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LEGISLATION, REGULATIONS AND STANDARDS

FDA to Re-Examine Bisphenol A Data; Congress Concerned About Industry Involvement in Safety Debate

Food and Drug Administration (FDA) Commissioner Margaret Hamburg has reportedly indicated that the agency will review its 2008 decision that bisphenol A (BPA) in children's food and beverage containers is, for the most part, safe. An agency spokesperson has apparently indicated that a new decision on the chemical, which is also used to seal canned food containers, will be released within "weeks not months."

The action comes after House Energy and Commerce Committee Chair Henry Waxman (D-Calif.) <u>asked</u> the commissioner to reconsider the agency's decision in light of "longstanding questions about the scientific data relied on by FDA under the previous Administration, as well as new press accounts detailing the influence of industry lobbyists on FDA's scientific analyses."

Waxman cites several *Milwaukee Journal-Sentinel* articles, based on agency e-mails and a leaked industry report of a public-relations strategy meeting, apparently indicating that (i) "when FDA conducted its review of BPA, it 'relied on chemical industry lobbyists to examine bisphenol A's risk, track legislation to ban it, and even monitor press coverage"; (ii) "FDA regulators sought information from [an industry trade group] to discredit a Japanese study that found [BPA] caused miscarriages"; (iii) "industry representatives discussed 'using fear tactics [e.g. "Do you want to have access to baby food anymore?"]"; and (iv) "industry officials 'hammered out' a public relations strategy they hoped would include the 'holy grail' of 'showcasing a pregnant woman to talk about the chemical's benefits.""

According to Waxman's June 2, 2009, letter, "These new press accounts raise serious questions about the extent to which FDA relied on the industry for independent scientific advice under the previous Administration." In addition to asking the agency to reconsider its position on BPA, Waxman calls for the agency to "examine its processes to determine whether its interaction with and reliance on industry groups was appropriate in this case, and whether changes are needed going forward."



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If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550. The same day, Waxman wrote to the chair of the North American Metal Packaging Alliance, Inc. (NAMPA) raising the issue of the purported joint trade association meeting "during which industry officials discussed a public relations strategy to counter efforts to regulate BPA." He requested that NAMPA provide to the committee by June 16 all materials relating to BPA meetings in April and May 2009, a list of all attendees and a list of all members of the "BPA Joint Trade Association."

While several NAMPA spokespersons have reportedly confirmed that the industry meeting took place and that the leaked memo accurately summarized some of the points made during this "brainstorming session," NAMPA Chair John Rost also indicated that the summary was incomplete and did not accurately reflect all of the discussions held over a five-hour period. NAMPA continued to accuse the media of selectively reporting only negative findings, reportedly stating that "BPA's use in metal packaging is critical to protecting food contents from microbiological contamination by enabling high temperature sterilization." According to one news source, NAMPA dismissed the leaked meeting memo as "blatantly inaccurate and fabricated," but defended the meeting's rationale, asking whether it should "come as a surprise that our industry seeks to defend the legitimate scientific process that has concluded BPA is safe to use in food contact applications?"

A spokesperson for the Environmental Working Group, which advocates banning the chemical, reportedly responded to news about the leaked memo by saying, "The BPA industry has adopted the tactics of tobacco and asbestos—when they had no science to make their case, they resorted to scare tactics and public relations. It seems pretty desperate."

Meanwhile, the European Food Safety Authority (EFSA) and the UK Food Standards Agency (FSA) have reportedly confirmed their approval of BPA's use in food-contact materials like hard, clear food containers and sealants in the linings of food and beverage cans. EFSA was quoted as saying, "None of the studies which have so far been published have brought into question EFSA's previous findings on BPA." According to an FSA spokesperson, "The view of the FSA on the chemical has not changed. We do not believe that UK consumers are exposed to levels of BPA that would be considered a danger."

And in related developments, Connecticut's House and Senate have apparently approved legislation by veto-proof majorities that would prohibit bisphenol A in products marketed for use by children younger than age 3, while California's Senate has approved a bill that calls the chemical a "known hormone disruptor" and would limit BPA to 0.1 ppb in any liquid, food or beverage intended primarily for infants or children ages 3 or younger. A similar proposal reportedly failed in the California Assembly in 2008 where it faced stiff industry opposition.

