



September 12, 2008

Carlos Peña
Office of Science and Health Coordination,
Office of the Commissioner (HF-33),
Food and Drug Administration (FDA),
5600 Fishers Lane, (for express delivery, rm. 14B-08)
Rockville, MD 20857
Office: 301-827-3340
Carlos.Peña@fda.hhs.gov

Re: Public Comments on the FDA Draft Assessment of Bisphenol A (BPA)

Dear Mr. Peña:

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy.

GMA appreciates the opportunity to provide comments in response to FDA's most recent draft assessment. GMA submits that BPA allows for the production of technologically and commercially feasible, safe packaging that is essential for food safety and quality; that BPA is well studied and regulated; and BPA's safety for all consumers is once again reaffirmed by FDA's careful, thorough and conservative evaluation.

BPA as used in epoxy can coatings allows for the production of technologically and commercially feasible packaging that is essential for food safety and quality. The broader issues of public health need to be considered. Epoxy coatings are essential technology for modern food and beverage cans. Internal coatings are necessary to prevent interaction between the food and the metal packaging. The "product resistance" provided by these coatings is critical for the cans to withstand the wide range of chemical conditions associated with food and beverages, and to prevent adulteration of the food or beverage that would result from can corrosion, dissolved metal concentrations and bacterial contamination, particularly under the high-temperature processing conditions necessary for sterilization. Epoxy coatings have been used safely to protect the world's food supply for over 50 years. All major can manufacturers and coating suppliers are continually evaluating and developing new coating chemistries for commercial uses, but

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in more than 90% of food and beverage product applications, epoxy's toughness, adhesion, formability, and product resistance under high-temperature processing conditions are unsurpassed.¹

The safety of human exposures to BPA is well studied and regulated. The FDA assessment is consistent with other recent expert and regulatory evaluations that have concluded that the weight of the available evidence indicates BPA is safe in food contact applications. The European Food Safety Authority (EFSA), the U.K. Food Standards Agency, the Japanese Ministry of Health, Labor and Welfare, and other regulatory agencies around the world recognize epoxy resins based on BPA as safe when used as intended and have carefully and thoroughly reviewed the use of these coatings in food contact applications.² Recent risk assessments have been performed by the European Union,³ the Norwegian Scientific Committee on Food Safety,⁴ the European Food Safety Authority (EFSA),⁵ and NSF International,⁶ an independent, not-for-profit third-party organization.

GMA commends FDA for performing a thorough, well-documented review of the available toxicological information and research using a sound analytical approach. FDA has appropriately focused its in-depth analysis of the peer-reviewed literature on the specific health concerns identified in other reviews (reproductive and developmental effects), and emphasized the subpopulation of concern (infants) in its exposure assessment.

GMA supports the use of studies that meet comprehensive, stringent regulatory guidelines in safety assessment, including Good Laboratory Practice (GLP) (21 CFR Part §58.1) regulations. Guidelines such as the FDA Redbook 2000 protocols for reproductive and developmental studies and the GLP regulations establish criteria and requirements for study design, conduct and reporting that assure the data will be valid, reliable and useful for human safety assessment. Guideline study protocols are based on internationally recognized toxicological endpoints having known significance for human safety. Many BPA studies in the peer-reviewed literature that reported developmental or neurotoxicity concerns do not meet the FDA or other international guideline because they have, for example, limited sample size, lack of reproducibility, absence of internal dose measurements when inappropriate routes of exposure are used, lack of positive controls, use of single dose, insufficient or inappropriate dosing regimen, lack of supporting histochemistry data, or lack of controls for other confounding factors in study design, etc. Other studies constitute research on biological mechanisms, i.e., observed changes having no known relevance to human safety.

FDA's evaluation of the science on BPA for purposes of a safety assessment is comprehensive, objective, and transparent, with clear explanations of any failings in study design, conduct and interpretation in the reviewed literature. GMA commends FDA on its careful and conservative analysis of the issues and concerns that have been raised with respect to BPA, and its conclusion that food contact applications of BPA are safe.

Sincerely yours,



Craig Henry, Ph.D.
Senior Vice President and Chief Operating Officer
Science and Regulatory Affairs

¹ Letter from Dr. William Hoyle, Inter-Industry Group, to Dr. Michael D. Shelby, CERHR, June 20, 2007.

² <http://www.bisphenol-a.org/pdf/HumanSafetyOctober2002.pdf>

³ Updated European Risk Assessment Report 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A)

http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDEDENDUM/bisphenola_add_325.pdf

⁴ Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety (18 June 2008):

Assessment of four studies on developmental neurotoxicity of bisphenol A,

http://www.vkm.no/eway/default.aspx?pid=0&oid=-2&trg=_new&_new=-2:17919

⁵ Toxicokinetics of Bisphenol A Scientific Opinion of the Panel on Food Additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) (July 9, 2008)

http://www.efsa.eu.int/efsa/efsa_locale-1178620753812_1211902017492.htm

⁶ Willhite, C. C., G. L. Ball, and C. J. McLellan. 2008. Derivation of a Bisphenol A Oral Reference Dose (RfD) and Drinking-Water Equivalent Concentration. *Journal of Toxicology and Environmental Health, Part B.* 11(2): 69-146.