHHA heard at the April 20, 2010 forum, FDA records reveal no incidence of food-borne illness resulting from a failure of metal packaging *in over three decades*.¹² The use of BPA has been an indispensable component of that remarkable record.

For these reasons, and because they will not break and do not require additional water for preparation, canned foods are a staple component of emergency preparedness. They figure prominently on lists of items universally recommended by government and private response organizations for inclusion in emergency kits.¹³ For these uses, fresh or frozen foods are not, and cannot be, substituted.

2. Canned foods are an important source of affordable, high-quality nutrition for all Californians.

Fresh meats, fruits, and vegetables are not readily available at all times of year. Even when fresh foods are available, their optimal nutritional content wanes quickly – often within days.¹⁴ For some Californians living in economically depressed urban and rural areas, access to fresh foods is limited.¹⁵ Transportation difficulties may prevent frequent trips to grocery

¹¹ Center for Disease Control, Food Borne Illness: Frequently Asked Questions, at 8, available at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#howmanycases, visited May 6, 2010. For example, as the result of high-temperature sterilization techniques, botulism in canned foods “has disappeared in this country.”)

¹² Testimony of Kathleen M. Roberts on behalf of the North American Metal Packaging Alliance, Inc., April 20, 2010.

¹³ See, e.g., Federal Emergency Management Agency, United States Department of Homeland Security, *Food and Water in an Emergency*, at pp. 2-3 (Aug. 2004), available at <http://www.fema.gov/pdf/library/f&web.pdf> (visited March 7, 2010); Los Angeles Fire Department, *Emergency Preparedness (2008 Edition)*, available online at <http://www.ci.la.ca.us/lafd/eqbook.pdf>, at pp. 17 (list of foods for emergency kits); American Red Cross, *Talking About Disaster: Guide for Standard Messages: Stocking and Storing Food and Water Safely*, available online at http://www.redcross.org/images/pdfs/code/Storing_Food%20_and%20_Water_Safely.pdf (visited May 7, 2010), at pp. 1, 2; see also, San Francisco Chronicle, *Make Your Own Preparedness Kit*, available at <http://www.sfgate.com/cgi-bin/article.cgi?f=/earthquakes/archive/ready.dtl> (visited May 7, 2010).

¹⁴ Joy C Rickman, Diane M Barrett and Christine M Bruhn, *Nutritional Comparison of Fresh, Frozen And Canned Fruits And Vegetables. Part 1. Vitamins C and B And Phenolic Compounds*, 87:6 J. Sci. Food & Agriculture, pp. 930-944 (April 30, 2007) (hereinafter, *Rickman*).

¹⁵ See, e.g., *Access to Healthy Foods in Low-Income Neighborhoods: Opportunities for Public Policy*, Ruud Report, Ruud Center For Food Policy & Obesity, Yale University (Fall 2009), available

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stores, which are often located far away, making reliance on fresh foods impractical.¹⁶ And the fact that fresh fruits and vegetables generally cost more than “fast food” alternatives has been a source of substantial media attention and public health concern. Canned fruits and vegetables, and meals made from them, generally provide a practical, accessible, and affordable alternative.¹⁷

Moreover, canned foods retain comparable levels of nutrients over a longer period of time than fresh or frozen foods.¹⁸ Thus, they can be purchased in bulk and remain available (i.e., safe, nutritious, and flavorful) for longer periods, thereby stretching their value to consumers.

It is no surprise, therefore, that consumers and institutions that cater to them – schools, hospitals, nursing homes, and others – have long depended on this reliable and affordable source of nutrition for a significant part of their diets.¹⁹ According to consumption data collected between 1999 and 2008 by the United States Department of Agriculture (“USDA”), on average, canned goods make up approximately 27% of total fish and shellfish, 24% of vegetables, and 15% of fruits consumed nationwide.²⁰

Guidelines published in 2005 by the U.S. Departments of Health and Human Services and Agriculture suggest that males and females increase their overall fruit and vegetable

at

<http://www.yaleruddcenter.org/resources/upload/docs/what/reports/RuddReportAccessToHealthyFoods2008.pdf>.