The American Chemistry Council has apparently criticized the California bill as "not based on science" and one that "will not improve public health." ACC accuses the state's legislators of bowing "to pressure from vocal special interest groups," claiming, "If this bill becomes law, it will do nothing to enhance product safety; it will, however, result in reduced product choice for consumers and needlessly more expensive food products." *See Milwaukee Journal-Sentinel*, May 29, 2009; *The*



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Washington Post, May 31, 2009; *Product Liability Law 360*, May 29 and June 3, 2009; *FoodQualityNews.com*, June 1, 2009; and *FoodProductionDaily.com*, June 2 and 3, 2009.

New FDA Commissioner Supports Food Safety Enhancement Act of 2009

U.S. Food and Drug Administration (FDA) Commissioner Margaret Hamburg has expressed support for the Food Safety Enhancement Act of 2009, which seeks to increase the agency's authority over U.S. and foreign food producers, including the power to issue mandatory recalls of tainted foods. "FDA needs new legal authorities to succeed in these roles and protect the public health," she was quoted as saying before the U.S. House Committee on Commerce and Energy on June 3, 2009. "This legislation would provide those tools."

A group of congressional Democrats in late May released a <u>discussion draft</u> of the Act, which would take effect in 18 months if passed. The legislation includes provisions that would (i) create an up-to-date registry of all food facilities serving American consumers, (ii) require such facilities to pay a \$1,000 fee to generate resources to support FDA oversight of food safety, (iii) strengthen criminal penalties and establish civil monetary penalties for food facilities that failed to comply with safety requirements, (iv) require high-risk facilities to be inspected at least once every six to 18 months, low-risk facilities once every 18 months to three years, and warehouses that store food to be inspected at least once every three to four years, and (v) enhance FDA's ability to trace the origin of tainted food in the event of an outbreak of foodborne illness.

Hamburg also endorsed the annual registration fee of \$1,000 on food companies and facilities, asserting that the fees would "represent a burden on companies" but signify "an investment in a robust and effective food safety system." According to Democratic lawmakers, the fees would generate an estimated \$378 million for increasing plant oversight and other FDA activities. Hamburg, however, did not recommend a specific number of inspections, noting that the fees would "not be adequate to implement the portfolio of activities laid out in the plan."

Republican representatives have cautioned that the bill could grow bureaucracy and place financial burdens on small businesses through mandatory fees and more stringent food-tracing systems. The food industry has reportedly accepted the necessity of some fees, but criticized the draft legislation for its sweeping implications. "We are not opposed to all fees," stated Pamela Bailey, president and chief executive of the Grocery Manufacturers Association. "We are concerned that a broadly applied fee to finance basic FDA functions, including inspections and enforcement, creates an inherent conflict of interest that would erode, rather than improve, consumer confidence in our food supplies." *See Product Liability Law 360* and *The Wall Street Journal*, June 3, 2009; *Reuters*, June 4, 2009.



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New FDA Bottled Water Rules Aim to Combat E. Coli

The Food and Drug Administration (FDA) has issued a <u>final rule</u> that requires bottled water manufacturers to face stricter standards to prevent *E. coli* contamination . All manufacturers are currently required to test source water for germs each week, but starting December 1, 2009, if tests prove positive for *E. coli*, companies must explain in writing how they eliminated the bacteria and retest samples before use.

FDA states that "bottled water containing *E. coli* will be considered adulterated and source water containing *E. coli* will not be considered to be of a safe, sanitary quality and will be prohibited from use in the production of bottled water." *E. coli* infection indicates fecal contamination that can apparently cause stomach cramps, diarrhea or possible fatal infections.

Although bottled water is currently tested for coliforms–a group of mostly harmless bacteria–and fecal contamination, the new rules require the water source itself to be tested. The new rules were reportedly developed to meet the 2006 U.S. Environmental Protection Agency standards for public drinking water. FDA said the 19 responses to its proposals from trade associations, industry, a law firm, an environmental advocacy organization, and consumers generally supported the rule. *See FoodNavigator-USA.com*, May 28, 2009; *Federal Register*, May 29, 2009.

