Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Congress Continues to Consider Food Safety, Nutrition and Wellness Bills; Out on Recess

The 111th Congress is now on recess until April 20, 2009, but before legislators left Washington, D.C. for their district offices, they introduced several more bills relating to food safety, nutrition or wellness. They include:

- H.R. 1869 – Introduced April 2, 2009, by Representative James McGovern (D-Mass.), this bill would require the president to convene a "White House Conference on Food and Nutrition." The main focus of the bill is addressing hunger and food insecurity. It has been referred to the House Committee on Agriculture.

- H.R. 1897 – Introduced April 2, 2009, by Representative Earl Blumenauer (D-Ore.), this proposal would amend the Internal Revenue Code to give employers a tax credit for the costs of implementing workplace wellness programs that would have health awareness, employee engagement, behavioral change, and supportive environment components. Among the targets of the legislation are obesity and fitness. The bill, which has a companion in the Senate (S. 803), has been referred to the House Committee on Ways and Means.

- H.R. 1907 – Introduced April 2, 2009, by Representative Michael Castle (R-Del.), this bill would amend the Federal Food, Drug, and Cosmetic Act to allow the Food and Drug Administration to require food retailers to use information they maintain on customer purchases to issue recall notices. The bill has been referred to the House Committee on Energy and Commerce.

- S. 753 – Introduced March 31, 2009, by Senator Charles Schumer (D-N.Y.), this bill would prohibit the manufacture, sale or distribution of food and beverage containers with bisphenol A (BPA), marketed for infants and toddlers. The "BPA-Free Kids Act" would also mandate testing and certification by plastics and container manufacturers and would require the Consumer Product Safety Commission to audit plastic resin test data provided by suppliers and manufacturers. The bill would ensure that consumers can identify containers made from tested materials by requiring "Compliant with BPA-Free Kids Act 2009" on product labels. Criminal and civil penalties would be set for violations, and any children's food or beverage

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containers manufactured with BPA would be considered a "banned hazardous substance" under the Federal Hazardous Substances Act. The bill has been referred to the Senate Committee on Commerce, Science, and Transportation.

Schumer, who co-sponsored similar legislation in 2008, reportedly gave his support to a New York county initiative that would also have banned BPA. He apparently praised the Suffolk County Legislature as the first governmental body in the country to pass a BPA ban, saying at a press conference that it was "ahead of the curve." *See Product Liability Law 360*, March 30, 2009.

In a related development, Illinois lawmakers are also considering a proposal (H.B. 2485) that would prohibit the sale or distribution of food and beverage containers with BPA, intended for children younger than age 3. It was amended in the House to include an exemption for metal cans and has been re-referred to that body's Rules Committee. A news editorial called on the state legislature to approve the law, asking whether legislators would "want your son, daughter, grandson or granddaughter to drink milk from a BPA-laced bottle or cup today?" *See Daily Herald*, April 2, 2009.

USDA Amends Swine Health Protection Rules

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service has amended swine health protection rules to clarify that regulations regarding the treatment of garbage consisting of industrially processed materials are subject to the same treatment requirements of other regulated garbage except for materials that meet the definition of "processed product." The action ensures that garbage fed to swine has been treated to inactivate disease organisms that pose a risk to the U.S. swine industry. Comments must be received by June 2, 2009. *See Federal Register,* April 3, 2009.

Peanut and Pistachio Recalls Lead FDA to Issue Tougher Food Safety Warnings

The Obama administration has reportedly issued a tough warning that it will substantially change the way government oversees food safety. According to published reports, food-handling practices that formerly would have resulted in mild warnings from FDA may now lead to wide-ranging and expensive recalls." The food industry needs to be on notice that FDA is going to be much more proactive and move things faster," David Acheson, FDA associate commissioner for food protection, was quoted as saying. "We're going to try to stop people from getting sick in the first place, as opposed to waiting until we have illness and death before we take action."

Meanwhile, the Centers for Disease Control and Prevention (CDC) issued a **report** April 9 claiming the nation's food safety system needs a thorough overhaul and that even though cases of *Salmonella* may be increasing, their incidence is not statistically significant. The system should be overhauled, the report states, because it was created when most of the U.S. food supply was grown, prepared and consumed locally and now should address an increasingly global food industry. *See foodnavigator-usa.com* and *Reuters,* April 6, 2009, *The New York Times*, April 7 and 10, 2009.

