

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

DOJ Hearings on Concentration in Agriculture Continue

Hundreds of farmers reportedly attended one in a continuing series of Department of Justice (DOJ) hearings on antitrust issues in agriculture. The focus of the meeting held at the University of Wisconsin-Madison was on the dairy industry. According to U.S. Agriculture Secretary Tom Vilsack, the number of dairy farms has fallen from 111,000 in 2000 to 65,000 today. Farm consolidation and voluntary retirement are reportedly responsible for some of the losses, but most are purportedly due to farmers forced out of business by high costs and the low prices they receive for dairy products.

Some of the dairy farmers who spoke during the June 25, 2010, meeting reportedly complained about how prices are set for dairy products by mercantile exchanges; others pointed to the largest dairy companies as the source of reductions in competition. A spokesperson for a cooperatives trade association was quoted as saying, "There are five people who understand how dairy products are priced. Four of them are dead, and the fifth one is lying." David Ward also reportedly said, "If anything comes out of this, I hope it's that we are able to create a pricing system that is transparent and makes sense, and that nobody is manipulating anything." The head of DOJ's antitrust division said it is "keeping a watchful eye on this industry. We will go to court and block mergers" that are anticompetitive. See *Journal Sentinel*, June 25, 2010.

FDA Issues Guidance Intended to Help Reduce Antibiotic Use in Food-Producing Animals

The Food and Drug Administration (FDA) has issued [draft guidance](#) that urges the "judicious" use of antibiotics in food-producing animals to minimize drug resistance in humans.

The guidance recommends limiting "medically important" antimicrobial drugs to uses deemed necessary for animal health on the basis of veterinary oversight or consultation. It supports the theory that "nontherapeutic" or "subtherapeutic" antibiotic use for production or growth-enhancing purposes "is not in the interest of protecting and promoting the public health." FDA has [requested](#) written comments by August 30, 2010. See *FDA News Release*, June 28, 2010; *Federal Register*, June 29, 2010.

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For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com



or

Madeleine McDonough
816-474-6550
202-783-8400
mcdonough@shb.com



If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

FDA Principal Deputy Commissioner Joshua Sharfstein has called the matter an urgent public health issue, telling news sources that the agency would issue new regulations if farmers do not voluntarily adhere to them. "We're not handcuffed to the steering wheel of a particular strategy, but I'm not ruling out anything that we can do to establish these important public-health goals," he was quoted as saying. See *The New York Times*, June 28, 2010; *The Washington Post*, June 29, 2010.

Meanwhile, farming interests such as the National Pork Producers Council have reportedly requested more evidence before calling for changes to long-standing practices. "Top scientists with the Centers for Disease Control and Prevention and the National Institutes of Health recently told a U.S. House committee that there is no scientific study linking antibiotic use in food animal production with antibiotic resistance," stated a June 29, 2010, council press release.

Public health groups, however, have expressed concern that the agency's actions were timid. "The FDA should define and regulate what constitutes judicious use," opined Laura Rogers, project director of the Pew Campaign on Human Health and Industrial Farming, in a June 29, 2010, statement. "The authorization for the therapeutic use of antibiotics should be limited to treatment of sick animals, in cases that have been diagnosed and documented by a veterinarian. As it currently stands, the agency's attempt to define appropriate therapeutic uses of antibiotics in food animal production may actually create a loophole, jeopardizing effectiveness of the drugs in humans and animals."

FDA Announces Science Board Meeting

The Food and Drug Administration (FDA) has [announced](#) that its Science Board will hold a public meeting on August 16, 2010, in Bethesda, Maryland. Tasked with advising officials on "specific complex and technical issues, as well as emerging issues within the scientific community in industry and academia," the board keeps pace with "technical and scientific evolutions in the fields of regulatory science." At this meeting, it will hear a subcommittee's final report on research at the Center for Food Safety and Applied Nutrition (CFSAN), as well as discuss the agency's nano-technology research program, among other agenda items.

FDA has stated that it intends to make background material available on its Website "no later than [two] business days before the meeting." The agency will also accept written data submissions on or before August 9, 2010, and proposals for formal oral presentations on or before August 2, 2010. See *Federal Register*, June 29, 2010.

Agencies Plan Two Meetings on Food Safety Progress

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) has [announced](#) two public meetings with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to hear stakeholder input on collective efforts to reduce illness, harm and death from contaminated food. Extensions of an initial workshop held in March 2010, the meetings will be held July 21, in Chicago, Illinois, and October 20 in Portland, Oregon.

