Food & Beverage

LITIGATION UPDATE

Issue 285 • December 12, 2008

Table of Contents

Shook, Hardy & Bacon L.L.P.®

www.shb.com

Legislation, Regulations and Standards

Government Accountability Office (GAO)

[1] Report Calls on Agencies to Better Coordinate Oversight of GE Crops

The GAO, which serves as the investigative arm of the U.S. Congress, has released a **report** that analyzes federal oversight of genetically engineered (GE) crops and recommends steps the agencies could take to better address the unauthorized release of these crops into food, animal feed or the environment. Titled *Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight but Could Take Additional Steps to Enhance Coordination and Monitoring*, the 109-page report discusses the roles that the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) play in regulating GE crops. It also notes how six unauthorized releases of GE crops in recent years may not have adversely affected human or animal health, but did result in lost trade opportunities.

The GAO's assessment was undertaken at the request of Senators Tom Harkin (D-Iowa) and Saxby Chambliss (R-Georgia), the chair and ranking member respectively of the Committee on Agriculture, Nutrition, and Forestry. In its report transmittal letter to the senators, the GAO notes, "Currently, the United States accounts for about 50 percent of the GE crops planted globally. In 2008, GE varieties accounted for about 80 percent of the corn, 92 percent of the soybeans, and 86 percent of the cotton planted in the United States. In 2005, GE varieties accounted for about 93 percent of the canola. . . . Food industry sources indicate that over 70 percent of processed foods sold in the United States contain ingredients and oils from GE crops."

According to the report, "USDA and FDA do not have a formal method for sharing information that could enhance FDA's voluntary early food safety review for certain GE crops in the field trial stage and support USDA's oversight. Also, the three agencies do not have a coordinated program for monitoring the use of marketed GE crops to determine whether the spread of genetic traits is causing undesirable effects on the environment, non-GE segments of agriculture, or food safety, as recommended by the National Research Council and others."

In light of the purported shortcomings identified and the potential risks posed by the spread of plant genetic material in the environment, the report recommends that "FDA post on its Web site the results of its early food safety evaluations, and that USDA and FDA develop a formal agreement to share information concerning GE crops with novel genetic traits that could cause, or are likely to cause, health concerns if unintentionally released into the food or feed supply. We are also recommending that USDA, EPA, and FDA develop a coordinated strategy for

monitoring the marketed use of GE crops for unintended consequences to the environment, non-GE segments of agriculture, or food safety."

According to the GAO, most of the stakeholders consulted in the preparation of its report "told us that future unauthorized releases of low levels of regulated GE material are likely to occur" in light of "the porous nature of biological systems and the potential for human error." Harkin reportedly said in a prepared statement, "When unapproved genetically engineered crops are detected in the food and feed supply, food safety concerns rise, markets are disrupted and consumer confidence falls. I urge the agencies to implement GAO's recommendations." The Center for Science in the Public Interest also supported the recommendations, saying in part,"[u]ploading decision documents to the Web should simply be normal operating procedure." *See Center for Science in the Public Interest Press Release*, December 5, 2008; *Product Liability Law 360* and *Reuters*, December 8, 2008.

In a related development, the FDA, EPA and USDA released a joint **statement** on December 3 to announce that "there is no food or feed safety concern from an incident in which a small portion of an unauthorized genetically engineered (GE) cotton variety was harvested along with commercially available GE cotton." The accidental release was apparently reported voluntarily by the Monsanto Co. According to the government's statement, "This unauthorized GE cotton variety produces a pesticide that is a plant-incorporated protectant (PIP) nearly identical to the registered product already in a marketed corn variety. EPA and FDA have concluded that there are no food or feed safety concerns related to this incident. Also, if animals had consumed meal made from the unauthorized GE cotton variety, there would be no residues in the meat, milk or eggs. Additionally, USDA has determined that the unauthorized GE cotton poses no plant pest concerns."

Meanwhile, the European Union's highest court has reportedly fined France US$12.9 million for failing to update its laws on genetically modified crops and foods. The country is required under EU law to adopt a 2001 directive that regulates how these crops may be grown and approved, from the cultivation of the seeds to importation of genetically modified products and their processing for industrial uses. *See Reuters*, December 9, 2008.

