Shook, Hardy & Bacon L.L.P.

ISSUE 422 | JANUARY 13, 2012

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

House Committee Completes Investigative Report on Tainted Cantaloupe

The House Energy and Commerce Committee's report on the 2011 *Listeria* outbreak that was traced to cantaloupes grown and processed at Jensen Farms in Colorado has identified a number of problems that led to the "deadliest foodborne illness outbreak in over 25 years."

The bipartisan investigation found that a third-party auditing company (i) gave the farm high food-safety marks despite identifying major and minor deficiencies, (ii) did not hold the farm to anything other than baseline industry standards, and (iii) had no procedures in place to require corrective actions.

One of the problems that led to the outbreak was the farm's failure to use an anti-microbial solution in the cantaloupe wash water. Jensen Farms apparently stopped using the solution after consulting with the third-party auditing company in 2010 about ways to enhance its food-safety efforts. In 2011, the farm had adopted an alternative to the hydrocooler it previously used to process cantaloupe; on the auditing company's recommendation, it used new food processing equipment without an anti-microbial wash, consisting of retrofitted equipment that had been used to process potatoes.

Another problem highlighted in the report was the farm's failure to comply with Food and Drug Administration (FDA) guidance. According to the report, the auditing company was and is concerned only with FDA regulations. In the words of the auditing company's president, "we are not supposed to be opinionated on this, we are supposed to go by FDA's regulations . . . FDA should have mandated that you cannot sell cantaloupes that have not been sanitized." While his company noted that no anti-microbial solution was used in the wash water, no points were deducted from the Jensen Farms' 2011 audit for this omission. The report observed that the Food Safety Modernization Act requires that FDA establish an accreditation system and model auditing standards for third-party audits. The committee will monitor those efforts.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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FDA Restricts Use of Cephalosporin in Livestock

The U.S. Food and Drug Administration (FDA) has issued a **final rule** prohibiting the extralabel use of cephalosporin antimicrobial drugs in livestock. Citing "evidence that certain extralabel uses… will likely cause an adverse event in humans," the agency has specifically barred using cephalosporins (i) "at unapproved dose levels, frequencies, durations, or routes of administration"; (ii) "in cattle, swine, chickens, or turkeys that are not approved for use in that species (e.g., cephalosporin intended for humans or companion animals)"; and (iii) "for disease prevention."

The final rule, however, still permits the use of an older drug, cephapirin, while allowing veterinarians to oversee limited extralabel cephalosporin use "in cattle, swine, chicken, or turkeys as long as they follow the dose, frequency, duration, and route of administration that is on the label."

"We believe this is an imperative step in preserving the effectiveness of this class of important antimicrobials that takes into account the need to protect the health of both humans and animals," said FDA Deputy Commissioner of Foods Michael Taylor in a January 4, 2012, press release. The move has already drawn support from groups such as the Keep Antibiotics Working (KAW) coalition and the Pew Campaign on Human Health and Industrial Farming, which in a January 4 press release praised the final rule as "a victory for human health, as it will help ensure we can still rely on cephalosporins to treat life-threatening infections today and in the future."

Nevertheless, KAW has continued to criticize FDA's December 22, 2011, decision to **withdraw** two 1977 notices of opportunity for a hearing (NOOHs) on penicillin and tetracycline in animal feed. According to FDA, the agency closed the two dockets because it is already engaged in "other regulatory strategies" designed to address microbial food safety and needs to "prioritize any withdraw proceedings (for example, take into account which withdrawal(s) would likely have the most significant impact on the public health)." But KAW member Steven Roach argued that since FDA first proposed the withdrawals, "data connecting antibiotic resistance with overuse in animals has only gotten stronger. Yet the FDA refuses to fulfill its mandate to protect the public health and withdraw drugs that have been shown to be unsafe," Roach said. *See KAW Press Release,* December 22, 2011, and January 6, 2012.

EPA Watchdog Recommends Action on Nanomaterials

The U.S. Environmental Protection Agency's (EPA's) Office of Inspector General (IG) has issued a **report** critical of how effectively the agency "is managing the human health and environmental risks of nanomaterials." Noting that EPA has the statutory authority to regulate nanomaterials, the IG found that it "currently lacks the environmental and human health exposure and toxicological data to do so effectively."

