

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

FTC Settles Charges over False-Advertising Claims for Cereal

The Federal Trade Commission (FTC) has [announced](#) that Kellogg Co. agreed to settle false-advertising charges involving Frosted Mini-Wheats® advertisements that claimed the product was "clinically shown to improve kids' attentiveness by nearly 20 percent." According to FTC, the clinical study on which the ads were based showed that "only about half the children who ate Frosted Mini-Wheats for breakfast showed any improvement in attentiveness, and only about one in nine improved by 20 percent or more."

Under the consent order, Kellogg agrees to pull its offending ads and not to express or imply that its cereal improves attentiveness "unless, at the time [the claim] is made, the representation is true and non-misleading." The company also agreed not to make any representation "about the benefits, performance, or efficacy of such product for cognitive function, cognitive processes, or cognitive health, unless the representation . . . relies upon competent and reliable scientific evidence that substantiates the representation."

FTC will publish the order in the *Federal Register* for public comment. If finalized, the order will have the force of law as to future actions and each violation "may result in a civil penalty of \$16,000." FTC Chair Jon Leibowitz was quoted as saying, "We tell consumers that they should deal with trusted national brands. So it's especially important that America's leading companies are more 'attentive' to the truthfulness of their ads and don't exaggerate the results of tests or research. In the future, the commission will certainly be more attentive to national advertisers."

The Center for Science in the Public Interest (CSPI) applauded FTC's action, calling it "a strong sign the false advertising cop is back on the beat, and the agency will no longer tolerate misleading health claims." CSPI characterized the ads as "astonishing," and added "if Kellogg sincerely wanted to improve children's attentiveness, it would phase out the use of Blue 1, Blue 2, Red 40, and any other synthetic food dyes that show up in some varieties of Mini-Wheats. Those dyes exacerbate some children's hyperactivity and behavioral problems, and have no place in foods aimed squarely at children."

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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Kellogg reportedly issued a statement following the agreement's announcement, stating "Kellogg Company has a long history of responsible advertising. We stand behind the validity of our clinical study yet have adjusted our communication to incorporate FTC's guidance." See *FTC Press Release*, *CSPI Press Release*, *Product Liability Law 360*, and *MSNBC.com*, April 20, 2009.

CDC Tracks Rise of Swine Influenza in Humans

The U.S. Centers for Disease Control and Prevention (CDC) have reportedly noted an increase in rare human swine influenza infections, documenting two similar cases in California children not directly exposed to livestock. The agency stated that it typically registers one human swine influenza case every year or two in the United States, but has verified 12 infections between December 2005 and February 2009. CDC also [confirmed](#) seven additional cases in Texas and California during March 2009, describing a unique influenza strain that combines segments of a human virus, an avian virus from North America, and pig viruses from North America, Europe and Asia. In addition, Mexican health officials have reported that a swine influenza outbreak recently killed 16 people, including children and young adults, and sickened as many as 943 in the Mexico City area.

Meanwhile, the World Health Organization and other experts have expressed concern that the cases, if related, could trigger a pandemic. According to CDC, "this new strain of swine influenza A (H1N1) is substantially different from human influenza A (H1N1) viruses, that a large proportion of the population might be susceptible to infection, and that the seasonal influenza vaccine H1N1 strain might not provide protection." The agency has advised clinicians in California and Texas to consider animal as well as seasonal influenza in patients presenting with febrile respiratory illness. "The lack of known exposure to pigs in the two cases increases the possibility that human-to-human transmission of this new influenza virus has occurred," said the CDC, which in 1976 tracked a human swine influenza outbreak that shared viral characteristics with the 1918-19 worldwide epidemic. See *MMWR Dispatch*, April 21, 2009; *MSNBC.com*, April 21 and 24, 2009; *Reuters*, April 24, 2009.

FDA Confirms Effective Date, Sets Compliance Deadline for Feed Ban Rule

The Food and Drug Administration (FDA) has [confirmed](#) April 27, 2009, as the effective date for the final rule titled "Substances Prohibited From Use in Animal Food or Feed," which establishes "measures to further strengthen existing safeguards against bovine spongiform encephalopathy (BSE)." The agency earlier this month considered delaying the rule for 60 days after industry stakeholders requested additional time to arrange alternative disposal methods for high-risk materials. In light of these requests, FDA has set an October 26, 2009, compliance date for renderers and other affected persons, but believes that "the rendering, livestock, meat and animal feed industries have addressed many of the compliance and carcass disposal challenges and are prepared to meet the April 27, 2009, effective date of the final rule." See *Meatingplace.com*, April 23, 2009; *Federal Register*, April 24, 2009.

