



May 13, 2010

Via E-mail

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
P.O. Box 4010
MS-19B
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)¹ is pleased to submit these comments in response to the Office of Environmental Health Hazard Assessment's (OEHHA) consideration of a petition from the Natural Resources Defense Council (NRDC) to list bisphenol A (BPA) as a reproductive toxicant under the Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65 or Prop 65). As discussed below, NAMPA strongly disagrees with NRDC's July 15, 2009, petition, which asserts that the authoritative bodies listing mechanism under Prop 65 should be triggered by the report on BPA by the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR).²

¹ NAMPA's membership includes companies and associations representing various sectors along the supply chain for the food and beverage packaging industry. NAMPA and its members support sound science and trust the scientific review process that has protected our food supply for decades.

² National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction. NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. NIH Publication No. 08-5994 (Sept. 2008) (NTP Report).



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NTP Report Already Thoroughly Reviewed under Prop 65

NAMPA notes that the report on BPA by NTP-CERHR was part of a focused and thorough review by the Developmental and Reproductive Toxicant Identification Committee (DARTIC) during its consideration of BPA in July 2009. At that time, the DARTIC carefully considered all the issues highlighted in the NTP Report and unanimously agreed BPA did not meet the Prop 65 criteria.

Furthermore, there are new data available that address the specific reproductive concern raised in the NTP Report. For the NTP finding of “some concern,” the report stated the studies in laboratory animals provided only limited evidence for adverse effects on development and that more research is needed. Several new, scientifically robust studies showing no adverse effects have been published since the NTP Report was finalized, including a U.S. Environmental Protection Agency (EPA) study specifically designed to address the reproductive concerns raised by NTP. The EPA study provides compelling new scientific evidence that exposure to BPA at extremely low doses has no effect on female development and fertility in test animals. This study is very important to OEHHA’s consideration of the NRDC petition because it provides scientifically valid data that were not considered by NTP and clearly settles those concerns, providing comprehensive answers to questions raised by NTP.

Finally, NTP itself has noted that its report “is not a quantitative risk assessment nor is it intended to supersede risk assessments conducted by regulatory agencies.” Given this statement, any attempt to rely on the NTP Report for Prop 65 listing purposes would be inconsistent with NTP’s own advice and thus entirely inappropriate.

Finding in NTP Report Is Not Relevant or Plausible for Humans

The California Code of Regulations clearly state that if the authoritative body listing is used based on experimental animal data, the data must show “that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.”³

The NRDC petition references the high dose study review included in the NTP Report, which states:

These “high” dose effects of bisphenol A are not considered scientifically controversial and provide clear evidence of adverse effects on development in laboratory animals. However, the

³ Cal. Code Regs. tit. 27, § 25306(g)(2).

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administered dose levels associated with delayed puberty (≥ 50 mg/kg bw/day), growth reductions (≥ 300 mg/kg bw/day), or survival (≥ 500 mg/kg bw/day) are far in excess of the highest estimated daily intake of bisphenol A in children (< 0.0147 mg/kg bw/day), adults (< 0.0015 mg/kg bw/day), or workers (0.100 mg/kg bw/day).⁴

The NTP Report also notes that the majority of human exposure to BPA occurs through food and beverages. Based on a Canadian sampling of beverage cans, the average amount of BPA found in beverages was 0.57 $\mu\text{g/l}$.⁵ With this in mind, NAMPA notes that to achieve the lowest dose level reference above that elicited adverse effects (≥ 50 mg/kg bw/day), a person would need to consume over 14 million cans of food or beverage per day, every day over a lifetime.⁶ Clearly, such consumption levels are not physically or biologically possible. Even incorporating a 100-fold safety factor, persons will still have to ingest 14,000 cans of food or beverage per day.

Additional Government Reviews of BPA

Since the unanimous decision by DARTIC in July 2009, the following government reviews or decisions have been issued:

- On January 15, 2010, the U.S. Food and Drug Administration (FDA) issued its interim update on BPA. In its announcement, FDA clearly stated that BPA has not been proven to be harmful to children or adults in any of its current uses.

⁴ NTP Report at 7.

⁵ Survey of Bisphenol A in Canned Drink Products. Health Canada Bureau of Chemical Safety (Mar. 2009).

⁶ Based on the following calculation:

The Health Canada beverage analysis of 72 samples yielded an average of 0.57 $\mu\text{g/l}$ per can. Assuming the average can is 12 ounces, or 355 ml, which equals 0.355 liters, the intake of an entire can containing 0.57 $\mu\text{g/l}$ would be 0.355 liters X 0.57 $\mu\text{g/l}$, or 0.2024 μg . Applying the dose referenced in the NPT report (50 mg/kg bw/day) to an average human (60 kg), the human equivalent intake would be 3,000 mg/day.

$$(3000 \text{ mg /day})(0.2024 \text{ } \mu\text{g/can})(1000 \text{ } \mu\text{g/mg}) = \mathbf{14,822,134 \text{ cans in a day}}$$



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- On October 2, 2009, the German Federal Institute for Risk Assessment (BfR) -- the German equivalent of the U.S. FDA -- 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 “[f]ollowing 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 February 2010, the European Commission’s Institute for Health and Consumer Protection issued a complete risk assessment report on BPA and included a new 2008 addendum to the substance’s original 2003 report. In this latest update, European Union 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.

