

Bottles, Cans, and Bans

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**A** look at how governments have reacted to existing BPA science and the political pressures arising from ever increasing publicity.

# The Latest Dispatch from the BPA Battlefield

Bisphenol A (BPA) is the subject of ever-increasing scrutiny by both consumer groups and governmental bodies in the United States and abroad. Some countries have passed legislation banning BPA in products targeted for use by

infants and children. A number of U.S. states have proposed or passed similar legislation, and the list of states considering BPA legislation is continually expanding. This legislation raises concerns in fields such as product liability, consumer protection law, and governmental regulation.

Consumers, through various outlets, are becoming more aware of allegations that products containing BPA might have toxic effects, particularly products produced for infants and children. As the wave of concern about alleged product safety swells, manufacturers and distributors of these products and their components could become targets for litigation or banning legislation.

### So What Is BPA Anyway?

BPA is a hardening additive that is used primarily to make polycarbonate plastic and epoxy resins. Polycarbonate plastics are used in numerous applications, including medical equipment, bicycle hel-

metts, safety glasses, automobile bumpers, compact discs, and DVDs, and most notably, baby bottles and sippy cups. Epoxy resins are used in many coatings and other applications, including protective liners in metal cans for canned foods and beverages. Given the variety of products that may contain BPA, it is important for manufacturers to determine whether their products contain BPA and be aware of the studies that are driving the current attention to its use and legislative reaction.

### What Is Driving the Growing Concern?

BPA's molecular shape may mimic estrogen, the female hormone. Some studies reportedly show that BPA, at a sufficiently high dose, may act as an endocrine disruptor in animals, including early onset of sexual maturity, altered development and tissue organization of the mammary gland, and decreased sperm production in offspring. Other studies reportedly sug-



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gest that BPA may harm humans most in the stages of early development. Previous U.S. reports estimate that more than 90 percent of Americans have BPA trace residues in their bodies, and trace amounts of the chemical are transferred from food and beverage containers, especially when the plastic is heated, exposed to strong dish-washing chemicals, or comes into contact with acidic substances. A recent Harvard study also reports that BPA leaches into cold beverages during normal consumption, and BPA levels in the urine of test subjects were significantly raised during regular consumption from BPA-containing products. J.L. Carwile *et al.*, *Polycarbonate Bottle Use and Urinary Bisphenol A Concentrations*, 117 *Environmental Health Perspectives* 1368–72 (2009), doi: 10.1289/ehp.0900604. Yet studies have consistently shown that BPA is not carcinogenic at current consumer exposure levels.

Concern regarding BPA surged, however, in September 2008. The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction issued a monograph on BPA stating that studies of low-dose BPA “provide limited evidence of adverse effects on development in laboratory animals.” The monograph went on to state that there is “some concern” about the effects of BPA on the brain, behavior, and prostate gland of fetuses, infants, and children at current human exposure levels. It is this statement that has led to an increase in both legislation and litigation in the United States.

### **The Science of BPA Does Not Support the Frenzy**

Under normal circumstances humans are exposed to very low doses of BPA. Most human exposure occurs from residues contained in food or beverages that have been in contact with the two main products manufactured with BPA, polycarbonate plastic, which is used in water bottles, baby bottles, tableware, and food storage containers, and epoxy resins, which provide protective linings in food and beverage cans to prevent contamination.

Despite contact with packaging and containers, the concentration of BPA in food and beverages is very low. This fact, in addition to the low toxicity of BPA, means that the risk to humans from BPA exposure

in food and beverages is low. J.E. Goodman and L.R. Rhomberg, *Bisphenol A, in Endocrine-Disrupting Chemicals in Food* 406–436 (I. Shaw ed., Univ. Canterbury 2009); A. Goodson *et al.*, *Survey of Bisphenol A and Bisphenol F in Canned Foods*, 19 *Food Additives & Contaminants* 796–802 (2002).

