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ISSUE 386 | MARCH 18, 2011

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

U.S. Regulators to Scan Food Containers from Japan for Radiation

According to a news source, the Customs and Border Patrol will begin scanning shipping containers arriving in the United States from Japan for radiation, following the earthquake and tsunami that caused explosions at the country's nuclear plants, releasing high levels of radiation into the atmosphere. The Food and Drug Administration (FDA) reportedly indicated that it is "closely monitoring the situation in Japan and is working with the Japanese government and other U.S. agencies to continue to ensure that imported food remains safe."

The agency "will be examining both food products labeled as having originated in Japan or having passed through Japan in transit." Affected shipments are not expected until the week of March 21, 2011, so FDA is reportedly not concerned about imports already in U.S. ports. It is also believed that the earthquake and tsunami shut down fishing, harvesting and food processing operations in the region. According to an agency spokesperson, because radioactive material is rapidly and effectively diluted in Pacific Ocean waters, fish and seafood are likely to be unaffected. Food imports from Japan apparently represent just 4 percent of all foods imported by the United States and consist mainly of seafood, snack foods and processed fruits and vegetables. *See The Los Angeles Times*, March 17, 2011.

GAO Reviews Presidential Food Safety Working Group

The Government Accountability Office (GAO) recently issued a **report** reviewing the activities of the Food Safety Working Group (FSWG), an advisory panel established by President Barack Obama (D) to recommend improvements to the U.S. food safety system. According to GAO, the working group has spurred the Food and Drug Administration, U.S. Department of Agriculture and other federal agencies to implement "steps designed to increase collaboration in some areas that cross regulatory jurisdictions––in particular, improving produce safety, reducing *Salmonella* contamination, and developing food safety performance measures." The report concludes, however, that the FSWG did not develop "a governmentwide performance plan for food

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safety that provides a comprehensive picture of the federal government's food safety efforts."

GAO specifically faults the group for failing to include "results-oriented" goals, performance measures or "information about the resources that are needed to achieve its goals." The March 2011 GAO report highlights "options to reduce fragmentation and overlap in food safety oversight in the form of alternative organizational structures," while noting that "a detailed analysis of their advantages, disadvantages, and potential implementation challenges has yet to be conducted." To this end, GAO has apparently suggested "that Congress consider commissioning the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational structures for food safety." It has also urged the Office of Management and Budget to work with federal agencies on "a governmentwide performance plan for food safety that includes results oriented goals and performance measures for food safety oversight and a discussion about strategies and resources." *See GAO Report Highlights,* March 15, 2011.

FDA Meetings to Target Imported Food Safety

The Food and Drug Administration (FDA) has announced its first **public meeting** to discuss implementation of import safety provisions recently enacted by the Food Safety Modernization Act. Titled "FDA Food Safety Modernization Act: Title III—A New Paradigm for Importers," the March 29, 2011, meeting in Silver Spring, Maryland, seeks stakeholder input to develop regulations and guidance "on importer verification, the Voluntary Qualified Importer Program, import certifications for food, and third-party accreditation." FDA requests comments by April 29, 2011. *See Federal Register,* March 14, 2011.

In a related matter, FDA has also **announced** a public hearing on the agency's new initiatives for ensuring the safety of imported foods and animal feed to reduce food borne illness. The March 30-31 hearing in College Park, Maryland, will "provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations." In a separate discussion, FDA will focus on its "efforts to gather information from regulators in other countries regarding the regulatory policies, practices, and programs they currently use to ensure the safety of foods and animal feed imported into their countries." According to FDA, the agency wants to better understand other countries' control systems for importation of ingredients used in processed food and for transshipment of products. FDA requests comments by June 30, 2011. *See Federal Register,* March 14, 2011.

NOP Issues Final Rule on Methionine Use in Organic Poultry

The U.S. Department of Agriculture's National Organic Program (NOP) has issued a **final rule** extending the use of methionine in organic poultry production until October 1, 2012. Effective March 15, 2011, the rule amends the National List of Allowed and Prohibited Substances according to the recommendations of the National Organic Standards Board (NOSB), which governs the use of synthetic and non-synthetic substances in organic processing and production. A dietary supplement, methionine "is classified as an essential amino acid because it cannot be biologically produced by poultry and is necessary to maintain vitality." In 2009, the Methionine Task Force filed a petition requesting a five-year extension on the allowance for synthetic methionine, partly because wholly natural sources of the supplement are not available.

