Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

CRS Releases Policy Primer on Nanotechnology

Noting that higher crop yields and improved nutrition could be achieved with the application of nanotechnology, the Congressional Research Service (CRS) has issued its most recent **report** addressing topics that may affect the country's ability to move nanotech from research laboratories to commercial products. Those topics include federal research and development investments under the National Nanotechnology Initiative; U.S. international competitiveness; environmental, health and safety issues; nanomanufacturing; and public attitudes toward, and understanding of, nanotechnology.

According to the report, "widespread uncertainty" continues as to the potential environmental, health and safety implications of nanotechnology, and bringing nanotech products "into safe, reliable, effective, and affordable commercial-scale production in a factory environment may require the development of new and unique technologies, tools, instruments, measurement science, and standards for nanomanufacturing." CRS also reports that more than 42 percent of Americans had never heard of nanotechnology as of 2007, while 6 percent indicated that they had "heard a lot." Those most likely to believe that the benefits of nanotechnology outweigh the risks were those earning more than $75,000 annually, men, people who had heard about it, and those between the ages of 35 and 64.

USDA Confirms New BSE Case in Dairy Cow

The U.S. Department of Agriculture (USDA) has issued a **statement** confirming that its Animal and Plant Health Inspection Service identified a case of bovine spongiform encephalopathy (BSE) in a dairy cow from central California. According to the April 24, 2012, news release, the cow presented with an atypical type of BSE "not generally associated with an animal consuming infected feed" and was never destined for human consumption.

"The United States has had longstanding interlocking safeguards to protect human and animal health against BSE," said USDA Chief Veterinary Officer John Clifford, adding that milk does not transmit BSE. "For public health, these measures include the USDA ban on specified risk materials, or SRMs, from the food supply. SRMs are parts of the animals that are most likely to contain the BSE agent if it is present in the animal. USDA also bans all nonambulatory (sometimes called 'downer') cattle from entering the human food chain."

Clifford also noted that the nation's fourth BSE case should not alter its status as determined by the World Organization for Animal Health or otherwise affect international trade. Indonesia, however, has reportedly banned all imports of U.S. beef until officials prove "that its beef industry is free of any mad-cow disease," as Vice Agricultural Minister Rusman Heriawan was quoted as saying. "It could be one month or one year, it depends entirely on the U.S."

Meanwhile, the Center for Science in the Public Interest (CSPI) has already used the incident to reiterate its call for a livestock tracking program. "The United States has first-world resources and technology but a third-world animal identification system," CSPI's Sarah Klein opined in a April 24, 2012, statement. "If the cow were exposed to the typical strain of BSE via animal feed—and the government says that's not the case here—that would have represented a significant failure. The government's ability to track down other cattle that may have been exposed via feed would have been hampered without an effective animal I.D. program."

FDA Issues Second Annual Reportable Food Registry Report

The Food and Drug Administration (FDA) recently published its second annual **Reportable Food Registry (RFR) report** summarizing information submitted by manufacturers, processors, packers and holders through the online Food Safety Portal from September 8, 2010, to September 7, 2011. Covering all human and animal food/feed regulated by FDA "except infant formula and dietary supplements," RFR tracks "patterns of food and feed adulteration" to help FDA administer inspection resources more effectively.

According to the report, FDA received 1,153 total entries in RFR's second year compared with 2,600 in its first year, a difference which the agency ascribes to three major events in 2009-2010 that generated 1,284 subsequent records related to sulfites in prepared side dishes, *Listeria monocytogenes* in cheese spreads and *Salmonella* in hydrolyzed vegetable protein. Without these entries, FDA stated, the tallies for the first and second years would have differed by only 74 records. In particular, the second annual report did not significantly deviate from its predecessor in terms of the distribution of primary RFR entries by food safety hazard, indicating that *Salmonella* accounted for 38.2 percent of reported food hazards; undeclared allergens for 33.3 percent; and *Listeria monocytogenes* for 17.8 percent.