The IG also found that lack of coordination between program offices, EPA's failure to communicate with stakeholders on nanomaterial risk issues and limitations in existing statutes that regulate chemicals "present significant barriers to effective nanomaterial management when combined with existing resource challenges." The agency has responded to the report by agreeing with the IG's recommendation to "develop a process to assure effective dissemination and coordination of nanomaterial information across relevant program offices" and has established a corrective action plan with milestone dates.

EU Urged to Limit Livestock Transportation

A petition reportedly signed by more than one million citizens has urged the European Union (EU) to impose stricter rules on the transportation of livestock intended for slaughter. Initiated by World Horse Welfare, the petition challenged current EU regulations allowing transportation times to exceed 24 hours and instead requested an eight-hour maximum on all such journeys. With more than one million signatures needed to trigger a legislative review under the Lisbon Treaty, the long-running campaign evidently gained traction after a November 2011 European Commission (EC) **report** highlighted alleged failings in the enforcement of livestock welfare regulations.

Meanwhile, Danish Socialist Member of Parliament (MEP) Dan Jørgensen has already collected pledges from 119 MEPs in an effort to acquire 378 signatures by March 15, 2012, at which point the European Parliament says it will officially back the measure. "I definitely expect the commission to act on this," said Jørgensen. "The commission always talks about how the EU should mean something for ordinary citizens. This is a very good example. It's clearly something the EU should do, it's a common problem, as animals are transported across borders." *See BBC News,* January 10, 2012; *The Parliament.com,* January 11, 2012.

New Soft Drink Tax Takes Effect in France

The Constitutional Council of France recently approved a tax on sweetened soft drinks to combat the health care-related costs of obesity. Effective January 1, 2012, the tax adds 1 euro cent per can and is expected to generate €120 million ($156 million) in state revenue to fund lower Social Security contributions by farm workers.

"Obesity is rising as swiftly in France as it is in other EU countries and action must be taken before it gets any more serious," a French health ministry spokesperson was quoted as saying. *See France 24,* December 28, 2011; *Daily Mail,* December 29, 2011.

New York City Launches Ad Campaign Urging Reduced Portion Sizes

The New York City Health Department has launched a "hard-hitting" ad campaign encouraging subway riders to cut their portions of food and sugary drinks to reduce the health risks associated with obesity. One poster, for example, depicts a diabetic man with an amputated leg with the tagline, "Cut Your Portions, Cut Your Risk."

"The portion sizes that are marketed are often much more than humans need," Health Commissioner Thomas Farley said. "We are warning people about the risks of super-size portions so they can make more informed choices about what they eat. Consuming too many calories can lead to weight gain, which greatly increases the risk of type 2 diabetes."

The American Beverage Association (ABA) has reportedly criticized the campaign, claiming that it inaccurately depicts the health impacts of soft drink consumption. "Instead of utilizing scare tactics, the beverage industry is offering real solutions like smaller portioned containers and new calorie labels that show the number of calories in the full container, right up front, to help people choose products and sizes that are right for them and their families," an ABA spokesperson said. *See NYC Health Department Press Release*, January 9, 2012; *Reuters,* January 10, 2012.

LITIGATION

Claims Rejected: Deregulation of GE Alfalfa, Lead in Fruit Juice, MDL Transfer of "All Natural" Skinnygirl Margarita® Actions, U.S. Supreme Court Review of $97.4-Million Nicaraguan Judgment in Banana Worker Exposure to Pesticides

According to news sources, the Center for Food Safety, which lost its challenge to the U.S. Department of Agriculture's (USDA's) decision to deregulate without restriction genetically engineered (GE) alfalfa, plans to appeal the matter to the Ninth Circuit Court of Appeals. A federal court in California determined on January 5, 2012, that the law does not require the agency to "account for the effects of cross-pollination on other commercial crops" in assessing whether a new crop poses risks.

U.S. District Judge Samuel Conti also reportedly said that USDA lacks the authority to require a buffer zone between GE crops and conventional or organic crops. Noting that the Environmental Protection Agency (EPA) has approved the use of glyphosate on Roundup Ready® alfalfa, Conti further observed, "If plaintiffs' allegations are true, then it is disturbing that EPA has yet to assess the effects of glyphosate on most of the species found near the acreage on which [GE alfalfa] will be planted and glyphosate will be used." *See Capital Press*, January 5, 2012; *San Francisco Chronicle*, January 7, 2012; *Sustainable Food News*, January 8, 2012; *Food Chemical News*, January 9, 2012.

