Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Feinstein Introduces Legislation Requiring "Pathogen Free" Certification for Food

U.S. Senator Dianne Feinstein (D-Calif.) has introduced legislation (S.B. 2819) "to require that food producers take responsibility for keeping food free from harmful pathogens," according to a November 30, 2009, press release. The Processed Food Safety Act would amend the Poultry Products Inspection Act, Federal Meat Inspection Act and Federal Food, Drug and Cosmetic Act to "prohibit the sale of any processed poultry, meat and FDA-regulated food that has not either undergone a pathogen reduction treatment, or been certified to contain no verifiable traces of pathogens." The Act also includes provisions to (i) require that "labels on ground beef, or any other ground meat product, specifically name every cut of meat that is contained in the product," and (ii) close loopholes "in current laws that allow for producers to add coloring, synthetic flavorings and spices to their products without informing the consumer."

In announcing the bill, Feinstein highlighted a recent foodborne illness outbreak in New Hampshire and New York that allegedly killed two people and resulted in a voluntary recall for 545,699 pounds of ground beef. "It is the responsibility of the food producer, not the consumer, to make sure our food is safe to eat," she said. "Serious reform is needed. This bill would require companies that process any kind of food, from ground beef to frozen pot pies, to test their finished products and their ingredients to make sure that they are safe to eat and pathogen free." *See FoodNavigator-USA.com,* December 2, 2009.

In a related development, Consumers Union (CU) has released its annual study of whole broiler chickens, claiming that, of the 382 samples purchased in 22 states, "two-thirds harbored salmonella and/or campylobacter, the leading bacterial causes of foodborne disease." According to a January 2010 *Consumer Reports* article titled "How Safe Is That Chicken?," independent laboratory analysis purportedly found that "campylobacter was in 62 percent of the chickens, salmonella was in 14 percent, and both bacteria were in 9 percent." Although CU lauded organic, air-chilled broilers as the "cleanest" option and noted a "modest improvement" in overall pathogen reduction from previous years, the group faulted both "inadequate" producer safeguards and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) for failing to institute *Campylobacter* controls similar to those in place for *Salmonella*. The magazine also reported that "68 percent

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of the salmonella and 60 percent of the campylobacter organisms" from the contaminated chicken showed "resistance to common antibiotics," as "most bugs could resist at least one antibiotic, and some evaded multiple classes of drugs."

"The message is clear: Consumers still can't let down their guard," stated the article, which recommended cooking chicken to at least 165° F and following proper storage procedures to prevent cross-contamination. The National Chicken Council, however, has pointed to a "more comprehensive survey by the U.S. Department of Agriculture [USDA]" that found fewer *Campylobacter* and *Salmonella* pathogens on raw chicken.

"More important is the fact that USDA found that the levels of microorganisms present are usually very low," the poultry trade group noted in a November 30, 2009, press release, which criticized *Consumer Reports* for failing to undertake this analysis. "The USDA survey also showed that poultry processing greatly improves the microbiological profile of raw chickens. In fact, the industry does an excellent job in providing safe, wholesome food to American consumers." *See FoodNavigator-USA.com,* December 1, 2009.

FDA Issues Proposed Rule Regarding Color Additives in Animal Food Labeling

The Food and Drug Administration (FDA) has issued a **proposed rule** that would amend the agency's animal-food regulations by requiring manufacturers to list the common or usual names of FDA-certified color additives on animal food labels, including animal feeds and pet foods. The amendment would make the regulations consistent with those that apply to human food and suggests how color additives not certified by FDA should be declared on the ingredient list of animal foods.

According to FDA, the proposal responds to the Nutrition Labeling and Education Act of 1990, which modified the Federal Food, Drug, and Cosmetic Act by requiring food labels to list the common or usual names of all FDA-certified color additives. The 1990 amendments apply both to human and animal foods, but apparently regulations pertaining to animal foods have yet to be issued. Written comments will be accepted until February 22, 2010. *See Federal Register,* November 23, 2009.

