

Office of Environmental Health Hazard Assessment



Matthew Rodriguez
Secretary for
Environmental Protection

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Edmund G. Brown Jr.
Governor

January 22, 2013

Geoffrey Cullen
Vice President of Government Relations
Can Manufacturers Institute
1730 Rhode Island Avenue NW, Suite 1000
Washington, DC 20036

Dear Mr. Cullen:

Thank you for your letter of May 10, 2010, responding to the Request for Relevant Information on the possible listing of bisphenol A (BPA) under Proposition 65.¹ BPA is a candidate for listing as known to cause reproductive toxicity. The listing would be based on the authoritative bodies provision² relying on findings by the National Toxicology Program (NTP) in a final report from the NTP Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) that BPA causes developmental toxicity at “high” doses (NTP-CERHR, 2008).³

After review of all the submissions received in response to the Request for Relevant Information, OEHHA has determined that BPA meets the criteria for listing under the authoritative bodies provision of Proposition 65. Accordingly, a Notice of Intent to List BPA will be published in the near future. Following its publication, there will be a 30-day period for submission of public comments regarding the possible listing. Comments should focus on whether or not the regulatory criteria for listing have been met.⁴ In the event that OEHHA finds the criteria have not been met after review of the comments, the chemical will be referred to the Developmental and Reproductive Toxicant Identification Committee (DARTIC) for its consideration as required by regulation.⁵

¹ The California Safe Drinking Water and Toxic Enforcement Act of 1986, California Health and Safety Code section 25249.5 et seq.

² Health and Safety Code section 25249.8(b) Title 27, Cal. Code of Regulations, section 25306.

³ National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2008). *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*. NIH Publication No. 08 – 5994.

⁴ Title 27, Cal. Code of Regs., section 25306.

⁵ Title 27, Cal. Code of Regs., sections 25306(i).

California Environmental Protection Agency

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption.

Your comments were submitted in opposition to the possible Proposition 65 listing of BPA. The comments endorsed other comments submitted by the Grocery Manufacturers Association, which raised technical issues related to the criteria provided above. A copy of our response to the Grocery Manufacturers Association is enclosed.

Your comments primarily discuss potential economic and public health consequences of the possible listing of BPA. You suggest that a Proposition 65 warning would undermine the U.S. Food and Drug Administration's (U.S. FDA's) goal of limiting warnings on food labels to only those deemed necessary to protect the public health and must be based on credible scientific evidence. Your comments state that a Proposition 65 warning would convey a threat to human health that is unsupported by appropriate scientific evidence and is not consistent with the conclusions about the safety of BPA drawn by U.S. FDA and other federal and international public health bodies.

The listing of BPA under Proposition 65 would be based on formal identification of the chemical as causing reproductive toxicity by the National Toxicology Program, a highly respected entity whose status as an authoritative body for purposes of Proposition 65 listings was reaffirmed by the DARTIC in 2011. Warnings would be required only if exposures to the public to the chemical from a given product exceeded the levels exempted in the statute from this requirement.⁶ The Proposition 65 statute and its regulations are directed toward helping California consumers make informed choices regarding the products that they purchase. In doing so, Proposition 65 promotes public health protection. The law and regulations do not allow OEHHA to consider the potential economic impact of chemical listings.

Your comments note that U.S. FDA has begun working with the food industry to reduce or eliminate BPA exposure and state that Proposition 65 activity would undermine the authority of the U.S. FDA and Obama Administration to effectively regulate the safety of food, including packaging.

OEHHA is aware that federal agencies such as U.S. FDA are currently involved in risk assessment and risk characterization of BPA. Any potential conflict between U.S. FDA and Proposition 65's warning requirements are speculative. In the event of an actual conflict between the federal requirements and Proposition 65, OEHHA will work with FDA to resolve the issue. Further, Proposition 65 expressly states that to the extent it conflicts with federal law, it does not apply.⁷

Where levels of BPA exposure are sufficiently low, warnings will not be required. If the chemical is listed, we will provide compliance assistance to businesses to reduce the

⁶ Health and Safety Code section 25249.10(c).

⁷ Health and Safety Code section 25249.10(a).