NOSB ultimately recommended that, at first, "the amount of synthetic methionine per ton of feed be limited to 4 pounds for laying chickens, 5 pounds for broiler chickens, and 6 pounds for turkeys and all other poultry." After October 1, 2012, the allowance would be reduced to "2 pounds for laying chickens, 2 pounds for broiler chickens and 3 pounds for turkeys and all other poultry through October 1, 2015." The final rule implements the first part of this recommendation. *See Federal Register,* March 14, 2011.

IOM Reviews "Healthy People 2020" Initiative

The Institute of Medicine (IOM) has issued a **report** analyzing the Department of Health and Human Services' (HHS) "Healthy People 2020" initiative aimed at improving the overall health of Americans over the coming decade. According to a March 15, 2011, IOM press release, HHS asked the institute to review and recommend "leading health indicators that could sharpen the focus of the agenda," which seeks to "identify nationwide health improvement priorities; increase public awareness and understanding of determinants of health, disease, disability, and understanding of opportunities for progress; provide measurable objectives and goals applicable at national, state, and local levels; engage multiple sectors to take actions to strengthen policies and improve practices that are driven by the best available evidence and knowledge; and identify critical needs for research evaluation and data collection."

In the new report, IOM has updated and expanded on "10 leading health indicators that served as priorities for Healthy People 2010," as well as singled out "12 indicators as immediate, major health concerns that should be monitored and 24 objectives that warrant priority attention in the plan's implementation." Among the 24 priority objectives included in the IOM framework are calls to (i) "reduce the proportion of obese children and adolescents," (ii) "reduce consumption of calories from solid fats and added sugars by people age 2 and older," (iii) "increase the proportion of adults who meet current federal guidelines for aerobic physical activity and for muscle-strengthening activity," and (iv) "reduce the proportion of people engaging in binge drinking of alcoholic beverages."

These Healthy People 2020 objectives "should prove valuable in eliciting interest and awareness among the general population; motivating diverse population groups to engage in activities that will exert a positive impact on specific indicators and, in turn, improve the overall health of the nation; and providing feedback on progress toward improving the status of specific indicators," concludes the IOM report brief. "HHS may wish to highlight the indicators and objectives in communications to state and local health departments, use them as a guide for funding priorities in department programs, and use them as priority guides for ongoing departmental public health data collection and reporting activities."

Codex Committee Recommends Adoption of Melamine Testing Guidelines

The Codex Committee on Methods of Analysis and Sampling has reportedly endorsed guidelines providing regulators and the dairy industry a standard reference for testing melamine in dairy products, including powdered infant formula. Developed by the International Dairy Federation (IDF) and the International Organization for Standardization (ISO) in the wake of a melamine contamination scandal in China that purportedly sickened thousands of young children, the guidelines represent an internationally harmonized procedure that will allow authorities to determine if levels of melamine in dairy products exceed the Codex maximum level of 1 mg melamine per kg of product.

The Codex Alimentarius Commission will consider the committee's endorsement and vote on the guidelines' adoption in July 2011. The guidelines, titled "ISO/TS 15495 IDF/RM 230:2010, Milk, milk products and infant formulae—Guidelines for the quantitative determination of melamine and cyanuric acid by LC-MS/MS," reportedly provide advice about sampling, test procedures and performance with examples of test results. While Codex standards and guidelines are not binding on national governments, they are often adopted by governmental entities and generally apply in disputes before the World Trade Organization and in trading contracts. *See DairyReporter.com*, March 15, 2011; *Food Ingredients First*, March 17, 2011.

LITIGATION

Court Again Dismisses Health-Based False-Labeling Claims Against Margarine Maker

A federal court in California has dismissed as preempted state-law claims that Smart Balance falsely labeled and advertised its Nucoa® margarine product; the court also denied the plaintiff's motion to certify a class. *Yumul v. Smart Balance, Inc.*, No. 10-00927 (U.S. Dist. Ct., C.D. Cal., order entered March 14, 2011). Additional information about the complaint, which has twice been amended after previous rulings on motions to dismiss, appears in **Issue 359** of this *Update*.

