

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] Food Industry Groups Fight Expansion of Renewable Fuel Standard

A coalition led by the American Meat Institute, the National Meat Association and the National Cattlemen's Beef Association recently sent a [letter](#) to Congress warning that a plan to increase the Renewable Fuel Standard (RFS) for grain-based ethanol will induce "a series of supply shocks" and further escalate the cost of food production. The "so-called barnyard lobby," according to *The Wall Street Journal*, has joined environmental organizations and the petroleum industry in opposing a bill passed by the Senate that would require oil refiners to blend 36 billion gallons of renewable fuels into the gasoline supply by 2022, with 15 billion gallons derived from corn-based ethanol. The RFS set in 2005 currently calls for the use of 7.5 billion gallons of renewable fuels by 2012, a goal that ethanol producers have already come close to surpassing.

"Our single biggest priority is for Congress to reject a new renewable-fuel mandate," said a spokesperson for the American Meat Institute, which has seen the price of corn-based animal feed increase by 60 percent since 2005. While ethanol and corn producers have reportedly sought a

heightened standard to ensure that supply does not outstrip demand, other agricultural groups have urged lawmakers to specify that "the mandate is to be met only with non-grain-based fuels" or to wait until 2012 to renew the RFS. In addition, environmental groups have opposed the measure as potentially detrimental to soil preservation and wildlife habitats as more lands are converted for corn production. See *The Wall Street Journal*, October 11, 2007; *Meatinplace.com*, October 16, 2007.

[2] Proposed Legislation Would Alter *Trans* Fat Labeling Regulations

U.S. Representative Steve Israel (D-N.Y.) has introduced a [bill](#) (H.R. 3783) that would close a loophole in food labeling regulations by prohibiting the marketing of food with less than 0.5 gram of *trans* fat per serving as "zero *trans* fat." The legislation calls on the Food and Drug Administration to revise section 101.9(c)(2)(ii) of the Code of Federal Regulations to specify that if the *trans* fat content of a serving of food is (i) less than 0.5 gram and (ii) declared on the nutrition label, then the *trans* fat content will be expressed "with an asterisk or other notation stating that the *trans* fat content of a serving is less than 0.5 gram (instead of expressing the *trans* fat content as zero)." The measure has reportedly gained the support of consumer advocates such as the Center for Science in the Public Interest, which has also asked Congress to eliminate *trans* fat as an ingredient in all foods. "Only in



Washington does $0.4 + 0.4 = 0$,” Israel was quoted as saying. “Now, I’m not proposing a ban on *trans* fat. But we should give consumers the necessary information to make informed nutrition choices.” See *FoodNavigator-USA.com*, October 11, 2007.

U.S. Department of Agriculture (USDA)

[3] National Organic Program Issues Final List of Allowed and Prohibited Substances

USDA’s National Organic Program (NOP) has issued a [final rule](#) reflecting changes to the National List of Allowed and Prohibited Substances (National List), which describes the synthetic ingredients (exemptions) permitted in organic food production and prohibited non-synthetics. The Organic Foods Production Act requires the National Organic Standards Board (NOSB) to reassess exempted and prohibited substances every five years in a sunset review process. The final rule, effective October 21, 2007, renews 165 substances currently on the National List and removes three substances previously approved for use in organic handling. The revised National List now prohibits in organic production the emergency use of antibiotic-free milk replacers, once allowed as a stopgap measure provided the replacers were not derived from animals receiving bovine growth hormones. In addition, the National List prohibits, in processed products labeled “organic,” the use of “non-agricultural” colors derived from non-synthetic sources only and the use of potassium tartrate made from tartaric acid.

In a related development, the NOSB has [announced](#) a public meeting, slated for November 28-30, 2007, to continue the sunset review process for 11 materials on the National List. The meeting

will also address standards for organic pet food and “issues related to fish feed and open net pens in regards to the aquaculture standards for finfish.” Members of the public wishing to make oral presentations should submit written comments to the NOSB executive director in advance of the meeting.