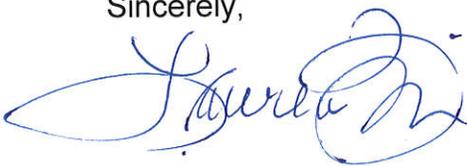
likelihood of unnecessary warnings or litigation. For example, in cases where the average use of a product by the average consumer does not result in exposure to a listed chemical that exceeds a maximum allowable dose level (MADL), no warning is required. OEHHA can assist interested parties by adopting a MADL.

OEHHA's general practice, when feasible, is to propose a MADL within one year of the listing of a chemical. In many cases, we have been able to adopt the MADL at or near the time the warning requirement for a newly listed-chemical takes effect.⁸ In some instances, OEHHA has been able to propose MADLs concurrent with or even prior to the listing of a chemical. If OEHHA makes a final determination to add BPA to the Proposition 65 list, we will consider whether it is feasible to release a draft MADL concurrent with the listing. At a minimum, we would make it a priority to develop and adopt a MADL for BPA at the earliest possible date following the chemical's listing. As you may be aware, Proposition 65 provides a "grace period" of 12 months after the chemical is listed before any interested party can sue for alleged violations of the Act. During that time, product manufacturers can evaluate their product exposures against the MADL and determine whether or not a warning is necessary.

OEHHA also can develop interpretive guidelines⁹ and safe use determinations¹⁰ to provide further guidance to businesses and the public concerning the applicability of Proposition 65 to specific products or uses of a chemical. OEHHA would consider developing these materials in the event BPA is listed.

Thank you for your interest in Proposition 65. If you have any questions or concerns, please contact me at (916) 322-6325 or by email at Lauren.Zeise@oehha.ca.gov.

Sincerely,



Lauren Zeise, Ph.D.
Deputy Director for Scientific Affairs

Enclosure:

Response to comments from Michelle Corash on behalf of the Grocery Manufacturers Association.

⁸ Health and Safety Code section 25249.10(b).

⁹ Title 27, Cal Code of Regulations, section 25203.

¹⁰ Title 27, Cal Code of Regulations, section 25204.

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Edmund G. Brown Jr.
Governor

January 22, 2013

Michele B. Corash
Morrison & Foerster LLP
425 Market Street
San Francisco, California 94105-2482

Dear Ms. Corash:

Thank you for your letter of May 13, 2010, on behalf of the Grocery Manufacturers Association (GMA), responding to the Request for Relevant Information on bisphenol A (BPA) as a chemical under consideration for listing as known to cause reproductive toxicity under Proposition 65¹. The potential listing is based on the authoritative bodies provision² of the Proposition 65 implementing regulations as applied to findings by the National Toxicology Program (NTP) on the basis of a final report from the NTP Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) that BPA causes developmental toxicity at “high” doses (NTP-CERHR, 2008)³.

Under the formal authoritative bodies listing process set out in the regulation, a chemical must be listed under Proposition 65 when the Office of Environmental Health Hazard Assessment (OEHHA) determines that the following criteria are met:

- 1) **Formal Identification:** An authoritative body formally identifies the chemical as causing reproductive toxicity (Title 27, Cal. Code of Regs., section 25306(d)⁴).
- 2) **Sufficiency of Evidence:** The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulation (Section 25306(g)). However, the chemical is not listed if scientifically valid data which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306(h)).

GMA's comments address both public policy and legal issues. GMA's comments assume that all manufacturers will stop using BPA in their products if the chemical is listed.

¹ The California Safe Drinking Water and Toxic Enforcement Act of 1986, California Health and Safety Code section 25249.5 et seq.

² Title 27, Cal. Code of Regulations, section 25306.

³ National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2008). *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*. NIH Publication No. 08 – 5994.

⁴ All further references are to sections of Title 27 of the California Code of Regulations unless otherwise stated.

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However, Proposition 65 does not ban the use of listed chemicals. It simply requires that consumers be given a warning prior to certain exposures to the chemical and prohibits the release of significant amounts of the chemical into sources of drinking water. It is not clear whether or not a warning might be required for exposures to BPA from food packaging and, in fact, GMA maintains that the manufacturers will be able to prove that any exposure is below the safe harbor level and therefore will not require a warning. Further, policy arguments about the potential impact on the food industry in California are not relevant to whether or not the chemical meets the listing criteria in the regulation. Proposition 65 does not allow consideration of economic impacts, a chemical's merits or the availability of alternative chemicals when making listing decisions.

