Shook, Hardy & Bacon L.L.P.

ISSUE 387 | MARCH 25, 2011

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Regulators Continue to Address Radiation Concerns

The World Health Organization (WHO), U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) have continued to address public concerns about food produced in Japan, where a recent earthquake and tsunami compromised the Fukushima prefecture's nuclear power plant, releasing radiation into the atmosphere. According to WHO, which has published a list of frequently asked questions about the disaster, "[f]ood safety issues are an additional dimension of the emergency," with some products likely to be deemed unsafe for human consumption. In areas where contamination has occurred, the organization has specifically urged citizens to avoid consuming milk or vegetables, slaughtering animals, hunting, harvesting aquatic animals and plants, or collecting other wild foods such as mushrooms. It has also asked producers to take numerous precautions to protect vegetables, livestock and rice harvests from fallout. "The presence of radioactivity in some vegetables and milk has been confirmed and some of the initial food monitoring results show radioactive iodine detected in concentrations above the Japanese regulatory limits," stated WHO, which has also confirmed the presence of radioactive cesium in lower concentrations. *See Reuters,* March 21, 2011.

Meanwhile, FDA has assured domestic consumers that "screening at U.S. borders will remain vigilant and will be augmented with radiation screening of shipments." The agency has since blocked all milk, spinach and kakina imports from Fukushima, as well as spinach and kakina from the nearby prefectures of Ibaraki, Tochigi and Gunma, while delaying other shipments from these four regions until they are "shown to be free from radionuclide contamination." As Agriculture Secretary Tom Vilsack reiterated, however, U.S. food imports from Japan are "quite limited" and must meet federal safety standards. "[A]t this time we have no reason to suggest that any of our meat, poultry, or processed egg products are unsafe for consumption due to the recent events in Japan," he said in a March 18, 2011, press release. *See The New York Times* and *Los Angeles Times,* March 22, 2011.

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 387 | MARCH 25, 2011

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.

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

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

or

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

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

These assurances were echoed on the West Coast by California Governor Jerry Brown (D), who in a March 18, 2011, press release indicated a radiation plume drifting over the Pacific Ocean poses "no threat" to domestic food and water supplies. Although health officials have reportedly pledged to screen the state's milk for signs of radiation, they have nevertheless warned residents *not* to take potassium iodide and other precautionary measures because of the risk of significant side effects. "The California Department of Public Health and our Emergency Management Agency are in constant contact with the federal agencies responsible for monitoring radiation levels in California, and we will tell the public if any precautions become necessary," said Brown. *See Bloomberg News,* March 18, 2011.

Some media outlets have also cited experts like Peter Caracappa, a health physicist at Renssealaer Polytechnic Institute, who told *NPR* that a person would need to drink more than 58,000 glasses of milk containing 1,510 becquerels of radiation per kilogram to raise her lifetime cancer risk by 4 percent. But attorneys quoted in a March 22, 2011, *Law360* article urged companies not to take such statistics or regulatory precautions for granted. "U.S. companies would be wise to conduct their own testing or lean on their suppliers to insure imports are radiation-free. If contaminated food hits the U.S. market, every company involved in the supply chain could find themselves facing litigation," concludes the report. *See NPR,* March 21, 2011.

FDA Denies Requests to Revoke Irradiation Rule

The Food and Drug Administration (FDA) has **denied** requests to delay a final rule amending food additive regulations "to provide for the safe use of ionizing radiation for the control of *Vibrio* species and other foodborne pathogens in fresh or frozen molluscan shellfish." According to FDA, it has reviewed opposition to the final rule and requests for a hearing, but concluded that objections filed by groups such as Public Citizen and the Center for Food Safety did not "justify a hearing or otherwise provide a basis for revoking the regulation."

In particular, the agency's latest decision dismisses allegations that (i) FDA failed to consider evidence indicating "harmful effects from consumption of irradiated molluscan shellfish"; (ii) the final rule does not ensure a product "that is microbiologically safe"; (iii) there is no reasonable certainty of no harm; (iv) FDA failed to consider "several factors that could make irradiated molluscan shellfish unsafe"; (v) FDA improperly failed to apply a "100-fold safety margin for 2-alkylcyclobutanones [2-ACBs]" produced during irradiation; (vi) FDA ignored "*in vivo* or *in vitro* mutagenicity studies"; (vii) FDA misrepresented "important published or unpublished warnings" about 2-ACBs; (viii) FDA failed to follow critical guidelines for food additives; (ix) FDA failed to address studies indicating that irradiating oysters "may cause unpleasant—perhaps unwholesome—byproducts"; (x) FDA made errors in

the review memoranda used to support the final rule; (xi) FDA ignored "the fact that irradiation can dramatically increase the concentration of many potentially toxic chemicals." Rejecting these claims, FDA has thus reconfirmed August 16, 2005, as the effective date of the final rule. *See Federal Register,* March 22, 2011.