National Research Council

[2] NRC Report Faults Federal Strategy for Nanotechnology-Related Research

The National Research Council (NRC) has published a report, titled *Review of Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*, that finds "serious weaknesses in the government's plan for research on the potential health and environmental risks posed by nanomaterials, which are increasingly being used in consumer goods and industry." NRC describes the research plan developed under the auspices of the National Nanotechnology Initiative (NNI) as "incomplete," noting that it does not "include research goals to help ensure that nanotechnologies are developed and used as safely as possible." According to a December 10, 2008, NRC press release, the NNI plan takes only a cursory look at important research areas like "Nanomaterials and Human Health," which should "include a more comprehensive evaluation of how nanomaterials are absorbed and metabolized by the body and how toxic they are at realistic exposure

levels." NRC also faults the NNI for failing to incorporate vital input from "industries that produce and use nanotechnologies, environmental and consumer advocacy groups, and other stakeholders." "The plan should identify research needs clearly and estimate the resources necessary to address gaps, as well as provide specific, measurable objectives and a timeline for meeting them," NRC concludes. "The current structure of NNI would make developing a visionary and authoritative strategy difficult."

Food and Drug Administration (FDA)

[3] Agency Revokes Order Banning Use of Antimicrobial Drugs in Animals

Reversing a position it took in July 2008, the FDA has issued a **notice** announcing the withdrawal of a final rule that prohibited the extralabel use of cephalosporin antimicrobial drugs in food-producing animals. As we noted in issue 266 of this Update, the FDA issued its prohibition "based on evidence that extralabel use of these drugs in food-producing animals will likely cause an adverse event in humans and, as such, presents a risk to human health."

According to the November 26 notice, "The agency received many substantive comments on the order of prohibition. Therefore, to allow more time to fully consider the comments, FDA has decided to revoke the order so that it does not take effect November 30, 2008." Should the agency again decide to ban use of the drugs, it will provide a public comment period before implementing it.

A number of organizations, including agriculture groups and animal-drug makers, apparently protested the ban, claiming that the antibiotics are needed to prevent infectious diseases in animals and that data about human impact used to support the ban were flawed. A spokesperson for the Association of Swine Veterinarians was quoted as saying, "You have to give the FDA credit for its good-faith response to our concerns."

Public health officials and the American Medical Association supported the ban out of concern that excessive drug use in food animals can promote resistance and produce bacterial strains that threaten human life. As recently as September, FDA's director of veterinary drugs, Steven Vaughn, reportedly said during an agricultural conference that antibiotic-resistant bacteria are becoming more common in cattle.

Keep Antibiotics Working, a group that seeks to end the overuse of antibiotics, responded to the revocation by calling on the FDA to "work with veterinarians to identify alternatives to extralabel cephalosporin use instead of continuing to allow an entrenched practice they know puts the public at risk." The group quoted a senior scientist with the Union of Concerned Scientists as saying, "The FDA continues to ignore the mounting body of evidence about the dangerous misuse of human antibiotics in animal production, and instead defers to the agribusiness interests by putting off this ban." *See Keep Antibiotics Working Press Release*, November 25, 2008; *The Wall Street Journal*, December 9, 2008.

World Health Organization

[4] WHO Tightens Tolerable Daily Intake for Melamine

WHO experts have reportedly determined that a tolerable daily intake (TDI) of melamine is 0.2 milligrams per kilogram of body weight (mg/kg bw/d). This threshold is lower than the one recently adopted by the U.S. Food and Drug Administration (FDA), which accepts 0.63 mg/kg bw/d as an appro-

priate TDI for dietary melamine. The WHO standard is also more stringent than the TDIs used in both Europe (0.5 mg/kg mw/d) and Canada (0.35 mg/kg bw/d). Although the organization felt that the U.S. measure provides an acceptable margin of safety, it nevertheless stressed that melamine is not ever considered "safe" for consumption. "Melamine is a contaminant that should not be in food. However, sometimes it is unavoidable," said WHO in a statement. "TDI represents the tolerable amount of unavoidable contaminant in food that a person can ingest on a daily basis without appreciable health risks." *See Bloomberg.com*, December 6, 2008; *Law360*, December 8, 2008; *FoodProductionDaily.com*, December 10, 2008.