Unintended Human Health Hazard Consequences

NAMPA urges OEHHA to evaluate the potential health hazards that might arise as unintended consequences of listing BPA as a Prop 65 reproductive toxicant and is no longer available for certain applications.

BPA is an essential component in the epoxy resin coatings used in metal food packaging. Epoxy coatings enable the high temperature sterilization of food products when initially packaged. Epoxy coatings are resistant to the wide range of chemistries found in food and beverage products; this chemical resistance virtually eliminates any interactions between the metal package and the food contents. This is critical in maintaining the sterility of the food product. The coating protects the food product from interacting with the metal package and prevents perforation defects from forming in the container that would allow bacteria and microorganisms to enter.

The use of epoxy coatings in metal packaging is the most effective way to protect the food product. The initial high temperature sterilization, coupled with the continued product protection enabled by the epoxy-based coatings, eliminates the dangers of food poisoning from microbial contaminants. According to FDA records, there has not been an incidence of food-borne illness resulting from a failure of metal packaging in more than 30 years. The same cannot



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be said for fresh, refrigerated, or frozen foods, all of which have been involved in the highly publicized tragic food poisoning cases that have occurred the last few years.

According to a March 2010 report from the Produce Safety Project, an initiative of the Pew Charitable Trusts and Georgetown University,⁷ food-borne illnesses cost the United States \$152 billion annually in health care and other losses. Each year, 76 million people become sick through food contamination, hundreds of thousands are hospitalized, and approximately 5,000 people die. We cannot dismiss the essential role of epoxy resin coatings in protecting against these very real, costly, and tragic results. By reducing the potential for the serious and often deadly effects from food-borne illnesses, epoxy coated metal packaging protects human health.

California citizens that receive assistance from food pantries as well as the Women, Infant, and Children (WIC) program rely significantly on the availability of metal packaged products. In 2009, more than 60% of all infants born in California were dependent upon WIC for nutritional support. WIC is an FDA supported program, with FDA issuing requirements and regulations for items provided. How will California's program -- which is the largest WIC program in the United States -- be impacted if it does not line up with the federal program? FDA has already clearly indicated that no changes should be made in food packaging or consumption, whether by industry or consumers, that could jeopardize either food safety or reduce access to and intake of food needed to provide good nutrition, particularly for infants.

With regard to other food assistance programs, according to an April 2009 policy paper from the California Association of Food Banks, five million Californians report that they are unable to afford the food they need. These include working parents and senior citizens. And the need is increasing. A June 2009 Los Angeles Regional Foodbank Policy Brief indicates the current distribution rate for food pantries has increased 31% compared to last year, and by 24% over the last six months. Even those who may not typically use food assistance programs could find themselves relying on metal packaged products in situations such as power outages, an earthquake, or other natural disasters.

Despite reports to the contrary, the simple fact is there is no readily available, suitable alternative to BPA-based can coatings that meets the essential safety and performance requirements for the broadest spectrum of foods now packaged in metal containers. There are some alternatives currently being used, but only for certain niche markets. They are not applicable for the wide range of food and beverages currently on the market. In an effort to

⁷ Richard Scharff. Health Related Costs From Foodborne Illness in the United States. Produce Food Safety Product at Georgetown University (Mar. 3, 2010).



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address marketplace concerns, the industry has and continues to research alternatives to BPA. But before any alternatives that might be under development today can be commercialized, they must undergo thorough, multi-year testing programs to ensure that food safety is not compromised. Assuming a new approach is found to be viable, modifications in production lines for the resin producers, the coating manufacturers, the package manufacturers, and fillers will need to be made. Furthermore, any alternative will require ongoing safety, environmental, and quality evaluations as required by law. At this time, there is no drop-in replacement available.

Conclusion

As previously noted, the listing of BPA and the conclusion in the NTP Report were carefully and thoroughly considered by the DARTIC. That Committee determined that BPA did not meet the listing criteria and voted unanimously not to include BPA on Proposition 65.

If OEHHA proceeds with listing BPA as a reproductive toxicant and consequently requires warning labels on metal packages, it will, in fact and reality, be encouraging its citizens to move away from a proven method for ensuring food safety and will put their health at risk. NAMPA strongly urges OEHHA not to proceed with any initiative to list BPA under Prop 65.

* * * * *

Thank you for consideration of our input. We look forward to OEHHA's decision on this very important matter.

Sincerely,

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