

# CLIENT ALERT



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## **BISPHENOL A DEVELOPMENTS IN 2008: THE YEAR IN REVIEW**

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The potential health effects of bisphenol A (“BPA”) have sparked scientific controversy for years, but in 2008 that controversy grabbed the attention of regulators, legislators, litigators, non-governmental organizations, and the general public as never before. This article reviews the highlights of the 2008 BPA developments and provides some thoughts about developments expected in 2009. This article also includes links to key BPA documents.

BPA is a monomer used to manufacture polycarbonate, a hard plastic with many applications, but in 2008 it was best known for use in baby bottles and sports bottles. BPA also is used to manufacture epoxy resins, the protective linings on the inside of food cans. Under some conditions, low levels of BPA can leach out of polycarbonate and epoxy into the contents of the food container, resulting in human exposure and bringing BPA under the jurisdiction of the Food and Drug Administration (“FDA”).

Using traditional toxicology methods and doses, government agencies around the world have found BPA to be safe, in that human exposure levels are generally well below the “no observable adverse effect level” (“NOAEL”) found by those studies. The BPA controversy revolves around the significance of “low-dose” studies indicating that the chemical may cause adverse health effects at exposure levels orders of magnitude below the NOAEL from traditional toxicological methods. Until 2008, no national governmental agency had sufficient confidence in these low-dose studies to express concern about BPA exposures in people. That changed in 2008, and with that change the level of public concern about BPA skyrocketed.

### **THE NTP MONOGRAPH**

A key development in 2008 was the release of a monograph on BPA (the “NTP monograph”) by the National Toxicology Program (“NTP”) Center for the Evaluation of Risks to Human Reproduction (“CERHR”). It followed up on a November 2007 CERHR expert panel report. A draft NTP monograph was released April 14, with the final version released September 3. The NTP Monograph concluded that, based on the weight of the evidence, there is “some concern” about the effects of BPA on the brain, behavior, and prostate gland of fetuses, infants, and children at current human exposures levels; “minimal concern” for some other effects; and “negligible concern” for others. These conclusions rested on NTP’s determination that low-dose studies “provide limited evidence of adverse effects on development in laboratory animals,” notwithstanding their “limitations.”

### **HEALTH CANADA AND ENVIRONMENT CANADA SCREENING ASSESSMENT**

Three days after NTP released its draft monograph, on April 17, 2008, Health Canada and Environment Canada (“HC/EC”) released a draft screening assessment on BPA, which was finalized in October. Like the NTP monograph, the HC/EC screening assessment relied on low dose studies on BPA exposure to make its recommendations. While “the overall

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weight of evidence was considered limited” and “highly uncertain,” the screening assessment nevertheless found that the neurodevelopmental and behavioral data set in rodents “is suggestive of potential effects at doses at the same order of magnitude to 1-2 orders of magnitude higher than exposures.”

In response to the screening assessment, in October HC/EC 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, and that BPA poses no known health risk to the general population.

## **PUBLIC REACTION**

Release of the draft NTP and HC/EC assessments led to widespread media coverage about BPA safety and advice to stop using polycarbonate baby bottles and sports bottles. Within days Wal-Mart, Toys “R” Us, and CVS/pharmacy announced they were phasing out polycarbonate baby bottles, and Nalgene said it would stop using polycarbonate in its consumer bottles. Non-governmental organizations, which had already adopted BPA safety as an issue, also ramped up their advocacy.

## **JAPAN**

The reliance of NTP and HC/EC on low-dose studies contrasted with the prior refusal of other scientific agencies to rely on low-dose studies for their conclusions. For example, Japan’s National Institute of Advanced Industrial Science and Technology (“NIAIST”) said in a 2007 English translation of its 2005 BPA risk assessment that, “we conclude that the human risk of BPA exposure is below the level of concern,” in part because “we do not consider uncertainty for low-dose effects.” NIAIST published no response to the NTP and HC/EC assessments in 2008.

## **EUROPE**

In June 2008 the European Commission (“EC”) released its updated draft BPA risk assessment, which found no need for further risk reduction measures. Regarding the low-dose studies, it concluded, “Overall, taking together the low confidence in the reliability of the developmental neurotoxicity studies and the lack of consistency in the results of behavioural testing, no conclusions can be drawn from these studies.” The EC assessment cited the November 2007 CERHR expert panel report but not the April 2008 draft NTP monograph or the draft HC/EC screening assessment.

