Food & Beverage

LITIGATION UPDATE

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Table of Contents

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Legislation, Regulations and Standards

National Toxicology Program (NTP)

[1] NTP Issues Draft Brief on Bisphenol A; Canada Poised to Declare Chemical Toxic

The National Toxicology Program (NTP), which evaluates the potential for adverse effects on human reproduction or development from exposure to environmental substances, has released a draft **brief** summarizing the scientific literature on bisphenol A, a chemical widely used in food and drink packaging, including water and infant bottles and food-can and bottle-top coatings, as well as water supply pipes.

NTP's brief explains that the highest rates of bisphenol A intake occur in infants and children and that clear evidence indicates adverse developmental effects at high doses in lab rodents. Thus, the agency finds a "possibility that bisphenol A may alter human development," particularly among infants and children. NTP finds it to be a negligible risk for adults. Comments on the draft report must be submitted no later than June 4, 2008; peer review will occur during a June 11-12 meeting. *See* ***Federal Register***, April 15, 2008.

The number of studies on humans exposed to the substance is limited, and levels found in urine, blood and breast milk is relatively low. Adverse health effects in lab animals exposed to high doses include delayed puberty, growth reductions, early onset of puberty in female mice, lesions in the prostate and mammary gland in rats, and neural and behavioral alternations in rats and mice. The draft reportedly follows an 18-month review "that was fraught with allegations of bias, heated disputes among scientists and the firing of a consulting company with financial ties to the chemical industry," according to a news source. Frederick vom Saal, a University of Missouri-Columbia research scientist, reportedly found the NTP report "very, very much in line" with a statement that 38 scientists signed in 2007, saying that the chemical could be harmful to the brains and reproductive tracts of human infants. *See The Los Angeles Times*, April 16, 2008.

Meanwhile, the Canadian government is apparently poised to declare that bisphenol A is toxic. Should Health Canada make a public health announcement to this effect within the next few weeks, it would be the first country to make such a finding. A spokesperson for an environmental group that opposes bisphenol A was quoted as saying, "If the government issues a finding of toxic, no parent in their right mind will be using products made with this chemical. We will be arguing strongly for a ban on the use of this chemical in food and beverage containers." *See The New York Times*, April 16, 2008.

Centers for Disease Control and Prevention (CDC)

[2] CDC Issues FoodNet Report Card on Incidence of Infection by Foodborne Pathogens

The Centers for Disease Control and Prevention (CDC) has released a **report** summarizing the data collected from 10 U.S. states regarding the incidence of disease caused by pathogens transmitted through food. Data for the report come from the CDC's Foodborne Diseases Active Surveillance Network (FoodNet), which "quantifies and monitors the incidence of these infections by conducting active, population-based surveillance for laboratory-confirmed infections." Among the illnesses reported are those caused by *Campylobacter, Listeria, E. coli, Salmonella, Shigella, Vibrio*, and *Yersinia*. According to the CDC, none of the targets for Healthy People 2010, which established national health objectives and goals, were reached in 2007, and the incidence of *Salmonella* infection "was the furthest from its national health target, suggesting that reaching this target will require new approaches."

According to speakers at a recent food safety conference in Seattle, FoodNet data do not likely report all cases of infection, because the vast majority are not confirmed through laboratory testing. Further information about the conference appears elsewhere in this Update.

Food and Drug Administration (FDA)

[3] FDA Seeks Comments on Food Protection Plan

FDA recently **established** a public docket to receive information and comments pertaining to its Food Protection Plan, which the agency issued in November 2007 in response to a mandate from the Department of Health and Human Services. The plan presents "a robust strategy to protect the nation's food supply from both unintentional contamination and deliberate attack," according to FDA. In addition to improving intervention and recall initiatives, the new strategy focuses on preventative measures by "promoting corporate responsibility so that food problems do not occur in the first place." FDA is specifically seeking comments from industry stakeholders on the best practices and key benefits and challenges to implementing the steps proposed in the plan. The docket will remain open to the public until July 31, 2008. *See Food Navigator-USA.com*, April 1, 2008.

