



## THE ONGOING ANTI-BPA CRUSADE IN THE STATES: A DISSERVICE TO SCIENCE AND CONSUMERS

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Bisphenol A (BPA) is a hardening chemical additive that is used primarily to make polycarbonate plastic and epoxy resins. By making consumer products and food packages safer, BPA has reduced risks of potential disease and injury for decades. Polycarbonate plastics are widely used in a number of applications including medical equipment, bicycle helmets, elbow/knee pads, safety glasses, automobile bumpers, compact discs and DVDs, and, until recently, baby bottles and sippy cups. Epoxy resins are used in many coatings and other applications, including as protective liners in metal cans for canned foods and beverages.

Despite overwhelming scientific evidence establishing BPA's general safety and supportive statements from numerous governmental sources, including the Food and Drug Administration (FDA), state legislators and regulators continue to pursue bans and limit use of BPA. This LEGAL BACKGROUNDER describes the status of state lawmaking activity, which threatens to establish a patchwork of laws that has more to do with satisfying activists' misguided desire for precautionary regulation than with promoting public health.

### Origins of Controversy Surrounding BPA

The U.S. National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction issued a monograph in September 2008 stating that low-dose studies of BPA "provide limited evidence of adverse effects on development in laboratory animals."<sup>1</sup> The monograph, however, noted "some concern" about BPA's effects on the brain, behavior, and prostate gland of fetuses, infants, and children at current human exposure levels. This concern inspired countless studies, litigation, and legislation aimed at curtailing BPA's use in consumer products.

BPA's molecular shape mimics the female hormone estrogen. Some studies claim that at a sufficiently high dose, BPA acts as an endocrine disruptor in animals, possibly causing early onset of sexual maturation, altered development and tissue organization of the mammary gland, and decreased sperm production in offspring. Other studies allege that BPA may be most harmful in the stages of early development. Previous U.S. reports opine that more than 90% of Americans have BPA trace residues in their bodies, which are purportedly transferred from food and beverage containers, especially when the plastic is heated, exposed to strong dishwashing chemicals, or comes into contact with acidic substances.<sup>2</sup>

<sup>1</sup> Shelby, MD, "NTP-CERHR monograph on the potential human reproductive and developmental effects of bisphenol A," NTP CERHR MON. 2008 Sept;(22):v, vii-ix, 1-64 passim.

<sup>2</sup> Antonia M. Calafat, *et al.*, *Exposure of the U.S. Population to Bisphenol A and 4-Tertiary-Octylphenol: 2003-2004*" ENV'T'L HEALTH PERSPECTIVES 116 (2007): 39-44.

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## Federal Studies and Legislation Aimed at BPA

Since first undertaking its “Draft Assessment of BPA for use in food contact applications” in 2008, FDA has performed extensive additional research. The agency has reviewed hundreds of studies and determined that BPA as currently used in food packaging poses no health threat.<sup>3</sup> In fact, FDA scientists investigating potential concerns raised by certain studies determined that infants’ exposure to BPA through baby food is much less than had been previously believed. A recent Johns Hopkins University study confirmed these findings.<sup>4</sup> FDA also found that the trace amounts of the chemical that do enter the body are rapidly metabolized and eliminated, posing no risk of harm to infants or adults.<sup>5</sup>

Since 2009, some Members of Congress have introduced different versions of the “Ban Poisonous Additives Act,” which is aimed at food containers composed, in whole or in part, of BPA, as well as food containers that can allegedly release BPA into food. In 2012, responding to a citizen petition received from the Natural Resources Defense Council (NRDC) requesting an outright ban of BPA in human food and food packaging, FDA reaffirmed its previous position that available studies support BPA’s safety.<sup>6</sup> FDA refused to ban or limit BPA’s use in food packaging or food contact materials, stating that it was not persuaded by the data and information the NRDC presented in its petition.<sup>7</sup>

FDA subsequently formalized a voluntary industry ban on the use of BPA in baby bottles, sippy cups, and baby formula packaging. Industry had filed a petition requesting such an action, which related that the use of BPA was being discontinued in those products.<sup>8</sup> In December 2014, FDA conclusively pronounced that “*BPA is safe at the current levels occurring in foods.*”<sup>9</sup>

Undaunted by repeated failures or FDA’s pronouncement, a group of U.S. Representatives reintroduced “The BPA in Food Packaging Right to Know Act” in March 2015. It would require manufacturers to label any packaging that contains BPA. A similar bill was introduced in 2013 but failed to garner any support.