A multidistrict litigation (MDL) court in Massachusetts has granted the motion to dismiss filed by a number of fruit juice manufacturers defending consolidated class actions alleging that they failed to disclose the presence of lead in their products. *In re: Fruit Juice Prods. Mktg. & Sales Practices Litig.*, No. 11-02231 (U.S. Dist. Ct., D. Mass, filed December 21, 2011). Most of the allegations involved purported violations of consumer protection laws; the plaintiffs also alleged breach of implied warranties of merchantability and fitness for a particular purpose and unjust enrichment. According to the court, the plaintiffs lacked standing to bring the claims because they failed "to allege any actual injury caused by their purchase and consumption of the products."

The plaintiffs' claim that they risked future harm from lead poisoning was "too speculative to constitute injury in fact," and their economic injury allegation, said the court, "lacks substance." Regarding the economic injury, the court also stated, "The fact is that Plaintiffs paid for fruit juice, and they received fruit juice, which they consumed without suffering harm. The products have not been recalled, have not caused any reported injuries, and do not fail to comply with any federal standards. The products had no diminished value due to the presence of the lead. Thus, Plaintiffs received the benefit of the bargain, as a matter of law, when they purchased these products."

The U.S. Judicial Panel on Multidistrict Litigation has issued an order denying the transfer of six actions pending in six districts involving claims that the defendants' Skinnygirl Margarita® beverage was marketed as "all natural" despite containing sodium benzoate. *In re: Skinnygirl Margarita Beverage Mktg. & Sales Practices Litig.*, MDL No. 2306 (J.P.M.L., decided December 14, 2011). According to the panel, the central allegation "appears to be undisputed, and plaintiffs have failed to detail how pretrial proceedings would benefit from centralization. Consequently, the common material disputed facts may be limited in number." Additional details about the case appear in **Issue 409** of this *Update*.

The U.S. Supreme Court has rejected a request that it review an Eleventh Circuit Court of Appeals ruling that a $97.4-million Nicaraguan court judgment against Dole Food Co. cannot be enforced in the United States. *Osorio v. Dow Chem. Co.*, No. 11-602 (U.S., *certiorari* denied January 9, 2012). More information about the case, which involves claims by 150 banana plantation workers that exposure to the pesticide DBCP caused their sterility, appears in **Issue 324** of this *Update*.

Settlement Proposals: Nutella® Marketing and Salad Dressing Labels

Seeking to certify a nationwide settlement class, excluding California consumers, in litigation against the company that makes the hazelnut spread Nutella®, two named plaintiffs alleging deceptive product marketing have filed their brief in support of preliminary approval of a class settlement. *In*

re: Nutella Mktg. & Sales Practices Litig., No. 11-1086 (U.S. Dist. Ct., D.N.J., brief filed January 10, 2012). According to the plaintiffs, the company has agreed to cease the advertising at issue, begin a revised and corrective labeling and advertising campaign, change its Website, and establish a $2.5 million settlement fund. Under the proposed agreement, settlement class members could submit claims for $4 per jar purchased during the class period and recover up to a maximum of $20. Nutella would also apparently agree not to oppose class counsel fees less than $3 million. According to the plaintiffs' brief, similar litigation pending in California is also being settled.

Twelve named plaintiffs in four separate class action lawsuits are seeking final approval of a settlement agreement with Galeos, LLC, which allegedly misstated the fat, calorie, sodium, and carbohydrate content on its salad dressing labels. *Cooperman v. Galeos, LLC*, No. 10-01815 (U.S. Dist. Ct., C.D. Cal., notice filed January 9, 2012). In their notice of joint motion for final approval, the parties indicate that the class of all U.S. citizens who purchased the products will receive refunds, the defendants will test its products semi-annually for the next five years "to ensure accurate product labels," and the named representatives will receive $500 each. No agreement has apparently been reached on class counsel fees.

New Lawsuits Filed: "Natural" Orange Juice, Mislabeled Butter, City vs. State in *Trans* Fat Dispute, Lack of FDA Action on Nanotechnology Petition

Putative class actions have been filed in New Jersey and California federal courts against Tropicana Products, Inc., alleging that the company misleads consumers by labeling and marketing its orange juice as "100% pure and natural," when it actually "undergoes extensive processing which includes the addition of aromas and flavors." *Lynch v. Tropicana Prods., Inc.*, No. 11-07382 (U.S. Dist. Ct., D.N.J., filed December 19, 2011); *Lewis v. Tropicana Prods., Inc.*, No. 12-00049 (U.S. Dist. Ct., E.D. Cal., filed January 6, 2012).