USDA Issues Proposed Rule Amending Substances for Organic Crops

The U.S. Department of Agriculture (USDA) has issued a **proposed rule** that would amend its national list of allowed and prohibited substances for organic crop production and organic processing. The rule adds six substances, including the fortified cooking wines marsala and sherry for organic processing, and removes one substance from the list. Written comments must be received by August 3, 2009. *See Federal Register*, June 3, 2009.

Oregon Proposal to Require Nutritional Information Advances

Oregon's Senate has reportedly approved a bill (H.B. 2726) that would require restaurants with more than 15 locations nationwide to post information about calories, saturated fats and sodium for all menu items. According to a news source, some 69 percent of state residents polled have said that they want more nutritional information on restaurant menus. The legislation, which now awaits the governor's signature, would require the information to be posted on menus, menu boards and drive-through displays. *See Oregon Senate Democrats Press Release*, June 1, 2009.

LITIGATION

FTC Approves Final Consent Order in Whole Foods Litigation

The Federal Trade Commission (FTC) has <u>announced</u> its approval of a final consent order in its challenge to the merger of Whole Foods Market, Inc. and Wild Oats Markets, Inc. Under the agreement, Whole Foods will sell 32 of its supermarkets and give up unrestricted rights to the "Wild Oats" brand. When the agreement was



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announced in March 2009, FTC Chair Jon Leibowitz claimed, "As a result of this settlement, American consumers will see more choices and lower prices for organic foods."

Whole Foods and Wild Oats completed their merger before an appeals court finally agreed with the FTC that the merger could have anti-competitive effects and allowed it to move forward with administrative proceedings against the company. Thus, it was unclear until the consent order was filed what remedies could be ordered if the FTC proved its case. *See FTC Press Release,* May 29, 2009.

MDL Court Dismisses Aurora Dairy Litigation with Prejudice

The multitdistrict litigation (MDL) court in Missouri before which nearly 20 putative class actions against Aurora Diary Corp., an accredited organic certifying agent and several retailers had been consolidated for pre-trial proceedings, has dismissed the lawsuits with prejudice finding that federal organic food laws preempt the claims. *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, MDL NO. 08-1907 (U.S. Dist. Ct., E.D. Mo., E. Div., decided June 3, 2009).

Relying on a U.S. Department of Agriculture (USDA) investigation that found the dairy in violation of national organic program requirements relating to pasturing and organic management, the plaintiffs alleged violations of various state consumer protection laws, breaches of express and implied warrantees, negligence per se, negligent misrepresentation, and unjust enrichment. The court discusses at length the program under which Aurora Dairy conducted its operations with the overall supervision and control of USDA. While the court found that the litigation claims were not expressly preempted by federal law, it did find conflict preemption, that is, the implied preemption that exists when an actual conflict exists between federal and state law.

According to the court, the plaintiffs' state law claims sought to prohibit dairy producers from using "organic" terms or seals "even if a producer's certification has not been revoked or suspended" under the federal program. "As a result, for Plaintiffs' claims to succeed, the Court would have to invalidate the regulatory scheme established under the [Organic Foods Production Act] and [National Organic Program]. These state claims ask that the Court find that the certification determinations under that scheme were invalid and insufficient under these various state laws."

Finding this result "directly contrary to congressional intent," the court ruled that the plaintiffs were barred "from recovering for conduct that was absolutely in compliance with federal law." Because the USDA had not suspended or revoked Aurora Dairy's certification, the court dismissed the claims against all defendants with prejudice and denied plaintiffs' motion for leave to file an amended class action complaint.

\$86 Million Verdict in Starbucks Tip-Sharing Class Action Overturned

A California appeals court has determined that Starbucks did not violate state labor laws by allowing shift supervisors to share the tips left by customers in collective



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tip boxes and thus, overturned an \$86 million award made to a class of current and former Starbucks' baristas. <u>Chau v. Starbucks Corp.</u>, No. D053491 (Cal. Ct. App., 4th Dist., Div. 1, decided June 2, 2009). Because shift supervisors serve customers and rotate such duties with baristas, the appeals court determined that the shift supervisors were among those for whom the tips were intended. So ruling, the court distinguished Starbucks' policy of equitably distributing collective tip-box proceeds from the prohibited practice of mandatory tip pooling.

