

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

White House Unveils FY2010 Budget

With critics and supporters lined up to do battle over President Barack Obama's proposed \$3.55 trillion fiscal year (FY) 2010 budget, the ultimate outcome for proposals relating to food safety and agricultural subsidies is a question mark. Still, the administration has proposed more than \$1 billion for the Food and Drug Administration (FDA) to increase inspections of food facilities and protect the nation's food supply, an additional \$1 billion for the U.S. Department of Agriculture's (USDA's) child nutrition programs, as well as a \$20 billion increase in food stamps. Additional funds would be provided for enforcement of the National Organic Program.

To pay for such spending increases, the proposed budget would reportedly phase out direct payments to farmers making more than \$500,000 in annual sales, reduce spending on crop insurance premiums, eliminate the promotion of branded agricultural products, and impose user fees at the Grain, Inspection, Packers and Stockyards Administration; Animal Plant and Health Inspection Service, and Food Safety and Inspection Service.

Meanwhile, the House of Representatives has reportedly approved an omnibus appropriations bill that would provide the FDA with an immediate funding increase of \$335 million, bringing the agency's FY2009 budget to \$2 billion. This legislation would add \$41 million to the FDA's Food Safety and Inspection Service budget this year for improvements to food safety and implementation of new requirements under the 2008 Farm Bill. According to a news source, the appropriations bill also includes provisions that would halt the progress of a USDA rule that would allow potentially unsafe poultry products into the United States from China and would implement a country-of-origin labeling (COOL) program for fresh fruits, vegetables, meats, and other products. The House bill would provide the USDA's Agricultural Marketing Service with \$9.6 million to administer the Farm Bill's COOL requirements. See *Congress Daily* and *Product Liability Law* 360, February 26, 2009.

USDA Sets COOL Implementation Date; Encourages Voluntary Measures

The U.S. Department of Agriculture (USDA) has announced that mandatory country-of-origin labeling (COOL) will take effect as scheduled on March 16, 2009. Pursuant to an Obama administration memorandum, USDA reviewed the final

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rule that requires country-of-origin labeling for muscle cuts and ground beef, veal, pork, lamb, goat, and chicken; wild and farm-raised fish and shellfish; fresh and frozen fruits and vegetables; and peanuts, pecans, macadamia nuts, and ginseng sold by some retailers. Agriculture Secretary Tom Vilsack also issued an open letter to industry that urged companies to adopt several voluntary measures, such as multiple countries-of-origin designations and additional information about each production step. Further noting that the final rule's definition of processed foods "may be too broadly drafted," Vilsack stated that COOL might also be applicable to products subject to "curing, smoking, broiling, grilling, or steaming."

Meanwhile, the American Meat Institute (AMI) has reportedly welcomed COOL implementation after taking an active role in the "six year rulemaking process." The organization has estimated that 95 percent of beef and pork products will bear a "Product of the USA" label under the COOL program. "To the extent that companies are able and elect to go beyond these federal labeling requirements... is an individual company decision, which will have to be made in collaboration with a company's retail grocery customers, which ultimately are the entities that provide country-of-origin information to the consumers," an AMI spokesperson was quoted as saying. See *USDA Press Release*, February 20, 2009; *Progressive Grocer*, February 23, 2009.

USDA Announces Public Meeting to Address Codex Agenda

The U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) have [announced](#) a public meeting on March 5, 2009, to discuss agenda items and draft U.S. positions for the Third Session of the Codex Committee on Contaminants in Foods (CCCF) slated for March 23-27, 2009, in Rotterdam, The Netherlands. Part of the Codex Alimentarius Commission established in 1963 by the Food and Agriculture Organization and World Health Organization, CCCF (i) sets maximum levels for contaminants and naturally occurring toxicants in food and feed; (ii) prepares priority lists of contaminants and naturally occurring toxicants for risk assessments by the Joint FAO/WHO Expert Committee on Food Additives; (iii) considers methods of analysis and sampling for contaminants and naturally occurring toxicants; and (iv) establishes other standards and codes of practice for related subjects. Specific agenda items for the session also include: (i) a draft practice code for the reduction of acrylamide in food; (ii) a draft practice code for the reduction of contamination of food with polycyclic aromatic hydrocarbons (PAH) from smoking and direct drying processes; (iii) a discussion paper on benzene in soft drinks; and (iv) a discussion paper on ethyl carbamate in alcoholic beverages.

Scientists Complain to EPA About Thwarted Research on GM Crops

The Environmental Protection Agency (EPA), which will hold hearings on genetically modified (GM) crops during the first week of March 2009, has reportedly received a statement submitted anonymously by 26 corn-insect specialists who apparently contend that biotechnology companies are preventing them from fully researching the effectiveness and environmental impact of the industry's GM crops.

