Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

111th Congress

[1] Congress Seeks Answers in Salmonella Outbreak; PCA President Takes the Fifth

A subcommittee of the House Energy and Commerce Committee conducted a **hearing** February 11, 2009, to hear from victims, regulators and the individuals who own and operate the Georgia peanut processing facility responsible for the latest *Salmonella* outbreak. Titled, "The *Salmonella* Outbreak: The Continued Failure to Protect the Food Supply," the hearing gave congressmen the opportunity to question Stewart Parnell who owns the Peanut Corp. of America (PCA) about the company's practice of shipping contaminated product to food processors even after it had tested positive for *Salmonella*. Parnell and the man who managed the plant invoked their Fifth Amendment privilege and refused to answer questions, including whether they would eat the recalled products, which now number in excess of 1,800 items.

The outbreak has reportedly sickened more than 600 in the United States and Canada, led to a suspected nine deaths and launched at least four personal injury lawsuits to date. Most damning to the company are e-mails released during the congressional hearing, apparently revealing Parnell's disregard for health for the sake of profits. The owners of the labs in which PCA products tested positive for *Salmonella* testified that it is not unusual for food companies to re-test their products once a positive result is found, as PCA did, but other companies never ship the products to customers after a positive test is reported. According to a news source, a Georgia legislative committee has just approved a law that would require food manufacturers to inform state inspectors within 24 hours if internal tests reveal that products are tainted, but it is apparently the only state that may require food companies to share internal data.

Center for Food Safety and Applied Nutrition Director Stephen Sundlof, who testified before the House committee, apparently did not take a firm position on whether private testing labs should be required to share their results with the Food and Drug Administration (FDA), but he did call for agency authority to access food records during routine inspections and to issue preventive controls for high-risk foods. A Georgia food inspector, who also provided testimony, noted that state inspections revealed sanitation problems at the PCA facility in 2007 and 2008, but they were minor. He responded to critics of the state's inspection system, saying, "We consider ourselves as having a good regulatory system here." The state apparently has 60 inspectors who oversee 16,000 food plants and did not find, during routine three-hour inspections, the flaws recently identified by FDA inspectors who spent 14 days investigating the Georgia plant.

According to new information learned since the FDA released its inspection report, of the 12 occa-

sions in 2007 and 2008 on which PCA peanut products tested positive for *Salmonella*, PCA (i) shipped product five times *before* the positive test results were received, (ii) had products re-tested six times and twice shipped product to customers before negative re-test results were received, and (iii) responded to a positive test result "by sending additional samples from the same lot to two different laboratories to be retested. PCA received one positive result and one negative result. According to FDA, PCA had shipped this product to its customers before the initial positive result was received."

While Congress is currently occupied with U.S. economic issues and no action has yet been taken on a number of new food-safety bills, influential members have reportedly pledged to make major changes in the nation's food protection system. Representative Diana DeGette (D-Colo.), who introduced two bills that would split the food oversight function away from the FDA's purview over food and drugs, was quoted as saying to the outbreak's victims and survivors, "I'll just make this commitment to you: We're going to do this, and we're going to do this in your loved ones' memories." *See House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations Staff Memorandum*, February 9, 2009; *The Wall Street Journal*, February 10, 2009; *CQ.com* and *Associated Press*, February 11, 2009; *The New York Times*, and *MSNBC.com*, February 12, 2009.

Food and Drug Administration (FDA)

[2] FDA Announces Science Board Meeting on BPA Assessment

The FDA Science Board has **announced** a public meeting on February 24, 2009, to discuss "the continued assessment of bisphenol A (BPA) in FDA-regulated products." The board will also receive updates from two working groups on "economically motivated adulteration of FDA-regulated products and rapid detection of *Salmonella* in foods." In addition, FDA intends to publish information on its BPA assessment later this month to facilitate public feedback. The board will accept written comments on these issues until February 17, 2009. *See FoodNavigator-USA.com*, February 10, 2009.

United Kingdom (UK)

[3] UK Sheep Farmers Threaten to "Revolt" over EU Animal ID Requirement

British sheep farmers have reportedly threatened to resist an EU proposal that would require them to implement an electronic animal identification system starting in January 2010. With 30 million sheep in the United Kingdom, many farmers have described the plan as prohibitively expensive and unnecessary. Designed to track livestock movement in the event of an epidemic, the system would rely on ear tags costing between £0.50 and £1.50 each with an additional £5,000 or £6,000 per scanning machine. But farmers have argued that their current method of tracking sheep is adequate and avoids the technological issues associated with Internet and broadband use in remote areas. "When you consider that the average sheep farmer only makes something like £6,000 a year, this could see a significant number of farmers deciding it is just too much," one farmer was quoted as saying.

