Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Bisphenol A in the Spotlight: FDA Refuses to Prohibit Use of BPA in Food Packaging

First synthesized by a Russian chemist in 1891 and deemed safe by the Environmental Protection Agency in 1976 when grandfathered in along with 62,000 other chemicals under the Toxic Substances Control Act, bisphenol A (BPA) was today confirmed for continued use in food packaging materials by the Food and Drug Administration (FDA). According to news sources, the agency rejected the Natural Resources Defense Council (NRDC) petition to ban the chemical, finding that the scientific evidence cited in the petition cannot be applied to humans, and the studies were too small or involved injecting BPA into animals rather than ingested over time, which is how human exposure occurs. *See The New York Times*, March 30, 2012.

Produced at an annual rate of more than 8 billion pounds worldwide, BPA has been detected in the urine of nearly every adult and child tested in the United States, and, while it is quickly "detoxified" by adults, the chemical's widespread use provides continuous exposures to low-level doses. It has been incorporated since the 1940s and 1950s into plastics, such as baby bottles, water bottles, and medical and dental devices, and as epoxy linings intended to extend shelf life for foods and beverages sold in metal cans. The American Enterprise Institute has estimated that the chemical lines nearly every one of the 130 billion food and beverage cans made in the United States each year. Jon Entine, "BPA: DOA?," *AEI, The Environmental Forum*, October 27, 2010.

BPA has also been found in infant foods sold in glass jars, because it is used to line the metal lids. Other sources of exposure include the thermal paper used as point-of-sale receipts and recycled paper such as toilet paper, newspapers and napkins. BPA has allegedly been shown to leach into foods and beverages especially when the containers are heated or cleaned with harsh detergents, or the foods stored in the containers are highly acidic.

Research on laboratory animals has purportedly indicated that the chemical is an endocrine disruptor that has been associated with abnormal weight gain,

SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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insulin resistance, prostate cancer, excessive mammary gland development, adverse neurological effects, breast cancer risk, fertility effects, heart disease, and diabetes. Among the earliest references to the scientific research in this *Update* is a breast cancer study reported in **Issue 130**. University of Missouri Professor Frederick vom Saal has been studying endocrine disruptors for some 20 years and has concluded that daily use of products containing BPA poses risks to human health even at low doses. A recent profile on vom Saal is summarized in **Issue 425** of this *Update*.

According to the chemical industry, BPA is among the most widely studied chemicals in the world, and most international regulatory bodies that have conducted literature reviews have concluded that the chemical does not pose a threat to human health. One of those reviews created some controversy in 2007, because it was found that the contractor which conducted the review for the National Institutes of Health worked for BPA manufacturers. Despite official pronouncements that the chemical is safe, a number of countries, states and local municipalities have banned its use in baby bottles and sippy cups, and the industry began phasing out its use in infant formula cans in 2009.

The government has apparently sought independent researchers to conduct the latest studies on the substance. According to Justin Teeguarden, the lead author of an EPA-funded study on whether BPA gets into the blood, "for the adult human population exposed to even very high dietary levels, blood concentrations of the bioactive form of BPA throughout the day are below our ability to detect them, and orders of magnitude lower than those causing effects in rodents exposed to BPA." *See The Examiner.com*, December 8, 2011. The study, titled "Twenty-four hour human urine and serum profiles of bisphenol a during high-dietary exposure," *Journal of Toxicological Sciences*, January 2012, found that serum concentrations were "on average, 42 times lower than urine concentrations," indicating that the body effectively metabolizes and eliminates the chemical. Teeguarden reiterated his findings during a March 30, National Public Radio **interview**.

Today's FDA response to the NRDC's 2008 petition seeking to prohibit the use of BPA as a food additive was required under a December 2011 settlement the agency reached in a lawsuit NRDC filed to force FDA to act on its petition. FDA publicly asserted in 1999 that BPA was safe when used in baby bottles, but, after indicating to Congress in 2008 that its safety assessment was based on industry-funded research, the agency suggested in **2010** that parents take steps to minimize their children's exposure to BPA, expressing its concern "about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children."