In 2007 the European Food Safety Authority (“EFSA”) had published an opinion on BPA safety which found that “conservative estimates of exposure were less than 30% of the [tolerable daily intake] in all population groups considered,” and that “low dose effects of BPA in rodents have not been demonstrated with sufficient certainty to serve as pivotal studies for risk assessment.” In July 2008 EFSA issued a reconsideration of its 2007 opinion in light of “ongoing discussions on the reported low-dose effects of BPA,” including the HC/EC draft screening assessment. However, the EFSA update concluded “that its previous risk assessment . . . can be considered as conservative for humans.”

## **LITIGATION**

Within days after NTP and HC/EC issued their draft BPA assessments in April 2008,

plaintiffs' attorneys began to file putative class actions in federal courts against the makers and retailers of BPA-containing products, mainly baby bottles and sports bottles. The complaints did not allege that exposure to BPA caused adverse health effects; instead, they alleged that implied representations that BPA-containing products were safe violated state consumer protection laws. On August 13 these actions were consolidated as a Multi-District Litigation matter in the Western District of Missouri, MDL-1967. As of November 3, 2008 there were 26 lawsuits pending in that consolidated proceeding.

## CONGRESS

In January 2008 the House Committee on Energy and Commerce, chaired by Rep. Dingell, and its Oversight and Investigations Subcommittee, chaired by Rep. Stupak, opened an investigation into the use of BPA in products intended for use by infants and children. This led to correspondence between the Committee and FDA over FDA's conclusion that exposure to food contact materials made with BPA is safe.

On April 29, 2008, two weeks after release of the draft NTP monograph, Senator Schumer and co-sponsors introduced the "BPA-Free Kids Act of 2008," S. 2928, a bill to ban BPA in children's products. On June 10 Rep. Markey and a co-sponsor introduced a bill in the House, the "Ban Poisonous Additives Act of 2008," H.R. 6228, which would ban BPA in food-contact materials. No further action was taken on either bill.

## FDA

Since most public and scientific attention has been focused on exposure to BPA from food-contact materials, FDA was a center of attention during 2008.

In February FDA sent a letter to the House Energy and Commerce Committee concluding that current exposure of adults and infants to BPA "is safe as defined in 21 CFR § 170.3(i)." (That provision states that "safe or safety means that there is reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use"). FDA sent additional information to that Committee in June.

On April 17, three days after release of the draft NTP monograph and the day HC/EC released its draft screening assessment, FDA Commissioner Andrew von Eschenbach formed an FDA-wide BPA Task Force, building on prior FDA staff reviews.

An FDA Assistant Commissioner presented testimony on BPA on May 14 to a subcommittee of the Senate Commerce, Science, and Transportation Committee, and on June 10 to a subcommittee of the House Energy and Commerce Committee. The testimony stated that "FDA's reassessment of possible 'low-dose' effects of BPA concluded that the current level of exposure to adults and infants is safe as defined in 21 CFR § 170.3(i)." It reported that FDA's evaluation of the draft NTP monograph was continuing, but in the meantime, "FDA is not recommending that consumers discontinue using food contact materials that contain BPA."

FDA's Center for Food Safety and Nutrition ("CFSAN") prepared an assessment of BPA for use in food contact applications as part of the BPA Task Force. In a draft released on August 15, CFSAN concluded that the low-dose studies on which the NTP draft monograph and the HC/EC screening assessment had relied were unreliable for risk assessment purposes: "In conclusion, the results of FDA's assessment indicate that the data on endpoints highlighted as of potential concern in recent reports . . . are insufficient to provide a basis to alter the NOAEL used to calculate the margin of safety . . . . FDA concludes that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and

adults.” Having dealt with BPA in food contact materials, FDA published a Federal Register notice requesting information on the use of BPA in other FDA-regulated products, 73 Fed. Reg. 61135 (Oct. 15, 2008).

The draft assessment on BPA in food contact materials was peer reviewed by the BPA subcommittee of FDA’s Science Board in a report submitted to FDA on October 31. Among other objections to the draft assessment, the peer review report disagreed with FDA’s rejection of the low-dose studies that NTP had found adequate: “the Subcommittee does not agree that the large number of non-GLP studies should be excluded from use in the safety assessment.” The BPA subcommittee considered that the margins of safety that CFSAN considered to be adequate “are, in fact, inadequate.” The report also made recommendations related to exposure, health effects, and proposed further avenues of research.