Crunchberries® Cereal Not Misleading, Says Federal Court

A federal court in California has dismissed a putative class action alleging that the maker of Cap'n Crunch with Crunchberries[®] cereal misrepresented its product in violation of the state's Business & Professions Code. *Sugawara v. Pepsico, Inc.*, No. 2:08-cv-01335 (U.S. Dist. Ct., E.D. Cal., decided May 21, 2009). Plaintiff alleged that the colorful "Crunchberries" depicted on the cereal box, combined with the use of the word "berry" in the product name, convey the message that the product contains fruit. She claimed that she purchased the product for some four years because she had been misled by defendant's advertising and misrepresentations, never discerning that the product has no berries of any kind and that the only fruit content is "strawberry fruit concentrate, twelfth in order on the ingredient list."

According to the court, "while the challenged packaging contains the word 'berries' it does so only in conjunction with the descriptive term 'crunch.' This Court is not aware of, nor has Plaintiff alleged the existence of, any actual fruit referred to as a 'crunchberry.'" The court also noted that Crunchberries® "are round, crunchy, brightly-colored cereal balls, and the [principal product display panel] clearly states both that the Product contains 'sweetened corn & oat cereal' and that the cereal is 'enlarged to show texture.' Thus, a reasonable consumer would not be deceived into believing that the Product in the instant case contained a fruit that does not exist."

The court found that the plaintiff failed to state her claims as a matter of law. Granting the defendant's motion to dismiss, the court refused to give the plaintiff leave to amend her complaint because "it is simply impossible for Plaintiff to file an amended complaint stating a claim based on these facts. The survival of the instant claim would require this Court to ignore all concepts of personal responsibility and common sense. The Court has no intention of allowing that to happen."

Importers of Melamine-Tainted Wheat Gluten to Plead Guilty

According to a news source, a Las Vegas-based company and its co-owners have agreed to plead guilty to charges that they imported from China melamine-tainted wheat gluten used to make the pet food that purportedly sickened and killed thousands of cats and dogs in the United States and Canada in 2007. More details about the criminal indictments appear in issue 247 of this Update. ChemNutra, Inc. and its co-owners, Stephen and Sally Miller, have apparently reached an agreement with federal prosecutors and will enter their pleas during a June 16, 2009, hearing.

The export broker, a Chinese company, allegedly mislabeled 800 metric tons of wheat gluten to avoid inspection in China and did not properly declare the



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contaminated product when it was shipped to the United States for use in pet food. ChemNutra took delivery of the wheat gluten in Kansas City and then sold it to various pet food manufacturers. While the indictments against the Millers did not allege that they knew the product was toxic, they were charged with knowing the product had been shipped to the United States under false pretenses and failing to notify their customers. The crimes charged, 26 misdemeanors and one felony count of wire fraud, carry the potential for hundreds of thousands of dollars in fines and significant prison terms in the aggregate. *See The Associated Press*, June 3, 2009.

OTHER DEVELOPMENTS

Traces of Cocaine Detected in Red Bull Cola®; CSPI Seeks Accounts of Negative Experiences with the Product

German officials are reportedly considering banning high-energy drink Red Bull Cola[®] after a food safety institute in North-Rhine Westphalia found traces of cocaine in the beverages. While the levels found did not pose a health threat, cocaine's presence in a product requires special licensing. German authorities in two states have reportedly ordered retailers to stop selling the beverage. The product's manufacturer reportedly admitted that it contains de-cocainized extract of coca leaf, but said the leaf "is used worldwide in foods as a natural flavoring." The drink, which also contains caffeine, vitamins and sugar, is apparently popular in bars where it is often mixed with vodka.

