Shook, Hardy & Bacon L.L.P.

ISSUE 396 | MAY 27, 2011

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

CSPI Wants FSIS to Declare *Salmonella* in Meat and Poultry an Adulterant

The Center for Science in the Public Interest (CSPI) has filed a citizen petition "requesting that the administrator of the Food Safety and Inspection Service (FSIS) . . . issue an interpretive rule declaring certain delineated strains of antibiotic-resistant [ABR] *Salmonella*, when found in ground meat and ground poultry, to be adulterants" under federal law. ***In re: CSPI Petition, No. n/a (USDA FSIS, filed May 25, 2011)***. Noting that FSIS declared *E. coli* an adulterant in 1994, the petition contends, "Scientific and medical research demonstrates that contamination of meat and poultry by ABR strains of *Salmonella* poses grave public health dangers that are comparable to those posed by *E. coli* 0157:H7 in 1994."

According to the petition, several ABR strains in ground meat and poultry products have resulted in recalls, outbreaks and deaths. Seeking expedited review, CSPI claims that 36 documented outbreaks, causing thousands of illnesses and some deaths, were linked to ABR bacteria since the 1970s, and 39 percent occurred in FSIS-regulated meat and poultry products. The organization also claims that "[a]n antibiotic-resistance pattern was reported for 25 of those 36 outbreaks." The petition cites studies that found ABR bacteria in some 20 percent of ground meat products purchased from supermarkets. CSPI argues that ABR *Salmonella* is an "added substance" under federal law because it "occurs due to an act of humans: the use of antibiotics on farms or feedlots."

This petition's filing coincides with a lawsuit filed the same day against the Food and Drug Administration by a coalition of organizations, including CSPI, calling for that agency to withdraw its approval for most non-therapeutic uses of two antibiotics in animal feed. The other action is summarized elsewhere in this *Update*.

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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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FDA Meeting to Target FSMA's Inspections, Compliance Provisions

The Food and Drug Administration (FDA) has **announced** a public meeting to discuss inspections and compliance provisions of the recently enacted Food Safety Modernization Act (FSMA). Set for June 6, 2011, in Silver Spring, Maryland, the meeting will allow stakeholders to comment on FSMA's implementation strategies regarding (i) "enforcement authorities"; (ii) "frequency and targeting of facility inspections"; (iii) "manner of inspection in a preventive controls environment"; and (iv) "improving the reportable food registry (RFR)." The meeting will also be available through live Webcast, and FDA encourages early registration. Details of FSMA were covered in **Issue 376** of this *Update*. *See Federal Register,* May 26, 2011.

FDA Studies Labeling Claims on Whole-Grain Products

The Food and Drug Administration (FDA) is **seeking** public comment on a study examining labeling claims on whole-grain products. Titled "Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages," the study is part of the agency's "continuing effort to enable consumers to make informed dietary choices and construct healthful diets," according to FDA.

The study will examine (i) "consumer judgments about a food product including its nutritional attributes, overall healthiness, and health benefits"; (ii) "consumer judgments about a label in terms of its credibility in conveying the product's nutritional attributes and its helpfulness in making product purchasing decisions"; (iii) "consumer perceptions about differences between different statements, such as 'Made with Whole Grain,' 'Contains Whole Grain,' and 'Whole Grain'"; (iv) "consumer extrapolation of whole grain statements beyond the scope of the statements themselves (*i.e.* halo effects)"; and (v) "how whole grain statements influence consumer use of the Nutrition Facts." FDA requests comments by July 25, 2011. *See Federal Register,* May 26, 2011.

Meanwhile, FDA has announced that the Office of Management and Budget has approved two collections of information involving the food sector. Approval for "**Color Additive Certification Requests and Recordkeeping**" expires on April 30, 2014. Approval expires on April 30, 2013, for "**Experimental Study of Nutrition Facts Label Formats**." *See Federal Register,* May 25, 2011.

British Docs to Fatten Wallets with Advice to Obese Patients

General practitioners (GPs) in the United Kingdom will reportedly receive payments each time they advise patients to lose weight and by maintaining lists of those who exceed weight guidelines. The GPs will apparently be able to offer free memberships in diet clubs, paid for by the National Health Service (NHS), as part of the new weight-control program. Critics are reportedly appalled

that simply advising a patient to lose weight, without more, will increase GP incomes. They recommend that referrals to programs, such as Weight Watchers® and Slimming World®, would be more effective in addressing an obesity problem that is purportedly costing NHS more than £6 billion annually. *See The Telegraph*, May 22, 2011.

Dutch Ministry Issues Nanotech Safety Guidance for Workplaces

The Dutch Ministry of Social Affairs and Employment has issued **guidance** for employers and employees working with nanomaterials and nanoproducts. The guidance provides information about designing suitable control measures to limit exposures according to the current state of knowledge about nanomaterial safety. It also recommends ways of instructing employees about good work practices, potential risks and risk management measures when new nanomaterials are introduced into the workplace. *See Nanowerk*, May 24, 2011.

