

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Expected to Declare Cloned Livestock Safe

“After more than six years of wrestling with the question of whether meat and milk from [cloned animals] are safe to eat, the Food and Drug Administration is expected to declare as early as next week that they are,” concludes a recent *Wall Street Journal* article that examines consumer and industry reaction to the anticipated verdict. FDA in 2006 tentatively ruled that food derived from cloned livestock was no different than that from conventionally bred adult animals, but issued a voluntary moratorium on producers selling products made from clones.

While several consumer groups have urged FDA and Congress to await further studies on the safety and potential ethical repercussions of cloned livestock, the food industry has remained divided on whether to accept cloning as a viable selective breeding practice. “Most consumers do not find this appealing,” a Dean Foods spokesperson told reporters, emphasizing that the lack of a mandatory tracking system has raised concerns over the ability to separate the offspring of cloned animals and conventional foods on the market.

Meanwhile, the European Food Safety Authority (EFSA) today launched a public consultation on its [draft scientific opinion](#) regarding the food safety implications of cloned products. Among other things, EFSA concluded that meat and milk from cloned animals are “very unlikely” to pose risks different than those of similar products derived from conventionally bred animals. The agency is accepting comments on the consultation until February 25, 2008. See *The Wall Street Journal*, January 4, 2008; *EFSA Press Release*, January 11, 2008.

Environmental Protection Agency (EPA)

[2] EPA's 2008 IRIS Agenda to Include Bisphenol-A

EPA recently [published](#) the 2008 agenda for its Integrated Risk Information System (IRIS), a database that “contains the agency’s scientific positions on human health effects that may result from exposure to chemical substances in the environment.” In addition to the chemical assessments already in progress, the agenda has identified 20 top priority substances, including the plasticizer bisphenol-A (BPA), compiled during an open nomination process. Public health watchdogs have targeted BPA in the past over concerns that the substance, which is commonly used in food containers, has caused reproductive and developmental harm in laboratory animals. EPA in 2008 will review the scientific literature for BPA and all priority chemicals, initiating assessments for those that support one or more toxicity values.



The agency has also announced a new process to solicit government and public input at the start of assessment development and to make the literature search results available for comment.

These changes to the administration of IRIS have reportedly presaged “the agency’s upcoming framework for reviewing risk assessments,” according to the publication *Inside EPA*, which has noted that “the Defense Department and other agencies have sought to ensure they win the right to participate early in the risk assessment process.” In addition, the proposed framework would apparently prohibit EPA from issuing draft risk assessments containing numeric risk values, thus preventing federal and state regulators from setting standards based on draft estimates. The defense department’s Paul Yaroschak, speaking at the Society of Risk Analysis meeting in December 2007, was also quoted as saying that the framework would represent, not a case of interagency “meddling,” but an opportunity to minimize uncertainty in EPA’s work. See *Inside EPA*, January 4, 2008.

[3] Acrylamide Less Toxic Than Previously Believed, Says EPA

EPA has [published](#) a draft toxicological assessment for acrylamide, concluding that the naturally occurring chemical found in baked and fried food is less harmful than previous studies have suggested. The agency, which released its findings under the Integrated Risk Information System (IRIS) program, has set a draft reference dose (RfD) for acrylamide of 0.003 milligrams per kilogram of bodyweight per day (mg/kg-day). Used by state and federal regulators to create health and environmental standards, an RfD establishes the amount of a given chemical that an average person could ingest orally over a lifetime without anticipating adverse health effects.

New evidence has reportedly shown that acrylamide, while likely a human carcinogen, is less toxic than indicated by the 1988 standard of 0.0002 mg/kg-day, according to EPA. In addition, the agency has issued a draft reference concentration (RfC) for acrylamide of 0.008 milligrams per cubic meter, a value that is similar to an RfD but addresses inhalation rather than oral exposure. “The draft assessment could help the food and chemical industry fight California’s push for strict acrylamide regulations,” concludes a recent *Inside EPA* article about the new standards. The article also points to several lawsuits, including litigation aimed at fast food restaurants, that seek to increase acrylamide regulation under the state’s toxics labeling law, Proposition 65. EPA will accept public comments on the draft toxicological assessment until February 26, 2008. See *Inside EPA*, January 4, 2008.

