Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Occupational Safety & Health Administration (OSHA)

[1] OSHA Committee to Consider Diacetyl Standards and Guidance

OSHA has announced that the National Advisory Committee on Occupational Safety and Health (NACOSH) will meet December 12, 2007, to consider, among other matters, "standards and guidance update" on diacetyl, beryllium and pandemic flu. The meeting is open to the public and comments may be submitted. *See Federal Register*, November 26, 2007.

Meanwhile, the International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations (IUF) has <u>called</u> on governments around the world to control the use of diacetyl, citing studies allegedly linking exposure to the butter-flavoring chemical with severe lung disease in workers. IUF recommends that unions with members in the food-processing industry take action to (i) educate their members about "the dangers of diacetyl," (ii) demand information from employers on its use in the workplace, (iii) ask that food manufacturers reveal which facilities use diacetyl, (iv) demand that government

agencies survey the health of exposed workers, and (v) call on regulatory agencies to "control the use of diacetyl in light of currently available knowledge, beginning with an immediate suspension of its use in food manufacturing."

Food and Drug Administration (FDA)

[2] FDA Proposes Limits to Labels Touting Omega-3 Fatty Acids

FDA has issued a **proposed rule** that would prohibit nutrient content claims for products containing the omega-3 fatty acids known as alphalinolenic acid (ALA), docosahexaeonic acid (DHA) and eicosapentaeonic acid (EPA). The rule responds to three notifications submitted to FDA that propose "high," "good source" or "more" claims for ALA, DHA or EPA in conventional foods and dietary supplements. FDA has argued that health experts have not set a daily recommended intake value for DHA and EPA and thus claims about their recommended intake "are not based on an authoritative statement." In addition, one notification by seafood processors supported a recommended daily intake of 1.3 grams of ALA, but the methodology used to set this value did not conform to FDA standard practices. As a result, the proposed rule would prohibit labels touting a product as a "good source" of fatty acids or "high" in fatty acids if the claim refers to DHA or EPA content or if an ALA claim relies on a value of 1.3 grams. The rule, however, would allow ALA claims based on a daily value of 1.6 grams, as





this benchmark appears "consistent with the method that FDA has used in determining [daily values] to date." The agency will accept comments on the proposed rule until February 11, 2007.

Meanwhile, the Global Organization for EPA and DHA (GOED) has asked the agency to set EPA- and DHA-recommended daily values as soon as possible. While scientists have linked natural sources of EPA and DHA to heart and general health benefits, many enhanced products containing mostly ALA do not disclose the type of fatty acid to consumers. *See The Wall Street Journal*, November 20, 2007; *Food Navigator-USA.com*, November 28, 2007.

U.S. Department of Agriculture (USDA)

[3] Brian Wansink Joins USDA as CNPP Director

Agriculture Under Secretary Nancy Johner this week announced the appointment of Dr. Brian Wansink as executive director of the Center for Nutrition Policy and Promotion (CNPP). Wansink, who currently heads the Cornell University Food and Brand Lab in Ithaca, N.Y., will oversee the development of the 2010 Dietary Guidelines for Americans, the food pyramid and other USDA nutritional programs. His latest commercial book, Mindless Eating: Why We Eat More Than We Think, incorporates more than 25 years of experience in nutritional science, food psychology, consumer behavior, food marketing, and grocery shopping behavior. Wansink has advised Americans to take small steps to reduce food intake by 100 or 200 calories per day and thus lose 10 to 20 pounds per year, a philosophy which will reportedly inform his CNPP role. "Wansink is the guy who does terrific research on environmental determinants of

overeating showing that large portions, wide drinking glasses, foods close by, and health claims encourage everyone to eat more calories than they need or want," said New York University Professor Marion Nestle in praise of the appointment, which proponents have lauded as free from industry ties. See CNPP News Release, November 19, 2007; WhatTo Eat.com, November 20, 2007; USA Today and U.S. Food Policy, November 26, 2007.

In a related development, FDA Commissioner Andrew von Eschenbach recently selected Dr. David Acheson to serve as the acting director of the Center for Food Safety and Applied Nutrition (CFSAN). Replacing former CFSAN Director Robert Brackett, Acheson will also retain his current post as assistant FDA commissioner for food protection. *See FDA Press Release*, November 20, 2007.

