nampa NORTH AMERICAN METAL PACKAGING ALLIANCE, INC.
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March 27, 2013

Via E-Mail

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

Re: Notice of Intent to List -- Bisphenol A

Dear Ms. Oshita:

The North American Metal Packaging Alliance, Inc. (NAMPA)[1] is pleased to respond to the Office of Environmental Health Hazard Assessment's (OEHHA) request for comment as to whether bisphenol A (BPA) meets the criteria set forth in the regulations for authoritative bodies listings of the Safe Drinking Water and Toxic Enforcement Act of 1986, or Proposition 65 (Prop 65). As outlined below, NAMPA does not believe that BPA meets the criteria for listing under the Prop 65 authoritative body mechanism, and therefore opposes the listing.

Background

In its Notice of Intent to List BPA, OEHHA stated that BPA meets the criteria for listing as known to the State to cause reproductive toxicity under Prop 65, based on findings of the U.S. National Toxicology Program – Center for the Evaluation of Risk to Human Reproduction (NTP-CERHR). In particular, OEHHA based its finding on the 2008 report, "NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A."[2]

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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.

2 NTP, CERHR, "NTP-CERHR, Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A" (Sept. 2008) (NTP-CERHR Bisphenol A Monograph), available at http://www.ntp.niehs.nih.gov/ntp/ohat/bisphenol/bisphenol.pdf.

The North American Metal Packaging Alliance 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.

According to the California Code of Regulations, a chemical is known to California to cause reproductive toxicity if OEHHA determines that an authoritative body has formally identified the chemical as causing reproductive toxicity.[3] That section further notes:

> (d) For purposes of this section a chemical is "formally identified" by an authoritative body when the lead agency determines that:
> (1) the chemical has been **included on a list of chemicals** causing cancer or reproductive toxicity **issued by the authoritative body**;
>
> or is the subject of a report which is published by the authoritative body and which **concludes that the chemical causes** cancer or **reproductive toxicity**;
>
> or has otherwise been **identified as causing** cancer or **reproductive toxicity** by the authoritative body **in a document that indicates that such identification is a final action**….[4]

As outlined below, the NTP-CERHR actions on BPA do not meet the criteria for formal identification of a chemical by an authoritative body and, as such, BPA should not be listed under the authoritative body mechanism.

NTP-CERHR Does Not Issue List of Chemicals

With regard to the first criterion for a chemical to be "formally identified" by an authoritative body, NAMPA notes that NTP-CERHR does not issue a formal list of chemicals causing reproductive toxicity. We understand that NTP staff members have made statements in past presentations regarding findings of reproductive or developmental hazards, but the fact remains that NTP-CERHR does not have a formal "listing" of reproductive toxicants on its website. Instead, the role of CERHR is as follows:

> The Office of Health Assessment and Translation (OHAT) (formerly Center for the Evaluation of Risks to Human Reproduction (CERHR)) serves as an environmental health resource to the public and to health research and regulatory agencies.

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[3] Cal. Code Regs. tit. 27, § 25306.

[4] *Id*. *(*extra spacing and emphasis added).

- Conducts technical assessments focused on understanding the potential for adverse effects on human health by agents, substances, mixtures, or exposure circumstances (collectively referred to as "substances"). These evaluations can lead to NTP opinions on whether these substances may be of concern given what is known about current human exposure levels.

- Organizes workshops or state-of-the-science evaluations to address other issues of importance in environmental health sciences.[5]

That NTP-CERHR has identified a substance "may be of concern" is not equivalent to a formal listing. Thus, the criterion for "formally identified" is not met.

NTP-CERHR BPA Monograph Does Not Conclude BPA Causes Reproductive Toxicity

Like all NTP-CERHR monographs, the BPA Monograph does not provide a conclusion or determination of reproductive toxicity. It only provides expressions of "levels of concern," as follows:

> **NTP Conclusions**
>
> The NTP reached the following conclusions on the possible effects of exposure to bisphenol A on human development and reproduction. Note that the possible levels of concern, from lowest to highest, are negligible concern, minimal concern, some concern, concern, and serious concern.
>
> **The NTP has *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A.**
>
> . . .