The proposal has drawn similar criticisms from farming organizations in Spain, Germany, Italy, the Netherlands, and Sweden, and South West England MEP Neil Parish has called for the sheep identification program to remain voluntary. "This could do to

the sheep industry what TB is doing to the cattle industry," stated a National Farmers' Union spokesperson. "It's a crazy rule. It's not wanted. It's not needed. And it could, potentially, devastate the sheep industry. We really need political pressure now." *See The Guardian*, February 8, 2009.

State and Local Governments

[4] Food Industry Objects to Prop. 65 Listing of Methanol

The Grocery Manufacturers Association (GMA) and individual food companies have reportedly asked California EPA's Office of Environmental Health Hazard Assessment (OEHHA) to delay taking action on its proposal to list methanol as a reproductive toxicant. While the chemical is used in varnishes, shellacs, paints, antifreeze, adhesives, and deicers, it also apparently occurs naturally in fresh fruits and vegetables, fruit juices, fermented beverages, and diet soft drinks. OEHHA has extended the deadline for comments on the listing proposal until March 4, 2009, in response to GMA's request.

According to an industry spokesperson, "The concern of the grocery manufacturers is that once a chemical is listed under Prop. 65, anyone who can detect it can file a claim, and many millions of dollars can be spent demonstrating that there's no harm. So we thought it important for the agency to think about the consequences of a list, and whether . . . it's appropriate to proceed, given those consequences, and what the alternatives are." OEHHA is apparently basing its proposed listing on rodent studies conducted by the National Toxicology Program, considered an "authoritative body" under California's Prop. 65 regulations. *See Inside EPA*, February 6, 2009.

Litigation

[5] Federal Court Allows "Natural" Suit to Proceed Against Arizona Beverage

A federal court in California has denied a motion to dismiss putative class claims that Arizona Beverage Co. deceptively labels its products as "100% Natural," "All Natural," or "Natural," despite using high-fructose corn syrup as an ingredient. *Hitt v. Arizona Beverage Co., LLC*, No. 08-809 (U.S. Dist. Ct., S.D. Cal., order entered February 4, 2009). The complaint also alleges that those beverages with fruit in the name are deceptively labeled because they "do not contain any substantial amount of the fruit named on the label." The defendants sought to dismiss claims that they violated consumer fraud statutes by contending that they are expressly and impliedly preempted under federal law.

The court summarily ruled that the plaintiff's claims were not expressly preempted because they do not fall within any of the express preemption provisions of the Nutritional Labeling and Education Act. The court also ruled that the claims were not impliedly preempted because (i) the Food and Drug Administration has not occupied the field of beverage labeling, marketing and promotion; and (ii) the plaintiff's claims do not stand as an obstacle to accomplishing federal objectives. According to the court, "Plaintiff's All Natural Claims do not stand as an obstacle to accomplishing Congress's objectives of uniformity and consistency in regulating beverage labeling because there are no federal requirements regarding the term 'natural' to be given preemptive effect."

The defendants also argued that the lawsuit should be dismissed for failure to state a claim, asserting that "no reasonable consumer, concerned about his/her health, after examining a

company's website (which depicts the products and their ingredients) would be able to convince a fact finder that they were deceived in this case." The plaintiff countered that she should have the opportunity to present evidence, such as consumer surveys, showing that the defendants' labeling and promotion are likely to deceive reasonable consumers. The court agreed with the plaintiff and compared the case to *Williams v. Gerber*, 523 F.3d 934 (9th Cir. 2008), in which the court "recognized that whether a business practice is deceptive will usually be a question of fact not appropriate for decision on demurrer." The court found the plaintiff's claims similar to those in *Gerber* and decided that the parties should have the opportunity to submit evidence to demonstrate whether consumers would find the labeling deceptive.