State and Local Governments

[4] Hawaii Agriculture Department Tests Food-Tracking Program

The Hawaii Department of Agriculture has reportedly launched a three-year pilot program that uses radio frequency identification (RFID) to track tomatoes and other produce from farm to market. The state has partnered with the University of Hawaii, Motorola Inc., Lowry Computer Products Inc., and GlobeRanger Inc. in enlisting four farms to label product containers with microchips that send information via an antenna to a centralized database. The program's administrators are apparently aiming to

expand the initiative when the cost of RFID technology declines, in addition to making the database available to consumers. "Our goal here is to develop a model that hopefully many other states can use," said the chair of the Hawaiian Board of Agriculture, which hopes that the system will improve recall capabilities during foodborne illness outbreaks. Some critics, however, have questioned whether the state intends to track individual products sold to the public. "It's crossing the line in the sand. Once you begin seeing them appear on individual consumer items, you open up a whole Pandora's box to track individuals," the founder of CASPIAN, an anti-RFID group, was quoted as saying. *See The Associated Press*, April 15, 2008.

Australia

[5] Australian Food Watchdog Tightens Regulations Pertaining to Product Health Claims

Food Standards Australia and New Zealand (FSANZ) this week recommended that the countries' food ministers further restrict product health claims by requiring companies to submit proposed marketing schemes to regulators. The food and health watchdog revised its regulations after a five-year review of "lite," "fat-free," "no added sugars," and similar claims, estimating that the new rules will close loopholes in existing laws and drastically decrease the number of years that the population loses to disability and premature death from heart attack over the next decade. FSANZ currently prohibits therapeutic claims, such as those linking certain foods to lower cholesterol, but allows general health or nutrition claims like "high in dietary fiber." The new rules would permit manufacturers to make therapeutic claims after vetting their products through FSANZ. In addition, companies proposing general health claims and content labeling will have to meet stringent product requirements, including threshold levels for specific ingredients. Those that fail to comply will also face penalties once the new recommendations become law. *See The Australian*, April 14, 2008.

Litigation

[6] Missouri Supreme Court Decertifies Fountain Diet Coke® Consumer Class

The Missouri Supreme Court has issued a permanent writ prohibiting a trial court from certifying a statewide consumer-fraud class of all purchasers of fountain Diet Coke® in Missouri, finding the proposed class definition impermissibly overbroad and improperly based on subjective criteria. So ruling, the court also determined that a writ of prohibition is the only way for an aggrieved party to invoke its jurisdiction where a court of appeals denies a request to review the trial court's certification order. ***State ex rel. The Coca-Cola Co. v. The Hon. W. Stephen Nixon*, No. SC99531 (Mo., decided April 15, 2008)**.

Pennington alleged that The Coca-Cola Company affirmatively misrepresented and omitted material information about the types of artificial sweeteners used in fountain Diet Coke® and thus violated state consumer-fraud laws. According to her complaint, the company's marketing scheme misled consumers into believing that fountain Diet Coke®, which is sweetened with a blend of aspartame and saccharin, is the same as bottled Diet Coke®, which is sweetened with aspartame only. Pennington claimed that she and many other consumers would not have purchased the fountain beverage had they known it

contained saccharin and further claimed that the deception itself caused irreparable harm. She sought to certify a class of consumers defined as "All individuals who purchased for consumption and not resale fountain Diet Coke in the State of Missouri after March 24, 1999, through the date of this order."

The court found this class definition indefinite because it included "an extremely large number of uninjured class members, that is, those who did not care if the Diet Coke they purchased contained saccharin." The court also found the definition indefinite because any attempt to modify the class by tying the definition more closely to the alleged injury would involve "an impermissible merit determination" that would be based on an individual's dislike of saccharin. In this regard, the court stated, "Membership may not depend on an individual's subjective preference."