Environmental Protection Agency (EPA)

[4] EPA Schedules Workshop on Endocrine Disruptor Screening Program

EPA has **scheduled** a workshop December 17, 2007, to consider its draft policies and procedures for completing initial screening and testing under its Endocrine Disruptor Screening Program. The agency suggests that those producing, manufacturing, using, or importing "pesticide/agricultural chemicals and other chemical substances" and those involved in the testing of chemical substances for potential endocrine effects should attend the workshop. EPA is implementing its program in three parts, identified as assay validation, priority setting, and policies and procedures. The latter part is at issue in the upcoming workshop; it involves (i) "The procedures that EPA is considering using to issue orders"; (ii) "How joint data development, cost





sharing, data compensation, and data protection would be addressed"; (iii) "Procedures that order recipients would use to respond to an order"; and (iv) "Other related procedures and/or policies." EPA is also inviting comments on its policies and procedures. *See Federal Register*, November 23, 2007.

World Health Organization (WHO)

[5] Nations Pledge to Increase Communication on Food Safety Issues

Delegates from more than 40 nations have reportedly signed a one-page agreement to share experience and information on food-related disease outbreaks and safety legislation in an effort to ensure the integrity of the global food supply. Officials from the United States, Canada, Australia, Malaysia, Thailand, Japan, and other countries met this week with experts from the World Health Organization at a two-day international food safety conference held in Beijing, where Chinese authorities reacted angrily to an EU trade official who urged China to improve product safety and regain its reputation as a reliable exporter. Jorgen Schlundt, the executive director of the WHO's Food Safety Department, also noted that increased communication would represent a "major improvement" over missed opportunities in the past. The agreement did not specify any particular safety measures, but the head of China's General Administration of Quality Supervision, Inspection and Quarantine said that the document will be "regarded as the important principle for everyone to observe in future efforts to intensify cooperation in international food safety." See The Wall Street Journal, November 27, 2007.

Canada

[6] Canadian Officials Investigate Alleged Chocolate Price-Fixing Scheme

Canada's Competition Bureau has reportedly opened an investigation into allegations that the Canadian divisions of Nestle S.A., Cadbury Schweppes PLC, Hershey Co. and other chocolate makers have been colluding in a major price-fixing scheme. "We can confirm that we are investigating alleged anticompetitive practices in the chocolate confectionary industry," said John Pecman, the bureau's assistant deputy commissioner in the criminal matters branch. Pecman also told reporters that the Ontario court recently "granted search warrants based on the evidence that there are reasonable grounds to believe that a number of the suppliers in the chocolate industry have engaged in activities contrary to the conspiracy provisions, that's a cartel, of the Competition Act." Although the bureau has stressed that the investigation is still in its initial stages, Pecman indicated that the "potential volume of commerce affected here is definitely potentially in the billions of dollars per year" and may extend to other confections beyond chocolate. See The Wall Street Journal, November 28, 2007.

Australia

[7] NSW Government Allows Genetically Modified Crops in State

The New South Wales (NSW) Minister for Agriculture has reportedly indicated that the ban on genetically modified (GM)crops has been lifted and approval has been given to the use of GM canola crops in the state. "All of the existing strict health and environment assessments will be maintained at





a national level through the Office of Gene Technology Regulator," Minister Ian Macdonald was quoted as saying. The policy change apparently involves the establishment of an expert committee to assess whether the agriculture industry is capable of segregating GM and non-GM crops. If the industry cannot do so, the minister is reportedly authorized to intervene and block the GM farming. *See The Sydney Morning Herald*, November 27, 2007.