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EU and U.S. Trade Officials Extend Discussions over Beef Dispute

The European Union's (EU's) trade commissioner and U.S. trade representative have reportedly agreed to extend discussions related to a decades-long dispute over the EU's ban on the import of hormone-treated beef from the United States. According to a press report, retaliatory U.S. duties on EU products will be delayed at least until May 8, 2009. Since the EU imposed the ban in the mid-1980s, the dispute has been before the World Trade Organization several times. More information about previous WTO rulings appears in issues 262 and 281 of this Update.

The deal that could resolve the matter apparently involves increasing the quota for non-hormone-treated U.S. beef. Currently set at 11,500 metric tons, the quota would reportedly be increased to 50,000 metric tons in three separate phases in exchange for eliminating the trade duties on EU products ranging from meats and cheeses to truffles and chocolates. An issue that might derail resolution, however, is U.S. meat producers' use of antimicrobial washes that are prohibited in the EU. See *Meatingplace.com*, April 22, 2009.

Chemicals in Food Working Group Considers Industry Proposal for Prop. 65 Warnings

A working group of California EPA's Office of Environmental Health Hazard Assessment (OEHHA) met on April 23, 2009, to consider how warnings under Proposition 65 could be provided to consumers of food products containing chemicals known to the state to cause cancer or reproductive harm. Participants discussed a [draft proposal](#) submitted by the California Grocers Association, California Retailers Association, California League of Food Processors, GMA, and American Beverage Association. It was the only proposed regulation to be submitted.

Generally speaking, the proposal offers food manufacturers the option of uploading product-related information to an OEHHA Web site, which could be used, in turn, by retailers to download information that could be made available to consumers via computer, notebook, kiosk, or other similar means. Stakeholders representing consumer interests would prefer that warning information be placed on each product or in close proximity to them. While no final decisions were made during this session, OEHHA Director Joan Denton pledged to move forward with input from each of the working group's meetings and hopes to have a draft OEHHA regulation to discuss by August.

LITIGATION

Certiorari Denied in Tuna Warnings Class Action

The U.S. Supreme Court has decided not to hear a putative class action lawsuit involving claims that Tri-Union Seafoods LLC fails to warn consumers about mercury concentrations in its canned tuna fish products. *Tri-Union Seafoods, L.L.C. v. Fellner*, No. 08-889 (U.S., cert. denied April 20, 2009). The plaintiff filed her claims in 2006,

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alleging that she developed severe mercury poisoning after eating Chicken of the Sea® canned albacore tuna almost exclusively for five years.

The district court dismissed the case on federal preemption grounds, but the Third Circuit Court of Appeals reinstated it after finding that the Food and Drug Administration (FDA) had taken no action about alleged risks posed by mercury in fish and thus, that the lawsuit would not conflict with FDA's "regulatory scheme." More information about the Third Circuit's ruling appears in issue 272 of this Update.

At least one legal commentator responded to news about the rejection of Tri-Union's appeal by reportedly stating, "Yet again, federal preemption took it on the chin. And a Pandora's Door of state lawsuits has possibly been thrown open in how the food industry does its labeling." See *Product Liability Law 360*, April 20, 2009; *LegalNewsline.com*, April 21, 2009.

Two Bellwether Nicaraguan Pesticide-Exposure Cases Found Fraudulent and Dismissed

The pesticide-exposure claims of Nicaraguan banana-plantation workers were dismissed in two cases after a hearing that began April 21, 2009, in a state court in Los Angeles, California. *Meija v. Dole Food Co.*, No. BC340049 (Cal. Super. Ct., Los Angeles County); *Rivera v. Dole Food Co.*, No. BC379820 (Cal. Super. Ct., Los Angeles County). Additional details about the events leading to the court's show-cause order and hearing appear in issue 297 of this Update.

The court agreed with Dole Food Co. allegations that Nicaraguan lawyers, seeking to collect millions of dollars in damages from the company, recruited poor men to pose as plantation workers and claim that pesticide exposure caused their sterility. Dole introduced evidence showing a decade-long conspiracy to defraud U.S. companies and perpetuate a massive fraud on the court. Dole alleged that the attorneys intimidated witnesses and paid plaintiffs, showed them videos depicting plantation life, falsified sterility documents, and hid records showing that some of the supposedly sterile men went on to father children.

