



June 30, 2009

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation
P.O. Box 4010
1001 I Street, 19th floor,
Sacramento, California 95812-4010
FAX (916) 323-8803

**Re: Public Comments on the Proposed Listing of Bisphenol A (BPA) for
Consideration by the Developmental and Reproductive Toxicant Identification
Committee (DARTIC)**

Dear Ms. Oshita:

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy.

GMA appreciates the opportunity to submit these comments for the Developmental and Reproductive Toxicant Identification Committee's (DARTIC) consideration. Bisphenol A (BPA) is well studied and regulated. The scientific evidence being provided to DARTIC does not "clearly show" a causal link between BPA and developmental and reproductive harm. The U.S. Food and Drug Administration (FDA) and many other leading regulatory agencies around the world re-evaluate the available evidence on BPA on a continuing basis to confirm its safety for intended food-contact uses. BPA allows for the production of safe, technologically effective and commercially acceptable packaging that is essential for food safety and quality. Current exposure levels of BPA are safe for consumers and the environment, as demonstrated not only by repeated testing and review by qualified experts, but also by the history of over 60 years of commercial canned food safety.

GROCERY MANUFACTURERS ASSOCIATION

BPA Plays a Critical Role in Food Safety and Provides Important Public Health Benefits

We would like to bring to DARTIC's attention BPA's critical function in protecting the integrity of certain metal packaging components. While OEHHA's May 2009 Report mentioned that BPA is a component in epoxy resins that coat metal products, including food cans, it does not convey the importance of BPA's role. DARTIC should be aware that can coatings are 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. The use of protective can linings slows down the rate of these interactions so much 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. Acidic foods and thermal processing present particular challenges. Although all the major coating and can manufacturers are working continually to research and develop new coating chemistries for commercial food applications, epoxy coatings containing BPA still have unparalleled performance across a wide range of critical parameters, including toughness, adhesion, formability and resistance under high-temperature processing conditions. Because metal packaging enables a significantly longer shelf-life than other kinds of packaging, canned goods are the mainstay for providing nutritious, economical food around the world, and for special programs, e.g., USDA's Women, Infants and Children (WIC) assistance program, food pantries, disaster relief, special military rations. Epoxy coatings have been used safely to protect the world's food supply for over 60 years.

BPA Has Not Been "Clearly Shown" to Cause Developmental or Reproductive Toxicity

In order to recommend listing a chemical as a reproductive toxicant under Proposition 65, the chemical must be "clearly shown through scientifically valid testing according to generally accepted principles to cause...reproductive toxicity."¹ DARTIC's Guidance Criteria specify that the body of available evidence must be evaluated using a "weight of the evidence" approach.² GMA submits that currently available evidence for BPA does not meet the "clearly shown" standard, and therefore, that listing as a Proposition 65 reproductive or developmental toxicant is unwarranted. GMA briefly summarizes the basis for our conclusion here. GMA urges DARTIC to carefully consider, in addition to our comments, the detailed and comprehensive comments submitted by the American Chemistry Council's Polycarbonate Global Group and the North American Metal Packaging Alliance.

¹ Health & Safety Code § 25249.8(b)

² Guidance Criteria, Section 1.D.

1. Repeated weight-of-the-evidence evaluations of all available scientific data and information by expert bodies around the world continue to show that BPA does not meet the criteria for Proposition 65 listing.

As mentioned above, the safety of human exposures to BPA continues to be very well studied and regulated. Assessments have lately been conducted by Food Standards Australia-New Zealand (FSANZ), Health Canada and the German Federal Institute for Risk Assessment. GMA notes that these reports were not among the materials made available to DARTIC by the Office of Environmental Health Hazard Assessment (OEHHA), but GMA urges the Committee to consider these comprehensive and detailed documents. Other re-evaluations conducted within the past few years have affirmed that epoxy resins based on BPA are safe when used as intended; these include the U.S. Food and Drug Administration (FDA), the European Food Safety Authority (EFSA), the U.K. Food Standards Agency, the Japanese Ministry of Health, Labor and Welfare, and other regulatory agencies around the world.³

The National Toxicology Program Center for Evaluation of Risks to Human Reproduction (CERHR) recently completed an exhaustive review of the human and animal data on BPA; a monograph was issued in September 2008. The NTP Brief did not conclude that BPA definitively causes developmental or reproductive toxicity in humans.⁴ In its conclusions, NTP expressed only minimal or negligible concern regarding most alleged health effects. Although NTP expressed “some concern” for exposures in fetuses, infants and children, it noted that “These [“low dose”] studies provide only limited evidence for adverse effects on development and more research is needed to better understand their implications for human health.”