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"With only two years of data, it would be premature to make meaningful statements about trends or patterns," warned FDA, which nevertheless noted an overall increase in amended reports and produce reports but a decrease in animal feed/pet food reports. Based on these findings, the agency has pledged to issue proposed rules on microbiological controls for produce "in the near future," to work with industry on identifying problems and developing solutions, and to revamp the registry itself to comply with the Food Safety Modernization Act. In the meantime, however, FDA has credited the RFR effort with decreasing its response time to food safety issues, improving its understanding of distribution and supply chains, and identifying key commodity risk points to consider when establishing preventive controls. *See FDA Center for Food Safety and Applied Nutrition Constituent Update,* April 19, 2012.

FDA Report Focuses on Safety of Imported Products

The Food and Drug Administration (FDA) has released a **report** describing its efforts to ensure the safety of imported food, drugs, medical devices, and other regulated products. Titled "Global Engagement," the report asserts that FDA-regulated products originate from more than 150 countries, 130,000 importers and 300,000 foreign facilities.

According to FDA, food imports have grown each year from 2005 to 2011 by an average of 10 percent, with Americans consuming approximately half of their fresh fruits, 20 percent of fresh vegetables and 80 percent of seafood from imports. "As the volume of imported food increases, so too does the risk that some products will fail to meet FDA standards," the report states. "The realities of the global marketplace add substantial challenges to FDA's ability to protect U.S. consumers."

Among its strategies to ensure imported product safety, FDA said it uses portable instruments to screen products, collaborates with coalitions of regulators around the world and "shares information and data globally to facilitate rapid identification of and response to public health emergencies." *See FDA Press Release*, April 23, 2012.

EU Member States Endorse New List of Flavoring Substances

During a recent meeting of the European Union's (EU's) Standing Committee on the Food Chain and Animal Health, EU member states reportedly endorsed a European Commission proposal to establish a new list of permitted flavoring substances for food products. The committee also approved a transitional measure on other flavorings, including those made from non-food sources.

Expected to be formally adopted unless opposed by the European Parliament, the two pieces of legislation aim to create clear rules for the use of flavoring substances within the European Union. The European Food Safety Authority and other scientific bodies assessed 2,800 flavorings to establish the list of allowable flavorings for use in food. Set for publication in an online database for consumers, industry and national food-control authorities, the list will be enforced six months after its adoption to provide sufficient time for the EU food industry to comply. *See Europolitics,* April 24, 2012.

Health Canada Closes Natural Health Product Loophole

Health Canada has reportedly notified companies that it will no longer accept natural-health product (NHP) applications for functional foods and similar products that are "represented, packaged and sold as foods." According to media sources, the agency in a letter to industry explained that NHPs such as prepackaged beverages, protein mixes and other products resembling conventional foods would henceforth fall under food regulations and must adhere to food safety, labeling and marketing standards. Among the approximately 1,000 products affected are those whose manufacturers must work with Health Canada to substantiate health claims, those ready for market without formulation, and those that will need reformulation before accessing the market. The agency anticipates that, with the exception of energy drinks, foods currently being marketed as NHPs will conclude the transition process by the end of December 2012. *See Post Media News,* April 19, 2012.

This latest move to re-categorize NHPs is apparently part of Health Canada's **three-year effort** "to ensure that products that look like foods and are consumed as foods are regulated as foods." It also follows on the agency's October 2011 decision to require energy drinks currently marketed as NHPs to transition to the food regulatory framework as well. Additional details about Health Canada's energy drink transition strategy appear in **Issue 413** of this *Update*.

LITIGATION

Ninth Circuit Dismisses "0 Grams Trans Fat" Class Action Against Ice Cream Co.

The Ninth Circuit Court of Appeals has affirmed the dismissal of a putative class action filed against Dreyer's Grand Ice Cream, Inc., alleging that the company misrepresented its products by labeling them as "0g Trans Fat" when they actually contain some *trans* fat per serving. *Carrea v. Dreyer's Grand Ice Cream, Inc.*, No. 11-15263 (9th Cir., decided April 5, 2012) (unpublished). According to the court, because the products contain less than 0.5 grams of

trans fat per serving, "the Nutrition Facts panel must express this amount as zero" under federal law, and the "same rule applies to the statement" on the front-of-package label. "In essence," said the court, "Carrea seeks to enjoin and declare unlawful the very statement that federal law permits and defines. Such relief would impose a burden through state law that is not identical to the requirements under section 343(r). These claims are therefore expressly preempted."

