September 20, 2011

Via E-Mail

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010

Re: Consideration of BPA by the Carcinogen Identification Committee under Proposition 65

Dear Ms. Oshita:

The North American Metal Packaging Alliance, Inc. (NAMPA)\(^1\) is pleased to submit these comments in response to the Office of Environmental Health Hazard Assessment's (OEHHA) notice related to the Carcinogen Identification Committee’s (CIC) consideration of bisphenol A (BPA) at its October 12 and 13, 2011, meeting. Based on available science, current government agency reviews, and importance of BPA for maintaining food safety, NAMPA believes that BPA should receive a low priority for possible preparation of hazard identification materials for consideration of listing under Proposition 65 (Prop 65).

**Government Reviews Conclude BPA Is Safe; No Listing as Carcinogen**

The OEHHA documentation on BPA appropriately notes that BPA is used to manufacture epoxy resins used in the interior coatings for food and beverage cans and packaging. The report also notes that the primary source of exposure to BPA for most people is through their diet. As outlined in Appendix A, the use of BPA in food contact applications has been intensely evaluated by multiple global agencies and health organizations, and all are in agreement that BPA use in metal packaging is safe. Among the international bodies that have recently convened BPA reviews or re-reviews within the last few years are the World Health Organization, the U.S. Food and Drug Administration (FDA), the European Food Safety Authority, the German Federal Institute for Risk Assessment, Food Safety Australia and New

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\(^1\) NAMPA is a not-for-profit corporation committed to protecting health through the safety of metal packaging and metal packaged foods. NAMPA’s membership includes companies and associations representing various sectors along the supply chain for the food and beverage packaging industry.
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Global

World Health Organization

In November 2010, the World Health Organization (WHO) convened a panel of experts to review and assess the current scientific research on bisphenol A (BPA). Participants included scientists from the European Food Safety Authority (EFSA), Health Canada, the National Institute of Environmental Health Sciences, and the U.S. Food and Drug Administration (FDA). The panel specifically considered “low dose” studies that have received a great deal of publicity, despite criticism from the scientific community regarding study design, applicability to humans, and other areas of concern.

In its summary report, the panel confirmed that human exposure levels are extremely low, that BPA does not accumulate in the body, and is rapidly eliminated through normal bodily functions. With regard to low dose studies, the panel noted that “[t]here is considerable uncertainty regarding the validity and relevance of these observations. While it would be premature to conclude that these evaluations provide a realistic estimate of the human health risk, given the uncertainties, these findings should drive the direction of future research with the objective of reducing this uncertainty.”

United States

Food and Drug Administration

On January 15, 2010, the FDA issued an interim update of its review of BPA, and announced its intention to continue the ongoing scientific research and evaluation of the substance. In a statement consistent with other international regulatory bodies, FDA reiterated its fundamental position that FDA approved uses are safe and that BPA exposure has not been proven to harm children or adults in current uses. On the basis of some recent studies, however, the agency slightly modified its previous stance to reflect “some” concern with BPA, a position similar to that expressed by the National Toxicology Program (NTP). As a result, the agency is seeking additional research to answer key questions and clarify uncertainties about the risks of BPA.

Prior to the January announcement, FDA had been reviewing emerging literature on BPA on a continuous basis for years. In 2008, FDA issued a report stating that there is a large body of evidence indicating that FDA-regulated products containing BPA are safe and that exposure levels to BPA from food contact materials, including for infants and children, are below those
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that may cause health effects. In October of 2008, the FDA Science Board recommended that FDA re-examine its conclusion, given a host of new studies, paucity of sample data, and several other issues. The latest review and assessment occurred in response to that recommendation.

**California Developmental and Reproductive Toxicant Identification Committee**

In July 2009, an independent regulatory panel in the State of California completed a thorough review of all the scientific evidence on BPA as part of a chemical review process required under Proposition 65, the state’s listing of dangerous chemicals. Following its review, the California Developmental and Reproductive Toxicant Identification Committee (DARTIC) concluded that BPA is not toxic and does not pose a risk to consumers. Committee members determined that BPA is not a developmental or reproductive toxicant, and as a result, the Committee voted unanimously not to include BPA on Proposition 65.