USDA Seeks Candidates for Advisory Committee on Biotechnology

The U.S. Secretary of Agriculture is requesting **nominations** for members to the Advisory Committee on Biotechnology and 21st Century Agriculture. Nominations for one- to two-year terms are requested by April 18, 2011. Members are selected to "achieve a balanced representation of viewpoints" to address USDA biotechnology policy issues. Issues of the most immediate concern involve providing practical suggestions "on ways to strengthen coexistence among different agricultural crop production methods." *See Federal Register,* March 18, 2011.

FSIS Issues New Performance Standards for *Salmonella* and *Campylobacter*

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **announced** new and revised performance standards to reduce *Salmonella* and *Campylobacter* incidence in young chickens and turkeys. Effective July 2011, the standards apparently draw on the FSIS Nationwide Microbiological Baseline Data Collection Programs and the recommendations of President Barack Obama's (D) Food Safety Working Group. According to a March 21, 2011, *Federal Register* notice, "The standards will be applied to sample sets collected and analyzed by the Agency to evaluate establishment performance with respect to requirements of the Hazard Analysis and Critical Control Points (HACCP) Rule."

FSIS has estimated that, after two years, the combined *Campylobacter* and *Salmonella* standards will prevent approximately 25,000 illnesses annually. "While the industry has made significant strides in recent years, far too many Americans continue to fall victim to these foodborne illnesses," said Under Secretary for Food Safety Elisabeth Hagen in a March 16, 2011, press release. "These improved standards will drive the industry to do better. They are tough but achievable. And when fully implemented, they will prevent tens of thousands of Americans from getting sick."

In a related development, the Food and Drug Administration (FDA) has **issued** draft guidance for industry that addresses *Salmonella* testing procedures for human foods and direct-human-contact animal foods. Exempting shell egg producers, the guidance would apply to firms that "manufacture, process, pack, or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors." In addition, FDA plans on publishing "a separate guidance document responding to

questions FDA has received on the shell egg final rule since its publication and include in that document guidance on environmental and egg testing for *Salmonella* Enteritidis." The agency has requested comments on the draft guidance by June 21, 2011. *See Federal Register,* March 23, 2011.

EU Ministers Divided on GM Corn, Cotton Import Approvals

European Union farm ministers have reportedly failed to agree to grant import and sale approval to three genetically modified (GM) corn and cotton crops. Meeting in Brussels, Belgium, the ministers were divided as to whether to approve herbicide- and insect-resistant maize by Monsanto and Dow Chemical Co., and a herbicide-tolerant cotton by Bayer CropScience. Now set to go before the European Commission for a decision, GM crop applications for import or cultivation have routinely divided EU ministers. *See Reuters,* March 17, 2011.

Canada, EU Reach Tentative Agreement in Hormone-Treated Beef Dispute

Canada and the European Union (EU) have signed a memorandum of understanding that tentatively settles a long trade dispute over hormone-treated cattle. According to the March 17, 2011, memorandum, European nations will expand market access to Canadian beef while Canada will suspend trade sanctions on $11 million worth of EU imports.

Effective since the early 1980s, EU's "non-discriminatory" ban on hormone-treated beef was challenged by Canada and the United States at the World Trade Organization (WTO) starting in 1996, according to the European Commission (EC), the oversight body for EU legislation. In 1999, Canada and the United States were given WTO permission to impose retaliatory sanctions on a number of EU exports. Canada's sanctions applied to a variety of meat products "in the form of 100% duties."

"The memorandum foresees that Canada suspends these sanctions and the EU would extend its duty-free tariff-rate quota of high quality beef by an additional 1,500 tons until August 2012," the EC said in a statement. "This quantity could be increased to 3,200 tons for the following year. Canada and the EU would then assess the situation and decide whether to reach a permanent settlement of the case. Both the suspension of sanctions and the increase to the EU tariff-rate quota remain subject to the domestic decision-making procedures." *See EC Press Release,* March 17, 2010.

Canada Publishes Names of Companies in Violation of Food Safety Regs

Canada has begun publishing the names of companies in violation of the country's food, animal and plant-supply regulations. Reportedly aimed at improving accountability and transparency, the Canadian Food Inspection

Agency's (CFIA's) Website initiative now publishes such information as the (i) "food imports that have been refused entry into Canada"; (ii) "federally registered food establishments whose licenses have been suspended, cancelled or reinstated"; and (iii) "notices of violations with warning and penalties, including identifying repeat offenders of animal transport regulations." *See CFIA Press Release,* March 16, 2011.