Hong Kong officials also found traces of cocaine in the beverage a few days after Taiwanese authorities reportedly confiscated some 18,000 cases of the product. The drink has been removed from the shelves of major supermarkets in Hong Kong, and its commissioner for narcotics is reportedly seeking legal advice about possible charges against importers and retailers. The company's Asia Pacific marketing director disputed the findings and said, "It would have been absolutely impossible for the Hong Kong or any other authorities to have found traces of cocaine in Red Bull Energy Drink."

In a related development, the litigation department of the Center for Science in the Public Interest (CSPI) is calling on consumers who have had negative experiences with Red Bull Cola[®] to submit a report to the organization. According to CSPI, "Research shows that, compared to drinkers who consume alcohol alone, drinkers who mix energy drinks such as Red Bull with alcohol are twice as likely to require hospitalization, to drive drunk, to ride with a drunk driver, to assault someone sexually, or to be a victim of sexual assault." *See Daily Mail*, May 25, 2009; *Agence France Presse*, June 2, 2009; *CSPI Litigation Project Docket*, 2009.

Northeastern University Project to Examine Ways Food, Tobacco Companies Shift Responsibility to Consumers

The National Cancer Institute has awarded a \$2.7 million grant to Northeastern University Law School for a five-year project led by anti-tobacco advocate Professor Richard Daynard. "Our goal is to examine how the tobacco industry has used



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personal responsibility rhetoric to influence courts, legislatures, regulatory agencies and public opinion, and to see to what extent the food and beverage industries have made use of similar strategies," Daynard said in a press release. "If the burden for addressing the harm is left with the consumer rather than the manufacturer, the manufacturer benefits – often at the expense of public health." *See Northeastern University Press Release*, May 28, 2009.

CSPI Announces "Xtreme Eating Awards 2009"

The Center for Science in the Public Interest (CSPI) has targeted a number of restaurants in its *Xtreme Eating 2009* report, which also singles out four plates as particularly high in calories, fat and sodium. The public watchdog has lambasted chain establishments for making "already bad foods even worse," claiming that some appetizers rival entrée-sized portions in terms of daily dietary intake. The report names Applebee's Quesadilla Burger, Chili's Big Mouth Bites, Cheesecake Factory's Chicken and Biscuits, and Red Lobster's Ultimate Fondue among the dishes that purportedly contribute to "America's epidemic of obesity and diet-related disease."

Pledging to make its "Xtreme Eating Awards" an annual affair, CSPI has backed legislation pending before the U.S. Congress that would introduce menu labeling laws similar to ones enacted in Nashville, New York City, Philadelphia, Portland, California, and Massachusetts. "Ultimately, Americans bear personal responsibility for their dining choices," stated CSPI director Margo Wootan in a June 2, 2009, press release. "But you can't exercise personal responsibility if you don't have nutritional information when you order. Who would expect 2,800 calories in a dessert?"

ACSH Criticizes Banzhaf's Call for Fast-Food Calorie Disclosures and Taxes on Snacks and Beverages

The director of nutrition at the American Council on Science and Health (ACSH), a non-profit "consumer education consortium," recently wrote a letter to the editor of the *Cleveland Plain Dealer* responding to an opinion piece authored by John Banzhaf, an anti-tobacco crusader and law school professor who in recent years has turned his attention to obesity-related issues.

Banzhaf suggested on May 15, 2009, that the key to lowering the cost of health care is to "directly attack the major preventable causes" of chronic illness: "smoking and obesity." He claimed that, at no cost to taxpayers, rates of obesity could be reduced by (i) charging the obese more for their health insurance; (ii) requiring restaurant chains to post the calorie and fat content of their offerings; (iii) mandating health warnings in fast food outlets; (iv) prohibiting deceptive food advertising, especially promotions targeted to children; (v) changing food subsidies to support "healthier foods"; and (vi) imposing sales taxes on soft drinks and foods "containing mostly 'empty calories."

Because a number of Banzhaf's suggestions for reducing obesity were the same as those he proposed for reducing smoking incidence, ACSH contended that he erred by "assuming obesity and smoking can be treated the same way." According to ACSH, posting calories and raising the prices of a few food items will not motivate people to "automatically choose a healthier diet." ACSH contends that promoting



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healthier lifestyles and educating people about how to make healthier nutritional choices are the key to behavior modification. *See Cleveland Plain Dealer*, May 21, 2009.