Dismissing two of the three bellwether lawsuits pending before her court, U.S. District Judge Victoria Chaney was quoted as saying, "What has occurred here is not just a fraud perpetrated on this court, but a blatant extortion of the defendants. I cannot in good conscience allow this case to continue." Apparently, most of the company's Nicaraguan records were destroyed in the aftermath of the Sandinista revolution, opening the door to fraudulent claims. The court reportedly said that the plaintiffs' U.S. law firm was not to blame for the fraud committed by Nicaraguan lawyers; she indicated that she would refer the case to appropriate bar associations and prosecutors.

The allegations arise from dozens of lawsuits involving the pesticide DBCP. A jury awarded six workers more than \$5 million in the first such case to go to trial in the United States, and a federal court in Miami, considering whether to enforce a multi-million dollar judgment won by banana workers in a Nicaraguan court, has reportedly stayed the proceedings pending the outcome of the California cases.

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Most of the plaintiffs in several of the 40 cases before her dropped out voluntarily after being deposed or undergoing medical exams “that revealed their claims were fraudulent,” the California judge said in her show-cause order, adding that she “became deeply concerned that fraud may be occurring and that it has tentacles that extend to all of the Nicaraguan (pesticide) cases pending before it.” See *The Wall Street Journal Law Blog* and *Reuters*, April 21, 2009; *The Los Angeles Times*, April 22, 2009; and *Bloomberg.com*, April 24, 2009..

Monsanto Sues German Government over GE Corn Ban

According to a news source, Monsanto has filed a lawsuit challenging the German government’s decision to prohibit farmers from planting the company’s genetically modified (GM) corn. Designed to produce a substance toxic to the corn borer pest, the GM seed has been permitted in Germany since 2005, and the corn has been used in Europe for animal feed since 1998. Earlier in April 2009, Germany’s agriculture minister, saying she had “legitimate reasons” to believe the corn is an environmental hazard, put a halt to plans to use the GM seed on nearly 9,000 acres in eastern states this year.

Monsanto contends that the ban is arbitrary and could only be imposed as to approved plants if new scientific evidence comes to light. Other European countries have banned the GM seed, although the European Food Safety Authority concluded that studies surfacing in 2008 did “not present new scientific evidence that would invalidate the previous risk assessments of maize MON810.” If Monsanto wins its administrative action, the government could apparently be forced to pay between €6 million and €7 million. See *FoodNavigator-USA.com*, April 22, 2009.

OTHER DEVELOPMENTS

Advocacy Groups Urge Food and Beverage Manufacturers Not to Use BPA in Packaging

Green Century Capital Management, an investment advisory firm focused on environmentally responsible companies, and As You Sow, an advocacy group that promotes corporate accountability, have issued a new [report](#) urging food and beverage manufacturers to stop using the packaging chemical bisphenol A (BPA) or risk possible repercussions in the marketplace. The report claims that 14 of the largest public packaged food and beverage companies still use BPA despite studies allegedly linking it to heart disease, diabetes, cancer, and metabolic disorders. The report states: “Companies that move toward BPA-free packaging are being recognized as putting their customers’ health first, while other companies refusing to phase out BPA may find themselves punished in the marketplace.”

In published reports, a Green Century director expressed concern about the lack of urgency the packaged food industry appears to have in addressing BPA. “Alternatives to BPA exist for many products. We believe companies should implement all

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feasible alternatives and increase investments into substitute can linings for all products, including highly-acidic foods." See *FoodProductionDaily.com*, April 22, 2009.

UCS Report Claims Promise of GE Higher Yields Proves Empty

The Union of Concerned Scientists (UCS) has produced a [report](#) concluding that despite 20 years of research and 13 years of commercialization, genetically engineered (GE) corn and soybean crops have not increased yields compared to other agriculture technologies.

Released in March 2009, the report reviewed two dozen academic studies of corn and soybeans and found that increase in yields for both crops over the last 13 years was largely due to traditional breeding or improvements in agricultural practices. It claims that genetic engineering is unlikely to play a significant role in increasing food production in the foreseeable future and recommends that the U.S. Department of Agriculture (USDA), state agricultural agencies and universities increase research and development for proven approaches to boost crop yields.