The defendant argued in its response to the plaintiff's motion for class certification that the claims were preempted by federal law and thus could not be certified. The plaintiff argued that the defendant had waived this defense by not asserting it in its previous motions to dismiss. According to the court, the defendant did not waive the defense, because it had been preserved in the company's answer and because the company "is entitled to raise the defense any time prior to or during trial." The court further noted, "[I]t would promote efficient resolution of the case to consider it in the context of the currently pending motion for class certification."

The court determined that federal food labeling laws preempted the plaintiff's claims, but dismissed them with leave to amend to allow the plaintiff to assert claims under California's Sherman Law, which the plaintiff had raised for the first time in response to the defendant's preemption arguments. She contended that the company's labeling and advertising constituted *per se* violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and that the state's Sherman Law, under which California has adopted federal regulations as its own, allowed her to enforce those violations. According to the court, "[T]he California Supreme Court has held that the Sherman Law imposes requirements that are identical to those under the FDCA; thus, claims brought under the Sherman Law are not expressly preempted." The plaintiff will, therefore, be allowed to assert that the defendant's labeling and advertising did not comply with the Sherman Law.

Statement of Decision Supports Oral Ruling on Fraudulent Pesticide Exposure Claims

A California court has issued a statement of decision in support of its July 2010 oral ruling vacating a judgment in favor of plaintiffs who alleged they had been rendered sterile from chemicals used on Nicaraguan banana plantations. *Tellez v. Dole Food Co., Inc.*, No. BC 312852 (Cal. Super. Ct., Los Angeles County, statement filed March 11, 2011). According to the court, the plaintiffs' attorneys "coached their clients to lie about working on banana farms, forged work certificates to create the appearance that their clients had worked on Dole-contracted farms, and faked lab results to create the impression that their clients were sterile." The court also stated that the attorneys "tampered with witnesses," "threatened witnesses and took other actions to carry out the fraud."

The court held more than 20 hearings, presiding over a year-long evidentiary process, and "reviewed the sworn testimony of 27 protected witnesses describing the fraud at work in these cases, heard plaintiff's fact witnesses and experts, and reviewed the more than 400 exhibits submitted by the parties." Rejecting the plaintiffs' claims that Dole's "John Doe" testimony about fraud was not credible and that Dole bribed witnesses and was not diligent in bring forward evidence of fraud, the court found that the "fraud permeates every aspect of the case and continues unchecked" and concluded that "retrial is not an option." Because of the costs to the court system and the jurors' employers, as well as a "reliably predic-

tive" history and ongoing nature of counsel's misconduct, the court dismissed the case with prejudice.

Peanut Butter Cookie Served to Allergic Child Not an Inherently Violent Act

A federal court in California recently dismissed with prejudice a claim against a school district and some of its personnel filed by the parents of a child with an allergy to nuts; they alleged that the defendants threatened harm to the child by refusing to keep him in a nut-free environment, which threat was undertaken to discourage the parents from exercising a legal right, i.e., requesting accommodations for him, in violation of state law. *McCue v. S. Fork Union Elementary Sch.*, No. 10-00233 (U.S. Dist. Ct., E.D. Cal., decided February 7, 2011).

The parents also alleged harm from an unspecified person giving the child a peanut butter cookie. Because the third amended complaint did not allege all of the facts needed to state a claim under the law and because "[s]erving a child a peanut butter cookie is not an inherently violent act," the court concluded that the complaint did not allege an act of violence or threat of violence against the child. This claim was dismissed with prejudice because it had not addressed the same claim's deficiencies as pleaded in the parents' second amended complaint. Other challenged claims can be amended and may proceed.

Hispanic Farmers Allege Unfair USDA Treatment in Settlement of Discrimination Claims

Five Hispanic farmers have filed a putative class action in a D.C. district court against the U.S. Department of Agriculture (USDA), to seek "redress from Defendants' unconstitutional treatment in the proposed settlement of discrimination claims by these Hispanic Plaintiffs . . . as compared to the manner in which Defendants have settled identical discrimination claims by similarly situated African-American and Native American claimants, . . . all of whom were undeniably discriminated against in like manner by [USDA] in the administration of its farm credit and non-credit farm benefit programs." *Cantu v. United States*, No. 11-00541 (U.S. Dist. Ct., D.D.C., filed March 15, 2011).