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Presentations are expected from consumer groups, industry, public health experts, and state and local regulators on recommended measures for assessing food safety performance. CDC, FDA and FSIS will present information on the Food Safety Working Group's "charge to create meaningful metrics to measure the effectiveness of the nation's food safety system," according to USDA. The agencies will also "present current thinking, focusing on how these metrics might be applied to evaluate the success of FDA's shell egg safety rule, FSIS implementation of broiler chicken controls, and CDC's efforts to collect and analyze human disease data." See *USDA Press Release*, June 29, 2010; *Federal Register*, June 30, 2010.

Russia and U.S. Reach Agreement on Poultry Exports

The U.S. Department of Agriculture (USDA) has announced a trade agreement with Russia that ends a January 2010 ban on chlorine-treated poultry from the United States. In exchange for lifting the ban, USDA has pledged to post on its Website information about "which disinfectants/pathogen reductions treatments are known to be approved by Russia for use on processing poultry and on food generally." U.S. officials will also provide (i) "information... on the solutions that companies use on poultry shipped to Russia," and (ii) "an updated list of poultry processing facilities authorized to ship poultry to Russia."

The accord came after 25 senators reportedly urged President Barack Obama (D) to take up the issue with Russian President Dmitry Medvedev. "I am pleased that after several months of negotiations, we have finally reached a breakthrough which will allow for U.S. poultry exports to resume to this important market," stated U.S. Trade Representative Ron Kirk, who estimated that in 2009, poultry exports to Russia reached \$767 million. See *Meatingplace.com*, June 22, 2010; *USDA News Release*, June 24, 2010.

EC Research Center Issues Report on Defining "Nanomaterial"

The European Commission's (EC's) Joint Research Centre has published a [report](#) that explores various definitions for the term "nanomaterial" currently in use around the world in an effort to devise a single definition that could make nanotechnology amenable to regulation. Titled "Considerations on a Definition of Nanomaterial for Regulatory Purposes," the report observes that nanomaterials are currently being used in food and nutritional ingredients as well as food packaging.

The authors call for a single definition of nanomaterial that will be "broadly applicable in EU legislation and policies, legally clear and unambiguous, enforceable through agreed measurement techniques and procedures, and in line with other approaches worldwide." According to the report, no official definition for the term has yet been adopted in the United States, but the Environmental Protection Agency has proposed a definition for "engineered nanoscale material" under the Toxic Substances Control Act.

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Ohio Reaches Deal with Animal Rights Interests

Ohio Governor Ted Strickland (D) has reportedly announced that the state has reached an [agreement](#) with The Humane Society of the United States so that a state constitutional proposal addressing animal-care reforms will not appear on the ballot in the fall. Under the agreement, animal rights interests will work with various state agencies to take action on farm animal care and welfare in exchange for the Humane Society not submitting more than 450,000 signatures to qualify an initiative for inclusion on the November 2, 2010, ballot. The agreement addresses, among other matters, a phase out of hog gestation crates, a transition to group housing for veal calves and the denial of permits to new egg facility applicants based on permitting standards calling for the use of battery cages. Also covered by the agreement are regulations for dog breeding kennels, the possession of dangerous animals and increased penalties on those engaging in cockfighting. See *The Columbus Dispatch*, June 30, 2010.

OEHHA Considers Adding Soy Sauce Ingredients to Prop. 65 List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has [announced](#) a meeting of its Carcinogen Identification Committee (CIC) on September 21-22, 2010, to consider whether to list 1,3-Dichloro-2-propanol (1,3 DCP) and 3-monochloropropane-1,2-diol (3-MCPD) under Proposition 65 (Prop. 65). These chemicals are apparently produced by treating proteins from hydrolyzed vegetables, such as soya, with hydrochloric acid and are commonly found in soy and related sauces that are not produced using traditional fermenting processes. They have also been found in malt products, sausage, minced beef, ham, and battered and fried fish.

Public comments on the 1,3 DCP and 3-MCPD documents that OEHHA has prepared on the basis of a recent request for information must be filed by August 24, 2010.

