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Bisphenol A (BPA) in Plastics and Possible Human Health Effects

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Summary

Bisphenol A (BPA) is used to produce certain types of plastic. Containers made of these plastics may expose people to small amounts of BPA in food and water. Some animal experiments have found that fetal and infant development may be harmed by small amounts of BPA, but scientists disagree about the value of the animal studies for predicting harmful effects in people. At least one regulatory decision in the face of the scientific disagreement has led to a congressional inquiry into the extent to which the decision was based on good science. Legislation proposed in April 2008, S. 2928, would prohibit use of BPA in some products intended for use by children. Legislation proposed in June 2008, H.R. 6228, would prohibit the use of BPA in food and beverage containers regulated by the Food and Drug Administration (FDA).

Introduction. Bisphenol A (BPA)[1] is a synthetic chemical compound produced in the United States in large quantities, approximately 2.3 billion pounds annually.[2] The dominant use is in manufacturing certain forms of plastic: relatively hard, clear polycarbonate (PC), and epoxy resins that are used to line food cans. Under certain conditions, BPA may *migrate* (i.e., be released) from PC containers and plastic-lined cans into the food or liquids they contain.

[1] Bisphenol A also is commonly known as carboxylic acid. It is the single molecule that is chained together (polymerized) to form polycarbonate.

[2] U.S. Department of Health and Human Services (HHS), National Toxicology Program, "Draft NTP Brief on Bisphenol A," April 14, 2008, at [http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPADraftBriefVF_04_14_08.pdf].

The widespread use of BPA and the potential for human exposure, together with accumulating scientific evidence about possible BPA toxicity, led the National Toxicology Program (NTP) at the National Institutes of Health (NIH) to select BPA for a comprehensive review. NTP released a draft "brief" on BPA on April 14, 2008.[3] Its conclusions prompted some to call for federal restrictions on certain BPA uses, and sparked congressional and media interest in the past and current positions of the Food and Drug Administration (FDA). FDA regulates BPA and other chemicals used in food containers and maintains that current uses of BPA are safe. A final NTP monograph on BPA was released September 3, 2008.[4]

Health Effects. Exposure to large amounts of BPA is acutely toxic to humans and animals, but levels of BPA exposure from plastics are low. The possibility of human health effects from exposure to low doses of BPA is controversial, although animal evidence of possible harmful effects has been mounting for about 10 years. It is clear that BPA is capable of interfering with the action of estrogen, an important regulator of reproduction and development. (Interference with hormonal action is often referred to as *endocrine disruption*.) Therefore, many recent studies have focused on the potential effects of low levels of BPA exposure on fetal or newborn rats or mice. Some of the developmental effects seen among rodents exposed to low doses of BPA include changes in brains and behaviors; precancerous lesions in the prostate and mammary glands; altered prostate and urinary tract development; and early onset of puberty.[5]

These low-dose experiments are difficult to conduct, in part because BPA is ubiquitous in the environment. Thus, different studies have produced different results. Scientists employed by BPA manufacturers and some independent contractors argue that the hundreds of studies conducted so far have produced inconsistent results and are insufficient justification for more stringent BPA regulation. Other scientists maintain that well-designed and executed studies of sufficient statistical power on sensitive strains of laboratory rodents have clearly demonstrated the toxicity of low doses of BPA in mammals, and justify actions to reduce exposure for potentially vulnerable human populations.

Some researchers have proposed that BPA may interfere with hormones that regulate functions other than reproduction. A recently released study found that low-level exposure to BPA inhibits the release of adiponectin from human adipose (fat) tissue. Adiponectin increases insulin sensitivity and helps regulate glucose metabolism.[6] The researchers hypothesize that environmental BPA exposure may increase susceptibility to

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[3] Ibid.

[4] U.S. Department of Health and Human Services (HHS), National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction, "NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A," NIH Publication No. 08-5994, September 2008, 321pp, at [http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf].

[5] NTP Monograph on Bisphenol A, p. 7-8.

[6] Hugo, Eric R., Brandebourg, Terry D., Woo, Jessica G., et al., "Bisphenol A at Environmentally Relevant Doses Inhibits Adiponectin Release from Human Adipose Tissue Explants and Adipocytes," *Environmental Health Perspectives*, online August 14, 2008, at [http://www.ehponline.org/members/2008/11537/11537.pdf].

obesity and diabetes. The body of research in this area is less extensive than that into BPA's potential effects on reproductive hormones.

