

March 26, 2013

Ms. Cynhia Oshita  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, California 95814

Re: Notice of Intent to List: Bisphenol A

Dear Ms. Oshita,

The International Formula Council (IFC) is responding to the January 25, 2013 Notice of Intent by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) to list the chemical Bisphenol A (BPA) as known to the State to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986. The IFC is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose members are based predominantly in North America.

The IFC supports the state's desire to protect its citizens from potentially harmful chemicals. The primary focus of the IFC and its member companies is and will always remain the health and welfare of infants and young children. The product we manufacture, infant formula, is the most highly regulated food in the world and continues to be the only safe, nutritious and recommended alternative to breast milk.

Although no infant formula manufacturer currently utilizes packaging in the US that is formulated with BPA as a component of the product contact surface, the IFC respectfully opposes OEHHA's listing of BPA on Proposition 65. Scientific consensus on potential health risks from BPA does not exist, and current evidence does not support labeling the presence of BPA on food packaging.

The source cited by OEHHA under the authoritative bodies listing to support its proposed action is a 2008 report by the National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR). In that report, the NTP-CERHR concluded there was "some concern" for BPA exposure in fetuses, infants, and children based on effects in the prostate gland, mammary gland, and earlier age for puberty in females. The NTP used laboratory animal studies to draw this and other conclusions made in the report, and have consistently commented that more research is needed to better understand the potential implications for human health.

We would also like to point out that OEHHA's own Developmental and Reproductive Toxicant Identification Committee (DART-IC) voted in 2009 not to list BPA as a chemical known to cause reproductive toxicity.

Consistent with this position, on March 30, 2012, the US Food and Drug Administration (FDA) announced "the scientific evidence at this time does not suggest that the very low levels of human exposure to BPA through the diet are unsafe." FDA continues to research and monitor studies to address uncertainties that have been raised about BPA, but was clear that BPA exposure from food contact materials is extremely low and safe for infants, children and adults.<sup>1</sup>

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<sup>1</sup> IFC members are Abbott Nutrition, Mead Johnson Nutrition, Nestlé Infant Nutrition and Perrigo Nutritionals.

Other recent scientific studies continue to confirm that BPA is safe for use in food applications. In December 2011, Food Standards Australia New Zealand (FSANZ) stated “the overwhelming weight of scientific opinion [regarding BPA] shows no human health and safety concerns at the levels people are exposed to.”<sup>ii</sup> In June 2011, a robust clinical exposure study funded by the U.S. Environmental Protection Agency and carried out by researchers from the FDA and the Centers for Disease Control and Prevention found that BPA concentrations in the blood are extremely low, including periods of high dietary exposure.<sup>iii</sup>

In addition, many international regulatory and health organizations have supported the safety of BPA:

- In December 2011, the European Food Safety Authority (EFSA) upheld its 2006 Tolerable Daily Intake (TDI) level for BPA of 0.05 mg/kg body weight. Over the past five years, EFSA has continuously evaluated new scientific information regarding BPA and repeatedly upheld the TDI, implying BPA does not pose a risk to human health.<sup>iv</sup>
- In November 2010, the World Health Organization, following an expert meeting to review the toxicological and health aspects of BPA, concluded that the “initiation of public health measures [to address BPA] would be premature.”<sup>v</sup>
- Health Canada has conducted numerous surveys of BPA in foods and beverages, including infant formula, and repeatedly stated: “The current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including infants and young children,” and, “The nutritional benefits of baby food products far outweigh any possible risk.”<sup>vi</sup>

Mandatory labeling of foods whose packaging contains BPA could also be confusing to consumers and cause unnecessary alarm. Manufacturers are permitted to voluntarily label their products as not containing BPA, so consumers have the option to purchase such products if desired. In addition, mandatory labeling would create an undue burden on manufacturers and retailers, without benefitting public health and safety.

In summary, mandatory labeling on foods whose packaging containing BPA is not justified by the totality of the scientific evidence and does not provide any meaningful benefit to consumers. In fact, such labeling will likely have the opposite effect – creating confusion and unnecessary alarm. For these reasons, IFC opposes OEHHA’s proposed listing of BPA on Proposition 65. Thank you for the opportunity to comment on this matter. If you have any questions, please contact me.

Sincerely,



Mardi K. Mountford, MPH  
Executive Vice President

<sup>i</sup> U.S. Food and Drug Administration. FDA Continues to Study BPA. March 2012.

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm297954.htm#2>

<sup>ii</sup> Food Safety Australia New Zealand. Consumer Information on Bisphenol A. December 2011.

<http://www.foodstandards.gov.au/consumerinformation/bisphenolabpa/>

<sup>iii</sup> Teeguarden JG, et al. 24-Hour Human Urine and Serum Profiles of Bisphenol A During High Dietary Exposure. Toxicological Sciences (2011). <http://toxsci.oxfordjournals.org/content/early/2011/06/24/toxsci.kfr160>

<sup>iv</sup> European Food Safety Authority Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). Statement on the ANSES reports on bisphenol A. December 2011.

<http://www.efsa.europa.eu/en/efsajournal/pub/2475.htm>

<sup>v</sup> World Health Organization. Summary of November 2010 Expert Meeting to Review the Toxicological and Health Aspects of BPA. [http://www.who.int/foodsafety/chem/chemicals/bisphenol\\_release/en/index.html](http://www.who.int/foodsafety/chem/chemicals/bisphenol_release/en/index.html)

<sup>vi</sup> Health Canada, Bureau of Chemical Safety, Food Directorate. Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature. December 2009. <http://www.hc-sc.gc.ca/fn-an/pubs/secureit/summ-bpa-temp-eng.php>