Since humans efficiently convert BPA into rapidly excreted, toxicologically inactive forms, BPA does not accumulate after ingestion. Human exposure to BPA can be estimated based on measurements of BPA in serum, plasma, and urine. BPA levels in urine are a more reliable biomarker of human exposure than serum or plasma. Goodman, *supra*; J.J. Pritchett *et al.*, *Metabolism of Bisphenol A in Primary Cultured Hepatocytes from Mice, Rats, and Humans*, 30 *Drug Metabolism and Disposition*, 1180–85 (2002).

### **Animal Studies to Date**

In 1997, scientists from Fredrick vom Saal’s laboratory reported that young mice that had been exposed to low levels of BPA in utero through oral dosing of pregnant mice had increased prostate weights. S.C. Nagel *et al.*, *Relative Binding Affinity-Serum Modified Access (RBA-SMA) Assay Predicts the Relative In Vivo Bioactivity of the Xenoestrogens Bisphenol A and Octyphenol*, 105 *Environmental Health Perspectives* 70–76 (1997). This led to the “low-dose hypothesis” that exceedingly low doses of BPA could lead to developmental and reproductive health effects that might not be observed at higher doses. With the exception of a minority view, there is an international consensus about safe dose levels and the enormous gap between demonstrably toxic levels for any endpoint and human exposure levels. Goodman, *supra*; *but see* F.S. vom Saal & C. Hughes, *An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment*, 113 *Environmental Health Perspectives* 929–33 (2005), doi:10.1289/ehp.7713; F.S. vom Saal *et al.*, *Chapel Hill Bisphenol A Expert Panel Consensus Statement*, 24 *Reproductive Toxicology* 131–38 (2007).

### **Reproduction and Development**

As mentioned, BPA may mimic estrogen at very high doses. J.E. Goodman *et al.*,

*Updated Weight of the Evidence Evaluation of Reproductive and Developmental Effects of Low Doses of Bisphenol A*, 36 *Critical Reviews in Toxicology* 387–457 (2006). Because humans are exposed to quite low doses of BPA, animal studies of low doses are more relevant for determining risks to human health than studies with of animal receiving high doses.

It is important for manufacturers to determine whether their products contain BPA and be aware of the studies that are driving the current attention to its use and legislative reaction.

Based on over 130 reproductive and developmental studies and several dozen supporting studies conducted in animals with dose < 5mg/kg/day, and an examination of the whole body of evidence, the studies finding that BPA exposure did not have developmental and reproductive effects overwhelmingly preponderated the findings that it did have effect. Goodman *et al.*, 2006, *supra*; J.E. Gray *et al.*, *Weight of the Evidence Evaluation of Low-Dose Reproductive and Developmental Effects of Bisphenol A*, 10 *Human and Ecological Risk Assessment* 875–921 (2004).

### **Neurology**

There is no consistent evidence that low doses of BPA cause adverse effects on behavioral endpoints, including: (1) sensory/motor behaviors and reflexes, *see, e.g.*, M. Ema *et al.*, *A Two-Generation Reproductive Toxicity Study of Bisphenol A*, 15 *Reproductive Toxicology* 505–523 (2001); P.L. Palanza *et al.*, *Exposure to a Low Dose of Bisphenol A During Fetal Life or in Adulthood Alters Maternal Behavior in Mice*, 110 *Environmental Health Perspectives* 415–



422 (2002); (2) frequently measured gross behaviors of ambulation, rearing, grooming, and defecation, *see, e.g.*, F. Farabollini *et al.*, *Perinatal Exposure to the Estrogenic Pollutant Bisphenol A Affects Behavior in Male and Female Rats*, 64 *Pharmacology Biochemistry and Behavior* 687–694 (1999); Ema *et al.*, *supra*; (3) complex cognitive behaviors, *see, e.g.*, Ema *et al.*, *supra*; K.

Based on the available data, none of the prominent government and international organizations classify BPA as a carcinogen.