And in related news, an article in the March 2009 issue of *Specialty Food Magazine*, says that food safety scares have caused many shoppers to turn toward "sacred foods" such as certified kosher and halal foods because of the perceived quality and hygiene used in their manufacturing. The article states that kosher food sales have increased by 10 to 15 percent annually for the last eight years.

FDA Announces Meeting to Address Intentional Food and Drug Adulteration

The Food and Drug Administration (FDA) has announced a public meeting slated for May 1, 2009, in College Park, Maryland, to discuss the economically motivated adulteration of foods and drugs, which the agency defines as the "fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain." FDA is seeking public input on how the food, drug, medical device, and cosmetic industries, regulatory agencies and other stakeholders "can better predict and prevent economically motivated adulteration with a focus on situations that pose the greatest public health risk." The agency will accept written or electronic comments until August 1, 2009. *See Federal Register,* April 6, 2009.

FDA Proposes 60-Day Delay for BSE Feed Ban Rule

The Food and Drug Administration (FDA) has proposed delaying for 60 days a final rule titled "Substances Prohibited From Use in Animal Food or Feed," which establishes "measures to further strengthen existing safeguards against bovine spongiform encephalopathy (BSE)." Scheduled to take effect April 27, 2009, the rule includes provisions that prohibit the rendering of spinal cords and brains from cows older than 30 months. Industry groups have reportedly requested additional time to arrange for alternative disposal methods, prompting the agency to consider pushing back the implementation date to June 26. FDA will accept comments on the proposed delay until April 16, 2009. *See Federal Register,* April 9, 2009.

United States and Canada Agree on Organic Equivalency Standards

The Organic Trade Association (OTA) has announced that the United States and Canada have agreed to finalize negotiations on their organic equivalency standards before the new rule is implemented on June 30, 2009, to ensure trade continues uninterrupted. The new Organic Products Regulations will require all Canadian organic products to be endorsed by a certification body accredited by the Canadian Food Inspection Agency (CFIA). The rules were designed to create a nationwide standard for Canadian products but raised fears that products previously accepted as organic from other countries, including the United States, could be shut out if they did not comply. The U.S. final rule on national organic standards was fully implemented in October 2002 and is slightly different than the new Canadian regulation.

An official of the OTA was quoted as saying, "Canadian consumers will definitely benefit from this, and will continue to enjoy quality year-round organic products from the United States. At the same time, Canadian farmers and manufacturers will be able to certify to our organic standards without having to take on additional redundant certifications to sell into the United States – so everybody wins." *See foodnavigator-usa.com,* April 3, 2009.

Kansas Governor Urged to Veto Milk Hormone Bill

The Institute for Responsible Technology (IRT) has urged Governor Kathleen Sebelius (D-Kansas) to veto a bill passed by the Kansas Legislature on April 3, 2009, that restricts U.S. dairies from labeling their milk products free from genetically engineered bovine growth hormone (rbGH or rbST). Sebelius, who is vying to become the new U.S. Secretary of Health and Human Services, has until April 16 to veto the bill.

According to the consumer advocacy group, which claims milk from hormone-treated cows can cause cancer, companies such as Wal-Mart, Starbucks and Dannon, and more than half of the nation's top 100 dairies have committed to stop using rbGH in some or all of their products. The Kansas legislation would require all manufacturers that sell rbGH-free products in the state, including national brands, to add a large disclaimer on their packages stating that the hormone does not change the quality of the milk. *See responsibletechnology.org*, April 6, 2009.

LITIGATION

Food Producers File $1 Billion Lawsuit Against Import Insurers and Federal Government

Companies that produce honey, mushroom, garlic, and crawfish products have filed a putative class action against major insurance companies and the U.S. government, alleging that the negligent issuance of customs surety bonds allowed the sale of massive quantities of competing, lower-cost Chinese products. *Sioux Honey Ass'n v. Hartford Fire Ins. Co.*, No. 09-00141 (Ct. Int'l Trade, filed April 7, 2009).

Filed in the U.S. Court of International Trade, the lawsuit claims that for eight years, insurers issued hundreds of the bonds to "thinly capitalized" and inexperienced shippers, guaranteeing the payment of any anti-dumping duties the government might decide were owed by U.S. importers for specific Chinese goods. The plaintiffs contend that the insurers failed to follow underwriting standards and thus issued bonds to importers posing an unacceptable risk of default. Had the insurers not issued the bonds to importers, "little if any of the imports that were secured by those bonds would have entered the U.S. market," according to the complaint. The importers have allegedly now defaulted on paying hundreds of millions of dollars in dumping duties assessed by the government.