[4] USDA Issues Standards for Grass-Fed Livestock Marketing Claims

USDA’s Agricultural Marketing Service (AMS) has [established](#) a voluntary standard for a grass (forage) fed livestock claim so that producers can “distinguish their products in the marketplace.” Livestock producers wishing to use a “USDA Verified Process” grass-fed claim must first submit labels to USDA’s Food Safety and Inspection Service, Labeling Program and Delivery Division, which will confirm that the feeding protocol meets the definition of a grass-based diet. “[T]he grass (forage) fed marketing claim will only apply to ruminant animals whose diet throughout their lifespan is derived solely from grass (forage), with the exception of milk consumed prior to weaning,” according to AMS, in describing forage as “grass (annual and perennial), forbs (.e.g., legumes, Brassica), browse, or cereal grain crops in the vegetative (pre-grain) state.” Animals must also have access to pasture during the growing season to qualify as grass-fed. In addition, AMS permits the use of stockpiled forage, including hay, haylage, baleage, silage, and crop residue without grain, to “address the lack of readily available grass (forage) through the year,” although the agency acknowledges that silage is not as “green” as other freshly chopped forages. AMS also allows mineral and vitamin supplements to maintain optimal health, but prohibits the following supplemental ingredients: cereal grains, grain byproducts (starch and protein sources), cottonseed and cottonseed meal,



soybean and soybean meal, non-protein nitrogen sources such as urea, and animal byproducts.

Food and Drug Administration (FDA)

[5] FDA Issues Draft Guidance on Adverse Event Recordkeeping for Dietary Supplements

FDA is [seeking](#) comments on its “Draft Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.”

The guidance addresses mandatory reporting under the Act “of serious adverse events associated with dietary supplements, the minimum data elements to be submitted in such reports, and records of serious and non-serious adverse events reported to a dietary supplement manufacturer, packer, or distributor.” The agency estimates that some 50,000 adverse events likely occur each year and is requesting comments on this estimate as well. All comments must be submitted by December 14, 2007. According to a news source, a number of trade associations and consumer organizations plan to submit comments on the draft. *See Citizens for Health Press Release*, October 15, 2007.

In a related development, at FDA’s request, U.S. marshals recently seized some \$71,000 worth of dietary supplements marketed and distributed by FullLife Natural Options, Inc. Promoted for use in treating diabetes, anemia and hypertension, Charantea Ampalaya Capsules and Charantea Ampalaya Tea are purportedly in violation of the drug and misbranding provisions of the Federal Food, Drug and Cosmetic Act. The company was warned not to make claims relating to the preven-

tion or treatment of disease, but FDA inspectors found “the offending claims were still being made.” *See FDA News*, October 12, 2007.

State/Local Initiatives

[6] Schwarzenegger Vetoes Menu Labeling Bill, Approves *Trans* Fat Ban in Public Schools

California Governor Arnold Schwarzenegger (R) has reportedly vetoed a Senate bill (S.B. 120) that would have required chain restaurants with at least 14 outlets in the state to post nutritional information on menus. Introduced by Senator Alex Padilla (D-Los Angeles), the measure gained the support of the American Heart Association but alienated the California Chamber of Commerce and the California Restaurant Association, which opposed the legislation as an unfair burden on restaurateurs.

“Inflexible mandates applied sporadically are not an effective way to continue our progress in educating Californians about healthy living,” Schwarzenegger was quoted as saying. In addition, the governor vetoed legislation (S.B. 63) seeking to label foods derived from cloned livestock, but approved a bill (S.B. 490) banning *trans* fat in public school cafeterias and vending machines. *See The San Francisco Chronicle* and *The Sacramento Bee*, October 15, 2007.