OEHHA also disagrees with GMA's contention that the law creates a "hierarchy" of listing mechanisms where the "state's qualified experts" mechanism trumps the three others. Proposition 65 provides four mechanisms for listing of chemicals, all of which are independent of each other. In fact, the Labor Code listing mechanism is established in a separate subsection from the other three. The Labor Code mechanism is set forth in Health and Safety Code section 25249.8(a) and the other three are listed in the disjunctive in Health and Safety Code section 25249.8(b). The only connection in the statute between the state's qualified expert's mechanism and the authoritative bodies' mechanism is the requirement that the authoritative bodies be identified by the state's qualified experts. No hierarchical structure, consensus requirement or other provision is made in the statute or regulations for establishing interdependent operation of the different mechanisms. The 2009 determination of the Developmental and Reproductive Toxicant Identification Committee (DARTIC) that BPA does not meet the criteria for listing pursuant to the state's qualified experts mechanism does not address the entirely separate question of whether BPA meets the criteria for listing pursuant to an alternative listing mechanism. Thus, the state's qualified experts cannot "overrule" the authoritative body process, and vice-versa. If the criteria for listing by any of the four mechanisms are met, the chemical is added to the list because it is "known to the state" to cause reproductive toxicity.

The fact that the Health and Welfare Agency originally expressed its opinion that the state's qualified experts would be the "primary approach to listing" at the time the authoritative bodies regulations were being adopted, does not change this analysis. Neither the Proposition 65 statute nor its implementing regulations refer to any hierarchy in which the state's qualified experts mechanism is the "primary approach to listing" chemicals.

OEHHA agrees with cited text from the statement of reasons for Section 25306, stating that the purpose of the authoritative bodies provision is to conserve the resources (time and effort) of the state's qualified experts. This is because the DARTIC (which serves as the state's qualified experts for reproductive toxicity) does not need to re-evaluate chemicals for which a thorough scientific evaluation has already been conducted. Generally, the chemicals that are brought to the DARTIC are there for a *de novo* review because the chemical has not been considered by an authoritative body. In the case of BPA, the NTP-CERHR report was published during the pendency of BPA's review by the DARTIC. OEHHA could have removed the chemical for DARTIC consideration, but chose not to do

so. However, OEHHA can and indeed must consider whether BPA meets the authoritative bodies listing criteria, whether or not it has been previously reviewed by the DARTIC. Nothing in the statute or regulations allows OEHHA to ignore a chemical that may qualify for listing under one of the four listing mechanisms, simply because it has already been considered under another mechanism.

Finally, we acknowledge GMA's request that a regulatory Maximum Allowable Dose Level (MADL) be proposed prior to the potential listing of BPA and agree that a safe harbor level would provide valuable compliance assistance to the food industry. It is OEHHA's practice to propose a safe harbor level, where sufficient data are available to do so, within one year of the listing of a chemical. Often these safe harbors become effective at or near the time the warning requirements of the law are effective and well before the time that discharges of the chemical to sources of drinking water are prohibited. In some instances, it has proved feasible to propose a MADL concurrent with or even prior to listing of a chemical. OEHHA will consider whether it is feasible to do so for BPA but would, at a minimum, make it a priority to timely propose such a level for BPA, should the chemical be listed. OEHHA also has regulatory authority to develop interpretive guidelines and safe use determinations to provide further guidance to businesses and the public concerning the applicability of Proposition 65 to specific products as well as uses of a chemical. OEHHA would consider developing these materials as appropriate if BPA were listed.

After review of all the submissions received in response to the Request for Relevant Information, OEHHA has determined that BPA meets the criteria for listing under the authoritative bodies provision of Proposition 65. Accordingly, a Notice of Intent to List (NOIL) BPA will be published in the near future. Following publication of the NOIL, there will be a further 30-day period for submission of comments on this proposed action.

Thank you for your interest in Proposition 65. If you have any questions or concerns, please contact me at (916) 322-6325 or by email at Lauren.Zeise@oehha.ca.gov.

Sincerely,



Lauren Zeise, Ph.D.
Deputy Director for Scientific Affairs