## Other Countries’ Studies and Legislation

Governmental bodies abroad have echoed the conclusions of those in the U.S. with regard to BPA’s safety. For instance, the European Food Safety Authority (EFSA) concluded in early 2015 after extensive study that dietary and other uses of BPA do not pose a health risk to consumers at any age.<sup>10</sup> EFSA’s study has not, however, motivated European nations with bans or strict limits on BPA to change their policies.

In January 2013, France banned the use of BPA in all packaging having direct contact with food marketed for children three years old and younger. France expanded the ban in January 2015 to include restrictions on the manufacturing, importation, or exportation of all products intentionally made with BPA that have direct contact with food. Sweden enacted a similarly broad ban on BPA in food containers for children under three in January 2013 and is considering further bans on BPA in drinking water pipes, toys, and other child care products.

<sup>3</sup> FDA Memorandum, *2014 Updated safety assessment for Bisphenol A (BPA) for use in food contact applications*, June 17, 2014.

<sup>4</sup> Nachman, RM, *et al.*, *Serial free bisphenol A and bisphenol A glucuronide concentrations in neonates*, J. OF PEDIATRICS, Apr. 23, 2015.

<sup>5</sup> FDA, *FDA Continues to Study BPA*, Mar. 20, 2012, available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm297954.htm>.

<sup>6</sup> FDA response to citizen petition, MS Docket No. FDA-2008-P-0577-0001YCP, Mar. 12, 2012, available at MS Docket No. FDA-2008-P-0577-0001YCP.

<sup>7</sup> *Id.*

<sup>8</sup> FDA, *Bisphenol A (BPA): Use in Food Contact Applications*, Jan. 6, 2015, available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>.

<sup>9</sup> *Id.*

<sup>10</sup> European Food Safety Authority, *No consumer health risk from bisphenol A exposure*, Jan. 21, 2015, available at <http://www.efsa.europa.eu/en/press/news/150121.htm>.

The Canadian government has taken a more science-based approach than authorities in France and Sweden, formally determining in 2012, that “current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and young children.”<sup>11</sup> A related Health Canada study published in 2014 reported similar findings.<sup>12</sup>

### Existing State Regulation

Some state legislatures and agencies in the U.S., rejecting science and siding instead with precaution-driven foreign regulators and non-governmental organizations, have taken up the anti-BPA mantle.<sup>13</sup>

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. The law also prohibits retailers from selling any such products, without exception. Minnesota also passed a law prohibiting BPA’s use in food packaging in 2013.

Other states quickly followed suit. Connecticut expanded on Minnesota’s sippy-cup ban in June 2009 and passed legislation targeting not only baby products, but also the manufacture, sale, or distribution of reusable food or beverage containers containing BPA, including sports bottles and thermoses. The law also prohibits baby food or infant formula from being sold in containers that contain BPA. Connecticut banned BPA’s use in thermal paper in 2011. In 2010, Wisconsin passed legislation that prohibits the use of BPA in baby bottles and sippy cups and requires such products to be labeled “BPA-free.”

Washington banned BPA-containing bottles and sippy cups in 2010, as did Maryland and New York. Massachusetts, the District of Columbia, Maine, and California banned BPA from baby bottles and sippy cups in 2011, as did Illinois in 2012 and Nevada in 2013. Vermont and Delaware have banned BPA’s use in reusable baby beverage containers and baby food packaging. Maine expanded existing BPA legislation in 2013 to include baby food packaging and children’s toys, and Maryland expanded its BPA ban to include baby food packaging in 2011.

Most recently, on May 11, 2015, California’s Office of Environmental Health Hazard Assessment (OEHHA) relisted BPA as a reproductive toxicant under Proposition 65. California originally added BPA to the Proposition 65 list in 2013, but it was removed when a state court issued a preliminary injunction sought in an industry lawsuit. Pursuant to a provision of Proposition 65, a “state qualified experts” committee convened on May 7, 2015 and determined that “BPA was clearly shown through scientifically valid testing according to generally accepted principles to cause reproductive toxicity, based on the female reproductive endpoint.”<sup>14</sup> In reaching its decision, the committee ignored a letter from FDA that unequivocally declared that exposure to BPA at current levels is safe for humans.

### Further State Efforts to Limit or Ban BPA

This year, state legislative sessions featured continued activity on BPA. Examples of proposals to either expand existing rules or initiate new controls are listed below.

- **Connecticut:** Senate Bill 367 would have required labeling for all food or drink packaging that contains BPA. The 2015 Regular Session of the Connecticut General Assembly adjourned on June 3, 2015 without enacting this legislation. A two-time loser, similar legislation was introduced in 2014 as Senate Bill 316 but was not enacted.

