



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 that are used in thousands of formulations for myriad products. Containers made with these plastics may expose people to small amounts of BPA in food and water. Medical devices and other more ubiquitous products, such as thermal paper coatings, also may contribute significantly to human exposure. 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.

In the United States and elsewhere, scientific disagreement about the possibility of human health effects that may result from BPA exposure has led to conflicting regulatory decisions regarding the safety of food containers, especially those intended for use by infants and children. In the United States, a conclusion by the Food and Drug Administration (FDA) that BPA use is safe conflicted with earlier findings by one panel of scientific advisors, and was later challenged by a second panel. These events prompted some to question FDA's process for the assessment of health risks such as this, and others to question the agency's fundamental ability to conduct such assessments competently. Recently, FDA expressed concern about possible health effects from BPA exposure and announced that it was conducting new studies on the matter, pending possible changes in its regulatory approach.

In March 2010, the U.S. Environmental Protection Agency (EPA) released a "chemical action plan" for BPA that proposes to list BPA as a chemical of concern that may present an unreasonable risk to certain aquatic species at concentrations similar to those found in the environment, to consider rulemaking to gather additional data relevant to environmental effects, and to initiate collaborative alternatives assessment activities under its Design for the Environment (DfE) program to encourage reductions in BPA releases and exposures.

Some food companies, bottle manufacturers, and paper receipt producers have voluntarily changed to BPA-free products. It is reported that some companies are exploring alternatives to BPA-containing food cans. However, others have said that for some types of canned foods, alternatives that preserve the safety and quality of the food currently may not be available.

In the 111th Congress, companion bills (S. 593/H.R. 1523) have been introduced that would prohibit the use of BPA in food and beverage containers regulated by the FDA. The Senate bill may be proposed as an amendment to pending food safety legislation (S. 510). A different approach to BPA regulation would be taken by a second pair of bills (S. 753/H.R. 4456) that would require Consumer Product Safety Commission (CPSC) prohibition of BPA use in children's food and beverage containers under the Federal Hazardous Substances Act. The House acted July 30, 2009, on a third approach when it approved H.R. 2749, the Food Safety Enhancement Act of 2009. Section 215 of the bill would require FDA to determine whether there was "a reasonable certainty of no harm for infants, young children, pregnant women, and adults, for approved uses of polycarbonate plastic and epoxy resin made with bisphenol A in food and beverage containers ... under the conditions of use prescribed in current [FDA] regulations." FDA would be required to notify Congress about any uses of BPA for which a determination could not be made and how the agency was planning to regulate to protect the public health. Finally, a fourth bill, H.R. 4341, would require a warning label on any food container containing BPA.

Contents

Introduction	1
Health Effects	1
Human Exposure.....	2
Current Federal BPA Regulation.....	3
Events Surrounding the Current Controversy.....	5
National Toxicology Program.....	5
Food and Drug Administration	5
State Government Actions	7
Selected Foreign Government Actions.....	8
Private Sector Actions	8
Congressional Activity	9
Conclusion.....	10

Contacts

Author Contact Information	10
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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 BPA is not found in nature. The dominant known uses are in manufacturing certain forms of plastic: relatively hard, clear polycarbonate (PC), and epoxy resins that are used to line food cans.³ 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 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, 2008.⁴ A final NTP monograph on BPA was released September 3, 2008.⁵ NTP’s 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 until recently maintained that current uses of BPA are safe. In August 2008, FDA reiterated this finding in a published risk assessment.⁶ The finding prompted criticism from an agency advisory committee and others. FDA is now reviewing its risk assessment for food exposures, and considering exposures from other products it regulates (such as drugs and medical devices), in response to the committee’s critique. In January 2010, FDA announced that it is evaluating recent scientific evidence and conducting additional studies.⁷

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.

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, http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPADraftBriefVF_04_14_08.pdf.

³ According to EPA, “Paper coatings are not a major use of BPA, but thermal paper has been reported to contain free BPA, which would be expected to be more available for exposure than BPA bound into resin or plastic.” (EPA, “Bisphenol A Action Plan,” Mar. 29, 2010, p. 17, http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa_action_plan.pdf.)

⁴ Draft NTP Brief, *ibid*.

⁵ 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, <http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf>.