¹⁶ Mark Vallianatos, Amanda Shaffer, Robert Gottlieb, *Transportation and Food: The Importance of Access, A Policy Brief of the Center for Food and Justice*, Urban and Environmental Policy Institute, at pp. 2-3 (October 2002).

¹⁷ See e.g., GMA, *Current WIC Authorized Fruit and Vegetable Formats by State* (summarizing an analysis of costs for fresh and frozen foods authorized for use under the WIC Program).

¹⁸ *Rickman*, at p. 942; see also, Juliann Schaeffer, Canned Foods Make a Comeback, *Today's Dietitian*, Vol. 11 No. 3, p. 44 (March 2009), available at http://www.todaysdietitian.com/newarchives/td_030909p44.shtml.

¹⁹ U.S. Department of Agriculture, Fact Sheet: *Meeting the Challenge of Rising Food Costs for Healthier School Meals*, available at http://www.fns.usda.gov/TN/Resources/DGfactsheet_challenge.pdf (recommending increased use of canned fruits and vegetables in school lunch programs as an affordable, nutritious alternative to more expensive fresh fruits and meats).

²⁰ Drawn from data available from the USDA Economic Research Service, *Food Availability (Per Capita) Data System*, available at www.ers.usda.gov/Data/FoodConsumption (visited May 6, 2010).

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consumption to nine servings per day as part of a 2000-calorie diet.²¹ The Guidelines explicitly recommend the use of canned fruits and vegetables to meet these goals.²² The Centers for Disease Control and Prevention also includes canned fruits and vegetables in its “Five-A-Day” program, designed to encourage the consumption of fruits and vegetables.²³

Canned foods are also an important part of programs aimed at providing nutritious meals to Californians in need of assistance. The California Women, Infants, and Children (“WIC”) Program, for example, provides “WIC checks” with which approved foods may be purchased from grocery stores around the state.²⁴ Canned fruits, vegetables, fish, and infant formula are all included on the WIC list of approved foods.²⁵ Canned foods also figure prominently in food donations most sought by organizations that provide supplementary nutrition to economically pressed Californians.²⁶

3. There is no proven alternative to BPA that will work for all products.

At the April 20, 2010 forum, a commenter appearing on behalf the Natural Resource Defense Counsel (“NRDC”), whose petition triggered this proposal by OEHHA, argued that alternatives to BPA are available. As evidence, the commenter pointed to a single food manufacturer’s announcement that it intends to introduce BPA-free cans for a single product.

²¹ U.S. Department of Health and Human Services, U.S. Department of Agriculture, *Dietary Guidelines for Americans*, at 24 (2005), available at www.healthierus.gov/dietaryguidelines.

²² *Rickman*, at 932.

²³ *Id.*

²⁴ *Id.* Canned fruits packed in water or juice are included, but those packed in syrup are not. Regular or low-sodium canned vegetables are allowed, but those packaged with added sugars, fats, or oils are excluded. A brochure describing foods included in the WIC program is available at <http://www.cdph.ca.gov/programs/wicworks/WIC%20Foods/WICAuthorizedFoodListShoppingGuide-4-2010.pdf>.

²⁵ *Id.*

²⁶ *See, e.g.*, “Most Wanted” Foods for the Food Bank of Contra Costa and Solano, available at <http://www.foodbankccs.org/docs-pdfs/mostwantedfoodflyer-color.pdf>; Top Foods Needed by the Marin Food Bank, available at <http://www.marinfoodbank.org/topItems.html>; San Francisco Food Bank, Food Dropoff Locations By Neighborhood, available at http://www.sffoodbank.org/give_food/dropoff_locations.html (“Our most-needed foods include rice and pasta, canned fruits and vegetables, tuna or other canned meats, soups and stews, peanut butter, and cereal. *Please, do not deposit glass containers in our food-drive barrels.*”)

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Even assuming that this company's single-product goal is realized, the fact is that there is no across-the-board replacement for BPA in can linings at this time. Despite substantial ongoing industry efforts, a substance that offers the exceptional combination of toughness, adhesion, formability, chemical resistance, and affordability that has made BPA the industry standard since the 1970s, has not yet been found. Those research efforts continue with the goal and expectation of identifying a substitute.