The plaintiffs also claim that U.S. Customs and Border Protection and the Commerce Department have failed to enforce four anti-dumping orders that were issued to protect domestic producers. They allege that the insurers have failed to pay the uncollected anti-dumping duties and that Customs has not filed any collection lawsuits against them to recover the duties. Alleging that they are intended third-party beneficiaries of the bonds, the plaintiffs claim that they suffered "severe financial damages" because they were forced to significantly lower the prices for their competing products and because the government is legally obligated to distribute to them the dumping duties ultimately paid by competing importers or their insurers. *See Dow Jones Newswire*, April 7, 2009.

ITC Finds No Infringement of Sucralose Patents

The International Trade Commission (ITC) has reportedly ruled that Chinese manufacturers and U.S. distributors did not infringe the sucralose patents owned by Tate & Lyle. The ITC's April 6, 2009, ruling affirms an administrative judge's September 2008 preliminary ruling about the sweetener patents. More details about the case appear in issue 276 of this Update.

According to a news source, Tate & Lyle is reviewing the latest determination and will decide whether appeals through the Federal Circuit Court of Appeals are feasible. Numerous sucralose competitors are apparently ready to try to break what has been characterized as Tate & Lyle's near monopoly of the global $1.3 billion sucralose market. The company's president called the ruling a disappointment, but, referring to the quality of its product and the efficiency of its manufacturing processes, was quoted as saying, "intellectual property is just one of the many components which define Tate & Lyle's formidable competitive advantage in the global sucralose business." *See Foodnavigator-usa.com*, April 7, 2009.

Federal Court Denies Class Certification in Pet Food Litigation

A federal court in Nevada has denied the motion to certify as a class claims filed against a major retailer and a number of pet food makers alleging that they deceived consumers by representing that Ol' Roy® brand pet food products are "Made in the USA," when, in fact, components are manufactured abroad. *Picus v. Wal-Mart Stores, Inc.*, Nos. 07-682, -686, -689 (U.S. Dist. Ct., D. Nev., filed March 16, 2009).

The case was filed in state court, removed to federal court, where it was consolidated with several other suits, and then transferred to a multidistrict litigation (MDL) court in New Jersey that ultimately settled hundreds of MDL claims against pet-food makers involving melamine-tainted products. After the MDL transfer was vacated, the plaintiff amended her claims in the Nevada litigation to limit the class to residents of Nevada, California, Colorado, Idaho, Illinois, Michigan, Ohio, and Oregon. She argued that these states "expressly outlaw sales of products mislabeled as to geographic origin," and thus, that no conflicts of law remained.

Ruling that the plaintiff would have to prove reliance to establish causation for her fraud claim, the court refused to presume reliance and found that it "would have to consider whether each class member relied on or even saw the 'Made in the USA' label when purchasing Ol' Roy products, as well as the damage each class member incurred as a result of that reliance." The court also found that class members in the subject states faced different legal requirements as to reliance and damages. Accordingly, the court found that individual issues of reliance and damages would predominate over common issues "thereby negating the efficiency of class treatment and increasing the risk of confusion."

Marshals Execute Warrant at N.J. Company That Refused to Recall Peanut Products

The Food and Drug Administration (FDA) has announced that U.S. marshals executed an inspection warrant at Westco Fruit and Nuts, Inc., in Irvington, New Jersey, after the company refused to recall its peanut products or provide access to distribution documents in the wake of the *Salmonella* outbreak involving peanuts from the Peanut Corp. of America (PCA).

An FDA spokesperson said, "FDA's enforcement action against Westco Fruit and Nuts is an appropriate step toward removing potentially harmful products from the marketplace, especially when, as in this case, a company is unwilling to share information FDA needs to ensure food safety. FDA uses all appropriate legal means necessary to obtain information and fully investigate firms or individuals who put the health of consumers at risk."

Apparently, Westco purchased oil-roasted and salted peanuts from PCA in November and December 2008. It sold them in various sizes and packages and used them as an ingredient in mixed nut and trail mix products. On February 9, 2009, New Jersey officials apparently executed an embargo action at Westco's distribution facility to prevent the company from further distributing potentially contaminated products in its inventory. In March, the FDA formally requested that Westco recall products containing PCA peanuts and sought access to company records about their distribution.

The company refused both requests because, according to owner Jacob Moradi, the FDA did not provide proof that his peanuts contained salmonella. "We have been requesting information to that effect, and they have not given us an iota of information whatsoever," he reportedly said. Thus, when the FDA issued a public warning on March 23 against consuming Westco's peanut products, specific brands or foods could not be and were not named. Some pointed to the incident as a weakness in the food safety system, because the FDA lacks mandatory recall authority. *See Kansas City InfoZine*, March 25, 2009; *FDA Press Release*, April 8, 2009.

