BNA, INC.

CHEMICAL REGULATION

BNA Employee-Owned Since 1947

REPORTER

The author of this article says an increasingly important area for environmental attorneys and managers is chemicals of concern used in making industrial, commercial, and particularly consumer products. It includes the design of products, their manufacture, warnings, distribution, use, disposal, recycling, and post-disposal impacts. The author notes that regulation of chemicals goes well beyond the Environmental Protection Agency to include other federal agencies, state and municipal legislatures and agencies, foreign countries, and international bodies. This article uses bisphenol A, a chemical used in many consumer products, to provide a case study of the regulation of chemicals in products.

Regulating Chemicals in Products: The Case of Bisphenol A

By Mark N. Duvall

Mark N. Duvall is a principal with Beveridge & Diamond, P.C., in Washington, D.C. He has over two decades of experience working in-house at large chemical companies and also chairs the Committee on Pesticides, Chemical Regulation, and Right-to-Know of the American Bar Association's Section on Environment, Energy, and Resources. Duvall can be reached at mduvall@bdlaw.com.

The opinions expressed here do not represent those of BNA, which welcomes other points of view.

An increasingly important area for environmental attorneys and managers is chemicals in products. This area relates to chemicals of concern used in making industrial, commercial, and particularly consumer products. It includes the design of products, their manufacture, warnings, distribution, use, disposal, recycling, and post-disposal impacts.

Regulation of chemicals goes well beyond just the Environmental Protection Agency to include other federal agencies, state and municipal legislatures and agencies, foreign countries, and international bodies. Working in this area requires a broad perspective to keep track of all the balls being juggled at once that may relate to a single product or chemical.

This paper provides a case study of the regulation of chemicals in products using bisphenol A (BPA), a

 ISSN 0148-7973

chemical used in many consumer products. BPA has become a poster child in the debate about chemicals in products. This case study recognizes that chemicals-in-products issues are mainly about product design. It identifies some of the science policy issues that can arise and their implications. It then reviews where chemicals-in-products issues can arise; with BPA, they have come up in state legislatures and agencies, in lawsuits, before a variety of federal agencies, in Congress, and in multiple international forums. Finally, the case study draws some insights for how to try to manage chemicals-in-products issues.

1. Background on BPA[1]

BPA[2] is a chemical building block (monomer) that is used primarily to make polycarbonate plastic and epoxy resins (polymers). Polycarbonate plastic is a lightweight, high-performance plastic that possesses a unique balance of toughness, optical clarity, high heat resistance, and excellent electrical resistance. Polycarbonate is used in a wide variety of common products including digital media (e.g., CDs, DVDs), electrical and electronic equipment, automobiles, sports safety equipment, reusable food and drink containers (notably clear plastic baby bottles), and many other products.

Epoxy resins have many uses, including engineering applications such as electrical laminates for printed circuit boards, composites, paints and adhesives, as well as for a variety of protective coatings. Cured epoxy resins are inert materials used as protective liners in metal cans to maintain the quality of canned foods and beverages. They are used as protective coatings because of their exceptional combination of toughness, adhesion, formability, and chemical resistance.[3]

Bisphenol A entered the public perception as a potential chemical of concern with a 1996 book, *Our Stolen Future*, by Theo Colborn and others.[4] The book advocated a theory that low doses of some contaminants, including BPA, can interfere with hormonal signaling, thereby altering fetal development. Scientific research stepped up afterward to assess that possibility. That research has led to the current debates about BPA.

2. Product Design

Whereas most aspects of environmental law relate to environmental releases during manufacturing or use or after disposal, chemicals-in-products issues relate primarily to product design up front.

Product design takes a lifecycle approach to look for potential impacts from including a chemical of concern in a product in the first place. Thus, for BPA, one focus of the issue has been on whether polycarbonate baby bottles should be sold at all, not on how they should be disposed of or on emissions during their manufacture.

A related issue is assessment of alternatives. Alternatives assessment is a key part of California's Green Chemistry Initiative, for example.[5] It is also an important aspect of EPA's chemical action plans under the Toxic Substances Control Act (TSCA) for chemicals of concern, discussed below. There are ready substitutes for polycarbonate baby bottles made with BPA, so substitution has been rapid in the marketplace. On the other hand, there is no easy alternative to epoxy resins made with BPA for the lining of food and beverage containers. The can industry is hard at work trying to develop effective alternatives, but progress has been slow for technical reasons. Because can linings save lives and preserve product quality, the lack of good alternatives has kept BPA-based epoxy resins in the marketplace.