Litigation

[4] Contaminated Pet Food Litigation Moves Forward

In recent weeks, press reports have noted developments in litigation involving pet food containing melamine-contaminated ingredients that allegedly sickened and caused the deaths of a number of cats and dogs across the country. Defendants in the multidistrict litigation (MDL) pending before a district judge in New Jersey reportedly filed an unopposed motion to limit their obligations to retain recalled product. *In re Pet Food Prods. Liab. Litig.*, MDL No. 1850 (D. N.J., filed December 11, 2007). According to Menu Foods’ motion, the cost of storing more than 4 million cases and 12 million individual cans, bags and pouches would cost \$3.7 million annually. The company will be required to retain a representative sample of the recalled products and wheat gluten



presently in storage. On January 4, 2008, the court issued an order extending a stay in the case until February 14, referring to progress the parties were making in mediation meetings. Additional mediation is apparently scheduled for January 28 and 29.

A federal judge in Hawaii has reportedly remanded a contaminated pet food case to state court, finding that the amount in controversy “per plaintiff would fall short of the \$75,000 threshold.” *Sylvester v. Menu Foods Inc.*, No. 07-00409 (D. Hawaii, decided December 5, 2007). The case involves the claims of 10 individual plaintiffs who filed suit in state court. Menu Foods removed it to federal court, and the case was conditionally transferred to the New Jersey MDL court because it appeared to involve common questions of fact. Thereafter, the plaintiffs sought a remand, and the federal court, observing that Menu Foods had left it to speculate about the amount in controversy, concluded that even assuming \$150,000 in compensatory damages, \$500,000 in punitive damages and \$7,750 per plaintiff in attorney’s fees, the total amount was insufficient for it to exercise jurisdiction.

In a related development, the Food and Drug Administration (FDA) has issued a [notice](#) of intent to schedule a public meeting early in 2008 “to obtain input from stakeholder groups,” regarding “the development of ingredient, processing, and labeling standards to ensure the safety of pet food.” Such standards were mandated by legislation enacted in 2007. The agency will announce the meeting date in a subsequent notice, but indicated that general comments can be submitted now.

Meanwhile, the Mississippi Supreme Court will consider this year whether to allow Mississippi State University and Iams Co. to shield documents about animal testing from People for the Ethical Treatment

of Animals (PETA). The university and pet food company reportedly argue that the research documents are protected as trade secrets. PETA sought the material under an open records request, and a state chancery judge agreed they should be released. In a December 2006 ruling, the court indicated that information about the type and number of animals used in experiments, whether surgery would be performed and animal pain and discomfort did not qualify as trade secrets. *See Federal Register, Mealey’s Food Liability and Associated Press*, January 7, 2008.

[5] U.S. Supreme Court Lets GE Soybean Ruling Stand

The U.S. Supreme Court has decided not to hear an appeal from a Mississippi farmer who was ordered to pay \$375,000 to Monsanto Co. for planting genetically engineered (GE) soybeans from seeds he had saved from a previous crop. *McFarling v. Monsanto Co.*, No. 07-241 (U.S., cert. denied January 7, 2008). He had asked the Court to find the award excessive. According to Monsanto, farmers who plant the GE seeds it produces sign an agreement restricting them to use the seeds for a single growing season; the company has reportedly sued nearly 100 farmers for violating such contracts since the 1990s. The lower federal courts have agreed with the company that an injunction barring second-generation seeds is “simply a prohibition against unlicensed use of the patented invention.”

In a related matter, the U.S. Department of Agriculture (USDA) has published a [notice](#) indicating that it will prepare an environmental impact statement on Monsanto’s Roundup Ready® GE alfalfa seed. A federal court ruled in March 2007 that federal authorities failed to fully consider the environmental, health and economic consequences



of allowing the seed's sale. The Center for Food Safety challenged the agency's determination that it posed no threat to the environment, and the court agreed that genetic drift could harm the interests of those raising conventional and organic alfalfa crops sold abroad for a premium price.