Fast Food Company Sues Packaging Supplier for Flaming Chicken Containers

KFC U.S. Properties, Inc. has filed a lawsuit in federal court against the company that allegedly supplied defective food containers for the sale of Popcorn Chicken® to KFC customers; the containers apparently burst into flames when the product is reheated in a microwave. *KFC U.S. Props., Inc. v. Paris Packaging, Inc.*, No. 09-00249

(U.S. Dist. Ct., W.D. Ky., filed April 3, 2009). According to the complaint, in February 2009, the defendant began using an ink with high carbon content for the graphics printed on the containers. After receiving customer complaints, KFC tested the containers and established that they "spontaneously combusted in a microwave within 13-20 seconds of reheating." While no personal injuries have been alleged, the company is seeking damages in excess of $75,000 for breach of contract.

Trans Fat Claims Against Wendy's Certified, Settled and Dismissed

A federal court in California has approved the settlement of class claims against Wendy's International, Inc. involving its use of *trans* fats in fried food products. *Yoo v. Wendy's Int'l, Inc.*, No. 07-04515 (U.S. Dist. Ct., C.D. Cal., filed March 13, 2009). In its revised order and final judgment, the court overruled objections to the settlement, certified a nationwide settlement class and dismissed the complaint with prejudice. The defendant was ordered to add $450,000 plus interest to the $1.8 million already in an escrow account to be divided equally among the American Cancer Society, American Diabetes Association, American Dietetic Association, and American Heart Association.

The court also ordered the defendant to ensure that its fried foods are cooked in oil containing a level of *trans* fat per serving that "can be represented as 0 grams of *trans* fat," under Food and Drug Administration regulations. Wendy's was further ordered to "pay for and subject its Fried Food to independent monitoring for one year to assure [sic] compliance." Class counsel was awarded $1.09 million plus interest, and the four named plaintiffs were awarded either $3,500 or $1,500 depending on whether they were deposed before the case settled.

OTHER DEVELOPMENTS

Bronchiolitis Obliterans Now Seen in Workers at Candy Factories

Investigative reporter Andrew Schneider has published an item on his blog about "popcorn lung" problems faced by workers in other industries, such as candy manufacturing, exposed to diacetyl, a butter-flavoring chemical. According to Schneider, five patients diagnosed with the sometimes-fatal lung disease worked at a now closed Brach's candy plant in Chicago. While federal occupational health and safety inspectors cannot investigate conditions in a closed facility, International Brotherhood of Teamster's officials are reportedly calling on them to inspect candy plants in Tennessee. The union is apparently concerned that workers outside the popcorn industry are also being exposed to disabling levels of diacetyl and are not aware of it.

Schneider also reports that a trial against flavoring manufacturers began on April 6, 2009, for claims involving a woman who allegedly developed bronchiolitis obliterans while working at a plant that produced popular brands of popcorn. A physician who was expected to be called as a witness at her trial was quoted as saying, "The cluster of new cases of bronchiolitis obliterans among candy makers has got to be the signal to even the most lethargic government agency that more

workers—hundreds if not thousands—that use these chemical flavoring agents are in danger. I'd use the cliché and say it was a wakeup call, but that happened years ago at the popcorn plants and [the Occupational Safety and Health Administration] has yet to do anything meaningful." *See andrewschneiderinvestigates.com*, April 6, 2009.

Farm Foundation Holds Public Forum on Food Safety Regulations

The Farm Foundation recently hosted a public forum titled "The Future of Food Safety Regulation" to discuss agricultural, food and rural policies designed to revamp the current regulatory system. Held April 7, 2009, at the National Press Club, the forum featured a panel of experts that included Jim Hodges of the American Meat Institute, Carol Tucker Foreman of the Consumer Federation of America's Food Policy Institute; Scott Horsfall of the California Leafy Greens Marketing Agreement; and Margaret Glavin, an independent consultant and former Food and Drug Administration (FDA) official.

Glavin reportedly identified the global food market as "the single biggest challenge" facing U.S. agencies and recommended modernizing laws to promote a uniform approach to food safety. Noting the high cost of legislative proposals that would create one umbrella agency, Glavin instead argued for increased FDA funding and the authority to enforce import requirements and conduct overseas inspections. "Our regulations and our program design both envision a regime of regular inspections of domestic food plants and an occasional look at foods from overseas," she was quoted as saying. "This is made worse by the fact that… imported products are treated completely differently by FDA and USDA [U.S. Department of Agriculture]." *See Congress Daily,* April 7, 2009.