LITIGATION

Federal Court Allows Diacetyl-Related Claims to Proceed Against Popcorn Maker

A federal court in California has denied defendant's motion to dismiss a putative class action alleging that the company deceived the public by promoting and labeling its reformulated microwave popcorn as containing "No Added Diacetyl." *Fine v. ConAgra Foods, Inc.*, No. 10-01848 (U.S. Dist. Ct., D.C. Cal., order entered June 29, 2010). According to the plaintiff, she relied on defendant's claims about "no added diacetyl" when purchasing its products, yet the popcorn still contains diacetyl. Accepting the plaintiff's allegations as true for the purpose of ruling on the motion, the court noted that while plaintiff does not have "direct knowledge of the presence of diacetyl in Defendant's products, Plaintiff relies on the work and statements of several health experts and alleges that "[k]nown "substitutes" for diacetyl still contain molecules of diacetyl."

The defendant sought to dismiss the claims on the grounds that the plaintiff did not allege a cognizable injury and thus lacks standing; her claims failed for lack of

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specificity under Federal Rules of Civil Procedure 8(a) and 9(b); and she failed to state a claim under California's unfair competition, false advertising and consumer legal remedies laws as a matter of law under Rule 12(b)(6). The court found no merit to any of the defendant's challenges. This lawsuit was previously brought under the name of plaintiff Dale Emery, but the parties stipulated to dismissing Emery as the named plaintiff and putative class representative. The parties also apparently stipulated to Emery's replacement with Courtney Fine.

Chocolate Drink Makers Sued for Alleged Misleading Marketing Claims

The attorneys for a woman who recently reportedly sued General Mills for failing to properly disclose that its fruit snack products contain partially hydrogenated oil also represent a man who has filed similar claims against the companies that make and sell Yoo-Hoo®, a chocolate beverage. [*Dahl v. Mott's LLP, No. n/a \(U.S. Dist. Ct., E.D.N.Y., filed June 29, 2010\)*](#). Information about the General Mills lawsuit appears elsewhere in this *Update*.

According to plaintiff Timothy Dahl, the defendants promote Yoo-Hoo® as a nutritious and healthy product, claiming that it contains vitamins and minerals, has no preservatives and is 99 percent fat free and 99 percent caffeine free. The complaint states, "Unfortunately for consumers and, in certain cases their children, all these claims are false and misleading. Defendants' healthful claims are misleading since the Product fails to properly disclose they contain a highly unhealthy, non-nutritious ingredient known as partially hydrogenated oil. This partially hydrogenated oil is an artificial, man-made substance known to cause a number of health problems, including coronary disease, heart attacks and death."

Alleging injury "in that he would not have paid a premium when purchasing the Product had these misrepresentations not been made," the plaintiff brings his claims on behalf of a putative nationwide class. He alleges false advertising under the Lanham Act; violations of the Texas Business & Commerce Code and the New York General Business Law; breach of express warranty, implied warranty of merchantability and implied warranty of fitness for a particular purpose; deceit and/or misrepresentation; and unjust enrichment. He seeks restitution and disgorgement, declaratory and injunctive relief, compensatory and punitive damages, and the costs of suit.

Consumer Claims Fruit Snack Marketing is False and Misleading

According to news sources, a New York woman is seeking \$5 million in damages in a putative class action against General Mills, alleging that the company falsely promotes its Fruit Roll-Ups® and other fruit snacks as nutritious and healthy while failing to properly disclose to consumers that partially hydrogenated oil is a product ingredient. *McClure v. General Mills, Inc.*, No. 10-05015 (U.S. Dist. Ct., S.D. N.Y., filed June 29, 2010). Plaintiff Payton McClure, who reportedly describes herself as a "life-long consumer" of General Mills products, contends that partially hydrogenated oil is "dangerous" and "unhealthy." She apparently seeks compensatory and punitive damages, among other remedies. See *Reuters* and *NYDailyNews.com*, June 29, 2010.

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OTHER DEVELOPMENTS

NRC Report Tackles Sustainability in the 21st Century

The National Research Council (NRC) recently issued a report titled [Toward Sustainable Agricultural Systems in the 21st Century](#), which reviews farming practices, technologies and management systems that seek to promote environmental, social and economic sustainability.

According to NRC, “the scale, organization, enterprise diversity, and forms of market integration associated with individual farms provide unique opportunities or barriers to improving their ability to contribute to global or local food production, ecosystem integrity, economic viability, and social well-being.”

The report apparently evaluates agricultural systems on whether they are sufficiently productive, robust and efficient in their efforts to meet these four goals. It also proposes “two parallel and overlapping efforts to ensure continuous improvement in the sustainability performance of U.S. agriculture: incremental and transformative.” The former approach “would be directed at improving the sustainability of all farms, irrespective of size or farming system type,” while the latter “would apply a systems perspective to agricultural research to identify and understand the significance of the linkages between farming components and how their interconnectedness and interactions with the environment make systems robust and resilient over time.”