Florida School District Deals with Student's Life-Threatening Peanut Allergies

Leaders of Edgewater Elementary School in Edgewater, Florida, are reportedly planning to meet with parents disgruntled over the school's accommodation of a 6-year-old girl with severe peanut allergies. Noting that the girl's allergies are life-threatening and considered a disability under the Americans with Disabilities Act, Volusia County School District spokesperson Nancy Wait said the meeting will help dispel inaccurate rumors that other students' mouths were being wiped with disinfectant to protect the first-grader's health.

Wait said the girl's fellow classmates are required to wash their hands before entering the classroom in the morning and after lunch, and rinse their mouths. A peanut-sniffing dog has also apparently visited the school. In answer to some parents' suggestion that the girl be removed from the classroom and home-schooled, Wait said that was not an option because it violated the federal law. *See MSNBC.com*, March 22, 2011.

LITIGATION

USDA Action on GE Alfalfa Draws New Lawsuit

The Center for Food Safety, Earthjustice and a number of other public interest groups have sued the U.S. Department of Agriculture (USDA), challenging its decision to deregulate genetically engineered (GE) alfalfa. ***Ctr. for Food Safety v. Vilsack*, No. 11-1310 (U.S. Dist. Ct., N.D. Cal., filed March 18, 2011)**. Other plaintiffs include the Cornucopia Institute, Geertson Seed Farms, which successfully challenged a previous agency decision to deregulate GE alfalfa, the Sierra Club, and organizations representing the interests of organic and family farmers.

The complaint alleges that the environmental impact statement (EIS) that USDA's Animal and Plant Health Inspection Service (APHIS) prepared to support its deregulation decision violates the National Environmental Policy Act (NEPA), Plant Protection Act (PPA) and Administrative Procedure Act. The plaintiffs note that the court-ordered EIS "is the first (and only) EIS APHIS has ever completed for any GE crop, in over fifteen years of approving GE crops for commercial use."

Seeking declaratory and injunctive relief, the plaintiffs claim that the EIS is arbitrary and capricious because the agency's analysis of "the myriad environmental, socio-economic, agricultural, and cumulative impacts" of deregulating GE alfalfa "is erroneous, unsupported, and/or inadequate." The complaint characterizes the EIS as "superficial, lacking in detail or quantification, and conclusory," and contends that APHIS's analysis is based on "unreliable data and erroneous assumptions contrary to the record." According to the plaintiffs, the "NEPA analysis and its outcome were improperly predetermined, and its scope was erroneously confined, by the agency's misapplication of its underlying statutory authority under the PPA."

The plaintiffs seek a vacatur of the deregulation decision and the completion of a "proper environmental review." With numerous references to previous court rulings agreeing with the plaintiffs' position that APHIS improperly deregulated GE alfalfa once before, the complaint calls for the court "to vacate APHIS's decision to once again deregulate [GE alfalfa] without taking a 'hard look' at the environmental consequences of its decision."

In essence, the plaintiffs claim that GE alfalfa will contaminate conventional and organic crops, resulting in significant environmental and economic losses. Among other matters, they allege that alfalfa is widely consumed by livestock, is pollinated by several bee species and provides important wildlife habitat, all of which would be negatively affected by APHIS's deregulation decision. They also allege that because the alfalfa hay export market is valued at $192 million annually and many of the countries importing U.S. alfalfa either ban, restrict or impose regulations on GE crops, the agency's decision would devastate the conventional and organic alfalfa export market. They also claim that GE crops foster an epidemic of resistant weeds that agronomists call "one of the most serious challenges facing American agriculture."

Federal Court Dismisses Insurance Coverage Action in Tainted Baby Formula Case

A federal court in Virginia has issued an order dismissing without prejudice claims filed against two insurers by a company that makes baby formula; the parties stipulated to the dismissal after similar litigation concluded with a defense verdict following trial in state court. *PBM Nutritionals, LLC v. Arch Ins. Co.*, No. 09-194 (U.S. Dist. Ct., E.D. Va., Richmond Div., order entered March 23, 2011). The matter reportedly involves the failure of a hot-water supply system that leached melamine and other filtration materials into eight days' worth of formula production, contaminating $6 million in baby formula.