The court noted that other putative class actions with nearly identical claims have similarly not been certified due to their overbroad and unascertainable class definitions. *See, e.g., Oshana v. The Coca-Cola Co.*, 225 F.R.D. 575 (N.D. Ill. 2005), *aff'd*, 472 F.3d 507 (7th Cir. 2006). Shook, Hardy & Bacon Managing Partner **John Murphy** and Partners **Lori Schultz**, **Andy Carpenter** and **Adam Moore** along with Chris Murphy and Mike Pope of McDermott Will & Emery and Taylor Fields of Fields & Brown formed the team that successfully argued the case on behalf of the appellants.

[7] NYC Fast-Food Caloric Content Rules Upheld in Federal Court Challenge

A federal court in New York has upheld a New York City regulation that will require chain restaurants with at least 15 outlets across the country that sell standardized meals to post caloric content information in their menus and on their menu boards. *N.Y. State Rest. Ass'n v. New York City Bd. of Health*, No. 08 Civ. 1000 (U.S. Dist. Ct., S.D.N.Y., decided April 16, 2008). The new rule, which will apparently take effect April 21, 2008, was written "to cure the constitutional infirmities" that the court identified in a ruling on a challenge to an earlier version of the regulation. Previously, the rule would have applied only to those restaurants that had already voluntarily disclosed nutrition information; now the rule is mandatory for all restaurants of a certain size and type. Seeing no reason to alter its prior analysis, the court determined that the revised regulation is not preempted by the federal Nutrition Labeling and Education Act of 1990.

The court also found that it would be "reasonable to expect that some consumers will use the information disclosed pursuant to Regulation 81.50 to select lower calorie meals when eating at covered restaurants and that these choices will lead to a lower incidence of obesity." Thus, the court concluded that "the required disclosure of caloric information is reasonably related to the government's interest in providing consumers with accurate nutritional information and therefore does not unduly infringe on the First Amendment rights of [New York State Restaurant Association] members."

The city's health department has apparently indicated that it would not start issuing fines for noncompliance with the regulation until June 3. The restaurant association has evidently not yet indicated whether it will appeal the court's ruling to the Second Circuit Court of Appeals. *See The New York Times*, April 16, 2008.

[8] Court Denies Request to Dismiss False Advertising Suit Against Poultry Producer

According to a press report, the federal district court considering claims that Tyson Foods Inc. misled consumers by advertising its chickens as "raised without antibiotics" has denied the company's motion to dismiss the case. Additional details about the litigation appear in issue 256 of this Update. Still pending is the request for preliminary injunction filed by plaintiffs Sanderson Farms, Inc. and Purdue Farms, Inc.; the court apparently planned to issue its ruling on that matter a week after the April 7-8, 2008, hearing. Tyson uses ionosphores in its chicken feed to prevent intestinal illness and received the U.S. Department of Agriculture's approval to claim that its chickens are "raised without antibiotics that impact antibiotic resistance in humans." The plaintiffs contend that the qualifying language is ineffective and deceives consumers. *See Product Liability Law 360*, April 11, 2008.

[9] Briefing Underway in Pet Litigation Involving Claims for Emotional Loss

An appeal pending before the Vermont Supreme Court raises issues involving whether pet owners can recover damages for the negligent infliction of emotional distress for harms to their pets. *Goodby v. Vetpharm, Inc.*, No. 2008-030 (Vt., appeal date n/a). While the claim arose from alleged shortcomings in veterinary treatment, similar claims were recently advanced in some of the litigation that followed the contamination of pet food by the melamine in wheat gluten imported from China. A number of animal care organizations and trade associations have filed an *amicus* brief in the Vermont case, urging the court not to recognize liability for emotional loss for owners whose pets are negligently injured or killed. They contend that the state has a history of controlling the circumstances under which people can be compensated for emotional harm and that expanding liability to benefit pet owners will cause increases in the cost of pet care that will ultimately be a detriment to the pets of owners who will be unable to afford necessary treatment.