And in another development, USDA has reportedly concluded an agreement with Monsanto giving farmers in Illinois, Indiana, Iowa, and Minnesota a price break on federal crop insurance if they plant Monsanto-brand seed corn in spring 2008.

According to agency officials, the agreement is legal under a 2000 law that gives economic breaks to farmers who use higher-yield corn seeds that are resistant to insects and other threats. While the deal has an appearance of favoritism, a USDA spokesperson said other companies can "do the same thing." Organic farmers object to the deal, claiming that USDA should not be promoting GE corn. Under the Biotech Yield Endorsement program, farmers can apparently save about \$2 per acre if they use GE corn. *See Chicago Tribune* and *CNNMoney.com*, January 7, 2008; *Casper Star-Tribune*, January 8, 2008.

[6] Chocolate Purchasers Bring Price-Fixing Claims Against Manufacturers

In late December 2007, three putative class action lawsuits were filed in federal courts in two states seeking class certification and treble damages for an alleged price-fixing scheme involving the worldwide chocolate market. According to the [complaint](#) filed in New Jersey, the world's leading chocolate manufacturers conspired to "fix, raise, maintain, and/or stabilize prices of chocolate" in violation of federal antitrust laws. *CNS Confectionery Prods, LLC v. The Hershey Co.*, (U.S. Dist. Ct., D. N.J., filed December

21, 2007). The complaint refers to investigations into pricing practices that U.S. and Canadian authorities launched in late 2007 against the companies.

Plaintiffs seek to certify a worldwide class of "[a]ll persons or entities who purchased Chocolate directly from the Defendants or their co-conspirators (the 'Class'), at any time from at least December 21, 2003 through the present (the 'Class Period'), the exact date being unknown." They identify as common questions of law and fact (i) "Whether Defendants conspired, contracted or combined with others, for the purpose of and with the effect of raising, fixing, maintaining, pegging, or stabilizing the price of Chocolate which was purchased by the Class"; (ii) "Whether Defendants undertook actions to conceal the unlawful conspiracies, contracts or combinations described herein and"; (iii) "Whether Defendants' conduct violated the relevant federal antitrust laws and caused injury to the business and property of Plaintiffs and the Class and, if so, the proper measure of damages."

The New Jersey complaint describes frequent meetings that gave the defendants and their trade associations "an opportunity to conspire." An attorney for one of the consumers, who is among those who filed similar complaints in Pennsylvania, reportedly contended that the litigation was not "premature" despite the fact that criminal charges have not been filed in either the United States or Canada. The defendants include The Hershey Co., Mars Inc., Nestle USA, and Cadbury Schweppes Americas. They have apparently attributed their price increases to higher prices for cocoa and milk. Adverse weather conditions in Africa and South America have reportedly contributed to a global chocolate production deficit. *See International Herald Tribune*, January 5, 2008; *FoodNavigator-USA.com*, January 8, 2007.



[7] Dairies Challenge California Standards on Unpasteurized Milk

According to a news source, California dairies that produce unpasteurized (raw) milk have filed a lawsuit in San Benito Superior Court against the state Department of Food and Agriculture, seeking to derail a new law (A.B. 1735) that requires raw milk to meet the same bacterial standards as pasteurized milk. Organic Pastures and Claravale Farms are asking the court to declare the law, which took effect January 1, 2008, unconstitutional, arguing that it will put them out of business without any evidence that it will improve public safety. Raw milk proponents contend that pasteurization destroys beneficial enzymes and bacteria despite recent foodborne illness outbreaks in Kansas and Massachusetts traced to raw dairy products. See *Cheesemarketnews.com*, January 4, 2008; *Worcester Telegram & Gazette*, January 9, 2008.