In a related development, Tucker Foreman addressed these issues at an April 2 hearing before the House Agriculture Committee, where she apparently suggested that FDA model its food safety arm after USDA's Food Safety and Inspection Service (FSIS). "I've come to think of [FSIS] as the Rodney Dangerfield of food safety," she said. "It gets no respect for having made major strides in the last 15 years to improve its food safety efforts." *See Meatingplace.com,* April 6, 2009.

CCFC Objects to "Highly Sexualized" Burger King Ad

Campaign for a Commercial-Free Childhood (CCFC) has **launched** a letter-writing initiative to dissuade Burger King from using a "highly sexualized" television commercial to advertise its 99-cent SpongeBob Kids Meal. According to CCFC, the ad features Burger King's mascot "singing a remix of Sir Mix-A-Lot's 1990 hit song, 'Baby Got Back,' with the new lyrics, 'I like square butts and I cannot lie," intercut with images of Nickelodeon's popular cartoon character dancing on a TV screen in the background. The consumer watchdog has also criticized Burger King for airing the commercial during the NCAA basketball finals. "It's bad enough when companies use a beloved media character like SpongeBob to promote junk food to children, but it's utterly reprehensible when that character simultaneously promotes objecti-

fied, sexualized images of women," CCFC Director Susan Linn was quoted as saying. "That Burger King and Nickelodeon would sell kids meals by associating a beloved, male character like SpongeBob with lechery shows how little either company cares about the well-being of the children they target."

Meanwhile, Burger King has reportedly noted that the commercial advertises "a value-based offer aimed at adults" and is only being shown "during shows targeting adult audiences." The chain restaurant has released a "completely different" set of SpongeBob promotions for use during children's programming. *See MediaPost,* April 8, 2009.

U.S. Food Policy Blog Discusses Eggs Branded with Disney Characters

The *U.S. Food Policy* blog has posted a **response** to the announcement that Disney Food, Health & Beauty would begin marketing a line of "farm fresh" eggs branded with a rotating cast of cartoon characters. According to Disney Food, the available products will include Large, Extra Large, 18-pack Large, Disney Cage Free, and Disney Organic eggs, all produced by hens raised without hormones, steroids or antibiotics and fed Eggland's Best patented feed containing "healthy grains, canola oil, and an all-natural supplement of rice bran, alfalfa, sea kelp, and vitamin E." But the marketing plan has drawn criticism from one blog contributor, who blamed the egg supplier for furthering "the agrarian myth that people's food is coming from an idealistic farm with a red barn" and who questioned the motives behind Disney's foray into food marketing. "I side with Marion Nestle on the point that kids don't need special 'kid-friendly' foods to eat," stated the writer. "Should we be inundating kids with more advertising? Campaign for a Commercial-Free Childhood would say no. I would argue that this contributes to more disconnect between people and food culture." *See U.S. Food Policy Blog,* April 3, 2009.

SCIENTIFIC/TECHNICAL ITEMS

CDC Study Finds Perchlorate in Commercial Infant Formula

Researchers from the Centers for Disease Control and Prevention (CDC) recently published a study identifying perchlorate in 15 brands of powdered infant formula (PIF), which included products made from cow's milk with lactose; cow's milk without lactose; soy milk; and synthetic amino acids (elemental). Joshua G. Schier, "Perchlorate Exposure From Infant Formula and Comparisons With the Perchlorate Reference Dose," *Journal of Exposure Science and Environmental Epidemiology,* March 18, 2009. The study authors purportedly found that some PIF samples exceeded the daily reference dose of 0.7 µg/kg per day set by the Environmental Protection Agency. More than one half of the formulas would exceed the reference dose when reconstituted with drinking water contaminated with 4 µg/l of perchlorate, according to the study.

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The CDC researchers have reportedly claimed that the two brands with the highest perchlorate levels comprise approximately 87 percent of the powdered milk market in the United States. Scientists apparently believe that perchlorate, an oxidizer used in fireworks, airbags and solid rocket fuel, inhibits the uptake of iodine, an essential component of neurological development. "Perchlorate was found in all brands and types of infant formula tested," the authors wrote. "All bovine milk-based PIFs with lactose have significantly higher concentrations of perchlorate than the other three types tested (soy-based, lactose-free, and elemental)." *See FoodNavigator-USA.com,* April 6, 2009.

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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.