3. Science Policy Issues

Chemicals-in-products issues often raise questions of science policy. BPA raises four such issues: the so-called low-dose hypothesis; whether there is a potential for bias in studies arising from funding sources; how to determine the weight of the evidence; and the relevance of biomonitoring.

a. The Low-Dose Hypothesis

One of the cornerstones of traditional toxicology is ''the dose makes the poison.'' This statement suggests that while high exposure to a chemical may be harmful, there may be a lower exposure level that is not harmful. Exposure levels below that ''no observable adverse effect level'' (NOAEL) also would be expected not to cause harm.

The BPA debate has involved efforts to challenge the precept that ''the dose makes the poison'' with evidence that exposure levels orders of magnitude below the NOAEL do cause harm. The biological basis is said to be that endocrine system receptors are stimulated by very tiny doses, while much higher doses shut down those receptors so that they are not stimulated. Disruption of the endocrine system by such low doses is said to result in a wide variety of health effects later in life, including obesity, cancer, and developmental abnormalities.

BPA has a variety of health effects at relatively high doses. BPA has attracted widespread attention because

[1] For more information on BPA developments, see the following client alerts by Beveridge & Diamond: ''Bisphenol A Developments in 2008: The Year in Review'' (Jan. 9, 2009), available at http://www.bdlaw.com/news-461.html; ''Bisphenol A Ban Proposals Proliferate'' (Apr. 17, 2009), available at http://www.bdlaw.com/news-548.html; ''Bisphenol A: A Hot Topic at FDA, EPA, States, and the Courts'' (Feb. 19, 2010), available at http://www.bdlaw.com/news-810.html; and ''TSCA Reform Efforts Turn to Biomonitoring Studies for Support'' (Feb. 12, 2010), available at http://www.bdlaw.com/news-809.html.

[2] Chemical names for bisphenol A include phenol, 4,4'-(1-methylethylidene)bis-; 4,4'-isopropylidenediphenol; and 2,2-bis(4-hydroxyphenyl)propane. Its Chemical Abstract Service Number is 80-05-7.

[3] About Bisphenol A, http://www.bisphenol-a.org/about/index.html.

[4] Colborn, T.; Dumanoski, D.; Myers J.P.; *Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival?—A Scientific Detective Story* (1996).

[5] See, e.g., Department of Toxic Substances Control, California Environmental Protection Agency, Safer Consumer Product Alternatives (proposed regulations issued Sept. 14, 2010, implementing A.B. 1879, Cal. Health & Safety Code 25252 et seq.), available at http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs_APA-format-9-07-10-rev-9-12.pdf.

  CHEM ISSN 0148-7973

it is ''weakly estrogenic,''[6] meaning that it mimics the effects of estrogen on the endocrine system.

A particular concern has been the potential for residual BPA in polymers to leach out of food-contact materials made from those polymers, such as baby bottles and sports bottles made from polycarbonate and food can linings made from epoxy resins. There has been quite a battle about the health significance of such low-level exposures, particularly in the very young.

b. Potential for Bias in Studies Based on Funding

Another science policy issue is whether the funding of studies by industry implies bias, such that their results should be discounted. Generally, studies of BPA using standardized protocols and good laboratory practices (GLPs) have shown no adverse health effects from BPA at exposure levels experienced by consumers. These studies were generally funded by industry, which can afford the substantial costs of conducting such studies.

On the other hand, there is a body of BPA studies, generally from research laboratories, using non-standard protocols and not using GLPs. These non-standard studies have found a variety of adverse health effects at exposure levels experienced by consumers, levels which the more traditional studies found to present no adverse effects at all. These so-called low-dose studies are much less expensive to conduct. Industry efforts to replicate these studies have generally been unsuccessful.

BPA critics have pointed to the industry funding sources of the BPA studies finding no low-dose effects as one explanation for why there are such discrepancies between the study results. To resolve some of those discrepancies, the Food and Drug Administration (FDA) and the National Institute of Environmental Health Sciences (NIEHS) are sponsoring their own studies, using standardized protocols and GLPs. Those studies are now ongoing. FDA has held up taking decisive action on the use of BPA in food contact materials until those studies are completed.

c. Determining the Weight of the Evidence

Weight-of-the-evidence debates are often part of advocacy in chemicals-in-products issues. The different results of BPA studies have triggered a debate about what weight to give to low-dose studies, given their methodological weaknesses. The different results also raise the question of the extent to which the precautionary principle should affect decisions about the weight of the evidence.

As defined in Principle 15 of the United Nations Conference on Environment and Development, held in Rio de Janiero in 1992, the precautionary principle says that ''[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.''[7]

Advocacy starts with data. Industry groups have entered the fray by supporting weight-of-the-evidence reviews of the hundreds of studies, and by sponsoring original research to answer outstanding questions about health effects at low doses. Stakeholders also presented information and comments to governmental review bodies assessing BPA studies.

