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Statement of the North American Metal Packaging Alliance, Inc.
on FDA's Draft Assessment of Bisphenol A (BPA) for Use in Food Contact Applications
Before the BPA Subcommittee of the Science Board to the FDA

September 16, 2008

My name is Dr. John Rost and this statement is presented on behalf of the North American Metal Packaging Alliance, Inc. (NAMPA). As Chair of NAMPA, I appreciate the opportunity to speak this afternoon to the distinguished members of the BPA Subcommittee and look forward to responding to questions you may have.

NAMPA represents the interests of the North American light metal packaging industry, including raw material producers, resin formulators, metal packaging manufacturers and converters, food processors, beverage manufacturers, and other allied entities. NAMPA is committed to the safety of the metal packaging products its members produce.

Bisphenol A (BPA) is a critical component in the manufacture of epoxy coatings used to line metal packaging. For over 50 years, epoxy coatings have been used in metal food packaging. The combination of toughness, adhesion, formability, resistance to a wide range of chemistries found in food and beverage products, and the ability to sustain the high temperatures required for sterilization make these coatings unsurpassed and are, without exception, the coatings of choice. The use of epoxy coatings in metal packaging is the most effective way to bring nutritious wholesome foods to people throughout the world because it dramatically increases the shelf life of packaged food and decreases food waste due to product expiration. Moreover, no other food packaging performs as well in situations such as disaster response, storage for homeland security, or famine relief.

BPA may remain in trace quantities after the polymerization and thermal curing that converts the liquid coating into a light metal packaging film. The very small residual concentrations of BPA, however, that may exist in the film will not increase with time after thermal processing, storage, hydrolysis, or even damage to the polymer, *i.e.*, scratching or denting.

NAMPA endorses FDA's efforts to assess the safety of BPA. In this regard, FDA's Draft Assessment of BPA for Use in Food Contact Applications represents a thorough, comprehensive, and objective review of the scientific literature focused on the endpoints of carcinogenesis and reproductive and developmental toxicity of BPA. FDA's rigorous assessment of studies was particularly critical in evaluating the alleged "low dose" developmental effects attributed to BPA.

NAMPA welcomes FDA's conclusion in the Draft Assessment that "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants

and adults."[1] Importantly, in reaching this conclusion, FDA "used unmodified, typical study type UFs [uncertainty factors] and considers them conservative based on the large body of knowledge for BPA and the findings observed in the pivotal studies,"[2] and thoroughly reviewed data "on endpoints highlighted as of potential concern in recent reports, such as developmental effects on the prostate gland and developmental neural and behavioral toxicity. . . ."[3] To the extent scientific uncertainties surrounding the Draft Assessment exist, NAMPA supports FDA's proposed tiered testing strategy to decrease these uncertainties.

NAMPA also fully concurs with FDA's conclusion "that safety assessments . . . should be based on laboratory animal studies using oral routes of exposure since this is the most relevant route of human exposure for food contact materials. Studies based on other routes of exposure . . . are likely not comparable to typical human exposures to food contact materials and will not produce results relevant to safety assessments of food contact materials."[4]

NAMPA, however, believes that the levels of BPA reported in food, and attributed to migration of residual monomer from the epoxy coating on metal food and beverage containers, are often significantly overstated. Unless an analytical methodology suitable for measuring very low BPA levels in complex matrices is utilized, the reported results can be influenced by interferences from other food constituents. Sampling to date often has been done utilizing Gas Chromatography with Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) with fluorescence detection, that are prone to interferences from other substances naturally present in food products.

BPA exposure estimates would be more reliable if the residue data utilized to develop such estimates are collected with more robust and defensible analytical technologies and protocols.

I would be pleased to answer any questions you might have.

Thank you.

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1 Draft Assessment at 36.

2 Draft Assessment at 34.

3 Draft Assessment at 36.

4 Draft Assessment at 19.