Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Lawmakers Sign Petition Urging FDA to Label Genetically Engineered Foods

Fifty-five members of Congress have sent a letter to the Food and Drug Administration (FDA) in support of a legal petition demanding the labeling of genetically engineered (GE) foods. Signed by 10 senators and 45 representatives, the March 12, 2012, letter urges FDA "to protect a consumer's right to know, the freedom to choose what we feed our families, and the integrity of our free and open markets."

Filed in October 2011 by the nonprofit Center for Food Safety, the petition reportedly has the support of more than 400 health and consumer agencies and has received nearly a million comments in favor of GE labeling, the lawmakers said. They assert that FDA's 1992 policy statement allowing GE foods to be marketed without labeling is inadequate and outdated because it merely covers foods changed "materially" by taste, smell or other senses.

"The use of novel food technologies like genetic engineering on a commercial scale has so far slipped underneath FDA's limited threshold for 'materiality' because technologies make silent, genetic, and molecular changes to food that are not capable of being detected by human senses," states the letter, which was spearheaded by Senator Barbara Boxer (D-Calif.) and Representative Peter DeFazio (D-Ore.) and signed by several lawmakers who have recently focused on food-safety issues, including Representative Louise Slaughter (D-N.Y.) and Senator Jon Tester (D-Mont.).

GAO Report Urges Preslaughter Inventions to Reduce *E. Coli*

The U.S. Government Accountability Office (GAO) has issued a March 2012 report urging the U.S. Department of Agriculture (USDA) to adopt several measures to reduce Shiga toxin-producing *Escherichia coli* (STEC) in cattle before they are slaughtered. According to GAO, USDA currently recognizes bacteriophages, probiotics, vaccines, and sodium chlorate as preslaughter interventions able to control STEC, but has received few applications for commercial products that use these methods. The report notes that even in

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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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the case of STEC vaccines, USDA's requirements for approval are "unclear" and do not address "some of the unique challenges faced by manufacturers of animal health products."

GAO found that, unlike the Canadian Centre for Veterinary Biologics, USDA fails to specify when it requires laboratory or field demonstrations of vaccine efficacy, resulting in delayed application approval. There is also apparently a lack of available products designed to test for six STEC strains—other than STEC O157:H7—that are now considered adulterants in raw ground beef and beef trim. To this end, GAO has called on USDA "to provide more specific public guidance on the license approval requirements of STEC vaccines" and to consider strategies used by the European Union and Sweden to manage STEC outbreaks. The report highlights EU measures that require regulators to inspect the cleanliness of cattle before slaughter and to collect data on STEC in live cattle, as well as Swedish efforts to trace STEC-contaminated cattle back to the source farm, where additional testing is carried out.

"Since 2006, the U.S. beef industry has recalled over 23 million pounds of beef owing to contamination from pathogenic strains of [STEC]. These strains do not harm cattle but may contaminate meat during slaughter… USDA has stated that interventions to reduce STEC before slaughter offer a significant opportunity to improve food safety," concludes the report, which relied on agency documents, slaughterhouse inspections, and input from officials, industry representatives and other experts on STEC in cattle.

FDA Warns Office Supply Company About Sanitary Conditions Near Stored Foods

The Food and Drug Administration (FDA) has issued a **warning letter** to Staples, Inc. concerning inspections conducted at its California facility where food products are stored. FDA apparently discovered "serious violations of the Current Good Manufacturing Practice (CGMP) regulation for foods." Among other matters, rodent excreta pellets were found on or near "at least 11 different food products, including various brands of candies, crackers, creamers, pistachios, ramen noodles, and bottled water." The inspectors also apparently found dead rodents in traps throughout the facility and rodent gnawed holes on individual food packages.

