Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] Senators Request GAO Investigation After Poultry Worker Exposé

U.S. Senators Patty Murray (D-Wash.) and Edward Kennedy (D-Mass.) have asked the U.S. Government Accountability Office (GAO) to investigate "whether the Occupational Safety and Health Administration (OSHA) is effectively working to ensure that employers are accurately reporting injuries and illnesses in the workplace," according to a joint press release issued April 22, 2008. The announcement followed a Senate Health, Education, Labor and Pensions Committee hearing called in response to several Charlotte Observer articles alleging that a local poultry processor was underreporting worker injuries and illnesses. In particular, the senators have requested that GAO (i) "ensure that employers are properly recording injuries and illnesses"; (ii) "assess the trends in the number and types of recordkeeping audits and targeted inspections OSHA has conducted"; (iii) provide information on any studies or research available on the extent to which employers underreport injuries and illnesses"; (iv) "conduct a survey of occupational physicians in professional associations such as the American College of Occupational and Environmental Medicine who have expressed concerns about employer underreporting"; and (v) "provide suggestions on how to improve OSHA's efforts." "I want the GAO to take a good hard look at injury and illness reporting because frankly, it's a system that seems all too easy to game," said Murray. *See Meatingplace.com*, April 24, 2008.

U.S. Department of Agriculture (USDA)

[2] USDA and HHS Solicit Nominations for Dietary Guidelines Advisory Committee

USDA and the Department of Health and Human Services (HHS) have issued a **notice** announcing their intent to form a Dietary Guidelines Advisory Committee. Nominations for membership must be submitted by May 24, 2008. Federal law requires the publication of new dietary guidelines every five years. They form the basis for federal food and nutrition policy and education initiatives. The guidelines, "based on the preponderance of scientific and medical knowledge which is current at the time," were first published in 1980 and last revised in 2005. The agencies are seeking individuals who are knowledgeable about current scientific research in human nutrition and are respected and published experts in their fields. "They should be familiar with the purpose, communication, and application of the Dietary Guidelines and have demonstrated interest in the public's health and well-being through their research and/or educational endeavors." Relevant expertise includes the prevention of chronic





disease, energy balance, epidemiology, food safety and technology, general medicine, gerontology, nutrient bioavailability, nutrition biochemistry and physiology, nutrition education, pediatrics, public health, and evidence review methodology. *See Federal Register*, April 10, 2008.

[3] Meat and Dairy Trade Groups Support Ban on Downer Cows

In a petition filed with the USDA's Food Safety and Inspection Service (FSIS), the American Meat Institute, National Meat Association and National Milk Producers Federation reportedly requested that the agency amend its rules to keep all non-ambulatory, disabled cattle out of the nation's meat supply. Current rules apparently allow the meat of some non-ambulatory animals to enter the food supply after they pass antemortem inspection. The trade groups have reportedly pledged to encourage their members to adopt a voluntary moratorium on the slaughter and processing of sick cattle until FSIS revises its rules. A spokesperson for the American Meat Institute was quoted as saying, "Allowing the current rule to remain in force could ultimately undermine the confidence of U.S. consumers and foreign customers, in markets that are proving difficult to reopen in the first place." See Associated Press, April 22, 2008; Meatingplace.com, April 23, 2008;

Food and Drug Administration (FDA)

[4] FDA Announces Public Meeting to Discuss Pet Food Standards

FDA has <u>announced</u> a public meeting to solicit information from various stakeholders on "the development of ingredient standards and definitions, processing standards, and labeling standards