The manufacturer has apparently recovered $2 million under a contamination policy issued by one of its insurers, but lost its bid to recover under other policies that contained "perils excluded" clauses and pollution/contamination endorsements. The perils-excluded clauses deny coverage for damages

resulting from a pollutant discharge unless the discharge is caused by a "peril" insured against. The insurers relied on contamination endorsements that exclude all pollution-related losses except in the case of fire, lighting or explosion. Still, the manufacturer, which has appealed the state court judgment to the Virginia Supreme Court, contends that inconsistencies between the clauses and endorsements render the insurers liable for coverage. According to the manufacturer, contamination from the loss of the filters qualified as an exception to the perils-excluded clause. The trial court disagreed, finding that the endorsements modified the clause and controlled the coverage issue. *See Law360*, March 23, 2011.

Court Rules Tip-Sharing at Starbucks Violates Massachusetts Law

A federal court in Massachusetts has certified a class of Starbucks' employees alleging that the company's policy of requiring tip-sharing by baristas and their supervisors violates state law; the court also granted the plaintiffs' motion for summary judgment on that issue. *Matamoros v. Starbucks Corp.*, No. 08-10772 (U.S. Dist. Ct., D. Mass., decided March 18, 2011). So ruling, the court rejected the defendant's argument that "intractable intra-class conflict" precludes certification. According to the court, "an interest by certain putative class members in maintaining the allegedly unlawful policy is not a reason to deny class certification. Indeed, were the Court to hold otherwise, an employer could readily insulate itself from class liability simply by establishing a communal 'tip pool' for both managerial and non-managerial employees. Such an 'end run' clearly contravenes the purpose of the Tips law."

Johnny Love Vodka Sues Pucker Vodka for Infringement of Distinctive Label

The company that makes Johnny Love Vodka® has filed a trademark infringement suit against the companies making "Pucker Vodka," alleging that the lip imprint on the Pucker labels is likely to confuse consumers because of its similarity to the registered lip imprint on the plaintiff's flavored-vodka bottles. *JL Beverage Co., LLC v. Fortune Brands, Inc.*, No. 11-00417 (U.S. Dist. Ct., D. Nev., filed March 18, 2011). According to the complaint, JL Beverage Co. has used the Johnny Love Vodka mark, which incorporates a parted lip imprint as the "o" in the word "Love," since 2004 and registered it in 2005. The lipstick color apparently varies depending on the vodka's flavor. Alleging that the defendants recently began promoting and selling a line of flavored vodkas with a label incorporating a "nearly identical" parted lip imprint in varying colors, the plaintiff seeks injunctive relief, an order to recall and destroy all infringing products, an accounting, compensatory and treble damages, interest, costs, and attorney's fees.

Arkansas Jury Awards $136.8 Million to Rice Cooperative

A farmer cooperative in Arkansas has reportedly been awarded $11.8 million in compensatory damages and $125 million in punitive damages in litigation against Bayer CropScience, which allegedly contaminated conventional rice crops with its genetically modified (GM) Liberty Link rice. *Riceland Foods, Inc. v. Bayer CropScience LP*, No. n/a (Arkansas County Cir. Ct., Stuttgart, Ark., verdict reached March 18, 2011). The cooperative apparently claimed that the company's negligence cost it $380 million when foreign markets closed in 2006 to U.S. long-grain rice imports contaminated with traces of the unapproved strain of GM rice.

According to a news source, rice farmers have sued the cooperative, alleging that it knew for more than six months that rice supplies had been tainted with the experimental GM rice, but failed to inform them. Bayer has reportedly lost a number of rice contamination bellwether lawsuits and, unless they are overturned on appeal, faces more than $50 million in adverse verdicts to date. Bayer is reportedly considering its options in wake of the Arkansas verdict; it contends that Arkansas law caps punitive damages at $1 million. *See Law360, Reuters*, March 21, 2011.

Caffeinated Alcoholic Drink Allegedly Caused Man's Heart Arrhythmia

According to news sources, a New Jersey tire salesman has filed a personal injury lawsuit in a state court against the company that makes Four Loko®, an alcoholic beverage that until late 2010 also contained caffeine; he alleges that after drinking two and one-half cans, he was taken to a hospital with heart arrhythmia. *Mustica v. Phusion Projects*, No. n/a (N.J. Super. Ct., Atlantic County, filed March 16, 2011). Each can purportedly contained the equivalent of three cans of beer and the same amount of caffeine as two cups of coffee. While the maker of the energy drink apparently continues to maintain that mixing alcohol and caffeine is safe, it agreed to remove caffeine from the product in November 2010.

The plaintiff claims that he consumed the beverage on a visit to Atlantic City in October, fell asleep and, on waking, had a racing heart and trouble breathing. Alleging permanent heart damage, the plaintiff also claims that the company "deceitfully packaged" the product to target youth and failed to provide warnings about the potential health risks of mixing a depressant with a stimulant. *See MSNBC.com, NJ.com*, and *Associated Press*, March 21, 2011.