The court also found that no reasonable consumer would believe, as plaintiff contended, that the company's other labeling statements, "Original Sundae Cone," "Original Vanilla" and "Classic," implied that the product "is more wholesome or nutritious than competing products." The court further opined that "no reasonable consumer is likely to think that 'Original Vanilla' refers to a natural ingredient when that term is adjacent to the phrase, 'Artificially Flavored,'" or that "a reasonable consumer would be misled to think that an ice cream dessert, with 'chocolate coating topped with nuts,' is healthier than its competitors simply by virtue of these 'Original' and 'Classic' descriptors." Additional details about the case appear in **Issue 342** of this *Update*.

NLRB Judge Finds Fast-Food Facebook® Post Encouraged Harassment of Union Supporter

A National Labor Relations Board (NLRB) administrative law judge has determined that the owner of 10 Jimmy John's fast-food restaurants in the Minneapolis-St. Paul area violated federal law during a labor dispute by, among other matters, posting a pro-union employee's phone number on its Facebook® page and suggesting that members text the employee to "let him know how they feel." *Miklin Enters., Inc. d/b/a Jimmy John's and IWW*, Nos. 18-CA-19707, -19727, -19760 (N.L.R.B., Div. of Judges, decided April 20, 2012). According to the judge, the assistant manager's posts encouraged other employees and managers to "harass" the employee "for activities that were protected, as well as some that were arguably unprotected." A co-owner's subsequent Facebook® posts disparaging the employee further "condoned such harassment."

The employer terminated the pro-union employee and several others for posting flyers on restaurant bulletin boards and in areas near the restaurants suggesting that public health could be affected by the company's sick leave policies, which, according to the judge, could have provided "a powerful economic incentive for employees to work when ill and to conceal illness that would exclude them from work." The employer also apparently encouraged managers and employees to tear the posters down. The judge determined that the posters were protected under federal law and that the employer, therefore, violated the law by removing them and disciplining the employees

who posted them. The employer was ordered to offer the terminated employees reinstatement and remove any disciplinary warnings as to others from its employment files.

Grand Jury Indicts Distributors of Adulterated and "Washed" Cheese from Mexico

A federal grand jury in Illinois has brought criminal indictments against four individuals who allegedly distributed more than 110,000 pounds of Mexican cheese in the United States in 2007 despite Food and Drug Administration (FDA) "hold" orders and also allegedly "washed" cheese returned by dissatisfied customers by scraping off mold and fungus so it could be resold. *United States v. Zurita*, No. n/a (U.S. Dist. Ct., N.D. Ill., E. Div., indictment returned April 18, 2012). No illnesses or other public health issues were attributed to the adulterated cheese distribution in the six-count indictment.

The charges involve three separate shipments of cheese from Mexico that FDA ordered to be held and then later ordered either "detained" or "refused" after testing revealed the presence of *Salmonella, E. coli,* Alkaline Phosphate (found in unpasteurized products), and *Staphylococcus.* The defendants allegedly conspired to distribute the shipments despite FDA orders not to do so. They also allegedly distributed cheese before inspection, failed to show FDA inspectors all of the cheese in a given shipment and placed "phony stand-in cheese" at one of the plants "with no labels in case the FDA inspector arrived at the plant looking for the 311 boxes from the April Shipment that had already been sold and distributed by Company A." They also allegedly created false bills of lading.

According to the Department of Justice, the conspiracy count and one of the FDA obstruction counts carry a maximum five-year prison term, and each count of violating the Food, Drug, and Cosmetic Act carries a maximum 20-year term. The FDA obstruction count against two defendants also carries a maximum 20-year term, "and all six counts in the indictment carry a maximum fine of $250,000." *See U.S. Department of Justice News Release*, April 19, 2012.