In making these recommendations, however, the report emphasizes that farmers must balance productivity and cost with other mitigating factors, such as public concern over air and water pollution, animal welfare and food safety. The NRC Committee on Twenty-First Century Systems Agriculture thus noted that achieving sustainability will require “long-term research, education, outreach, and experimentation by the public and private sectors in partnership with farmers.” As committee chair Julia Kornegay was quoted as saying, “Many modern agricultural practices have unintended negative consequences, such as decreased water and air quality, and farmers have to consider these consequences while trying to increase production. If farmers are going to meet future demands, the U.S. agricultural system has to evolve to become sustainable and think broadly—past the bottom line of producing the most possible.” See *NRC Press Release*, June 29, 2010.

CSPI Report Calls for Ban on Food Dyes

The Center for Science in the Public Interest (CSPI) has issued a [report](#) urging the Food and Drug Administration (FDA) to ban several food dyes that allegedly pose “risks of cancer, hyperactivity in children, and allergies.” According to a June 29, 2010, CSPI press release, “Dyed foods should be considered adulterated under the law, because the dyes make a food ‘appear better or of greater value than it is’—typically by masking the absence of fruit, vegetable, or other more costly ingredient.”

CSPI has charged FDA with failing to enforce “a stricter standard of safety for color additives than other food additives,” despite a five-fold increase in per capita consumption of dyes since 1955. It has specifically asked the agency to prohibit (i)

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Red 3 and Citrus Red 2 “because they caused cancer in rats,” (ii) Red 40, Yellow 5 and Yellow 6, “which are tainted with cancer-causing contaminants,” including benzidine and 4-aminobiphenyl; and (iii) Blue 1, Blue 2, Green 3, Red 40, and Yellow 6 because there is “certainly not ‘convincing evidence’ of their safety.”

The consumer watchdog has also lauded the steps taken by UK regulators to phase out these colorings, as well as a new EU regulation requiring warning labels on most dyed foods. “Dyes add no benefits whatsoever to foods, other than making them more ‘eye-catching’ to increase sales,” one scientist with the National Institute of Environmental Health Sciences was quoted as saying. “Some dyes have caused cancer in animals, contain cancer-causing contaminants, or have been inadequately tested for cancer or other problems. Their continued use presents unnecessary risks to humans, especially young children.”

Massive Cereal Recall Puts Spotlight on Chemicals in Food Packaging

Following Kellogg Co.’s voluntary recall of some 28 million boxes of breakfast cereals for a “waxy” smell and flavor emitted from package liners, some have pointed to growing public concern over chemicals, such as bisphenol A, that are allegedly leaching into foods from packaging materials. The Kellogg recall involved an unknown substance added to the liners at the company’s Omaha, Nebraska, facility; it reportedly gave rise to complaints about nausea and vomiting, and the company warned parents that it could cause vomiting or diarrhea in sensitive children.

Writing about the recall, *The Daily Green* discusses a 2009 study of legal food packaging substances that purportedly have endocrine disrupting properties. Among the food-packaging chemicals with potential health effects are lead in glass, ortho-phenylphenol in beer and soda cans, perfluorinated compounds in paper packaging, and benzophenone in milk, juice and wine cartons. See *The Associated Press*, June 25, 2010; *The Daily Green*, June 28, 2010.

Report Claims Adult Obesity in U.S. Has Increased in 28 States

A new [report](#) has claimed that adult obesity in the United States has increased in 28 states in the past year and that 38 states have adult obesity rates above 25 percent. Titled “F as in Fat: How Obesity Threatens America’s Future 2010,” the report from Trust for America’s Health (TFAH) and the Robert Wood Johnson Foundation “highlights troubling racial, ethnic, regional and income disparities in the nation’s obesity epidemic.”

“This report shows that the country has taken bold steps to address the obesity crisis in recent years, but the nation’s response has yet to fully match the magnitude of the problem,” TFAH Executive Director Jeffrey Levi was quoted as saying. “Millions of Americans still face barriers—like the high cost of healthy foods and lack of access to safe places to be physically active—that make healthy choices challenging.”