The European Food Safety Authority (EFSA) Panel on Food Additives, Flavourings, Processing Aids and Material in contact with Food evaluated the developmental and reproductive toxicity of BPA in 2006 and again in 2008. EFSA’s findings are generally consistent with the CERHR evaluation. EFSA, like CERHR, selected a high dose, multigeneration reproductive toxicity study, and the finding of systemic toxicity as the most sensitive effect, as the basis to establish a safe human exposure (acceptable daily intake), expressing “considerable doubts about the relevance of any low-dose observations in rodents for humans” because of species differences in toxicokinetics that render BPA less bioavailable in humans than in rodents,” as well as the mouse’s high sensitivity to estrogens.⁵ In 2008 EFSA re-examined its 2006 evaluation to specifically

³ For current information see <http://www.bisphenol-a.org>

⁴ <http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf>,

⁵ EFSA Journal (2006), 428, p. 5.

“reconsider the possible age-dependent toxicokinetics of BPA in animals and humans and their implication for hazard and risk assessment of BPA in food” as requested by the European Commission. They concluded that the major metabolic pathway in fetuses and infants would efficiently detoxify BPA.⁶

The EU completed its “Updated Risk Assessment of BPA” in April 2008 (EU RAR 2008) which is slated to be published.⁷ This report concluded that there is “no convincing evidence that BPA is a developmental toxicant.”

The FDA formed a Task Force in 2008 to evaluate the safety of all FDA-regulated BPA products, including food contact substances such as packaging. The Agency issued a Draft Assessment of Bisphenol A for use in Food Contact Applications on August 14, 2008.⁸ Like EFSA and CERHR, FDA determined that systemic toxicity in a high dose, multigeneration reproductive toxicity study was the most sensitive effect. FDA is currently conducting additional research including pharmacokinetics to address areas key to refining the assessment that had been identified by the Agency and endorsed by the peer review subcommittee of the FDA Science Board, and will update the draft assessment as appropriate.

2. The human and animal evidence do not support a conclusion that BPA causes either developmental toxicity or selective reproductive toxicity.

There is no human evidence to suggest that BPA causes selective developmental or reproductive toxicity. There is a robust body of animal data from five high-quality reproductive toxicity studies that meet or exceed current internationally validated and accepted regulatory guidelines for the design, conduct and reporting of toxicity investigations. These data indicate that the most sensitive effect of BPA, i.e., the one that occurs at the lowest dose, is systemic toxicity. There are many unconventional studies of BPA that examined a variety of endpoints purported by the authors to be indicative developmental or reproductive toxicity. The expert reviews discussed above all noted that most of these unconventional studies employed unvalidated methodologies, and all have major limitations and inadequacies that make them either irrelevant to human exposures, or inappropriate for human hazard identification. Thus, according to the

⁶ The EFSA Journal (2008) 759, pp. 2-10.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/afc_ej759_bpa_%20toxicokinetics_op_en.pdf?ssbinary=true

⁷ European Union Updated Risk Assessment of 4,4'-Isopropylidenediphenol (Bisphenol-A), Final Approved Version Awaiting for Publication (April 2008), p. 1. http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf

⁸ FDA, Draft Assessment of Bisphenol A for use in Food Contact Applications, August 14, 2008.
http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-0038b1_01_02_FDA%20BPA%20Draft%20Assessment.pdf

requirements in California's Health and Safety Code [§25249.8(b)] these "low dose" studies cannot be used as basis to conclude that BPA is "clearly shown" to cause developmental toxicity. The determinations by such well-respected scientific experts as CERHR, EFSA and FDA that the conventional studies (large, multigenerational studies whose protocols meet or exceed established international study guidelines including adherence to Good Laboratory Practices) are the appropriate basis for assessing human health impacts of BPA confirm that these conventional studies constitute the "scientifically valid testing" evidence that DARTIC should consider. Furthermore, since these studies demonstrate that effects relating to development/reproduction are only observed at doses that cause systemic toxicity, it cannot be concluded "according to generally accepted principles" that BPA causes "reproductive toxicity."

In summary, GMA understands that the standard for Proposition 65 listing as a reproductive/developmental toxicant requires that the effects be "clearly shown through scientifically valid testing according to generally accepted principles..." This requirement is necessarily a very high bar, because the consequence of listing is a warning that states the listed ingredient is "*known* to the state of California to cause birth defects and other reproductive harm." The weight-of-evidence for BPA indicates otherwise; "scientifically valid testing according to generally accepted principles" has not demonstrated that BPA causes reproductive or developmental toxicity. Thus, the "clearly shown" standard for Proposition 65 listing is not met. Listing of BPA is unwarranted, would mislead and unnecessarily alarm California citizens, and would compromise the availability of safe, affordable and nutritious foods.

Sincerely,

A handwritten signature in dark ink, appearing to read "Robert E. Brackett". The signature is fluid and cursive, with the first and last names being the most prominent.

Robert E. Brackett, Ph.D.
Senior Vice President
and Chief Science and Regulatory Officer