Global Food Crisis Challenges Policymakers; Malthus May Have Been Right

Known as outsourcing's "third wave," the trend among wealthy nations to buy farmland in developing countries is reportedly raising concerns among those dealing with issues like world hunger and water shortages. When the price of staples like wheat, rice and corn skyrocketed in recent years, food exporting countries, faced with food riots, restricted their exports to limit price increases in their own countries. That led wealthy food importing nations to begin investing in significant land acquisitions or leases on terms not necessarily advantageous to their targets. The food grown on these farms is all sent to the wealthy nations owning them, while the host countries continue to be threatened by hunger and malnutrition.

Host governments apparently claim that they are giving up land that is vacant or owned by the state, but empty land may actually be grazing land or farmed under arrangements recognized by local custom but not by law. The right to land also brings the right to access water, which Nestlé Chair Peter Brabeck-Letmathe has called "the great water grab." In Madagascar, a proposed land deal that would have taken half of the island's arable land resulted in the government's overthrow. A Washington, D.C.-based food policy think tank, trying to resolve such conflicts, has called for foreign investors to sign a code of conduct to improve the terms of deals for local residents. This would apparently mean respect for customary rights, shared benefits among locals, including hiring them to work the land, increased transparency, and promises not to export food if the host country is in the midst of a famine.

To end the global food crisis, some are calling for a new "green" revolution like the one that occurred from the 1950s to the 1990s and increased crop yields dramatically with the use of fertilizers, irrigation, pesticides, and monoculture. They point to advances in genetically modified crops that will be resistant to infestations and drought. But others contend that water sources have been depleted or poisoned from the "green" revolution, soils have been stripped of nutrients, and the world has grown more dependent on fossil fuels. They tout the benefits of sustainable and ecologically friendly practices that improve the well-being of small farmers and their families.

While some say that Thomas Robert Malthus, who claimed in the 1700s that "[t]he power of population is indefinitely greater than the power in the earth to produce subsistence for man," has been proven wrong, given our ability to feed most of the six billion people "added to the planet's dinner tables" since his time, others worry that the next doubling of the world's population will outpace even science's ability to create new ways to feed us all. *See The Economist*, May 21, 2009; *Financial Times* May 24, 2009; *Truth About Trade & Technology*, May 29, 2009; *National Geographic Magazine*, June 2009.



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MEDIA COVERAGE

New Butter Flavoring Target of Andrew Schneider Investigation

"Diacetyl-linked jury verdicts of tens of millions of dollars for injured flavoring workers and diagnoses of lung damage in at least three popcorn-loving consumers forced popcorn packers and other food processors to stop using the chemical butter-flavoring two years ago," writes investigative journalist Andrew Schneider in a May 28, 2009, article examining claims that possible diacetyl replacements– starter distillate and diacetyl trimmer–still include the "lung-destroying chemical." According to *Andrew Schneider Investigates*, scientists with the National Institute of Occupational Safety and Health (NIOSH) have published a book, titled *Advances in Food and Nutrition Research*, that suggests these diacetyl alternatives pose an even greater health risk because they penetrate "the deepest parts of the lung." Starter distillate is reportedly a product of milk fermentation that contains up to 4 percent diacetyl, while the diacetyl trimmer contains three diacetyl molecules. "The wording here (no added diacetyl) is telling," said co-author Kathleen Kreiss, who heads NIOSH's Field Studies Branch. "The chemical may not be added, but diacetyl is still in butter-flavored popcorn."

Schneider also reports that proposed diacetyl regulations may not include these substitutes, noting that occupational health experts have criticized the butter-flavoring industry for withholding information as proprietary. "We know far too little about the substitutes to diacetyl or reformulated diacetyl-compounds that food manufacturers are now using, or planning to use," one researcher at George Washington University's Department of Environmental and Occupational Health was quoted as saying.