Governmental reviews in Europe[8] and Japan[9] gave relatively little weight to low-dose studies. Those governmental reviews found BPA to pose no risk to consumers at current exposure levels. Their evaluations have been cited frequently in the U.S. debates over BPA.

A critical event happened on April 14, 2008, when the National Toxicology Program (NTP), having reviewed essentially the same studies as those considered in the European and Japanese assessments, issued a draft monograph finding ''some concern'' for certain health effects from BPA at current human exposure levels. (The final monograph was issued with some changes in September 2008.)[10] This was the first time that a national governmental body (albeit not a regulatory agency) had reached such a decision, and the decision rested mainly on the low-dose studies. NTP recognized the limitations of the studies, but felt, unlike previous governmental reviewers, that the study results were sufficient to support a basis for concern.

Three days after the NTP draft monograph came out, Health Canada and Environment Canada released a draft screening assessment on BPA. (The final screening assessment was issued in October 2008.)[11] While finding the overall weight of evidence to be ''limited'' with respect to rigor, power, and biological plausibility, those agencies nevertheless said ''it is considered appropriate to apply a precautionary approach.'' They subsequently proposed to ban polycarbonate baby bottles due to BPA concerns.

These two developments were widely reported in the media. They fundamentally changed the dynamics of

[6] EPA, Bisphenol A Action Plan Summary, http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/bpa.html.

[7] Rio Declaration on Environment and Development (June 14, 1992), available at http://www.un-documents.net/rio-dec.htm.

[8] European Union Risk Assessment Report of 4,4'-Isopropylidenediphenol (Bisphenol-A), CAS No: 80-05-7, EINECS No: 201-245-8 (Feb. 2010, combining a 2003 risk assessment and its 2008 update), available at http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf; European Food Safety Authority, ''Toxicokinetics of Bisphenol A: Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC)'' (July 9, 2008) (hereinafter EFSA, Toxicokinetics of Bisphenol A), available at http://www.efsa.europa.eu/fr/scdocs/doc/759.pdf.

[9] National Institute of Advanced Industrial Science and Technology, ''AIST Risk Assessment Document Series No. 4: Bisphenol A'' (2007), available at http://unit.aist.go.jp/riss/crm/mainmenu/e_1-10.html.

[10] NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A, NIH Publication No. 08-5994, available at http://op.bna.com/env.nsf/r?Open=thyd-89gmtr (32 CRR 839, 9/8/08).

[11] Environment Canada and Health Canada, ''Screening Assessment for the Challenge Phenol, 4,4' -(1-methylethylidene)bis- (Bisphenol A)'' (Oct. 2008), available at http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf (32 CRR 1028, 10/27/08).

the BPA debate; within a few days, some retailers were phasing out sales of polycarbonate baby bottles, lawsuits were filed, and legislation was introduced. Thus, the basic scientific challenge of determining the weight of the evidence and the role of the precautionary principle has had a huge impact on the outcome of this chemicals-in-products issue.

d. Role of Biomonitoring

Biomonitoring has become an important aspect of some chemicals-in-products issues. ''Biomonitoring'' refers to the assessment of human exposure to chemicals by measuring the presence of biomarkers—either the chemical itself or its metabolites—in human tissue or fluids, most commonly blood or urine. The quantity or concentration of biomarkers in a sample is an indication of aggregate exposure to the chemical without regard to the relevant route of entry into the body, timing of exposure, or any particular source in the environment. Biomonitoring helps answer the exposure side of the risk equation, but does not answer the hazard side, i.e., it does not help explain whether observed levels of internal exposure are resulting in adverse health effects.

The Centers for Disease Control and Prevention (CDC) published a much-cited biomonitoring study in 2008 that detected BPA in 92.6 percent of a large national sample of persons 6 years of age and older.[12] CDC's Fourth National Report on Human Exposure to Environmental Chemicals (2009) included detailed biomonitoring results for BPA in that large sample.[13] However, CDC cautioned that:

> The measurement of an environmental chemical in a person's blood or urine is an indication of exposure; it does not by itself mean that the chemical causes disease or an adverse effect. Research studies, separate from these data, are required to determine which blood or urine levels are safe and which are associated with disease or an adverse effect.[14]