FDA acknowledged that the company voluntarily destroyed food products under the agency's supervision in October 2011 and that the company repaired six roll-up doors at the facility. Still, because the company did not document its corrections with photographs or include a site map indicating the placement of rodent traps or pest control records with its response, it had not "addressed how your actions will prevent future violations or adequately address the source of rodent infestation in your facility." Staples was given 15 days to specify the steps it has taken to correct the noted violations.

CDC Claims Outbreaks Linked to Imported Foods on the Rise

The Centers for Disease Control and Prevention (CDC) has released an analysis showing that disease outbreaks linked to imported foods apparently increased in 2009 and 2010.

CDC experts reviewed data collected by the Foodborne Disease Outbreak Surveillance System from 2005 to 2010, finding that 39 outbreaks and 2,348 illnesses were tied to imported foods from 15 countries.

According to CDC, 17 of the 39 outbreaks occurred in 2009 and 2010. Since 2005, imported fish was the most common source with 17 total outbreaks, followed by spices with six outbreaks, including five from fresh or dried peppers. Nearly 45 percent of the imported foods linked to outbreaks came from Asia. "It's too early to say if the recent numbers represent a trend, but CDC officials are analyzing information from 2011 and will continue to monitor for these outbreaks in the future," said CDC epidemiologist and lead author Hannah Gould. *See CDC Press Release*, March 14, 2012.

Polish Authorities Recall Food Tainted with Road Salt

Polish officials have reportedly withdrawn from commerce more than 500,000 pounds of food possibly contaminated with industrial salt intended for deicing roads in winter conditions. According to media sources, Poland's Central Bureau of Investigation has arrested five individuals accused of selling road salt to food processors for use in dairy, fish, meat, and baked goods. The Chief Sanitary Inspectorate (GIS) has since identified the non-iodized salt, which contains "minimal" levels of dioxin and heavy metals, at 48 different locations, but has reportedly emphasized the overall low risk to human health. "It can be concluded with a very high probability that the amounts of these compounds per 100 g of the food products do not pose a health hazard," one GIS investigator was quoted as saying. *See Polskie Radio,* February 27 and March 7, 2012; *Warsaw Business Journal,* March 5, 2012; *EurActiv.com,* March 7, 2012.

Despite this finding and the precautionary recall, the arrests have apparently raised concerns among trade partners over the safety of Polish food exports. At a March 9, 2012, meeting, Polish Agriculture Minister Marek Sawicki hastened to reassure the Czech Republic's ambassador, Jan Sechter, that the food producers in question fell victim to business fraud and that "all necessary tests had been conducted and Polish food was safe," with "no grounds to be concerned with consumers' health or product quality." *See Ministry of Agriculture and Rural Development News Release,* March 9, 2012.

OEHHA Adds Methanol to Prop. 65 List for Reproductive Toxicity

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has added **methanol** to the list of chemicals known to the state to cause reproductive toxicity (Prop. 65). The listing, which is effective as of March 16, 2012, is based on the National Toxicology Program's identification of the chemical as a reproductive toxicant.

Because the chemical forms naturally in fruits and vegetables that contain pectin, OEHHA has determined that "methanol that is the by-product of naturally occurring pectin in the food is not considered an exposure under Section 25501. This applies to consumption of both unprepared and prepared fruits and vegetables." This **exception** does not apply, however, where pectin is intentionally added "in the production or processing of food, or to non-food exposures." According to OEHHA, methanol is formed when "fruits and vegetables are physically prepared for consumption by methods that include, but are not limited to, slicing, chopping, pureeing and juicing." The highest concentrations apparently occur in orange and grapefruit juices.

OEHHA has also **proposed** establishing maximum allowable dose levels (MADLs) for methanol of 47,000 micrograms per day for inhalation and 23,000 micrograms per day for ingestion. Exposures at or below MADLs are exempt from Prop. 65 warning requirements. Comments are requested by April 30. If a request for a public hearing on this matter is made before April 15, OEHHA will schedule a hearing. *See OEHHA News Release*, March 16, 2012.