for pet food." Slated for May 13, 2008, in Gaithersburg, Maryland, the meeting invites the Association of American Feed Control Officers (AAFCO), veterinary medical associations, animal health organizations, and pet food manufacturers to comment on the FDA Amendments Act of 2007 (FDAAA), which directs the FDA to establish within two years "pet food ingredient standards and definitions, processing standards, and updated standards for pet food labeling that include nutritional and ingredient information." In particular, FDA has solicited feedback on whether to develop these standards for all animal feeds, noting that "the agency believes the most appropriate course of action is to develop ingredient standards and definitions and processing standards for all animal feeds, including pet food." FDA has also asked stakeholders to consider an array of relevant questions, including: (i) How to improve the nutritional information, ingredient information and feeding recommendations already present on pet food labels?; (ii) Whether to include on pet food labels a "Nutritional Facts" box similar to the one on human food products?; (iii) "What kind of ingredient definitions would provide adequate information to ensure the safe and suitable use" of pet food ingredients?; (iv) "Should formal standards be a part of ingredient definitions?"; and (v) "Would standards based on a risk-based, preventative and comprehensive approach . . . adequately address [the FDAAA's] processing standards requirement?" FDA is encouraging both stakeholders and the general public to submit comments before the meeting to ensure that all topics are considered.

In a related development, FDA has <u>announced</u> a public meeting titled "Meeting to Present Changes to the Animal Feed Safety System (AFSS) Project and the Ranking of Feed Hazards According to the Risks





They Pose to Animal and Public Health; Part 3: Swine Feed Example" for May 14, 2008, in Gaithersburg, Maryland. The meeting aims to gather further information from stakeholders on the third draft of the AFSS Framework and work-in-progress method "for ranking animal feed contamination by their risks to animal and human health." AFSS covers "the entire spectrum of agency activities from preapproval of food additives for use in feed, to establishing limits for feed contaminants, providing education and training, and conducting inspections and taking enforcement actions for ensuring compliance with agency regulations," according to FDA.

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[5] Environmental Department Proposes Ban on Bisphenol A in Baby Bottles

Canada's Department of the Environment has **proposed** prohibiting the use of bisphenol A in baby bottles based on the results of a draft toxicity assessment currently available for public comment. The draft assessment, conducted under the Canadian Environmental Protection Act, found that while most Canadians need not be concerned, exposure to bisphenol A can cause harm to newborn children. The proposed ban would apply to the "import, sale, or advertising of polycarbonate baby bottles." According to the government, adults can safely use products that contain bisphenol A. The chemical is used in a range of other products, but those products are not subject to the proposed ban. Health Canada and Environment Canada will accept comments on the proposed ban and its scientific basis until June 19, 2008.

Meanwhile, bisphenol A media coverage is proliferating in the wake of Canada's proposal and the

most recent pronouncement on the issue by the National Toxicology Program (NTP). Additional information about NTP's draft brief appears in issue 257 of this Update. USA Today reported that U.S. retailers are removing products, like water and baby bottles, from store shelves while manufacturers are pledging to find substitutes for the chemical. According to *The New York Times*, the bisphenol A "scare" is proving profitable to those manufacturers and chemical companies using and making plastic without the substance as well as those who make glass and food-grade stainless steel. A lengthy article appearing in a Kansas City weekly newspaper explores the issue from the perspective of Missouri biologist Frederick vom Saal, who has been studying "the harmful biological effect of bisphenol A" for years and is viewed as a "leading expert." He claims, after reviewing 115 scientific studies, that 90 percent of government studies found adverse lowdose effects from bisphenol A exposure, while industry-funded studies uniformly found no effect. Vom Saal advises consumers to stay away from plastic food packaging, especially where microwaving is involved, and, because the chemical is used in the lining of aluminum cans, calls for beer drinkers to "drink it out a glass bottle instead of out of a can."

In a related development, a Ph.D candidate at Columbia University has released some of her unpublished bisphenol A <u>dissertation</u> at *defending-science.org*. Sarah Vogel notes that political pressure to re-evaluate the chemical is mounting and reports that states, including California, Maryland, Minnesota, and Michigan, are considering banning bisphenol A in children's products. She is apparently concerned that these approaches are taking too long and urges the Food and Drug Administration to update its current safety standard.