Nongovernmental organizations have utilized their own biomonitoring studies for advocacy about BPA, with strong suggestions that BPA ''may'' be causing various health effects. These studies have generally used very small, targeted samples, making them of little scientific value. Nevertheless, they have been used effectively to raise concerns about BPA and other chemicals detected.[15] For example, on Dec. 2, 2009 the Environmental Working Group (EWG) released a biomonitoring study finding multiple chemicals, including BPA, in cord blood from 10 minority infants.[16] EWG released the study the same day that the Senate Environment and Public Works Committee opened hearings on TSCA reform, and Sen. Frank Lautenberg (D-N.J.) cited EWG's findings in his introductory statement.[17] At a subsequent congressional hearing on biomonitoring, with TSCA reform as a subtext, EWG President Ken Cook presented testimony on the results of that study, stating that it had ''uncovered a startling truth—babies are coming into the world pre-polluted with toxic chemicals.''[18]

4. BPA Regulation at the State Level

Another aspect of some chemicals-in-products issues is that much of the relevant activity does not take place before EPA or even other federal agencies. States are very active in addressing chemicals of concern in products.

States and localities have not waited for the federal government to address BPA concerns. One of the first regulatory actions involving BPA occurred in 2006, when the San Francisco City Council, relying on its official endorsement of the precautionary principle, passed an ordinance to ban toys and child care articles intended for use by children under 3 years that are made with or contain BPA.

A group of companies filed a lawsuit in state court challenging the ordinance. One argument was that the Federal Food, Drug, and Cosmetic Act (FFDCA) preempted the ordinance. Without waiting for a court decision, the City Council amended the ordinance in 2007, essentially dropping its BPA provisions, in expectation that the California Legislature would take up the issue later that year.[19] (It did so, but did not pass a BPA bill.)

Bills to prohibit the use of BPA in food contact materials or child care articles were introduced shortly after the draft NTP monograph appeared. Legislation has now been passed in at least seven states and four localities, including Connecticut,[20] Maryland,[21] Minnesota,[22] New York,[23] Vermont,[24] Washington,[25] and Wisconsin.[26] In addition, the City of Chicago and the counties of Albany, Schenectady, and Suffolk in New York have adopted their own legislative bans, all in 2009.

---

[12] Calafat, A., et al., ''Exposure of the U.S. Population to Bisphenol A and 4-tertiary-Octylphenol: 2003-2004,'' Environmental Health Perspectives 116:39-44 (2008), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2199288/?tool=pubmed.

[13] Available at http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf.

[14] Id. at 1.

[15] See, e.g., Wilding, B., et al., Physicians for Social Responsibility, ''Hazardous Chemicals in Health Care: A Snapshot of Chemicals in Doctors and Nurses'' (2009), available at http://www.psr.org/resources/hazardous-chemicals-in-health.html.

[16] EWG, ''Pollution in People: Cord Blood Contaminants in Minority Newborns'' (2009), available at http://www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf.

[17] Opening Statement of Sen. Lautenberg, Oversight Hearing on the Federal Toxic Substances Control Act Before the S. Comm. on the Environment & Public Works, 111th Cong. (Dec. 2, 2009), available at http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Statement&Statement_ID=117d5500-2696-453a-a8a2-3a56f2a63d6b.

[18] Testimony of Kenneth A. Cook, Hearing, ''Current Science on Public Exposures to Toxic Chemicals'' Before the Subcomm. on Superfund, Toxics and Environmental Health, Sen. Comm. on Environment & Public Works, 111th Cong. (Feb. 4, 2010), available at http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=31bcb6cf-26ff-4415-b04d-87988118af33.

[19] San Francisco Health Code Chap. 34, §§ 34.1 through 3.43, added by Ord. No. 120-06 (approved June 15, 2006), revised by Ord. No. 86-07 (approved Apr. 27, 2007).

[20] Conn. Gen. Stat. §§ 21a-12b and -12c (approved June 3, 2009).

[21] Md. Health-General Code Ann. § 24-304 (approved Apr. 13, 2010).

[22] Minn. Ann. Stat. § 325F.173 (approved May 7, 2009).

[23] N.Y. Envtl. Conserv. Law Art. 37, Tit. 5 (approved July 30, 2010).

[24] Vt. Stat. Ann. § 1512 (approved May 19, 2010).

[25] Rev. Code Wash. Chap. 70.280 (approved June 10, 2010).

[26] Wis. Stat. § 100.335 (approved Mar. 3, 2010).

  CHEM ISSN 0148-7973

These BPA bans apply inconsistent restrictions, making compliance challenging for national marketers of affected products.

In addition, in 2009 the attorneys general from Connecticut, New Jersey, and Delaware asked the six largest baby bottle manufacturers to stop using BPA in U.S. baby bottles, which they agreed to do.[27]

Not all bills introduced have become law. In 2009 more than 40 BPA measures were introduced in 19 states, but only a handful passed. Of note is that the California Legislature is still debating a BPA ban bill.[28]

5. Lawsuits

With BPA, as with some other chemicals-in-products issues, lawsuits seeking class certification and damages have been filed. The first lawsuits were filed in federal court within days after NTP released its draft monograph on BPA.