⁶ FDA, “Draft Assessment of Bisphenol A for Use in Food Contact Applications,” August 14, 2008, http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-0038b1_01_00_index.htm.

⁷ FDA, “Bisphenol A (BPA), Update on Bisphenol A (BPA) for Use in Food: January 2010,” February 19, 2010, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>.

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.⁸

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 functions other than reproduction and development, potentially causing additional types of health effects. The body of research in this area is less extensive than that into BPA's potential effects on reproductive hormones, but this appears to be an area of active investigation. For example, a recently published 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.⁹ The researchers hypothesized that environmental BPA exposure may increase susceptibility to obesity and diabetes. Another study found that urinary BPA levels in humans were associated with increased prevalence of diabetes and cardiovascular disease.¹⁰ Investigators called for long-term studies to determine whether high BPA levels are associated with specific health effects later on, an approach that would provide stronger evidence, one way or the other, regarding a possible causal role of BPA on adverse health effects.

Human Exposure

Bisphenol A exposure in the general population comes primarily from consumption of food and beverages. The latest national survey by the Centers for Disease Control and Prevention (CDC) found BPA in the urine of more than 90% of the people studied, which included children six years of age and older and adults.¹¹ Among these people, the highest average concentrations were found

⁸ NTP Monograph on Bisphenol A, pp. 7-8.

⁹ Eric R. Hugo, Terry D. Brandebourg, and Jessica G. Woo, et al., "Bisphenol A at Environmentally Relevant Doses Inhibits Adiponectin Release from Human Adipose Tissue Explants and Adipocytes," *Environmental Health Perspectives*, vol. 116, no. 12 (December 2008), pp. 1642-1647, <http://www.ehponline.org/members/2008/11537/11537.pdf>.

¹⁰ Iain A. Lang, Tamara S. Galloway, and Alan Scarlett, et al., "Association of Urinary Bisphenol A Concentration With Medical Disorders and Laboratory Abnormalities in Adults," *JAMA*, vol. 300, no. 11 (September 17, 2008), pp. 1303-1310.

¹¹ Centers for Disease Control and Prevention (CDC), National Center for Environmental Health, *Fourth National Report on Human Exposure to Environmental Chemicals*, Executive Summary, Atlanta, GA, 2009, p. 3, <http://www.cdc.gov/exposurereport/>.

in children.¹² The NTP monograph estimates that the highest daily intakes of BPA occur in infants and children.¹³ 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,¹⁴ 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.¹⁵

More recently, some scientists have concluded that sources of exposure other than food may be important.^{16,17} There have been calls for assessments of human exposure from other FDA-regulated products such as drugs and medical devices.¹⁸ Some are especially concerned about implanted medical devices that could leach the chemical into tissues, and, in particular, the possible health effects of such exposure in premature or critically ill infants, in whom such products may be used for long periods of time.¹⁹ Other potential sources of exposure are regulated by EPA. For example, in July 2010, several studies indicated that skin contact with BPA in thermal paper coatings (for example, the paper used for cash register receipts) may contribute significantly to human exposure.²⁰

Current Federal BPA Regulation

Depending on its use, BPA is potentially regulated by various regulatory agencies, including the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and the Food and Drug Administration.

EPA recently announced that BPA would be the focus of a “chemical action plan” to gather information and possibly to regulate the chemical beginning in 2010. The plan was released in March 2010.²¹ It proposes to include BPA on a list of chemicals of concern, a list created under

¹² Ibid.

¹³ Certain occupational groups are estimated to have the highest human exposure levels. NTP Monograph on Bisphenol A, p. 2.

¹⁴ Ibid., p. 3.

¹⁵ Ibid., pp. 7-8.

¹⁶ Kellyn S. Betts, “Body of Proof: Biomonitoring Data Reveal Widespread Bisphenol A Exposures,” *Environmental Health Perspectives*, v. 118, no. 8 (Aug. 2010), pp. a353-a353.

¹⁷ Tanya Tillett, “Bisphenol A, Chapter 2: New Data Shed Light on Exposure, Potential Bioaccumulation,” *Environmental Health Perspectives*, v. 117, no. 5 (May 2009), pp. A210-A210.