FDA Seeks Comments on Nutrition Facts Labeling Study

The Food and Drug Administration (FDA) has published a **notice** seeking public comment on a proposed experimental study that would examine consumer reaction to possible modifications in the nutrition facts labeling format. The study results will reportedly help the agency understand whether label modifications "could help consumers to make informed food choices."

FDA intends to randomly select 3,600 people to review nutrition facts labels from a selection of different formats, foods and nutrition information, and then judge their reactions as to the foods' "nutritional attributes and overall healthfulness" and whether the labels help "calculate calories and estimate serving sizes to meet objectives." FDA invites comments on (i) whether the information collected

"will have practical utility"; (ii) the "validity of the methodology and assumptions used"; (iii) "ways to enhance the quality, utility and clarity of the information to be collected"; and (iv) "ways to minimize the burden of the collection of information." Written comments will be accepted until January 19, 2010. *See Federal Register,* November 18, 2009.

LITIGATION

Ninth Circuit Rejects Challenge to USDA Position on Humane Handling of Poultry

The Ninth Circuit Court of Appeals has determined that animal rights activists and organizations lack standing to challenge the U.S. Department of Agriculture's (USDA's) interpretation of a 1958 humane animal slaughtering statute in a manner that excludes poultry from its application. ***Levine v. Vilsack*, No. 08-16441 (9th Cir., decided November 20, 2009)**. The issue arose in a case alleging that "inhumane methods" of poultry slaughter increased the risk of food-borne illness to plaintiff consumers as well as health and safety dangers to plaintiff poultry workers. The court reversed a district court order granting USDA's motion for summary judgment and remanded the case with instructions to dismiss.

According to the court, the plaintiffs had the burden of establishing that their alleged injury "was likely to be redressed by a favorable court decision." The key to the court's redressability determination was that the 1958 law's only enforcement mechanism was later repealed. If the USDA secretary were ordered to interpret the phrase "other livestock" in the 1958 law to include poultry, there would be no way to compel poultry processors to comply with it.

This meant that the court would be forced to speculate that the USDA secretary would deem chickens, turkeys and birds to be "amenable species" under a 2005 amendment to a meat inspection law that had enforcement provisions for violations of humane animal treatment rules. Because the meat inspection law and its amendment were not at issue in the litigation, the court could not compel the secretary to add poultry as an "amenable species." The court also noted that third parties not before the court, that is, poultry processors, would have to abide by whatever regulations the secretary chose to adopt "for any injury suffered to be redressed." Third party behavior, said the court, cannot be controlled or predicted.

Observing that the secretary's decision on this issue "may be subject to a number of political and legal factors quite independent from this court's determination with respect to the meaning of" the 1958 law, the court concluded that the plaintiffs' claims were not redressable and "there is a lack of standing to proceed with this action."

MDL Court Denies Motions for Judgment as Matter of Law in GM Rice Litigation

A federal court in Missouri has denied motions for judgment as a matter of law filed by the defendant and its subsidiaries after two weeks of trial in bellwether cases seeking damages for the purported contamination of conventional rice in 2006 with

a genetically modified (GM) variety that was not approved for human consumption when tested. *In re: Genetically Modified Rice Litig.*, MDL No. 1811 (U.S. Dist. Ct., E.D. Mo., E. Div., motions denied November 19, 2009). Defendants Bayer AG and its subsidiaries had argued, among other matters, that the rice farmers failed to show that "but for" the company's specific conduct, the GM rice would not have entered the commercial rice supply and that the parent corporation had nothing to do with the GM field trials conducted in 1999-2002. *See Law 360,* November 20, 2009.