These lawsuits have been brought against companies that manufacture certain consumer products made with BPA. The cases have been consolidated as a Multi-District Litigation matter in the Western District of Missouri.[29]

The cases have not alleged adverse health effects from BPA exposure, for which proof of causation would have been required. Instead, they allege that implied representations that certain BPA-containing products were safe violated state consumer protection laws. Because of this theory, an appeals court has ruled that bodily injury insurance carriers are not required to defend the cases.[30]

A separate set of lawsuits have been brought against companies that manufacture certain other consumer products. These cases alleged misrepresentations that the products were ''BPA-free.''[31]

6. BPA Regulation at the Federal Level

Even at the federal level, EPA is not necessarily the focal point for chemicals-in-products issues. FDA is the lead regulatory agency on BPA. Scientific agencies, such as NTP and CDC, also have been involved. Congress is also considering BPA legislation.

a. FDA Activity[32]

FDA originally approved use of polycarbonate, epoxy resins, and other polymers made from BPA for use in food contact materials in the 1960s.[33] As questions arose about BPA safety, FDA personnel issued letters stating its continuing conclusion that use of such polymers in food contact materials is safe. Nevertheless, in 2007 FDA quietly began a formal reassessment of BPA focusing particularly on low-dose effects.

In early 2008, Congress got involved. A House investigations subcommittee asked FDA to explain its position, leading FDA to commit to re-evaluate BPA safety in light of the low-dose studies. Three days after NTP released its draft monograph, FDA formed an agency-wide BPA task force.

In August 2008, FDA issued a Draft Assessment which discounted the low-dose studies and concluded that ''an adequate margin of safety exists for BPA at current levels of exposure from food contact uses.''[34] This draft was heavily criticized by the BPA subcommittee of FDA's Science Board in October 2008 for its exclusion of the low-dose studies.[35]

With the new Obama administration, FDA took a fresh look at the low-dose studies. On Jan. 15, 2010, FDA announced that it was changing its position on BPA.[36] The announcement said, ''[s]tudies employing standardized toxicity tests continue to support the safety of current low levels of human exposure to BPA.'' It then cited the low-dose studies and aligned itself with NTP in expressing ''some concern'':

> However, on the basis of results from recent studies using novel approaches to test for subtle effects, both [NTP] and FDA have some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children.

FDA explained that it considers there to be ''uncertainties about the risks of BPA.'' It announced that it was sponsoring in-depth studies on BPA. Results from some of the newly commissioned studies are expected to become available in 2010, others in 2012.

FDA also announced a number of interim steps and recommendations. On April 5, 2010, FDA released for comment a set of scientific study reviews and exposure

---

[27] Press Release, Connecticut Attorney General's Office, ''Attorney General Announces Baby Bottle Makers Agree To Stop Using BPA; Calls For Legislative Ban'' (Mar. 5, 2009), http://www.ct.gov/ag/cwp/view.asp?A=3673&Q=435360.

[28] S.B 797 (coauthored by Assembly member Ma, who sponsored the original San Francisco ordinance). On Aug. 31, 2010, the Senate refused by 1 vote to concur with Assembly amendments to S.B. 797. See http://www.leginfo.ca.gov/cgi-bin/postquery?bill_number=sb_797&sess=CUR&house=B&author=pavley (34 CRR 879, 9/13/10).

[29] *In re Bisphenol-A (BPA) Polycarbonate Plastics Products Liability Litigation*, 571 F. Supp. 2d 1374 (J.P.M.L. 2008).

[30] *Medmarc Casualty Ins. Co. v. State Farm Fire & Casualty Co.*, 612 F.3d 607 (7th Cir. 2010).

[31] See, e.g., *In re: Gaiam, Inc., Water Bottle Marketing, Sales Practices and Products Liability Litigation*, 672 F.Supp. 2d 1373 (J.P.M.L. 2009).

[32] See generally FDA's webpage on BPA, http://www.fda.gov/Food/FoodIngredientsPackaging/ucm166145.htm.

[33] For example, the polycarbonate food additive regulation was adopted in 1963. 28 Fed. Reg. 1963 (May 22, 1963), adopting 21 C.F.R. § 121.2574, later recodified as 21 C.F.R. § 177.1580.

[34] FDA, Draft Assessment of Bisphenol A for Use in Food Contact Applications (Aug. 14, 2008), available at http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008-0038b1_01_02_FDA%20BPA%20Draft%20Assessment.pdf (32 CRR 819, 8/25/08).