Moreover, each food product formulation has its own set of demands. Technology that works for tomatoes may not work for canned peaches or canned tuna. Acidic and thermally processed foods present particular challenges. Once a BPA replacement candidate is identified, its performance must be ascertained over the entire shelf life of the food product and its safety, and regulatory approval and compliance with other applicable regulations must be assured before it can be commercially used. Retooling of can manufacturing and food processing equipment may be necessary. While a search for alternatives is underway, a universal conversion to non-BPA linings that will work for all canned foods is at least several years away.²⁷

4. Listing BPA will discourage consumers from eating fruits, vegetables, and other canned foods and will reduce the availability of safe, affordable nutrition provided by these foods.

As OEHHA's Chief Deputy Director Allan Hirsch reminded the audience at the April 20, 2010 forum, Proposition 65 does not ban the use of a listed chemical in consumer products. However, as discussed below, listing BPA will subject foods packaged with even trace amounts of the chemical to expensive and burdensome litigation over Proposition 65's warning requirement, despite the fact that they pose no real risk to consumers. Because there is no reliable alternative available for BPA, these effects will be felt by companies that make and sell all foods on the canned food aisle of every supermarket. This result is contrary to a fundamental purpose of the statute.

²⁷ Even companies that have switched to alternative technologies have discovered that eliminating low levels of BPA from packaged foods is difficult. See Lindsey Layton, *Alternatives to BPA Containers Not Easy for U.S. Foodmakers to Find*, Washington Post, Tuesday February 23, 2010, available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/02/22/AR2010022204830.html?referrer=emailarticle>. For this reason, even the twelve-month statutory "grace period" for warnings about newly listed chemicals will not prevent these effects. Cal. Health & Saf. Code § 25249.10(b).

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5. The scientific record is clear: any BPA present in canned foods poses no risk to consumers.

OEHHA is relying on high-dose animal studies cited in the September 2008 NTP Monograph as the basis concluding that NTP has formally identified BPA as a developmental toxicant:

In 2008, the NTP-CERHR published a report on BPA (NTP-CERHR, 2008). This report concludes *that the chemical causes developmental toxicity at high levels of exposure*, and appears to satisfy the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations²⁸

OEHHA has received ample evidence from its own qualified experts on the DART IC and numerous commenters about why these studies do not provide a proper scientific basis for identifying BPA as a chemical “known to cause reproductive toxicity” under Proposition 65.²⁹ GMA agrees with the DART IC and other commenters on this point, and will not repeat these arguments here.

Separately, taking the NTP Monograph at face value, it makes clear that the adverse effects observed in the studies on which its conclusions were based occurred only at doses that are completely irrelevant to human exposure – doses thousands, or even hundreds of thousands of times above the worst case estimates of combined exposures to BPA from *all dietary sources*:

The “high” dose effects of bisphenol A that represent clear evidence for adverse effects on development, i.e., reduced survival . . . , reduced birth weight and growth of offspring early in life . . . , and delayed puberty in female rats and male rats and mice . . . , ***are observed at dose levels that are more than 3,500- times higher than “worst case” daily intakes*** of bisphenol A in infants and children less than 6 years of

²⁸ OEHHA, *Request for Relevant Information on a Chemical Being Considered For Listing by the Authoritative Bodies Mechanism: Bisphenol-A* (Feb. 12, 2010), available at http://www.oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html (visited May 8, 2010) (emphasis added).

²⁹ See Transcript from July 15, 2009 Meeting of the State of California Office of Environmental Health Hazard Assessment Proposition 65 Developmental and Reproductive Toxicant Identification Committee (hereinafter “DART IC Tr.”); May 13, 2010 comment letter submitted by Stan Landfair of McKenna & Aldridge LLP on behalf of the American Chemical Council.