State and Local Governments

[8] Hormone-Free Labeling Regulation On-Again, Off-Again in Pennsylvania

Bowing to pressure from groups opposing a regulation that would prohibit the use of labels on milk products asserting they are free from synthetic growth hormones, Pennsylvania's Department of Agriculture is reportedly reconsidering its decision, which will postpone the rule at least one month beyond its January 1, 2008, effective date. The state agency announced earlier in November 2007 that dairy labels could no longer claim that the products did not contain pesticides or added hormones, such as recombinant bovine somatotropin (rbST). According to Agriculture Secretary Dennis Wolff, such claims are misleading because they imply that other milk is unsafe and they cannot be verified because the hormones, which are used to stimulate milk production, are not detectable in milk. Food & Water Watch mounted a campaign against the regulation, urging opponents to contact the governor. A spokesperson for Governor Ed Rendell (D) reportedly indicated that opposition from rural lawmakers and farm lobbyists has prompted additional review. See Pittsburgh Tribune-Review, November 19, 2007; Philly.com, November 29, 2007.

Litigation

[9] Wendy's Sued over Trans Fats in Foods

A Florida woman has filed putative class action claims against Wendy's International, Inc., alleging that the company is misleading consumers about the level of *trans* fats in its foods. *Fitch v. Wendy's Int'l, Inc.*, No. 02148 (U.S. Dist. Ct., M.D. Fla., filed November 23, 2007). According to the complaint, Wendy's engaged in an advertising campaign, beginning in mid-2006, claiming it would reduce the amount of *trans* fats in its products "so that in the french fries that are part of Wendy's Kids' Meal, the amount of *trans*-fat would be zero, and that its other fried food products would contain nominal amounts of 0.5 grams or less."

Relying on studies conducted by *Consumer Reports*, the Center for Science in the Public Interest, "and plaintiff's counsel," the plaintiff alleges, "Independent studies have shown, however, that Wendy's representations regarding the level of *trans*-fats in its products were materially misleading." She claims that some Wendy's foods contain as much as 500 percent more *trans* fats than the levels disclosed.

Plaintiff seeks to certify a class of Florida plaintiffs "who purchased french-fries, chicken sandwiches or any other deep-fat fried products (collectively, 'fried food products') from Wendy's during the Class Period." She alleges violations of Florida's Unfair and Deceptive Trade Practices Act, breach of implied in fact contract, unjust enrichment, and breach of the strict liability duty to warn. Plaintiff requests compensatory damages in excess of \$5 million, restitution, disgorgement, costs and fees, interest, and punitive damages. While the complaint provides information about the purported health risks of consuming *trans* fats, no physical injuries are alleged.



[10] Los Angeles Court to Hear Dismissal Motion in Next Splenda® False Ad Case

A federal court in California will consider on December 3, 2007, whether to dismiss claims filed by five U.S. sugar companies alleging that the company which makes Splenda®, an artificial sweetener, falsely advertised its product as "made from sugar, tastes like sugar." Defendant McNeil Nutritionals will reportedly argue that the suit lacks merit and should be dismissed for the sugar companies' failure to promptly take legal action; they apparently waited four years after the ad campaign was launched before filing their suit. The Center for Science in the Public Interest (CSPI) has filed an amicus brief in support of the plaintiffs. While CSPI does not dispute the safety of the artificial sweetener, it conducted a survey in 2004 that found nearly half the consumers who used it thought it was a natural product, despite the fact that it is made by a chemical process involving the addition of chlorine. This lawsuit is one of several involving the product; in 2005, McNeil filed a lawsuit in Delaware to prevent the sugar association from making claims about Splenda® "designed to injure its reputation and good will." Details about additional sweetener suits appear in issues 209, 210 and 215 of this Update. See The Los Angeles Times, November 30, 2007.

[11] Pet Food Defendants Seek Dismissal from Class Action

A litigation periodical is reporting that two grocery retailers and the parent company of a pet food maker have filed motions to dismiss claims against them in a class action pending in a Florida federal court. *Blaszkowski v. Mars Inc.*, No. 21221 (U.S. Dist. Ct., S.D. Fla., motion filed September 20, 2007). The suit, which names most major pet food

makers as defendants, reportedly alleges that their products contain "inedible garbage" despite marketing claims that they were made of choice meats, grains and other "human quality" ingredients. The lawsuit does not appear to raise claims of pet injury from melamine-contaminated pet food. In its motion, Nestlé S.A. contends that the court lacks personal jurisdiction over it and that it has no control over or responsibility for its subsidiary Nestlé Purina PetCare. Safeway Inc. and Stop & Shop Supermarket Co. also seek dismissal for lack of jurisdiction; they reportedly argue that the amended complaint does not allege facts specifically directed at them regarding the court's jurisdiction and that they lack the necessary contacts with Florida for its courts to exercise jurisdiction. See Andrews Class Action Litigation Reporter, November 16, 2007.