[35] FDA Science Board, ''Scientific Peer-Review of the Draft Assessment of Bisphenol A for Use in Food Contact Applications'' (Oct. 31, 2008), available at http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4386b1-05.pdf (32 CRR 1045, 11/3/08).

[36] FDA, ''Update on Bisphenol A for Use in Food Contact Applications: January 2010,'' available at http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm (34 CRR 77, 1/25/10).

estimates relating to food contact materials made with BPA.[37]

b. EPA Gets Involved

EPA has initiated its own BPA review. EPA has authority under TSCA to regulate uses of ''chemical substances,'' a term that excludes uses of chemicals that are regulated by FDA, such as food additives.[38]

On Sept. 29, 2009, EPA Administrator Lisa Jackson announced a new chemicals management strategy that would begin with the preparation of chemical action plans intended to ''target the Agency's risk management efforts on chemicals of concern.'' In her speech promoting the new strategy, Jackson singled out BPA as a high priority for EPA, referring to it as ''a chemical that can affect brain development and has been linked to obesity and cancer,'' and noting its presence in baby bottles.[39]

EPA issued a chemical action plan for BPA on March 29, 2010.[40] It recognized that most human exposure to BPA is from food contact substances, which fall under the jurisdiction of FDA rather than EPA. Nevertheless, the EPA action plan targeted potential environmental effects of BPA, which EPA can address under TSCA.

The action plan announced that EPA was considering a number of actions. Those actions were issuing a proposed rule to add BPA to the ''Concern List'' under TSCA section 5(b)(4) on the basis of its potential for chronic effects on aquatic species; issuing a proposed rule to require environmental effects testing and exposure/concentration monitoring under TSCA section 4(a); and using EPA's Design for the Environment program under the Pollution Prevention Act of 1990 to analyze readily available alternatives that would reduce BPA uses and exposures in applications such as thermal and carbonless paper coatings, foundry castings, and pipe linings.

c. Congress

Within two weeks after NTP released its draft monograph, Sen. Charles Schumer (D-N.Y.) introduced the first of multiple bills to address BPA. His bill, the ''BPA-Free Kids Act of 2008,''[41] would have designated children's products containing a detectable level of BPA as banned hazardous substances under the Federal Hazardous Substances Act. The bill is noteworthy in that it would vest jurisdiction over BPA in children's food and beverage containers in the Consumer Product Safety Commission (CPSC), rather than FDA. CPSC has had little involvement with BPA, despite concerns about its use in consumer products.

Another set of bills targeting BPA are known as the ''Ban Poisonous Additives Act.''[42] Championed by Sen. Dianne Feinstein (D-Calif.) in the Senate, they would deem any food container that can release BPA into food to be adulterated under the FFDCA.

A third approach is that of the ''BPA Consumer Information Act of 2009,'' introduced by Rep. Tim Ryan (D-Ohio).[43] Citing the scientific uncertainties about BPA at low doses, it embraces another common aspect of some chemicals-in-products issues, which is ingredient disclosure. It would deem a food container to be misbranded under the FFDCA if it is made from or could release BPA and fails to display a label warning that the container is composed of or could release BPA.

While none of these bills has yet emerged from committee, Sen. Feinstein recently said that she will seek to amend a broader FDA food safety bill, S. 510, to add a BPA ban when it comes to the Senate floor.[44]

Congress also may address BPA through legislation to amend TSCA. House legislation introduced in July 2010 by Rep. Bobby Rush (D-Ill.) and others included BPA on a short list of chemicals for which EPA would be required to perform a safety standard determination on an expedited basis, then regulate appropriately.[45]

7. Developments Outside the United States

Characteristic of other chemicals-in-products issues, the BPA debate is also playing out on stages outside the United States. The actions of foreign governments and the United Nations on BPA could influence what happens to BPA in the United States, and vice versa.

Canada has been assessing BPA under the Canadian Environmental Protection Act 1999. On April 17, 2008, three days after NTP released its draft monograph, Health Canada and Environment Canada released a draft screening assessment on BPA, which was finalized in October 2008.[46] Like the NTP monograph, the screening assessment relied on low-dose studies on BPA exposure to make its recommendations.

In response to the screening assessment, in October 2008 Health Canada and Environment Canada proposed ''to ban the importation, sale and advertising of polycarbonate baby bottles made with bisphenol A monomer''; ''to adopt a precautionary approach for bisphenol A in food packaging for products intended for newborns and infants''; and ''to explore the option of establishing stringent migration targets for bisphenol A in canned foods in general.'' The Canadian government noted, however, that the risks posed to humans from exposure to BPA are limited to infants and newborns,

---

[37] 75 Fed. Reg. 17145 (April 5, 2010).