In a related development, Walgreen Co. has issued a recall for teddy bears sold in its stores because the accompanying chocolate bars may contain melamine. Walgreen publicized a voluntary recall for 173 "Dressy Teddy Bear With Chocolate" products after FDA discovered an unacceptable amount of melamine in some of the 4-ounce chocolate bars sold with the toy. FDA has not specified the exact melamine levels found in the chocolate. *See Law360*, December 8, 2008.

Ireland

[5] Regulators Warn Consumers After Finding Dioxins in Irish Pork, Beef

The Irish government this week recalled all pork products from pigs slaughtered in the country after testing revealed high levels of dioxin in animal feed and pork fat samples. Authorities have thus far linked the carcinogen to 10 pig farms that received feed from Millstream Power Recycling Limited, a Carlow company which reprocesses foodstuffs to make livestock meal. In addition, Ireland's Department of Agriculture has placed 45 cattle farms under restrictions because they may have received feed potentially contaminated with dioxins. Health officials stated that three cattle herds of 11 tested had "technically non-compliant" dioxin levels, but stressed that there is "no public health concern" with regard to Irish beef. The government has also declared 490 pig farms "dioxin-free," although the prohibition on the sale of domestic pork products has remained in effect. *See CNN*, December 8 and 9, 2008; *The Associated Press*, December 9, 2008.

Meanwhile, the European Commission has apparently denied emergency funds to compensate Irish pig farmers and pork processors encompassed by the widespread recall. The European Food Safety Authority (EFSA), however, released a safety assessment finding "no concern" about "the most likely scenario" in which "someone ate an average amount of Irish pork each day throughout the period of the incident (90 days), 10 percent of which was contaminated at the highest recorded concentration of dioxins." Moreover, EFSA concluded, the most extreme scenario would "not necessarily lead to adverse health effects," even if "someone ate a large amount of Irish pork each day throughout the period of the incident (90 days), 100 percent of which was contaminated at the highest recorded concentration of dioxins." *See EFSA Press Release*, December 10, 2008; *The Irish Times*, December 10, 2008.

State and Local Governments

[6] California Science Panel Considers Substances to Monitor in Humans

The California Environmental Contaminant Biomonitoring Program's Scientific Guidance Panel decided at a December 4-5, 2008, meeting that it would designate diesel exhaust and flame retardants as the first substances the state will monitor in

humans under a 2006 law (SB 1379) requiring the establishment of a state biomonitoring program. The panel also reportedly agreed that the program's pilot project would focus on analyzing maternal-infant blood samples from 250 subject pairs. A spokesperson with the state's Office of Environmental Health Hazard Assessment (OEHHA) apparently indicated that antimicrobials and synthetic hormones used in animal husbandry will be discussed at a future meeting. Environmentalists who attended the meeting reportedly urged the panel to prioritize other chemicals such as bisphenol A, nano silver and phthalates.

According to a press report, panel members asked OEHHA legal counsel whether another 2006 law (A.B. 289) could be applied to the biomonitoring program. That law apparently authorizes a state agency to gather from chemical manufacturers or importers information needed to detect the chemical's presence in the environment and allows state agencies to collaborate with the manufacturers to develop other information that could be useful to the biomonitoring program, such as analytical test methods. An OEHHA spokesperson was quoted as saying that "no official position has been developed" to date as to whether the law could be used for the program; apparently logistical and timing issues need to be addressed. *See Inside Cal/EPA*, December 12, 2008.

Litigation

[7] Whole Foods Seeks to Stop Administrative Proceedings Before FTC

Whole Foods Market, Inc., concluding that it cannot get a fair hearing before the Federal Trade Commission (FTC) in proceedings over the competitive effect of its merger with Wild Oats Markets, Inc., has filed a lawsuit in federal court seeking to terminate the proceedings as fundamentally flawed under the Due Process Clause. *Whole Foods Market, Inc. v. FTC*, No. 08-02121 (U.S. Dist. Ct., D.D.C., filed December 8, 2008).

