NIEHS
National Institute of Environmental Health Sciences –

3 SEPTEMBER 2008: NTP FINALIZES REPORT ON BISPHENOL A

Current human exposure to bisphenol A (BPA), a chemical used in many polycarbonate plastics and epoxy resins, is of "some concern" for effects on development of the prostate gland and brain and for behavioral effects in fetuses, infants and children, according to a final report released today by the National Toxicology Program (NTP).

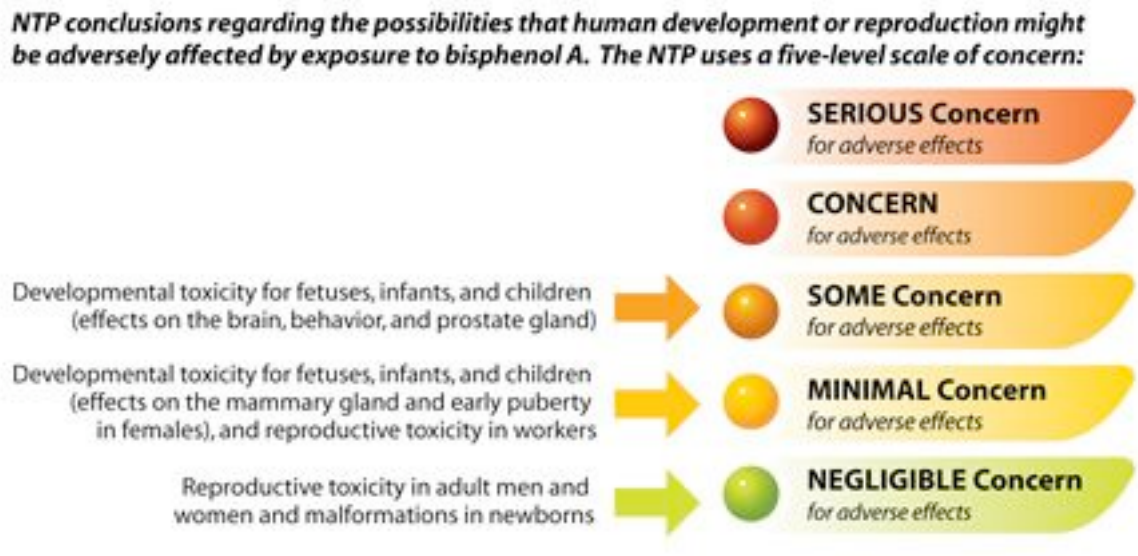
The report provides the NTP's current opinion on BPA's potential to cause harm to human reproduction or development. The conclusions are based primarily on a broad body of research involving numerous laboratory animal studies. The report is part of a lengthy review of the scientific literature on BPA and takes into consideration public and peer review comments received on an earlier draft report. The final report is available at http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf (http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf) Download Adobe Reader (1.0MB).

"There remains considerable uncertainty whether the changes seen in the animal studies are directly applicable to humans, and whether they would result in clear adverse health effects," said NTP Associate Director John Bucher, Ph.D. "But we have concluded that the possibility that BPA may affect human development cannot be dismissed."

About the impact that these findings may have on consumers, CERHR Director Michael Shelby, Ph.D., said, "Unfortunately, it is very difficult to offer advice on how the public should respond to this information. More research is clearly needed to understand exactly how these findings relate to human health and development, but at this point we can't dismiss the possibility that the effects we're seeing in animals may occur in humans. If parents are concerned, they can make the personal choice to reduce exposures of their infants and children to BPA."
NTP conclusions regarding the possibilities that human development or reproduction might be adversely affected by exposure to bisphenol A. The NTP uses a five-level scale of concern. No serious concern for adverse effects. No concern for adverse effects. Some concern for adverse effects: Developmental toxicity for fetuses, infants, and children (effects on the brain, behavior, and prostate gland). Minimal concern for adverse effects: Developmental toxicity for fetuses, infants, and children (effects on the mammary gland and early puberty in females), and Reproductive toxicity in workers. Negligible concern for adverse effects: Reproductive toxicity in adult men and women and malformations in newborns.
Chart showing NTP Conclusions on BPA

The NTP, an interagency federal research program at the National Institute of Environmental Health Sciences (NIEHS), part of the National Institutes of Health, uses a five-level scale ranging from negligible to serious, with “some concern” being the midpoint.

“We are expressing this level of concern because we see developmental changes occurring in some animal studies at BPA exposure levels similar to those experienced by humans,” Bucher said.



The report also expresses “minimal concern” that BPA exposure will affect development of the mammary gland or accelerate puberty in females. The NTP expressed “negligible concern” that exposure of pregnant woman to BPA will result in fetal or neonatal mortality, birth defects or reduced birth weight and growth in their offspring.

The NTP also expressed “negligible concern” that exposure to BPA causes reproductive effects in non-occupationally exposed adults and “minimal concern” for workers exposed to higher levels in occupational settings.

“The literature on experimental animal studies is large and filled with many conflicting findings. There are a number of remaining uncertainties in the scientific information on BPA,” said Bucher. The report discusses many of the uncertainties, including the very limited data from studies in humans and the difficulty in relating the often subtle developmental endpoints in animal studies to human health risks.

The NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) conducted the BPA evaluation. The CERHR follows a formal process for review and evaluation of nominated chemicals that includes convening panels of scientific experts to review the world’s scientific literature on the chemical being studied and a peer review process, as well as numerous opportunities for public input. For a summary of the NTP evaluation of BPA, please see http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm#4.

CERHR publishes monographs that assess the evidence that environmental chemicals, physical substances, or mixtures cause adverse effects on reproduction and development and provide opinion on whether these substances are hazardous for humans. Other agencies, such as the US Food and Drug Administration, apply this science in carrying out their regulatory responsibilities and in accordance with their statutory authority.

Last month, FDA released a “Draft Assessment of Bisphenol A for Use in Food Contact Applications” for peer review and public comment, available at http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-0038b1_01_02_FDA%20BPA%20Draft%20Assessment.pdf.
The FDA will hold a public meeting of its BPA subcommittee of the FDA Science Board on September 16 to discuss this FDA draft assessment.

“We are pleased to see the finalization of the NTP report,” noted Frank Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist at the FDA. “The FDA will consider this final report in our role as a regulatory agency and joins NTP in the call for additional research in this important area.” Reporters interested in speaking to FDA about this issue, may contact the FDA press office at 301-827-6242.
