Shook, Hardy & Bacon L.L.P.

ISSUE 432 | MARCH 23, 2012

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Consumer Advocate Calls for FDA Enforcement Action Against Lemon Juice Makers

The National Consumers League has written to Food and Drug Administration (FDA) Commissioner Margaret Hamburg, asking the agency to take enforcement action against several companies that label their products as "100%" lemon juice, while they actually contain 35 percent or less lemon juice. According to the March 21, 2012, **letter**, "The products tested omit requisite amounts of real lemon juice and substitute water, citric acid, and in some cases sugar. The cheating is concealed by labeling the products as '100%' lemon juice or simply 'Lemon Juice from concentrate,' and the producers make it appear that the products are of greater value than they really are."

Included with the letter are labels from four different products and lab reports from the company that apparently tested them. The National Consumers League characterizes the juice as "heavily diluted with water beyond what is necessary and appropriate to reconstitute the product." Its letter also notes that this product "is a staple in the American diet. More than 5000 recipes call for the use of lemon juice on just one cooking World Wide Web site alone." Given weather fluctuations that affect the citrus harvest, the league suggests that "some companies have a motivation to cheat."

USDA Proposes Updated Bovine Import Regulations to Open Trade Barriers

The U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) has issued a 66-page **proposed rule** that would update import rules for bovine spongiform encephalopathy (BSE). The topic was discussed in **Issue 427** of this *Update*.

Current U.S. trade rules prohibit beef imports from countries that have outbreaks or high risks of BSE, commonly known as mad cow disease. Under the proposal, APHIS would adopt criteria used by the World Organization for Animal Health (OIE) that identify a country's BSE risks as negligible, controlled or undetermined. Basing its import policy for a particular country on that

country's risk classification, APHIS would also conduct its own assessment, such as when a country is not yet classified by the OIE for BSE risk and requests APHIS to conduct a risk evaluation using OIE criteria. Countries would be considered an undetermined BSE risk unless officially recognized as negligible or controlled.

Calling the proposal an "important step forward" in bringing U.S. import regulations in line with science-based, international health standards, APHIS Deputy Administrator and Chief Veterinary Officer John Clifford noted that the proposal will also assist the agency "in future negotiations to reopen important trade markets that remain closed to U.S. beef." APHIS seeks comments by May 15, 2012. *See APHIS News Release*, March 9, 2012; *Federal Register,* March 16, 2012.

Scottish Health Minister Urges Pre-Watershed Ban on Junk Food Advertising

Scottish Health Minister Michael Matheson has reportedly written to U.K. Health Secretary Andrew Lansley, urging him to support a ban on all TV advertising for foods high in fat, sugar and salt (HFSS) before the 9 p.m. watershed. According to media sources, Matheson cited OfCom studies allegedly indicating that, while children's broadcasting adheres to strict advertising restrictions, young viewers were still seeing ads for HFSS foods during programs intended for older audiences such as talent shows. "Broadcast advertising influences the choices made by children and can shape their attitudes to food as they grow into adulthood," Matheson was quoted as saying. "Tackling obesity and encouraging people to make healthier life choices is one of the most important things we can do to improve the health of our nation."

Although the initiative has since been lauded by groups like the National Heart Forum and British Medical Association, it has also drawn fire from critics of the Scottish National Party (SNP), who view the announcement as a political ploy. "At a time when we have lost 2,000 nurses, our hospitals are crumbling and we don't have enough blankets for elderly patients, I am amazed that the SNP government is picking a fight with the UK government about what time we can show McDonald's adverts on television," said one Scottish Labour spokesperson. "This is the same government which rejected my colleague Richard Simpson's *Trans*-fats Bill, something they did have the power to do. The SNP's obsession with constitutional politics knows no bounds and is distracting from real problems in our health service." *See BBC News Scotland,* March 17, 2012; *Sunday Mail,* March 18, 2012.

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For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

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.

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 432 | MARCH 23, 2012

LITIGATION

Federal Court Orders FDA to Initiate Withdrawal Proceedings on Antibiotics in Animal Feed

A federal magistrate judge in New York has ordered the Food and Drug Administration (FDA) to begin proceedings to withdraw approval for the subtherapeutic use of certain antibiotics in animal feed, agreeing with the Natural Resources Defense Council (NRDC) and a coalition of advocacy organizations that the agency had a statutory duty to hold withdrawal proceedings after issuing notices in 1977 of its intent to withdraw approval because the use of such drugs had not been shown to be safe. ***NRDC v. FDA*, No. 11-3562 (U.S. Dist. Ct., S.D.N.Y., decided March 22, 2012)**. According to the court, "if the Secretary finds that an animal drug has not been shown to be safe, he is statutorily required to withdraw approval of that drug, provided that the drug sponsor has notice and an opportunity for a hearing."