She concludes that because bisphenol A at low doses alters breast and prostate tissues, disrupts brain development and behavior, and may increase the risk of developing insulin resistant diabetes and obesity, "lawmakers across the U.S. and world should support the removal of bisphenol A from our food, water, air, and bodies." *See USA Today*, April 21, 2008; *The Pitch*, April 24, 2008; and *The New York Times*, April 25, 2008.

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[6] China Considers Life Sentence for Violators of Food Safety Laws

The Chinese government has reportedly released a draft food safety law that would impose several penalties, including life imprisonment, for those convicted of producing substandard food. Under the proposed law, violators would face sentences ranging from fines, the confiscation of incomes and the revocation of food production certificates, to prison terms of three years to life. In addition, the regulations would create a system to track food products, as well as allow costumers to trace the place and time of origin. The National People's Congress (NPC) is seeking public input on the proposal until May 20, 2008, when the draft regulation and comments will go to the NPC Standing Committee for further study and approval.

Meanwhile, the China National Food Association has already criticized the plan as likely to raise production costs at a time when China's food prices are soaring. Some food and beverage companies have also asserted that the new regulations will continue to bypass the smaller operations responsible for previous violations of food safety laws. A Chinese official, however, apparently contended

that the law will boost international and domestic confidence in the country's food supply while expanding public participation in the political process. *See The New York Times*, April 20, 2008; *Portfolio Media* and *A Product Liability Prof Blog*, April 21, 2008.

Japan

[7] Japan Blocks Beef Imports from California Meat Packing Plant

The Japanese Ministry of Agriculture has blocked beef imports from a meat packing plant in California after allegedly finding that a shipment contained vertebral columns, which are banned as a precaution against bovine spongiform encephalopathy (BSE). Japanese importer Itochu Corp. has reportedly claimed that one of 700 boxes received from a National Beef Packaging Co. facility held prohibited cow parts, although no high-risk materials were found in other containers. The Ministry of Agriculture has since stated that the agency will increase spot inspections to 10 percent from 1 percent of all U.S. beef imports, including those from compliant companies. Chief Cabinet Secretary Nobutaka Machimura, however, told reporters that the incident did not represent a "systematic problem" and was unlikely to affect negotiations to relax trade restrictions between the two countries. The Japanese government previously halted U.S. beef imports from 2003 through 2006, citing BSE as a concern. See Portfolio Media, April 23, 2008; Bloomberg.com, April 24, 2008.





State and Local Governments

[8] Ohio to Allow Qualified Hormone-Free Milk Labels

Ohio lawmakers reportedly approved labeling for milk products that allows producers to indicate that their cows were not treated with synthetic growth hormones as long as the labels also include a disclaimer to the effect that there is no significant difference between milk produced by cows receiving the hormone and cows that do not. According to a press report, some organic dairy producers have decided to stop advertising that their products are free of the growth hormone, claiming it will be easier not to label the milk than to comply with the new rule. *See Associated Press*, April 21, 2008.

In a related development, a recent *Vanity Fair* article focuses on the efforts Monsanto has undertaken to prevent dairies across the country from advertising their products as growth hormone free. The company has apparently been active at the federal and state levels to both gain approval of its growth hormone and to prohibit milk advertising that it claims "reflects adversely on Monsanto's product." The article also addresses efforts the company has undertaken to protect its patents for genetically modified seeds by enforcing its licensing agreements with farmers.

[9] Maine Increases Taxes on Beer, Wine and Soft Drinks

Maine Governor John Baldacci (D) has reportedly signed legislation that will increase the excise tax on large beer and wine manufacturers and impose a new tax on the syrup used in soft drinks. The revenues raised will be used to fund a health insur-

ance program. The taxes will apparently increase the cost of beer by 12 cents per gallon, while the wine excise taxes will go from 30 cents to 65 cents per gallon. Soda syrup will now be taxed at \$4 per gallon, and the new levy on bottled soft drinks will be 42 cents per gallon. If passed on to consumers, the cost for a liter-bottle of soda could increase by 11 cents, and a can could increase by 4 cents.

