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## Product Safety Consumer Products

### Bisphenol A Expert Panel Finds NTP Overstated Concerns About BPA's Mammary Gland, Puberty Effects

RESEARCH TRIANGLE PARK, N.C.--The National Toxicology Program overstated the concerns about bisphenol A's effects on mammary glands and the onset of puberty in young females, an expert review panel said June 11.

At a meeting in Research Triangle Park, the Board of Scientific Counselors voted to drop the levels of concern stated in NTP's draft report on bisphenol A (CAS No. 80-5-07) with regard to such effects from "some concern" to "minimal concern." The expert review panel did agree with the other levels of concern expressed by NTP in the draft report evaluating scientific studies on the substance's potential for reproductive and developmental toxicity.

Bisphenol A is a chemical used to make plastics such as food and beverage packages, water and infant bottles, compact discs, and medical devices. According to NTP, about 2.3 billion pounds were produced in the United States in 2004, with more than 90 percent of the population being exposed to the substance.

#### NTP Draft Report

In April, NTP issued its draft report for public comment that concluded it had "some concern" that the neurological system and behavior of fetuses, infants, and children might be affected by exposure to low levels of bisphenol A (36 PSLR 402, 4/21/08 <sup>11</sup>). The draft report also said there was "some concern" about the effects of low-level exposures on young people with regard to mammary and prostate glands and the onset of puberty in girls.

NTP also said in its draft report that it had negligible concern that exposure of pregnant women to bisphenol A will result in fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring. Finally, NTP said there was negligible concern that exposure to bisphenol A caused reproductive effects in non-occupationally exposed adults and minimal concern for workers exposed to higher levels in occupational settings.

The toxicology program uses "statements of concern" about different types of exposures and different groups that may be exposed to a substance. Those categories--from most to least concern--are serious concern, concern, some concern, minimal concern, and negligible concern.

A statement of concern also may not be assigned if it is found there is insufficient hazard or exposure data to make such a decision.

Following its review of the draft report, the scientific panel decided that NTP had overstated bisphenol A's potential effects on mammary glands and the onset of puberty in young females. The panelists generally said that there were insufficient scientific studies and data to support the stronger level of concern.


However, the review panel said there was sufficient evidence in the studies considered by

NTP to support its other statements of concern.

The panel also said additional information was needed to better understand bisphenol A's potential to adversely affect human health. Better exposure information--particularly that for pregnant women, fetuses, and young children, as well as in the occupational setting--is needed, panelists said.

### FDA Reviewing BPA in Food

The Food and Drug Administration is reviewing the use of bisphenol A in food-contact products. Paul Howard, a research scientist at the FDA National Center for Toxicological Research, told meeting participants that it was important to note that the report was not a qualitative risk assessment but rather a "hazard identification based on animal data," so further analysis is needed to make regulatory decisions.

Members of Congress have recently asked four infant-formula manufacturers to voluntarily stop using bisphenol A in infant-formula packaging (36 PSLR 474, 5/12/08 ). Legislation (S. 2928) has been introduced in the Senate to prohibit its use in children's products, and in the House (H.R. 6228) to prohibit the use of bisphenol-A (BPA) in all food and beverage containers.

Canada has banned the use of bisphenol A in polycarbonate baby bottles, and a bill that would ban the use of the chemical in children's products (S.B. 1713) also is pending in California.

In comments on NTP's draft report, the American Chemistry Council said that in reaching its conclusions that there was "some concern for adverse effects," the program relied on numerous studies that were not of sufficient quality. Public interest and environmental groups sought stronger statements of concern.

*Text of NTP's draft report on bisphenol A, public comments on the draft, and other related material are available at <http://ntp.niehs.nih.gov/go/165>. *

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