[12] Claims Settled in Spinach Contamination Case

According to a news source, a Wisconsin couple whose children were sickened by E. coli-contaminated spinach have settled their claims for damages against Natural Selection Foods LLC, Dole Food Co., Natural Selection Foods Manufacturing, and Mission Organics. While details of the confidential agreement have not been disclosed, Neil and Anne Grintjes had apparently sought in excess of \$75,000 plus costs. Their 6-year-old son reportedly developed a potentially fatal form of kidney failure that hospitalized him for two weeks and required multiple blood transfusions. He and his 3-year-old sister, who also fell ill, apparently tested positive for the same E. coli strain after eating from several packages of Dole baby spinach. Plaintiffs were represented by William Marler, who was quoted as saying, "we were all satisfied with the result." His Seattle-





based firm is reportedly handling 83 contaminatedspinach cases, 51 of which have recently been resolved. *See Associated Press*, November 27, 2007.

Other Developments

[13] USDA Rescinds Tyson's Antibiotic-Free Label over Antimicrobial Medicine

The U.S. Department of Agriculture (USDA) has reportedly rescinded its earlier decision to allow Tyson Foods Inc. to label its chicken products as "raised without antibiotics." USDA, which approved the multimillion dollar labeling program in May 2007, apparently stated that agency officials were not aware that Tyson's chickens received ionophores, a medication added to poultry feed to prevent intestinal colonization by a single-celled organism known as coccidia. While FSIS regards ionophores as antibiotics, other experts have described the drug as an antimicrobial agent that does not target bacteria and cannot cause resistance in humans. Margaret Mellon, the director of the food and environment program for the Union of Concerned Scientists, has said she was "mystified" and "troubled" by USDA's knee-jerk response and opposes the decision to classify ionophores as antibiotics. The agency has given Tyson the opportunity to eliminate ionophores from its poultry feed, to petition for a public meeting to debate the classification, or to resubmit its label application with new supporting documents. Tyson has opted to request approval for new antibiotic-free labels that explain to consumers the role of ionophores in maintaining healthy poultry. "Despite this process that we're going through, we remain committed to the raised-without-antibiotic program, and we fully intend to proceed with it," a Tyson spokesperson was quoted as saying. See The Wall Street Journal, November 20, 2007.

[14] Smithfield Foods to Eschew Meat Products from Cloned Animals

Smithfield Foods, which once supported pig cloning research, has reportedly announced that it will not produce meat products from cloned animals, regardless of whether the Food and Drug Administration confirms its position on the safety of these products. According to a company statement, "Smithfield foods is not planning to produce meat products from cloned animals. The science involved in cloning animals is relatively new. As thoughtful leaders in our industry, we will continue to monitor this technology." Other companies, such as Dean Foods, Stonyfield Farms and Ben & Jerry's have already pledged not to accept milk from cloned cows. *See FoodUSAnavigator.com*, November 23, 2007.

[15] CDC Report Shows Obesity Rates Unchanged

The Centers for Disease Control and Prevention (CDC) has issued a **report**, "Obesity Among Adults in the United States - No Change Since 2003-2004," which finds that while one-third of Americans (more than 72 million people) are obese, no statistically significant change in obesity rates among men or women occurred between 2003-2004 and 2005-2006. The highest obesity rates are found in adults aged 40-49, and race-ethnic disparities in obesity prevalence is found among women. Some 53 percent of non-Hispanic black women and 51 percent of Mexican-American women aged 40-59 are obese, while 39 percent of non-Hispanic white women in that age group are obese. Calling the findings alarming, CDC has reportedly made obesity one of its top health priorities. See CDC Press Release, November 28, 2007.