LITIGATION

FTC False Claims Hearing Against POM Wonderful Underway

An administrative law judge has apparently begun hearing a Federal Trade Commission (FTC) **complaint** alleging that POM Wonderful LLC makes false and unsubstantiated claims that its pomegranate juice products will prevent or treat "heart disease, prostate cancer, and erectile dysfunction." According to a news source, the government opened its case by asserting that the studies on which the company relied do not support the marketing claims and that its executives "repeatedly ignored warning signs that the marketing didn't match the science."

Food and beverage companies and advertisers are reportedly watching the dispute closely; if the agency prevails, the companies will have to support their advertising with more scientific evidence. POM contends that its product claims are supported by $35 million in research and that the company has "sponsored or participated in more than 90 scientific investigations with over 65 studies on POM products, including 17 clinical trials." POM will also try to show that the FTC's complaint violates the company's First Amendment free speech rights.

New York University Nutrition Professor Marion Nestle is following the case on her blog. She was quoted as saying, "It's so unregulated. The standards have gotten lower and lower and lower. You can't sell food without a health claim nowadays. Nobody will buy it." She said that if POM prevails, it would be "open season on health claims, and companies can say anything they want." It is anticipated that the hearing will continue over the next four months. *See Food Politics*, May 23, 2011; *Bloomberg*, May 24, 2011.

Advocacy Non-Profits Call for FDA to Address Antibiotics in Animal Feed

A coalition of non-profit advocacy organizations has filed a complaint for declaratory and injunctive relief against the Food and Drug Administration (FDA), alleging that the agency has unreasonably delayed action on several of its petitions relating to the use of antibiotics in animal feed. *Natural Res. Def. Council v. FDA*, No. 11-3562 (U.S. Dist. Ct., S.D.N.Y., filed May 25, 2011). The plaintiffs seek orders compelling the agency to "withdraw approval for subtherapeutic uses of penicillin and tetracyclines, unless FDA's findings are reversed in new administrative proceedings." According to the complaint, while FDA determined in 1977 that these drugs" have not been shown to be safe," it never withdrew its approvals for the drugs' subtherapeutic uses.

Contending that "misuse and overuse of antibiotics has given rise to a growing and dangerous trend of antibiotic resistance," the coalition alleges that some of its organizations filed citizen petitions in 1999 and 2005 requesting that FDA "withdraw approvals for nontherapeutic uses of antibiotics in livestock if those antibiotics are also important in human medicine." FDA has apparently never finally acted on either petition. The coalition cites a number of studies purportedly showing that the use of antibiotics in livestock leads to the development of antibiotic-resistant bacteria in animals and quotes FDA as follows: "[a]ntimicrobial use in animals can contribute to the emergence of antimicrobial resistance which may be transferred to humans, thereby reducing the effectiveness of antimicrobial drugs for treating human disease."

Alleging violations of the Administrative Procedure Act and the Food and Drug Act, the coalition seeks a declaration that FDA has violated the law and that its delay in responding to the petitions is unreasonable. The coalition also seeks an order compelling FDA to withdraw its approval for the drugs' uses and to issue a final response to the petitions. The coalition includes the Natural Resources Defense Council, Inc.; Center for Science in the Public Interest; Food Animal Concerns Trust; Public Citizen, Inc.; and Union of Concerned Scientists, Inc.

Insurer Seeks Declaration of No Duty to Defend or Indemnify Maker of Four Loko®

Selective Insurance Co. of South Carolina has filed a declaratory judgment action against Phusion Projects, Inc., which makes and sells the caffeinated alcohol beverage Four Loko®, claiming that it owes no duty to defend or indemnify Phusion in a number of pending lawsuits. *Selective Ins. Co. of S. Car. v. Phusion Projects Inc.*, No. 11-03378 (U.S. Dist. Ct., N.D. Ill., E. Div., filed May 19, 2011). The lawsuits involve claims that the product was responsible for teenagers' deaths or injury, its promotions violated consumer protection laws, and the product's packaging infringed trade dress. According to the insurer, (i) its policy was not in effect as to some of the plaintiffs, whose alleged injuries occurred either before the policy took effect or after the insurer cancelled the policy; and (ii) the policy's terms expressly or unambiguously preclude coverage for certain claims, including those involving intoxication. The insurer seeks a declaration that the policy does not provide coverage for Phusion and that it has no duty to defend or indemnify Phusion.