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age *The differences in exposures are much greater, more than 160,000- times different, when the high oral dose level is compared to estimated daily intakes for children ages 6 – 11 and adult women*³⁰

The most recent – and most definitive – work on the subject also describes the only levels found to produce any discernable reproductive effects in animals to be thousands of times below the worst-case human exposure scenario:

The results from Ryan et al. (2009) are unequivocal and robust and are based on a valid and rational scientific foundation. They tell us that, in vivo in female rats, bisphenol A is an extremely weak estrogen—so weak that even at levels of exposure 4000-fold higher than the maximum exposure of humans in the general population there are no discernible adverse effects.³¹

These data, published in the leading toxicology journal, *Toxicological Sciences*, appeared after the NTP Monograph was published, raising further doubts about the legality and appropriateness of relying on the Monograph to make a decision about listing that is blinkered to the scientific and public health policy issues raised by such listing.

Whatever one’s views of the merits of the NTP Monograph as far it goes, there is no remaining doubt that BPA levels reported in canned foods are safe, individually and collectively. As is well known, however, that does not immunize businesses that produce, sell, or serve foods containing a detectable amount of BPA from being sued under Proposition 65 if BPA is added to the list.

6. The fact that canned foods are safe will not prevent Proposition 65 lawsuits if BPA is listed.

Despite the mythology to the contrary, Proposition 65, by its plain language, prohibits a business from exposing an individual to a detectable amount of a Proposition 65 reproductive toxicant without first providing a warning that the product it makes, sells, or serves contains

³⁰ National Toxicology Program, Center of the Evaluation of Risks to Human Reproduction, *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A* (“Monograph”), at 36 (emphasis added).

³¹ *Sharpe*, at 1 (discussing Bryce C. Ryan, Andrew K. Hotchkiss, Kevin M. Crofton, and L. Earl Gray Jr., *In Utero and Lactational Exposure to Bisphenol A, in Contrast to Ethinyl Estradiol, Does Not Alter Sexually Dimorphic Behavior, Puberty, Fertility, and Anatomy of Female LE Rats*, *Toxicological Sciences* 114, no. 1 (2010): 133–48).

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a chemical known to cause birth defects or other developmental or reproductive harm. Period. If it does not do so, it can be sued (and, given the vehemence with which organizations that regularly bring Proposition 65 enforcement actions have advocated this listing, there is little doubt there will be such lawsuits).

Proposition 65 enforcement actions, whether private or public, can be and have been brought not only against the manufacturers of the food packaging, but also against the food processors and their retailer or restaurant customers. Once sued – assuming that they have the financial resources to do so and that their downstream customers provide them the flexibility to defend the case – those companies may assert various affirmative defenses that are fact- and expert-intensive, take many years to litigate, and represent a substantial and unrecoverable expense to the defendants.³²

From data considered in the NTP Monograph and that more recently published, it is plain that businesses whose products contain trace levels of BPA will be able to demonstrate that they satisfy the affirmative defense. But it is equally true that they and their customers can be sued under Proposition 65, forcing them to incur the burden and expense of discovery and to endure the adverse publicity which may accompany such lawsuits. The situation will be made worse if OEHHA lists BPA without a “safe harbor” MADL, rendering it impossible for companies whose products cause only a miniscule exposure to make a threshold showing and that could deter protracted litigation.³³

³² Two of the recent acrylamide cases – *People v. Frito-Lay, Inc., et al.*, (Los Angeles Superior Court Case No. BC338956) and the related case of *Center for Education and Research on Toxics v. McDonald's Corp., et al.*, (Case No. BC 280980) – are illustrative. Eight separate experts offered evidence on subjects related to toxicology, risk assessment, and epidemiology to establish the proper warning threshold for acrylamide. Another six experts testified about acrylamide concentrations, test methodologies, consumption levels, and statistical analysis to determine the “average intake” by the “average consumer” of the french fries and potato chips at issue in that case. The trial court in that case found that factual disputes on each of these issues prevented resolution of the case on summary judgment. The Attorney General’s case was filed in 2005 and was not fully resolved until 2008. The *CERT* case was filed in 2002 and resolved in 2007. Unlike plaintiffs, who can recover fees incurred in successfully prosecuting an enforcement action, Cal. Code Civil Proc. § 1021, companies cannot recover the cost of successfully defending such claims.

