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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

U.S. Congress Turns Attention to Nanotechnology Issues

Legislation recently introduced in the House and Senate would take different approaches to the continuing development and use of nanotechnology. Senators Mark Pryor (D-Ariz.) and Benjamin Cardin (D-Md.) have co-sponsored a bill (S. 2942), the "Nanotechnology Safety Act of 2010," that would establish a program within the Food and Drug Administration (FDA) to investigate nanoscale materials used in FDA-regulated products to assess their "potential toxicity" and interactions with biological systems. The measure would appropriate $25 million for each year from 2011 through 2015 to carry out the program.

Among other matters, the proposal calls on FDA to assess scientific literature and data, develop models to formulate general principles for "the behavior of classes of nanoscale materials with biological systems," undertake collaborative efforts to understand the "science of novel properties at the nanoscale that might contribute to toxicity," build agency expertise on these issues, ensure ongoing training, and "participate in international and national consensus standards activities." The bill has been referred to the Senate Committee on Health, Education, Labor, and Pensions.

Representative David Wu (D-Ore.) has introduced the "Nanotechnology Education Act" (H.R. 4502), which calls for the National Science Foundation director to establish "a nanotechnology in the schools program to strengthen the capacity of eligible institutions to provide instruction in nanotechnology." The director would be authorized to award $400,000 grants to eligible secondary and post-secondary schools to acquire nanotechnology equipment and software, develop appropriate instructional programs and provide related teacher education and certification. Designed to strengthen the capacity of the nation's schools to "prepare students for careers in nanotechnology," the proposal has one co-sponsor and has been referred to the House Committee on Science and Technology.

FDA Science Board to Review Food Safety Research

The Food and Drug Administration's Science Board has announced a February 22, 2010, public meeting to discuss "an interim report from its subcommittee reviewing research at the Center for Food Safety and Applied Nutrition."

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The advisory board is also slated to discuss "plans to establish another subcommittee to review research programs at the Center for Drug Evaluation and Research" and "updates on science programs at the Office of Regulatory Affairs and the National Center for Toxicological Research." FDA plans to make background material available no later than two business days before the meeting. *See Federal Register,* January 27, 2010.

OSHA to Address Combustible Dust Workplace Hazards

The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) has **announced** a series of stakeholder meetings intended to address the "views, concerns, and issues surrounding the hazards of combustible dust," which may be formed in agricultural and grain-handling workplaces and factories that manufacture food, animal food, pesticides, and pharmaceuticals. For the February 17, 2010, meeting in Atlanta, Georgia, OSHA is soliciting feedback on (i) possible regulatory approaches to handling the hazards of combustible dust; (ii) the scope of any rulemaking; (iii) the organization of a prospective standard; (iv) the role of consensus standards; and (v) consequent economic impacts. OSHA held a similar meeting December 14, 2009, and additional meetings are planned for 2010.

The agency previously published an advance notice of proposed rulemaking that requested comments, including data and other information, on issues related to the hazards of combustible dust in the workplace. According to OSHA, "Materials that may form combustible dust include, but are not limited to, wood, coal, plastics, biosolids, candy, sugar, spice, starch, flour, feed, grain, fertilizer, tobacco, paper, soap, rubber, drugs, dried blood, dyes, certain textiles, and metals (such as aluminum and magnesium)." *See Federal Register,* January 25, 2010.

U.S. Codex Delegates Schedule Meeting to Discuss Food Additives

The U.S. Department of Agriculture's Food Safety and Inspection Service and the Food and Drug Administration have **announced** a February 8, 2010, public meeting to discuss draft U.S. positions for the 42nd Session of the Codex Committee on Food Additives (CCFA) slated for March 15-19, 2010, in Beijing, China.

Co-sponsored by the U.S. Department of Health and Human Services, the meeting will include discussions concerning (i) "endorsement and/or revision of maximum levels for food additives and processing aids in [C]odex standards"; (ii) "draft and proposed draft food additive provisions of the General Standards for Food Additives (GSFA)"; (iii) "proposals for changes or additions to the International Numbering System (INS) for food additives"; (iv) "identification of problems and recommendations related to the inconsistent presentation of food additives provisions in Codex commodity standards; and (v) "the Codex standard for food grade salt." *See Federal Register,* January 28, 2010.