¹⁸ See, for example, Congresswoman Rosa L. DeLauro, “DeLauro Presses for Expanded FDA Inquiry of BPA Health Risks,” press release, June 16, 2008, <http://www.house.gov/delauro/news.html>.

¹⁹ For example, one study found urine BPA levels in infants receiving neonatal intensive care that substantially exceeded levels found in young children in the CDC national exposure survey (footnote 11). Antonia M. Calafat, et al., “Exposure to Bisphenol A and Other Phenols in Neonatal Intensive Care Unit Premature Infants,” *Environmental Health Perspectives*, vol. 117, no. 4 (April 2009), pp. 639-644.

²⁰ Janet Raloff, “Cashiers May Face Special Risks from BPA,” *Science News*, Aug. 2, 2010, http://www.sciencenews.org/index/generic/activity/view/id/61740/title/Cashiers_may_face_special_risks_from_BPA.

²¹ U.S. Environmental Protection Agency, “Bisphenol A (BPA) Action Plan Summary,” April 15, 2010, <http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa.html#action>.

the authority of the Toxic Substances Control Act (TSCA),²² section 5(b)(4), “on the basis of its potential for long-term adverse effects on growth, reproduction and development in aquatic species at concentrations similar to those found in the environment.” A chemical of concern is “a substance that may present an unreasonable risk of injury to the environment.” A notice of proposed rulemaking is planned for publication in autumn 2010. In addition, EPA proposes to consider initiating rulemaking in late 2010 under section 4(a) of TSCA to develop data with respect to environmental effects. Finally, EPA plans to initiate “collaborative alternatives assessment activities” under its Design for the Environment (DfE) program. These activities aim to reduce BPA releases and environmental exposures.

The safety of most foods, thought to be the primary source of human exposure to BPA, is the responsibility of FDA. Current 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 additives, based on approvals issued more than 40 years ago. Under this approach, any manufacturer may use BPA-containing packaging without notifying FDA of that use. In its January 2010 announcement, FDA said that it is considering regulating BPA-containing substances under its newer and more rigorous food contact notification program, under which manufacturers advise FDA of specific uses, giving the agency an opportunity to review and consider safety information.²³ FDA also announced that its National Center for Toxicological Research was conducting additional studies on the effects of low-dose BPA exposure, to guide future regulatory efforts. In April 2010, FDA announced the availability of several documents related to its continuing assessment of BPA, and solicited public comments.²⁴

FDA is also responsible for the safety of drugs and medical devices. In October 2008, FDA issued a request for information regarding BPA in all types of products it regulates.²⁵ Subsequently, FDA has asked its Science Board, which advises the Commissioner, to review the agency’s proposals to study the possible effects of exposure to BPA from drugs and medical devices, noting that there is limited information available at this time with which to balance possible BPA exposure risks against the therapeutic benefits provided by the drugs and devices.²⁶

²² CRS Report RL31905, *The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements*, by Linda-Jo Schierow.

²³ FDA, “Bisphenol A (BPA), Update on Bisphenol A (BPA) for Use in Food: January 2010,” Feb. 19, 2010, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>. See also FDA’s Food Contact Substance Notification Program, at <http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/default.htm>.

²⁴ U.S. Department of Health and Human Services, Food and Drug Administration, “Food Additives; Bisphenol A; Availability,” *75 Federal Register* 17145-17147, April 5, 2010.

²⁵ See FDA’s request for information regarding other routes of exposure at FDA, “FDA–Regulated Products that Contain Bisphenol-A: Request for Information,” *73 Federal Register* 61135-61136, October 15, 2008. In response, an organization representing companies that manufacture medical devices provided information from a membership survey, listing adult and pediatric medical devices that contain BPA. Comment and accompanying attachment, “Medical Devices and Articles Used in Product Manufacturing Containing Bisphenol-A Related Materials,” from Advanced Medical Technology Association (AdvaMed) to FDA, docket number FDA-2008-N-0523, December 22, 2008, <http://www.regulations.gov>.

²⁶ See, for example, FDA, “Safety Assessment of BPA in Medical Products, August 7, 2009,” Briefing Information for the August 17, 2009 Meeting of the Science Board to the FDA, <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/default.htm>.

