Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

110th Congress

[1] Bills Introduced to Label Products from Animal Clones and Forbid Organic Labels for Clone Progeny

Responding to an FDA announcement that clones and their offspring are safe for human consumption, three bills were recently introduced in the 110th Congress to address the issue of cloned animals entering the food supply. S. 414 and H.R. 992 propose amending the Federal Food, Drug and Cosmetic Act and the Federal Meat Inspection Act to require products made from clones to bear a label stating, "THIS PRODUCT IS FROM A CLONED ANIMAL OR ITS PROGENY." The bills also outline civil suit procedures and potential penalties for violators.

Meanwhile, S. 536 was introduced on February 8, 2007, to "prohibit the labeling of cloned livestock and products derived from cloned livestock as organic." Co-sponsors Patrick Leahy (D-Vt.) and Herb Kohl (D-Wis.) reportedly seek to repair a loophole in the Organic Foods Production Act of 1990, which forbids certain cloning methods but does not make provisions for clone progeny. "Any attempt to allow cloned animals to carry the organic label would be inconsistent with the national organic standards and labeling program," said Leahy in a press statement. The Agricultural Marketing Service and the National Organic Standards Board will meet in March to discuss the issue. *See Press Release of U.S. Senators Leahy and Kohl,* February 8, 2007; *Food Navigator USA.com*, February 13, 2007.

In related developments, Representative Jo Ann Emerson (R-Mo.) introduced a bill (H.R. 1018) to prohibit USDA from implementing a mandatory National Animal Identification System (NAIS). H.R. 1018 would also require USDA to protect information gathered from any voluntary animal identification program. In December 2006, USDA announced that NAIS would remain optional after industry groups criticized the plan to compel animal tagging and registration by 2009.

Government Accountability Office (GAO)

[2] GAO Comptroller Testifies on Food Safety Report

General Comptroller David Walker recently delivered to Congress a GAO report on the federal food safety system. His testimony focused on the network's fragmentation and redundancy, with the Department of Agriculture (USDA) and the Food and Drug Administration (FDA) often overlapping duties but commanding 90 percent of the $1.7 billion allocated to food safety oversight. Walker recommended that decision makers consider (i) how agencies can "partner or integrate their activities," share accountability and evaluate their contributions when working toward a common outcome; and (ii)

how agencies can "more strategically manage their portfolio of tools and adopt more innovative methods" to achieve national food safety goals. He also added that any efforts to improve the system "would need to address criticisms that have been raised about USDA's dual mission as both a promoter of agricultural and food products and an overseer of their safety." A blue ribbon panel was proposed to assist Congress in creating "comprehensive, uniform, and risk-based food safety legislation" that would provide a framework for complementary agency activities.

Food and Drug Administration (FDA)

[3] FDA Issues Industry Guidance on Labeling Claims

FDA has issued an industry **guidance letter** to remind food manufacturers and distributors about the following labeling issues: (i) health claims (ii) structure/function claims, (iii) nutrient content claims, and (iv) dietary guidance. According to the letter, health claims describe a food or ingredient's relationship to disease risk reduction – for example, "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors." Structure/function claims, such as "calcium builds strong bones," express how substances affect normal structure or function in humans. Nutrient content claims use terms such as *free, high* and *low*, or comparative language such as *more*, *reduced* and *lite*, to describe nutrient levels in food. Dietary guidance, which typically focuses on a food category, highlights general dietary practices that promote good health, i.e., "Carrots are good for your health." FDA regulates health and nutrient content claims by passing regulations in accordance with scientific standards, or by prohibiting or modifying a claim within 120 days of notification. Structure/function claims and dietary guidance may be made without FDA authorizations provided they are "truthful and not misleading." *See Food Navigator USA.com*, February 12, 2007.

U.S. Department of Agriculture (USDA)

[4] Planning Underway for Codex Meeting on Food Contaminants

The Food Safety and Inspection Service (FSIS) has **announced** a public meeting to consider comments on agenda items and draft U.S. positions to be discussed by the First Session of the Codex Committee on Contaminants in Foods of the Codex Alimentarius Commission. The FSIS meeting, cosponsored by the Food and Drug Administration and the U.S. Department of Health and Human Services, will be held March 8, 2007. Among other matters, the Codex Committee, which is meeting in Beijing, China, April 16-20, 2007, will be discussing a general standard for contaminants and toxins in foods; codes of practice to reduce acrylamide and polycyclic aromatic hydrocarbons in foods; discussion papers on contaminants in coffee, cocoa and figs; draft maximum levels for tin in canned foods and beverages; and a draft sampling plan for aflatoxin contamination in nuts.