Both plaintiffs seek to certify nationwide classes. The New Jersey plaintiff alleges unjust enrichment, breach of express warranty, violation of the New Jersey Consumer Fraud Act, and injunctive and declaratory relief. He requests compensatory, treble and punitive damages; prejudgment interest; restitution; injunctive relief; attorney's fees; and expenses and costs of suit.

The California plaintiff, who also seeks to certify a subclass of California consumers, alleges unjust enrichment; breach of express warranty; violation of the state Consumers Legal Remedies Act, Unfair Competition Law and False Advertising Law; and violation of consumer fraud laws "of the various states." He also requests compensatory, treble and punitive damages; prejudgment interest; restitution; injunctive relief; attorney's fees; and expenses and costs of suit.

Seeking to certify nationwide and California classes, another California resident has filed a lawsuit in state court against a retailer and the company that makes a line of products called "spreadable butter," alleging that it is mislabeled because it is not butter; rather, it contains "edible oils and other ingredients." *Simpson v. The Kroger Corp.*, No. BC475665 (Cal. Super. Ct., Los Angeles County, filed December 21, 2011). Claiming that such labeling violates state law governing the labeling of dairy products, the plaintiff alleges unfair competition, untrue and misleading advertising and violation of the Consumers Legal Remedies Act. She seeks restitution, injunctive relief, attorney's fees, and costs of suit.

The City of Cleveland has filed a complaint for declaratory judgment against Ohio challenging the state's attempt to block the city's effort to ban the sale of foods containing *trans* fat. *City of Cleveland v. Ohio*, No. 12-772529 (C.P., Cuyahoga County, filed January 3, 2012). The Cleveland City Council adopted an ordinance in April 2011 that prohibited retail food establishments and food service operations from offering to patrons foods containing "industrially-produced trans fat," unless the food containing *trans* fat were served "in a manufacturer's original sealed package." The ordinance was scheduled to take effect in January 2013. In June 2011, Ohio's General Assembly amended an appropriations bill with a provision that states, in part, "No political subdivision shall . . . Ban, prohibit, or otherwise restrict food at food service operations based on the food nutrition information or on the provision or nonprovision of consumer incentive items."

The city contends that this provision is not a general law, it "represents an unconstitutional attempt to preempt the City's municipal home rule authority," and it violates the constitution's "one subject rule." According to Cleveland Mayor Frank Jackson, "The health and well-being of Cleveland is the responsibility of the City of Cleveland and we are taking proactive steps to help make everyone in Cleveland healthier. One of those steps was a ban on industrially produced *trans* fat in local restaurants and food shops. The state's subsequent amendment to the Ohio Revised Code taking away our ability to enforce this important health regulation is yet another attempt by the State to erode the Home Rule Authority that we have a constitutional right to." *See Office of the Mayor and Cleveland City Council News Release*, January 3, 2012.

A coalition of advocacy organizations, including Food and Water Watch and the Institute for Agriculture and Trade Policy, has filed a complaint against Food and Drug Administration (FDA) Commissioner Margaret Hamburg, alleging unreasonable delay in responding to a 2006 petition asking the agency to regulate products containing nanomaterials. *Int'l Ctr. for Tech. Assessment v. Hamburg*, No. 11-6592 (U.S. Dist. Ct., N.D. Cal., filed December 21, 2011).

While the 2006 petition specifically focused on sunscreen products, the complaint also mentions other "nano-products," such as dietary supplements, food packaging and pet products. The plaintiffs question the safety of nanomaterials and cite research on purported risks to human health and the environment. According to the complaint, "Over 65 months have passed since FDA received the 2006 Petition. To date, FDA has not directly responded to or acted on the 2006 Petition. The public has filed approximately 15,000 comments in the FDA docket for Plaintiffs' 2006 Petition, the overwhelming majority calling on the agency to respond and address this pressing issue." The coalition seeks an order requiring FDA to respond to the petition "as soon as reasonably practicable."

OTHER DEVELOPMENTS

Rudd Center Report Claims "Advergames" Promote Unhealthy Food to Kids

Yale University's Rudd Center for Food Policy & Obesity recently published a **study** claiming that "children are disproportionately targeted by food company Websites using branded computer games, known as advergames," which allegedly promote "calorie-dense nutrient-poor foods." Jennifer Harris, et al., "US Food Company Branded Advergames on the Internet: Children's exposure and effects on snack consumption," *Journal of Children and Media,* November 2011. According to the study's abstract, Rudd Center researchers found that 1.2 million children visit food company advergame sites every month and that "playing these games increases children's consumption of junk food."