In a related development, a Philippine court of appeals has reportedly reversed a lower court order that enjoined the government from granting Bayer Crop Science, Inc.'s application to use its GM rice in the country. The litigation, brought by Greenpeace Philippines, alleged that GM rice is not fit for human consumption and that the organization was denied information on Liberty Link Rice 62. The appeals court apparently ruled that Greenpeace failed to establish "a clear and positive right which should be judicially protected through the writ of injunction." According to the court, the petitioner's arguments were "too contingent and speculative to warrant injunctive relief," and the courts lack the competence or expertise to make decisions about GM crops. *See abs-cbnNEWS.com*, November 22, 2009*, Malaya.com*, November 23, 2009.

Meanwhile, China, France and the UK have recently weighed in on the use of GM crops. China's government has reportedly issued safety certificates to domestically developed strains of GM rice and corn. Additional approvals are apparently required before the crops can be grown commercially, but the news has been welcomed as a major step in the country's endorsement of biotechnology use in staple crops.

According to news sources, the French government has published an outline of rules for food processors choosing to adopt a GM-free labeling system. While the recommendations of the country's High Biotech Council are not currently binding, they establish a 0.1 percent threshold for levels of transgenic DNA that can be contained in products labeled "GMO-free," "fed on GMO-free feed" or "derived from animals fed without GM feed." The French government is expected to make the recommendation law in the second half of 2010. The council is also reportedly soliciting public comments on how to label products in the "grey area," that is, containing between 0.1 percent and 0.9 percent GM ingredients.

In the UK, the Food Standards Agency (FSA) is apparently poised to launch a year-long consultation on GM foods that opponents are characterizing as an effort to persuade the British public that so-called "Frankenstein foods" are safe. According to a news source, a focus group survey that FSA has published as a prelude to the consultation purportedly suggests that GM food opponents are more motivated by "emotion" than "reasoned" argument. Scientists, politicians and businesses have reportedly called for the government to reconsider the issue, arguing that increased food prices and concerns over future supplies could make the use of GM crops more acceptable to the general public. *See The Telegraph*, November 26, 2009; *ISAAA.org Crop Biotech Update*, November 27, 2009; *FoodNavigator-USA.com*, November 30, 3009; *Fish Information & Services* and *The Wall Street Journal,* December 1, 2009.

Unilever Files Motion to Dismiss in "I Can't Believe It's Not Butter"® Class Action

Unilever United States, Inc. has asked a federal district court to dismiss a putative class action charging the company with falsely advertising its "I Can't Believe It's Not Butter"® product. *Rosen v. Unilever U.S., Inc.*, No. 09-02563 (U.S. Dist. Ct., N.D. Cal, San Jose Div., motion filed November 30, 2009). According to Unilever's motion, this is a "Private Surgeon General" case that seeks refunds for products purchased over the last four years because Unilever allegedly (i) falsely claims that its products are "Made With A Blend of Nutritious Oils," and (ii) fails to disclose that the products contain trace amounts of *trans* fatty acids.

Unilever argues that the claims are preempted by federal law which requires a "zero" *trans* fat content label if the product contains less than 0.5 gram per serving. The company also seeks dismissal under the dormant Commerce Clause, contending that, "If successful, Rosen will Balkanize [*trans* fat] labeling rules—one set of rules for California that *he* prescribes and another prescribed by the FDA for everyone else." The company further argues that the court should abstain to avoid entanglement "in a complex area already subject to oversight by an agency having day-to-day supervision responsibilities." According to Unilever, "The debate over the relative benefits of butter versus other fats is ongoing and raises numerous complexities."

The company's motion also invokes the defense of truth, claiming that its "nutritious oil" assertions are true, and non-actionable puffery in regard to its comparisons to butter. Finally, the company argues that the plaintiff has not met applicable pleading standards, is not entitled to injunctive relief and cannot be awarded damages under the Consumers Legal Remedies Act.

ConAgra Seeks to Sever and Transfer Additional Claims in Peanut Butter MDL

ConAgra Foods, Inc. has asked a multidistrict litigation (MDL) court to sever and transfer the claims of 68 plaintiffs from 14 different states in an action (*Bowman v. ConAgra Foods, Inc.*) recently filed against the company arising out of the purported *Salmonella* contamination of its peanut butter. *In re: ConAgra Peanut Butter Prods. Liab. Litig.*, MDL No. 1845 (U.S. Dist. Ct., N.D. Ga., Atlanta Div., motion filed November 24, 2009). The motion is similar to one filed earlier in November. Additional details about that motion appear in issue 327 of this Update.