Kubo *et al.*, *Exposure to Bisphenol A During the Fetal and Sucking Periods Disrupts Sexual Differentiation of the Locus Coeruleus and of Behavior in the Rat*, 304 *Neuroscience Letters* 73–76 (2001); R. Carr *et al.*, *Effects of Neonatal Rat Bisphenol A Exposure on Performance in the Morris Water Maze*, 66 *Journal of Toxicology and Environmental Health Part A* 2077–88 (2003); T. Negishi *et al.*, *Effects of Perinatal Exposure to Bisphenol A on the Behavior of Offspring in F344 Rats*, 14 *Environmental Toxicology and Pharmacology* 99–108 (2003); (4) complex emotional behaviors such as impulsivity, anxiety and pain perception, *see, e.g.*, Farabollini *et al.*, *supra*; K. Sashihara *et al.*, *Effects of Central Administration of Bisphenol A on Behaviors and Growth in Chicks*, 38 *Journal of Poultry Science* 275–281 (2001); A.M. Aloisi *et al.*, *Exposure to the Estrogenic Pollutant Bisphenol A Affects Pain Behavior Induced by Subcutaneous Formalin Injection in Male and Female Rats*, 937 *Brain Research* 1–7 (2002); W. Adriani *et al.*, *Altered Profiles of Spontaneous Novelty Seeking, Impulsive Behavior, and Response to D-amphetamine in Rats Perinatally Exposed to Bisphenol A*, 111 *Environmental Health Perspectives* 395–401 (2003); and (5) social behaviors such as play, aggression, maternal behavior, and

sexual behavior, *see, e.g.*, Farabollini *et al.*, *supra*; F. Dessi-Fulgheri *et al.*, *Effects of Perinatal Exposure to Bisphenol A on Play Behaviour of Female and Male Juvenile Rats*, 110 *Environmental Health Perspectives* 403–407 (2002); Palanza *et al.*, *supra*; Kubo *et al.*, *supra*.

Some animal studies suggest that low BPA doses cause female behavior to become more masculine or male behavior to become more feminine on individual measures, but the patterns have not been consistent nor convincingly supported the conclusion that BPA has those effects. *E.g.*, Farabollini *et al.*, *supra*; Kubo *et al.*, *supra*; Dessi-Fulgheri *et al.*, *supra*; Adriani *et al.*, *supra*.

#### **Immune Systems**

Because the immune system and estrogen naturally interact, several investigators have studied whether BPA can alter immune function. Current data are insufficient to draw firm conclusions about possible immunological effects at relatively low doses such as those experienced by humans.

Several multigenerational animal studies have not reported pathology indicative of immune system dysfunction at low BPA doses, so it is unlikely that humans exposed to low levels of BPA would face risk of immune system dysfunction. *See* Ema *et al.*, *supra*; R.W. Tyl *et al.*, *Three-Generation Reproductive Toxicity Study of Dietary Bisphenol A in CD Sprague-Dawley Rats*, 68 *Toxicology and Science* 121–46 (2002); R.W. Tyl *et al.*, *Two-Generation Reproductive Study of Dietary Bisphenol A in CD-1® (Swiss) Mice*, 104 *Toxicology and Science* 362–84 (2008).

#### **Carcinogenic Effects**

Because BPA may mimic estrogen, several researchers have examined whether it could also be carcinogenic. BPA was first tested for carcinogenicity by the National Toxicology Program in a lifetime feeding bioassay using rats and mice. The test report concluded that “[u]nder the conditions of this bioassay, there was no convincing evidence that BPA was carcinogenic for F344 rats or B6C3F1 mice of either sex.” National Toxicology Program, *Carcinogenesis of Bisphenol A (CASRN 80-05-7) in F33 Rats and B6C3F Mice*, NIH Publication No. 821771, 1982.