Nutella® Consumer Class Action Settlement Website Up and Running

The claims process under two settlements reached with the company that makes the hazelnut spread Nutella® is underway, and consumers can recover up to $20, or $4 each for up to five jars purchased during the relevant periods. *In re: Ferrero Litig.*, No. 11-CV-205 H (U.S. Dist. Ct., S.D. Cal.) (California class, Aug. 1, 2009 – Jan. 23, 2012); *In re: Nutella Mktg. & Sales Practices Litig.*, No. 3:11-cv-01086 (U.S. Dist. Ct., D.N.J.) (Nationwide class, except California, Jan. 1, 2008 – Feb. 3, 2012).

The settlement funds available to both classes total $3.05 million, but if the claims exceed this amount, individual payments "will be reduced proportionately." Under the settlement agreement, the company, which continues to deny any wrongdoing, will modify its product label and certain marketing statements, create new TV ads, and change the Nutella® Website.

The company also agreed not to object to a California fee award of $900,000 and New Jersey fee award of $3 million. Claims must be submitted no later than July 5, 2012, and requests for exclusion from the classes must be postmarked no later than June 8. If more than 5,000 class members seek exclusion from the New Jersey settlement, the agreement may be terminated. If 500 class members seek exclusion from the California settlement, the agreement may be terminated. Fairness hearings will be held before both the New Jersey and California courts on July 9. Details about the litigation appear in issues 380, 394, 401,406, 408, 415, 418, 420 and 422 of this *Update*. *See N.Y. Daily News* and *Huffington Post*, April 26, 2012.

Italian Vintner Alleges Trademark Infringement by German Wine Distributor

A Venice, Italy-based wine producer has sued a German wine distributor for unfair competition and trademark and copyright infringement in a federal court in California, alleging that the defendant ships to the United States for sale by a U.S. distributor a "gray market" product purporting to be the plaintiff's pinot grigio wine. *Santa Margherita, S.p.A v. Unger Weine KG*, CV12-3499 (U.S. Dist. Ct., C.D. Cal., filed April 23, 2012). According to the complaint, the U.S. distributor entered a consent order with the plaintiff in 2011 prohibiting it from importing, selling, marketing, and distributing Santa Margherita Pinot Grigio in the United States.

The plaintiff contends that it sells its wine in the United States exclusively through an Illinois distributor and closely monitors the distribution network to ensure product quality. The complaint alleges, "Gray Market Santa Margherita Wine is sold and distributed outside this authorized distribution channel and is not subject to the same quality control standards as Authorized Santa Margherita Wine." The product labels purportedly share some characteristics but differ in number, color, content, font, and border styles. Seeking preliminary and permanent injunctive relief, the plaintiff also seeks an order requiring an accounting for all profits and "trebling such profits for payment to Plaintiff," compensatory and punitive damages, attorney's fees, and costs.

Trademark Infringement Alleged over Pistol-Shaped Bottle for Adult Beverages

The Mexican owner of U.S. and Mexican trademarks for an "automatic pistol-shaped bottle design[] used in connection with alcoholic beverages, with the exception of beers" and its exclusive U.S. distributor have filed trademark infringement claims against the company that sells, markets and imports into the United States Eagle Shot Tequila® in a pistol-shaped bottle. *Mexcor Distribs. Inc., v. Purveyors LLC*, No. 4:2012cv01240 (U.S. Dist. Ct., S.D. Tex., Houston Div., filed April 19, 2012). The plaintiffs allegedly demanded that the defendant cease and desist from doing so, and the defendant failed to respond.

Seeking preliminary and permanent injunctive relief, the plaintiffs also seek an accounting and payment of profits earned from the date of first use of the mark, treble damages, attorney's fees, and costs. They allege trademark infringement and unfair competition under the federal Lanham Act, as well as Texas common law on trademarks and unfair competition. According to the complaint, the defendant's use of the mark "is likely to cause confusion, mistake, and deception among the public as to the origin or sponsorship of its products" and has caused the plaintiffs "irreparable damage to their reputations and goodwill."