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To conduct their research, the scientists must evidently seek permission from the GM seed companies because the buyers of these products are often restricted by agreements requiring them to honor patent rights and environmental regulations. The researchers reportedly claim that the companies sometimes deny permission or insist on reviewing findings before they can be published. "No truly independent research can be legally conducted on many critical questions," according to the statement.

The scientists also apparently claim that the industry's control of GM research means they are unable to provide farmers with some information about how to best grow the crops and the data provided to government regulators is being "unduly limited." Company officials reportedly defend the policies, noting that government regulations require the companies to carefully police how the GM crops are grown and that contracts with seed buyers are intended to protect intellectual property and meet environmental regulations. According to an EPA spokesperson, however, the government requires management of crops' insect resistance only and that any other contractual restrictions are being imposed for non-regulatory reasons.

During the two EPA hearings, the agency will consider (i) a biotechnology company's request for a new method to reduce how much of a particular field must be set aside as a refuge to prevent insects from becoming resistant to its insect-resistant corn, and (ii) insect-resistant biotech crops in general. The scientists who supported the statement reportedly indicated that many did so anonymously because many are dependent on industry grants to fund their research. See *The New York Times*, February 20, 2009.

Health Canada Seeks Comments on Acrylamide Proposal

Health Canada has [recommended](#) adding acrylamide to the country's list of toxic substances. The chemical is produced when sugars and an amino acid in starchy foods are cooked at high temperatures, causing a reaction called the Maillard effect. Acrylamide has been detected in breakfast cereals, pastries, cookies, breads and rolls, coffee, and potato products such as French fries and potato chips. The chemical's presence at high levels in carbohydrate-rich foods was discovered in 2002 by the Swedish food safety authorities. It has apparently been found to cause cancer in laboratory rats. According to a notice published in the February 21, 2009, *Canada Gazette*, current consumption levels "may constitute a danger in Canada to human life or health." Comments on the recommendation must be submitted by April 22. See *Globe and Mail*, February 21, 2009; *Foodnavigator-usa.com*, February 26, 2009.

Meanwhile, research recently published in the *American Journal of Epidemiology*, reportedly shows that acrylamide does not raise the risk of breast cancer. Swedish researchers studying more than 61,000 women born before 1949, apparently found that those with the highest acrylamide intake were no more likely than those with the lowest intakes to develop the disease. The scientists cautioned, however, that acrylamide intake in the entire group studied was fairly low, so it is not clear whether the findings can be extrapolated to other population groups. See *Reuters*, February 25, 2009.

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EFSA to Provide Risk Assessment for Food Packaging Chemical

German authorities have reportedly asked the European Food Safety Authority (EFSA) to provide a risk assessment for 4-methylbenzophenone, a food packaging chemical similar to benzophenone and hydroxybenzophenone that both have a tolerable daily intake (TDI) of 0.01 mg/kilogram of body weight. Officials alerted EFSA through the Rapid Alert System for Food and Feed after a customer identified the common photo-inhibitor in a chocolate crunch muesli product at levels approaching 798 μm /kilogram parts per billion (ppb). The European Commission has also requested a reevaluation of the TDI set for the two related chemicals. EFSA anticipates that it will publish its assessment of 4-methylbenzophenone by March 3, 2009, with an opinion on other food contact materials, enzymes, flavorings and processing aids expected by the end of May. See *FoodProductionDaily.com*, February 24, 2009.

LITIGATION**Aurora Dairy Seeks Insurance Coverage for Consumer Class Actions**

Aurora Dairy Corp., which is defending multidistrict litigation involving putative class claims that it sold its products as “organic” without following national organic program standards, has sued one of its insurance carriers in federal court seeking a declaration that the insurer has wrongly failed to provide defense coverage. *Aurora Dairy Corp. v. Nationwide Agribusiness Ins. Co.*, No. 09-00346 (U.S. Dist. Ct., D. Colo., filed February 19, 2009). According to the complaint, “Aurora has been named in thirteen consumer class actions filed in the courts of six different states.” The claimants in those lawsuits allege a variety of causes of action including “that the milk provided by Aurora that they purchased allegedly exposed them, their families and their friends to pesticides, hormones, antibodies, and other chemicals and/or has generally caused them injury or damage.” Additional details about the underlying lawsuits appear in issues 251, 279 and 286 of this Update.

