Order Code RS22869
May 5, 2008

CRS Report for Congress

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

Linda-Jo Schierow
Specialist in Environmental Policy
Resources, Science, and Industry Division

Sarah A. Lister
Specialist in Public Health and Epidemiology
Domestic Social Policy Division

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, amounts to which many people may be exposed, 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.

Introduction. Bisphenol A (BPA)[1] is a synthetic chemical compound produced in the United States in very 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 the 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.

The widespread use of BPA and the potential for human exposure, together with accumulating scientific evidence about possible BPA toxicity, led the National

[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], visited April 29, 2008.

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 have led some to call for federal restrictions on certain BPA uses, and have 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 reportedly maintains that current uses of BPA are safe.[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 more controversial, although animal evidence of possible harmful effects has been mounting for about 10 years.

It is clear that BPA is capable of mimicking and otherwise interfering with the action of estrogen, an important regulator of reproduction and development. (This effect on reproductive hormones 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 neural and behavioral alterations in rats and mice; precancerous lesions in the prostate and mammary glands in rats; altered prostate and urinary tract development in mice; and early onset of puberty in female mice.[5] Many of these experiments were conducted using levels of BPA exposure that may be typical for humans living in developed countries.

These low-dose experiments are notoriously difficult to conduct, in part because they are easily confounded by environmental contamination. Thus, different studies have produced different results. These difficulties have led to scientific discussions about such topics as the amount of soy (which contains natural plant estrogens) in rat feed, the relative sensitivity of different strains of rats and mice, and the comparability of effects in rats or mice given BPA by mouth or by injection. Scientists employed by BPA manufacturers and some independent contractors, therefore, 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 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 in potentially vulnerable human populations.

Human Exposure. Bisphenol A exposure in the general population comes primarily from consumption of food and beverages.[6] The latest national survey by the

---

[3] 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], visited April 29, 2008.

[4] "Studies on Chemical in Plastics Questioned," *The Washington Post*, April 27, 2008, p. A-1, A-10.

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

[6] 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/ (continued...)

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.[7] Among these people, who are representative of the U.S. population as a whole, women had higher BPA levels than men, concentrations were higher among people with lower incomes, and the highest average concentrations were found in children.[8] The draft NTP brief estimates that within the general population, the highest daily intakes of BPA occur in infants and children.[9] BPA has been found in human breast milk, but the NTP report estimates that young infants who are formula-fed have higher daily BPA intake levels than those who are breast-fed. This is due to higher levels of BPA in infant formula compared with breast milk, and the use of PC baby bottles for formula feeding, especially if the bottles are heated before feeding.

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 NTP draft brief.[10]

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*.[11] 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.[12] 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 sought for more than 10 years to have FDA declare uses of BPA-containing food contact substances unsafe, especially in packaging for infant formula.

---

[6] (...continued)
BPADraftBriefVF_04_14_08.pdf], visited April 29, 2008.

[7] 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.

[8] Ibid.

[9] Certain occupational groups are estimated to have the highest human exposure levels.

[10] Draft NTP Brief on Bisphenol A, p. 32.

[11] For background, see CRS Report RL34247, *Federal Regulation of Substances Generally Recognized As Safe (GRAS) and the Use of Carbon Monoxide in Packaging for Meat and Fish*, by Vanessa K. Burrows and Cynthia Brougher. Regulations for PC polymers are at 21 CFR § 177.1580, and those for epoxy-based products are at 21 CFR §§ 175.300(b)(3)(viii), 177.1440, and 177.2280. Information about FDA's Food Contact Substance Notification Program is at [http://www.cfsan.fda.gov/~dms/fcnrpt.html].

[12] 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].

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.[13] It stated 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. 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 because they were completed or published in late 2007 and early 2008. NTP then issued its draft "brief" on BPA 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."[14] 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.[15] Public comment on the draft brief was invited through May 23, 2008.[16]

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 that they were beginning an investigation into the use of BPA in products intended for use by infants and children.[17] In particular, they asked the FDA commissioner to comment on the agency's determination, in November 2007, that currently approved uses of BPA-containing food contact substances were safe.[18] Subsequently, the chairmen questioned the FDA commissioner regarding the agency's use of two industry-funded studies to support its conclusion of safety.[19]

---

[13] 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], visited April 29, 2008.

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

[15] 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.

[16] National Institute of Environmental Health Sciences, "Since You Asked - Bisphenol A," at [http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm], visited April 29, 2008.

[17] 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], visited April 29, 2008.

[18] 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).

[19] February 25, 2008, letter of FDA Commissioner Andrew C. von Eschenbach in response to the committee's request for information regarding the use of BPA in products intended for use by infants and children. In the letter, FDA said that the two studies were performed under applicable

(continued...)

Canada completed its own risk assessment of BPA and released it the same week that the draft NTP brief was issued. The Canadian assessment found 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 bisphenol A 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]

Therefore, the government of Canada 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.[21]

Also in the same week that the NTP brief was released, 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."[22]

Shortly thereafter, FDA announced that it had formed an agency-wide BPA task force to review current research and new information, including the NTP draft brief and the Canadian risk assessment, with regard to BPA in all FDA-regulated products.[23] The agency commented that BPA risk assessments conducted by the European Food Safety Authority and the Japanese National Institute of Advanced Industrial Science and Technology had concluded that current low BPA exposure levels do not constitute a health risk. FDA did not recommend that consumers discontinue using products that contain BPA, but noted that several alternatives to PC baby bottles exist, including glass baby bottles.

---

[19] (...continued)
regulatory guidelines and were submitted to a food master file. This suggests that the studies may have been conducted by the industry sponsors for a specific regulatory purpose, but the letter does not address this specifically. According to the letter, the studies looked at reproductive effects in mice across two generations in one study, and three generations in the other. Only one of the studies was published in the peer-reviewed scientific literature. The other is not publicly available.

[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]. 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.

[21] Ibid.

[22] 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].

[23] FDA, "Bisphenol A," at [http://www.fda.gov/oc/opacom/hottopics/bpa.html], visited April 29, 2008.

Various states have enacted, or are considering, legislation to restrict use of BPA in products intended for use by infants and children.[24] Also, concerns about the effects of bisphenol A 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]

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.

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.

---

[24] See, for example, Connecticut legislation at [http://www.cga.ct.gov/2008/FC/2008HB-05601-R000670-FC.htm], visited April 29, 2008.

[25] "Companies Move to Curb Risk From Chemical BPA," *Associated Press*, April 21, 2008.