Meanwhile, the American Chemical Council (ACC) has asked FDA to prohibit the chemical's use in polycarbonate bottles and sippy cups, contending that BPA is no longer being used in these products. Representative Edward Markey

(D-Mass.) recently filed three petitions with FDA calling for a ban on the chemical's use in canned products and reusable food and beverage packaging. He reportedly claimed that ACC's rationale could be extended to these products. ACC responded by calling on the congressman to demonstrate that food and beverage packaging manufacturers have stopped using BPA, according to a news source. *See Representative Ed Markey Press Release*, March 19, 2012; *FoodQualitynews.com*, March 28, 2012.

FTC Issues Guidance on Consumer Data Protection

The Federal Trade Commission (FTC) has released a **report** recommending best business practices "to protect the privacy of American consumers and give them greater control over the collection and use of their personal data." Titled "Protecting Consumer Privacy in an Era of Rapid Change: Recommendations for Businesses and Policymakers," the guidance reportedly expands on preliminary findings first issued in December 2010 and covered in **Issue 374** of this *Update*.

In particular, the March 2012 report urges companies to protect consumer privacy by (i) building protections into every stage of product design, including "reasonable security for consumer data, limited collection and retention of such data, and reasonable procedures to promote data accuracy"; (ii) giving consumers a "Do Not Track" mechanism to opt out of data collection; and (iii) providing greater transparency about the collection and use of consumer information. Unlike the preliminary version, which applied its framework to all businesses, the final report excludes smaller entities that "collect and do not transfer only non-sensitive data from fewer than 5,000 consumers a year." It also refines the guidance "for when companies should provide consumers with choice about how their data is used," stating that companies need not provide this choice if the practice of collecting data is consistent with the context of the transaction and the company's relationship with the consumer, "or as required or specifically authorized by law."

In addition to encouraging industry "to accelerate the pace of its self-regulatory measures," FTC calls on Congress to enact privacy legislation that would mandate greater transparency about data collection practices and give consumers the right to access and dispute personal data held by information brokers. In the meantime, however, the commission intends to promote enforceable self-regulatory codes and "take action against companies that engage in unfair or deceptive practices, including the failure to abide by the self-regulatory programs they join." To this end, the framework stipulates five main action items that include the implementation of "an easy-to use, persistent and effective Do Not Track system" and improvements to mobile service privacy, but also address "the invisibility of… data brokers" as well as issues related to comprehensive tracking instituted by large platforms, "such as Internet Service Providers, operating systems, browsers, and social media."

"If companies adopt our final recommendations for best practices—and many of them already have—they will be able to innovate and deliver creative new services that consumers can enjoy without sacrificing their privacy," said FTC Chair Jon Leibowitz in a March 26, 2012, press release. "We are confident that consumers will have an easy to use and effective Do Not Track option by the end of the year because companies are moving forward expeditiously to make it happen and because lawmakers will want to enact legislation if they don't." *See The Wall Street Journal,* March 28, 2012.

LITIGATION

Court Narrows Claims in *Quaker Oats Labeling Litigation*

A federal court in California has granted in part and denied in part the motion to dismiss filed by Quaker Oats in consolidated cases alleging that the company falsely advertises products such as granola bars and instant oatmeal containing small amounts of *trans* fats as healthy. *In re: Quaker Oats Labeling Litig.*, No. 10-cv-00502-RS (U.S. Dist. Ct., N.D. Cal., San Jose Div., decided March 28, 2012).

According to the court, the plaintiffs' "primary contention" is that consuming "any amount of artificial 'trans fat' is unhealthy, and that therefore various aspects of the labeling on Quaker's products" are false and misleading under California law. The court earlier determined that some of the claims were preempted by federal law. Additional information about the litigation appears in **Issue 369** of this *Update*.

Regarding the plaintiffs' expanded pleadings, which complain of "various additional statements and images on Chewy Bars, Instant Oatmeal, and Oatmeal To Go Bars," the court refused to dismiss the claims on the ground that the Food and Drug Administration (FDA) has "thoroughly evaluated and rejected the key scientific premises" underlying the plaintiffs' liability theory. While Quaker Oats may use such evidence to rebut the plaintiffs' allegations, "there is no basis on a motion to dismiss to conclude the FDA is so infallible that it is wholly implausible for plaintiffs to contend trans fats present a health risk," the court said.

Addressing each labeling statement that the plaintiffs alleged were misleading, the court found some permissible under federal law and thus claims based on them preempted. Among these statements were (i) "Adds a dietarily insignificant amount of trans fat"; and (ii) "Heart Healthy" and images of hearts. The statements and images on which the plaintiffs could bring claims, according to the court, were (i) "Helps Reduce Cholesterol"; (ii) "All the nutrition of a bowl of oatmeal"; (iii) images of oats, nuts, fruits, and brown sugar; and (iv) statements such as "wholesome" and "smart choices made easy."