The FTC lifted a stay on its administrative proceedings shortly after a federal appeals court, reversing a district court ruling denying the FTC's request to stop the merger, ruled that the commission could proceed with its preliminary-injunction proceeding in the courts. The appeals court remanded the case for the district court to consider whether the equities favor the FTC now that the merger has taken place and Whole Foods has closed or sold a number of Wild Oats stores.

Among other matters, Whole Foods claims that (i) the FTC has prejudged the case and is on record as declaring the merger anticompetitive and Whole Foods' witnesses and evidence unreliable; (ii) the FTC locked in an unreasonable scheduling order, signed by a commissioner, who initially served as the presiding judge, before appointing an administrative law judge to preside over the hearings; and (iii) the procedures the FTC has instituted in the case were proposed as a "fundamental change" to existing procedures in an October 2008 Federal Register notice for public comment, which proposal has been criticized by the American Bar Association, U.S. Chamber of Commerce and former FTC commissioners and counsel.

Whole Foods alleges that it was given only a few months to conduct discovery and subpoena third parties in the 29 geographic markets the FTC identified in its challenge to the merger. Apparently, a number of competitors have balked at providing any trade secret information, and the list of witnesses

that Whole Foods seeks to depose has grown to more than 100.

The FTC hearing is currently set for February 2009, which means, according to Whole Foods, that it will take place before the district court makes its post-merger findings on remand, which findings "would illuminate, if not determine, many of the issues that will be addressed at the administrative proceedings. A remand before the District Court will consider the benefits to consumers and the public in general arising from the Whole Foods/Wild Oats combination. A finding that such benefits resulted from the merger would gut the Commission's case."

Whole Foods chief executive John Mackey conducted a rare press conference about the lawsuit, accusing the FTC of conducting a "vendetta" against his company. According to Mackey, "From the very beginning, I think (the FTC) treated Whole Foods Market very disrespectfully. I don't understand what is motivating them." In 2007, a federal court allowed Whole Foods to proceed with the merger, a ruling that was reversed a year later, after the merger had already been consummated.

Legal costs to the company have been mounting, reportedly standing at $16 million at this stage of the proceedings, while the company's stock has lost 75 percent of its value this year. Mackey also said, "At a time when our economy is under pressure, Whole Foods Market is under more competitive stress than it has before. We're having to waste our time dealing with regulators." S*ee Austin American-Statesman*, December 9 and 10, 2008.

Meanwhile, a California resident filed a putative class action lawsuit against Whole Foods in the D.C. District Court, alleging that the company violated federal antitrust laws and "acquired an unlawful monopoly" in the premium, natural and organic food market. *Kottaras v. Whole Foods Market, Inc.*, No. 08-01832 (U.S. Dist. Ct., D.D.C., filed October 27, 2008). According to the complaint, which seeks class certification, treble compensatory and statutory damages, fees, and costs, Whole Foods and Wild Oats controlled more than a 90 percent share of their relative market and that the merger has injured putative class members "by causing them to overpay for their purchases."

[8] MDL Court Finds Bottled Water Claims Preempted Under Federal Law

A multidistrict litigation court (MDL) in New York has dismissed putative class claims filed against PepsiCo., Inc. for allegedly misrepresenting the source of its Aquafina® bottled water, "by using a label designed to create the impression that the water came from a mountain source and failing to inform consumers that the true source . . . was public drinking supplies commonly known as 'tap water.'" *In re: PepsiCo., Inc. Bottled Water Mktg. & Sales Practices Litig.*, MDL No. 1903 (U.S. Dist. Ct., S.D.N.Y., decided December 5, 2008).

The court determined that plaintiffs' state-law unfair and deceptive trade practices claims were expressly preempted under the Food, Drug, and Cosmetic Act (FDCA). According to the court, "the FDCA's statutory framework and regulatory history, . . . reveal that the FDA specifically addressed the disclosure of source information and determined, in its expert opinion, that representations of source are immaterial in the context of purified water." The court also concluded, "the FDA never intended or required that purified water include the 'municipal water supply' disclosure required for certain types of water, including spring water, and was not concerned with any misleading potential of graphics

on bottles of purified water, based on its conclusion that with respect to purified water, the purification, and not the source, is the reason consumers buy it."