LITIGATION

Federal Labeling Law Does Not Preempt Claims Against JOOSE® Maker

A federal court in California has refused to dismiss most of the putative class claims filed by a consumer against a company that made an alcoholic beverage containing high levels of caffeine, finding that a federal alcohol labeling law did not preempt state-law claims based on labeling or advertising and that the allegations of economic injury are sufficient to establish standing under California's Unfair Competition Law (UCL). *Ceuvas v. United Brands Co., Inc.*, No. 11-991 (U.S. Dist. Ct., S.D. Cal., order entered March 8, 2012).

The defendant manufactured and sold JOOSE®, a flavored beverage with about 125 mg caffeine and 9.9 to 12 percent alcohol, from 2007 until it voluntarily removed the product from the market in December 2010 after receiving a warning letter from the Food and Drug Administration (FDA). The plaintiff allegedly purchased the product on two occasions in April and August 2010 and subsequently filed suit alleging that the defendant violated various state consumer fraud laws, breached express and implied warranties,

and violated the Magnuson-Moss Warranty Act. She claimed that she was misled into purchasing the products because the company failed to disclose either the amount of caffeine in its products or the purported risks associated with caffeine as used in the products. Among other matters, the company argued in its motion to dismiss that a federal law requiring certain warnings on the labels of alcoholic beverages preempted the plaintiff's claims that failure to warn about the interaction of caffeine and alcohol was deceptive and misleading.

The court refused to interpret the law's express preemption provision broadly, finding instead that while Congress, in enacting 27 U.S.C. § 213, intended "to prevent a patchwork of state requirements with respect to the warnings about the health hazards of consuming alcohol," it did not intend "to ban warnings regarding other *non-alcoholic ingredients* in an alcoholic beverage that may have adverse health effects in and of themselves or when combined with alcohol." The court also determined that an interaction warning "would not interfere with congressional goals" relating to uniform package warnings "regarding the health risks associated with consuming or abusing alcohol," thus turning aside the defendant's implied preemption argument.

The court further ruled that (i) the federal Alcohol Beverage Labeling Act applies to product labels and cartons only, so the plaintiff's claims relating to marketing not involving JOOSE® containers or packaging are not preempted; (ii) because the plaintiff notified the company about the complaint 30 days before filing her first amended complaint, the notification requirements of California's Consumers Legal Remedies Act were satisfied; (iii) the plaintiff had sufficiently pleaded an economic injury under California's Proposition 64, which restricts UCL standing, citing *Kwikset Corp. v. Super. Ct.*, 51 Cal. 4th 310 (2011), in which the California Supreme Court indicated that economic injury from unfair competition may be shown in "innumerable ways"; and (iv) the plaintiff failed to allege that the defendant had made express representations or warranties about the safety of consuming caffeine with alcohol and thus could not state a claim for breach of express warranty.

As to the plaintiff's claim for breach of an implied warranty, the court noted that the inherently dangerous product exception to liability applies to "pure and unadulterated products," such as sugar, castor oil, alcohol, and butter, and that in this case, the plaintiff claims that the defendant's "alcoholic beverage was adulterated with caffeine. Plaintiff alleges that the addition of caffeine made the alcoholic beverage unreasonably dangerous." Accordingly, the court ruled that the exception does not apply to her implied warranty claim and allowed it to proceed.

The court denied the defendant's request to strike certain portions of the first amended complaint as irrelevant or prejudicial; these included FDA's warning letter, communications between the defendant and the agency, articles about

caffeinated alcoholic beverages, and congressional remarks about the products. The court found that the allegations "generally relate to safety concerns regarding caffeine in alcoholic beverages and may relate to Defendant's knowledge of such concerns."