Further details about the lawsuit appear in **Issue 396** of this *Update*. Questions about whether the agency has unreasonably delayed acting on citizen petitions filed by the plaintiffs in 1999 and 2005 requesting that FDA take action on the use of antibiotics in animal feed remain pending.

The court indicated that the proceedings must begin, but it did not express an opinion as to the outcome, recognizing that the drug sponsors must be given the opportunity to prove that the antibiotic use is safe. FDA was apparently under an obligation to begin such proceedings once it issued notices expressing concerns about the purported development of antibiotic-resistant "superbugs" in humans from the widespread use of antibiotics—penicillin and tetracycline—in livestock feed. Hearings were never scheduled despite requests by numerous drug sponsors, and the agency's approval remained in place. According to the court, "In the intervening years, the scientific evidence of the risks to human health from the widespread use of antibiotics in livestock has grown, and there is no evidence that the FDA has changed its position that such uses are not shown to be safe."

FDA indicated that the process begun in 1977 and formally abandoned in December 2011 was outdated and that it intended to take other action to address any potential food safety issues. Among other matters, it issued non-binding draft guidance in June 2010 urging the judicious use of medically important antimicrobial drugs in food-producing animals. It also argued that the lawsuit was now moot because of the abandoned process. The court disagreed and further noted, in granting the plaintiffs' motion for summary judgment on their first claim, "The FDA has not issued a single statement since the issuance of the 1977 (notices) that undermines the original findings that the drugs have not been shown to be safe."

Public Citizen quoted NRDC attorney Jen Sorenson as saying, "Thanks to the Court's order, drug manufacturers will finally have to do what FDA should have made them do 35 years ago: prove that their drugs are safe for human health, or take them off the market." *See Reuters*, March 22, 2012; *Public Citizen News Release*, March 23, 2012.

Product with Stevia Targeted in "All Natural" False Advertising Lawsuit

A California resident has filed a putative class action in federal court against the Jamba Juice Co., alleging that it falsely advertises its fruit smoothie kits as "All Natural," when they actually contain "unnaturally processed, synthetic and/or non-natural ingredients," such as ascorbic acid, citric acid, xanthan gum, and steviol glycosides. *Anderson v. Jamba Juice Co.*, No. 12-1213 (U.S. Dist. Ct., N.D. Cal., filed March 12, 2012). Plaintiff Kevin Anderson brings the action in federal court under the Class Action Fairness Act, claiming that the damages will exceed $5 million and that the class includes more than 100 individuals who have citizenship diverse from that of the defendant.

Anderson alleges that he and a nationwide class of consumers "did not receive the benefit of their bargain when they purchased the smoothie kits. They paid money for a product that is not what it claims to be." Contending that the defendant "is a leading healthy food and beverage retailer" with a reputation for promoting healthy living, the plaintiff alleges that reasonable consumers lack the "specialized knowledge necessary to identify ingredients in the smoothie kits as being inconsistent with the 'All Natural' claims." Alleging violations of California's Consumers Legal Remedies Act, False Advertising Law and Unfair Competition Law, Anderson seeks refunds, injunctive relief including a corrective advertising campaign, attorney's fees, costs, and interest.

Federal Court Consolidates Frito-Lay "All Natural" Lawsuits

A federal court in New York has reportedly consolidated three putative class actions against Frito-Lay North America Inc. involving claims that the company falsely advertised its chips as "all natural" despite using genetically modified corn and oil in the products. *In re: Frito-Lay N. Am. Inc. "All-Natural" Litig.*, No. 12-00408 (U.S. Dist. Ct., E.D.N.Y., order entered March 20, 2012). Two of the suits were filed in December 2011 in California, and the plaintiffs agreed to transfer the claims to New York where a similar action had been filed in January 2012. The parties reportedly stipulated to the consolidation "to streamline the litigation and conserve judicial resources." *See Law 360*, March 21, 2012.

Insurer Agrees to Pay $11 Million to Settle Coverage Dispute in *Salmonella* Outbreak

A company that insured Basic Food Flavors Inc. has asked a court to approve its settlement in a coverage dispute concerning a 2010 *Salmonella* outbreak involving hydrolyzed vegetable protein, a flavorings ingredient used in processed foods. *Employers Fire Ins. Co. v. Basic Food Flavors Inc.*, 10-1109 (U.S. Dist. Ct., D. Nev., motion to approve settlement filed March 21, 2012). The ensuing recall apparently affected more than 100 of Basic Food's customers, in addition to downstream suppliers, distributors and retailers. Under the agreement, the insurance company agreed to pay its coverage limits of $11 million. According to a news source, a neutral administrator has approved more than $34 million in claims against Basic Food. *See Law 360*, March 22, 2012.