Events Surrounding the Current Controversy

National Toxicology Program

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, 2007.²⁷ 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.”²⁸ 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, 2008.²⁹

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.³⁰ This vote is reflected in the final version of the NTP brief, which was included in the NTP monograph and issued September 3, 2008.³¹ 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.

Food and Drug Administration

During the week of April 14, 2008, in response to the release of the NTP draft BPA brief, FDA formed an agency-wide task force to review current information regarding BPA in all FDA-

²⁷ 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>.

²⁸ Draft NTP Brief on Bisphenol A, p. 9.

²⁹ National Institute of Environmental Health Sciences, “Since You Asked - Bisphenol A,” <http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm>.

³⁰ 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,” http://ntp.niehs.nih.gov/files/BSCactionsBPA_508.pdf.

³¹ NTP Monograph on Bisphenol A, p. vii.

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.³²

On August 14, 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."³³ Consumer groups and some Members of Congress questioned the finding, which appeared to contradict earlier findings by the NTP. Among other things, concerns were raised about whether FDA relied too heavily on industry-sponsored studies, and whether the agency should have considered more recent evidence of health effects other than the reproductive and developmental effects on which it focused.³⁴ FDA said that it relied heavily on the industry-sponsored studies because they followed the agency's guidance for good laboratory practices (GLPs) and constituted robust evidence for that reason, but that other studies were also considered.

On October 15, 2008, FDA issued a notice in the *Federal Register* requesting information regarding types of FDA-regulated products that contain BPA, and any information relating to the leaching of BPA from packaging into a product, and/or leaching from a product during its use in humans.³⁵ FDA said that its agency-wide task force had completed the assessment of the potential exposure to BPA from food-contact materials (published in August), and was interested in additional information on other types of products, specifically medical devices, biological products (including blood, blood products, vaccines, and cell and gene therapies), and drugs.

On October 31, 2008, the BPA Subcommittee of the FDA Science Board released its review of FDA's draft risk assessment. The subcommittee concurred with FDA's focus on food exposures and exposures in children. It differed with the agency on several other matters, however, urging, among other things, more emphasis on cumulative exposures: non-food exposures (especially in neonates); and evidence from non-GLP studies. Overall, the subcommittee determined that "Coupling together the available qualitative and quantitative information (including application of uncertainty factors) provides a sufficient scientific basis to conclude that the Margins of Safety defined by FDA as 'adequate' are, in fact, inadequate."³⁶

³² FDA, "FDA's Chief Scientist Asks Science Board Subcommittee to Review Research on Bisphenol-A," press release, June 6, 2008, <http://www.fda.gov/opacom/hpnews.html>.

³³ FDA, "Draft Assessment of Bisphenol A for Use in Food Contact Applications," August 14, 2008, p. 2, 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).

³⁴ See, for example, Jennifer C. Smith, "Lawmakers, Consumer Groups Question FDA's BPA Summary," *InsideHealthPolicy.com*, September 23, 2008.

³⁵ FDA, "FDA-Regulated Products that Contain Bisphenol-A: Request for Information," 73 *Federal Register* 61135-61136, October 15, 2008.

³⁶ FDA Science Board Subcommittee on Bisphenol A, *Scientific Peer Review of the Draft Assessment of Bisphenol A for Use in Food Contact Applications (Draft)*, October 31, 2008, <http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4386b1-05.pdf>. The subcommittee considered scientific evidence that included presentations made at a public meeting on September 16, 2008.

On December 3, 2008, FDA provided an initial response to the subcommittee in a letter, saying that it generally agreed with the subcommittee's concerns and planned further assessments, including expanding its work to consider sources of exposure other than food.³⁷

One year later, in January 2010, FDA announced,

on the basis of results from recent studies using novel approaches to test for subtle effects, both the National Toxicology Program at the National Institutes of Health and FDA have some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children. In cooperation with the National Toxicology Program, FDA's National Center for Toxicological Research is carrying out in-depth studies to answer key questions and clarify uncertainties about the risks of BPA.