[9] Chinese Court Refuses to Accept Group Lawsuit in Tainted Milk Scandal

A Chinese court has reportedly refused to accept a lawsuit filed by dozens of families whose children were sickened or died from consuming infant formula contaminated with melamine. Apparently the first-known group lawsuit to arise in the wake of the scandal, the complaint sought nearly US$2 million from the state-owned Sanlu Group Co., the dairy company that allegedly produced the tainted products. According to a news source, Chinese courts often turn down group suits, preferring to deal with individual cases and avoid angering party officials. Some one dozen individual cases are currently pending in courts around the country, but they have not yet been accepted. A lawyer for the affected families reportedly indicated that the group lawsuit was ostensibly not accepted because government departments are still investigating. *See Associated Press*, December 8, 2008.

Other Developments

[10] American Soybean Association Urges USDA to Investigate Alleged Misuse of Checkoff Program

The American Soybean Association (ASA) has asked the U.S. Department of Agriculture's Office of the Inspector General to investigate the administration of the federally mandated soy checkoff program that is responsible for industrywide marketing and promotion efforts. "Serious ethical, legal and financial allegations have been raised about how farmer checkoff funds and program activities are being conducted," stated ASA President John Hoffman in a press release that levied several charges against the United Soybean Board (USB) and the U.S. Soybean Export Council (USECC) for their oversight of checkoff resources.

The association's allegations include "the improper and wasteful expenditure of both checkoff and federal funds; potential evasion of mandated salary and administrative spending caps by USB; conflicts of interest at USB; use of checkoff funds for prohibited purposes by USB; and wasteful and excessive spending by USB." In addition, ASA cited concerns about "improper USB oversight and tolerance of actions that have taken place at the USECC," such as "the firing of whistleblowers; improper employee relationships; contracting violations; management malfeasance and the inability of ASA Directors serving on the USSEC Board to obtain an independent and objective investigation of the allegations." ASA apparently elaborated on these issues in a separate statement, which reported the "use of a knife by a USSEC employee at a USSEC function, whistleblower complaints of an improper employee relationship, a whistleblower complaint of receiving direction to break overseas laws and American regulations, and whistleblower complaints regarding the awarding of no-bid contracts, wasteful or fraudulent feeding trails and more." *See ASA Press Release* and *U.S. Food Policy Blog,* December 10, 2008; *The Des Moines Register*, December 11, 2008.

Meanwhile, USB has apparently denied the allegations, claiming that the board operates under USDA guidance and within the scope of the law. "The specific allegations made are anonymous and without apparent or visible substantiation," USB Chair Chuck Myers said during a press conference. "USB will not make any attempt to respond to each and every anonymous allegation. That would create

unfair and unfounded speculation without any basis in fact. It is not ASA's responsibility to ensure the checkoff program runs properly. It's USDA's responsibility." *See AgWeb.com*, December 11, 2008.

[11] BBB Ad Division Asks General Mills to Change Yogurt Advertising

According to a news source, the Better Business Bureau's National Advertising Division, at the request of Dannon, has asked General Mills Inc. to change the way it advertises the purported digestive health benefits of its Yoplait Yo-Plus® yogurt. Dannon apparently contended that General Mills' claims about its ingredients helping to "regulate digestive health naturally" were not scientifically sound, and the division agreed, saying the studies that General Mills submitted "are not sufficient to support a health-related product performance claim." A General Mills spokesperson apparently responded that the company disagreed with the division's findings, "but we respect the process and will take these recommendations into account." *See Product Liability Law 360*, December 9, 2008.

Media Coverage

[12] Nicholas D. Kristof, "Obama's 'Secretary of Food'?," *The New York Times*, December 11, 2008

This op-ed piece advises President-Elect Barack Obama to select a reformer for the top position in the Department of Agriculture and to recast the agency as the Department of Food, thereby "giving primacy to America's 300 million eaters." Appointing a "secretary of food" would signal Obama's intention to "move away from the bankrupt structure of factory farming that squanders energy, exacerbates climate change and makes American unhealthy – all while costing taxpayers billions of dollars," according to columnist Nicholas Kristof. He faults both Republicans and Democrats on congressional agriculture committees for "kowtowing" to industrial farming interests, which have allegedly used their influence "to inflict unhealthy food on American children in school-lunch programs, exacerbating our national crisis with diabetes and obesity."