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<sup>11</sup> Health Canada, *Health Canada’s Updated Assessment of Bisphenol A (BPA) Exposure from Food Sources*, Sept. 2012, available at [http://www.hc-sc.gc.ca/fn-an/securit/packag-emball/bpa/bpa\\_hra-ers-2012-09-eng.php](http://www.hc-sc.gc.ca/fn-an/securit/packag-emball/bpa/bpa_hra-ers-2012-09-eng.php).

<sup>12</sup> Health Canada, *Bisphenol A*, Jan. 15, 2014.

<sup>13</sup> California, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, South Dakota, Vermont, Washington, Wisconsin, and the District of Columbia have all enacted legislation to regulate the use of BPA.

<sup>14</sup> California Office of Environmental Health Hazard Assessment, “Bisphenol A Listed as Known to the State of California to Cause Reproductive Toxicity, Effective May 11, 2015.”

- **Maryland:** Senate Bill 175 would have prohibited the use of BPA in cash register receipts. However, the Maryland General Assembly adjourned its 2015 session on June 5, 2015 without enacting this legislation.
- **Massachusetts:** Senate Bill 1200 would prohibit the use of BPA in cash register receipts, and Senate Bill 1223 would expand the existing BPA ban to all consumer products intended to hold food or liquids intended primarily for consumption from that container.
- **New Jersey:** Citing an outdated 2007 pronouncement from the U.S. Department of Health and Human Services in its text, New Jersey Assembly Bill 1821 (also introduced jointly as Senate Bill 1401) would prohibit the use of BPA in food packaging, beverage packaging, and reusable food and beverage containers. Marketing of a BPA-containing product in violation of this bill would subject a manufacturer, distributor, or retailer to monetary sanctions and each violation would constitute an additional, separate, and distinct offense. Likewise, New Jersey Senate Bill 1925 would prohibit BPA's use in hard plastic beverage containers. Finally, Assembly Concurrent Resolution 109 urges Congress to ban BPA from use in all children's products.
- **New York:** Assembly Bill 2997 would have banned the sale of toys, liquids, foods, and beverages for children under the age of three in containers containing BPA. Senate Bill 2763 (jointly introduced as Assembly Bill 3267) would have banned BPA in thermal receipt paper. Assembly Bill 3359 would have prohibited the manufacture, distribution, and sale of certain toys and child care products containing BPA. Assembly Bill 3276 would have banned the packaging of liquids, foods, and beverages in containers containing BPA, with a least-toxic-alternative replacement requirement. Under that bill, manufacturers of BPA-containing cans, jars, or other containers could continue producing those products by offering proof that no available alternatives to BPA currently exist. Additionally, the least-toxic-alternative provision of Assembly Bill 3276 states that manufacturers cannot substitute a chemical for BPA that is a known human carcinogen, endocrine disruptor, or reproductive toxin. On June 25, 2015, the New York legislative session of 2015 ended without passing any BPA legislation.

## Conclusion

A patchwork of state laws and regulations, based on ill-informed, generalized fear, will not advance public health. Such laws, and states' efforts to impose further BPA restrictions, mislead consumers into irrational market behavior and have a significantly negative impact on businesses. BPA bans force businesses to pursue alternative production practices with BPA replacements that may not be as safe or effective, while at the same time increasing costs for consumers. Likewise, retailers are left in limbo.

The consequences of France's complete ban of BPA illustrate a significant downside of precautionary overkill. The country's metal packaging industry has reportedly shrunk by an estimated 40% due to the ban on BPA-containing can liners.<sup>15</sup> French industry has tested over 1,700 different replacement formulas for a varnish-like lining for use in canned goods in place of BPA-containing liners that prevent botulism caused by foods' contact with contaminated metal.<sup>16</sup> Not only are the experimental can varnishes less effective than existing BPA-containing can linings, they are more expensive, resulting in higher costs for consumers and decreased industry productivity.

Consumers and businesses in the U.S. will suffer a similar fate if enough individual states succeed in their drive to ban or severely restrict BPA use in food and beverage packaging. Companies will be forced to find less effective and more costly replacements for BPA. The Balkanization caused by inconsistent BPA regulation will also force companies who market nationally to choose between the lesser of two evils: replace BPA in all of their products unnecessarily or create separate production processes so lower-cost, and likely safer, BPA can be used in products sold to states without bans. Those are the kinds of unfortunate, and entirely counterproductive, decisions that businesses are forced to make when regulations are based in fear and precaution, rather than sound science.

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<sup>15</sup> Mitchell, Rick, *French Metal Packaging Industry Struggling Under BPA Ban, Lobby Says*, Bloomberg BNA PRODUCT SAFETY & LIABILITY REPORTER, Apr. 10, 2015.

<sup>16</sup> *Id.*