Based on the available data, none of the prominent government and international organizations classify BPA as a carcinogen. In the latest edition of the Report on Carcinogens in 2005, the National Toxicology Program did not list BPA as a carcinogen. National Toxicology Program, Report on Carcinogens (11 ed. 2005), <http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540>. The International Agency for Research on Cancer (IARC), a division of the World Health Organization, also does not list BPA as a carcinogen, nor does the U.S. EPA in the EPA Integrated Risk Information System (IRIS). The European Union also concludes that BPA does not have carcinogenic potential, based on the results of the National Toxicology Program study.

#### **Human Studies to Date**

Very few completed studies have focused on the possible health effects of BPA in humans. All the studies have major methodological shortcomings, which makes their results difficult to interpret. All studies were based on one BPA measurement per person. Because of the short half-life of BPA, the degree of exposure over the period of causation of the observed effects is unknown. It is also doubtful that BPA measurements in all of these studies were accurate. Goodman *et al.*, 2009, *supra*. The outcomes of different studies show inconsistencies. Miscarriages in study cases and controls and median BPA levels in cases and controls were equal. M. Sugiura-Ogasawara *et al.*, *Exposure to Bisphenol A is Associated with Recurrent Miscarriage*, 20 *Human Reproduction* 2325–29 (2005). In a study involving women with polycystic ovarian syndrome (PCOS), the researchers reported that BPA levels were correlated with women who were obese, with PCOS, and with several hormone levels, but it is unclear whether BPA levels were caused by or a result of these conditions or hormones. T. Takeuchi *et al.*, *Positive Relationship Between Androgen and the Endocrine Disruptor, Bisphenol A in Normal Women and Women with Ovarian Dysfunction*, 51 *Endocrine Journal* 165–69 (2004). In a report showing lower BPA concentrations in the serum of women carrying normal fetuses than of those carrying fetuses with abnormalities, levels in the amniotic fluid from karyotypically normal and ab-

normal fetuses were not statistically different. H. Yamadam *et al.*, *Maternal Serum and Amniotic Fluid Bisphenol A Concentrations in the Early Second Trimester*, 16 *Reproductive Toxicology* 735–39 (2002). With more study subjects than other studies and with more reliable methods of measuring BPA levels, one study showed no association between BPA exposure and endocrine-related symptoms, chromosomal abnormalities, or reproductive parameters. M. Yang *et al.*, *Urinary Concentrations of Bisphenol A in Relation to Biomarkers of Sensitivity and Effect of Endocrine-Related Health Effects*, 47 *Environmental and Molecular Mutagenesis* 571–578 (2006).

Taken together, the human studies conducted to date fail to solidly support the position that BPA exposure causes reproductive or developmental health effects in humans. Goodman *et al.*, 2009, *supra*.

In one occupational cohort study by Kaiser Permanente Northern California, Chinese workers from BPA-exposed and control factories were recruited. The workers had been exposed to very high BPA levels in their workplace. It was reported that exposed workers had consistently higher risk of male sexual dysfunction across all domains of male sexual function than the unexposed workers. The findings, while all self-reported, provide the first evidence that exposure to BPA in the workplace could have an adverse effect on male sexual dysfunction. In connection with the study, further research of the men with and without occupational exposure to BPA showed a statistically significant relationship between increased BPA in urine and decreased sperm concentration and vitality. D. Li *et al.*, *Occupational Exposure to Bisphenol-A (BPA) and the Risk of Self-Reported Male Sexual Dysfunction*, 25 *Human Reproduction* 519–27 (2010).

### **Government Regulation and Positions in Reaction**

Several government bodies have undertaken reviews in response to claims of low-dose BPA toxicity (*e.g.*, mg/kg/day). Based on urine bio-monitoring, scientists conclude that human adults generally are exposed to much lower levels of BPA in everyday life, around 0.04–0.08 µg/kg/day. So far, no review has concluded that reported adverse effects associated with

exposure to BPA levels below the traditionally defined no-effect level constitute a health threat.