The United Nations established the Codex Alimentarius Commission in 1963 and charged it with adopting food standards, codes of practice and other guidelines for adoption and implementation by national governments to protect consumer health. FSIS represents the United States on commission committees. The food contaminants committee was formed in 2006, when the Codex Committee on Food Additives and Contaminants

was split. Thus, delegates to its first session will also be considering the endorsement and/or revision of maximum levels for contaminants in existing Codex standards.

Department of Health and Human Services (HHS)

[5] NIEHS Issues Report on Animal Feed Ingredients and Human Health

The National Institute of Environmental Health Sciences (NIEHS) has issued a **report** titled "What Do We Feed to Food Production Animals? A Review of Animal Feed Ingredients and Their Potential Impacts on Human Health." The researchers reviewed U.S. animal feeding practices and the etiologic agents detected in animal feed; they also evaluated evidence that "current feeding practices may lead to adverse human health impacts." According to the report, current practices "can result in the presence of bacteria, antibiotic-resistant bacteria, prions, arsenicals, and dioxins in feed and animal-based food products." The NIEHS report identifies research gaps and concludes that there is a need to (i) implement a nationwide reporting system as to feed ingredients of concern to public health; (ii) fund and develop "robust surveillance systems that monitor, biological, chemical and other etiologic agents throughout the animal-based food product chain 'from farm to fork' to human health outcomes"; and (iii) increase "communication and collaboration among feed professionals, food animal producers and veterinary and public health officials."

State/Local Initiatives

[6] Philadelphia Bans *Trans* Fat

Philadelphia will reportedly join New York City in prohibiting *trans* fats from city restaurants, lunch carts and cafeterias. The city council approved legislation that requires eateries to remove *trans* fat from frying oils and spreads by September 1, 2007, and from all non-prepackaged foods by September 1, 2008. The ban, which currently carries no penalties for violations, will be enforced by city health inspectors. While some restaurateurs reportedly anticipated the law by removing *trans* fat years ago, others see the move as "feel-good politics" that avoids tackling the more complex issue of obesity. "A fat is a fat is a fat," the director of culinary arts at the Restaurant School told reporters. "It's more education than legislation." *See Philadelphia Inquirer*, February 9, 2007.

Meanwhile, a recent **study** in *Nutrition and Metabolism* claims that an increasingly popular *trans* fat replacement known as chemically interesterified (IE) fat increases blood glucose to pre-diabetic levels. IE fats are created by transferring saturated fatty acids from some fat molecules to others, a process also called fatty acid randomization that "hardens oil to a plasticity comparable to earlier *trans* fat preparations." The study measured the cholesterol and blood glucose of 30 volunteers who ate tightly controlled diets for three rotations of four weeks. The first-rotation diet relied on palm oil for fat; the second, partially hydrogenated soybean oil; and the third, IE fat. *See Science News Online*, February 10, 2007.

[7] California Adopts State Certification Seal for Leafy Greens

In an effort to restore consumer confidence after two *E. coli* outbreaks last year, California's Department of Food and Agriculture recently announced a voluntary state certification program for spinach, lettuce and other leafy greens. The **marketing agreement**, which was developed with industry feedback, states that the certification seal "shall only be applied to leafy green products that [have] been grown, packed, shipped, processed and/or handled in accordance [with] the Best Practices, other Marketing Agreement requirements and any federal trademark registration requirements." Inspections will ensure compliance with food safety standards established by a state-appointed board.

While some farm trade associations have reportedly welcomed the agreement as a first step toward improved safety, others are still calling for federal regulation. *See The Los Angeles Times*, February 8, 2007.

Litigation

[8] *Salmonella* Investigation Could Bring Criminal Charges

According to a news source, the U.K.-based Cadbury Schweppes company could be facing criminal charges for producing food unfit for human consumption by releasing *salmonella*-contaminated chocolate for sale. The Food Standards Agency is apparently investigating the matter; should it decide to prosecute, the costs the company has already incurred recalling its products and losing consumer confidence could rise significantly. The confectionary company was forced to remove millions of dollars of product from U.K. shelves in 2006 after traces of *salmonella* were discovered in the chocolate. The source of the contamination was a leaking waste-water pipe in one of the company's factories. The company has reportedly indicated that it will be changing its manufacturing processes; it was criticized for failing to correctly implement European Union food-hygiene rules, known as Hazard Analysis and Critical Control Point (HACCP), which are now in effect and apply to all food processors. *See Food Production Daily*, February 13, 2007.

[9] Court Rules Against USDA in Genetically Engineered Alfalfa Case

A federal court in California has determined that the U.S. Department of Agriculture violated the National Environmental Policy Act by failing to prepare an environmental impact statement (EIS) before deregulating genetically engineered (GE) alfalfa. ***Geertson Seed Farms v. Johanns*, No. 06-01075 (U.S. Dist. Ct., N.D. Calif., decided Feb. 13, 2007)**.