"If we are going to make headway in combating hunger due to overpopulation and climate change, we will need to increase crop yields," the report's author, Gurian Sherman, was quoted as saying on the UCS Web site. "Traditional breeding outperforms genetic engineering hands down."

Former FDA Commissioner Criticizes Food Industry in Book on "Conditioned Hypereating"

Former Food and Drug Administration (FDA) Commissioner David Kessler has reportedly written a book, titled *The End of Overeating: Taking Control of the Insatiable American Appetite*, that criticizes the food industry for contributing to a culture of "conditioned hypereating," a phenomenon allegedly comparable to drug addiction that encourages millions of people to eat high-fat, high-sugar foods even when not hungry. The book cites neurological research suggesting that foods high in fat and sugar can trigger dopamine pathways in the brain, which then becomes conditioned to associate specific aromas, tastes and places with positive experiences and to thus promote overeating.

According to Kessler, people prone to hypereating must learn to resist temptations in an environment rife with inexpensive high-fat, high-calorie foods. He also apparently hopes more restaurants will rein in portion sizes and reveal calories on menus. "The food industry has figured out what works. They know what drives people to keep on eating," Kessler was quoted as saying. "It's the next great public health campaign, of changing how we view food, and the food industry has to be part of it." See *The Associated Press*, April 20, 2009.

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SCIENTIFIC/TECHNICAL ITEMS

Study Claims Fructose Increases Some Cardiovascular Disease Risk Factors

A recent study has reportedly claimed that consumption of fructose-sweetened beverages raised blood lipid levels in overweight subjects, whereas glucose-sweetened beverages did not incur analogous effects. Kimber L. Stanhope, et al., "Consuming Fructose-Sweetened, Not Glucose-Sweetened, Beverages Increases Visceral Adiposity and Lipids and Decreases Insulin Sensitivity in Overweight/Obese Humans," *Journal of Clinical Investigation*, April 20, 2009.

University of California, Davis, researchers created two groups from 32 overweight men and women matched for age, weight, fasting triglyceride levels, insulin concentrations, total cholesterol, and other factors. Each group then consumed either fructose-sweetened or glucose-sweetened beverages for 10 weeks while living at a research center and while eating a normal diet as outpatients. The results indicated that although both groups experienced similar amounts of weight gain, the group assigned to fructose-sweetened beverages had larger gains in abdomen fat and increased blood levels of triglycerides and low-density lipoproteins when compared to their counterparts in the "glucose" group.

Meanwhile, the study authors have apparently cautioned that their work does not examine the health effects of high-fructose corn syrup. The findings "do not imply that anyone should avoid fruit, which contains only small amounts of fructose and has other important nutritional benefits," according to lead researcher Dr. Peter J. Havel. See *FoodNavigator.com*, April 22, 2009; *The New York Times*, April 23, 2009.

Research Suggests Phthalates Linked to Child Obesity

A long-term study by the Mount Sinai Medical Center for Children's Environmental Health and Disease Prevention Research has reportedly suggested a link between childhood obesity and endocrine disruptors, including phthalates and bisphenol A. Part of a study titled "Growing Up Healthy in East Harlem," the project followed 520 children ages 6 to 8 for five years in an effort to determine "how the area where the children lived affected diet, physical activity and risk for obesity." Researchers apparently found that study participants had "higher levels in their urine of three endocrine disruptors – 2,5 DCP, MBP and MEHHP – than a national sample of children the same age."

According to the New York City Department of Health and Mental Hygiene, approximately 43 percent of East Harlem kindergarteners were also overweight or obese for their age in 2003. "The heaviest girls have the highest levels of phthalates metabolites in their urine," said Dr. Phillip J. Landrigan, one of the lead researchers. "It goes up as the children get heavier, but it's most evident in the heaviest kids." See *Mount Sinai Press Release*, April 16, 2009; *New York Times City Room Blog*, April 17, 2009.

As a result of these findings, Mount Sinai Center has recommended that parents reduce children's exposure to these chemicals, which are used in "fragrance and products with fragrances, nail polish, vinyl, flexible plastics such as shower curtains

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and a variety of household products." In addition, the researchers have urged families "to avoid use of mothballs and toilet bowl deodorizers in the home" because these products can contain high levels of DCP. "Right now it's a correlation; we don't know if it's cause and effect or an accidental finding," Landrigan was quoted as saying. "The \$64,000 question is, what is causal pathway? Does it go through the thyroid gland? Does it change fat metabolism?"

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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.