New "All Natural/100% Pure" Suits Filed Against Juice Makers and Retailers

An Alabama resident has reportedly filed seven lawsuits in federal court against companies that make or sell orange juice products advertised as 100 percent pure or natural when they are actually "a product of industrial processing and laboratory-flavored juices." *Veal v. Topicana Prods., Inc.*, No. 12-00804 (U.S. Dist. Ct., N.D. Ala., filed March 13, 2012). John Veal apparently alleges breach of contract and breach of warranty against each defendant on behalf of nationwide classes of consumers. According to a news source, he claims that he would not have purchased the products had he known the truth about their contents and would not have paid the higher prices charged for them. Among those sued were Simply Orange Juice Co., Tropicana Products Inc. and Winn Dixie Stores Inc. *See Everything Alabama Blog, blog.al.com,* March 15, 2012.

OTHER DEVELOPMENTS

U.S., Canada and EU Agree to End Beef Growth Hormone Rift

According to news sources, a 25-year-old trade dispute pitting European Union (EU) laws prohibiting the import of beef treated with growth hormones and U.S. and Canadian trade sanctions imposing hundreds of millions of dollars of duties on EU exports of Roquefort cheese, truffles, chocolates, and other comestibles has been resolved. The U.S. and Canadian tariffs reportedly cost EU exporters more than US$250 million annually. In exchange for lifting a 100 percent ad valorem duty against EU products, the EU has agreed to increase quotas on imports of hormone-free beef to 48,200 metric tons under the deal. The agreement will allow the EU to maintain its ban on imports of hormone-treated beef. Additional details about the dispute appear in Issues **103**, **255**, **262**, **278**, and **289** of this *Update. See Law 360* and *European Parliament News*, March 14, 2012.

Greenwashing Foes Tackle Food and Fitness Marketing with Health Claims

A marketing company that bills itself as a "champion of authentic green marketing" and crusades against product "greenwashing" claims has launched a new **Website** on which the health-related claims of food and fitness products can be rated. EnviroMedia Social Marketing created the online tool to expose "exaggerated or misleading health claims through advertising, marketing or packaging," a practice it has dubbed "leanwashing." When visited

on March 15, 2012, the Website, which uses a 1-5 rating scale with 1 corresponding to "authentic" ad claims and 5 corresponding to "bogus" product representations, listed a number of sugary cereal products at the high end of the scale and products such as POM Wonderful 100% Pomegranate juice on the low end. Children's products are rated using a separate set of criteria. Consumers are urged to post and rate ads on the site. *See BusinessWire*, March 13, 2012.

SCIENTIFIC/TECHNICAL ITEMS

Study Allegedly Links Red Meat Consumption to Increased Mortality

A recent Harvard School of Public Health (HSPH) study has claimed that daily meat consumption is associated with an increased risk of mortality from cardiovascular disease (CVD), cancer and other causes. An Pan, et al., "Red Meat Consumption and Mortality," *Archives of Internal Medicine,* March 2012. Relying on data from 37,698 men in the Health Professionals Follow-up Study and 83,644 women in the Nurses' Health Study, researchers assessed participant diets using questionnaires administered every four years. The results reportedly suggested that consuming one three-ounce serving of unprocessed red meat each day "was associated with a 13% increased risk of mortality," while one daily serving of processed red meat such as bacon, sausage or salami "was associated with a 20% increased risk."

According to a March 12, 2012, HSPH press release, the findings accounted for "chronic disease risk factors such as age, body mass index, physical activity, family history of heart disease, or major cancers." They also apparently showed that replacing one serving of red meat with another protein source correlated "with a lower mortality risk: 7% for fish, 14% for poultry, 19% for nuts, 10% for legumes, 10% for low-fat dairy products, and 14% for whole grains."

"This study provides clear evidence that regular consumption of red meat, especially processed meat, contributes substantially to premature death," said lead author and HSPH Professor of Nutrition and Epidemiology Frank Hu. "On the other hand, choosing more healthful sources of protein in place of red meat can confer significant health benefits by reducing chronic disease morbidity and mortality." *See Los Angeles Times, NPR* and *The New York Times,* March 12, 2012.