The Center for Science in the Public Interest (CSPI) lauded the measure; Executive Director Michael Jacobson was quoted as saying, "Here's an idea that Democrats and Republicans alike should get behind. Use small taxes on soda and booze to fund inexpensive interventions that improve diet, encourage physical activity and otherwise prevent disease. Before too long we'd eventually spend billions less mopping up the mess with angioplasties, bypasses, statins, and other expensive surgeries and drugs." Maine Republicans evidently do not support the plan, saying that a tax increase "in this economy is a very bad idea." See Maine Sunday Telegram, April 17, 2008; CSPI Press Release, April 18, 2008.

Litigation

[10] Ninth Circuit Allows Deceptive Marketing Claims to Proceed Against Gerber

The Ninth Circuit Court of Appeals has reversed an order dismissing putative class claims filed under California law alleging that Gerber Products Co. misled consumers in the packaging for its Fruit Juice Snacks®. Williams v. Gerber Prods. Co., No. 06-55921 (9th Cir., decided April 21, 2008).

Plaintiffs claimed that Gerber deceived consumers by (i) using the words "Fruit Juice" on its packaging alongside images of oranges, peaches, strawberries,





and cherries, when the product contains only white grape juice from concentrate; (ii) including a package side panel statement describing the product as made "with real fruit juice and other all natural ingredients," despite the fact that the two most prominent ingredients in the product are corn syrup and sugar; and (iii) labeling the product as a "snack" instead of a "candy," "sweet" or "treat." After the complaint was filed, Gerber made some changes to its packaging, including renaming the product "Fruit Juice Treats" and removing the word "nutritious" from the label.

The trial court dismissed the claims, finding that the statements were not likely to deceive a reasonable consumer given the ingredient list on the side of the box and that the "nutritious" claim was nonactionable puffery. The appeals court decided to consider the merits of the appeal despite briefing deficiencies because *amicus* briefs from the Center for Science in the Public Interest and the California attorney general provided additional support for an otherwise meritorious appeal.

The district court found that "no reasonable consumer upon review of the package as a whole would conclude that Snacks contains juice from the actual and fruit-like substances displayed on the packaging particularly where the ingredients are specifically identified." The appeals court disagreed, finding that reasonable consumers should not "be expected to look beyond the misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box. The ingredient list on the side of the box appears to comply with FDA regulations and certainly serves some purpose. We do not think, however, that a busy parent walking through the aisles of a grocery store should be expected to verify

that the representations on the front of the box are confirmed in the ingredient list."

The court further noted, "We do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield for liability for the deception." Finding that plaintiffs had stated a claim and, "given the opportunity," might be able to prove that a reasonable consumer would be deceived by the product packaging, the court determined that the district court "erred in concluding, without considering any evidence beyond the packaging itself, that [plaintiffs'] complaint failed to state a viable claim." The court declined to consider Gerber's argument that some of the claims were preempted under the Federal Food, Drug, and Cosmetic Act because the issue was raised for the first time in Gerber's answering brief.

[11] Federal Appeals Panel Considers Whole Foods, Wild Oats Merger

According to a news source, the Federal Trade Commission's (FTC's) appeal of a district court order rejecting its request to block a merger of premium natural grocery chains was heard before a three-judge panel of the D.C. Circuit Court of Appeals on April 23, 2008. The FTC contended that Whole Foods Market Inc.'s takeover of Wild Oats violated antitrust laws and would harm consumers. The agency apparently argued before the appeals court that the district court erred by failing to consider all of its evidence and applied an incorrect legal standard. Most of the hearing was reportedly devoted to arguments about the transaction; left unaddressed was how the deal could be rescinded. Whole Foods' counsel reportedly noted after the hearing that Wild Oats no longer exists; he was





quoted as saying, "We believe the case is moot at this point." It is unknown when the legal panel will issue its decision. *See Associated Press*, April 23, 2008.