New Zealand Takes Stand on GM Advertising

In a development only recently noticed in the United States, New Zealand's Commerce Commission took action in late 2009 against a poultry producer that claimed its chickens contained no genetically modified (GM) ingredients. According to a November 18, 2009, commission news release, Inghams Enterprises (NZ) Pty. Limited was warned that it

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risked breaching the Fair Trading Act by stating that its chicken products contained "No … GM ingredients" and "have no added hormones, GM ingredients or artificial colours," when the company's chickens were fed with a product that contained 13 percent GM soy.

The commission based its action on a report issued by a Canterbury University genetics and molecular biology professor who concluded that "GM plant material can transfer to animals exposed to GM feeds in their diets or environment, and that there can be a residual difference in animals or animal-products as a result of exposure to GM feed."

The report reviews the scientific literature to determine whether the DNA of GM plants can be present in animal products. Author Jack Heinemann did not consider "whether eating GM plants poses an overall health risk to the animal or transfers a health risk to humans through the animal" or "whether significant differences between animals fed GM-derived substances were of 'biological significance,' or within the range of physiological diversity seen in those species." The findings were specifically tailored to the question presented, which focused on the "high likelihood" that a consumer would be "able to avoid ingestion of DNA, protein or other substances that might be unique to a GM plant or its method of cultivation and processing, or be able to avoid animal physiological or immunological responses to substances unique to GM plants, through consumption of animals raised on GM feed." According to Heinemann, the answer to that question is no.

While the EU requires mandatory labeling of GM ingredients in food and feed, New Zealand's action has been characterized as "landmark," because no other country or region requires similar labels for the meat, dairy or egg products from animals fed with GM feed. *See ktradionetwork.com*, January 15, 2010.

BPA Bans Gain Traction in State Legislatures

The Washington and Wisconsin legislatures have reportedly passed bills that would prohibit the use of bisphenol A (BPA) in baby bottles, sipping cups and other food and beverage containers intended for children younger than age 3. In light of the Food and Drug Administration's (FDA's) recent decision to reassess the plasticizer's safety, the Washington House of Representatives voted 95-1 in favor of legislation (H. 1180) that would prohibit BPA in bottles, cups or other containers designed primarily for this age group, as well as any sports water bottles, as of July 1, 2011. The bill now heads to the Senate, where the Health and Long-Term Care Committee has delivered a similar version to legislators.

Meanwhile, the Wisconsin Senate has adopted its own BPA measure (S. 127), an identical version of which has already passed the Assembly Consumer Protection Committee and now awaits that chamber's approval. In addition, Vermont lawmakers recently proposed a bill (S. 247) that would forbid the manufacture, distribution or sale of "any reusable food and beverage container containing BPA," as well as "any infant formula or baby food stored in a plastic container, jar, or can that contains BPA."

If their legislative efforts remain on schedule, these states would apparently join Connecticut, Minnesota, Chicago, and three New York counties in restricting the use of BPA in children's products. "The FDA's announcement… which was a compete about-face… has really galvanized support for passing bans in the states," one spokesperson for

Safer Chemicals, Healthy Families was quoted as saying. "That was enough of a red flag for states to be able to say, 'If we know enough now that it's a concern, let's do enough to protect kids.'" *See The Journal Sentinel*, *Law360* and *The Olympian,* January 26, 2010.

California DTSC May Take Action Under Carbon Nanotube Information Call-In Program

California's Department of Toxic Substances Control (DTSC) has been gathering information from companies that produce or import carbon nanotubes in the state and has **posted** the information received by its January 22, 2010, deadline on the agency's Web site. The agency has also indicated which companies did not submit the information requested; a news source reports that DTSC may take action through the attorney general's office against them.

DTSC launched the information call-in program in 2009, hoping to identify information gaps and build data about carbon nanotubes. Manufacturers and importers were requested to supply information about "analytical test methods, fate and transport in the environment, and other relevant information." The agency's initial request involved reactive nanometal oxides, including aluminum oxide, silicon dioxide, titanium dioxide, and zinc dioxide. It has since identified as nanomaterials of interest nano silver, nano zerovalent iron and cerium oxide.

According to a press report, agency sources have found some trends emerging from the company responses, including (i) research facilities and manufacturers use existing environmental health and safety policies to contend with human health exposures; (ii) universities treat nanomaterial waste like other lab waste; (iii) no one appears to know what customers are doing with carbon nanotubes or how they are disposing of them; and (iv) this lack of knowledge can be attributed to a lack of regulatory parameters or business practices requiring or promoting the collection of this data, which also could involve confidential business information and trade secrets. *See Inside CalEPA*, January 29, 2010.