Aurora claims that it has complied with its obligations under the insurance policy, which requires Nationwide to “defend Aurora in any suits seeking damage for ‘bodily injury,’ ‘property damage,’ or ‘personal or advertising injury.’” The dairy company seeks a declaration that Nationwide is required to provide its defense and, alleging breach of contract and bad faith breach of insurance contract, calls for judgment for all of its costs of defense, interest and punitive damages. According to a news source, Aurora’s other liability insurers filed a suit for declaratory judgment in June 2008, claiming that the costs of the consumer class action lawsuits are exempt under the policies because the plaintiffs are either seeking damages or raise claims not covered by the policies. See *Product Liability Law 360*, February 23, 2009.

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ConAgra Seeks Insurance Coverage for 2007 Peanut Butter *Salmonella* Outbreak

ConAgra Foods, Inc. has reportedly filed a lawsuit against its umbrella insurer, seeking coverage for the claims that were filed by people who alleged injury from a *Salmonella* outbreak in 2007 linked to the company's Sylvester, Georgia, peanut butter processing facility. *ConAgra Foods, Inc. v. Lexington Ins. Co.*, No. 09C-02-170 (New Castle County Super. Ct., Del., filed February 19, 2009). The complaint alleges that Lexington Insurance Co. has failed to pay for any of the 2,400 claims settled or resolved to date. ConAgra reportedly anticipates an additional 20,000 cases from the outbreak. According to a news source, the company is seeking a declaratory judgment, compensatory and punitive damages, interest, and attorney's fees. See *Product Liability Law* 360, February 24, 2009.

Pelman v. McDonald's Corp.: Motions to Compel Dismissed with Leave to Renew

The district court judge to whom this obesity-related litigation was reassigned in 2008 has dismissed motions to compel filed by plaintiffs and defendants, but has given the parties leave to renew after the court rules on motions for class certification. *Pelman v. McDonald's Corp.*, No. 02 Civ. 7821 (S.D.N.Y., filed Sept. 30, 2002). Judge Robert Sweet recused himself from the proceedings following the pre-trial conference, held April 9, 2008, and the matter was reassigned to Judge Sidney Stein in May. The plaintiffs, a putative class of obese and overweight teens, alleged that the fast-food company misled them with deceptive ads. They are seeking damages for obesity-related health problems.

Information about the lawsuit has periodically appeared in this Update since it was filed in 2002. It has been appealed twice to the Second Circuit Court of Appeals, its issues have been narrowed, and it has been followed closely by consumer advocates and the food industry. While some predicted that obesity lawsuits would proliferate as plaintiffs' lawyers sought new deep pockets following waves of asbestos and tobacco litigation, causation has been identified as a significant obstacle in light of the multitude of factors recognized as contributing to obesity.

OTHER DEVELOPMENTS

Sheep Belching Researched to Reduce Greenhouse Gas Emissions

The Wall Street Journal reports that scientists in New Zealand are studying ways to keep sheep and other ruminants from belching methane when they eat and regurgitate grass. Methane is apparently a significant contributor to greenhouse gases, and researchers currently believe that livestock is more responsible for greenhouse gas emissions than cars. Among the approaches being considered to reduce belching incidence is to change the animals' diets, feed them various chemicals or even breed new sheep. A livestock expert from Massey University reportedly acknowledged that "[a] lot of people think we're insane," but as awareness of the problem has grown, governments around the world are looking for ways to address it. Farmers, reportedly skeptical of environmental concerns, worry that

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regulatory agencies will eventually tax “bovine belches,” and face activist campaigns to decrease meat consumption in the name of slowing climate change. See *The Wall Street Journal*, February 26, 2008.

MEDIA COVERAGE

Elizabeth Nord, “Top 10 Reasons for Using Nanotech in Food,” *Discovery.com*, February 20, 2009

This article explores recent nanotechnology innovations designed to “extend food shelf life, add health benefits, impact flavor or even signal bacteria contamination,” likening current public concern to the mishandled controversy over genetically modified crops. According to the article, “the top ten reasons why we should continue the conversation about using nanotechnology in food” include cutting-edge devices that could (i) signal contamination; (ii) provide antimicrobial packaging; (iii) improve food storage; (iv) enhance nutrient delivery; (v) produce environmentally friendly products; (vi) reduce pesticide use; (vii) track brands and products; (viii) improve texture; (ix) boost flavor profiles; and (x) identify and eliminate bacteria. The article also suggests greater transparency in research and development to assuage any consumer trepidation about nanoparticles in food. “The security intended to deter competitors from stealing ideas can also make identifying potential harm more difficult for the regulatory agencies trying to manage risks and create law for this emerging technology,” states the article, which nevertheless claims that the safety and nutritional benefits provide two-in-one solutions to these common problems.