While waiting for research results, FDA is "taking reasonable steps to reduce human exposure to BPA in the food supply," and adopting "a more robust regulatory framework for oversight of BPA."³⁸

FDA's struggles with BPA regulation would seem to illustrate a number of charges of systemic problems within the agency made by the FDA Science Board. In November 2007, the board issued a highly critical report finding that FDA's regulatory mission was severely compromised by inadequate and eroding scientific and technical resources, including the size and capability of its workforce, and its processes for risk assessment and related activities.³⁹ The board said that the agency's food safety program, in particular, was "in a state of crisis" as a result of a constellation of problems that flowed from increasing scientific, technical, and regulatory demands, coupled with inadequate resources.⁴⁰

State Government Actions

Many states have considered or are considering legislation to restrict use of BPA in products intended for use by infants and children. Connecticut and Minnesota have enacted such legislation. North Carolina and New Mexico acted to authorize studies, while Pennsylvania passed legislation that "[u]rges the Congress of the United States and the Food and Drug Administration to encourage the use of reduced bisphenol-A in the manufacture of plastic food containers and bottles."⁴¹

³⁷ Letter from Norris Alderson, FDA Associate Commissioner for Science, to Barbara J. McNeil, Chair, FDA Science Board, December 3, 2008.

³⁸ FDA, "Bisphenol A (BPA): Update on Bisphenol A (BPA) for Use in Food: January 2010," <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>.

³⁹ FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, November 2007, http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf.

⁴⁰ *Ibid.*, pp. 4 and 22.

⁴¹ State legislation is cataloged by the National Conference of State Legislators and may be searched at <http://www.ncsl.org/?tabid=17322>.

Selected Foreign Government Actions

Canada published a BPA risk assessment 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 [BPA] exposure to newborns and infants is below levels that may pose a risk, however, the gap between exposure and effect is not large enough.”⁴² The Canadian government said, in essence, that although exposure levels are below those that could cause health effects, they are close enough to those levels that the government wanted 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. On October 17, 2008, the Canadian government announced it was drafting regulations to prohibit the importation, sale and advertising of polycarbonate baby bottles that contain BPA.⁴³ Canada will be hosting a World Health Organization meeting of scientific experts to discuss BPA in food packaging in October 2010 in Ottawa.⁴⁴

The European Food Safety Authority (EFSA), a component of the European Union, reached a different conclusion from a risk assessment it published in 2006, saying that current levels of exposure in food were safe for all age groups evaluated, including infants.⁴⁵ The EFSA has since announced that it would evaluate new information as it became available—including consideration of regulatory and advisory actions in the United States and Canada—but has concluded recently that changes to its findings were not warranted.⁴⁶

Private Sector Actions

In April 2008, concerns raised by the NTP draft brief about the health effects of BPA prompted Wal-Mart, Playtex Infant Care, and Nalgene, among other companies, to stop allowing BPA in the beverage bottles they produce or sell.⁴⁷ At the same time, the American Chemistry Council (ACC), 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

⁴² Health Canada, “Government of Canada Takes Action on Another Chemical of Concern: Bisphenol A,” press release, April 18, 2008, http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2008/2008_59-eng.php.

⁴³ Health Canada, “Government of Canada Protects Families With Bisphenol A Regulations,” press release, October 17, 2008, http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2008/2008_167-eng.php.

⁴⁴ Health Canada, About Health Canada, “Health Canada to host 2010 World Health Organization scientific experts meeting on Bisphenol A,” Mar. 3, 2010, http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2009/2009_198-eng.php.

⁴⁵ European Food Safety Authority, *Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids, and Materials in Contact with Food (AFC) related to [BPA]*, November 29, 2006, http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620772817.htm.

⁴⁶ See, for example, European Food Safety Authority, *Statement of EFSA on a Study Associating Bisphenol A with Medical Disorders*, October 22, 2008, http://www.efsa.europa.eu/cs/BlobServer/Statement/cef_ej838_statement%20on%20bpa_medical%20disorders_statem_en.pdf?ssbinary=true, in response to a scientific article finding an association between human urinary BPA levels and certain chronic diseases.