Other Developments

[10] Marler's Food Safety CLE Conference Brings Diversity of Opinions and Expertise to Seattle

Organized and co-sponsored by counsel for both plaintiffs and defendants, "Who's Minding the Store? The Current State of Food Safety and How It Can Be Improved," a continuing legal education conference, convened in Seattle, Washington, April 11-12, 2008. Among the opening speakers was Richard Raymond, Undersecretary for Food Safety, U.S. Department of Agriculture (USDA), who discussed the jurisdiction of the Food Safety and Inspection Service (FSIS) over meat, poultry, eggs, and humane animal treatment. The food safety initiatives FSIS supports are implementing risk-based inspections that will focus on those plants presenting the highest risk and releasing the names of stores that have sold recalled products to consumers. A rule-making to this effect is making its way through USDA.

Among the nearly three dozen conference speakers were scientists, public health officials from all levels of government and agencies around the world, politicians, consumer advocates, educators, the media, and lawyers (representing both plaintiff and defense interests). Key points currently being debated among food safety experts include the

merits of a single federal food safety agency and mandatory recall authority; the relative roles of industry, state and federal governments and consumers in ensuring food safety; and the effectiveness of current food safety efforts such as product testing and audits, HACCP, consumer education, and product labeling.

Presenters addressed a range of issues; highlights include: (i) the Centers for Disease Control and Prevention released its annual foodborne illness report card on April 11 (further details appear elsewhere in this Update); (ii) a new method of gene sequencing will provide a better way to determine if produce has been contaminated with fecal material (*E. coli* cultures take too long and may miss its presence on the sample); (iii) the European Union plans to expand its RASFF alert and information network and go worldwide by 2015; and (iv) a World Health Organization food safety official is pushing to spend money on improvements to food safety in the developing world as a better way to enhance third world economies than providing development aid; this includes the efforts of the Codex Alimentarius Commission to provide food safety guidance to the governments of developing countries.

Conference materials contain presentation summaries and comprehensive resources on food safety regulation in Australia/New Zealand, the EU and the United Kingdom.

[11] Advocacy Groups Target Genetically Engineered Sugar Beets

A consumer advocacy organization is reportedly urging consumers to e-mail concerns about the use of genetically engineered (GE) sugar beets to sugar companies and candy manufacturers. Citizens for Health, which alleges that GE crops may pose health and environmental risks, apparently claims that Monsanto's GE sugar beets are ready for planting, and the companies have not renewed their pledge. The Organic Consumers Organization is also apparently urging consumers to take action on GE sugar beets and warns that consumers will not be informed that food products contain sugar made from bioengineered beets because the United States does not require such labeling.

Meanwhile, litigation challenging the deregulation of Roundup Ready® sugar beets remains pending in federal court in San Francisco. Farmers, food safety advocates and conservation groups apparently filed the lawsuit in January 2008, seeking a more thorough investigation into the environmental, health and economic effects of the U.S. Department of Agriculture's decision to deregulate the GE beets in March 2005 after finding that deregulation "would not present a risk of plant pest introduction or dissemination." *See FoodUSAnavigator.com*, April 16, 2008.

Scientific/Technical Items

[12] European Study Links *Trans* Fat Consumption to Breast Cancer

A European study has reportedly claimed that women with the highest blood-levels of *trans* fats have twice the breast cancer risk compared to women with the lowest blood-levels. Véronique Chajès, et al., "Association between Serum *trans*-Monounsaturated Fatty Acids and Breast Cancer Risk in the E3N-EPIC Study," *American Journal of Epidemiology*, April 4, 2008. Researchers with the French national scientific center at the University of Paris–South examined blood samples from 25,000 women enrolled in a large cancer trial between 1995 and 1998. Comparing the 363 study partici-

pants diagnosed with breast cancer to those without the disease, the study found that women with higher serum *trans* fat levels were more likely to develop breast cancer and that obese women were also at an increased risk for breast and other types of cancer. In addition, the study results suggested that women with higher levels of omega-3 fatty acids did not receive any benefits in cancer reduction. "At this stage, we can only recommend limiting the consumption of processed foods, the source of industrially products *trans*-fatty acid," the researchers concluded. *See Reuters*, April 11, 2008.

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