A coalition of alfalfa growers, the Sierra Club and other farmer and consumer organizations challenged USDA's action, presenting a question of first impression, i.e., "whether the introduction of a genetically engineered crop that might significantly decrease the availability or even eliminate all non-genetically engineered varieties is a 'significant environmental impact' requiring the preparation of an environmental impact statement, at least when it involves the fourth largest crop in the United States."

This particular GE alfalfa is resistant to the herbicide in RoundUp® and has been regulated through USDA's Animal and Plant Health Inspection Service (APHIS), which requires those seeking to introduce the crop to seek its permission before doing so. Monsanto requested nonregulated status for

"Roundup Ready" alfalfa in 2003, and APHIS approved its petition after preparing an environmental assessment, which represents an agency determination as to whether the environmental impact is significant enough to warrant the preparation of an EIS. Public commenters objecting to Monsanto's petition complained that (i) conventional and organic alfalfa would become contaminated by GE alfalfa, (ii) they would no longer be able to market their crop as "organic," and (iii) the contamination would affect those who sell organic livestock fed on contaminated alfalfa, as well as the export market to Japan which does not permit the import of GE alfalfa. APHIS issued a finding of no significant impact despite these challenges, concluding the seeds could be sold and planted without further regulation. Plaintiffs raised similar issues in their complaint.

Finding that "[a] federal action that eliminates a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, is an undesirable consequence," the court ruled that such an effect was "sufficiently significant" to require that APHIS prepare an EIS before deciding that GE alfalfa can be deregulated. The court was particularly concerned that APHIS placed the burden of avoiding contamination on organic farmers. According to the court, because alfalfa seeds are pollinated by bees that travel as far as two miles from the pollen source, once a seed crop is contaminated with the Roundup Ready gene, "there is no way for the farmer to remove the gene from the crop or control its further spread. . . . [and APHIS did not] identify a single method that an organic farmer can employ to protect his crop from being pollinated by a bee that travels from a nearby genetically engineered seed farm, even assuming the farmer maintains a 'buffer zone.'" The court further accused APHIS of "a cavalier response" to the argument that another potential impact of GE alfalfa is the development of herbicide-resistant weeds.

While the court granted the plaintiffs' motion for summary judgment on its claim that APHIS is required to prepare an EIS, the parties must submit a proposed judgment to the court on or before February 26, 2007, outlining specific remedies to implement its decision. A news source has indicated that plaintiffs will likely seek an injunction to halt commercial sales of GE alfalfa seeds. *See The New York Times*, February 14, 2007.

Other Developments

[10] Physicians Group Wants FTC Ban on Junk Food Ads During Children's TV Programs

"Just as it protects children from tobacco advertising, the Federal Trade Commission should safeguard young people from the food industry's aggressive million-dollar ad campaigns pushing pizza, cheeseburgers and other unhealthy products," charges a spokesperson for Physicians Committee for Responsible Medicine (PCRM) in a recent press release. In a letter to the FTC, the group apparently requests a ban, modeled after a measure passed in the United Kingdom, that would prohibit all cheese and junk food advertising during children's TV programs. PCRM alleges that every American consumes 30 pounds of cheese annually, a habit allegedly responsible for rising obesity rates. *See PCRM Press Release*, February 8, 2007.

[11] British Grocery Chains to Start Advising Patrons About Nutrition

The Center for Consumer Freedom, a Washington, D.C.-based nonprofit coalition of restaurants, food companies and consumers, **reports** that Marks & Spencer, one of the U.K.'s largest grocery chains, will be hiring 1,500 new employees to patrol supermarket aisles and advise shoppers about the food selections they make. They will apparently wear Healthy Eating Advisor badges and discuss the fat, sugar and salt content of the foods in shoppers' carts. Competitor Sainsbury's has also reportedly gotten into the act, donating US$5.9 million to a government program that trains "food advisors" for deployment in stores and classrooms.

Scientific/Technical Items

[12] Binge-Eating Disorder Gains Credibility with New Study

A recent study in *Biological Psychiatry* claims that binge-eating disorder, which is not yet recognized by the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), is more common than anorexia nervosa and bulimia. James I. Hudson, et. al, "The Prevalence and Correlates of Eating Disorders in the National Comorbidity Survey Replication," *Biological Psychiatry*, February 1, 2007. After interviewing 2,900 men and women, Harvard researchers found that 2.8 percent of the general population suffers from binge-eating disorder, a diagnosis often associated with severe obesity. People diagnosed with the disorder eat large quantities at least twice a week but lack control over the episodes. "This brings in a lot of medical consequences and suggests it's a major health problem," the lead researcher told the media. "This information will help us make decisions on public health policy." *See The New York Times*, February 13, 2007.

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