



New Restrictions Emerging on the Use of Bisphenol-A in Consumer Products

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By James M. Meister

2009 has seen new legal initiatives—some successful—to restrict or ban Bisphenol-A (“BPA”) at state, national, and international levels. BPA (4, 4’-ISOPROPYLIDENEDIPHENOL, CAS No. 80-05-7) is an organic monomer that has been widely used in the manufacture of two common consumer goods: bottles made of polycarbonate plastics and food and beverage cans that contain an epoxy resin internal protective lining. Several million tons of BPA are produced annually in the United States. BPA is also an estrogenic compound and may have possible effects upon reproductive health and development. Public concern and scientific studies are now turning into restrictive legislation, creating market pressures to move away from BPA.

BPA Use. BPA has been widely used as a hardening monomer in creating consumer polycarbonate plastics. Eyeglass lenses, baby and water bottles, reusable food and drink containers, compact discs, impact-resistant safety equipment, and even medical devices are common exemplar products. BPA is also an ingredient for epoxy resins that are found in dental composites, paints and adhesives, and most notably, protective coatings in food packaging and beverage containers. While over ninety percent of BPA is used in producing polycarbonates and epoxy resins, BPA is also found in polyester resins, polysulfone resins, polyacrylate resins, tetrabrominated flame retardants, and thermal paper, such as purchase receipts, self-adhesive labels, and fax paper. The primary exposure for humans is through ingestion of food and liquids from BPA-containing packaging, after BPA separates from compounds and leaches into food and liquids.

Current health concerns focus on evidence that BPA’s estrogenic hormone qualities cause endocrine disruption leading to reproductive, developmental, and other serious adverse health effects. As BPA polycarbonate containers and epoxy resin can lining are such commonplace consumer items, it is not surprising that studies show BPA has been found in over 90 percent of humans tested.

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New State and Local Restrictions - U.S. In May, 2009, Minnesota became the first state to enact legislation banning BPA from baby bottles and sippy cups. (The Minnesota Toxic Free Kids Act, S.F. No. 247, was signed on May 7, 2009. Minn. Rev. Stat. § 325F.173 (2009).) Connecticut followed in June, more broadly banning BPA from all “reusable food or beverage containers,” including infant formula and baby food jars. (See Connecticut Public Act No. 09-103 (June 3, 2009).) Disposable containers are not covered by Connecticut’s law. Both bans take effect in 2011.

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The City of Chicago banned BPA in any bottle or cup designed for food or liquids for children under age three. (See BPA-Free Kids Ordinance, Municipal Code of Chicago § 7-28-367.) This ban becomes effective January 31, 2010. Suffolk County in New York also recently banned the sale of children’s beverage containers, including straws and lids, if they contain BPA. (See Suffolk County, New York, Resolution No. 154-2009, Laws of Suffolk County, NY, Ch. 323-1 (March 3, 2009) (amended by Local Law 7-2009 on March 24, 2009).) This ban becomes effective later this year.

California And Proposition 65. Legislation is pending in California that would prohibit BPA at a level above 0.1 parts per billion in “any bottle or cup or a liquid, food, or beverage in a can, jar or plastic bottle” that is intended for children 3 years of age or younger. The bill—the Toxin-Free Toddlers and Babies Act, SB797—would also require manufacturers to use the least toxic alternative when replacing BPA in containers. SB797 passed the California Senate and now resides in the Assembly, where similar legislation failed in 2008. (The California Bill, SB797, can be tracked at the California Legislature website at http://www.legislature.ca.gov/the_state_legislature/bill_information/bill_information.html.)

On a separate track, on July 15, a panel of seven scientific experts at the California Office of Environmental Health Hazard Assessment declined to list BPA as a reproductive toxicant under California Proposition 65. (See Safe Drinking Water And Toxic Enforcement Act of 1986, California Health & Safety Code, § 25249.5 et seq.) The expert panel considered EU risk assessment reports and a monograph from the National Toxicology Program (“NTP”). While these studies provided evidence that BPA showed adverse effects in animal studies, the expert panel concluded that these studies did not clearly show that BPA causes reproductive toxicity or developmental problems in humans. (The Office of Environment Health Hazard Assessment website, which includes information regarding the July 15 decision to not list BPA, is located at http://www.oehha.org/prop65/public_meetings/dart071509ag.html.) The panel’s decision could have been very significant, as any food container with a BPA-containing epoxy resin liner might have required a Proposition 65 warning.

United States Federal Law. In March, 2009, the Banning Poisonous Additives Act was introduced both the House and Senate. (See Banning Poisonous Additives Act of 2009, H.R. 1523 and S. 593 (111th Congress).) The legislation, perhaps ambitiously, seeks to ban BPA in all food and beverage containers. It follows last year’s Consumer Product Safety Commission Improvement Act, (See Pub. Law H.R. 110-314 (2008)), which permanently banned three types of phthalates from certain limited-types of children’s toys and child care articles, and banned three additional phthalates from other children’s products pending study of their reproductive and developmental health effects. (See Pub. Law H.R. 110-314, Section 108(a)-(b).) BPA, like these phthalates, is an endocrine disrupter.