California Olive Garden Workers Bring Wage-Related Claims

Two California men who allegedly worked as cooks at a Riverside County Olive Garden have filed a putative class action as private attorneys general under the California Labor Code, claiming that they performed off-the-clock work, were not provided meal or rest breaks as required by law or paid overtime, and had the cost of shoes deducted from their paychecks. *Romo v. GMRI, Inc.*, No. RIC1203891 (Cal. Super. Ct., Riverside County, filed March 19, 2012). They also claim that their employer failed to pay them promptly as required by law when they left their jobs.

They seek to represent all non-exempt or hourly paid Olive Garden employees in the state. According to the complaint, the off-the-clock and overtime work the plaintiffs performed was necessitated due to the volume of work and frequent understaffing. Claiming unpaid overtime, unpaid minimum wages, non-compliant wage statements, unlawful deductions, and wages not timely paid upon termination, the plaintiffs seek damages, restitution, injunctive relief, and attorney's fees in excess of $25,000 but less than $5 million. The plaintiffs indicate that they provided notice of suit to the employer and are thus authorized to recover civil penalties unless the Labor and Workforce Development Agency "provides timely notice of its intent to investigate Plaintiffs' Labor Code claims."

Cantaloupe Importer Withdraws Tort Claims Against Epidemiologist and Oregon Public Health

Del Monte Fresh Produce has reportedly informed Oregon Public Health and state Senior Epidemiologist William Keene that it will not act on its notice to sue over their identification of the company's imported cantaloupes as the source of a 2011 *Salmonella* outbreak. Additional details about the litigation threat appear in **Issue 408** of this *Update*. While a spokesperson refused to comment on the company's action, its letter apparently indicated that the

withdrawal was "a show of good faith" in its food safety discussions with the state; it is seeking a meeting with state food safety scientists.

Del Monte Fresh Produce also sued the Food and Drug Administration (FDA), claiming that the agency lacked an adequate factual basis to conclude that the company's Guatemalan cantaloupe supplier was the source of the contamination. The company sought to lift FDA's import alert which prohibited it from importing from its Guatemalan source without proving the fruit was "negative" for *Salmonella* and other pathogens. In an ethics complaint filed against Oregon's epidemiologist, the company reportedly accused him of conducting a shoddy investigation and of instigating the FDA recall. According to a news source, the import alert has since been lifted and Oregon's Government Ethics Commission dismissed the ethics complaint. *See OregonLive.com*, March 14, 2012.

OTHER DEVELOPMENTS

CHEM Trust Investigates Chemical Causes of Obesity

The U.K.-based Chemicals, Health and Environment Monitoring (CHEM) Trust has issued a March 2012 **report** claiming that recent studies have linked "hormone disrupting chemicals in food and consumer products" to obesity and Type 2 diabetes in humans. The report apparently analyzes 240 research papers offering epidemiological or laboratory evidence to suggest that certain chemicals—such as persistent organic pollutants (POPs), bisphenol A (BPA) and phthalates—are obesogenic or diabetogenic. "The chemicals implicated include some to which the general population are typically exposed on a daily basis," states the report, which also speculates that some "endocrine disrupting chemicals" (EDCs) stored in body fat "may play a role in the causal relationship between obesity and diabetes."

Based on its findings, CHEM Trust argues that obesity prevention strategies like dietary interventions "should not obscure the need for government policies within and outside the health sector" to reduce chemical exposure through the food chain, food containers and other environmental sources. Advocating a precautionary approach, the report calls on the European Union and member states to replace EDCs with "safer alternatives" as well as educate health professionals, companies and consumer organizations as to their supposed effects.

"The epidemics in obesity and diabetes are extremely worrying. The role of hormone disrupting chemicals in this must be addressed. The number of such chemicals that contaminate humans is considerable," said a report co-author in a March 20, 2012, CHEM Trust press release. "We must encourage new poli-

cies that help minimize human exposure to all relevant hormone disruptors, especially women planning pregnancy, as it appears to be the fetus developing in utero that is at greatest risk."

MEDIA COVERAGE

Mark Bittman, "Is a Calorie a Calorie?," *The New York Times,* March 20, 2012

"The 'calorie is a calorie' argument is widely used by the processed food industry to explain that weight loss isn't really about *what* you eat but about how many calories you eat," writes *New York Times* columnist Mark Bittman in a March 20, 2012, "Opinionator" post about Marion Nestle and Malden Nesheim's new book, *Why Calories Count: From Science to Politics* (University of California Press 2012). Initially interested in how calories are processed by the human body, Bittman concludes after interviewing Nestle that "the situation is not so simple," with many factors beside calorie intake determining how metabolism regulates weight. "It's hard to lose weight, because the body is set up to *defend* fat, so you don't starve to death;" explains Nestle, "the body doesn't work as well to tell people to stop eating as when to tell them when to start."