OTHER DEVELOPMENTS

New Research Presented at Childhood Cancer Conference Targets Sucralose

New research conducted by Morando Soffritti, director of the Ramazzini Institute in Bologna, Italy, has allegedly found that male mice systematically dosed with sucralose throughout their life cycles were more likely to develop a specific type of cancer. Presented at the April 25 Childhood Cancer 2012 Conference in London, the research evidently relied on 843 mice and appeared to identify a dose-dependent relationship between sucralose consumption and leukemia in male mice only. "Health concerns over aspartame are leading consumers to switch to the widely promoted alternative: sucralose," said Soffritti, who has long lobbied European regulators to take aspartame off the market. "Now that we have found evidence of a link between sucralose and cancer in mice, similar research should be urgently repeated on rats, and large-scale observational studies should be set up to monitor any potential cancer risk to human health." *See Childhood Cancer 2012 Press Release,* April 25, 2012.

Meanwhile, industry leaders have reportedly dismissed the new studies as junk science. "This study, by a laboratory whose work has been dismissed by regulatory agencies, seems designed to produce scary but entirely false allegations," one Tate & Lyle spokesperson said. "It has not been reviewed by independent scientists, has not been published for independent review and

does not follow internationally agreed scientific procedures." *See BeverageDaily.com,* April 25, 2012.

Book Complements Upcoming "Weight of the Nation" HBO Documentary

The Institute of Medicine's (IOM's) executive officer has co-authored a book examining America's obesity epidemic. Judith Salerno's *The Weight of the Nation: To Win We Have to Lose* was published to complement a four-part HBO documentary on obesity debuting May 14-15, 2012, and a national campaign to curb obesity rates, both of which were featured in **Issue 423** of this *Update*. The book was co-written by the documentary's executive producer, John Hoffman, and its co-producer, Alexandra Moss.

According to IOM, the book explores "the array of factors that feed America's obesity problem—from the human body itself, which evolved to crave more food than it needs, to restaurant portion sizes that pack a day's worth of calories into one meal, to neighborhoods and workplaces that encourage little physical activity." IOM also plans to release a report titled "Accelerating Progress in Obesity Prevention" at the Centers for Disease Control and Prevention's Weight of the Nation conference on May 8 in Washington, D.C. *See IOM Press Release*, April 24, 2012.

MEDIA COVERAGE

Margo Wootan & David Ludwig, "Sugary Cereal: Breakfast Candy or Obesity Cure?," *The Atlantic,* April 24, 2012

"Ready-to-eat cereals are the fourth biggest source of added sugars in Americans' diets, behind sugary drinks, desserts, and candy," opine Center for Science in the Public Interest Director of Nutrition Policy Margo Wootan and New Balance Foundation Obesity Prevention Center Director David Ludwig in this article, disputing claims that children who eat sugary cereals for breakfast are less likely to be overweight than those who do not eat breakfast at all. According to Wootan and Ludwig, the research supporting such claims "cannot prove cause and effect, and most have been funded or conducted by the industry." They argue instead that manufacturers should market their lower-sugar offerings to children as well as adults, citing studies conducted by Yale University's Rudd Center for Food Policy and Obesity that show such products "are well accepted by children" even though cereals targeted to youth typically "contain 85 percent more sugars and 65 percent less fiber than cereals marketed to adults."

Although Wootan and Ludwig praise current industry efforts to reduce the sugar content of some cereal products, they ultimately urge food companies to drop their alleged opposition to voluntary government guidelines that would affect how cereals are marketed to children. "The fate of those voluntary marketing recommendations is at risk," conclude the authors. "Cereal and other food and entertainment companies convinced Congress to include a provision in the Federal Trade Commission's FY2012 spending bill to block agencies' efforts, unless they jump through hoops that usually apply only to mandatory requirements, such as cost-benefit analysis… Instead of lobbying to keep marketing breakfast candy to kids, cereal and other companies should work with the Obama administration on sensible food marketing guidelines for children."