Human Exposure. Bisphenol A exposure in the general population comes primarily from consumption of food and beverages.[7] The latest national survey by the Centers for Disease Control and Prevention (CDC) found BPA in the urine of more than 92% of the people studied, which included children six years of age and older and adults.[8] Among these people, the highest average concentrations were found in children.[9] The NTP monograph estimates that the highest daily intakes of BPA occur in infants and children.[10] BPA has been found in human breast milk, but the NTP report estimates that infants who are formula-fed have higher daily BPA intake levels than those who are breast-fed,[11] because there is more BPA in infant formula than in breast milk, and because BPA may increase when PC baby bottles are used for formula feeding, especially if the bottles are heated. These BPA exposure levels in humans "are similar to levels of [BPA] associated with several 'low' dose laboratory animal findings of effects on the brain and behavior, prostate and mammary gland development, and early onset of puberty in females," according to the final NTP monograph.[12]

Current Federal BPA Regulation. Depending on its use, BPA is potentially regulated by various regulatory agencies, including the Consumer Product Safety Commission, the Environmental Protection Agency, and the Occupational Safety and Health Administration. BPA-containing PC polymers and epoxy resins used in food containers — such as baby bottles and infant formula cans, respectively — are regulated by FDA as *food contact substances*.[13] FDA conducts research into the possible endocrine disrupting effects of BPA. Agency regulations and guidance for industry include recommendations and guidelines for studies of potential reproductive, developmental, and neurological toxicity that may result from exposure to food contact substances.[14] These sources do not suggest that there is a systematic review process to study such effects that may result from exposure to previously approved products. Some consumer groups have

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[7] NTP Monograph on Bisphenol A, p. 1.

[8] Calafat, Antonia M., Xiaoyn Ye, Lee-Yang Wong, et al., 2008, "Exposure of the U.S. Population to Bisphenol A and 4-tertiary-Octylphenol: 2003-2004," *Environmental Health Perspectives*, v. 116, n. 1, p. 39-44.

[9] Ibid.

[10] Certain occupational groups are estimated to have the highest human exposure levels. NTP Monograph on Bisphenol A, p. 2.

[11] Ibid., p. 3.

[12] Ibid., p. 7-8.

[13] Applicable FDA regulations are at 21 CFR §§ 177.1580, 175.300(b)(3)(viii), 177.1440, and 177.2280. See also FDA's Food Contact Substance Notification Program, at [http://www.cfsan.fda.gov/~dms/fcnrpt.html], and FDA's Consumer Update, "Safety and Food Packaging" at [http://www.fda.gov/consumer/updates/foodpackaging081908.html].

[14] See, in particular, FDA, "Toxicological Principles for the Safety Assessment of Food Ingredients," (the "Redbook"), updated July 2007, at [http://www.cfsan.fda.gov/~redbook/red-toca.html].

sought for more than 10 years to have FDA declare uses of BPA-containing food contact substances unsafe, especially in packaging for infant formula.

Events Surrounding the Current Controversy. In early 2007, NTP convened an expert panel to conduct a comprehensive review of the scientific literature on BPA. The panel met during 2007 and issued its report on November 26, 2007.[15] It concluded that animal studies were sufficient to elicit "some concern" about possible effects of BPA exposure on the neurological development of human fetuses and newborns, but "minimal concern" about effects on the early onset of puberty or development of mammary or prostate cancer. (The expression of "some concern" is midway in a qualitative scale used by NTP. In order, from greatest to least, the levels of concern are serious concern, concern, some concern, minimal concern, and negligible concern.) Some scientists disagreed with these conclusions.

NTP's own scientists reviewed the panel report, as well as numerous studies that were not considered by the panel, many that were completed or published in late 2007 and early 2008. NTP then issued its draft BPA "brief" on April 14, 2008, which largely agreed with the panel report, but expressed a higher level of concern with respect to early puberty and effects on the mammary and prostate glands. The draft report concluded, "... the possibility that [BPA] may alter human development cannot be dismissed."[16] Specifically, the NTP report concluded that there is "some concern" for neural and behavioral effects in fetuses, infants, and children at current levels of human exposure, and "some concern" in those same groups for effects on the prostate gland, mammary gland, and on earlier age of puberty in females. Public comment on the draft brief was invited through May 23, 2008.[17]

On June 11, 2008, the NTP Board of Scientific Counselors met to review the draft report and public comments. The Board voted to lower the level of concern for BPA's effects on the mammary gland and on the onset of puberty in females.[18] This vote is reflected in the final version of the NTP brief, which was included in the NTP monograph and issued September 3, 2008.[19] Thus, the official NTP view is that current levels of human exposure to BPA warrant "some concern" for possible effects on the brain, behavior, and prostate gland in fetuses, infants, and children; "minimal concern" for effects on the mammary gland and an earlier age for puberty in female fetuses, infants, and children, and for workers exposed occupationally; and "negligible concern" for all other current exposures and reproductive or developmental effects.

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[15] HHS, National Toxicology Program, "Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A," at [http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPAFinalEPVF112607.pdf].

[16] Draft NTP Brief on Bisphenol A, p. 9.

[17] National Institute of Environmental Health Sciences, "Since You Asked - Bisphenol A," at [http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm].

[18] National Institute of Environmental Health Sciences, "Actions on the Draft NTP Brief on Bisphenol A by the NTP Board of Scientific Counselors (BSC), June 11, 2008," at [http://ntp.niehs.nih.gov/files/BSCactionsBPA_508.pdf].

[19] NTP Monograph on Bisphenol A, p. vii.