The report’s key policy recommendations include (i) support for obesity- and disease-prevention programs through the new health reform law, (ii) alignment of federal policies and legislation with the forthcoming National Prevention and Health Promotion Strategy, (iii) expanded commitment to community-based prevention

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programs, and (iv) continued investment in research and evaluation on nutrition, physical activity, obesity and obesity-related health outcomes. *See Trust for America's Health Press Release, June 29, 2010.*

MEDIA COVERAGE

Andrew Pollack, "Genetically Altered Salmon Get Closer to the Table," *The New York Times*, June 25, 2010

"The Food and Drug Administration [FDA] is seriously considering whether to approve the first genetically engineered [GE] animal that people would eat—salmon that can grow at twice the normal rate," reports *New York Times* biotechnology correspondent Andrew Pollack in this article about the decade-long regulatory process. Pollack identifies the petitioner as a Waltham, Massachusetts, company named AquaBounty Technologies, which has now submitted "most or all of the data the [FDA] needs to analyze whether the salmon are safe to eat, nutritionally equivalent to other salmon and safe for the environment."

The fish under review is an Atlantic salmon that contains "a growth hormone gene from Chinook salmon as well as a genetic on-switch from ocean pout." As AquaBounty Chief Executive Ronald Stotish explained to Pollack, the accelerated maturation would not result in "salmon the size of the Hindenburg," but would help bring fish to market in one half the usual timeframe. "Our fish is identical in every measurable way to the traditional food Atlantic salmon," confirmed Stotish, who indicated that his product is indistinguishable from the non-engineered version "in terms of taste, color, vitamins, minerals, fatty acids, proteins and other nutrients."

Nevertheless, FDA Principal Deputy Commissioner Joshua Sharfstein has purportedly suggested that mandatory or voluntary labeling is still a possibility for GE animals brought to market. Such a move, according to Pollack, would break from past FDA policies that required labeling only if a product differed in nutritional properties or other characteristics. "It's going to be a P.R. issue," one anonymous government official was quoted as saying.

Noting that pushback is likely from some consumer and environmental groups, Pollack claims that FDA could hold a public meeting on the issue "as early as this fall." In particular, groups like the Union of Concerned Scientists (UCS) have expressed concern that the agency treats and evaluates GE animals in a confidential manner reserved for veterinary drugs. "There is no opportunity for anyone from the outside to see the data or criticize it," opined one UCS spokesperson.

David Lazarus, "Junk Food and Obesity: Taking a Cue from Tobacco Control," *The Los Angeles Times*, June 29, 2010

This article calls for government authorities to treat "junk food" and the obesity epidemic exactly as they addressed smoking. Noting that the U.S. Department of Agriculture's latest dietary guidelines have recycled the same advice given 30 years ago, while the rate of obese Americans has roughly doubled in that time, columnist David Lazarus calls for "draconian" measures to reduce consumption of

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high-fat, high-salt, high-sugar products. Among other matters, he contends that such an aggressive campaign could mean anything from making certain foods less appealing by removing them from schools, government buildings and workplaces, to taxing sweetened beverages, stepping up wellness programs and subsidizing healthy foods instead of corn.

SCIENTIFIC/TECHNICAL ITEMS

CDC Report Claims Most Sodium Comes from Common Foods

The Centers for Disease Control (CDC) has issued a [report](#) that claims less than 10 percent of American adults limit their daily sodium intake to recommended levels.

Titled "Sodium Intake Among Adults—United States, 2005-2006," the report also suggests that processed grains and meats, including poultry and luncheon meats, provide two-thirds of sodium in the U.S. diet. In addition, approximately 77 percent of dietary sodium purportedly comes from processed and restaurant foods, many of which do not taste salty.

U.S. adults consume more than twice the current recommended limit of 2,300 milligrams of sodium per day, according to the report, which examined data from the National Health and Nutrition Examination Survey. "Sodium has become so pervasive in our food supply that it's difficult for the vast majority of Americans to stay within recommended limits," said lead author Janelle Peralez Gunn. "Public health professionals, together with food manufacturers, retailers and health care providers, must take action now to help support people's efforts to reduce their sodium consumption." See *CDC Press Release*, June 24, 2010.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000

Houston, Texas
+1-713-227-8008

Irvine, California
+1-949-475-1500

Kansas City, Missouri
+1-816-474-6550

London, England
+44-207-332-4500

Miami, Florida
+1-305-358-5171

San Francisco, California
+1-415-544-1900

Tampa, Florida
+1-813-202-7100

Washington, D.C.
+1-202-783-8400

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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.