While ConAgra does not object to the court retaining jurisdiction over the *Bowman* claims for purposes of pre-trial proceedings, it asks that the plaintiffs' claims be severed and transferred for trial because they were improperly joined and "because trial of these claims as a single action is likely to result in undue prejudice to the litigants and confusion to the jury," which would have to apply the law of 14 states to the claims. According to the company, little evidence remains in Georgia, and the plaintiffs have no factual or legal nexus to the MDL court's district.

WTO Judges Agree to Consider COOL Dispute

As anticipated, Canada reportedly renewed its request that the World Trade Organization (WTO) establish a panel to resolve a dispute over U.S. country-of-origin labeling (COOL) requirements. The request was accepted, and the panel is expected

to issue its report sometime in the second half of 2010, according to a news source. The WTO can authorize those countries winning such disputes to adopt commercial sanctions against countries violating its rules.

Canada and Mexico have both challenged COOL, which requires U.S. meat processors to handle and label imported products separately, claiming violations of international trade agreements. Canadian meat producers reportedly contend that the rules have caused many U.S. processors to simply exclude Canadian products, and U.S. Department of Agriculture figures purportedly show that U.S. imports of Canadian livestock were 34 percent lower in the first half of 2009 compared to the same period in 2008.

Canada's agriculture minister was quoted as saying, "We are confident that we will win our challenge." The U.S. government released a statement expressing disappointment with the WTO's decision and stating, "Nonetheless, we are confident that our measures provide information to consumers in a manner consistent with our WTO commitments." COOL applies to a range of food products, including beef, chicken, pork, lamb, goat, wild and farm-raised fish, nuts, and other agricultural commodities. *See Bloomberg.com*, November 19, 2009; *FoodNavigator-USA.com,* November 20, 2009.

Chinese Civil Trial Opens in Tainted Milk Scandal; Two Milk Producers Executed

According to a news source, a Chinese court began hearing claims on November 27, 2009, in a civil suit brought against a dairy company and supermarket by the parents of a child allegedly sickened by melamine-contaminated milk. The parents are reportedly seeking US$8,080, claiming that the milk caused their 20-month-old son's kidney stone.

The companies have apparently argued in their defense that the injury should be covered under a government compensation program and that no medical records link the child's kidney problems to drinking tainted milk. The judge has scheduled another hearing for December 9 and requested that the parties produce additional evidence.

The case is the first to be heard in the tainted milk scandal, which purportedly resulted in the deaths of six infants, injury to 300,000 children and a worldwide recall of products containing contaminated milk powder. The largest company implicated, the Sanlu Group, paid US$132 million into a US$161 million fund and declared bankruptcy. Government officials have reportedly been harassing parents seeking redress beyond the compensation fund or waging a public campaign to hold more officials accountable.

In the meantime, two milk producers were apparently executed on November 25 for their role in the scandal. They allegedly sold more than 3 million pounds of milk powder laced with melamine to create the illusion of a higher protein content. Nineteen other people involved in the scandal were tried and sentenced in January; 15 were imprisoned for two to 15 years, one received a suspended sentence of death, and three were sentenced to life in prison. *See The New York Times*, November 25 and 29, 2009.

OTHER DEVELOPMENTS

CSPI Report Criticizes Children's Food and Beverage Advertising Initiative

The Center for Science in the Public Interest (CSPI) has issued a report alleging that "nearly 80 percent of food ads on the popular children's network Nickelodeon are for foods of poor nutritional quality." Titled "Better-For-Who? Revisiting company promises on food marketing to children," the analysis purportedly revealed that one-fourth of the food and beverage advertisements aired on Nickelodeon "were from companies that don't participate in the industry's self-regulatory program," the Children's Food and Beverage Advertising Initiative (CFBAI). The watchdog also criticized CFBAI signatories for promoting products that failed to meet CSPI's stringent nutritional benchmarks. "Of the 452 foods and beverages that companies say are acceptable to market to children, CSPI found that 267, or nearly 60 percent, do not meet CSPI's recommended nutrition standards for food marketing to children," claimed the group in a November 24, 2009, press release.