[6] Claims for Neurological Illness Against Pork Processor Dismissed

A federal inspector who alleged that he was injured after coming into contact with an air compression machine used to harvest pig brains in a pork processing plant has apparently agreed to dismiss his claims. *Kinney v. Hormel Foods & Quality Pork Processors*, No. n/a (3d Jud. Dist., Minnesota, claimed filed January 2009). Dale Kinney, a U.S. Department of Agriculture inspector, reportedly sought $50,000 in damages for injury allegedly caused by his proximity to a machine that has purportedly been linked to neurological illness in some employees. According to a news source, a state court judge entered an order dismissing the suit with prejudice. A Hormel spokesperson reportedly said, "We were pleased to receive notification that the plaintiff offered to drop the suit and that the case was dismissed." *See Meatingplace.com*, February 9, 2009.

[7] Criminal Animal Abuse Charges Filed Against Former Turkey Farm Employees

Video footage of former Aviagen Turkeys, Inc. employees allegedly abusing birds has reportedly led to criminal indictments for animal abuse. The People for the Ethical Treatment of Animals (PETA) apparently caught three turkey farm employees in the act, and 19 counts, including 11 felony charges, for cruelty to birds have been brought against them. Alabama-based Aviagen Turkeys reportedly fired all three workers for violating company policy. They could face significant jail time and fines if convicted. *See meatingplace.com*, February 9, 2009.

Other Developments

[8] Industry and Consumer Perspectives Presented During ABA Food Law Seminar

The American Bar Association's Litigation Section sponsored a "Hot Topics in Food Law" program via the Web and telephone on February 10, 2009. Speakers included in-house counsel for a large food manufacturing company, a Grocery Manufacturers Association (GMA) representative and Stephen Gardner, the director of litigation for the Center for Science in the Public Interest (CSPI).

They focused on the most recent "ingredient-driven" foodborne contamination outbreaks, including pet food and infant formula containing melamine and peanut butter products tainted with *Salmonella*. In light of such incidents, the speakers emphasized that food companies must carefully manage their supply chains through independent, reliable audits and the establishment and communication of clear, achievable food safety standards. After the recent peanut butter recall, companies will likely focus on company-to-company tracing issues.

A speaker representing the outside counsel perspective focused on bisphenol A and discussed recent initiatives to ban it in Canada and list it as a reproductive toxicant under Proposition 65 in California. He also discussed litigation pending against the manufacturers of infant formula and baby bottles. He stressed that scientific evidence linking the chemical to human health hazards is lacking. GMA representative Robert Brackett, Ph.D, suggested that any company thinking of submitting data or other information to government agencies as they consider bisphenol A issues should determine how the information will be used and whether it will be further disseminated before they submit it.

Stephen Gardner's presentation involved products labeled "natural," "green," "organic," and "sustainable." Comparing high-fructose corn syrup (HFCS) and sugar to plastic and dinosaurs, Gardner noted that CSPI has had success suing or threatening to sue companies that put HFCS in their products and then promote them as "natural." According to Gardner, some of them have reformulated their products. He suggested that companies consider, after they are sued, whether it is better to litigate or change their practices. He also cautioned food companies to make better products and stop lying when they market their products.

Final comments focused on supply chain oversight, the establishment of "special situations management teams" before crises arise and focusing on prevention even in a tight economy.

[9] Pew Environment Group Releases FDA Documents on Chilean Salmon Farms

The Pew Environment Group has released **documents** obtained through a Freedom of Information Act request showing that the U.S. Food and Drug Administration (FDA) faulted three Chilean salmon farming companies, "including the two largest producers of farmed salmon," for using a number of drugs not approved by the U.S. government. FDA inspections apparently uncovered use of the antibiotics flumequine and oxolinic acid and the pesticide emamectin benzoate, as well as trace residues in products intended for the U.S. consumers. The agency then informed the Chilean companies that, "if the drug is not listed in the approved drug list… they are not allowed to use the drug to treat salmon destined for distribution in the U.S., not even if they meet withdrawal periods and no tissue residue can be detected."

The Pew Environment Group applauded the FDA stance, but urged the agency to enforce its standards abroad. "Standards and enforcement should be the same for Chile as they are for China," stated Andrea Kavanagh, manager of the Salmon Aquaculture Reform Campaign at the Pew Environment Group. "If the Chilean companies do not comply with instructions to stop using these chemicals then the FDA should consider taking similar action as it did with China." *See The Pew Charitable Trusts Press Release*, February 5, 2009.