[12] Federal Court Orders Tyson to Stop Using "Raised Without Antibiotics" Advertising

Finding that consumers are misled by ads that claim its chickens are raised without antibiotics, a federal court in Maryland has issued a preliminary injunction against Tyson Foods, Inc. in litigation brought by rival chicken producers under the Lanham Act. *Sanderson Farms, Inc. v. Tyson Foods, Inc.*, No. RDB-08-210 (U.S. Dist. Ct., D. Md., decided April 22, 2008). Plaintiffs alleged that Tyson advertisements containing the claims "Raised Without Antibiotics" and "Raised Without Antibiotics that impact antibiotic resistance in humans" are false and misleading to consumers.

According to the court, the unqualified claim is literally false because Tyson, in addition to using an antibiotic in its chicken feed, injects eggs with an antibiotic two to three days before they hatch. While the antibiotic at issue has not been found to affect antibiotic resistance in humans, the court, relying on survey evidence, also found that a majority of consumers did not understand the qualified label despite its approval by the U.S. Department of Agriculture (USDA). Many apparently believed that Tyson chickens are free of all antibiotics. The court further found significant harm to the plaintiffs because Tyson increased its sales while the plaintiffs lost sales due to Tyson's purportedly aggressive marketing campaign.

Although the court did not address the merits of the litigation in deciding plaintiffs' request for preliminary injunctive relief, it found "a strong likelihood of success by Plaintiffs on the merits of this case when it proceeds to trial" and that "the public interest compels the issuance of a preliminary injunction during the pendency of this case." The court found unpersuasive Tyson's argument that plaintiffs generally do not prevail on Lanham Act claims where the government has determined that certain labeling information is not false or misleading. According to the court, the cases cited involved the Food and Drug Administration which has broader jurisdiction, including reviewing advertisements. The court refused to "extend USDA expertise into an area, i.e., advertising, which the agency has no congressional authority to enter, while at the same time curtailing the congressional protections explicitly accorded to 'persons engaged in such commerce' under the Lanham Act."

Affected by the court's order are all of Tyson's non-label promotions such as TV commercials, radio spots, print ads, billboards, circulars, and posters, as well as point-of-purchase materials. Tyson has pledged to appeal the ruling. A spokesperson was quoted as saying, "We strongly disagree with this decision and will appeal since we firmly believe we have acted responsibly in the way we have labeled and marketed our products." *See Tyson Food Service Press Release*, April 22, 2008.

[13] Restaurant Association Obtains Stay of NYC Menu-Posting Requirements

The New York State Restaurant Association, which unsuccessfully challenged a New York City regulation requiring certain restaurants to post caloric content information on their menus and menu boards, has reportedly obtained a brief stay of the rule's implementation. A three-judge panel of the Second Circuit Court of Appeals will consider on April 29, 2008, whether to continue the delay while the association appeals the lower court's ruling. The





association contends that the case raises novel legal issues. Further details about the district court's decision upholding the regulation appear in issue 257 of this Update. Among the issues the association apparently plans to raise on appeal is whether the city is violating the First Amendment by forcing its view on restaurant customers, i.e., that caloric information is the only nutritional factor they need to consider in making their choices. City officials have reportedly indicated that any delay in implementation would "likely have a negative effect on the public health." *See Associated Press*, April 22, 2008; *The New York Times*, April 24, 2008.