"Nickelodeon should be ashamed that it earns so much money from carrying commercials that promote obesity, diabetes, and other health problems in young children," said CSPI Nutrition Policy Director Margo Wootan. "If media and food companies don't do a better job exercising corporate responsibility when they market foods to children, Congress and the FTC will need to step in to protect kids' health."

Meanwhile, CFBAI has defended its role in reshaping "the landscape of children's food." According to CFBAI Vice President Elaine Kolish, CSPI's "yes or no matrix" does not track significant changes made by companies committed to reformulating their products and improving nutritional profiles. When asked whether the CSPI survey is helpful, Kolish reportedly stated, "A little bit of both. When it is perceived as negative, it can be discouraging for companies trying to do the right thing." *See FoodNavigator-USA.com,* December 1, 2009.

Ocean Spray Disputes Assertions That New Cranberry Product Is Falsely Labeled

Ocean Spray, which introduced its Choice® dried cranberries in March 2009, has called "inaccurate" National Consumer League (NCL) allegations that the product is falsely labeled because it contains more sugar than cranberry. The NCL also reportedly contended that Choice® sweetened dried cranberries, which are sold to food manufacturers for use in baked products, trail mix, granola bars, and cereals, are made from cranberry skins. NCL apparently had the product tested and is concerned whether enough cranberry is being used to confer the fruit's purported health benefits.

A company spokesperson was quoted as saying, "Our Choice product is made from Grade A superior frozen whole cranberries which are then sliced and sent through our patented process including infusion of sugar, citric acid and elderberry juice to infuse flavor and color specifically developed to meet our industrial consumers' needs for their variety of recipes. Being made from whole cranberries, Choice retains many of the same healthful compounds." *See FoodNavigator-USA.com,* November 20 and 23, 2009.

MEDIA COVERAGE

"Nanoceuticals: Tiny Size, Big Potential," *nanovip.com*, December 1, 2009

Noting the absence of significant regulatory oversight, this article discusses the use of nanotechnology in foods, food packaging and food supplements. While the Food and Drug Administration has decided not to regulate products according to the technology used, it will apparently issue a guidance document on nanotechnology in 2010. The article cautions that "companies need to realize the EU, Canada and the State of California have all requested information from manufacturers of nanoscale products."

According to the market data on nanotechnology, while little food with nanotech ingredients are on grocery store shelves today, food packaging is an active application that accounts for billions in sales. Manufacturers are apparently using the technology to develop "improved tastes, color, flavor, texture and consistency of foodstuffs, increased absorption and bioavailability of nutrients and health supplements, new food packaging materials with improved mechanical, barrier and antimicrobial properties, and nano-sensors for traceability and monitoring the condition of food during transport and storage."

The article also discusses how nanotechnology is being incorporated into nutrition via micelles, "the tiniest of capsules that form naturally when nature requires a fat-soluble substance to be soluble in water," and liposomes. An Israeli-based company is reportedly using micelles as a delivery system for vitamins, omega-3s, beta-carotene, isoflavones, and lutein, while Australian researchers are developing "chitosan-based biopolymers to encapsulate and protect antioxidants from the low pH in the gut, so they can make it to the small intestines and be released in a controlled manner."

The article concludes by observing how little is known about where "nano-enabled substances will go in the body and how they will affect health.. . . . This lends to a fear by regulators and consumers, both of which have been slow to learn about nanotech. It is truly an infant frontier that hopefully does not become another cowboy-filled Wild West the natural products industry does not need."