Meanwhile, Schwarzenegger’s decision on S.B. 120 drew immediate criticism from the Center for Science in the Public Interest, which described the veto as a “giant, greasy stain” on the governor’s health record. “[Schwarzenegger] is single-handedly keeping Californians in the dark when it comes to restaurant nutrition,” stated a press release from CSPI Nutrition Policy Director Margo Wootan, who also contended that the governor yielded to lobbying by McDonald’s, Burger King and other fast-



food franchises. Wootan further alleged that consumers “might as well throw darts” without prominently displayed nutrition information, suggesting that the Web sites, brochures and tray liners offered by most restaurants do not help customers exercise “personal responsibility” when dining out. See *CSPI Press Release*, October 15, 2007.

[7] California Prop. 65 Implementation Agency Seeks Input on Food Nutrients Proposal

California’s Office of Environmental Health Hazard Assessment (OEHHA), which implements the state’s Safe Drinking Water and Toxic Enforcement Act (Prop. 65), has [announced](#) that it will convene a public workshop November 2, 2007, to consider “updates that could be taken to clarify existing regulatory provisions, add new provisions dealing with emerging issues, or delete provisions that may no longer be necessary.” Among the potential regulatory initiatives on which OEHHA seeks stakeholder input is “a regulation addressing exposures to beneficial nutrients in foods.” Prop. 65 requires the governor to publish a list of chemicals known to the state to cause cancer, birth defects or other reproductive harms. Companies selling products in California must provide warnings if such substances are contained in their products.

Litigation

[8] Pot Pie Class Action Filed in Western Missouri

Residents of California, Kansas, Maine, and Tennessee who allegedly became sick after eating *Salmonella*-contaminated pot pies have filed a putative class action in a Missouri federal court against manufacturer ConAgra Foods, Inc. *True v. ConAgra*

Foods, Inc., No. n/a (U.S. Dist. Ct., W.D. Mo., Western Div., filed October 12, 2007). The named plaintiffs seek to certify nationwide classes of consumers who purchased those pot pies subject to ConAgra’s October 11, 2007, recall, and all persons who ate the pot pies “and have suffered physical injuries.” They allege that common questions of fact and law include (i) the source of the outbreak, (ii) the cause of the outbreak, (iii) “whether the Defendants’ negligence caused or contributed to the Salmonella outbreak,” and (iv) whether defendants are strictly liable for the outbreak.

The complaint includes counts for strict liability, negligence, breach of implied warranty of fitness, negligence per se, and violations of state consumer protection and unfair and deceptive acts or practices statutes. Without specifying their alleged losses, plaintiffs seek statutory damages, compensatory damages, punitive damages, interest, and costs. They are represented by Missouri, Pennsylvania and Maryland attorneys. Details about similar litigation filed in Minnesota appear in issue 224 of this Update.

Meanwhile, consumer advocates have reportedly criticized ConAgra for mishandling its pot pie recall and suggested that its delay in issuing one reveals the ineffectiveness of the nation’s food-safety system because it relies on voluntary recalls. According to a news source, a company spokesperson indicated that the problem with its pot pies was still unknown and that it had issued the recall as a precaution while an investigation is underway. *The New York Times* featured the outbreak in a recent article that also explores whether the microwave-cooking instructions for frozen foods adequately account for variations in cooking power. Apparently, widely varying times are included in the instructions, making it difficult to determine whether a given



microwave has cooked the products thoroughly without using a thermometer. *See The New York Times*, October 14, 2007; *The Los Angeles Times*, October 15, 2007.

[9] Federal Court Upholds Maine Alcohol Sale Restrictions

The First Circuit Court of Appeals has rejected a dormant commerce clause challenge to a Maine statute that places restrictions on the sale of alcohol. [*Cherry Hill Vineyard, LLC v. Baldacci, No. 07-1513 \(1st Cir., decided October 11, 2007\)*](#). The plaintiffs argued that the state's farm winery program and its prohibition on direct shipping had the effect of discriminating against interstate commerce. They sought a declaration that the statute was unconstitutional "insofar as it prevents out-of-state wineries from selling their merchandise directly to Maine consumers." The statute requires both in-state and out-of-state wineries producing less than 55,000 gallons of wine annually to sell their wines in face-to-face transactions and forbids residents from bringing more than four quarts of wine into the state. Because the statute made farm winery licenses available on equal terms to in-state and out-of-state vineyards, the court found no interstate discrimination either explicit or implicit.