SCIENTIFIC/TECHNICAL ITEMS

Study Claims BPA from Polycarbonate Bottles Identified in Humans

A Harvard School of Public Health (HSPH) study has reportedly found that "participants who drank for a week from polycarbonate bottles, the popular, hard-plastic drinking bottles and baby bottles, showed a two-thirds increase in their urine of the chemical bisphenol A (BPA)." Jenny L. Carwile, et al., "Use of Polycarbonate Bottles and Urinary Bisphenol A Concentrations," *Environmental Health Perspectives*, May 12, 2009. HSPH researchers followed 77 participants who first minimized their BPA exposure for a week, then drank all cold beverages out of plastic polycarbonate bottles for seven days, during which time their "urinary BPA concentrations increased 69 percent." According to the study authors, their work is the first to show that BPA leached from plastic bottles can result in "a corresponding increase in urinary BPA concentrations in humans." The study also forbid washing the bottles in dishwashers or putting hot liquids in them, as "heating has been shown to increase the leaching of BPA from polycarbonate."



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"This study is coming at an important time because many states are deciding whether to ban the use of BPA in baby bottles and sippy cups," stated the lead author in a May 21, 2009, HSPH press release, which further suggested that BPA "has been shown to interfere with reproductive development in animals and has been linked with cardiovascular disease and diabetes in humans." *See FoodProduction-Daily.com*, May 25, 2009.

In a related development, a separate study has claimed that mice with prenatal exposure to BPA "at environmentally relevant doses" and during "critical periods of differentiation" exhibited "long-term adverse reproductive and carcinogenic effects." Retha Newbold, et al., "Prenatal Exposure to Bisphenol A at Environmentally Relevant Doses Adversely Affects the Murine Female Reproductive Tract Later in Life," *Environmental Health Perspectives,* June 2009. Researchers apparently modeled their study on previous work involving the pharmaceutical diethylstilbestrol (DES), which has a chemical structure resembling BPA. Their results reportedly indicated "the induction of numerous abnormalities, including both benign and malignant lesions, in reproductive tissues of aged female mice exposed prenatally to a broad range of BPA doses (0.1-1,000 µg/kg maternal body weight)."

"In summary," the authors concluded, "the findings of the present study raise concerns about widespread exposure to BPA and, in particular, exposure to fetuses, infants, and children."

Study Alleges Reusable Grocery Bags May Pose Safety Threat

Reusable grocery bags and packages can apparently contain a high level of bacteria, yeast, mold, and coliform that can pose a significant food safety risk because of cross contamination, claims a new microbiological <u>study</u> funded by the Environment and Plastics Industry Council (EPIC). The study, reportedly the first of its kind in North America, looked at whether reusable grocery bags become an active bacterial growth habitat and breeding ground for yeast and mold after persistent use.

Richard Summerbell, former chief of Medical Mycology for the Ontario Ministry of Health and research director of an environmental microbiology lab in Toronto called Sporometrics, was commissioned to evaluate the findings of the EPIC study. He claimed that swab testing of a scientifically meaningful sample of both single-use and reusable grocery bags by two independent laboratories found unacceptable levels of bacteria in the reusable bags, with some bags having detectable levels of fecal intestinal bacteria. He said the study revealed that 64 percent of the reusable bags were contaminated with some level of bacteria and close to 30 percent had elevated bacterial counts higher than what is considered safe for drinking water.

"The main risk is food poisoning," Summerbell was quoted as saying. "But other significant risks include skin infections such as bacterial boils, allergic reactions, triggering of asthma attacks, and ear infections."

Meanwhile, some observers have reportedly questioned the study's findings given that the plastics industry would benefit from the greater use of plastic bags. "I definitely think that this is their last, final, desperate attempt to scare people off of reusable bags," said a spokesperson for the Toronto Environmental



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Alliance. In response, an EPIC spokesperson asserted that the plastics industry "strongly supports reduction and reuse, and recognizes use of reusables as good environmental practice, but it does not want to see these initiatives inadvertently compromise public health safety." *See CNW Group Press Release*, May 19, 2009; *foodproductiondaily.com*, May 22, 2009.

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FOOD & BEVERAGE LITIGATION UPDATE

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.