Court Dismisses Remaining Claims in Milk Antitrust Litigation

A federal court in Tennessee has dismissed the two remaining claims in antitrust litigation filed by certain retail processed milk sellers against Dean Foods Co. and the Dairy Farmers of America, Inc. *In re: Se. Milk Antitrust Litig.*, No. 2:08-MD-1000 (U.S. Dist. Ct., E.D. Tenn., Greeneville Div., decided March 27, 2012) (ruling applies to *Food Lion, LLC v. Dean Foods Co.*, No. 2:07-CV-188).

At issue were claims for violation of sections 1 and 2 of the Sherman Act (agreement not to compete and conspiracy to monopolize). The court found that the plaintiffs' expert failed to "create a material issue of fact on the question of whether the price increases were 'by reason of' an illegal conspiracy in violation of the antitrust laws and Plaintiffs do not allege an injury of the kind which the antitrust laws are designed to prevent." Because the plaintiffs were unable to establish antitrust injury, the court determined that the defendants were entitled to summary judgment "on this basis alone."

The court also decided that the plaintiffs could not prove the relevant antitrust geographic market and that their claims had to be judged by a rule-of-reason standard because the agreement between the defendants had "substantial vertical elements." According to the court, it is for the court, and not for a jury, to decide which legal standard to apply. Had the court found that the essence of the agreement was horizontal, that is, between "two horizontal competitors," the issues would have been analyzed under a *per se* standard.

Seventh Circuit Reinstates Claim That Jail Food Violated 8th Amendment

The Seventh Circuit Court of Appeals has reversed in part a district court dismissal of claims that being fed nutriloaf in a county jail subjected an inmate to cruel and unusual punishment in violation of his Eighth Amendment rights. ***Prude v. Clarke*, No. 11-2811 (7th Cir., decided March 27, 2012)**. The plaintiff was apparently serving time in a state prison facility but was transferred to and stayed in a county jail on several occasions during court proceedings on his post-conviction petition. He was fed only "nutriloaf," "a bad-tasting food given to prisoners as a form of punishment" and, during his third stay at the county facility began vomiting and experiencing stomach pains and constipation. He ultimately lost 8.3 percent of his weight.

According to the court, "[t]he defendants' response to his suit has been contumacious, and we are surprised that the district judge did not impose sanctions. The defendants ignored the plaintiff's discovery demands, ignored the judge's order that they comply with those demands, and continued their defiance even after the judge threatened to impose sanctions. But the judge failed to carry through on his threat, so the threat proved empty." The court also noted that the defendants failed to file a brief in the appeals court "and failed to respond to our order to show cause why they hadn't filed a brief. They seem to think that the federal courts have no jurisdiction over a county jail."

Discounting a "preposterous affidavit from a sheriff's officer," who stated that "Nutriloaf has been determined to be a nutritious substance for regular meals," the court determined that the uncontradicted evidence was sufficient to support the plaintiff's first claim. In this regard, the court stated, "Deliberate withholding of nutritious food or substitution of tainted or otherwise sickening food, with the effect of causing substantial weight loss, vomiting, stomach pains, and maybe an anal fissure, or other severe hardship, would violate the Eighth Amendment." While acknowledging that not all nutriloaf is unhealthful, the court observed that the defendants' failure to comply with the plaintiff's discovery demands left the court without information about the recipe for the nutriloaf served to the plaintiff, "or whether the ingredients were tainted or otherwise unhealthful."

Allowing this claim to proceed, the court suggested that the lower court request that a lawyer assist the plaintiff in litigating the matter and "also consider imposing sanctions on the defendants." The court further ordered the defendants to show cause within 14 days why they "should not be sanctioned for contumacious conduct in this court. If they ignore this order to show cause like the last one, they will find themselves in deep trouble."

OTHER DEVELOPMENTS

U.S. Appeals WTO's Stance on COOL Regulations

The Office of the U.S. Trade Representative (USTR) has **appealed** a ruling made by a World Trade Organization (WTO) panel against the United States in a dispute with Mexico and Canada over country-of-origin labeling (COOL) laws for beef and pork products.