[38] TSCA § 3(2)(B)(vi), 15 U.S.C. § 2602(2)(B)(vi).

[39] EPA, Administrator Lisa P. Jackson, Remarks to the Commonwealth Club of San Francisco (Sept. 29, 2009), available at http://yosemite.epa.gov/opa/admpress.nsf/a883dc3da7094f97852572a00065d7d8/fc4e2a8c05343b3285257640007081c5!OpenDocument.

[40] EPA, ''Bisphenol A Action Plan,'' available at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/bpa_action_plan.pdf (34 CRR 466, 5/17/10).

[41] S. 2928 (Apr. 29, 2008). Sen. Schumer introduced a revised version of the bill in 2009, in the 110th Congress, S. 753 (Mar. 31, 2009).

[42] H.R. 6228 (June 10, 2008); S. 593 (Mar. 12, 2009); H.R. 1523 (Mar. 16, 2009) (33 CRR 277, 3/23/09).

[43] H.R. 4311 (Dec. 16, 2009).

[44] Press release, Sen. Feinstein's office, ''Senator Feinstein to Offer Amendment Banning Bisphenol A from Baby Bottles, Infant Formula'' (Aug. 10, 2010), available at http://feinstein.senate.gov/public/index.cfm?FuseAction=NewsRoom.PressReleases&ContentRecord_id=6865856d-5056-8059-76ff-11523a29dded.

[45] ''Toxic Chemicals Safety Act of 2010,'' H.R. 5820 (July 22, 2010).

[46] Environment Canada and Health Canada, ''Screening Assessment for the Challenge Phenol, 4,4' -(1-methylethylidene)bis- (Bisphenol A)'' (Oct. 2008), available at http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf.

   ISSN 0148-7973

and that BPA poses no known health risk to the general population.[47]

On May 16, 2009, Canadian agencies issued a proposed order listing BPA on Schedule I of CEPA, which would allow the adoption of various regulatory and other measures.[48] An industry group objected to the proposed order and requested a board of review,[49] but the request was denied.[50] On March 11, 2010, Canada officially banned the sale of baby bottles made from polycarbonate, becoming the first country in the world to do so.[51] Its announcement noted that in the United States, bills had been introduced in Congress and some states to ban polycarbonate baby bottles.

A 2008 European Commission BPA risk assessment that pre-dated the NTP monograph concluded that ''there are no concerns for repeated dose toxicity and reproductive toxicity'' for the general population.[52] Subsequently, the European Food Safety Authority (EFSA) noted the Canadian Draft Screening Assessment and ''ongoing discussions on the reported low-dose effects of BPA,'' but nevertheless confirmed its previous judgment that current exposure levels from food are safe.[53]

Nevertheless, some individual countries in the European Union have enacted temporary bans on polycarbonate baby bottles, including France[54] and Denmark.[55]

Australia and New Zealand have jointly reviewed BPA safety. In a series of announcements, they have commented on developments in the United States, Canada, and the European Union. Most recently, they announced that ''there is no health risk to consumers, including infants'' from polycarbonate baby bottles, but also noted a voluntary phase-out by Australian retailers of polycarbonate baby bottles.[56]

In 2009 the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) issued a note on the current state of knowledge about BPA, which cited developments mentioned above in Europe, Canada, the United States, and elsewhere.[57] In November 2010, they will sponsor an expert meeting and stakeholder meeting to review BPA health effects in light of the uncertainties. The meetings will be supported by FDA, NIEHS, EFSA, and Health Canada.[58] These meetings could be quite influential for future regulatory decisions around the world.

8. Managing Chemicals-in-Products Issues

The case of BPA illustrates some of the considerations companies may want to weigh in trying to manage chemicals-in-products issues.

First, it reflects the importance of building the science basis for decisionmaking. Industry stakeholders have helped counter the influence of non-guideline, non-GLP, low-dose studies by investing in high-quality studies of their own using standardized protocols and GLPs and by supporting assessments of the toxicological literature.

Second, it shows the importance of effective scientific and public policy advocacy. Debate about the weight of the evidence to be accorded to low-dose studies continues today, and this has tempered the instinct of regulators to act prematurely. Many more bills to ban BPA have been proposed than have passed, in part because of aggressive industry advocacy.

Third, it reflects the importance of the precautionary principle. Health Canada and Environment Canada recognized the limited evidentiary basis for banning polycarbonate baby bottles, but they did so with express reliance on the precautionary principle. The San Francisco City Council also acted on the basis of the precautionary principle. In jurisdictions where the precautionary principle is not official policy, advocates can urge regulatory restraint in the absence of adequate information.