SCIENTIFIC/TECHNICAL ITEMS

High Sodium Intake Allegedly Tied to Stroke Risk

A recent study has claimed that sodium intake exceeding the 1,500 mg per day recommended by the American Heart Association (AHA) was "associated with an increased risk of stroke independent of vascular risk factors." Hannah Gardener, et al., "Dietary Sodium and Risk of Stroke in the Northern Manhattan Study," *Stroke,* April 2012. Researchers evidently relied on data from 2,657 Northern Manhattan Study participants, of whom only 12 percent met the AHA-recommended levels for sodium. In particular, the 21 percent of subjects who consumed more than 4,000 mg sodium daily based on self-reported food surveys had an increased risk of stroke compared with those who consumed less than 1500 mg. Although the study authors also identified "a 17 percent relative increase in the hazard of stroke for every 500-mg/day increase in dietary sodium intake," their findings did not suggest "a linear dose-response relationship between sodium consumption and stroke risk."

"Our study provides excellent evidence for a strong relationship between excess sodium intake and increased stroke risk in a multiethnic population," wrote the authors. "The new AHA strategic dietary goals for 2020, which include sodium reduction to ≤1500 mg/day, will promote ideal cardiovascular and brain health. Our findings underscore the need for public health initiatives to reduce the sodium level in the food supply."

Meanwhile, the Center for Science in the Public Interest (CSPI) has written an April 24, 2012, letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg, calling on the agency to "implement strong regulations that would substantially cut sodium levels—and save tens of thousands of lives annually—in processed and restaurant foods." Citing a study co-authored by CSPI Executive Director Michael Jacobson in the *Canadian Medical Association Journal,* the letter argues that the sodium content of fast food items varies

widely "from one country to another" and that U.S. franchises have plenty of leeway to reduce sodium levels to match their overseas counterparts. "There is virtually nothing else the FDA could do to improve America's food supply that would provide a greater benefit to public health than to reduce sodium levels," concludes the letter, which notes that the Institute of Medicine recommended mandatory sodium limits two years ago. "We urge the FDA to issue strong rules that will protect Americans' health." *See CSPI Press Release,* April 24, 2012.

Food Ingredient Fraud Database Launches

Researchers with the U.S. Pharmacopeial Convention have published an article discussing the development of a database that compiles reports on food fraud and highlights those ingredients most prone to fraud in the food supply. Jeffrey Moore, et al., "Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010," *Journal of Food Science*, April 2012. The **database** "provides baseline information and data useful to governments, agencies, and individual companies assessing the risks of specific products produced in specific regions as well as products distributed and sold in other regions."

Among other matters, the information collected shows that olive oil, milk, honey, saffron, orange juice, coffee, and apple juice "were the most common targets for adulteration reported in scholarly journals." They are represented in more than 50 percent of the scholarly records in the database. Other "potentially harmful issues identified include spices diluted with lead chromate and lead tetraoxide, substitution of Chinese star anise with toxic Japanese star anise, and melamine adulteration of high protein content foods." According to the report, chemometrics, "a multivariate data analysis tool often coupled with data-rich instrumental methods such as infrared spectroscopy, mass spectrometry, or nuclear magnetic resonance," is a powerful tool to detect adulterants in samples.

Discussing the utility of the database, the authors observe, "Every node in the supply chain presents an opportunity for food fraud. Each aggregator, shipper, or wholesaler who collects, blends, or repackages can change the identity, purity, and authenticity of the ingredient. Integration of the database information described in this research into supply chain analytics systems is a potential opportunity to help manage food fraud risks. The information in the database provides supply chain managers with a scholarly assessment of vulnerabilities that are often not understood or considered."

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The U.S. Pharmacopeial Convention is a non-profit scientific organization that "develops standards to help ensure the identity, quality and purity of food ingredients, dietary supplements and pharmaceuticals." Its standards are published in the "Food Chemicals Codex." *See U.S. Pharmacopeial Convention News Release*, April 5, 2012.

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FOOD & BEVERAGE LITIGATION UPDATE

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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.