"Sleepy" Tea Designations Brew Trademark Dispute

Celestial Seasonings has filed a complaint against Mexican and Texas companies that are allegedly infringing its Sleepytime trademark with a tea product sold under a "Sleeping Time" mark. *The Hain Celestial Group, Inc. v. Royal Tea S.A. de C.V.*, No. 11-2504 (U.S. Dist. Ct., E.D.N.Y., filed May 24, 2011). According to the complaint, Celestial began registering its marks for tea and dietary supplements in 1975. Contending that the defendants' Sleeping Time mark is "confusingly similar," Celestial alleges that the defendants were fully aware of Celestial's rights to the Sleepytime mark because they tried to cancel Celestial's Mexican trademark registration. The complaint alleges trademark infringement, trademark dilution and unfair competition under federal law, and related counts under state law. The plaintiff seeks a permanent injunction, destruction of infringing inventory and advertising, treble damages, costs, and attorney's fees.

Amount of Fat in Meat Products Draws New Class Action

According to a news source, a Florida resident has filed a putative class action against Kraft Foods Global, Inc., alleging that the packaging for its Oscar Mayer® deli meat products misleads consumers by declaring the meat to be 98 percent fat free, with 50 calories per serving. *McDougal v. Kraft Foods, Inc.*, No. 11-61202 (U.S. Dist. Ct., S.D. Fla., filed May 23, 2011). The plaintiff contends that consumers are misled to believe that just 2 percent of the 50 calories come from fat, when 20 percent of the calories per serving actually come from fat.

Seeking to certify statewide and nationwide classes, the plaintiff alleges violation of consumer protection laws, breach of express warranty and unjust enrichment. The complaint is similar to one filed in a different federal district in Florida in April. Additional details about that lawsuit appear in **Issue 391** of this *Update*. *See Law360*, May 24, 2011.

Illinois Plaintiff Files Personal Injury Action Against Ocean Spray

A man who claims that his consumption of Ocean Spray's 100% Cranberry Pomegranate Juice® caused his food poisoning and other related injuries, has filed an individual action against the company, retailers and a testing laboratory in an Illinois state court. *Mihalopoulos v. Ocean Spray Cranberries, Inc.*, No. 2011L005420 (Cook County Cir. Ct., Ill., filed May 25, 2011). The plaintiff alleges that the product was contaminated with a "fungus known as Penicillium Glabrum." Part of the complaint alleges that a testing laboratory confirmed the presence of the fungus in the product, but failed to preserve the juice sample, which the plaintiff contends will prejudice his ability to prosecute the remainder of his claims.

Alleging strict products liability, negligence and spoliation of evidence, the plaintiff seeks damages in excess of $50,000 for his "severe and permanent injury," medical costs and future economic losses.

OTHER DEVELOPMENTS

Rumors of Marmite Ban Spark Online Uprising

Rumors that Denmark banned the sale of Marmite and other savory, yeast-extract spreads because they contain added vitamins have apparently given rise to online protests and calls to boycott iconic Danish brands such as Lego®. Media sources have reported that Marmite fans rallied on Facebook and other social media sites after hearing that the Danish Veterinary and Food Administration (DVFA) ordered the product off store shelves along with other fortified foods like Ovaltine and Vegemite. "Spread the word, but most importantly spread the Marmite," wrote the founder of one Facebook page devoted to expat Marmite aficionados. "Let the rise of the Marmite army begin!"

According to DVFA, however, authorities have not banned the spread but simply reiterated that foods with added vitamins, minerals or other substances cannot be marketed in Denmark without agency review and approval. "Products with food additives, vitamins and minerals claims in their marketing need to be approved and been received," a spokesperson for the Danish Embassy in Canberra, Australia, was quoted as saying. "With fortified food products, you have to submit an application, that is nothing new." *See DVFA Press Release* and *The Guardian,* May 25, 2011; *mX (Sydney),* May 26, 2011.

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SCIENTIFIC/TECHNICAL ITEMS

WCRF/AICR Report Links Bowel Cancer Risk to Meaty Diet

The World Cancer Research Fund/American Institute for Cancer Research (WCRF/AICR) has issued a colorectal cancer report allegedly concluding "that red and processed meat increase risk of the disease." Part of the groups' Continuous Update Project, which in 2007 covered 749 papers on colorectal cancer, the 2011 report reviews 263 additional papers examining "the links between colorectal cancer risk and diet, physical activity and weight." According to a May 23, 2011, press release, the findings provide "convincing evidence that both red and processed meat increase colorectal cancer risk," while "foods containing fiber offer protection."

Billed by WCRF/AICR as "the most comprehensive and authoritative report on colorectal cancer risk ever published," the meta-analysis also suggested that "ounce for ounce, consuming processed meat increases risk twice as much as consuming red meat." WCRF/AICR recommends that "people limit consumption to 18 ounces (cooked weight) of red meat a week – roughly the equivalent of five or six small portions of beef, lamb or pork – and avoid processed meat."

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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.