Fourth, the role of the states and localities in chemicals management should not be underestimated. The

[47] Proposed Risk Management Approach for Bisphenol A, at 4 (Oct. 2008), available at http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm_en.pdf (32 CRR 1028, 10/27/08).

[48] Proposed Order adding toxic substances to Schedule 1 to the Canadian Environmental Protection Act, 1999 (May 16, 2009), available at http://gazette.gc.ca/rp-pr/p1/2009/2009-05-16/pdf/g1-14320.pdf#page=40.

[49] American Chemistry Council, ''Notice of Objection and Request for Board of Review in relation to the Proposed Order to add Phenol, 4,4' -(1-methylethylidene) bis- (bisphenol A) CAS No. 80-05-7 to Schedule 1 to the Canadian Environmental Protection Act, 1999'' (July 15, 2009), available at http://www.ec.gc.ca/lcpe-cepa/documents/consultations/avis-notices/20100730_bpa_avis-notice.pdf.

[50] Letter from Minister of Environment to American Chemistry Council (July 27, 2010), available at http://www.ec.gc.ca/lcpe-cepa/documents/consultations/avis-notices/20100730_bpa_min.pdf.

[51] *Canada Gazette*, ''Order Amending Schedule I to the Hazardous Products Act (bisphenol A)'' (Mar. 11, 2010), available at http://www.gazette.gc.ca/rp-pr/p2/2010/2010-03-31/html/sor-dors53-eng.html (34 CRR 331, 4/5/10).

[52] European Commission, Updated Risk Assessment of 4,4'-Isopropylidenediphenol (Bisphenol-A) (Feb. 2010, combining a 2003 risk assessment and its 2008 update), available at http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf.

[53] EFSA, Toxicokinetics of Bisphenol A, *supra* note 8. EFSA further reaffirmed that opinion in a ''Statement of EFSA on a study associating bisphenol A with medical disorders'' (Oct. 22, 2008), available at http://www.efsa.europa.eu/fr/scdocs/doc/838.pdf.

[54] LOI n° 2010-729 du 30 juin 2010 tendant à suspendre la commercialisation de biberons produits à base de bisphénol A, available at http://www.legifrance.gouv.fr/jo_pdf.do?cidTexte=JORFTEXT000022414734.

[55] Danish Ministry of Food, Agriculture, and Fisheries, ''Danish ban on bisphenol A in materials in contact with food for children aged 0-3'' (Mar. 26, 2010), available at http://www.fvm.dk/Default.aspx?ID=18488&PID=168823&NewsID=6014.

[56] Food Standards Australia New Zealand, ''Bisphenol A (BPA) and food packaging'' (Sept. 2010), available at http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2010/bisphenolabpaandfood4911.cfm.

[57] WHO and FAO, ''Bisphenol A (BPA)—Current state of knowledge and future actions by WHO and FAO'' (Nov. 27, 2009), available at http://www.who.int/foodsafety/publications/fs_management/No_05_Bisphenol_A_Nov09_en.pdf.

[58] WHO, ''Joint FAO/WHO Expert meeting to review toxicological and health aspects of Bisphenol A and Stakeholder Meeting, Ottawa, Canada, 1-5 November 2010,'' available at http://www.who.int/foodsafety/chem/chemicals/bisphenol/en/index.html; WHO/FAO, ''Project to review toxicological and health aspects of Bisphenol A: Announcement of Stakeholder Meeting,'' available at http://www.who.int/entity/foodsafety/chem/chemicals/BPA_Stakeholder.pdf.

San Francisco City Council jumpstarted a legislative drive to restrict some uses of BPA that continues today. Those state and local restrictions can have the effect of national bans for companies that sell products made with BPA nationally.

Fifth, at the federal level, EPA is not always the lead agency. FDA is the lead regulatory agency for BPA. EPA found that most exposures to BPA are from FDA-regulated products. Nevertheless, EPA has found a niche for itself with the environmental aspects of BPA, which can in turn influence the availability of components for FDA-regulated products.

Sixth, the BPA debate highlights the importance of having a broad international perspective. Scientific assessments in Europe and Japan influenced FDA's evaluation. Actions by Health Canada and Environment Canada helped start a cascade of effects.

Finally, the BPA case study shows the importance of strategic market withdrawal. Much of the BPA debate has focused on polycarbonate baby bottles, which represent a tiny fraction of the BPA market. Shortly after the NTP draft monograph appeared, retailers announced they were phasing out those baby bottles. The baby bottle manufacturers themselves later announced they would no longer use BPA in their products. Strategic market withdrawals can sometimes save most of a market that would otherwise be threatened in its entirety.

  CHEM ISSN 0148-7973