Court Advocate General Calls French Ban on GM Crops an EU Law Violation

An advocate general to the European Court of Justice has reportedly issued an opinion stating that French authorities violated European Union (EU) law by suspending the cultivation of genetically modified (GM) maize on French

soil without first asking the European Commission to adopt emergency measures. While such opinions do not bind the court, sources indicate that they are generally adopted. The opinion is apparently expected to affect policies in other member nations, such as Austria and Greece, that turned to the court for guidance after GM crop companies filed suit challenging national restrictions.

According to Advocate General Paolo Mengozzi, the EU authorized cultivation of the GM seed at issue for animal feed in 1998, and when Monsanto sought reauthorization of the 10-year license in 2007, France outlawed the seed's cultivation. The country invoked an EU law safeguard provision, adopted in 2004, that provides where "new or additional information" emerging after original consent shows that a product "constitutes a risk to human health or the environment," an EU state "may provisionally restrict or prohibit" the GM organism. Mengozzi opined that this provision cannot be invoked by member states on their own, because only Europeanwide action is sufficient to protect health and the environment. *See Reuters, Agence France Presse*, March 22, 2011; *Courthouse News Service*, March 24, 2011.

Heirs of Colombian Murder Victims Seek Damages from Chiquita

Nearly 700 heirs and estates of Colombian citizens allegedly killed by "a right-wing terrorist organization" that purportedly received financial and other support from Chiquita Brands International and its subsidiaries and affiliates have sued the companies seeking monetary, injunctive and declaratory relief. *Does 1 through 677 v. Chiquita Brands Int'l, Inc.*, No. 11-00582 (U.S. Dist. Ct., D.D.C., filed March 17, 2011). The lawsuit involves claims and litigants not included in similar litigation filed in 2010. The plaintiffs, who claim to be the "family members of trade unionists, banana workers, political organizers, social activists, and others targeted and killed by terrorists," allege that the defendants "funded, armed, and otherwise supported" a paramilitary organization "to produce bananas in an environment free from labor opposition and social disturbances." According to the plaintiffs, the companies' actions violated Colombian, U.S. and international law "prohibiting crimes against humanity, extrajudicial killing, torture, war crimes, and other abuses."

Cereal Maker Sues Canadian Packaging Company for Defective Liners

Kellogg Co. has filed a lawsuit in a Michigan federal court against the Canadian packaging company that supplied allegedly defective liners with "offensive characteristics" (taste and odor) that purportedly caused nausea and diarrhea in some Kellogg cereal consumers and forced a "costly nationwide recall" of four company products. *Kellogg Co. v. FPC Flexible Packaging Corp.*, No. 11-272 (U.S. Dist. Ct., W.D. Mich., S. Div., filed March 18, 2011). The cereal maker alleges violations of Michigan's Uniform Commercial Code, breach of contract and express and implied indemnification. Alleging damages in excess of $75,000, Kellogg also seeks a declaratory judgment that it is not liable for payment of $3.3 million in materials

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 387 | MARCH 25, 2011

still in the packaging company's possession or for the $1.04 million in defective liners provided to Kellogg. According to the complaint, the packaging company has demanded payment for the liners and the materials used in their production.

SCIENTIFIC/TECHNICAL ITEMS

No Link Between Dietary Mercury Exposure and Cardiovascular Disease, Says New Study

A recent study based on toenail clippings has reportedly turned up "no evidence" of any link between dietary mercury exposure and coronary heart disease, stroke, or total cardiovascular disease. Dariush Mozaffarian, et al., "Mercury Exposure and Risk of Cardiovascular Disease in Two U.S. Cohorts," *New England Journal of Medicine,* March 24, 2011. Researchers evidently used toenail clippings from approximately 7,000 people to gauge long-term mercury and selenium exposure from fish consumption, as well as collected dietary and health data from a second cohort of 173,000 participants. The results reportedly found no difference in heart disease and stroke rates for those in the top quintile for mercury concentrations and those in the bottom.

Previous research had raised questions about whether the mercury content of shark, swordfish and other predatory species outweighed the cardiovascular benefits associated with high fish consumption. "Basically, what we found was very simple and very clear," one study author was quoted as saying. "I think this is the most definitive study, and I'm not sure more studies are actually needed. It's nice to be able to answer an important research question. This is observational, so there's possibly some subtle effect we missed. But I think this provides the most definitive evidence available." *See HealthDay News*, March 23, 2011.

OFFICE LOCATIONS

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