Regulatory studies using standard toxicity measures for global regulation support the safety of currently established BPA exposure level for humans. The following government agencies have conducted regulatory reviews: European Commission Joint Research Centre (ECJRC), the European Scientific Committee on Food (SCF), the European Food Safety Authority (EFSA), the European Union Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), the Japanese Ministry of Economy, Trade, and Industry (METI), the Japanese Ministry of Environment, the U.S. Food and Drug Administration (FDA), Health Canada, the U.S. National Toxicity Program, and National Toxicity Program Center for the Evaluation of Risks to Human Reproduction (CERHR). In addition, the FDA and similar agencies in Australia-New Zealand, Canada, and Europe have all confirmed that manufacturers may safely use BPA to make protective linings for metal-based food and beverage cans. Even though those regulators have concluded using BPA at low levels in manufacturing may be safe, many agencies are continuing to review additional materials and to conduct independent studies of the potential health effects of BPA.

A press release on July 13, 2010, stated that an European Food Safety Authority scientific panel was reviewing more than 800 publications about BPA in an effort to release a “comprehensive opinion” about BPA’s safety. Press Release, European Food Safety Authority, EFSA Considers More Than 800 Studies on BPA, to Finalise [sic] Opinion in September (July 13, 2009), <http://www.efsa.europa.eu/en/press/news/cef20100713.htm>. At that time the authority announced that the panel had decided to maintain the agency’s “tolerable daily intake” (TDI) for BPA of 0.05 mg/kg bw per day. After considering the Stump study, which led Denmark to ban BPA in materials for food for children 0–3 years of age, the panel concluded that the study did not provide enough evidence to change its daily intake recommendation. *Id.* (referencing D.G. Stump *et al.*, *Developmental Neurotoxicity Study of Dietary Bisphenol A in Sprague-Dawley Rats*, *Toxicol. Sci.* (2010), doi: 10.1093/toxsci/kfq025).

On November 9, 2010, in Ottawa, Canada, a World Health Organization international expert panel concluded that acting to restrict exposure to BPA was premature because links between ingestion and serious health issues remained unconfirmed. In a joint statement with the United Nations Food and Agriculture Organization, the World Health Organization said, “until these associations are confirmed, initiation of public health measures would be premature.”

### **The National Toxicology Program’s Classification of Risk**

In April 2008, the National Toxicology Program issued a draft “brief” on BPA, in which it stated: “The NTP concurs with the conclusion of the CERHR [Center for the Evaluation of Risks to Human Reproduction] Expert Panel on Bisphenol A that there is some concern for neural and behavioral effects in fetuses, infants, and children at current human exposures. The NTP also has some concern for Bisphenol A exposure in these populations based on effects in the prostate gland, mammary gland, and an earlier age for puberty in females.” National Toxicology Program, U.S. Department of Health and Human Services, Draft Brief on Bisphenol A 15 (Apr. 28, 2008).

The National Toxicology Program had negligible concern that exposure of pregnant women to BPA would result in fetal and neonatal mortality, birth defects, reduced birth weight or growth of offspring, or that BPA would cause reproductive effects in adults exposed to it through means other than work. The National Toxicology Program also expressed minimal concern for reproductive effects in workers exposed to higher levels in occupational settings. National Toxicology Program, U.S. Department of Health and Human Services, NTP-CERH Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A, NIH Pub. No. 08-5994 (2008).

### **The U.S. EPA’s Position**

Currently, despite all of the science to date, the U.S. Environmental Protection Agency (EPA) is considering initiating rulemaking under the Toxic Substances Control Act (TSCA) to add BPA to its “chemical con-



cern” list and to further study the environmental effects of BPA. The March 2010 EPA Bisphenol A Action Plan includes provisions to: (1) add BPA to the EPA chemical concern list; (2) require information on concentrations in surface water, ground water, and drinking water; (3) require manufacturers to provide test data; (4) research ways to reduce exposures, including identi-

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fication of substitutes; and (5) further evaluate the potential disproportionate impact on children or other sub-populations. U.S. Environmental Protection Agency, Bisphenol A Action Plan (Mar. 29, 2010), [http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa\\_action\\_plan.pdf](http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa_action_plan.pdf).