[8] Confidentiality Order Entered in *Trans Fat* Litigation Against Fast-Food Chain

In December 2007, parties to California litigation involving claims that Wendy's International, Inc. made misleading claims about the level of *trans* fat in its french fries entered a stipulated confidentiality agreement. *Bokhyun Yoo v. Wendy's Int'l, Inc.*, No. 07-4515 (U.S. Dist. Ct. C.D. Calif., W. Div., filed December 14, 2007). According to the order formalizing the agreement, confidential or proprietary information produced in discovery will be protected in this action and in cases pending against Wendy's in federal courts in New York and Florida.

Legal Literature

[9] Michael Anderson & David Matsa, "Are Restaurants Really Supersizing America?," (unpublished) (December 30, 2007)

Economists from U.C. Berkeley and Northwestern University have authored a [paper](#) discussing research they conducted to determine whether a correlation exists between the consumption of food in restaurants and obesity. The authors, who studied populations in rural areas with and without access to lower-cost interstate-highway restaurant fare, found "no evidence of a causal link between restaurants and obesity, and the estimates are precise enough to rule out any meaningful effect." They conclude, therefore, that "public health policies targeting restaurants are unlikely to reduce obesity." The authors further posit that "although restaurant meals are associated with greater caloric intake, many of these additional calories are offset by reductions in eating throughout the rest of the day. We also find evidence of selection – individuals that frequent restaurants appear to be those who eat more even when at home."

[10] Michael Cardin, et al., "Preventing Obesity and Chronic Disease: Education v. Regulation v. Litigation," *Journal of Law, Medicine and Ethics* (Winter 2007 Supplement)

This article consists of a panel discussion held during a public health and law conference; the speakers were a physician who has worked for the Centers for Disease Control and Prevention, a policy director for a California public health advocacy organization, and a Connecticut state representative. Physician Tom Farley discussed how environmental factors have caused Americans to



consume more calories each day and suggested that taxing calorie-dense snack foods could affect consumption. He also suggested limiting fast food restaurants and soft drink and snack vending machines and further called for removing soft drinks and junk food from workplaces. Policy director Amanda Purcell discussed efforts her group, the California Center for Public Health Advocacy, has undertaken to address school nutrition issues. She described campaigns to enact specific legislation and noted the “tremendous amount of opposition from the food industry.” Connecticut Representative Michael Cardin also discussed legislation dealing with school nutrition and claimed that his state adopted strong legislation in 2006 removing all soda and electrolyte beverages from school vending machines.

Other Developments

[11] CSPI Leads Campaign to End Marketing of Soft Drinks to Youth Under 16

The Center for Science in the Public Interest (CSPI) has initiated an international campaign to persuade soft drink companies to stop marketing sugary or caffeinated beverages to youth younger than age 16. In a letter signed by consumer organizations in 20 countries, CSPI also asked companies to (i) “stop selling sweetened beverages, including sports drinks and non-carbonated fruit-flavored beverages and teas,” in all public and private schools; (ii) “prominently display the calorie content per serving” on container labels; (iii) “include rotating consumer alert messages” on soft drink labels; and (iv) “limit sponsorships to promoting physical activity and health to blind trusts overseen by government agencies.” In addition, CSPI has requested that the food and beverage

industry stop opposing taxes on soft drinks. “These are global companies and their marketing policies should be consistent around the globe,” CSPI Director of Legal Affairs Bruce Silverglade said of the international focus. A recent report published in the *International Journal of Food Science and Nutrition*, however, reportedly concluded that soft drink consumption was not a significant contributor to rising obesity levels in the United Kingdom. See *CSPI Press Release*, January 3, 2008; *FoodNavigator-USA.com*, January 8, 2008.