Nestle suggests that more is needed to reduce obesity rates than advising individuals to consume less calories. Agreeing with Bittman that "the calorie is political," she advocates several policy changes that would affect the food-safety system, farm subsidies, school lunch programs, and front-of-package labeling regulations. "Stop marketing food to kids. Period. Just make it go away," Nestle tells Bittman, in addition to nixing health claims on food packages "[u]nless they're backed up by universally accepted science. Which would get rid of all of them."

SCIENTIFIC/TECHNICAL ITEMS

Scientists Question Food-Addiction Model for Obesity

A recent opinion piece published in *Nature Reviews Neuroscience* has questioned efforts to conceptualize obesity and overeating "as a food addiction accompanied by corresponding brain changes," in the process raising concerns about the rush to adopt this model as a foundation for clinical and policy recommendations. Hisham Ziauddeen, et al., "Obesity and the brain: how convincing is the addiction model?," *Nature Reviews Neuroscience,* April 2012.

From the outset, the article distinguishes between two popular views of food addiction, one of which posits that certain foods are addictive and one of which attempts to define food addiction as a "behavioral phenotype" seen in

some people with obesity that "resembles drug addiction." In light of these differing perspectives, the article reviews the "five key pieces of evidence cited in support of addiction model," that is, (i) "a clinical overlap between obesity (or, more specifically BED [binge-eating disorder]) and drug addiction"; (ii) "evidence of shared vulnerability to both obesity and substance addiction"; (iii) "evidence of tolerance, withdrawal and compulsive food-seeking in animal models of overexposure to high-sugar and/or high-fat diets"; (iv) "evidence of lower levels of striatal dopamine receptors (similar to findings in patients with drug addiction) in obese humans"; and (v) "evidence of altered brain responses to food-related stimuli in obese individuals compared with non-obese controls in functional imaging studies."

After analyzing the current body of published work, the authors report that, although animal studies provide the strongest basis for a food-addiction syndrome, other lines of research are not as conclusive as first suggested by backers of the food-addiction model. According to the article, not only have "the vast majority of overweight individuals... not shown a convincing neurobiological profile that resembles addiction," but further inconsistencies in the neuroimaging literature suggest that "the application of a single model is likely to be more of a hindrance than a help to future research." Even studies that limited their data to individuals with obesity caused by binge-eating disorder (BED) apparently failed to concur that food addiction mimics drug addiction, yielding evidence described in the article as "weak or inconsistent."

"[G]iven the absence of good evidence, the ubiquitous influence of the addiction model of overeating and consequent obesity is remarkable," observe the co-authors, who suggest several alternatives for future research that would better handle the complexity of cognitive responses to food consumption and possibly involve creating "a more precise neurobehavioral definition of food addiction" separate from that of drug addiction. As they conclude, however, "successful development of such a model will demand progression beyond existing clinical definitions of addiction to ideas that are guided by the developing neuroscientific literature."

Meta-Analysis Alleges Link Between White Rice Consumption and Type 2 Diabetes

A recent meta-analysis of prospective cohort studies has claimed that "higher white rice consumption was associated with a significantly elevated risk of type 2 diabetes." Emily Hu, et al., "White rice consumption and risk of type 2 diabetes: systemic review," *BMJ*, March 2012. Harvard School of Public Health researchers apparently examined four articles with "seven distinct prospective cohort analyses in Asian and Western populations" that included a total of 13,284 incident cases of type 2 diabetes among 352,384 participants. The results purportedly suggested that the correlation "seems to be stronger for

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 432 | MARCH 23, 2012

Asians than for Western populations," with each serving per day of white rice "associated with an 11% increase in risk of diabetes in the overall population."

The authors also speculated on potential mechanisms to explain the association, especially among Asian populations where "white rice is consumed as a staple food" and "is the predominant contributor to dietary glycaemic load." As they concluded, "The recent transition in nutrition characterized by dramatically decreased physical activity levels and much improved security and variety of food has led to increased prevalence of obesity and insulin resistance in Asian countries. Although rice has been a staple food in Asian populations for thousands of years, this transition may render Asian populations more susceptible to the adverse effects of high intakes of white rice, as well as other sources of refined carbohydrates such as pastries, white bread, and sugar sweetened beverages."

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400