On November 1, 2010, the EPA began to work on an advance notice of the proposed rulemaking that would seek comment on whether it should require manufacturers of BPA to test for its potential to cause endocrine-related adverse effects. The EPA hopes to publish that notice by the end of March 2011.

#### The U.S. FDA's Position

In January, 2010, the Food and Drug Administration said, “studies have supported the safety of BPA. However recent studies using novel approaches have (raised) some concerns. Therefore, FDA is carrying out studies to clarify uncertainties.” In the Draft Assessment of Bisphenol A for Use in Food Contact Applications, the FDA reported that it believed that the 5 mg/kg/day level exposure was safe. U.S. Food and Drug Administration, Draft Assessment of Bisphenol A for Use in Food Con-

tact Applications (2008). And in updated materials, the FDA vowed to continue evaluating BPA through National Center for Toxicological Research studies that include physiological-based pharmacokinetic modeling with rodents and nonhuman primates; rodent subchronic in-dose-response relationship in the prostate and mammary glands for oral administration of BPA, including potential metabolic changes and cardiovascular endpoints, using an *in utero* phase, mimic bottle feeding, and various dose ranges; and rodent behavioral/neuroanatomical pilot studies for dose levels related to behavioral, neuroanatomical, neurochemical, and hormonal endpoints.

In response to the FDA's position, several interest groups have expressed concern and opposed the FDA's assessment. The American Nurses Association said, “We urge the FDA to ban all BPA in food and beverage containers.” According to the Natural Resources Defense Council, “Current levels of exposure to BPA are not safe and BPA should not be allowed for use in food packaging.” The Environmental Working Group took a stronger stance:

We urge the Agency to stop relying on discredited, industry-funded studies, discard the proposed ‘no effect’ level of 5 mg/kg-day, adopt a protective safe exposure limit that comports with the overwhelming weight of scientific evidence, and take immediate action to remove BPA from canned foods, baby formula and baby food.

Not to be outdone, the Internet commentary also was aggressive. “Throw out your tin cans, takeout coffee cups, heinz products, plastic food wrap, baby bottles, canned foods. ... (or maybe mail them to manufacturers C.O.D.)” was posted on <http://indianinthemachine.wordpress.com/>, and more commentators posted unsupported allegations against industries on <http://www.healthfreedomusa.org/>: “Very much like the tobacco-death industry during recent decades, these people are willing to endanger public health to extend their profits a few more years. They expect that you will do nothing about their disinformation plans to fool you.”

#### Current and Pending Legislation and Bans

The United States, Canada, France, Den-

mark, and the European Union have all joined the BPA research and legislative fray.

#### Legislation in the United States

More than 20 states, the District of Columbia, and the United States Congress have introduced or enacted legislation banning the use of BPA in certain products. The bans and proposed bans target BPA used in baby bottles, sippy cups, and formula containers, as well as in food containers, including beverage containers and water bottles.

In May 2009, Minnesota became the first state to ban BPA in baby bottles and sippy cups. The Minnesota statute, which went into effect on January 1, 2010, prohibits manufacturers and wholesalers from selling any product containing BPA that can be filled with food or liquid and is intended for use by children under three. As of January 1, 2011, the law prohibited retailers from selling those products, without exception. Given the steps being taken by the U.S. Congress and the legislatures of states, including Connecticut, Maine, Massachusetts, Michigan, New York, Vermont, Washington, and Wisconsin on BPA, it is clear that additional BPA bans are on the way. On August 31, 2010, surprisingly, amended California BPA legislation failed by two votes in the Senate, dowsing the BPA legislation wildfire in that state—at least until a new version of the bill is introduced.