[12] FBI Investigates High-Priced Counterfeit Wines

The Federal Bureau of Investigation has reportedly launched a national probe into wine counterfeiting, a practice that has become increasingly common as the price of rare vintage bottles has skyrocketed. Several collectors have recently sued dealers and auction houses, accusing them of failing to adequately verify a wine’s provenance, or authenticity, in instances where bottles might sell for more than \$100,000 each. With European wines notoriously difficult to trace and many buyers unable to spot fakes, dealers have apparently come under fire for selling dubious collections like the clarets allegedly belonging to Thomas Jefferson. The scandal first came to light when William Koch, a Florida industrialist and avid wine collector, had his 40,000-bottle cellar vetted by expert wine appraisers. The appraisers discovered, however, that 5 percent of Koch’s collection was fake, including several bottles from the so-called Jefferson lot unearthed two decades ago at his 1780s Paris residence. The revelation focused international attention on counterfeit wines and warned of legal repercussions for dealers who fail to investigate a wine’s origins. As a result, one Chicago wine broker recently pulled three



magnums of a rare Bordeaux off the auction block after competitors and authorities warned that the bottles could be counterfeit. “In just a five minute search on the Internet, it was easy to figure out that bottles like these are really questionable,” one dealer was quoted as saying about the wine in question. “The auction business lives on its credibility, and customers expect more from us than caveat emptor.” See *The Chicago Tribune*, December 21, 2007.

Media Coverage

[13] Seattle Newspaper Commissions Diacetyl Exposure Study

The Seattle Post-Intelligencer has reportedly commissioned a study to measure the levels of diacetyl released from the skillet during cooking. The controversial butter flavoring is contained in many shortenings used by professional grill cooks and has been linked to the development of a debilitating respiratory disease. While some 234 parts per million (ppm) of the substance were reportedly measured at skillet level, diacetyl levels of an estimated 2 or 6 ppm reached workers’ breathing zones, amounts that “could result in exposures for professional cooks . . . as high or higher than some severely ill workers at a Jasper, Mo., popcorn plant were exposed to in their eight-hour shift.” According to the newspaper, physicians are familiar with several cases of professional cooks who contracted lung disease from cooking-vapor exposure. Researchers studied butter, margarine and cooking sprays and found higher diacetyl levels than expected in unsalted butter, it is apparently added to stabilize the dairy product in the absence of salt. The article discusses diacetyl research conducted by the National Institute for Occupational Safety and Health, whose scientists have apparently

acknowledged the purported risk and called for research focused on workers in commercial kitchens. See *Seattle Post-Intelligencer*, December 21, 2007.

[14] Media Outlets Review Michael Pollan’s Latest Book on Nutritional Science

“In this lively, invaluable book . . . [Michael Pollan] assails some of the most fundamental tenets of nutritionism: that food is simply the sum of its parts, that the effects of individual nutrients can be scientifically measured, that the primary purpose of eating is to maintain health, and that eating requires expert advice,” opines Janet Maslin in her January 3, 2008, review of *In Defense of Food: An Eater’s Manifesto*, the latest offering from food writer and fellow *New York Times* columnist Michael Pollan. The review praises the book as a “tough, witty, cogent rebuttal to the proposition that food can be reduced to its nutritional components without the loss of something essential,” adding that Pollan’s agenda takes on “the industry-financed branch of nutritional science” for backing health claims on highly processed food products. In addition, Maslin argues that the book “underscore[s] a sense of food’s downhill slide” allegedly brought about by food industry interests like the beef lobby, which opposed legislation that would replace, in Pollan’s words, “the big chunk of animal protein squatting in the middle of [the] plate.” “Mr. Pollan advocates a return to the local and the basic, even at the risk of elitism,” Maslin concludes, noting that while the book supplies “elementary advice,” it also reiterates the warnings of other famous food writers, from Barbara Kingsolver to Marion Nestle, about the state of the modern Western diet.