According to the complaint, the government has paid African-American farmers about $1 billion in settlement benefits, and legislation signed into law in December 2010 provides an additional $1.25 billion to settle African-American farmers' claims. Native American farmers were purportedly offered $680 million in compensation and $80 million in debt forgiveness to resolve their claims. In contrast, the government allegedly offered $1.33 billion to settle the combined claims of Hispanic and female farmers, who outnumber African-American farmers by at least 12 to 1 and as much as 27 to 1, according to government statistics cited in the complaint. The plaintiffs also allege that the settlement dispute resolution system for African-Americans and Native Americans is less expensive and burdensome than the system offered to settle the Hispanic and female claims.

The complaint details the discriminatory treatment purportedly accorded the named plaintiffs when they sought special loan packages, loan servicing, disaster relief, or operating loans for their farming operations from federal agencies. Among other matters, the plaintiffs contend that USDA has "willfully failed to investigate complaints of discrimination in its farm benefit programs filed by Hispanic farmers and continues to fail to investigate such complaints of discrimination (including those of Plaintiffs) to this day." They seek to represent a class of Hispanic farmers "who farmed or ranched, or attempted to farm or ranch, during the period January 1, 1981 to the present and who complained to the USDA about its acts of discrimination."

Alleging violations of their equal protection and due process rights by governmental and individual defendants, the plaintiffs request a declaration that their constitutional rights were violated, a permanent injunction prohibiting the defendants from treating Hispanic farmers "unequally" in the settlement of their claims, attorney's fees, and costs.

Hedonists Claim Idaho Imposes Religious Beliefs via Alcohol Control Laws

A group calling itself "The Ethereal Enigmatic Euphoric Movement Towards Civilized Hedonism, Ltd." has sued Idaho in federal court, alleging that a state law allowing cities to "prohibit the sale of distilled spirits" violates members' fundamental right to practice their religion. *The Ethereal Enigmatic Euphoric Movement Towards Civilized Hedonism, Ltd. v. Idaho*, No. 11-00097 (U.S. Dist. Ct., D. Idaho, E. Div., filed March 11, 2011).

According to the complaint, the city of Preston in Franklin County has relied on the state law to forbid the sale of liquor by the drink. The plaintiff contends that this happened because more than 80 percent of local voters belong to The Church of Christ of the Latter Day Saints, whose members allegedly "believe that drinking alcoholic beverages is a mortal sin."

The plaintiff alleges that these voters "are allowed to force their morality on those of us who don't believe in their religion," and that, in fact, Euphoric Movement members "believe the consumption of distilled spirits is both our moral obligation and sacred right." Denying Euphoric Movement members "the right to drink is a violation of our constitutional rights," according to the complaint, which was filed *pro se* and signed by an individual named Philip Henry Mockli.

SCIENTIFIC/TECHNICAL ITEMS

Rat Study Alleges Link Between Poor Prenatal Diet, Diabetes in Offspring

The UK's University of Cambridge has conducted an animal **study** suggesting that poor diet during pregnancy may lead to an increased risk of offspring developing diabetes later in life. Ionel Sandovici, et al., "Maternal diet and aging alter the

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epigenetic control of a promoter-enhancer interaction at the *Hnf4a* gene in rat pancreatic islets," *Proceedings of the National Academy of Sciences*, March 8, 2011. Researchers exposed female rats to either a normal or low-protein diet during their pregnancies and then collected pancreatic cells from their offspring at ages 3 and 15 months.

Researchers reportedly found that the offspring of rats fed a protein-deficient diet had a higher rate of type 2 diabetes, according to the study. But they also discovered that the offsprings' *Hnf4a* gene—thought to play a role in pancreas development and insulin production—was apparently silenced as the rats aged, a factor that may cause diabetes.

"This study has identified a fundamental mechanism by which diet, during critical periods of development, interacts with the genome to influence long-term health," assert the study's authors. "We found that suboptimal nutrition during early life modifies a promoter-enhancer interaction at the *Hnf4a* locus through alternations in histone marks. Our study also provides molecular insight into how diet and aging can interact over the life course to determine gene expression and, consequently, tissue function and disease risk."

Noting that further research is needed to determine whether high-fat or other imbalanced diets could cause similar outcomes in rats, Cambridge researcher Susan Ozanne told a news source that humans could experience similar mechanisms as those in the diabetes study. "Having a healthy well-balanced diet any time in your life is important for your health, but a healthy well-balanced diet during pregnancy is particularly important because of the impact on the baby long-term and potentially even on the grandchildren as well," she said. *See BBC News,* March 7, 2011.

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FOOD & BEVERAGE LITIGATION UPDATE

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.