Legislation banning the use of BPA has also been introduced in both the U.S. House of Representatives and the U.S. Senate as the Ban Poisonous Additives Act of 2009, which is still under consideration. The act would ban *all* food containers composed, in whole or in part, of BPA or any container that could release BPA into food, although under certain circumstances a waiver could be granted for the container as long as a prominent warning of the potential health effects associated with BPA was displayed on the container's label.

On April 15, 2010, the Safe Chemicals Act of 2010 was introduced in the U.S. Senate, and the Toxic Chemicals Safety Act of 2010 was introduced in the U.S. House of Representatives. Both acts would amend the Toxic Substances Control Act to provide the EPA with additional authority to regulate the use of chemicals, including BPA, and they would require the chemical industry to submit certain safety testing data to the EPA.

In addition, in May 2010, Senator Dianne Feinstein introduced a controversial amendment to ban the use of BPA in food and drink containers, to the FDA Food Safety Modernization Act, Pub. L. No: 111-353. Feinstein's amendment, however, was blocked after the Grocery Manufacturers of America, and the U.S. Chamber of Commerce threatened to oppose the bill if it contained Feinstein's proposed language. The American Chemistry Council and other interest groups also voiced concerns and opposition to the amendment, and the final version of the act passed with strong support in the Senate without the BPA amendment.

The concern about BPA legislation is that currently manufacturers do not have a readily available, safe alternative to BPA epoxy resins to use in metal can linings. Letter from Grocery Manufacturers of America President and CEO Pamela Bailey to U.S. Senate leadership. John M. Rost, chair of the North American Metal Packaging Alliance, representing the canned food and beverage industry, pointed out that manufacturers have used BPA "safely in metal food packaging for decades," and those packages "have been deemed safe by regulatory agencies around the world." Lyndsey Layton, *Alternatives to BPA Containers Not Easy for U.S. Food-makers to Find*, Washington Post, Feb. 23, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/02/22/AR2010022204830.html>. According to the *Washington Post*, "He also said there hasn't been a case of food-borne illness resulting from a failure of metal packaging since the industry began using BPA in its linings more than 30 years ago." *Id.*

### Canada's Approach

Despite its regulatory research finding that low-level exposures are safe, Canada became the first country to ban BPA in baby bottles. "We have immediately taken action on bisphenol A because we believe it is our responsibility to ensure families, Canadians and our environment are not exposed to a *potentially* harmful chemical." Tony Clement, former Canada Minister of Health (Oct. 2008) (emphasis added). Billed as a "precautionary and prudent" move, in June 2010 Canada's government proposed a Consumer Product Safety Act that

would, among other things, add polycarbonate baby bottles that contain BPA to the schedule of prohibited products. "Although our science tells us that exposure levels to newborns and infants are below the level that cause effects, we believe that the current safety margin needs to be higher... We have concluded that it is better to be safe than sorry," Clement said.

On October 13, 2010, Canada Health added BPA to its toxic substance list with proposed additional legislation in April 2012. Following the designation, Environment Canada released a draft pollution prevention planning notice that would require manufacturers and users of BPA to develop plans to reduce discharges of the chemical in industrial effluents.

### France and Denmark's Reactions

In June 2010, the French National Assembly passed a law to ban BPA in baby bottles, but it rejected an amendment that would have prohibited its use in all food-related plastic containers. The law bans the manufacture, importation, exportation, and marketing of baby bottles containing BPA until the French food safety agency issues an opinion approving BPA use.

In March 2010, the Danish government, together with the Danish People's Party, decided to invoke precaution by introducing a temporary national ban on BPA in materials in contact with food for children aged 0-3 years, infant feeding bottles, feeding cups and packaging for baby food. The Danish Minister of Food said,

From DTU Food we have received an assessment based on new comprehensive studies of rats. Danish experts say there is no clear evidence that bisphenol A has harmful effects on the behaviour [sic] observed. However, the experts find that the new studies raise uncertainties about whether even small amounts of bisphenol A have an impact on the learning capacity of new-born rats. In my opinion these uncertainties must benefit the consumers, so we will utilize the precautionary principle to introduce a national ban.