³³ A MADL would also make it easier for the California Attorney General to evaluate certificates of merit accompanying 60-day notices and determine whether to pursue enforcement or to intervene, as has happened on a few occasions, to dissuade a private plaintiff from pursuing meritless claims. *See, e.g.*, March 3, 2008 letter from then-Supervising Deputy Attorney General Edward G. Weil to JL Sean Slattery, David Lavine, and Larelei Paras, available at http://ag.ca.gov/prop65/pdfs/Lipstick_Letter-a.pdf (concluding that threatened claims against cosmetic companies lacked merit because the products did not exceed the safe harbor MADL for lead).

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Thus, companies that have no means of eliminating BPA epoxy resins – and there currently is no commercially available substitute for most uses – face powerful pressure to put warnings on their products, *even where such a warning is not legally required, as the Court of Appeal has recognized:*

Even though [the company] could demonstrate that its products do not pose a significant risk of causing cancer in humans, it had to provide a stigmatizing warning to the contrary – which could dissuade the public from using its products – or risk having to defend itself against being slapped with an injunction and costly civil penalties.

See Baxter Healthcare Corp. v. Denton, 120 Cal. App. 4th 333, 344 (2004). The result will be pointless litigation, widespread food warnings, and/or decisions to discontinue the production and sale of certain products in California. Any combination of these effects could reduce the availability of safe, nutritious, and useful food products to California consumers with *no* commensurate benefit.

The effect of such widespread defensive warnings on foods that are actually safe for consumers is contrary to the purpose and intent of Proposition 65. *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 660-661 (1991). In *Nicolle-Wagner*, the Court of Appeal upheld the regulation exempting chemicals that are “naturally occurring” in foods from the scope of the statute. *Id.*³⁴ The Court reasoned that grocers and other businesses, which bear the burden of proof under section 25249.10(c), would feel compelled to provide warnings to avoid litigation, even on foods that have been eaten safely “for thousands of years.” *Id.*

The Agency’s final statement of reasons for section 12501 includes the observation that the “[a]bsence of such an exemption could unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could distract the public from other important warnings on consumer products.” Since one of the principal purposes of the

³⁴ This reasoning is present elsewhere in Proposition 65’s regulations as well. The so-called “cooking exception” to the default 10-5 no significant risk level for carcinogens in foods was also adopted in part to avoid indiscriminate defensive warnings on food products. Final Statement of Reasons for Cal. Code Regs., tit. 27 § 25703(b), at p. 5 (“Businesses may have considerable difficulty determining in any particular case whether cooking has resulted in the concentrations of listed chemicals which meet the 10-5 standard. Thus, businesses may feel compelled to provide a warning to protect them from liability in the event the level of risk does exceed 10-5. The confusion which would result if all purveyors of cooked or heat-processed foods provide a warning with their product, to avoid any potential liability, could be enormous.”).

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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.

Id. at 660-61. Stigmatizing canned foods by forcing them to carry warnings that they contain a chemical “known to the State to cause reproductive toxicity” will almost certainly lead to the same type of counterproductive overwarning described by the Court of Appeal in *Nicolle-Wagner*.³⁵

C. OEHHA has Authority to Consider—And Avoid—the Adverse Consequences of Listing BPA.

At the April 20, 2010 forum, OEHHA heard from numerous commenters concerning the public health benefits delivered by epoxy resins formulated from BPA for use in food packaging and the negative effects that would occur as the result of requiring Proposition 65 warnings.³⁶ OEHHA’s Senior Council acknowledged these comments, and asked for legal authority for the proposition that OEHHA can consider these facts in its decision whether to list BPA. As discussed below, OEHHA not only has legal authority for considering the consequences of its interpretation, it must do so to avoid acting in contravention of the voters’ intent in adopting Proposition 65.

1. OEHHA has ample legal authority to consider the consequences of its actions in implementing Proposition 65.

OEHHA has cast its consideration of BPA as a ministerial application of the authoritative body criterion, over which it has little discretion. But what OEHHA has proposed is, in fact, a legal interpretation of how the three criteria for listing found in subsection (b) of section 25249.8 work together to achieve the goals of the statute. As such, the ordinary rules of statutory and regulatory construction apply. *Schmidt v. Found. Health*, 35 Cal. App. 4th 1702, 1710-11 (1995).

