SCIENCE BOARD TO THE FDA (Science Board)

Charge to the Science Board

In April of 2008, Commissioner von Eschenbach formed an FDA Task Force to evaluate the safety of all BPA-containing FDA-regulated products. As a component of the work of this task force, FDA/CFSAN has conducted this safety assessment to determine if current exposure to BPA through the use of food additives is safe, meaning that there is reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use in food contact applications. This assessment is focused on the endpoints of carcinogenesis and reproductive and developmental toxicity of BPA. At a later date, FDA will publish a separate document that provides a safety assessment of BPA exposure from other FDA-regulated products.

FDA's Draft Assessment of Bisphenol A For Use In Food Contact Applications is particularly focused on the concerns for developmental toxicity identified in recent assessments of BPA, including those of the National Toxicology Program and their expert panel. BPA is an impurity in FDA-regulated food additives, including epoxy-based food can liners and polycarbonate baby bottles. FDA estimates that BPA exposure from use in food contact materials in infants and adults is 2.42 µg/kg bw/day and 0.185 µg/kg bw/day, respectively. FDA has determined the appropriate no observed adverse effect level (NOAEL) for its assessment of BPA to be the NOAEL for systemic toxicity of 5 mg/kg bw/day (5000 µg/kg bw/day) derived from two multigenerational rodent studies. This NOAEL results in adequate margins of safety of approximately 2,000 and 27,000 for infants and adults, respectively. The data reviewed on highlighted endpoints, such as the prostate gland and developmental neural and behavioral toxicity, were insufficient to provide a basis to alter the NOAEL used to calculate the margins of safety. FDA has concluded that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses. At a later date, FDA will publish a separate document that provides a safety assessment of BPA exposure from other FDA-regulated products.

Because of the potential impact of the FDA's Draft Assessment of Bisphenol A For Use In Food Contact Applications on important public policies or private sector decisions, the agency requested the Science Board to establish a Subcommittee to assess FDA's Draft Assessment. The BPA Subcommittee was provided with a copy of FDA's Draft Assessment and a written charge. The BPA Subcommittee held a public meeting to hear and discuss the draft assessment of BPA for use in food contact applications, including oral presentations from the public. The BPA Subcommittee also prepared a report and submitted this report to the Science Board.

Temporary subcommittees consisting of two or more Board members may be established by the Commissioner or designee as needed to address specific issues within their respective areas of expertise. Subcommittees make preliminary recommendations regarding specific issues for subsequent action by the full Board. Based on the information you have received about FDA's Draft Assessment of Bisphenol A For Use In Food Contact Applications, including the BPA Subcommittee report, please advise the agency concerning FDA's Draft Assessment of Bisphenol A For Use In Food Contact Applications.