**Europe**

**European Food Safety Authority**

In September 2010, EFSA issued its latest review of the scientific research on BPA concluding that, based on current scientific evidence, there is no reason to revise the current recommended human exposure level for BPA. Specifically, the members of this renowned international government authority on food safety, in a majority opinion, stated clearly that they “could not identify any new evidence which would lead them to revise the current Tolerable Daily Intake for BPA of 0.05 mg/kg body weight” as previously established by EFSA in 2006.

Following a “detailed and comprehensive review” of recent scientific literature and studies, EFSA also stated “the data currently available do not provide convincing evidence of neurobehavioral toxicity of BPA.” The panel specifically considered recent neurotoxicity studies, including the research conducted by Stump et al., and found the Stump data to be “inconclusive with respect to learning and memory and of limited value for the risk assessment of BPA.” Based on the 2010 literature review, EFSA “…does not consider the currently available data as convincing evidence that BPA has any adverse effects on aspects of behaviour, such as learning and memory.”

This latest assessment is consistent with EFSA’s past statements that the current Tolerable Daily Intake (TDI) provides a sufficient margin of safety for the protection of infants, children, or adults. In July 2008, the EFSA Panel reaffirmed its 2006 risk assessment findings on BPA. The Panel also concluded that the differences in age-dependent toxicokinetics of BPA in animals and humans would have no implication for its original findings.
European Commission’s Institute for Health and Consumer Protection

In February 2010, the European Commission’s Institute for Health and Consumer Protection issued a complete risk assessment report for BPA and included a new 2008 addendum to the substance’s original 2003 report. In this latest update, EU officials concluded that for consumers exposed to BPA, “there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.” The Commission stated that there are no risks from physico-chemical properties arising from the use of BPA, and as a result, there is no need for further information and/or testing and for risk reduction measures beyond those that are being applied already.

Germany

In July 2010, the German Federal Institute for Risk Assessment (BfR) -- the German equivalent of the U.S. FDA -- released its latest assessment of two new studies that sought to determine effects of BPA on neurological and behavioral development in test animals exposed to the chemical. Following its review of the two studies (Stump et al. and Ryan), the BfR concluded that the results “do not substantiate the concerns for a specific toxic potential of bisphenol A adverse to neurological and behavioural development.”

This latest action by the BfR is consistent with its previous assessments of BPA, released on October 2, 2009, when the agency reiterated its conclusions that BPA does not pose a health risk to people. In an updated Frequently Asked Questions (FAQ) document posted to its website, BfR responded to several questions about the safety of BPA in plastic baby bottles, stating that “Following careful examination of all studies, in particular the studies in the low dose range of bisphenol A, BfR comes to the conclusion in its scientific assessment that the normal use of polycarbonate bottles does not lead to a health risk from bisphenol A for infants and small children.”

In evaluating the effects of BPA, the German body concluded that BPA has low acute toxicity, has no carcinogenic effects, and though it is considered an “endocrine disruptor,” the effects are significantly different in humans versus laboratory animals. BfR stated: “In the human body bisphenol A is rapidly converted into a metabolite that no longer has any oestrogenic activity and is eliminated via the kidneys. More recent findings indicate that this constitutes a major difference to rodents which present slower elimination of bisphenol A in experimental studies.”

Australia/New Zealand

In October 2010, Food Standards Australia New Zealand (FSANZ), an independent statutory agency responsible for setting food standards in the two countries, announced that following a
recent survey of BPA levels found in foods and beverages in Australia, the agency affirmed its earlier conclusion that consumers are exposed to very low levels of BPA through food and beverage consumption. FSANZ stated that the results of its survey “provide additional assurance that BPA concentrations in Australian food do not pose a health risk to consumers.” While acknowledging that there are some unresolved uncertainties in the data on BPA, the agency noted that further studies are currently being conducted in the US to address these uncertainties, and that FSANZ will assess these new studies when they become available and provide advice to government on the level of risk.