In a December 3 letter, FDA provided an initial response to the peer review report. The letter indicated that FDA “is reevaluating studies,” “revising the draft assessment,” and “planning to conduct” a number of additional studies. FDA promised to respond further to the peer review report in the future. Of note, FDA did not change its bottom-line assessment that food contact materials made with BPA are safe, nor did it propose any regulatory action. FDA’s previous statements about BPA safety remain on its website. On December 15 Laura Tarantino, head of the CFSAN Office of Food Additive Safety, explained, “[a]t this moment, with all information in front of us, we do not believe we have the data on which we could base a regulatory ban.” She also said that “I can’t tell you when we will finalize” the planned BPA studies, adding “There is a lot of work.”

FDA has been asked by various NGOs and citizens to adopt a ban on BPA in food contact materials. On October 28 the Natural Resources Defense Fund submitted a citizen petition to FDA asking FDA to “revoke all regulations permitting the use of a food additive that results in BPA becoming a component of food.” FDA has not yet responded to this petition. Under 21 C.F.R. § 10.30(e), FDA must provide at least a tentative response to the petition within 180 days of receipt. As of the end of 2008, FDA had established a public docket for the petition, FDA-2008-P-0577, but otherwise had not taken any action.

## **PROSPECTS FOR 2009**

The new Congress is likely to continue to pressure FDA to deal with BPA. Rep. Markey and Senator Schumer have indicated that they plan to re-introduce their BPA ban bills. While Rep. Dingell will no longer chair the House Energy and Commerce Committee, his successor, Rep. Waxman, has also expressed concerns about BPA. Rep. Waxman co-sponsored the Kid-Safe Chemicals Act of 2008, H.R. 6100, and its 2005 predecessor. His 2005 remarks about that bill specifically mentioned BPA as a chemical of concern.

The incoming Administration has already been approached about BPA. In November a coalition of 29 non-governmental organizations sent “environmental transition recommendations for the Obama Administration” which, among other things, called for FDA to revoke all approvals for BPA in food packaging and for the Administration to support a Congressional ban on the use of BPA in food packaging. Representatives of the group were scheduled to meet with the Obama transition team in December on environmental issues, with a key element being a push to ban BPA.

The head of the Obama transition team looking at FDA, and a rumored leading candidate to become FDA Commissioner, is Joshua Sharfstein, Commissioner of the Baltimore City Health Department and a former staffer for Rep. Waxman. Another candidate mentioned is Susan Wood, formerly Assistant FDA Commissioner for Women’s Health, for whom BPA might be an appealing issue. Other candidates mentioned include Steven Nissen, a

cardiologist at the Cleveland Clinic, and Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research. Although these candidates are associated with the pharmaceutical side of FDA, BPA will be an issue any incoming FDA Commissioner will find difficult to ignore.

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Key documents referred to above can be obtained through the following links:

- [National Toxicology Program monograph on BPA \(Sept. 2008\)](#)
- [Health Canada and Environment Canada screening assessment on BPA \(Oct. 2008\)](#)
- [Health Canada and Environment Canada proposed risk management approach for BPA \(Oct. 2008\)](#)
- [Japan's National Institute of Advanced Industrial Science and Technology risk assessment on BPA \(Nov. 2007\)](#)
- [European Commission, updated risk assessment on BPA \(final approved version awaiting publication, Apr. 2008\)](#)
- [European Food Safety Authority opinion on BPA \(adopted Nov. 29, 2006\)](#)
- [European Food Safety Authority opinion on BPA \(adopted July 9, 2008\)](#)
- [U.S. Judicial Panel on Multidistrict Litigation transfer order for BPA lawsuits \(Aug. 13, 2008\)](#)
- [BPA-Free Kids Act of 2008, S. 2928 \(introduced Apr. 29, 2008\)](#)
- [Ban Poisonous Additives Act of 2008, H.R. 6228 \(introduced June 10, 2008\)](#)
- [FDA congressional testimony on BPA \(Jan. 29, 2008\)](#)
- [FDA letter to House Energy and Commerce Committee on BPA \(Feb. 25, 2008\)](#)
- [FDA letter to House Energy and Commerce Committee on BPA \(June 5, 2008\)](#)
- [FDA congressional testimony on BPA \(May 14, 2008\)](#)
- [FDA congressional testimony on BPA \(June 10, 2008\)](#)
- [FDA draft assessment on BPA in food contact applications \(Aug. 14, 2008\)](#)
- [FDA request for information on FDA-regulated products made from BPA \(Oct. 15, 2008\)](#)
- [FDA Science Board Subcommittee on BPA peer review of FDA draft assessment \(Oct. 31, 2008\)](#)
- [FDA response to Science Board peer review \(Dec. 3, 2008\)](#)
- [Natural Resources Defense Council citizen petition to FDA on BPA \(Oct. 21, 2008\)](#)
- [NGO coalition recommendations to Obama transition team](#)

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