New York Bill Proposes Warning Labels for Energy Drinks

New York Assemblyman Nelson Castro (D-86) has proposed an amendment (**A09754**) to the state's agriculture and markets law that would require a warning label on all energy drinks. Citing "serious health risks including heart attack, stroke and even heart disease," the provision calls for product warnings to appear in a black box and in letters "not less than eight point type." It would also impose civil liability fines of $1,000 per violation.

But unlike a similar proposal in Kentucky that reportedly focuses on caffeine content, the New York law defines an energy drink as containing "a combination of some or all of the following ingredients: sugar, methylkanthines, caffeine, vitamin E, herbs, guarana, acai, taurine, ginseng, maltodextrin, inositol, carnitine, creatine, glucuro-nolactone and ginkgo biloba." This definition would exclude coffee, according to a January 26, 2010, article in *Law360,* which noted that the American Beverage Association has questioned the practicality of enforcing such laws. "If you check out our products you'll find that the vast majority of them have clear advisory statements on their packaging already," one association spokesperson was quoted as saying. "All of a sudden you'll have bouncers outside of Starbucks."

In a related development, Labour MEP Catherine Stihler has called on the European Union (EU) to prohibit the sale of caffeinated alcoholic beverages, citing a recent BBC investigation linking one popular product to more than 5,000 crime reports filed in Strathclyde, Scotland, from 2006 to 2009. The January 18, 2010, BBC article focused on Buckfast tonic wine, which allegedly contains 15 percent alcohol and as much caffeine as eight standard cans of cola. Although the wine comprises only 0.5 percent of the Scottish alcohol market, one police officer told the BBC that, in addition to being mentioned in a number of crime reports, "the Buckfast bottle was used 114 times as a weapon."

Noting these statistics, Stihler has urged the EU Committee on Internal Market and Consumer Protection to implement a ban on Buckfast and similar beverages. "With it taking only one can of energy drink to rapidly increase the chance of heart attack or stroke, then surely it is high time for a ban on alcoholic caffeinated drinks," she stated in a January 26 press release issued by the Scottish Labour Party. "The fact is many consumers are unaware of the damage they are doing to their bodies and lack the essential information to make an informed decision about what they purchase." *See The Daily Record,* January 17, 2010.

LITIGATION

DOJ Challenges Dairy Processors' 2009 Merger

The Department of Justice (DOJ) has filed a civil antitrust lawsuit against Dean Foods Co., claiming that the company's 2009 acquisition of Foremost Farms USA's Consumer Products Division "eliminates substantial competition between the two companies in the sale of milk to schools, grocery stores, convenience stores and other retailers in Illinois, Michigan and Wisconsin." The attorneys general of these states joined the complaint. According to a *Wall Street Journal* report, this is the first such action DOJ has filed under the Obama administration.

The complaint apparently seeks to undo the deal and require Dean Foods to notify the department at least 30 days before any future purchase of a milk processing operation. According to DOJ, the companies were the first and fourth largest in the region and their merger gave Dean Foods some 57 percent of the market for processed milk there. Local school districts evidently have fewer choices now when bidding on milk suppliers, and some "have been left with a monopoly provider."

Dean Foods has reportedly pledged to vigorously defend the action, claiming that its acquisition "is fully compliant with antitrust laws" and benefits Wisconsin dairy farmers by giving them a stable and growing outlet for their milk. Contending that "competition is alive and flourishing in Wisconsin," the company also reportedly said that its acquisition has produced cost savings for customers and will increase competition when the processing plants it acquired are fully integrated into Dean's network. *See DOJ Press Release*, January 22, 2010; *FoodNavigator-USA.com*, January 25, 2010; *U.S. Agricultural & Food Law and Policy Blog*, January 26, 2010.

Federal Court Denies Dispositive Motion in Second GM Rice Bellwether Trial

A multidistrict litigation (MDL) court in Missouri has reportedly denied Bayer AG's motion for judgment as a matter of law in the second bellwether trial that recently began in a dispute over losses allegedly incurred by U.S. rice farmers when traces of a genetically modified (GM) rice were found in the 2006 long-grain rice harvest. *In re: Genetically Modified Rice Litig.*, MDL No. 1811 (U.S. Dist. Ct., E.D. Mo., motion denied January 27, 2010). The alleged contamination caused international markets to ban U.S. rice imports, and the price dropped precipitously.