Kristof points readers to an online petition that names six potential reform candidates for the secretary of agriculture post, including the Center for Rural Affairs' executive director, Chuck Hassebrook. In addition, Kristof urges the president-elect to eschew any nominees endorsed by the food industry, noting that "Society is becoming increasingly concerned not only with little boys who abuse cats but also with tycoons whose business model is abusing farm animals."

Scientific/Technical Items

[13] Study Claims Childhood Obesity Alters Thyroid Function and Structure

A recent study has apparently claimed that pediatric obesity may alter thyroid function and structure. Giorgio Radetti, et al, "Thyroid Function and Structure Are Affected in Childhood Obesity," *Journal of Clinical Endocrinology & Metabolism*, December 2008. Italian researchers performed thyroid ultrasounds on 186 overweight and obese children over three years, as well as measuring their thyroid hormone and antibody levels. The ultrasounds of 73 children reportedly revealed symptoms of Hashimoto's thyroiditis, an autoimmune disease in which T-cells attack the thyroid, despite an absence of the antibodies usually indica-

tive of this ailment. "The ultrasound findings are a bit mysterious," the lead author was quoted as saying. "However, the findings do suggest the existence of a low-grade inflammation state, which has been known to characterize obesity."

Scientists have long suspected that thyroiditis can lead to obesity, but this recent study suggests that obesity plays a role in the development of thyroid disorders. In addition, the authors found that thyroid function returned to normal after weight loss. They recommended further research to determine the long-term effects of pediatric obesity on thyroid function into early adulthood. *See Medical News Today*, December 4, 2008.

[14] New Global Study Seeks Origin of Food Allergies

A new international study seeking to pinpoint the origin of food allergies has reportedly started to gather environmental, genetic and health information from hundreds of families in Boston, Chicago and Anhui Province in China. Led by Xiaobin Wang and Jacqueline Pongracic from Children's Memorial Hospital, the study uses a multicenter design to compare diverse populations and their prevalence of allergic disease. Moreover, the initial findings have already produced some unexpected results. Although skin-tests found that 16.7 percent of one rural Chinese community was sensitive to shellfish and 12.3 percent to peanuts, allergic reactions occurred in less than 1 percent of that population. "The apparent disassociation between high allergenic sensitization and low allergic disease in this Chinese population is not seen in our two U.S. study populations," Pongracic said. "What can explain the U.S. and Chinese difference? Is it urban versus rural exposure? Diet and lifestyle? Or genetic susceptibility? These are all questions we are trying to find some clear answers for." *See The New York Times*, December 9, 2008.

In a related development, a recent column published in the *British Medical Journal* claims that a plethora of allergy warnings could backfire by perpetuating a cycle of avoidance and over-sensitization to common foods. Harvard Medical School Professor Nicholas Christakis likens the current anxiety about food allergies to a "mass psychogenic illness" (MPI) that contributes to a "feedback loop" in which "the policy of avoidance ends up creating the epidemic it is trying to stop." Although he acknowledges that some reactions can be serious, Christakis explains that children who lack early exposure to allergens like nuts are more likely to become sensitized to them in the future. In addition, a culture that disproportionately stresses the danger of food allergies has encouraged parents to have their children skin-tested for food allergies, "thus detecting mild and meaningless 'allergies' to nuts." "And this," Christakis writes, "encourages still more avoidance of nuts, leading to still more sensitization." *See British Medical Journal*, December 13, 2008.

Food & Beverage

LITIGATION UPDATE

Food & Beverage Litigation Update is distributed by
Leo Dreyer and Mary Boyd in the Kansas City office of SHB.
If you have questions about the Update or would like to receive back-up materials,
please contact us by e-mail at ldreyer@shb.com or mboyd@shb.com.
You can also reach us at 816-474-6550.
We welcome any leads on new developments in this emerging area of litigation.

Shook, Hardy & Bacon L.L.P.®

Geneva, Switzerland

Houston, Texas

Kansas City, Missouri

London, United Kingdom

Miami, Florida

Orange County, California

San Francisco, California

Tampa, Florida

Washington, D.C.