

September 17, 2012

Dr. Margaret Hamburg  
Commissioner  
U.S. Food and Drug Administration

Re: Public Comment on Docket No. FDA-2012-F-0728-0001

Dear Commissioner Hamburg:

On behalf of the Glass Packaging Institute (GPI), I am writing to submit a public comment in support of the above-referenced petition. This petition proposes that the Food and Drug Administration's (FDA) food additive regulations be amended to no longer provide for the use of bisphenol A (BPA)-based epoxy resins as coatings in packaging for infant formula.

In July, [the FDA amended the food additive regulations](#) to no longer provide for the use of polycarbonate resins in baby bottles and spill-proof cups. This action came in response to a [petition submitted by the American Chemistry Council](#) (ACC). GPI applauds this decision. The FDA's decision to support the ACC petition is not surprising, given that manufacturers have voluntarily discontinued the chemical's use in baby bottles and sippy cups due to increased consumer concerns about potential safety risks presented by products containing BPA, particularly in the context of these products, which are used exclusively for infants and young children. This voluntary abandonment of BPA by the manufacturers of baby bottles and sippy cups was noted in ACC's petition to the Agency.

The petition would add infant formula packaging to the list of items in which BPA is prohibited which would serve to further protect infants and small children from the potential dangers of BPA. The extension by the FDA of the restriction of BPA's permitted uses to prohibit use of the material in infant formula packaging would be consistent with the Agency's policy to proactively protect infants and small children, and respond to ongoing consumer concerns about the safety of these BPA-containing products.

However, as the FDA considers further actions with respect to BPA, there remains a larger question: should steps be taken to protect the safety of all consumers by limiting BPA exposure in a broader range of products? When consumers eat foods or drink beverages in packaging that contains BPA, they may increase their exposure to a chemical that has prompted extensive study and regulatory action around the globe, including significant restrictions on uses deemed acceptable by several foreign government regulatory authorities. There are several peer-reviewed, independent, scientific studies demonstrating that BPA is present in the human body after consumption of goods packaged in BPA-lined containers (e.g., Wolstenholme JT, Edwards M, Shetty SR, Gatewood JD, Taylor JA, Rissman EF, et al. 2012. It also is well-known that gestational exposure to BPA produces transgenerational changes in behaviors and gene expression. *Endocrinology* 153(8): 3828-3838). Based on these and other authoritative,

publicly available reports and data, GPI believes that the relatively narrow scope of prohibitions on uses of BPA in the U.S. reasonably should be expanded to protect consumers of all ages.

In a decision earlier this year responding to requests that all food-contact uses of BPA be prohibited, the FDA announced its commitment to continue its review of emerging data on BPA. The agency also announced its commitment to perform, monitor, and review new studies and data concerning the health and safety impacts of BPA, to ensure that any new developments properly informs future regulatory decisions. GPI supports the FDA's commitment to study the significant emerging science around BPA, and would encourage the agency to expand the scope of its review beyond just infants, small children and other vulnerable populations.

The fact that consumers voted with their feet by gravitating to glass baby bottles is not surprising given that glass is the only widely-used packaging designated by FDA as "generally recognized as safe." As such, it remains the optimal packaging choice, safely preserving the flavor and integrity of the foods and beverages it contains while lowering the potential for exposure to toxic compounds. For this reason, as concerns about BPA continue to mount, one can expect to see increased consumer migration to glass containers.

Again, I urge the FDA to both support the petition and expand its actions restricting BPA beyond vulnerable populations.

Lynn Bragg  
President  
Glass Packaging Institute

*On behalf of the North American glass container manufacturers, the Glass Packaging Institute promotes glass as the optimal packaging choice, advances environmental and recycling policies, advocates industry standards and educates packaging professionals. GPI member companies manufacture glass containers for food, beverage, cosmetic and many other products. GPI associate members represent a broad range of suppliers to the industry.*