The court apparently disagreed with Bayer AG that (i) the evidence was insufficient to show that it failed to exercise due care or that its alleged negligence cause the plaintiffs' harm; (ii) claims for future damages and alternate crop damages were unduly speculative, and the plaintiffs failed to meet their burden of proof as to punitive damages; (iii) the nuisance claim failed as a matter of law; and (iv) the claims failed under the economic loss doctrine and were preempted by federal law.

The first bellwether trial resulted in a plaintiffs' verdict of $2 million in compensatory damages. Additional information about that trial appears in issues 330 and 331 of this Update. *See Law 360*, January 27, 2010.

OTHER DEVELOPMENTS

IOM Meeting Targets Front-of-Package Labeling

The Institute of Medicine (IOM) has **announced** a February 2, 2010, public meeting in Washington, D.C., to solicit government perspectives on front-of-package nutrition labeling systems. The IOM Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols has invited input from various government agencies and study sponsors, including the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and the U.S. Department of Agriculture. Created in response to a congressional mandate, the committee is working on behalf of CDC and FDA to review "the elements of the nutrition rating criteria and science underlying the front-of-package systems." In particular, the group is gathering information on (i) "front-of-package systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad"; (ii) "the purpose and overall merits of front-label nutrition icons"; (iii) "the criteria underlying the systems and… their scientific basis"; and (iv) the "advantages and disadvantages of various approaches for adults and children." The committee will then publish a 2010 report offering its recommendations for a second research phase that "would consider the potential benefits of a single, standardized front-of-package food guidance system regulated by the Food and Drug Administration and would develop conclusions about which system(s) are most effective in promoting health and how to maximize the use and effectiveness of the system(s)."

Sweetener Spat Provokes Recommendation to Discontinue "Natural" Ad Claims

The Council of Better Business Bureaus' National Advertising Division (NAD), which serves as the investigative arm of the advertising industry's voluntary self-regulation program, has recommended that Heartland Sweeteners cease making some claims about its Ideal®

sweetener product. The recommendation apparently followed a complaint by Merisant Co., a Heartland competitor, that Ideal® is not "natural" or "more than 99 percent natural" as the company claims because the majority of its sweetness comes from the artificial sweetener sucralose. While Heartland agreed that its sweetener contains sucralose, the company contends that the natural sweetener Xylitol is the product's main ingredient.

According to NAD, Ideal® as a whole may be "more than 99% natural," but "the context in which it is presented may still cause it to convey a message that is false or misleading to consumers." NAD found that the product's sweetness is "not due primarily to Xylitol, but, rather, the synthetic sucralose it contains, and the artificial ingredients that make up one percent of the advertiser's product are not inconsequential or insignificant. Given that the artificial sweetener contained in the product provides approximately 80% of the product's sweetness and considering the audience to whom the product is directed—health conscious consumers seeking low or no-calorie sugar substitutes (or sweetening agents) that are not artificial—NAD determined that it was not accurate for the advertiser to promote its artificial sweeter, Ideal, as 'natural' or as 'more than 99% natural' or as being 'different from other no calorie sweeteners on the market.'"

Heartland has reportedly indicated that it intends to appeal the NAD recommendation to the National Advertising Review Board, contending that its advertising claims are entirely accurate. According to a company statement, "The NAD ruling is factually unsupported and may have dramatic and unintended adverse consequences for the market for non-sugar sweeteners." The company expects to prevail in its appeal, but even if unsuccessful is apparently not required to change its claims because the NAD lacks any enforcement authority. *See NAD News Release*, January 11, 2010; *FoodNavigator-USA.com*, January 25, 2010.

Whole Foods Offers Better Discounts for Slimmer, Healthier Employees

Whole Foods Market CEO John Mackey has **announced** to company employees that those meeting specific health-related criteria, including blood pressure, cholesterol, body mass index, and smoking status, will be eligible for an increased store discount. According to the announcement, the company spent more than $150 million in 2009 on employee health care, and the company is offering this "incentive" to lower its health care costs. Health screenings under the new program apparently began January 21, 2010, and discounts of up to 30 percent will be available to qualifying employees. The discount for those deciding not to participate in the program or those not qualifying is 20 percent.