Canada published its risk assessment of BPA in April 2008, finding that "... the main source of exposure [to BPA] for newborns and infants is through the use of polycarbonate baby bottles when they are exposed to high temperatures and the migration of [BPA] from cans into infant formula. The scientists concluded in this assessment that bisphenol A exposure to newborns and infants is below levels that may pose a risk, however, the gap between exposure and effect is not large enough."[20] The Canadian government has said that although exposure levels are below those that could cause health effects, they are close to those levels, and the government wants to be prudent and reduce exposures further. It announced its intention to reduce BPA exposure in infants and newborns by (1) banning PC baby bottles, (2) developing stringent migration targets for BPA in infant formula cans, and (3) working with industry to develop alternative food packaging and a code of practice.

Also in April 2008, the American Chemistry Council, which represents chemical manufacturing companies, called on FDA to update its review of the safety of BPA in food contact applications, saying, "The extensive body of scientific study regarding [BPA] is well documented and well reviewed. Nevertheless, recent media reports have raised concerns about the safety and use of polycarbonate plastic and epoxy resins, unnecessarily confusing and frightening the public."[21]

Shortly thereafter, FDA formed an agency-wide task force to review current information regarding BPA in all FDA-regulated products. In June 2008, FDA asked its Science Board, the advisory board to the FDA Commissioner, to establish a subcommittee to review research on BPA and exposures from food containers, and deliver its findings to the Board's annual meeting in the fall.[22] Subsequently, Rosa DeLauro, Chairwoman of the House Appropriations Subcommittee on Agriculture (which funds FDA), wrote to FDA urging that the Science Board review BPA exposures from medical devices as well.[23] In August 2008, FDA published a draft risk assessment of BPA in food contact applications, saying, "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."[24] The BPA Subcommittee of the FDA Science Board is

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[20] Health Canada, "Government of Canada Takes Action on Another Chemical of Concern: Bisphenol A," press release, April 18, 2008, at [http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2008/2008_59_e.html].

[21] American Chemistry Council, "ACC Calls on FDA to Update Review of Bisphenol A," press release, April 17, 2008, at [http://www.americanchemistry.com/s_acc/index.asp].

[22] FDA, "FDA's Chief Scientist Asks Science Board Subcommittee to Review Research on Bisphenol-A," press release, June 6, 2008, at [http://www.fda.gov/opacom/hpnews.html].

[23] Congresswoman Rosa L. DeLauro, "DeLauro Presses for Expanded FDA Inquiry of BPA Health Risks," press release, June 16, 2008, at [http://www.house.gov/delauro/news.html].

[24] FDA, "Draft Assessment of Bisphenol A for Use in Food Contact Applications," August 14, 2008, p. 2, at [http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-0038b1_01_00_index.htm]. FDA's definition of safety in this context is that "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 CFR § 170.3(i).

due to meet on September 16, 2008, to review the draft risk assessment, the NTP Brief, and other information regarding the safety of current food-contact uses of BPA.

Various states have enacted, or are considering, legislation to restrict use of BPA in products intended for use by infants and children. Also, concerns about the effects of BPA are affecting decisions in the marketplace, such as those by Wal-Mart, Playtex Infant Care, and Nalgene to stop allowing BPA in the bottles they produce or sell.[25]

Congressional Activity. On January 17, 2008, John D. Dingell, chairman of the House Committee on Energy and Commerce, and Bart Stupak, chairman of the Subcommittee on Oversight and Investigations, announced an investigation into the use of BPA in products intended for use by infants and children, and FDA's determination of the safety of current uses of BPA in FDA-regulated products.[26]

On April 29, 2008, legislation (S. 2928) was introduced that would prohibit the use of BPA in some products intended for use by a child seven years old or younger. On June 10, 2008, legislation (H.R. 6228) was introduced that would amend FDA's authority such that food or beverage containers composed of BPA, or that could leach BPA into food or beverages, would be considered adulterated and could not be marketed. The latter bill was introduced during a hearing of the House Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection on the safety of BPA and phthalates.[27]

Conclusion. There is scientific consensus that exposure to high levels of BPA can cause adverse reproductive effects in mammals. It is less clear that low-dose exposures are harmful. There is, however, growing concern about low-dose exposures among the public, and among many scientists, sharpened by the fact that BPA exposures within the general population are, without question, highest in infants. The scientific debate about the safety of BPA is likely to continue, and further reaction in the policy, regulatory, and commercial arenas is expected.

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[25] See, for example, Connecticut legislation at [http://www.cga.ct.gov/2008/FC/2008HB-05601-R000670-FC.htm], and "Companies Move to Curb Risk From Chemical BPA," *Associated Press*, April 21, 2008.

[26] Correspondence related to the investigation is at U.S. Congress, House of Representatives, Committee on Energy and Commerce website, at [http://energycommerce.house.gov/Investigations/Bisphenol.shtml].

[27] House Energy and Commerce Committee, Subcommittee on Commerce, Trade, and Consumer Protection, hearing on "Safety of Phthalates and Bisphenol-A in Everyday Consumer Products," June 10, 2008, 110th Cong., 2nd Sess., Washington, D.C. Phthalates are a class of chemicals that are used to soften plastics, and that are found in a variety of consumer products. For more information, see CRS Report RL34572, *Phthalates in Plastics and Possible Human Health Effects*, by Linda-Jo Schierow and Margaret Mikyung Lee.