Other Developments

[14] Agroterrorism Conference Participants Learn About Latest Foodborne Illness Developments

During the *Third International Symposium on* **Agroterrorism** held April 22-24, 2008, in Kansas City, Missouri, participants heard what the Food and Drug Administration (FDA) is doing to address food safety and defense issues from Assistant Commissioner for Food Protection David Acheson. Acheson, who is a fellow of the U.K.'s Royal College of Physicians, focused on the FDA's Food Protection Plan, which was introduced in November 2007. He outlined how the increasing incidence of foodborne illness has made it essential for government and the private sector to do more to protect the nation's food supply and pointed to the various administrative actions and legislative proposals that have been launched under the new plan. The agency is calling for mandatory recall authority and is seeking legislation that will expand its authority in a number of areas, including accrediting third parties to do food inspections and establishing a system of electronic

import certification to keep out high-risk, uncertified goods.

The symposium was coordinated by the Federal Bureau of Investigation and the U.S. Department of Justice, and Shook, Hardy & Bacon served as a cosponsor. SHB Partner Chris McDonald addressed contingency plans for agroterrorism events. A representative from plaintiff's firm Marler Clark discussed "The Economics, Law and Politics of Foodborne Illness Litigation." Attorney Denis Stearns provided a history of food safety regulation to place current initiatives in perspective and described how product liability law developed so that injured consumers could recover from manufacturers without having to prove fault. According to Stearns, simply showing that a product is defective and that the defect caused injury is enough to prove liability and recover damages. Stearns opined that companies have little incentive to invest in food safety because steps taken to ensure safety are invisible, and it is, consequently, difficult to charge a premium for safer products. Stearns referred to litigation as an incentive for food safety and said his firm will not take a foodborne illness case unless the facts and law support the claim, the likely recovery is high enough for both the client and law firm to recover, and the likelihood of settlement is high.

[15] Swiss Retailers Association Adopts Code of Conduct for Nanotechnology in Consumer Products

The Swiss retailers association known as IG DHS has adopted a <u>Code of Conduct</u> for the handling of nanotechnology in consumer products. The code requires that nano-specific aspects of materials be taken into account in the workplace and during storage and transport. It also requires that new health-related or environmentally related findings





be communicated quickly and openly by manufacturers and suppliers. Under the code, retailers are responsible for requesting relevant information from their manufacturers and suppliers. Most major retailers in Switzerland have reportedly indicated they would comply with the code, in part to avoid the consumer criticism that accompanied the increased presence of genetically modified foods in the marketplace. *See BNA Daily Environment Report*, April 21, 2008; *Food Navigator-USA.com*, April 23, 2008.

Scientific/Technical Items

[16] Study Finds Life Expectancy Declining for Some American Women

A recent study by the University of Washington and Harvard School of Public Health claims that life expectancy has declined to pre-1980s standards for 12 percent of the nation's women. Majid Ezzati, et al., "The Reversal of Fortunes: Trends in County Mortality and Cross-Country Mortality Disparities in the United States," PLoS Medicine, April 2008. Looking at U.S. mortality and cause-of-death data from 1961 through 1999, researchers found that between 1983 and 1999, life expectancy for women in 1,000 counties fell to 75.5 years from 76.5 years, while the longevity of those in the healthiest areas reached 83 years. The study attributed the downward trend to increased mortality from diabetes, lung cancer, emphysema, kidney failure, and other obesity-related diseases that mainly affected populations in rural and low-income areas in the Deep South, Appalachia, the lower Midwest, and parts of Maine. In addition, the researchers reportedly predicted that an obesity epidemic could continue to affect other regions of the United States, ending a nearly unbroken rise in life expectancy since the

mid-1800s. "This is a harbinger. This is not going to be isolated to this set of counties, is my guess," the study's lead author was quoted as saying. *See The Washington Post*, April 22, 2008.



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LITIGATION UPDATE

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Leo Dreyer and Mary Boyd in the Kansas City office of SHB.

If you have questions about the Update or would like to receive back-up materials, please contact us by e-mail at ldreyer@shb.com or mboyd@shb.com.

You can also reach us at 816-474-6550.

We welcome any leads on new developments in this emerging area of litigation.





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