Meanwhile, Mackey, who voluntarily cut his annual salary to $1 in 2007, reportedly donated the after-tax compensation he received in 2009 from a previous incentive bonus plan to the Global Animal Partnership, a nonprofit organization developing new standards for the treatment of farm animals. The donation was nearly $380,000. A Whole Foods spokesperson reportedly said that the company's practices will be in keeping with the animal welfare group's standards, expected to be released later in 2010. *See Associated Press*, January 25, 2010; *Slashfood.com*, January 26, 2010.

MEDIA COVERAGE

James McWilliams, "Beware the Myth of Grass-Feed Beef," *Slate,* January 22, 2010

In this article, *Slate* contributor James McWilliams questions "the conventional wisdom among culinary tastemakers" that pasture-raised cattle does not harbor *E. coli* O157:H7 at the same levels as conventional livestock. "In fact," he writes, "exploring the connection between grass-fed beef and these dangerous bacteria offers a disturbing lesson in how culinary wisdom becomes foodie dogma and how foodie dogma can turn into a recipe for disaster."

McWilliams traces the misconception to a 2006 *New York Times* op-ed piece by food activist Nina Planck, who claimed that *E. coli* was "not found in the intestinal tracts of cattle raised on their natural diets of grass, hay, and other fibrous forage." According to McWilliams, Planck drew her conclusions from a 1998 report published in *Science* that found more acid-resistant *E. coli* in grain-fed cattle, but failed to specifically test for the O157:H7 strain. Further studies have apparently shown that grass-fed cattle "do become colonized with *E. coli* O157:H7 at rates nearly the same as grain-fed cattle," while recent research has focused on whether O157:H7 "behaves differently from other strains" in acidic environments because "it develops in a different part of the cow's intricate digestive system."

"The point in dredging up these studies—ones the media never covered—is not to play gotcha with advocates of grass-fed beef," concludes McWilliams. "Instead it's a warning that advocacy for a trendy food choice might result in a public health hazard. Such a fear is confirmed by consulting the cooking directions provided by many purveyors of grass-fed beef. The home page for one major producer explains that 'cooking "real food" is not the same as cooking concocted food… Grass-fed meats are best when raw (steak tartar), rare or medium rare.'"

SCIENTIFIC/TECHNICAL ITEMS

Study Claims Link to Dry Fat-Rich Foods and Increased Acrylamide Levels

A recent study has reportedly linked dry food containing low amounts of carbohydrates to increased acrylamide levels. Edoardo Capuano, et al., "Lipid oxidation promotes acrylamide formation in fat-rich model systems," *Food Research International*, (January 2010). Sponsored by the European Science Foundation, researchers formulated a range of fat-rich model systems and then measured acrylamide levels after heating. Results apparently showed that the degree of fat oxidation significantly influenced the presence of acrylamide, a chemical by-product of some high-temperature cooking processes that has been linked to cancer in laboratory rats.

According to the study's abstract, foods formulated with antioxidants such as catechins and certain oils reduced acrylamide levels particularly in fat-rich, sugar-free foods "presumably by trapping carbohydrates and/or preventing lipid oxidation. More acrylamide was formed in model systems composed with sunflower oil than in those containing palm oil which is less susceptible to oxidation."

The abstract noted that acrylamide formation was delayed in systems containing higher amounts of water due to evaporative cooling. In these systems, "the effect of catechin was more pronounced and the effect of lipid oxidation became detectable only after a prolonged reaction time. These findings suggested that lipid oxidation could become a relevant factor for acrylamide formation, particularly for dry foods with low carbohydrate content." *See FoodNavigator.com*, January 28, 2010.

Animal Protein Consumption Allegedly Linked to Increased Diabetes Risk

A recent study has reportedly linked the consumption of animal protein to an increased risk of developing type 2 diabetes. Ivonne Sluij, et al., " Dietary Intake of Total, Animal, and Vegetable Protein and Risk of Type 2 Diabetes in the European Prospective Investigation into Cancer and Nutrition (EPIC)-NL Study," *Diabetes Care,* January 2010. Using data from 38,094 participants in the European Prospective Investigation into Cancer and Nutrition (EPIC)-NL study, researchers apparently examined the association among diabetes incidence and dietary intake of vegetable and animal proteins. The study claims that diabetes risk increased 30 percent for every 5 percent of calories consumed from animal protein at the expense of carbohydrates or fat. According to the authors, "Our findings also suggest a similar association for total protein itself instead of only animal sources... This finding indicates that accounting for protein content in dietary recommendations for diabetes prevention may be useful." *See PCRM Medical News,* January 22, 2010.

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