Summary of FDA’s Current Perspective on BPA in Food Contact Applications

FDA’s current perspective, based on its most recent safety assessment, is that BPA is safe at the current levels occurring in foods. Based on FDA’s ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.

Overview of BPA Usage in Food Contact Applications

BPA is a structural component in polycarbonate beverage bottles. It is also a component in metal can coatings, which protect the food from directly contacting metal surfaces. BPA has been used in food packaging since the 1960s. As is the case when foods are in direct contact with any packaging material, small, measurable amounts of the packaging materials may migrate into food and can be consumed with it. As part of its premarket review of food packaging materials, FDA’s food contact regulations and food contact notification program assesses the likely migration from the packaging material to assure that any migration to food occurs at safe levels. Heightened interest in the safe use of BPA in food packaging has resulted in increased public awareness as well as scientific interest. As a result, many exploratory scientific studies have appeared in the public literature. Some of these studies have raised questions about the safety of ingesting the low levels of BPA that can migrate into food from food contact materials. To address these questions the National Toxicology Program, partnering with FDA’s National Center for Toxicological Research is carrying out in-depth studies to answer key questions and clarify uncertainties about BPA. On the regulatory front, FDA’s regulations authorize FDA to amend its food additive regulations to reflect when certain uses of an additive have been abandoned. FDA can take this action on its own initiative or in response to a food additive petition that demonstrates that a use of a food additive has been permanently and completely abandoned. Recently, FDA granted two petitions requesting that FDA amend its food additive regulations to no longer provide for the use of certain BPA-based materials in baby bottles, sippy cups, and infant formula packaging because these uses have been abandoned. As a result, FDA amended its food additive regulations to no longer provide for these uses of BPA.

Background

BPA is an industrial chemical used to make polycarbonate, a hard, clear plastic, which is used in many consumer products. BPA is also found in epoxy resins, which act as a protective lining on the inside of some metal-based food and beverage cans. Uses of all substances that migrate from packaging into food, including BPA, are subject to premarket approval by FDA as indirect food additives or food contact substances. FDA can make regulatory changes based on new safety or usage information. The original approvals for BPA were issued under FDA’s food additive regulations and date from the 1960s. In 2008 FDA released a document titled Draft Assessment of Bisphenol A for Use in Food Contact Applications. This draft assessment was reviewed by a Subcommittee of FDA’s Science Board, which released its report at the end of October 2008. Also in 2008, the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction, part of the National Institutes of Health, released the Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. By 2009, FDA released reassessments of studies cited in the NTP Monograph in addition to other relevant studies that became available after the Monograph’s release. The studies were evaluated for their relevance for regulatory hazard and/or risk assessment. In addition to the FDA review process, FDA’s Acting Chief Scientist asked five expert scientists from across the federal government to provide independent scientific review of these documents in the fall of 2009. The results of the independent evaluations were released in April 2010, as FDA made the CFSAN report and other relevant information available for public comment. Although the reassessments indicated a need to further evaluate a number of endpoints or biological outcomes, the analyses did not recommend any adjustments to BPA levels reported in food at that time.
Since that time, the FDA has continued to review additional studies as they became available, including those addressing possible low-dose effects. In the fall of 2014, FDA experts from across the agency, specializing in toxicology, analytical chemistry, endocrinology, epidemiology, and other fields, completed a four-year review of more than 300 scientific studies. The FDA review has not found any information in the evaluated studies to prompt a revision of FDA’s safety assessment of BPA in food packaging at this time.

The studies reviewed were published or available from November 1, 2009 to July 23, 2013. The review was documented in four memoranda and their attachments:

- “Final report for the review of literature and data on BPA” – 6/6/2014
- “2014 Updated Review of Literature and Data on Bisphenol A” - 6/6/2014
- “2012 Updated Review of Literature and Data on Bisphenol A” - 8/22/2013
- “Updated Review of the ‘Low-Dose’ Literature (Data) on Bisphenol A and Response to Charge Questions Regarding the Risk Assessment on Bisphenol” - 5/24/2011