Media Coverage

[16] Julie Schmit, "Loophole Keeps FDA in the Dark on Tainted Food Imports," USA Today, November 26, 2007

This article claims that independent food testing laboratories are not required to report failing results to the Food and Drug Administration, thus opening a potential loophole in the current inspection system. "The concern is that unscrupulous importers who get bad test results from one lab will hire another lab to test the food, get a passing result and give only that to the FDA. The agency would then likely give the food a green light for sale in the USA," opines USA Today writer Julie Schmit, who notes that a 2004 FDA proposal also highlighted similar issues in an attempt to reform the testing process. Schmit argues that companies placed on "import alert" for past violations pose the greatest risk because they need five consecutive clean shipments to regain good standing. These importers might then attempt to conceal negative results in the hopes of deceiving FDA inspectors, although the agency has said that unreported results count as a failed grade against the company's record. In addition, FDA has reportedly announced plans to issue guidance-setting standards for imported food testing and proposed an accreditation process to close the loophole. The agency would also require importers to disclose their testing locations in advance to discourage last-minute lab substitutions. "The FDA hasn't done the hard work of establishing standards," a former FDA attorney was quoted as saying. "The lack of standards promotes the impression that [the labs] are out of control. But it's not the labs' fault. It's really the FDA's fault."

Meanwhile, a recent *New York Times* editorial has urged FDA and the Bush administration to require

independent lab accreditation through the International Standards Organization. The editorial also recommends that Congress allocate funds to update FDA testing equipment and "to develop a system to more efficiently track data about imports, companies and their past performance." "After years of mollycoddling the industry, the Bush administration needs to start protecting America's consumers," the editorial concludes, adding that the Food Marketing Institute has also called on Congress to enact legislation in favor of these changes. *See The New York Times*, November 26, 2007.

Scientific/Technical Items

[17] Researchers Find Possible Link Between Sucrose, Fructose and Pancreatic Cancer

Researchers studying more than 160,000 participants in the eight-year Hawaii-Los Angeles Multiethnic Cohort Study have reportedly concluded that while glycemic load, added sugars and soda intake are not significantly associated with pancreatic cancer, a significant association was found with fructose, fruit and fruit juice intake. Ute Nöthlings, et al., "Dietary Glycemic Load, Added Sugars, and Carbohydrates as Risk Factors for Pancreatic Cancer: The Multiethnic Cohort Study," The American Journal of Clinical Nutrition, November 2007. The study also found a greater risk of cancer in overweight and obese individuals with a high sucrose intake. The findings apparently cast doubt on the researchers' original hypothesis, i.e., that a high glycemic load could be a cancer risk.

[18] Studies Focus on Acrylamide in Foods

University of Maastricht researchers studying more than 2,500 Dutch women in the Netherlands Cohort Study have observed "increased risks of





postmenopausal endometrial and ovarian cancer with increasing dietary acrylamide intake, particularly among never-smokers." Janneke Hogervorst, et al., "A Prospective Study of Dietary Acrylamide Intake and the Risk of Endometrial, Ovarian, and Breast Cancer," *Cancer Epidemiology, Biomarkers & Prevention*, November 1, 2007. The risk among those consuming the highest average amounts of acrylamide per day (40.2 micrograms) increased the risk of endometrial cancer by 29 percent and ovarian cancer by 78 percent. For never-smokers with the highest average acrylamide intake, the risks increased to 99 percent and 122 percent, respectively. Acrylamide is created when starchy foods are heated by baking, roasting, frying, or toasting.

Meanwhile, a European Union research project, Heat-Generated Food Toxicants (HEATOX) has concluded a three-year study into the formation of acrylamide and other chemicals in cooked foods and released its **report**. HEATOX researchers conclude that the evidence of cancer risk from acrylamide "has been strengthened," and that there are ways to reduce acrylamide levels by making changes to ingredients and processing. The report also shows that home-cooked foods contribute relatively small levels of acrylamide to the diet "when compared with industrially or restaurant-prepared foods." The project's scientific team has created a database of some 800 heat-induced compounds they also found and are recommending further research into 52 that, based on chemical structure, could pose a cancer risk. Additional material generated by the project includes an acrylamide reduction guide for food processors focusing on potatoes, cereal products and coffee.



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We welcome any leads on new developments in this emerging area of litigation.



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