SCIENTIFIC/TECHNICAL ITEMS

New Study Challenges FDA Draft Assessment of Mercury in Fish

A new study from the Connecticut Department of Health has challenged a recent Food and Drug Administration (FDA) draft assessment weighing the benefits of fish consumption against the risks associated with mercury exposure. Gary L. Ginsberg and Brian F. Toal, “Quantitative Approach for Incorporating Methylmercury Risks and Omega-3 Fatty Acid Benefits in Developing Species-Specific Fish Consumption Advice,” *Environmental Health Perspectives*, February 2009. FDA had concluded that consumers may derive greater benefits from the lean protein, omega-3 oils and minerals in fish if they exceed the current safety threshold set at 12 ounces of fish per week. But the Environmental Protection Agency (EPA) and other groups have since criticized this assessment for “serious scientific flaws,” urging consumers to abide by the safety standards currently recommended by both agencies.

Meanwhile, the Connecticut Department of Health study has expanded on the FDA study by identifying some fish species, such as swordfish and shark, that contain higher methylmercury levels and are not safe for daily consumption. Noting that several other species – like farmed salmon, herring and trout – are low in methylmercury, the researchers also warned that even “safe” fish could contain other

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contaminants, including polychlorinated biphenyls, which may offset any significant health benefits. See *Inside EPA*, February 27, 2009.

Researchers Hypothesize Refined Food Addiction

Relying on the DSM-IV criteria for substance dependence and other substance use disorders, researchers have hypothesized that the over-consumption of refined foods can be described as an addiction that “could account for the global epidemic of obesity and other metabolic disorders.” J.R. Iffland, et al., “Refined Food Addiction: A Classic Substance Use Disorder,” *Medical Hypotheses* (2009).

They match the statements obtained from obese people involved in a clinical observation study with substance dependence criteria such as progressive use over time, withdrawal symptoms, use more than intended, and tried to cut back, and show how “reports from self-identified food addicts seem to comprise behaviors that conform to the DSM-IV criteria. The pathology of behavior and the elements of loss control and distress that are prevalent in other addictions also appear in this qualitative data.”

While calling for further empirical research, the article also cites animal research and obesity literature as additional support for the validity of the refined food addiction hypothesis. The authors suggest that the development of a new diagnostic category could lead to a useful therapeutic approach, which they believe would involve abstinence from the substances that lead to loss of control, “as is the practice with other substance use disorders.”

They acknowledge that their hypothesis could, like the concepts of alcohol and nicotine dependence, take “decades to gain acceptance.” Noting that “patients’ attempts to lose weight have been disturbingly resistant to known treatment approaches,” the article concludes, “In the absence of an addiction framework, irrational overeating of refined foods remains a puzzle without a solution. With the possible validation of the refined food addiction syndrome, the health community could move forward with recommendations of abstinence from specific substances.”

Three Studies Examine Impact of Location on Dietary Choices, Stroke Risk

Two recent studies have reportedly examined the impact of location on the accessibility and quality of healthy food. Manuel Franco, et al., “Availability of Health Foods and Dietary Patterns: The Multi-Ethnic Study of Atherosclerosis,” *American Journal of Clinical Nutrition*, March 2009. Manuel Franco, et al., “Neighborhood Characteristics and Availability of Healthy Foods in Baltimore,” *American Journal of Preventative Medicine*, December 2008. Researchers with the Johns Hopkins Bloomberg School of Public Health, the University of Texas, and the University of Michigan apparently found that approximately 46 percent of lower-income neighborhoods in Baltimore City and Baltimore County, Maryland, had a low availability of fresh fruits and vegetables, skim milk, and whole wheat bread. The studies relied on information gleaned from 759 participants in the Multi-Ethnic Study of Atherosclerosis (MESA) and a systematic survey of 159 neighborhoods and 226 neighborhood stores in the Baltimore area. “Previous studies have suggested that race and income are related

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to healthy food intake and our choice of foods play a major role in our health and diet," one study author was quoted as saying. "Our studies show that where you live is a major determinant of your health. The joint efforts of public health researchers in collaboration with community groups and policymakers will be required to effectively change the current picture of the less-than-optimal availability of recommended healthy foods." See *Johns Hopkins Bloomberg School of Public Health Press Release*, February 25, 2009.

In a related development, a University of Michigan study presented before the 2009 International Stroke Conference has claimed that "the risk of stroke increases with the number of fast-food restaurants in a neighborhood." The researchers identified 1,247 ischemic strokes reported to the Brain Attack Surveillance in Corpus Christi (BASIC) between January 1, 2000, and June 2003. According to the study, "residents of neighborhoods with the highest number of fast-food restaurants had a 13 percent higher relative risk of suffering ischemic strokes than those living in areas with the lowest number of restaurants." In addition, the authors concluded, "the relative risk of stroke increased 1 percent for each fast food restaurant in a neighborhood." See *University of Michigan Press Release*, February 20, 2009.

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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.