Responding to complaints filed by Canada and Mexico, WTO's Dispute Settlement Panel ruled in November 2011 that although the United States has the right to require COOL regulations, specific requirements enacted in 2008 such as those calling for segregation of imported livestock before processing provide less favorable treatment to Canadian and Mexican livestock. The ruling was covered in **Issue 419** of this *Update*.

According to the appeal, USTR found several errors in the panel's ruling and contends, among other issues, that its COOL labeling does not impose unfavorable treatment of imported products because it "requires meat derived from both imported and domestic livestock to be labeled under the exact same set of circumstances." It also claims that "the Panel errs in its analysis of crucial facts related to segregation, commingling, and the price differential in the U.S. livestock market."

Canadian and Mexican officials were among those reportedly disappointed with the appeal. "The WTO panel decision recognized the integrated nature of

the North American supply chain and marked a clear win for our industry," said Canadian Agriculture Minister Gerry Ritz. "We are confident that the decision will be upheld so trade can move more freely, benefiting producers and processors on both sides of the border." *See Reuters,* March 23, 2012.

Food Companies Sign UK Government Pledge to Reduce Calories

The U.K. Department of Health has announced a new "Public Health Responsibility Deal" signed by 17 major food and beverage companies that have agreed to cap calories in their products. According to a March 24, 2012, department press release, the pledge aims "to cut five billion calories from the nation's diet" by asking signatories to actively promote lower-calorie options and to offer additional reduced-calorie items. The companies supporting the initiative include chain restaurants, retailers and manufacturers such as Coca-Cola Great Britain and Mars, Inc.

"We all have a role to play – from individuals to public, private and non-governmental organizations – if we are going to cut five billion calories from our national diet. It is an ambitious challenge but the Responsibility Deal has made a great start," said Health Secretary Andrew Lansley. "This pledge is just the start of what must be a bigger, broader commitment from the food industry. But it is a great step in the right direction and will help millions of us eat and drink fewer calories."

MEDIA COVERAGE

Analysts Suggest Parallels Between Soft Drink and Cigarette Companies

A March 27, 2012, "Great Speculations" column on *Forbes.com* draws parallels between carbonated soft drink (CSD) companies and the tobacco industry, claiming that a recent decline in CSD consumption in the United States has created a competitive market environment similar to that faced by cigarette manufacturers. Authored by contributors from Trefis.com, an investment and market research tool, the article notes that decreased CSD sales volume has prompted soft drink manufacturers to adopt strategies allegedly used by tobacco companies, such as raising product prices, promoting alternatives like energy drinks and juices, and arguing against taxation.

"Part of the reason why these industries attract high taxation is because the fiscal deficit of the government is in a mess and imposing taxes on these industries ensures higher revenue collection in the name of political mileage," concludes the article. "Cola companies won't hesitate to increase the prices periodically (although certainly not as aggressively as cigarette companies) especially since the cost of sales continues to rise. Soft drink companies will also continue to innovate/launch new products to lure consumers to increase consumption."

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SCIENTIFIC/TECHNICAL ITEMS

Researchers Present Rapid *Salmonella* Test at ACS Meeting

Researchers from Jackson State University in Mississippi have reportedly developed a rapid test for detecting *Salmonella* on food that uses popcorn-shaped gold nanoparticles. Presented March 27, 2012, at the 243rd National Meeting and Exposition of the American Chemical Society (ACS), the application relies on antibodies attached to gold nanoparticles that then transfer to *Salmonella* bacteria if present, in the process changing color from pink to blue.

"The test for lettuce requires just a tiny sample of lettuce leaf," explained lead researcher Paresh Ray. "It doesn't take a trained laboratory technician to perform the test or read the results. If the color changes from pinkish to bluish, that signals the presence of *Salmonella*. The test is suitable for use in farm fields and in remote areas of the developing world. We believe it may have enormous potential for rapid, on-site pathogen detection to avoid the distribution of contaminated foods."

Although they are still testing the solution's long-term toxicity and overall safety, the researchers have meanwhile used the technique to detect other microbes such as *E. coli*, speculating that the mechanism could also serve to eliminate bacteria altogether. "When you shine the right wavelength of light into contaminated water, for instance, the gold nanoparticles absorb that light and heat up. Those hot particles burn through the outer membrane of the *Salmonella* bacteria, killing the bacteria," Ray was quoted as saying. *See ACS Press Release,* March 27, 2012.

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Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.