In September 2008, the National Institute of Health (“NIH”) issued a monograph on BPA’s effects on human reproduction and development. (See The National Toxicology Program-Center For the Evaluation of Risks To Human Reproduction, Monograph on The Potential Human Reproductive and Developmental Effects of Bisphenol A (September 2008). Available on the NIH website at <http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf>.) The NTP reported some concern for BPA’s effects on the brain, behavior, and the prostate gland in fetuses, infants, and children at current exposure levels. The NTP reported negligible or minimal concern for effects in other reproductive health areas, such as birth defects or mortality of fetuses.

The FDA maintained in 2008 that BPA does not pose a health risk at current exposure levels. Congress and the public criticized the FDA’s reliance upon certain studies and, in June 2009 testimony to Congress, an FDA commissioner explained that the FDA’s acting chief scientist was going to reconsider the science surrounding BPA. (See Testimony of Margaret A. Hamburg, M.D. Commissioner of Food and Drugs, Food and Drug Administration, before the Subcommittee on Health, House Committee on Energy and Commerce (June 3, 2009).)

Canadian Law. In April 2009, Canada began moving to ban the manufacture or sale of polycarbonate baby bottles as a means of reducing exposure of newborns and infants to BPA. (See Canada Gazette, Part I, Vol. 143, No. 26 – June 27, 2009 (Order Amending Schedule I to the Hazardous Products Act (bisphenol A)).) Also, while Canada’s main regulatory entity—Environment Canada—concludes that present levels of exposures to the general population do not create health concerns, it is concerned that BPA existing in the environment may break down slowly and, with continued high volumes of production and use, may cumulate in the environment. (See Canada Gazette, Part I, Vol. 143, No. 20 – May 16, 2009 (Order Adding to Schedule 1 to the Canadian Environment Protection Act).) Environment Canada expressed concern about BPA’s potential for adverse reproductive and developmental effects upon animals and organisms. (Id.)

European Union. A 2003 European Chemicals Bureau (ECB) Risk Assessment Report initially concluded that further information and study was needed regarding adverse effects of BPA on human development. (See European Union Risk Assessment Report on 4,4’-Isopropylidenediphenol (Bisphenol-A), Final Report 2003.) A 2008 Updated Risk Assessment considered intervening studies and identified concerns of reproductive toxicity related to fertility and development and repeated dose toxicity effecting bodyweight, liver, and kidneys. (See European Union Updated of the Risk Assessment of 4,4’-Isopropylidenediphenol (Bisphenol A), Final Human Health Draft for Publication (to be read in conjunction with published EU RAR of BPA, 2003), April 2008.) The report found no concerns related to carcinogenicity or mutagenicity. The update did conclude that human exposure to BPA was higher than previous estimates, but concluded that these levels were considered safe. The EU risk assessments have concluded that BPA is biodegradable and not bio-cumulative. (EU Risk Assessment Report 2003, Section 1.4.) This conclusion is seemingly at odds with Environment Canada’s recent concerns.

Currently, under EU Directive 2004/19/EC, food packaging may have a specific migration limit for BPA of no more than 0.6 milligrams/kg. (European Commission Directive 2004/19/EC, Annex I (amending Directive 2002/72/EC, Annex II).) In late 2006, the European Food Safety Authority (“EFSA”) lowered its Tolerable Daily Intake (TDI) level from 5 down to .05 milligrams/kg/day. (European Food Safety Initiative, Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to 2,2-

BIS(4-HYDROXYPHENYL)PROPANE (November 26, 2006.) This new TDI level, based upon new scientific studies, reflects the EFSA's decision to apply an uncertainty factor of 100.

Risks, Benefits, And Alternatives To BPA. The risks of BPA will continue to be the subject of scientific study. As many past studies have been scrutinized, one can expect the quality of studies into both high and low-level toxicity studies to improve. Revised and improved assessments of actual human and infant exposure levels will further weigh upon the risk calculations.

BPA's benefits are found in the everyday consumer and industrial use polycarbonate plastic products, which require BPA as a hardening agent. Epoxy resin liners in metal food containers are credited with protecting the quality and integrity of food and its flavor.

The weighing scales of risks and benefits will likely be an ongoing rigorous political and scientific debate. An interesting question becomes whether there are reasonably available safer alternatives to BPA. Canada has expressly determined that safer non-BPA polycarbonate baby bottles are readily available. (See Canada Gazette, Part I, Vol. 143, No. 26 – June 27, 2009 (Order Amending Schedule I to the Hazardous Products Act (bisphenol A)).) Major companies like Wal-Mart and Nalgene have already moved away from BPA bottles and containers. (Bottle Maker to Stop Using Plastic Linked to Health Concerns, New York Times, April 8, 2008.)

With respect to epoxy resins used in the lining of metal food containers, it is less clear that an alternative is readily available—industry groups assert that epoxy resin is the best available lining for canned beverages and foods. (Id.) However, if legislative and regulatory measures are enacted, the food industry may be forced to find or develop new BPA-free packaging alternatives in the not too distant future.

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