NORTH AMERICAN METAL PACKAGING ALLIANCE, INC.
1203 19th Street NW, Suite 300 • Washington, DC 20036-2401 • 866-522-0950 • www.metal-pack.org

June 30, 2009

Via E-mail and Regular Mail

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
P.O. Box 4010
1001 I Street, 19th floor
Sacramento, California 95812-4010

Re: Consideration of BPA Listing under Proposition 65

Dear Ms. Oshita:

The North American Metal Packaging Alliance, Inc. (NAMPA) is pleased to submit these comments in response to the Office of Environmental Health Hazard Assessment's (OEHHA) notice related to the Developmental and Reproductive Toxicant Identification Committee's (DARTIC) consideration of bisphenol A (BPA) at its July 15, 2009, meeting.[1] NAMPA is an organization whose objectives are to support risk-based regulations in North America, influence regulation in other geographies, provide customers with needed information regarding well-founded technologies, and advocate risk-based decision-making in technology decisions. NAMPA and its members support sound science and trust the scientific review process that has protected our food supply for decades.

Additional Government Reviews of BPA

According to the notice, the DARTIC will use the following documents at its July 15 meeting to consider whether BPA should be added to the Proposition 65 list as a chemical known to cause reproductive toxicity:

[1] OEHHA, Availability of Hazard Identification Materials for Bisphenol A for the July 15, 2009 Developmental and Reproductive Toxicant Identification Committee Meeting (May 1, 2009), available at http://www.oehha.ca.gov/prop65/CRNR_notices/state_listing/data_callin/BisA043009.html.

- Evidence of Developmental and Reproductive Toxicity of Bisphenol A, a report generated by OEHHA's Reproductive and Cancer Assessment Branch;[2]

- Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A prepared by the National Toxicology Program-Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2008); [3]

- European Union Risk Assessment Report on 4,4'-Isopropylidenediphenol (Bisphenol A), Final Report 2003; and

- Update of the Risk Assessment of 4,4'-Isopropylidenediphenol (Bisphenol A), Final Human Health Draft for Publication (to be read in conjunction with published EU RAR of BPA, 2003), April 2008.

NAMPA urges the DARTIC to also consider assessments recently issued by the Food Standards Australia New Zealand (FSANZ), Health Canada, and German Federal Institute for Risk Assessment.

Human Health Impacts of BPA Epoxy Resin Coatings

The OEHHA May 2009 Report appropriately indicates that BPA is used in epoxy resins that coat metal products, such as food cans. BPA, the epoxy resin coating, and the metal packaging positively impact human health by maintaining food and beverage safety. Metal packaging protects food quality and nutrition, while enabling high temperature sterilization that eliminates the dangers of food poisoning from microbial contaminants. According to U.S. Food and Drug Administration records, there has not been an incidence of food-borne illness from metal packaged foods in more than 30 years. The same cannot be said for fresh, refrigerated, or frozen foods, all of which have been involved in tragic food poisoning cases over the last few years.

In addition to the benefits of food safety, canned food products play a critical role in feeding those in need; a role that cannot be easily or effectively replaced by fresh, refrigerated, or frozen alternatives. Metal packaged products offer a significantly longer shelf-life for foods,

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[2] OEHHA May 2009 Report, *available at* http://www.oehha.ca.gov/prop65/CRNR_notices/state_listing/data_callin/pdf/BPAd050109.pdf.

[3] NTP-CERHR Monograph, *available at* http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf.

making them the best option to provide nutritious foods at the lowest possible cost to people around the world. Metal packaged products offered through local food pantries or Women, Infant and Children (WIC) programs provide invaluable assistance to citizens in need. The Committee should recognize that in 2008, almost 60% of all infants born in California depended upon WIC each month.

Relevance of NTP Finding for BPA Listing

As it evaluates the findings in the NTP-CERHR Monograph, the Committee should carefully consider the level of concern ratings available to NTP and those used for the BPA assessment. The levels of concern are -- from lowest to highest -- negligible concern, minimal concern, some concern, concern, and serious concern. NTP did not issue any findings of "concern" or "significant concern" for BPA. For the finding of "some concern," the NTP-CERHR Monograph stated the studies in laboratory animals provided only limited evidence for adverse effects on development and that more research is needed.[4] We do not believe the NTP finding of "some concern" is sufficient for a Proposition 65 listing.

DARTIC Should Consider Research from Health Canada

The OEHHA May 2009 Report notes that BPA "is known to leach from . . . food containers such as cans. . . ."[5] The OEHHA May 2009 Report does not include relevant information on the levels of BPA seen in such applications. Health Canada has conducted several studies measuring BPA levels in various food products. For example, in March 2009, Health Canada released research findings that showed levels of BPA in soft drinks were far below established regulatory levels. The report concludes: "The results of this survey clearly indicate that exposure to BPA through the consumption of canned drink products would be extremely low. The low levels of BPA found in canned drink products available for sale in Canada confirm Health Canada's previous assessment conclusion that the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population."[6] A similar study with liquid infant formula found that BPA levels were below

4 NTP-CERHR Monograph at 38.

5 OEHHA May 2009 Report at 21.

6 Health Canada, Survey of Bisphenol A in Canned Drink Products (Mar. 2009) at 6, *available at* http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/securit/bpa_survey-enquete-can-eng.pdf.

established regulatory levels.[7] Additional data have been developed for jarred baby food and powdered infant formula but study reports have not yet been issued. DARTIC should commence a dialogue with Health Canada on its findings and include them in its consideration.

Harvard Study Does Not Demonstrate Adverse Effects

If the Committee chooses to consider the May 2009 report, "Use of Polycarbonate Bottles and Urinary Bisphenol A Concentrations,"[8] in its deliberations, it should be aware of a recent statement by FSANZ:

> On the 12 May 2009 a group of investigators from the Harvard School of Public Health published a report in the journal 'Environmental Health Perspectives' entitled 'Use of Polycarbonate Bottles and Urinary Bisphenol A Concentrations'. The purpose of the study was t o examine the association between use of polycarbonate drinking bottles and urinary bisphenol A (BPA) concentrations in humans.
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> The study concluded that the concentration of BPA in the urine of 77 college age students increased following ingestion of cold beverages in polycarbonate drinking bottles. Background levels of BPA in urine were reduced by avoiding consumption of fluids from polycarbonate drinking vessels for one week (a washout phase).
>
> FSANZ has reviewed this study and has found that it only confirms that inactive BPA excreted in urine may be derived from polycarbonate plastics drinking. BPA is metabolised differently in humans relative to that in rats. As it is effectively deactivated (turned into a safe form) in the liver and is then excreted in

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7 Health Canada, Survey of Bisphenol A in Canned Liquid Infant Formula Products (Aug. 2008), *available at* http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/securit/bpa_survey-enquete-eng.pdf.

8 Carwille, J.L., *et al*. (2009). Use of Polycarbonate Bottles and Urinary Bisphenol A Concentrations. *Envtl. Health Perspect.*, *available at* http://www.ehponline.org/members/2009/0900604/0900604.pdf.

inactive form in the urine. This study does not indicate that these levels of BPA pose a risk to human health.[9]

Thank you for consideration of our input. We look forward to the July 15, 2009, meeting and the decision of the DARTIC.

Sincerely,

John M. Rost, Ph.D.
Chair, NAMPA

[9] FSANZ, Bisphenol A (BPA) and food packaging (May 2009), *available at* http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2009/bisphenolabpaandfood4218.cfm.