Other Developments

[10] Scientists and Nutritionists Meet to Discuss Nutritional Genomics

According to a news source, scientists and dietitians met recently in California for a conference on nutritional genomics. Understanding individual genetic codes could apparently lead to the development of personally tailored diets dictated by those codes, although "eating for your genotype is prob-

ably decades away," said one nutrition academic. Researchers have been exploring the links between genetic variations and how people process various substances such as caffeine and fat, and a few companies are reportedly offering diets based on genetic testing. The experts dismiss such efforts as "infotainment," suggesting that we do not know enough yet to individualize diets. Heart health researcher Dean Ornish, M.D., presenting to a standing-room-only audience, argued that relying too much on genetics to make predictions about health would be a mistake. Ornish explained that new research shows our behaviors can change how our genes function; for example, exercise in older people affects some 300 genes by increasing or dampening activity in some but not others. He was quoted as saying, "You're not a victim of your genes. You can actually change to a much larger degree than we once realized." *See The Sacramento Bee*, October 15, 2007.

Media Coverage

[11] Kathryn Masterson, "Food Cop: Love Him or Hate Him," *Chicago Tribune*, October 14, 2007

The executive director of the Center for Science in the Public Interest (CSPI) is the focus of this feature, which opens with a description of Michael Jacobson's appearance on Comedy Central's "The Colbert Report," a parody of programs appearing on conservative cable networks such as Fox News. After Colbert asked Jacobson if his science was the "science of bumper-ology" and hectored him about being against the all-American hot dog and apple pie, CSPI's director reportedly joked that the Ben & Jerry's ice cream named after the comedy show host wasn't all bad "because consumers could save time



by getting all their daily saturated fat in one cup.” Colbert retorted, “Cut off his mike!” and later asked if he was allowed “to hit a guest,” which pleased CSPI’s supporters and staffers, who saw the comedic moment as a public relations victory.

The article discusses Jacobson’s scientific and advocacy background and reports that, under his leadership, CSPI has grown to an organization with 60 employees and a \$17 million budget funded by its 850,000-subscriber newsletter. Jacobson’s annual salary is \$200,000, and he is recognized by supporters for his “showman’s flair” and effectiveness. Critics disagree; they refer to him as “the food police” and compare CSPI’s lawsuits to blackmail. They also contend that his message fails to reach the wider public. According to the article, Jacobson practices what he preaches and will not allow “junk food” or soda in CSPI’s offices.

Scientific/Technical Items

[12] Study Claims Low-Fat Diet Associated with Reduced Ovarian Cancer Risk

A study funded by the National Institutes of Health has concluded that adhering to a low-fat diet might reduce the risk of ovarian cancer. R.L. Prentice, et al., “Low-fat dietary pattern and cancer incidence in the Women’s Health Initiative dietary modification randomized controlled trial,” *Journal of the National Cancer Institute*, 2007. After surveying more than 40,000 postmenopausal women enrolled in the Women’s Health Initiative, researchers reported that those who maintained a low-fat diet for at least eight years decreased their ovarian cancer risk by 40 percent. Scientists have reportedly speculated that high-fat foods might increase the amount of estrogen in the blood, thus

“overstimulating” sensitive ovaries and initiating the cancer that will kill 15,280 women this year, according to the American Cancer Society. “It’s quite noteworthy,” said co-author Ross Prentice, M.D., of Seattle’s Fred Hutchinson Cancer Research Center. “We’re really pleased to have something positive to say to American women – that undertaking a low-fat diet likely reduces your risk of ovarian cancer and perhaps other cancers as well.” See *Associated Press*, October 9 and 12, 2007; *PCRM Press Release*, October 16, 2007.



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