[5] National Institute of Environmental Health Sciences, Health Assessment and Translation, About OHAT (last visited Mar. 4, 2013), available at http://www.niehs.nih.gov/research/atniehs/dntp/ohat/index.cfm.

> **The NTP has *minimal concern* for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children at current human exposures to bisphenol A.**
>
> . . .
>
> **The NTP has *negligible concern* that exposure of pregnant women to bisphenol A will result in fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring.**
>
> . . .
>
> **The NTP has *negligible concern* that exposure to bisphenol A will cause reproductive effects in non-occupationally exposed adults and *minimal concern* for workers exposed to higher levels in occupational settings.**[6]

There is no definitive statement in the Monograph concluding that NTP-CERHR determined that BPA causes reproductive toxicity. Though the conclusion of the Monograph highlights certain concerns, it provides no definitive conclusions. Indeed, the lack of definitive conclusions in NTP-CERHR reports generally was identified as a problematic factor when OEHHA and the Developmental and Reproductive Toxicant Identification Committee (DARTIC) initially deliberated as to whether NTP-CERHR should be considered an authoritative body.[7]

NTP-CERHR BPA Monograph Does Not Identify BPA As a Reproductive Toxicant in a Final Action

As stated in the 2008 BPA Monograph, the purpose of a CERHR report "is to provide timely, unbiased, scientifically sound evaluations of the potential for adverse effects on reproduction or development resulting from human exposures to substances in the environment."[8] CERHR is not designated to identify reproductive toxicants, nor does it issue

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6 NTP-CERHR Bisphenol A Monograph at 38-39.

7 Transcript of Public Meeting of DARTIC, held on December 4, 2002, at 125-127.

8 NTP-CERHR Bisphenol A Monograph at v.

final actions. Indeed, the 2008 BPA Monograph states that the animal data, which OEHHA is purportedly relying on in its Notice of Intent to List, "provide **limited evidence** that bisphenol A has adverse effects on development."[9] A finding of limited evidence is not sufficient to meet the required specification of formal identification in a final action.

State's Qualified Experts' Decision Not to List BPA Should Not Be Ignored

NAMPA respectfully disagrees with OEHHA's view that the 2009 DARTIC decision not to list BPA under Prop 65 is somehow irrelevant. The very document that OEHHA is using as a basis for its 2013 Notice of Intent to List was thoroughly and comprehensively reviewed by California's own set of scientific experts, and those experts unanimously concluded that the data do not support listing. For OEHHA now to dismiss as irrelevant a careful and concentrated review of the data by scientists chosen by the State of California, and instead rely solely on an automatic listing mechanism, is arbitrary, irrational, and disturbingly self-serving.

As articulated by Dr. Jay Murray[10] in his June 28, 2011,[11] letter to the DARTIC:

> There is something inherently wrong with the authoritative bodies process if the same chemical you declined to list can be proposed for listing six months later based on the same document you considered, and nothing more.

For the reasons listed above, NAMPA does not believe that the criteria for an authoritative body mechanism listing under Prop 65 has been met, and, therefore, opposes the OEHHA Notice of Intent to List.

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9 *Id.* at 34 (emphasis added).

10 Dr. F. Jay Murray is a toxicologist who heads the consulting firm of Murray & Associates in San Jose, California. He is a former member of the California Governor's Scientific Advisory Panel for the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

11 Jay Murray, Murray & Associates, letter to Dorothy Burk, Ph.D., Chairperson, and Committee Members of the Developmental and Reproductive Toxicant Identification Committee (June 28, 2011).

Thank you for this opportunity. If you or your staff has any questions regarding this letter, please do not hesitate to contact me. I can be reached at kroberts@metal-pack.org or 443-964-4653.

Regards,

Kathleen M. Roberts
Executive Director