⁴⁷ See, for example, “Companies Move to Curb Risk From Chemical BPA,” *Associated Press*, April 21, 2008.

raised concerns about the safety and use of polycarbonate plastic and epoxy resins, unnecessarily confusing and frightening the public.”⁴⁸

In March 2009, the six largest manufacturers of baby bottles announced that they would stop selling BPA-containing bottles in the United States, partly in response to growing numbers of retailers that would no longer carry the products.⁴⁹ Noting the announcement, the ACC reiterated FDA’s assessment, at that time, that currently approved uses of BPA were safe.⁵⁰

Although it is reported that many food companies are considering a switch to BPA-free food packaging, manufacturers of cans represented by the North American Metal Packaging Alliance maintain that suitable alternatives to BPA are not available and in almost all cases are not likely to become available in the immediate future.⁵¹ Until alternatives for all uses are developed, they argue that BPA linings will be necessary to ensure a tight seal on cans and lids, and thus to prevent food spoilage and food poisoning risks to consumers. Manufacturers are actively searching for alternatives to meet consumer demand, trade representatives report, but development will take time as new containers are produced and tested for diverse foods with different properties.⁵² Thus, the good intentions of food companies may not suffice.

Also, in 2009, Consumers Union found measurable amounts of BPA in two food brands labeled “BPA-free.” This prompted one of the manufacturers to suggest that the chemical may be ubiquitous, and could not be completely eliminated from the food supply.⁵³

Congressional Activity

On January 17, 2008, John D. Dingell, then 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.⁵⁴

The 111th Congress is considering six bills that address BPA. Companion bills (S. 593/H.R. 1523) have been introduced that would prohibit the use of BPA in food and beverage containers regulated by the FDA. A different approach to BPA regulation would be taken by a second pair of bills (S. 753/H.R. 4456) that would require Consumer Product Safety Commission prohibition of BPA use in children’s food and beverage containers under the Federal Hazardous Substances Act.

⁴⁸ American Chemistry Council, “ACC Calls on FDA to Update Review of Bisphenol A,” press release, April 17, 2008, http://www.americanchemistry.com/s_acc/index.asp.

⁴⁹ Lyndsey Layton, “No BPA For Baby Bottles In U.S.,” *The Washington Post*, March 6, 2009.

⁵⁰ American Chemistry Council, “ACC Statement on Manufacturers Decision not to Use Bisphenol A in Baby Bottles,” press release, March 6, 2009, http://www.americanchemistry.com/s_acc/index.asp.

⁵¹ John Rost and Kathleen Roberts, personal communication, April 15, 2010. See also Lyndsey Layton, “Replacing BPA in Cans Gives Foodmakers Fits; FDA Safety Concerns Prompt Scramble to Remove the Chemical,” *The Washington Post*, February 23, 2010.

⁵² *Ibid.*

⁵³ Alan K. Ota, “Food Safety Bill Held Up By Split Over Fine Lining,” *CQ Today Online News*, July 21, 2010.

⁵⁴ Correspondence related to the investigation is at U.S. Congress, House of Representatives, Committee on Energy and Commerce website, http://energycommerce.house.gov/index.php?option=com_content&view=article&id=392&catid=17:benefits&Itemid=58.

The House acted July 30, 2009, on a third approach when it amended and approved H.R. 2749, the Food Safety Enhancement Act of 2009. Section 215 of the bill would require FDA to determine whether there was “a reasonable certainty of no harm for infants, young children, pregnant women, and adults, for approved uses of polycarbonate plastic and epoxy resin made with bisphenol A in food and beverage containers ... under the conditions of use prescribed in current [FDA] regulations.” FDA would be required to notify Congress about any uses of BPA for which a determination of safety could not be made and how the agency would regulate such use to protect the public health. Finally, H.R. 4341 would require a warning label on any food container containing BPA.

It is reported that Senator Dianne Feinstein may seek to amend comprehensive food safety legislation (S. 510) with S. 593, the bill that would ban BPA in FDA-regulated food containers.⁵⁵ The food safety legislation is expected to be considered by the Senate during the fall of 2010. For more information related to the food safety legislation, see CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111th Congress*, by Renée Johnson.

Conclusion

There is scientific consensus that exposure to high levels of BPA can cause adverse reproductive effects in mammals. It is less clear whether low-dose exposures are harmful. There is, however, growing concern among the public, and among many scientists, about low-dose BPA exposures, sharpened by the fact that such 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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⁵⁵ Jerry Hagstrom, “Senate Expected To Take Up Food Safety Bill Next Week,” *CongressDaily/A.M.*, April 15, 2010.