Paul McCartney and Edward McMillan-Scott, "Less Meat = Less Heat," *The Parliament Magazine,* November 30, 2009

Writing for the European Parliament's news, policy and information service, Sir Paul McCartney in this article urges members of Parliament (MEPs) and other government stakeholders to promote "meat free Mondays," a campaign calling on consumers to eat less meat in an effort to slow climate change. According to McCartney, who also brought his message to the Global Warming and Food Policy Conference held December 3, "having one designated meat-free day a week is a meaningful change that everyone can make—that goes to the heart of several important political, environmental and ethical issues all at once." He subsequently appeals to "world leaders converging on Copenhagen for the climate change talks to remember that sustainable food policy is an essential weapon in the fight against global warming."

The article cites a 2006 Food and Agriculture Organization (FAO) report titled "Livestock's Long Shadow," which apparently "warned that emissions from global livestock production comprise about 18 percent of annual global greenhouse gas emissions, and could more than double by 2050." Similarly, as McCartney notes, a Friends of the Earth and Compassion in World Farming study has estimated that "if the industrialized world cut its meat consumption by half it would be possible to feed the world in 2050 without massive agricultural expansion, intensive crop and animal farming, or any further deforestation." According to McCartney, "A lower-meat diet could see greenhouse gases reduced by as much as 80 percent."

Conservative MEP Edward McMillan-Scott echoes these predictions, commenting that "A change of diet is literally our biggest chance to stop global warming, as well as improving our health and saving money." He also recognizes the role that the European Parliament has played in addressing climate change "at all levels," applauding its efforts to thoroughly examine "the changing environment with respect to agriculture, food and development policies—including the publication of a special temporary committee of inquiry report on climate change."

Their conclusions have since drawn fire from agriculture groups like the Irish Farmers' Association, which told reporters that McCartney was leading a "flawed campaign" rife with contradictions. In addition, UKIP MEP Paul Nuttall has accused the EU of "using climate change to justify its own existence. Much of what is said about climate change is highly debatable." *See The Parliament,* December 4, 2009.

SCIENTIFIC/TECHNICAL ITEMS

Study Examines Autoimmune Illnesses Linked to Pork Processing Plants

A recent study has reportedly confirmed that 21 meatpackers working at a Quality Pork Processors, Inc., facility contracted a neurological disorder after inhaling aerosolized pig proteins. Daniel H. Lachance, et al., "An outbreak of neurological autoimmunity with polyradiculoneuropathy in workers exposed to aerosolised porcine neural tissue: a descriptive study," *The Lancet Neurology,* November 30, 2009. Researchers identified the proteins as the trigger for an autoimmune response involving debilitating pain, weakness and numbness in extremities. The authors also examined blood samples from 100 asymptomatic workers, finding that one-third had the same antibody response as those reporting neurological ailments. "The pattern of nerve involvement suggests vulnerability of nerve roots and terminals where the blood-nerve barrier is most permeable," stated the study abstract, which did not offer an explanation for why some workers became ill while others appeared healthy.

The study noted that subjects with the strongest antibody response were closest in proximity to a work station where a high-pressure hose separated pig brains from the skull. In particular, the workers told investigators that their symptoms began after the facility sped up production line operations. "[It] sounds as if as the line speed increased, the operator was not able to handle the process properly and as a consequence the material was being directed in all directions," the lead author was quoted as saying. *See StarTribune.com,* November 29, 2009; *The Associated Press,* December 1, 2009.

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CONFERENCES AND SEMINARS

SHB Partner to Address 2010 GMA Consumer Complaints Conference

Shook, Hardy & Bacon Agribusiness & Food Safety Co-Chair Madeleine McDonough will discuss "Pre-Litigation Risk Management Strategies" at the GMA Consumer Complaints Conference slated for April 7-9, 2010, in Washington, D.C. The conference is designed specifically for food industry staff working in the areas of consumer affairs, call center management, consumer complaints, product liability claims, and quality assurance. For more information, please visit the GMA site by clicking here.

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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.