Canada

Despite advising Canadian consumers that BPA does not pose a human health risk, the Canadian government took action in October 2010 to add BPA to its list of toxic substances, under the Canadian Environmental Protection Act (CEPA). The decision was based on findings by the Canadian government of potential human health and environmental effects, stemming from concerns with effects to aquatic environment and previously cited uncertainties raised in some studies relating to the potential effects of low levels of BPA exposure on infants and young children. There are no regulations associated with the CEPA listing, aside from providing Canada the ability to consider regulatory options that may or may not involve food packaging at some point in the future.

The CEPA listing of BPA does not negate the perspective offered by Health Canada regarding use of BPA in food contact applications. A government fact sheet advises Canadian consumers that they can continue to use polycarbonate water bottles and consume canned foods and beverages because exposure levels are very low. The Health Canada Food Directorate specifically states “the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and infants.”

The government’s reiteration of the safety of BPA for use in food packaging is supported by several recent studies conducted by Health Canada. In June 2010, Health Canada released the results of a new survey of BPA exposure levels in a variety of canned foods, which confirmed that foods packaged in BPA epoxy resin coated metal cans do not pose a health risk. At that time, Health Canada officials confirmed their previous conclusion regarding dietary exposure to BPA through food packaging.

In March 2009, Health Canada released research findings that showed levels of BPA in soft drinks were far below established regulatory levels. The report concluded: “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.”

In July 2009, Health Canada released the results of a series of new studies investigating BPA exposure levels in baby food in glass jars with metal lids, powdered infant formula, and bottled water. The results from these three government studies provided definitive confirmation that baby food products packaged in glass jars with metal lids, powdered infant formula, and bottled water do not pose a health risk.

Researchers found that all levels of BPA found in tested products were exceedingly low and all are well below the level established as safe for consumers by the Canadian government. In issuing the final reports, Canadian officials concluded that the assessments of baby food, powdered infant formula, and bottled water all confirmed that current dietary exposure is “not expected to pose a health risk to the general population, including infants and newborns.” Moreover, exposure to BPA through consumption of bottled water or jarred food would be “extremely low” and far below the migration limit set by Health Canada.

Japan

In July 2011, the Japanese Research Institute of Science for Safety and Sustainability (RISS) released a comprehensive investigative review of all scientific studies on BPA that characterized possible risks from BPA exposure as “very small.” The report was prepared by RISS, a division of the National Institute of Advanced Industrial Science and Technology (AIST), a publicly funded research organization that conducts risk and hazard assessments of chemicals. Scientists at RISS reviewed studies published after 2005 to update their previous hazard assessment, published in 2005. The review included an assessment of published, peer-reviewed studies of reproductive toxicity, neurotoxicity, and carcinogenicity from BPA exposure. This review, like the 2005 review, found that current uses of BPA pose very little risk to consumers.
Zealand, Health Canada, and most recently, the Research Institute of Science for Safety and Sustainability in Japan. The exhaustive reviews by these esteemed authoritative bodies included all available data on BPA, including in-vivo and in-vitro research, epidemiology studies, mutagenicity/genotoxicity studies, and carcinogenic assays. All the organizations determined that the current science does not support the listing of BPA as a carcinogen.

It would be repetitive and unnecessary for California to engage in yet another review of BPA, when the federal and international level organizations have already engaged in such reviews, and will continue to assess BPA as new data are developed.

Positive Human Health Impacts of BPA-Based Epoxy Resin Coatings

In addition to the reviews already conducted, which negate the need for California to engage in its own review, NAMPA requests that CIC members also consider the important role that epoxy resin coatings derived from BPA and the metal packaging play in 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 FDA 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, 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, Infants, and Children (WIC) programs provide invaluable assistance to citizens in need. The Committee should recognize that in over the last several years, more than half of the infants born in California depended upon WIC each month.

It is clear that the use of BPA-based epoxy coatings in metal packaging provides real, important, and measurable health benefits. By reducing the potential for the serious and often deadly effects from food-borne illnesses, epoxy coated metal cans protect human health. As the industry that is responsible for providing packaging that ensures safe and nutritious food, we are seriously concerned about the impact on food safety if BPA is listed as a high priority under the CIC process. We do not want the citizens of California to move away from a proven method for ensuring food safety, and put their health at risk.
Thank you for consideration of our input. We look forward to the October 12 and 13, 2011, meeting and feedback of the CIC.

Sincerely,

[Signature]

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