Scientific/Technical Items

[15] Two Studies Examine Link Between Dairy and Risk of Prostate Cancer

Two recent studies published in the *American Journal of Epidemiology* have examined the alleged link between dairy foods and prostate cancer, finding in both cases that only low-fat or nonfat milk could be related to an increased risk of prostate cancer in the cohorts under observation. One study relied on questionnaires completed by 293,888 participants in the National Institutes of Health-AARP Diet and Health Study, which reported 10,180 total cases of prostate cancer during the six-year follow-up period. Yikyung Park, et al., "Calcium, Dairy Food, and Risk of Incident and Fatal Prostate Cancer," *American Journal of Epidemiology*, December 1, 2007. These researchers found no significant correlation between total and supplemental calcium intake and non-advanced, advanced and fatal cases of prostate cancer. While the study reported that "skim milk, but not other dairy foods, was associated with increased risk of prostate cancer," it concluded that "in contrast, calcium from nondairy foods was associated with lower risk of non-advanced prostate cancer." "Although the authors cannot definitely rule out a weak association for aggressive prostate cancer, their findings do not provide strong support for the hypothesis that calcium and dairy foods increase prostate cancer risk."

The other study examined food frequency questionnaires completed by 82,483 participants in the Multiethnic Cohort Study, which reported 4,404 total cases of prostate cancer during the four-year follow-up period. Song-Yi Park, et al., "Calcium, Vitamin D, and Dairy Product Intake and Prostate

Cancer Risk," *American Journal of Epidemiology*, December 1, 2007. This study also found "no association . . . between calcium and vitamin D intake and total, advanced or high-grade prostate cancer risk, whether for total intake, intake from foods, or intake from supplements, among all male participants or among nonusers of supplemental calcium." Furthermore, researchers concluded that, in "analyses of food groups, dairy product and total milk consumption were not associated with prostate cancer risk." The study ultimately found that while low-fat or nonfat milk "was related to an increased risk and whole milk to a decreased risk of total prostate cancer; . . . these effects were limited to localized or low-grade tumors." The authors stated that the study results "do not support an association between the intakes of calcium and vitamin D and prostate cancer risk," but that the findings "do suggest that an association with milk consumption may vary by fat content, particularly for early forms of this cancer." See *PCRM Press Release*, January 9, 2008.

[16] Drug-Resistant *E. Coli* More Common in Poultry Workers, New Study Claims

A recent study by researchers at the Johns Hopkins Bloomberg School of Public Health has reportedly found that poultry workers are more likely than others in the community to carry antimicrobial-resistant *E. coli* bacteria. Lance B. Price, et al., "Elevated Risk of Carrying Gentamicin-Resistant *Escherichia coli* among U.S. Poultry Workers," *Environmental Health Perspectives*, December 2007. The study sampled 16 poultry industry workers and 33 community residents from the eastern shore regions of Maryland and Virginia, which produce 600 million boiler chickens per year. Researchers discovered that poultry workers were 32 times more likely to harbor *E. coli* resistant to



gentamicin, a common antibiotic. “Occupational exposure to antimicrobial-resistant *E. coli* from live-animal contact in the broiler chicken industry may be an important route of entry for antimicrobial-resistant *E. coli* into the community,” the study authors concluded. See *FoodNavigator-USA.com*, January 2, 2008.

[17] Moderate Alcohol Intake Reduces Heart Disease Risk, Study Claims

Danish researchers have reportedly found that moderate alcohol intake combined with an active lifestyle can reduce the risk of ischaemic heart disease (IHD) by 50 percent when compared to the IHD rates of physically inactive non-drinkers. Jane Østergaard Pedersen, et al., “The combined influence of leisure-time physical activity and weekly alcohol intake on fatal ischaemic heart disease and all-cause mortality,” *European Heart Journal*, January 2008. The study followed approximately 12,000 men and women for nearly 20 years, concluding that people who did not drink alcohol or exercise had a 49 percent greater risk of heart disease than those who either drank, exercised or did both. While physically active non-drinkers had a 31 to 33 percent reduced risk of IHD compared to inactive non-drinkers, exercisers who drank one to 14 units of alcohol per week were 30 percent less likely to develop heart disease than their non-drinking counterparts. In addition, when researchers studied all causes of death, “moderate drinkers fared better than their abstemious peers across all physical activity levels,” according to *BBC News*. “Our study shows that being both physically active and drinking a moderate amount of alcohol is important for lowering the risk of both fatal IHD and death from all causes,” the lead researcher was quoted as saying. See *BBC News*, January 9, 2008.



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