[10] General Mills' Yoplait® to Use Milk from rBST-Free Cows

General Mills has announced that as of August 2009, its Yoplait® products will no longer contain milk produced by cows treated with synthetic growth hormone (rBST or rBGH). Although the artificial hormone increases a cow's milk production by one gallon per day, its use has drawn criticism from environmental and consumer advocates who fear the hormone could adversely affect human health. Its use is supported by the U.S. Department of Agriculture, but banned in Canada, Australia, Japan,

and other nations in part because of its purported impact on bovine health. "While the safety of milk from cows treated with rBST is not at issue, our consumers were expressing a preference for milk from cows not treated with rBST, and we responded," a General Mills spokesperson was quoted as saying. *See The Star Tribune*, February 9, 2009; *Food & Water Watch Blog*, February 10, 2009.

[11] European Animal Welfare Groups Push for Standards in Global Trade Agreements

European animal advocates and some European Commission (EC) members recently attended a Conference on Global Trade and Farm Animal Welfare in Brussels, Belgium, where they reportedly called on legislators to include animal welfare provisions in all global trade agreements. In particular, EC members noted that animal welfare restrictions have driven up the cost of meat production in Europe, making it more economical to import these products. They thus urged Europe to demand equivalency standards in international trade agreements similar to those already in place for biotechnology.

The National Cattlemen's Beef Association's chief veterinarian, Elizabeth Parker, noted that Europe bases its welfare standards on non-scientific factors, pointing to the practice of using "Eurobarometer" surveys to craft policies in line with public opinion. "The ultimate goal is to make sure we take care of our animals and produce safe and affordable beef supply and we do that," stated Parker in an interview with *Meatingplace.com*. "It is hard to see how the European regulations have improved animal handling." *See Meatingplace.com*, February 11, 2009.

Scientific/Technical Items

[12] Study Claims Additional Phosphorous in Fast Food May Compound Kidney Ailments

A recent study has claimed that processed and fast foods containing phosphorous may constitute a "hidden" danger to people seeking to limit their intake of the substance, which can cause heart disease, bone disease and death in patients with advanced renal disease. Catherine Sullivan, et al., "Effect of Food Additives on Hyperphosphatemia Among Patients With End-stage Renal Disease," *Journal of the American Medical Association*, February 11, 2009. Phosphorous occurs naturally in meats, dairy products, whole grains, and nuts, but food manufacturers also use sodium phosphate and pyrophosphate to enhance the shelf life and flavor of some products.

Researchers from the MetroHealth Medical Center and Case Western Reserve University School of Medicine followed 279 dialysis patients with advanced kidney disease and high blood phosphorous levels exceeding 5.5 milligrams per deciliter. Those in a control group received standard dietary instructions, while the intervention group also avoided additive-containing foods purchased in grocery stores and fast food restaurants. The study authors found that after three months, the intervention group's phosphorous levels had declined to 0.4 mg/dL, whereas the control group's phosphorous levels only reached 1 mg/dL. "The 0.6 mg/dL larger decline in average phosphorous level among intervention participants compared with control participants corresponds to a 5 to 15 percent reduction in relative mortality risk in observational studies," according to the study, which noted that appropriate policy action could include "mandating

that phosphorous content be listed on nutrition facts labels." *See FoodNavigator-USA.com* and *MSNBC.com*, February 11, 2009.

[13] Research Alleges Link Between Maternal Obesity and Birth Defects

A recent meta-analysis and systematic review of medical literature has suggested that obese women are more likely to have children affected by structural abnormalities such as tube defects, spina bifida, cardiovascular anomalies, septal anomalies, cleft palate, cleft lip and palate, anorectal atresia, hydrocephaly, and limb reduction anomalies. Katherine J. Stothard, et al., "Maternal Overweight and Obesity and the Risk of Congenital Anomalies," *Journal of the American Medical Association*, February 11, 2009. British researchers looked at 1,944 potential articles, ultimately including 39 articles in the systematic review and 18 in the meta-analysis. The results indicated that the children of obese women had double the risk of spina bifida and nearly twice the risk of other neural tube defects, as well as increased chances of heart defects, cleft palate, and problems with limb growth. "Maternal obesity is associated with an increased risk of a range of structural abnormalities, although the absolute increase is likely to be small," according to the study, which recommended further research to determine whether overweight women experience similar pregnancy complications. *See Reuters*, February 10, 2009.

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