Study Says Sugar-Sweetened Beverages Increase Heart Disease Risk in Men

A study based on 42,883 men enrolled in the Health Professionals Follow-up Study has allegedly determined that those who drank one 12-ounce sugar-sweetened beverage (SSB) per day increased their coronary heart disease (CHD) risk by 20 percent over those who did not drink any SSBs. Lawrence

de Koning, et al., "Sweetened Beverage Consumption, Incident Coronary Heart Disease and Biomarkers of Risk in Men," *Circulation,* March 2012. Led by Harvard School of Public Health researchers Lawrence de Koning and Frank Hu, the study, which reported 3,683 CHD cases over 22 years of follow-up, concluded that participants "in the top quartile of sugar-sweetened beverage intake had a 20 percent higher relative risk of CHD than those in the bottom quartile" while also exhibiting "some adverse changes in lipids, inflammatory factors, and leptin."

"This study adds to the growing evidence that sugary beverages are detrimental to cardiovascular health. Certainly, it provides strong justification for reducing sugary beverage consumption among patients, and more importantly, in the general population," said Hu in a March 12, 2012, American Heart Association press release, which noted that these recent results parallel analysis of the 2009 Nurses' Health Study involving women. These similarities also sparked commentary by Northwestern University Feinberg School of Medicine Assistant Professor Mark Huffman, whose concurrent *Circulation* article attempts to further contextualize the study using the late biostatistician Austin Bradford Hill's criteria to assess whether the associations between SSBs and CHD are causal or not.

As Huffman notes, "Bradford Hill's research legacy lay in the association between tobacco and lung cancer, which had a relative risk nine to ten times higher in smokers compared to non-smokers." The article thus reviews de Koning and Hu's work according to the Bradford Hill criteria used to establish evidence of causation, that is, (i) strength of association; (ii) consistency; (iii) specificity; (iv) temporality; (v) biological gradient; (vi) plausibility; (vii) coherence; (viii) experiment (reversibility); and (ix) analogy. Although Huffman ultimately finds that the association described in the study meets some of these criteria and appears "sufficiently strong to be considered causal," he cautions that "the question remains as to whether there is something specific about SSBs that leads to CHD or if residual confounding exists."

"Few would argue that SSB consumption should not decrease, particularly given high consumption rates and the current obesity epidemic, and de Koning and colleagues' findings are a provocative page in the evolving story of SSBs and CHD," concludes Huffman. "As additional research explores this relationship, the Bradford Hill criteria may be useful guideposts in placing future results into context."

Study Claims *Trans* Fat Intake Increases Risk of Stroke in Women

A study has claimed that *trans* fat consumption among healthy postmenopausal women is associated with an increased risk for ischemic stroke, although extended aspirin use seemed to mitigate that risk. Sirin Yaemsiri, et al., "*Trans* Fat, Aspirin, and Ischemic Stroke in Postmenopausal Women," *Annals*

of Neurology, March 2012. Researchers relied on data from 87,025 women ages 50 to 70 years who were enrolled in the Women's Health Initiative Observational Study, identifying 1,049 cases of ischemic stroke during the 663,041 person years of follow-up.

The results evidently suggested that "women in the highest quintile of *trans* fat intake had a 39 percent greater incidence of ischemic stroke than women in the lowest quintile." Moreover, this risk was apparently amplified among the group of non-aspirin users, where those in the top quintile of *trans* fat intake had a 66 percent higher incidence of ischemic stroke than those in the lowest quintile. Among aspirin users, however, "the positive associations between *trans* fat and ischemic stroke were substantially attenuated," according to the study.

"Our findings were contrary to at least two other large studies of ischemic stroke," said one author in a March, 1, 2012, University of North Carolina press release, "However, ours was a larger study and included twice as many cases of ischemic stroke. Our unique study base of older women may have increased our ability to detect the association between *trans* fat intake and ischemic stroke among non-users of aspirin."

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FOOD & BEVERAGE LITIGATION UPDATE

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.