### European Union Follows Suit

After the member states, including Denmark and France, pushed for a BPA ban, the European Union (EU) decided to imple-

ment a ban of BPA in the manufacture of baby bottles, effective March 1, 2011, and a general ban on the sale of such products, effective June 1, 2011. The EU Health Commissioner John Dalli said that the bans were "good news" despite conceding that the bans stem from "areas of uncertainty." The bans also come in the face of the European Food Safety Authority decision not to

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lower the agency-designated tolerable daily intake level "because of insufficient convincing evidence of risk, as noted above.

### The BPA Litigation Front

After the National Toxicology Program issued the draft report on BPA in 2008, plaintiffs' attorneys nationwide began filing numerous consumer class action complaints, alleging breach of express and implied warranties of BPA-containing products, negligent and intentional misrepresentation, unjust enrichment, and violations of various state consumer protection laws. The defendants were manufacturers of products used by infants, such as baby bottles and sippy cups, manufacturers of baby formula, and retail outlets that sold these products. So far, litigation in state courts has been limited, but the lawsuits filed in or removed to federal court have been consolidated as multidistrict litigation (MDL).

In May 2010, in the consumer class action MDL against manufacturers of baby bottles, sippy cups, baby formula, and retail-  
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ers, the U.S. District Court for the Western District of Missouri ordered discovery into the defendants' knowledge of BPA health effects and communications with consumers about the presence or absence of BPA in products. *In Re: Bisphenol-A (BPA) Polycarbonate Plastic Products Liability Litigation*, MDL No. 1967. A second BPA-related MDL in the Western District of Kentucky involves suits against an aluminum bottle manufacturer that claimed its products were BPA-free when they were lined with BPA-containing resins. *In Re: Sigg Switzerland (USA), Inc., Aluminum Bottles Marketing and Sales Practices Litigation*, MDL No. 2137.

Manufacturers and retailers have company as targets of litigation. After the Natural Resources Defense Council gave the FDA 90 days to accede to its request that the FDA drop the acceptable level of BPA below 5 mg/kg/day, the council filed a lawsuit against

the FDA for not acting on its petition. Natural Resources Defense Council Citizen Petition Requesting Regulation Prohibiting the Use of BPA (Oct. 21, 2008), [http://docs.nrdc.org/health/files/hea\\_08102001a.pdf](http://docs.nrdc.org/health/files/hea_08102001a.pdf).

Despite the science to date, litigation promises to expand in other ways. Industries other than the baby product industry that produce and distribute BPA-containing products that humans have contact with humans likely will become future targets, particularly those that manufacture or supply food containers or their components. Furthermore, the types of claims are likely to expand. Plaintiffs have not yet asserted claims for personal injury as a result of exposure to BPA, but they likely will. Until that time, manufacturers of BPA and BPA-containing products may face claims for medical monitoring. Many states recognize a cause of action for medical monitoring through which consumers can require manufacturers to establish funds to pay

for future medical tests and surveillance that consumers claim are necessary due to their or their children's alleged exposure to specific products. As with consumer class actions, some states do not require a plaintiff to have sustained a physical injury to pursue a medical monitoring action. Additionally, plaintiffs often pursue medical monitoring claims as class actions, increasing the complexity and scope of discovery and case management strategies. Because these recoveries are sought for a sensitive subpopulation—infants—mounting defenses to medical monitoring claims becomes quite difficult.

Even in the face of all of the scientific findings, the "controversy" regarding BPA is not going away. The press, consumer groups, and advocacy organizations' furor over a chemical with a clean record may well warn of things to come since sometimes regulation is driven more by rhetoric than by science. 