³⁵ See also, *Dowhal v. SmithKline Beecham Consumer Health Care* (2004) 32 Cal. 4th 910, 933. In *Dowhal*, the California Supreme Court also refused to interpret the statute in such a way that would avoid federal preemption and require birth defect warnings for nicotine in smoking cessation products that might scare women away from products that could help them stop smoking. *Id.* (“The mere existence of the risk, however, is not necessarily enough to justify a warning; the risk of harm may be so remote that it is outweighed by the greater risk that a warning will scare consumers into foregoing use of a product that in most cases will be to their benefit.”)

³⁶ Testimony of Patrick Leathers, on behalf of the Canned Food Institute; testimony of Kathleen Roberts on behalf of the North American Metal Packaging Alliance.

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Administrative agencies, like courts, are to utilize common sense and to consider the policy implications and likely consequences when they implement their enabling statutes. *People v. Sup. Ct. ex rel Maury*, 145 Cal. App. 4th 473, (2006) (“[S]tatutes must be construed in a reasonable and common sense manner consistent with their apparent purpose and the legislative intent underlying them – one practical, rather than technical, and one promoting a wise policy rather than mischief or absurdity.”); *City of Costa Mesa v. McKenzie*, 30 Cal. App. 3d 763, 770 (1973) (“[In] construing a statute the courts may consider the consequences that might flow from a particular interpretation. They will construe the statute with a view to promoting rather than to defeating its general purposes and the policy behind it.”)

Such considerations – where necessary to fulfill the purpose of a law – may even trump the literal language of a statute or regulation. *Times Mirror Co. v. Super. Ct. of Sacramento County*, 53 Cal. 3d 1325, 1335, n.7 (“Moreover, while ambiguity is generally thought to be a condition precedent to interpretation, this is not always the case. ‘The literal meaning of the words of a statute may be disregarded to avoid absurd results or to give effect to manifest purposes that, in light of the statute’s legislative history, appear from its provisions considered as a whole.’”); *Silver v. Brown* (1966) 63 Cal.2d 841, 845; accord *Friends of Mammoth v. Board of Supervisors* (1972) 8 Cal.3d 247, 259 (“Once a particular legislative intent has been ascertained, it must be given effect ‘even though it may not be consistent with the strict letter of the statute.’”); *County of Sacramento v. Hickman* (1967) 66 Cal.2d 841, 849, fn. 6.

OEHHA’s apparent belief that it has no discretion over what evidence it may consider in deciding how to proceed with regard to BPA is therefore misplaced. Nothing in the authoritative body criterion of subdivision (b) of section 25249.8 or its implementing regulations requires OEHHA to ignore the consequences of its listing decisions.³⁷ Specifically, there is no question that OEHHA is authorized to structure and/or time its actions and decisions with regard to BPA in a way that minimizes these consequences.

2. At a minimum, OEHHA must not list BPA without having first adopted a final safe harbor MADL.

As discussed above and in comments submitted by other interested parties, there are numerous legal and scientific reasons that OEHHA must not list BPA pursuant to the authoritative body criterion. Whatever its decision regarding listing, *at a minimum*, OEHHA must not add BPA to the list without the simultaneous adoption of a final “safe harbor”

³⁷ In apparent recognition of the principle described here, OEHHA’s Senior Counsel stated at the public forum that if OEHHA decided not to proceed with listing BPA under authoritative body criterion, OEHHA would not bother to refer the chemical to the DART IC for further consideration as provided in section 25306(i) of the authoritative body regulations because, as a practical matter, OEHHA already knows that the DART IC would not vote to list BPA.

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warning threshold based “on evidence and standards of comparable scientific validity” to the high-dose studies “which form the scientific basis” for the listing of the chemical. Cal. Code Regs., tit. 27 § 25801(a). This is the only way to assure that warnings reflect the affirmative defenses/warning thresholds adopted by the voters rather than serving simply and solely as a guard against litigation. It would also diminish overwarning by bringing the application of the warning requirement into alignment with the actual risks found in evidence from the Monograph on which OEHHA relies.³⁸

The adoption of a final MADL must occur simultaneously with listing BPA if it is to avoid the consequences set forth above. While chemicals added to the list do not become subject to its warning requirement for twelve months, Cal. Health & Saf. Code § 25249.10(b), the *effect* of adding a chemical to the list is immediate. Among other things, retailers will begin considering whether to continue to carry the relevant products, in light of the associated risks that they will be sued; government and quasi-governmental organizations, many of which have statutory or policy prohibitions on serving foods that pose a reproductive risk or are so labeled, may choose or be forced to consider alternative products; and so forth. The presence of a safe harbor threshold may reduce or eliminate such consequences. Given the abundance of recent data on the risk – or, rather, absence of risk – posed to human beings by BPA, the adoption of a safe harbor should be straightforward.