Online Food Marketing a "Cynical" Ploy to Target Children, Claims New Report

A recent **report** issued by the British Heart Foundation (BHF) and Children's Food Campaign (CFC) has described online food marketing to children as "pervasive," with more than 75 percent of Websites targeting children with high fat, sugar and salt (HFSS) products "linked to a corresponding product or brand page on a social networking site" such as Facebook or Twitter.

Titled "The 21st century gingerbread house: How companies are marketing junk food to children online," the report concluded that 80 percent of 100 food brand Websites analyzed between April and July 2011 did not meet the Food Standard Agency's nutrient profiling standards for advertising during children's TV programming. In particular, the report highlighted the use of (i) "bespoke websites which appeal to children through the use of language intended for, spoken by or directly to children"; (ii) "brand characters, cartoons and animations which are enormously popular with children"; (iii) "free gifts

including apps, downloads, ringtones and games of appeal to children"; and (iv) links to social networking sites "as a way to encourage children to share the brand with their friends."

"Like wolves in sheep's clothing, junk food manufacturers are preying on children and targeting them with fun and games they know will hold their attention. Regulation protects our children from these cynical marketing tactics while they're watching their favorite children's TV programs but there is no protection when they're online," said BHF Policy Manager Mubeen Bhutta in a December 18, 2011, press release. "With around a third of children classified as overweight or obese today, it's crucial that the UK Government takes action."

SCIENTIFIC/TECHNICAL ITEMS

"Zombie" Parasite Turns Bees into Buzzing Dead

Researchers have reportedly **identified** a new threat to North American honeybees after discovering evidence of a parasitic "zombie" fly infestation in some bee populations. Andrew Core, et al., "A New Threat to Honey Bees, the Parasitic Phorid Fly *Apocephalus borealis*," *PLOS One,* January 2012. According to the study, scientists detected a known paper-wasp and bumblebee parasite, the phorid fly *Apocephalus borealis,* in 77 percent of honeybee hives sampled in the San Francisco area, as well as in commercial hives located in South Dakota and California's Central Valley.

Known to manipulate behavior in other arthropods such as fire ants, phorid flies apparently cause their honeybee hosts to abandon the hive and die, at which point "up to 13 phorid larvae emerge from each dead bee and pupate away from the bee." The parasite could thus be one of the multiple factors contributing to colony collapse disorder (CCD), suggested the researchers, who also noted that the flies may themselves spread two other CCD pathogens, deformed wing virus and *Nosema ceranae,* often found among phorid carriers.

In particular, the report authors expressed concern that as phorid flies adapt to exploit honeybees, they could devastate mobilized commercial bee operations. "Bumblebees live in relatively small colonies that last only a single season with only queens overwintering," the scientists warned. "Honeybees, on the other hand, live in much larger colonies with tens of thousands of individuals living in hives that are warm even in winter. If these flies have or can gain the ability to reproduce within hives they could greatly increase their population size and levels of virulence."

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 422 | JANUARY 13, 2012

Red Meat Intake Allegedly Linked to Kidney Cancer

A recent study has reportedly suggested a link between red and cooked meat consumption and renal cell carcinoma (RCC). Carrie Daniel, et al., "Large prospective investigation of meat intake, related mutagens, and risk of renal cell carcinoma," *The American Journal of Clinical Nutrition,* December 2011. Researchers apparently monitored approximately 492,000 participants over nine years using a "detailed dietary assessment linked to a database of heme iron, heterocyclic amines (HCA), polycyclic aromatic hydrocarbons (PAHs), nitrate, and nitrite concentrations in cooked and processed meats." According to the study abstract, the results revealed that participants who consumed approximately 2.2 ounces of cooked red or processed meat per 1,000 calories were 19 percent more likely to be diagnosed with RCC than those consuming less than 0.3 ounces per 1,000 calories.

"Red meat intake may increase the risk of RCC through mechanisms related to the cooking compounds BaP and PhIP," speculated the study's authors, who elsewhere urged consumers to follow the American Cancer Society guidelines for preparing and consuming meat. As the lead author explained to *Reuters,* these cooking compounds "can be reduced by avoiding direct exposure of meat to an open flame or a hot metal surface, reducing the cooking time, and using a microwave oven to partially cook meat before exposing it to high temperatures." *See Reuters,* December 28, 2011.

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