II. CONCLUSION

The use of BPA in the manufacture of food packaging has provided concrete health benefits to consumers for over 30 years. The combination of toughness, flexibility, and reliability of the epoxy resins made with BPA render it an important component of delivering safe, affordable, available, reliable nutrition to all Californians. Whether through warnings that prevent litigation but unnecessarily scare consumers, disappearance of certain products from the market, or the switch to less effective alternatives, listing BPA stands to render these important benefits unavailable.

³⁸ That the low-dose studies about which NTP expressed concern are not of “comparable scientific validity” to the studies now cited by OEHHA as the basis for listing has been firmly established by studies published later than the Monograph. *See, e.g.*, Bryce C. Ryan, Andrew K. Hotchkiss, Kevin M. Crofton, and L. Earl Gray Jr., *In Utero and Lactational Exposure to Bisphenol A, in Contrast to Ethinyl Estradiol, Does Not Alter Sexually Dimorphic Behavior, Puberty, Fertility, and Anatomy of Female LE Rats*, *Toxicological Sciences* 114, no. 1 (2010): 133–48.; Sharpe, at 1–4 (“Ryan et al. (2009) and other similarly detailed studies in rodents more or less close the door on the possibility that bisphenol A is an environmental chemical to be concerned about because of its ER-mediated estrogenic activity.”).

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After more than ten years of controversy, it is clear that the scientific evidence does not support a conclusion that BPA causes developmental toxicity or other reproductive harm in humans:

For more than a decade, there has been a heated controversy over whether or not the environmental chemical, bisphenol A, exerts adverse estrogenic effects in animal studies, and by extrapolation, in humans. In the present issue of *Toxicological Sciences*, Ryan et al. (2009) publish a detailed study that throws cold water on this controversy by showing complete absence of effect of a range of bisphenol A exposures perinatally on reproductive development, function, and behavior in female rats.³⁹

Based on this record, it is time for OEHHA to close the books on BPA and to turn its attention and limited administrative resources to other issues:

Fundamental, repetitive work on bisphenol A has sucked in tens, probably hundreds, of millions of dollars from government bodies and industry which, at a time when research money is thin on the ground, looks increasingly like an investment with a nil return.⁴⁰

Should scientific evidence emerge in the future in support of a determination that BPA is a reproductive toxicant, OEHHA must, as it promised, return the chemical to the DART IC for further consideration. Until that time, the chemical should be returned to the pool of candidate chemicals. In the interim, the agency must *not* short-circuit the structure and intent of the statute by allowing a staff decision based on only part of the scientific record overrule the Committee's determination that BPA cannot be defined as a chemical "known to cause reproductive toxicity."

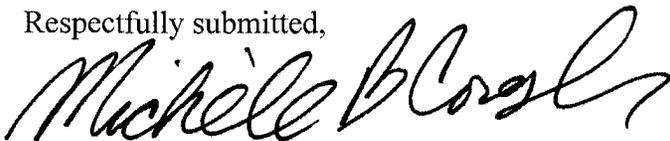
³⁹ Sharpe, at 1.

⁴⁰ *Id.* at 3.

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Should OEHHA decide to proceed in spite of the litany of contrary legal, scientific, and procedural reasons not to, it must delay listing until it has adopted a final safe harbor MADL in order to avoid the overwarning and loss of safe, affordable, nutritious foods that canned foods represent.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michèle B. Corash". The signature is fluid and cursive, with a large initial "M" and a long, sweeping tail.

Michèle B. Corash

cc: Dr. Joan Denton (jdenton@oehha.ca.gov)
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